

**IN THE CIRCUIT / SUPERIOR COURT FOR
MARION COUNTY, INDIANA**

STATE OF INDIANA,

Plaintiff,

vs.

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

Defendants.

COMPLAINT

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1. The State of Indiana, through its Attorney General, Curtis T. Hill, Jr., brings this suit to hold Defendants Richard Sackler, Theresa Sackler, Kathe Sackler, Jonathan Sackler, Mortimer D.A. Sackler, Beverly Sackler, David Sackler, and Ilene Sackler Lefcourt (collectively, “Defendants”) accountable for their key role in the epidemic of opioid overprescribing, misuse, abuse, and addiction that currently grips the State of Indiana, and to demand that Defendants contribute financially to the remediation of the opioid crisis. By way of Complaint, the State of Indiana states:

PRELIMINARY STATEMENT

2. Since the debut of OxyContin (an extended release (“ER”) opioid) in 1996, the volume of opioids prescribed nationwide and in Indiana has exploded—rising by 500%. Opioid prescription rates were so high in 2012 that, on average, there were 112 opioid prescriptions for every 100 residents in the State. Since then, the rate of opioid prescribing has declined but remains dangerously high. From 2012 through 2016, there were **58 Indiana counties** with opioid prescribing rates greater than 100+ prescriptions per 100 residents.

3. As recently as 2016, there was a **statewide** average of 84 opioid prescriptions per 100 residents. These numbers have placed Indiana among the highest opioid prescription rates in the entire country.

4. Indiana’s high opioid prescription rates have been coupled with even higher, illegal diversion rates—to devastating effect. While Indiana reported the ninth-highest rate of opioid prescriptions per capita in the United States in 2012, its rate of diversion was the fifth highest in the country. The proliferation of pills—moving through both legal and illegal channels—has increased opioid misuse, abuse, and addiction in Indiana.

5. The effects on the lives and well-being of Hoosiers and the State itself are profound: increased health care costs; premature death and disability; lost productivity during prime work years; increases in drug-related crime and incarceration; and the consequential devastation of households and extended families. These predictable outcomes have created a full-blown public health crisis.

6. The opioid epidemic in Indiana has claimed thousands of lives and damaged countless more. More than 3,000 Hoosiers died of opioid overdoses between 2010 and 2016 alone. In 2017, there were 17.2 opioid death in the State per 100,000 residents.



Deaths by county of occurrence, regardless of state or county of residence

7. Based on established health experts' estimates, as many as 89,000 Hoosiers currently are battling opioid dependence and addiction. Those who die leave behind grieving family members and financial dependents; the living face a lifetime of chronic disease management that can impair life-long productivity and earning power, injure their families, and interfere with personal relationships. The pain and cost of opioid dependence and addiction fall

heavily on those who use opioids and their immediate families—but where, as here, the scale of misuse and addiction rises to epidemic proportions, the costs affect entire communities and, ultimately, the State.

8. 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 has become 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 manufactures, markets, and sells 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 for 20 years has been the leading force in the prescription opioid market, both nationwide and in Indiana.

9. Over the last 20 years, Purdue has 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 owned the company and controlled the company’s board of directors: Richard Sackler, Theresa Sackler, Kathe Sackler, Jonathan Sackler, Mortimer D.A. Sackler, Beverly Sackler, David Sackler, and Ilene Sackler Lefcourt. The Sacklers’ ambition was to become unimaginably rich from the sale of opioids. Although they well understood the addictive and dangerous qualities of the drugs they manufactured, they did not allow concerns about individual consumers or public health to constrain their marketing and promotional plans. The Sacklers shaped the marketing campaigns that Purdue carried out and they set sales objectives. The Sacklers hired hundreds of workers to

¹ Purdue herein refers to a group of three related companies: Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company.

carry out their wishes and blanketed the country with disinformation about opioids. The Sacklers got more patients on opioids, at higher doses, for longer, than ever before. And over the years, the Sacklers distributed billions of dollars earned from the sale of Purdue opioids to themselves and other family members.

10. Since May 2007, Purdue has sold more than [REDACTED] units of opioids in Indiana. And since it launched OxyContin in 1996, Purdue has generated sales estimated at more than \$35 billion—about \$4 billion of which Defendants pocketed between 2007 and 2018. For Defendants, the Indiana prescriptions were a gold mine.

11. Prescription opioids are narcotics, closely related to heroin and its root ingredient, opium. In addition to dampening the perception of pain, opioids can create a euphoric high. Opioids also carry significant risks. They are addictive and withdrawal symptoms—including severe anxiety, nausea, headaches, tremors, delirium, and pain—can occur if opioids are delayed or discontinued. Depending on the length of use, substantial withdrawal symptoms may persist for months, or even years, after complete cessation of use.

12. At higher doses or with any sudden increase in dosage, opioids 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, thus increasing the risks of withdrawal, addiction, and fatal overdose.

13. Historically, the seriousness of these risks had been reflected in a careful and cautious approach to prescribing and taking opioids. Before the 1990s, opioids typically were used only to treat short-term, acute pain (e.g., trauma and post-surgical pain), cancer pain, or palliative care (including end-of-life care) because they were considered too dangerous, too addictive, and too debilitating for long-term use.

14. Beginning in the 1990s and continuing to the present day, Purdue aggressively and successfully set out to change the perception of opioids and to increase medical professionals' comfort with and patient demand for them—at the direction of the Sacklers. Purdue proselytized a new narrative—that pain was drastically undertreated and pain treatment should be a higher priority of health care providers. This narrative paved the way for increased prescribing of opioids for chronic pain.² To benefit the Sacklers, Purdue co-opted aspects of an otherwise appropriate and compassionate patient-centered care model to engage in a campaign of deception and concealment that promoted opioids as safer, more effective, and more appropriate than alternatives (like Tylenol and Advil) for long-term use to treat routine and moderate pain associated with common conditions like back pain, migraines, and arthritis.

15. Purdue, at the Sacklers' direction, has spent hundreds of millions of dollars on an array of promotional efforts that falsely denied or deceptively minimized the risk of addiction and overstated the benefits of opioids. These efforts included:

- directly marketing Purdue opioids to prescribers through advertising and in-person sales visits;
- indirectly marketing opioids to prescribers and consumers through seemingly-independent surrogates—key opinion leaders, professional associations, and advocacy groups—that were actually paid for or funded by Purdue; and
- generating a biased body of reference materials—scientific research, treatment guidelines, and continuing medical education seminars—that would encourage, rather than objectively evaluate, the use of opioids for chronic pain.

16. Purdue's massive marketing scheme, joined by other opioid manufacturers, materially changed the medical and patient communities' willingness to prescribe and take opioids. By 2012, opioids were among the most prescribed drugs; approximately 90% of

² As used in this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

prescription opioids were given for chronic pain conditions, and only 10% of prescription opioids were dispensed for post-surgical, palliative, and cancer pain treatments. This was an almost complete reversal of long-standing medical practice.

17. According to the Centers for Disease Control and Prevention (“CDC”), nearly 62 million Americans received at least one opioid prescription in 2016.

18. In the 2000s, federal and state law enforcement began investigating Purdue for deceptive marketing and misbranding. During the time period covered by the investigation, 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 were intimately involved in the launch of OxyContin and the marketing campaigns that led to the explosion of over-prescribing.

19. The investigations culminated in a series of settlements in 2007, under which, Purdue and three of its executives—but no Sackler—pleaded guilty to federal criminal charges for deceptive conduct in the sale and marketing of opioids. Purdue paid more than \$600 million to resolve federal and state government enforcement actions (“the 2007 Settlements”). 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 pleaded guilty. At the same time, the Sacklers continued to manage the company’s core business activities (marketing, sales, and product development) from what they believed to be a protected perch of remove.

20. From 2007 into 2018, the Sacklers charted a new—but equally crooked—course for Purdue. The Sacklers hired and supervised a large sales force, which was directed to visit

health care providers nationwide and in Indiana on a frequent basis and convince them to prescribe more and stronger opioids. While the specific messages that Purdue's sales representatives carried changed after 2007, they were still unfair, false, deceptive, misleading, and consistently misrepresented the risks and benefits of OxyContin and Purdue's other opioids.

21. The Sacklers also devised several additional schemes to fortify their market. First, they directed sales representatives to capture new initiates: the elderly and the opioid naïve (those who have not previously used these powerful drugs). Second, they directed sales representatives to promote 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 directed sales representatives to promote and distribute “savings cards” that provided substantial price discounts not just for initial prescriptions but for a number of refills engineered to induce dependence and addiction.

22. Purdue's deceptive marketing was largely carried out by its sales representatives nationwide and in Indiana. These sales representatives orally conveyed deceptive and misleading messages to health care providers, provided them deceptive and misleading sales materials, and referred them to deceptive and misleading sources online. In pursuit of the objectives set by the Sacklers, these sales representatives falsely and misleadingly presented the risks of opioids by:

- continuing to downplay the serious risk of addiction, including by claiming that signs of addiction merely reflected undertreated pain;
- overstating the effectiveness of screening tools in preventing addiction, giving prescribers unwarranted confidence they can safely prescribe opioids;
- denying or failing to disclose the increased dangers of opioids at higher doses, which increase the risk of addiction, overdose, and death; and
- exaggerating the effectiveness of “abuse-deterrent” opioid formulations by claiming and implying that these formulations prevent abuse and addiction.

23. Purdue also misrepresented the benefits of opioids by:

- claiming that long-term opioid therapy is appropriate and effective—and, in particular—would improve patients’ function and quality of life—without disclosing that there is no good evidence to support these claims;
- promoting the use of “low doses” of OxyContin (10 and 15 milligrams) to reluctant prescribers, even though Purdue had **no scientific evidence showing** that these low doses provided pain relief; and
- grossly overstating the risks of over-the-counter pain relief medications like acetaminophen and ibuprofen without fully disclosing the far greater risks associated with opioids.

24. The Sacklers met regularly as 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, and compensation of the sales force. Over the years 2008 to 2017, the Sacklers approved routine increases in the number of sales representatives and increases to their compensation while delivering unequivocal orders to meet with prescribers more frequently, to concentrate special efforts on the most prolific prescribers, and to persuade all prescribers to write more opioid prescriptions and higher dosage prescriptions. The Sacklers’ communications were not limited to quarterly Board meetings. They were in touch with Purdue employees throughout the year, to the point where Purdue executives and staff expressed concerns about the Sacklers’ constant involvement in day-to-day details.

25. The Sacklers’ personal involvement in the running of the company was so long- and well-established that the 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.”

26. The Sacklers were the architects and drivers of Purdue's promotional efforts. The Sacklers knowingly and intentionally sent sales representatives to promote opioids to Indiana health care prescribers more than 207,640 times from 2010 to 2018. The Sacklers knew and intended that the sales representatives in Indiana would deceptively and misleadingly promote opioid sales. The Sacklers knew and intended that prescribers, pharmacists, and patients, in Indiana 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 Indiana, distributing billions of dollars in Purdue profits to themselves and other family members over the years, including, on information and belief, many tens of millions of dollars from Indiana from 2007 to the present.

27. The State has sued Purdue in a separate action to hold the company accountable for its deceptive marketing. *See State of Indiana v. Purdue Pharma L.P. et al.*, No. 49D10-1811-PL-045447 (Marion Cty. Super. Ct. filed Nov. 14, 2018). The State now brings suit against the Sackler Defendants to hold each individual accountable for knowingly and intentionally directing Purdue's misconduct—and profiting from the harm and death of Indiana citizens taking the company's opioids.

28. The State asks the Court to make these culpable executives pay for the harm they inflicted in Indiana. Among other things, the State seeks a judgment requiring Defendants to pay civil penalties, disgorge ill-gotten gains, pay damages in connection with the false claims it caused to be submitted, and to reimburse Plaintiff's fees and costs.

PARTIES

29. The Plaintiff is the State of Indiana. The Attorney General brings this action in the public interest in the name of the State. The Attorney General is charged with the responsibility of enforcing the State laws at issue, including the Deceptive Consumer Sales Act and all regulations promulgated thereunder, as well as the False Claims Act and the Medicaid False Claims Act. The Attorney General also has standing on behalf of the State as *parens patriae* to protect the health and well-being, both physical and economic, of its residents and its municipalities.

30. Defendant Richard Sackler became a member of the Purdue board in 1990 and became its co-chair in 2003, which he remained 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 president from 1999 through 2003. At all times material to this Complaint, acting alone or in concert with others, Richard Sackler was personally aware of, was responsible for, engaged in, authorized, or directed the deceptive and unconscionable acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, Richard Sackler approved and oversaw deceptive and unconscionable conduct that was purposely directed at Indiana and gives rise to the State's claims as alleged in this Complaint. He resides in New York, Florida, and Texas.

31. Defendant Theresa Sackler was a member of Purdue's board from 1993 through 2018. At all times material to this Complaint, acting alone or in concert with others, Theresa Sackler was personally aware of, was responsible for, engaged in, authorized, or directed the deceptive and unconscionable acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, Theresa Sackler approved and oversaw deceptive and

unconscionable conduct that was purposely directed at Indiana and gives rise to the State's claims as alleged in this Complaint. She resides in New York and the United Kingdom.

32. Defendant Kathe Sackler was a member of Purdue's board from 1990 through 2018. At all times material to this Complaint, acting alone or in concert with others, Kathe Sackler was personally aware of, was responsible for, engaged in, authorized, or directed the deceptive and unconscionable acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, Kathe Sackler approved and oversaw deceptive and unconscionable conduct that was purposely directed at Indiana and gives rise to the State's claims as alleged in this Complaint. She resides in New York and Connecticut.

33. Defendant Jonathan Sackler was a member of Purdue's board from 1990 through 2018. At all times material to this Complaint, acting alone or in concert with others, Jonathan Sackler was personally aware of, was responsible for, engaged in, authorized, or directed the deceptive and unconscionable acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, Jonathan Sackler approved and oversaw deceptive and unconscionable conduct that was purposely directed at Indiana and gives rise to the State's claims as alleged in this Complaint. He resides in Connecticut.

34. Defendant Mortimer D.A. Sackler was a member of Purdue's board from 1993 to 2018. At all times material to this Complaint, acting alone or in concert with others, Mortimer Sackler was personally aware of, was responsible for, engaged in, authorized, or directed the deceptive and unconscionable acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, Mortimer Sackler approved and oversaw deceptive and unconscionable conduct that was purposely directed at Indiana and gives rise to the State's claims as alleged in this Complaint. He resides in New York.

35. Defendant Beverly Sackler was a member of Purdue's board from 1993 through 2017. At all times material to this Complaint, acting alone or in concert with others, Beverly Sackler was personally aware of, was responsible for, engaged in, authorized, or directed the deceptive and unconscionable acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, Beverly Sackler approved and oversaw deceptive and unconscionable conduct that was purposely directed at Indiana and gives rise to the State's claims as alleged in this Complaint. She resides in Connecticut.

36. Defendant David Sackler was a member of Purdue's board from 2012 through 2018. For the period 2012 through 2018, acting alone or in concert with others, David Sackler was personally aware of, was responsible for, engaged in, authorized, or directed the deceptive and unconscionable acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, David Sackler approved and oversaw deceptive and unconscionable conduct that was purposely directed at Indiana and gives rise to the State's claims as alleged in this Complaint. He resides in New York.

37. Defendant Ilene Sackler Lefcourt was a member of Purdue's board between 1990 and 2018. At all times material to this Complaint, acting alone or in concert with others, Ilene Sackler Lefcourt was personally aware of, was responsible for, engaged in, authorized, or directed the deceptive and unconscionable acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, Ilene Sackler Lefcourt approved and oversaw deceptive and unconscionable conduct that was purposely directed at Indiana and gives rise to the State's claims as alleged in this Complaint. She resides in New York.

38. In Indiana, directors, officers, and employees of corporations are not immune from jurisdiction or liability when they break the law. Instead, every individual is accountable for his or her actions.

39. 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 from 1990 through 2018, which gave them full power over both Purdue Pharma Inc. and Purdue Pharma L.P. Defendants directed deceptive sales and marketing practices deep within Purdue. From the money that Purdue collected selling opioids, they paid themselves and their family billions of dollars.

JURISDICTION AND VENUE

40. The Court has personal jurisdiction over Defendants because they purposely directed business activities into Indiana and engaged in unlawful practices in Indiana against Indiana consumers.

41. From 2010 through 2018, Defendants authorized the hiring and compensation of at least 123 different Purdue sales representatives and sales managers who were assigned to a sales territory in or including Indiana. In that period, Purdue's Indiana sales force made more than 207,640 sales visits regarding OxyContin and other Purdue opioids to Indiana health care providers. On information and belief, Purdue has generated hundreds of millions of dollars in revenue from the sale of its opioid products in Indiana.

42. Venue in this Court is proper, pursuant to Indiana Trial Rule 75(A)(10), because Plaintiff's claims arose, in part, in Marion County, and Defendants directed business there. Among other things, Purdue has made tens of thousands of sales visits regarding opioids to

health care providers in Marion County. In addition, this case is brought by the State of Indiana, a governmental entity whose principal offices are located in Marion County, Indiana.

GENERAL ALLEGATIONS COMMON TO ALL COUNTS

I. **The Sackler Defendants, Through Purdue, Changed the Medical Consensus by Working Every Channel to Reach Prescribers and Indiana Patients.**

43. From the launch of OxyContin in 1996, Purdue knew its claims about the risks and benefits of long-term opioid use lacked scientific support. From the first OxyContin label in 1996 and up to today, in 2018, the **only** clinical study Purdue has relied upon for OxyContin's efficacy in adults is a **two-week study of 133 patients**. No clinical trials on efficacy have extended past 12 weeks.

44. Yet, Purdue sold OxyContin as the cure for chronic pain. Purdue promoted OxyContin, and opioids generally, with the understanding and expectation that health care providers would prescribe it to their chronic pain patients over periods of months and years.

45. 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 good evidence to support these assertions.

46. Purdue changed the medical consensus on opioids through its campaign of deception. Purdue achieved this by ensuring that every channel a prescriber regularly consulted for information about opioids would deliver the same incomplete, misleading, and imbalanced information. Purdue effected this strategy through its sizeable sales force, through continuing medical education seminars and presentations, through academic literature, and through treatment guidelines.

A. Purdue regularly met face-to-face with prescribers to promote its opioid drugs.

47. Purdue marketed its opioids directly to prescribers through its sales force—sales representatives, also known as “detailers,” who made in-person sales visits to prescribers. By establishing frequent contact and personal relationships with health care providers, Purdue’s detailers were able to disseminate key misrepresentations in largely unmonitored and unregulated settings.

48. In-person sales visits to prescribers are highly effective. Purdue’s internal documents confirm that it was well-aware of the efficacy of detailing. For example, a 2012 report prepared by a research firm that Purdue hired to analyze trends in the pain market concluded that, even though physicians described sales visits as having only a small impact on prescribing habits, in reality, detailing had a high impact on levels of opioid prescribing. The report thus identified physician detailing as an “effort [that Purdue] ... should maintain in order to maximize [market] share.” The report also noted that, aside from medical journals, sales representatives were the top source of new information for healthcare providers about medications for the treatment of chronic pain. Similarly, Purdue sales executives have confirmed during detailer training programs that “[a]nalysis has demonstrated that [local dinner] programs, when combined with regular sales visits, do increase the prescribing habits” of physicians. Of the \$167 million that Purdue spent on promoting opioids nationwide in 2016, \$156 million of that—93.4%—was spent in connection with its in-person sales force.

49. Purdue targeted generalists—primary care physicians, nurse practitioners, and physician assistants—who were likely to see patients with chronic pain conditions but unlikely to have the specialized training to evaluate Purdue’s marketing and patients’ pain conditions.

50. Purdue’s internal marketing plans from 2013 reveal that Purdue targeted nurse practitioners and physician assistants as both the fastest growing specialty and particularly susceptible to marketing messages. In Purdue’s words, “NPs and PAs desperately seek information, typically from sales representatives.”

51. At least 123 different Purdue sales representatives and managers have detailed Indiana prescribers since 2010. Purdue’s performance requirements included the expectation that every detailer make at least 7.5 in-person sales visits to prescribers, two to three in-person sales visits to pharmacies, and one in-person sales visit to a hospital or other institutional target **each day**.

52. Purdue’s internal documents show that its sales representatives detailed at least 5,502 different Indiana prescribers between 2010 and 2017, and that these prescribers were visited by Purdue sales representatives in excess of 207,640 times. Most of these prescribers were visited regularly and repeatedly—according to one former Purdue sales representative in Indiana; offices housing multiple prescribers, including nurse practitioners and physician assistants, were visited weekly. On average, Purdue’s sales force in Indiana made a total of more than 22,000 prescriber visits per year.

53. Detailer compensation was not based on the number of sales visits or the strength of those relationships. Instead, compensation was tied to the number of prescriptions doctors wrote in a detailer’s territory over quarterly periods. Bonuses were awarded to detailers quarterly, based on their performance. At least one former Purdue detailer in Indiana had sales quotas of **over 3,300 OxyContin prescriptions per month**.

54. In fact, in 2012, at the peak of opioid prescribing, Purdue’s **highest achieving sales representative—nationwide—worked in Indiana**. This detailer, who was assigned to the

Fort Wayne area, was ranked No. 1 out of all 525 sales representatives in the country based on sales of OxyContin and Butrans.

55. Purdue used these rankings—as well as cash and prizes—to motivate sales representatives. In Purdue’s words:

Those colleagues who prevail will likely maximize available field time during these summer months, striving to implement our marketing strategies more effectively by focusing on Core and Super Core prescribers and using support materials to engage customers in an ongoing dialogue concerning the utilization of Purdue products, and always closing to increase usage with appropriate patients.

56. In just the first quarter of 2012, this Fort Wayne sales representative sold \$2,031,666 of OxyContin in her district. Purdue rewarded her and other “winners” who secured the highest volume of Purdue opioid prescriptions with generous bonuses. The Fort Wayne sales representative received a **first quarter bonus** of \$36,600 in 2012, plus a trip to Aruba.

57. The district managers who supervised Indiana detailers were evaluated and compensated on the expansion of opioid prescribing in their territory. Purdue trained its managers to encourage sales representatives to visit high-volume prescribers as frequently as 3x/week.

58. One Indiana district manager’s performance evaluation from 2015 instructed, “[i]t is important to work with team members to ensure they are seeing their highest value doctors ... with the suggested frequency. These HCPs [health care providers] provide us with the greatest opportunity to grow our business and achieve our sales results.”

59. Purdue developed sophisticated plans to select prescribers for sales visits based on their prescribing habits. Purdue purchased prescription sales data from vendors like IMS (later IQVIA), which allowed Purdue to analyze and closely track prescribing of its opioids and those of its competitors. According to former Purdue employees in Indiana, any prescribing of an

opioid—whether Purdue’s or a competitor’s—would cause a prescriber to be included on Purdue’s target list for sales visits.

60. Purdue also recognized that the State’s law enforcement efforts to halt overprescribing and diversion were affecting the prescribers Purdue was targeting. Following the highly-publicized closure of several practices that were essentially “pill mills,” a Purdue Regional Manager wrote in his evaluation of an Indianapolis-area District Manager:

During this review period, there were a number of things that took place that impacted your team: There were many representatives that had pain practices shut down by the Attorney General of Indiana. This contributed to many prescribers abandoning patients and the overall decline of the entire ERO [extended release opioids] market I am confident in your ability to help your team members continue to successfully launch Hysingla, protect OxyContin and grow Butrans for the remainder of 2015.

61. Through at least 2017, Purdue employed the same marketing tactics and messages in Indiana 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 to review those trainings, scripts, role-plays, supervisor tag-alongs, and periodic reviews of representatives’ written records of sales visits (“call notes”)—to ensure that individual detailers actually delivered the company’s desired messages. Purdue likewise required its sales representatives to deploy sales aids that were reviewed, approved, and supplied by the company.

B. Purdue co-opted and exploited seemingly-independent channels to reach prescribers.

62. In addition to its branded marketing efforts that showcased Purdue opioids, Purdue also undertook, or financially supported, a number of unbranded marketing initiatives that were designed to promote opioids generally, and to convey Purdue’s key messages about

opioids without properly disclosing that Purdue had created, funded, directed, or was otherwise influencing these endeavors. Purdue intended prescribers and patients to receive these materials and to perceive (incorrectly) that they were coming from neutral researchers, clinicians, and independent patient advocacy groups.

63. As part of its unbranded marketing scheme, 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 continuing medical education (“CME”) activities that misleadingly portrayed the risks and benefits of chronic opioid therapy. Purdue 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.

64. Purdue’s relationship with the American Pain Foundation (“APF”) is particularly instructive of its relationship with advocacy and professional groups. Purdue was APF’s second biggest donor, with donations totaling over \$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.

65. APF used funding from Purdue and others to distribute false and misleading information about the addiction risks associated with opioids.

(a) *Exit Wounds*, an APF book styled as the personal narrative of a veteran recovering from war injuries, 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 Indiana.

(b) *A Policymaker's Guide to Understanding Pain & Its Management* claimed that pain generally had been “undertreated” due to “[m]isconceptions about opioid addiction” and asserted, without support, 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 misleading information regarding a bogus phenomenon called “pseudoaddiction.” Purdue provided a grant for the development and distribution of *A Policymaker's Guide* and kept abreast of the content of the guide as it was formulated. On information and belief, Purdue had editorial input into *A Policymaker's Guide*.

66. Purdue also created a portfolio of unbranded materials, from websites to glossy brochures, that were copyrighted by Purdue but were designed to look like the work of independent organizations—with names like *Partners Against Pain* and *In the Face of Pain*.

67. 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 Indiana: (1) Purdue's capture, for its own ends, of physicians' increased focus on pain treatment; (2) Purdue's efforts to skew the scientific literature on chronic opioid therapy with biased studies; and (3) Purdue's corrupting influence on authoritative treatment guidelines issued by professional associations.

68. As described in more detail below, the Sackler Defendants 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]

1. Purdue co-opted the medical community's focus on pain.

69. 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 individuals leading the movement, and, in turn, they promoted the aggressive treatment of chronic pain, especially with opioids.

70. Purdue had already laid the groundwork for this strategy by financially supporting researchers who were willing to advocate for expanded use of opioids without adequate scientific support. Chief among these was Dr. Russell Portenoy, who wrote a seminal paper supporting chronic opioid therapy while receiving Purdue funding and serving as Purdue's consultant. Dr. Portenoy concluded—based on a 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.

71. 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 objectively measured indicator—that doctors should monitor alongside blood pressure, temperature, heartbeat, and breathing. Purdue provided substantial funding to APS both to promote pain awareness generally and, on information and belief, to support the group's “Pain as the 5th Vital Sign” campaign. 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.

72. In 2001, the Joint Commission on the Accreditation of Healthcare Organizations (“JCAHO”) issued pain treatment standards requiring assessment of pain in all patients during every 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 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.” JCAHO distributed the book to hospital officials and physicians nationwide at a series of Purdue-sponsored “leadership summits” on pain management.

73. Both the APS “Pain as the 5th Vital Sign” campaign and the JCAHO pain standards were widely integrated into medical practice. Although the JCAHO standards strictly applied only to pain management in hospitals, they influenced the entire medical profession through hospital-based residency training. Indiana health care providers interviewed by the State credit these initiatives with increasing the prescribing of opioids by requiring that doctors be aggressive in treating pain but did not know that Purdue had played a key role in launching these initiatives.

2. Purdue corrupted the science regarding opioids with flawed and biased research.

74. 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 and biased, and drew inappropriate conclusions from prior evidence. Purdue selectively promoted studies with favorable outcomes and relegated the problematic ones

to obscure journals. The result was an incomplete, inaccurate, and deceptive body of literature that was then cited by other researchers.

75. Some of these methodologically flawed studies made unsubstantiated claims that the risk of psychological dependence or addiction is low absent a history of substance abuse. One such study making this claim, published in the journal *Pain* in 2003 and widely referenced since (with nearly 600 citations in Google Scholar), ignored existing research showing actual addiction rates between 8% and 13% and instead relied heavily on a 1980 letter to the editor—not a peer-reviewed study or in-depth 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 Eng. J. Med.*, 123 (1980) (“Porter-Jick Letter”), is reproduced below.

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.**

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D.

76. 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 this misuse of the Porter-Jick Letter. Yet, the Porter-Jick “study” has become a mainstay in scientific literature due, in large measure, to Purdue’s efforts, with more than 1,000 citations in Google Scholar.

3. Purdue funded and influenced treatment guidelines.

77. Treatment guidelines inform health care providers’ prescribing practices, are cited throughout the scientific literature, and are referenced by third-party payors when determining whether prescriptions should be covered by insurance. Purdue financed and collaborated with three groups on guidelines that have been, and continue to be, broadly influential in Indiana and nationwide: (i) the American Academy of Pain Medicine (“AAPM”); (ii) the American Pain Society (“APS”); and (iii) the Federation of State Medical Boards (“FSMB”).

78. **The AAPM/APS Guidelines.** The 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. Purdue gave APS another \$500,000 and AAPM more than \$700,000 between 2012 and 2017. 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 tier organizations.”

79. 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. J. David Haddox, was a paid speaker for Purdue at the time. Shortly after issuing this statement, he became a senior executive for the company. Dr. Portenoy was the sole consultant for the consensus statement, which remained on AAPM’s website until 2011.

80. 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 since been exposed and the treatment approach discredited.

81. In 2009, AAPM and APS issued comprehensive opioid prescribing guidelines (“2009 AAPM/APS Guidelines”), drafted by a 21-member panel, that promoted opioids 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.

82. The 2009 AAPM/APS Guidelines reprinted in *The Journal of Pain* were distributed by Purdue sales representatives to Indiana prescribers. These guidelines, in addition to influencing physicians, have now been cited nearly 1,700 times in academic literature.

83. **FSMB Guidelines.** The FSMB is an association of the various state medical boards in the United States. The state boards that comprise the FSMB membership, including Indiana’s, have 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.

84. 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 stated that opioids “may be essential” for treatment of chronic pain but failed to mention risks of respiratory depression and overdose. Further, the FSMB Guidelines addressed addiction only to define the term as separate from physical dependence and state that an “inadequate understanding” of addiction can lead to “inadequate pain control.” Purdue sales representatives distributed the FSMB Guidelines to health care providers in Indiana.

85. 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.

86. *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 by Purdue, edited the book to ensure that pseudoaddiction was falsely 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]

87. Through at least 2015, the FSMB website described the book as the “leading continuing medical education (CME) activity for prescribers of opioid medications.” In all, more

than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationwide through state medical boards and non-profit organizations. On information and belief, copies were distributed in Indiana.

II. From Their Position of Control, the Sackler Defendants Drove and Benefitted from Purdue's Misconduct.

A. The Sacklers directed Purdue's misconduct leading to the 2007 Settlements.

88. 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.

89. The Sacklers always insisted that their family control Purdue. From 1990 through 2018, their family always held the majority of seats on the Board. Three Sackler Defendants—Richard, Kathe, and Jonathan Sackler—were high-ranking executives in the company until 2003. 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. A fourth family member, the father of Defendant Mortimer D.A. Sackler, was a Senior Vice President in the company during this time period. The other Sacklers were 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 Sackler Defendants participated in, authorized, and directed the deceptive and unfair marketing activities described below.

90. 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.”

91. 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 to oppose this dangerous idea. Kaiko wrote 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?”³

92. 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. Likening the launch of OxyContin to the Blizzard of 1996, 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

³ Original is in all caps.

white [REDACTED]” Over the next twenty years, the Sacklers made Richard Sackler’s statement come true. They created a blizzard of dangerous prescriptions that caused the deaths of children, parents, and grandparents across Indiana.

93. 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 than [REDACTED]. In fact, OxyContin is more potent than morphine. Richard Sackler recognized that the truth could reduce OxyContin sales [REDACTED]

94. 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,” like Viagra.

95. Most of all, the Sacklers were motivated by money. 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?”

96. 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 the 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.”

97. In addition to using the sales force to deceptively promote Purdue’s opioids, [REDACTED]

98. 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.”

99. 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.”

100. 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.”

101. 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.”

102. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

103. 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 advanced today, that criminal abusers—not the company that deceptively peddles the drugs—are to blame for the opioid crisis.

104. 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.”

105. When *Time* magazine published an article about OxyContin deaths in New England, 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],

106. 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?”⁴

107. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

⁴ The DEA official was Laura Nagel, head of the DEA Office of Diversion Control.

108. 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 U.S. Department of Justice. 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, however, kept 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.

109. 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 three Purdue executives (Michael Friedman, Paul Goldenheim, and Howard Udell)—but no member of the Sackler family—should plead guilty as individuals.

110. 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.

111. 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”

112. 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 were Vice Presidents; and Richard, Jonathan, Kathe, Mortimer, Ilene, Beverly, and Theresa Sackler were all on the Board.

113. 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.

114. The 2007 guilty pleas and Corporate Integrity Agreement should have ended the Sacklers’ misconduct for good. But Richard Sackler “” and “” The Sacklers broke the law again and again, expanding their deceptive sales campaign to make even more money from more patients on more dangerous doses of opioids.

B. Since the 2007 Settlements Through 2018, the Sacklers Continued to Direct Purdue's Misconduct.

115. From the 2007 Settlements through 2018, the Sacklers authorized and directed Purdue's deceptive marketing campaign. They authorized and 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 authorized and directed sales representatives to promote opioids to the elderly and opioid naïve. 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]

116. The Sacklers micromanaged Purdue's sales operations. 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, requiring the staff to create special reports just for them. Richard Sackler even went into the field to participate in promoting opioids to doctors and in supervising representatives face to face.

117. The staff sought relief from the Sacklers' micromanagement. The VP of Sales and Marketing wrote to the CEO:

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

118. 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 in a particular district, 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 that district:

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

119. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

120. The Sacklers’ main motivation was money. From 2007 to 2018, they voted to direct Purdue to pay their family **billions** of dollars, including, on information and belief, tens of millions of dollars from opioids sold in Indiana. 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 Indiana, at great cost to patients and families.

121. As detailed below, the Sacklers’ misconduct continued from 2007 into 2018.

-
-
- 2007 •
-
-

122. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[Redacted]

[Redacted]

[Redacted]

123.

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

124. The impact of Purdue’s sales representatives in Indiana was direct and profound. From the 2007 felony conviction until 2018, Purdue sales representatives [REDACTED]

[REDACTED]

125. **In May 2007**, while still in the midst of the criminal proceedings, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

126. **In July 2007**, 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. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] 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.⁵

127. Purdue’s self-interested failure to report abuse and diversion continued. 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. For example, Purdue sales representatives visited prescribers at the Wagoner Clinic located in Kokomo, Indiana [REDACTED] [REDACTED]—at times as often as twice a week. No wonder: This small family practice was writing **hundreds** of opioid prescriptions **weekly**. By the time its doctors were arrested in 2013, more than 125,000 prescriptions had been written and the overdose deaths of more than two dozen patients had been traced to the reckless prescribing at this clinic. Purdue sales representatives, despite their regular visits, did not report any suspicious activity to the State.

128. By July of 2007, [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

129. Also in July, staff reported to the Sacklers that they continued to mail out thousands of 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

⁵ The State’s review of Board minutes did not disclose any challenge to this course of conduct.

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.

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

131. 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.

132. 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.

133. **In August**, Mr. Udell was still serving as Purdue's top lawyer, even after his criminal conviction (described in paragraph 109 above). 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."

134. **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.

135. 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.” Focusing on sales of the highest doses—which were the most lucrative to Purdue and the Sacklers—would be a primary focus of the sales force from 2007 to the present, including in Indiana, as discussed in Section III.C.

136. 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.

137. **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 Indiana.

• • • **2008** • • •

138. **In January 2008**, 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.

139. 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.

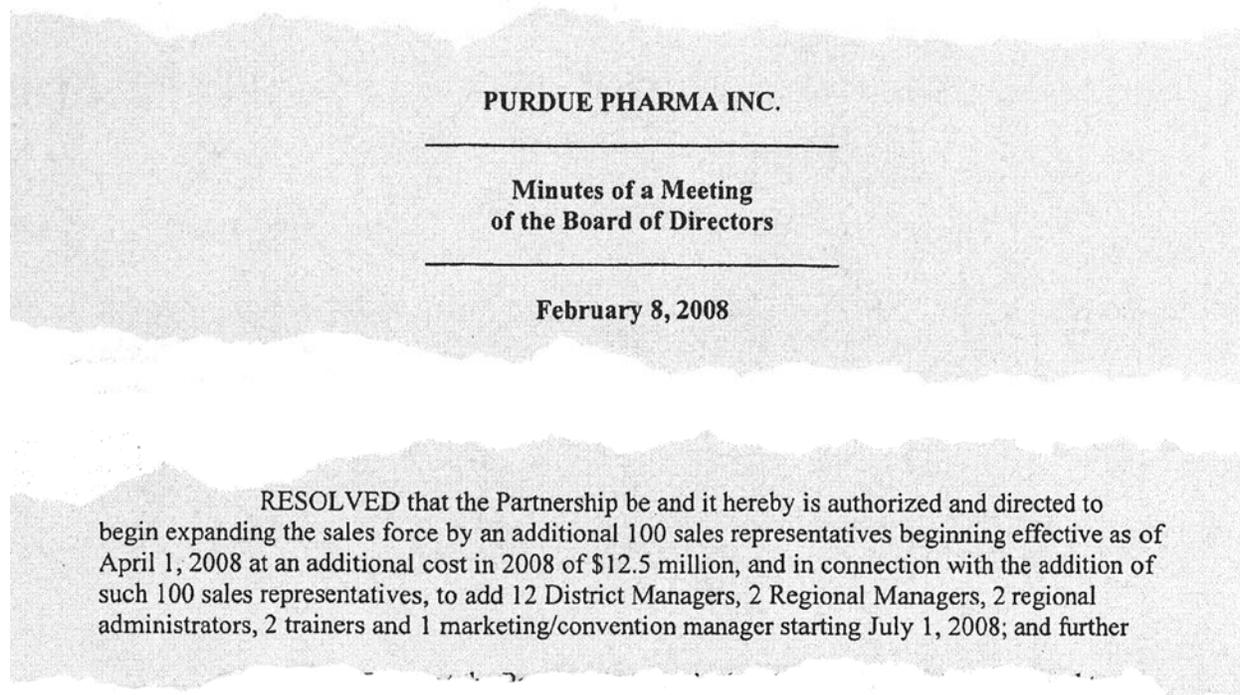
140. The Sacklers wanted more details on tactics for pushing sales. Richard Sackler wrote to Russell Gasdia, Vice President of Sales and Marketing (hereinafter “Sales VP”), demanding information about Purdue’s opioid savings cards. Richard Sackler asked Gasdia how long the opioid savings cards lasted, 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 the present, savings cards were a key element of the strategy to promote long-term use of opioids, including in Indiana, as discussed in Section III.D.5.

141. 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.

142. The Sacklers not only participated in the details, 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.

143. **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."⁶



144. The Sacklers knew and intended that, because of their orders, more sales representatives would promote opioids to prescribers in Indiana. 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. From 2008 to the present, sales representatives

⁶ The Sacklers had long experience controlling the company's sales force. They voted to direct Purdue to hire 50 more sales representatives in 1998, and directed the company to prepare for a 100-representative expansion in 2007.

hired in the 2008 expansion promoted Purdue opioids

[REDACTED]

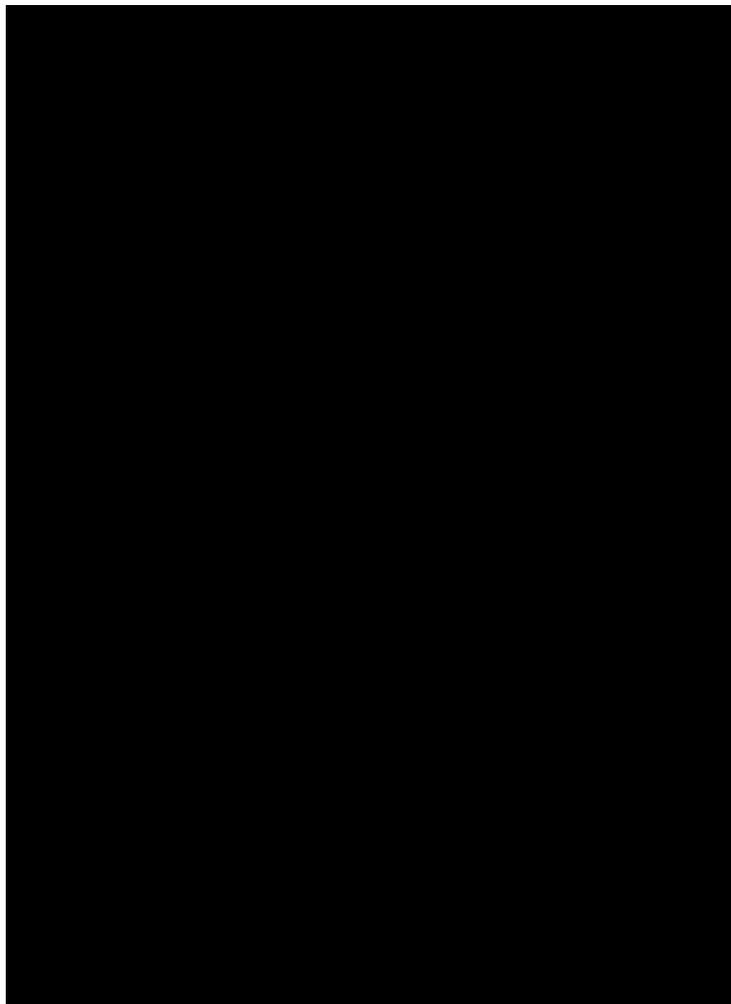
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



145. As the company expanded its sales force in 2008, it rewarded sales representatives who generated the most opioid prescriptions with bonuses and all-expense-paid trips to tropical islands, using them as examples to motivate other sales representatives to sell more opioids.

146. 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.”

147. On Valentine’s Day, the Sacklers voted to pay \$3,000,000 to former CEO Michael Friedman, one of three Purdue executives to plead guilty. It was one of several multi-million-dollar payments to the convicted executives.

148. Also in February, [REDACTED]

[REDACTED]

[REDACTED] Mortimer Sackler wrote to Richard Sackler [REDACTED]

[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 ...?”

149. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Acting President John Stewart met with his staff to plan how to phrase a carefully worded reply. Later that month, Stewart wrote to Richard Sackler that reformulating OxyContin “will not stop patients from the simple act of taking too many pills.”⁷ As discussed in Section III.B.2, Purdue and the Sacklers deployed as a marketing tool the abuse-deterrent formulation ultimately developed by the company, despite the fact that

⁷ Five years later, Purdue published two studies about the crush-proof formulation. Neither concluded the crush-proof tablets lowered the risks of addiction, overdose and death associated with OxyContin use; they simply found that reformulated OxyContin might be less attractive to recreational drug abusers. Purdue amended its OxyContin label to reference these studies in 2013.

its efficacy in reducing abuse was unproven. Further, as discussed in Section III, Purdue—at the Sacklers' direction—used its abuse-deterrent technology to deflect blame for the opioid crisis.

150. Meanwhile, 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 weighed 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.

151. **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 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 said: “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.⁸ 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.

⁸ A month earlier, when an employee did not answer a call from Richard Sackler during a Sunday morning church service, Richard immediately contacted an executive to complain. Richard then wrote that he expected answers from four different sales staff members the next day (President's Day) even though Purdue was closed.

152. Sales VP Russell Gasdia wanted Richard Sackler to “back off.” 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.

153. 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] for “exceeding 2007 Rx numbers on an adjusted basis (adjusted for strength and average number of tablets per Rx).” The very next day, Gasdia [REDACTED] [REDACTED] such as adding sales representatives, promoting Purdue’s existing opioid savings cards, and promoting more intermediate doses of OxyContin.

154. 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 redo of the annual plan as well as the 5-year plan for Purdue’s opioids.

155. 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 Indiana in 2008, [REDACTED]

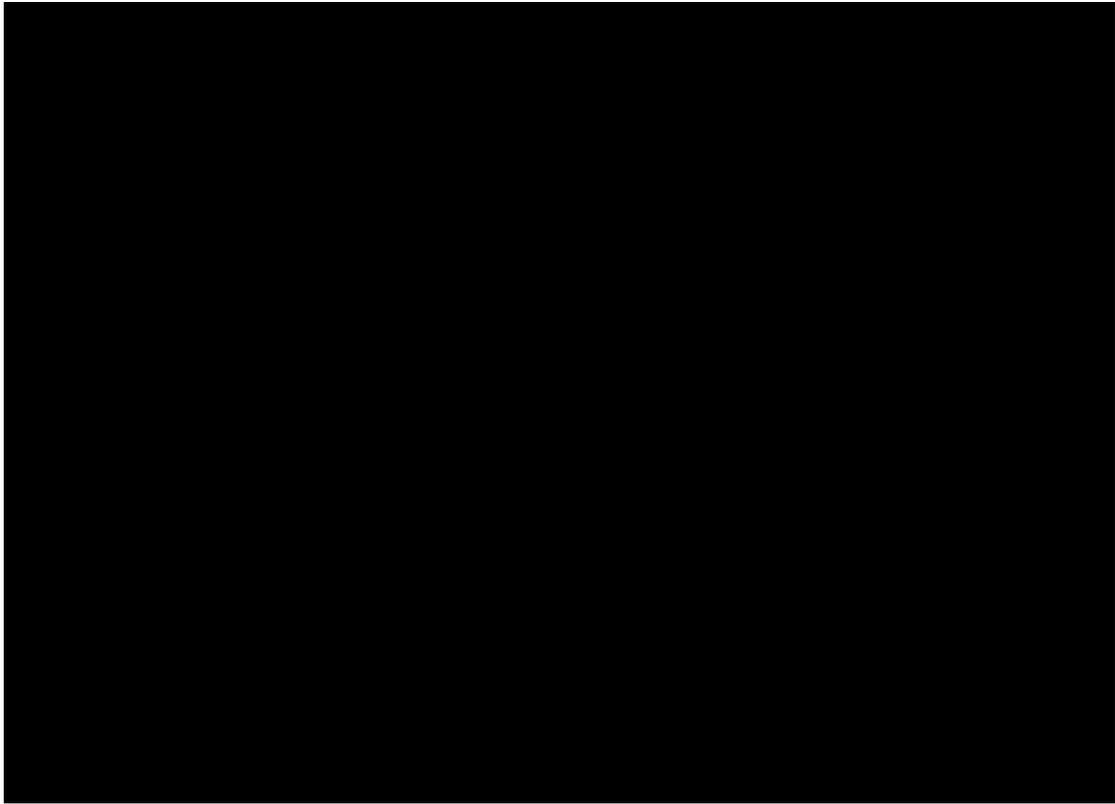
[REDACTED]

[REDACTED]

156. **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.

157. On April 18, Richard Sackler sent Kathe, Ilene, David, Jonathan, and Mortimer Sackler a secret memo about how to maintain their profits. Richard Sackler wrote that Purdue’s business posed a “dangerous concentration of risk.” 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.

158. 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 \$4 billion dollars**.



159. When the Sacklers directed Purdue to pay their family, they knew and intended that they were paying themselves from opioid sales in Indiana. Purdue reported to the Sacklers about potential lost 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]. Similarly, prescription data on over 500,000 individual prescribers that Purdue tracked from 2007 to 2017 confirm that



On information and belief, since May 15, 2007, the Sacklers paid their family tens of millions of dollars from Indiana.

160. 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. [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.

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

162. 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.

163. This stigmatization of opioid addiction and those addicted to opioids would underpin several deceptive strategies used by Purdue to minimize the risk posed by its opioids, including deceptions about the risk of addiction, the ability to screen out people at risk of becoming addicted, and the efficacy of abuse deterrent formulations of opioids, as discussed in Section III.B. 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 Sections III.B and III.C.

164. 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 impression that the drugs were not abusable or did not carry risks of addiction or overdose. Jonathan Sackler, [REDACTED]

165. **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.

166. Meanwhile, Richard Sackler asked sales staff for information about [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.

167. As explained below, many patients would face significant withdrawal symptoms if they tried to stop taking opioids after using them for 90 days. Staff informed Richard,

Jonathan, Kathe, and Mortimer Sackler that 27% of the savings cards had been used for all five prescriptions.

168. Also in June, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] As discussed in Section III.E, 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.

169. **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.

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

171. **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.

172. 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 Indiana. During Q3 2008, [REDACTED]

[REDACTED]

173. **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.

174. 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 • • •

175. **In March**, the Sacklers voted to pay Purdue sales representatives and sales managers bonuses of 103 percent 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.

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

██████████ “For the first time since January 2008, OxyContin ® 80mg strength tablets exceeded the 40mg strength.” ██████████ 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*. Through 2013, the *Partners Against Pain* website relied on and directed users to guidelines which endorsed the concept of pseudoaddiction, i.e., the claim that patients who engage in drug-seeking behaviors may not be addicted but simply have undertreated pain.

177. 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.

178. **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 ██████████ employees in the field and letting all the executives ██████████ keep their jobs.

179. **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%.

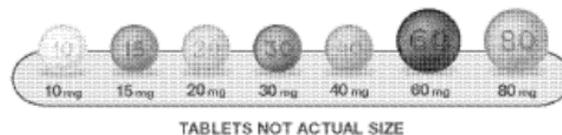
180. A few days later, staff reported to the Sacklers that Purdue had expanded its sales force at the Board’s direction: “As approved in the 2009 Budget, 50 New Sales Territories have been created ...” Staff told the Sacklers the expansion was focused on the most prolific opioid prescribers, because “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.

181. **In July**, staff reported to the Sacklers that Purdue employed 429 sales representatives. Richard Sackler [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.

182. **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).

183. [REDACTED] informing the Sacklers about Purdue's newest OxyContin sales campaign, with the slogan: *Options*. The *Options* campaign set the pattern that Purdue would follow for years: pushing doctors and patients up the ladder 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'

184. 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 (the Physicians Television Network): thousands of doctors would be given free digital video recorders for their home televisions, in exchange for watching advertisements for drugs.⁹

185. 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.

186. **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.

187. Also in September, [REDACTED]

[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 III.B–C and V.

188. **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

⁹ Purdue spent approximately \$100 for each doctor who watched the advertisement, but it made the money back when the doctors prescribed Purdue's opioids.

also instructed the Sales Department to report to the Board of Directors with more explanation about its activities.

189. That same month, the Sacklers and staff discussed federal sunshine legislation that would create a public database to disclose drug companies' payments to doctors. Purdue was paying many doctors to promote its opioids—[REDACTED]—but the payments could often be kept secret. Some of the Sacklers were concerned that doctors would be “much less willing” to work for Purdue if the payments were disclosed.

190. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

191. **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.

192. 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, meant pushing the doses that were highest and most profitable.

193. 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.

194. 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 for the reduced margin was the cost of the expanded sales force—which the Sacklers had directed and authorized.

195. **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 America was beginning to flatten—

Higher doses contain more of that active ingredient and are more profitable to Purdue.

• • • **2010** • • •

196. **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] to a sales report and saying it was “urgent” and should be provided “this weekend.”

197. That same month, [REDACTED]

[REDACTED]

198. Also in January, [REDACTED]

[REDACTED] As described in Section III.D.4, Purdue and the Sacklers knew that “Q12” dosing—dosing every 12 hours—was deceptive because OxyContin does not provide 12 hours of pain relief in some patients.

199. **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.

200. To achieve the target for sales visits, staff told the Sacklers that another sales force expansion ordered by the Board had been implemented and Purdue employed 490 sales representatives. That expansion was having the intended effect in Indiana. During Q4 2009,

[REDACTED]

[REDACTED]

201. 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 of these new tactics.

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

203. **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]

204. 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. From 2007 to the

present, expanding Purdue’s captive customer base by promoting opioids for the opioid-naïve was a key tactic of the sales force, including in Indiana, as discussed in Section III.E.

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

206. 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]

207. [REDACTED]

[REDACTED]

208. [REDACTED]

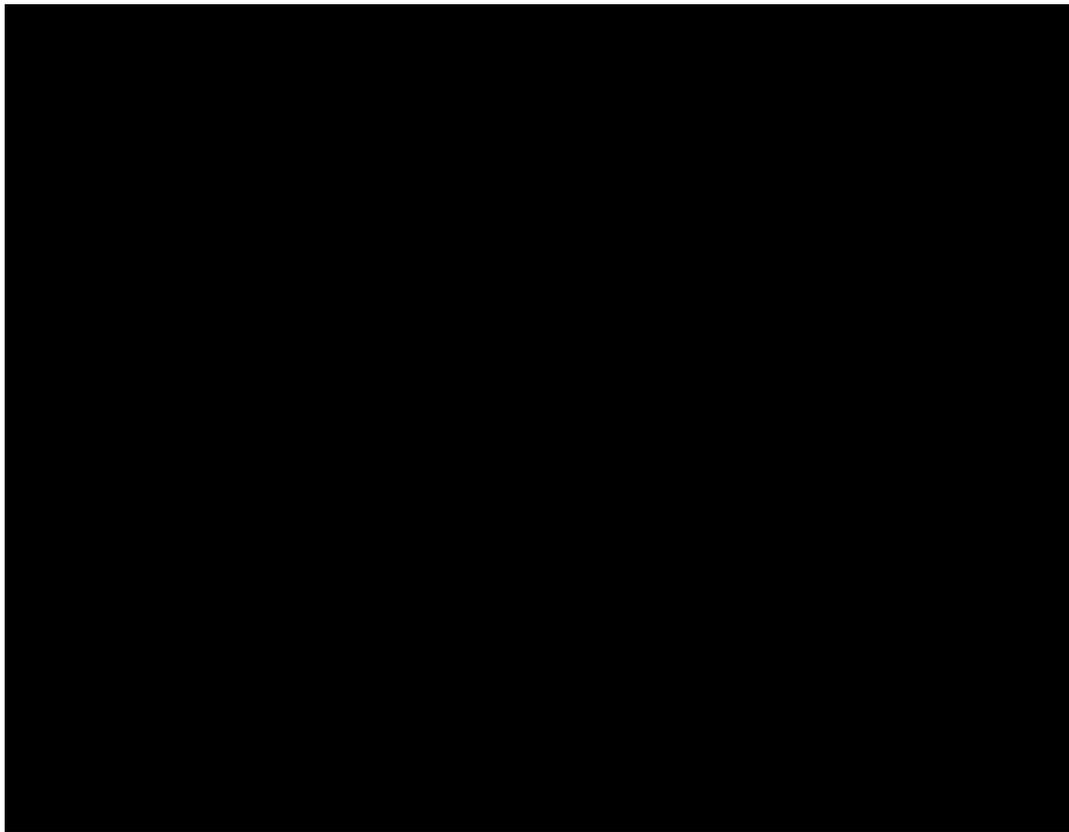
[REDACTED]

209. *The Sacklers’ Control of Sales Visits.* That same month (April 2010), staff gave the Sacklers one of many detailed reports on sales representatives’ visits to prescribers.

210. 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.

211. 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. The Sacklers tracked the total number of sales visits per quarter, every quarter, for at least the next four years.



212. [REDACTED] Indeed, they visited [REDACTED]
[REDACTED]

213. 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.

214. **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 as many opioids "will require significant salesforce support" so 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 opioid combination drugs (e.g., Vicodin and Percocet) and other short-acting opioids (e.g., tramadol and tapentadol) to Purdue's soon-to-be-released Butrans opioid, and that Butrans would become a billion-dollar drug.

215. **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 [REDACTED] get this out before the weekend." A staff member wrote to the CEO: "Are you expecting us to provide the marketing plan by tomorrow?" [REDACTED]

[REDACTED] 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.

216. 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%.

217. 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. 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."

218. 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.

219. Purdue was not legally allowed to claim that Butrans was effective for osteoarthritis ("OA") because the clinical trials testing Butrans for patients with osteoarthritis 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]

220. **Region Zero.** 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 then sent the data on those prescriptions to the Board. Staff told the Board that Purdue had identified [REDACTED] [REDACTED] Staff gave the Board a list of the specific problem prescribers by name, along with the exact number of prescriptions and dollars of revenue each provided to Purdue.

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

222. [REDACTED] [REDACTED] the Indiana Medical Licensing Board had unanimously voted to suspend Ballengee’s license. By then, Purdue and the Sacklers had collected hundreds of thousands of dollars from their dangerous prescriptions.

223. At that same Board meeting in Bermuda, the Sacklers voted to [REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

224. The Sacklers knew and intended that, because of their vote, more sales representatives would promote opioids to prescribers in Indiana. From 2010 to the present, [REDACTED]

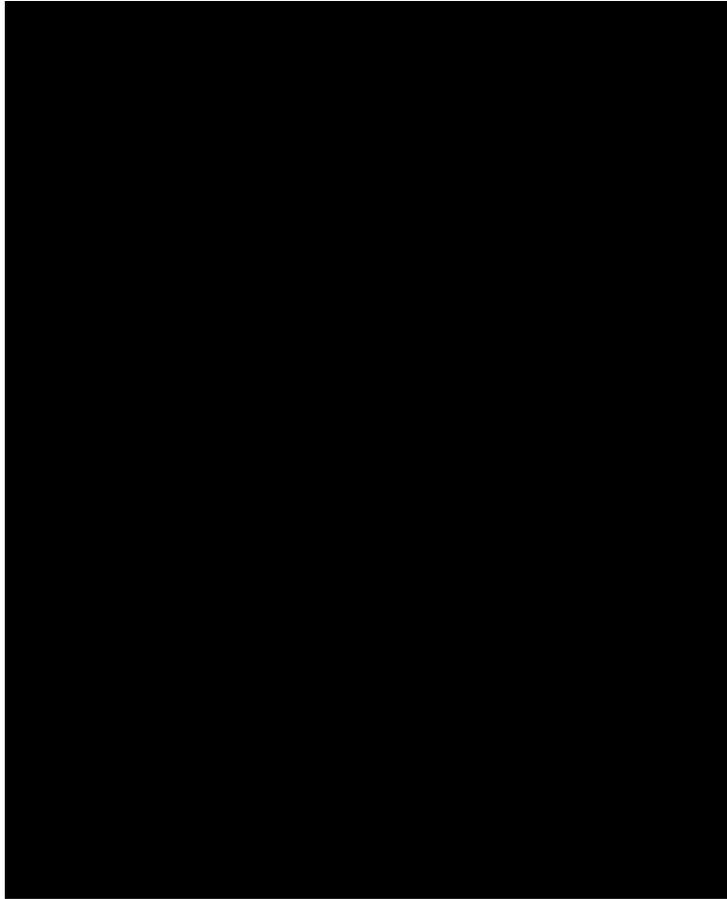
[REDACTED]

[REDACTED]

¹⁰

¹⁰ The sales representatives hired in the 2010 expansion promoted Purdue opioids in

[REDACTED]



225. At the same meeting, the Sacklers voted to pay \$10,000,000 to settle lawsuits by people injured by OxyContin.

226. Later that month, staff told the Sacklers that Purdue employed 491 sales representatives and that, during Q2 2010, they visited prescribers 135,824 times.¹¹ 

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

227. **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

¹¹ Staff told the Board that the target for visits was 142,657; that representatives visited 7.0 prescribers per day, on average, compared to the target of 7.5; that the average cost of a visit was \$219; and that they were still working to lower the cost to \$201.

focus” in sales representatives’ meetings with prescribers was too great a risk, and Purdue decided not to go through with the deal.

228. 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 identifies “doctor-shopping” when a patient gets opioids from multiple prescribers—an indication that the patient is at risk of addiction, overdose, and death.

229. **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 factor in Purdue and the Sacklers’ plans to keep patients on opioids longer. The same month, the Sacklers voted to pay their family \$240,000,000.

230. **In October**, staff told the Sacklers that Purdue employed 506 sales representatives and, during Q3 2010, they visited prescribers 141,116 times.¹² [REDACTED]

231. 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.

¹² Staff reported that the target was 144,414; representatives visited 6.8 prescribers per day, on average, compared to the target of 7.5; each sales representative visit to a prescriber cost Purdue \$219; and they were working to lower the cost to \$201.

232. **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: "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."

233. Staff also reported that the expansion of the sales force that the Sacklers had ordered was being implemented, including 125 new sales territories. The Sacklers voted to spend \$158,086,000 to employ sales representatives in 2011.

234. 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."

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

• • • 2011 • • •

236. In 2011, the Sacklers continued to direct Purdue's deceptive sales tactics and receive 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 "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.

237. **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.¹³ [REDACTED]

238. 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.

239. 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?

¹³ Staff told the Sacklers that, at the Board's direction, Purdue had hired 74 more sales representatives and planned to hire 51 more. Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 125,553 visits; and that representatives visited 6.2 prescribers per day, on average, compared to a target of 7.5; and that each visit cost Purdue \$219. They were still working to lower the cost to \$201.

240. Richard Sackler continuously intervened into sales tactics. When Richard followed up to ask for information “tomorrow,” CEO John Stewart warned staff that such requests would be “never-ending.”

241. 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.

242. 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, ██████ 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 ██████ 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?”

243. 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.

244. 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.”

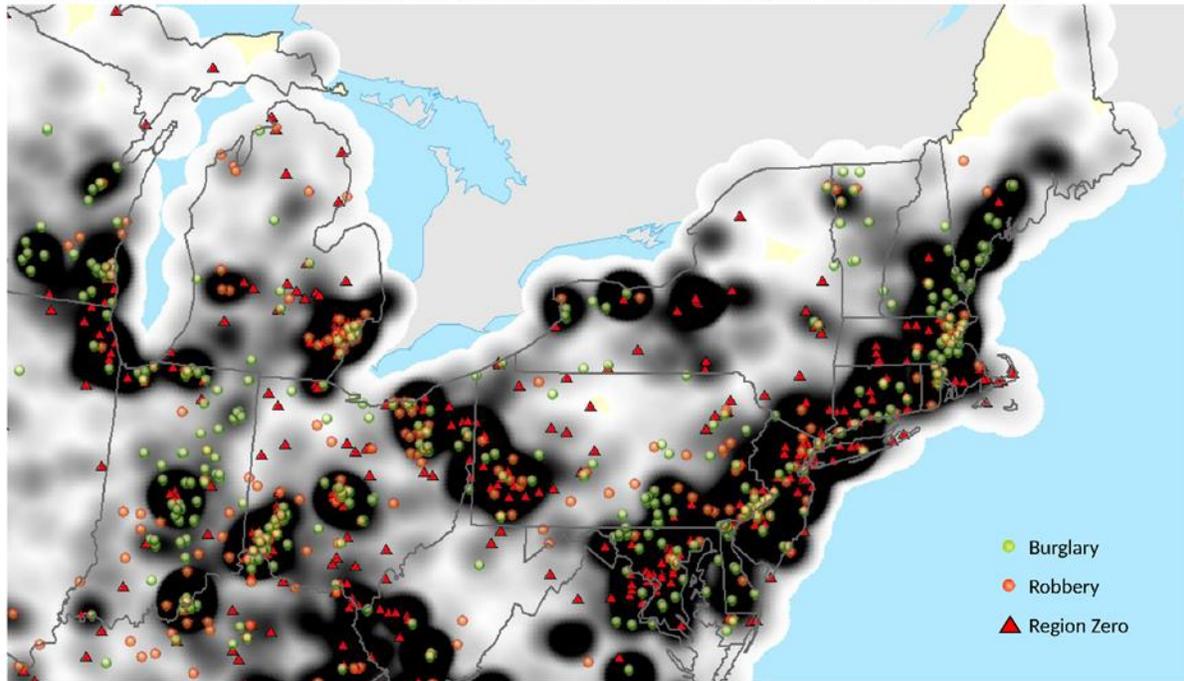
245. **In February**, staff reported to the Sacklers that law enforcement was increasingly concerned about lawbreaking by drug companies and the resulting “danger to public safety.” Staff also told the Sacklers that Purdue was receiving a rising volume of hotline calls and other compliance matters, reaching 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 to individual zip codes the correlation between poison control calls for OxyContin overdose, pharmacy thefts, and prescribers Purdue suspected of abuse and diversion in *Region Zero*.

246. Staff even gave the Sacklers a map correlating dangerous prescribers in Indiana 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

247. **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.

248. **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.

249. 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 select groups of [REDACTED] "Core" physicians that Purdue calculated would be most susceptible to sales representatives lobbying to prescribe more opioids. [REDACTED]

[REDACTED] In 2016, Guerrero was sentenced to eight years and four months in prison for health care fraud, money laundering and unlawfully distributing controlled substances, causing one patient's death.

250. 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." In Indiana, promotion for "specific patient types" meant pushing opioids for elderly patients with arthritis. [REDACTED]

[REDACTED] In the ensuing years, the tactic of focusing on the elderly would continue to be carried out extensively in Indiana and reported to the Sacklers, as reflected in Section III.E.

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

[REDACTED]

[REDACTED]

252. Jonathan Sackler was not satisfied that these tactics would be enough to boost sales. [REDACTED] he wrote to John Stewart: “this is starting to look ugly. Let’s talk.” Stewart and the sales team scrambled to put together a response and set up a meeting with Jonathan for the following week.

253. That same month, staff reported to the Sacklers that Purdue had hired 47 more sales representatives according to the Sacklers’ orders. Staff told the Sacklers that Purdue employed 639 sales representatives and, during Q1 2011, they visited prescribers 173,647 times.¹⁴ [REDACTED]

254. Meanwhile, the Sacklers voted to pay \$10,000,000 to try to settle a lawsuit by the Attorney General of Kentucky regarding Purdue’s marketing of OxyContin. Staff also told the Sacklers that they had received another 88 calls to Purdue’s compliance hotline, but not reported any of them to the authorities.

255. **In June**, staff reported to the Sacklers that Purdue’s opioid sales were hundreds of millions of dollars less than expected and that a prime reason was that doctors were not prescribing enough of the highest doses. The headline presented at the Board meeting read: “40 and 80mg tablet prescriptions have decreased significantly. The 10mg and 20mg tablet prescriptions initially increased, but given their lower value not enough to offset the higher strength decline.” Staff told the Sacklers: “As a result of the change in prescriptions by strength, OxyContin brand Kgs dispensed are below mid 2010 levels.” Staff reported to the Sacklers that

¹⁴ Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 168,210 visits; and that representatives visited 6.66 prescribers per day, on average, compared to a target of 7.0.

Purdue would rely on sales representative visits and paid physician spokespersons to maintain demand. For a “Super Core” of “Very High Potential” opioid prescribers, Purdue would order its sales representatives to make sales visits **every week**.

256. 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 that Purdue had hired 147 new sales representatives at the Board’s direction. Gasdia told Richard 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.

257. Sales representatives reported to Purdue [REDACTED]

258. In an email message, Gasdia told Richard Sackler 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. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

259. 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 scrambled to schedule 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.

260. 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.

261. 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." To make sure the Sacklers' involvement in marketing stayed secret, 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

262. Several 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.

263. 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

Vice President 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.

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

265. A few days later, sales and marketing staff scrambled 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.

266. 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.

267. **In August**, staff told the Sacklers that Purdue employed 640 sales representatives and, during Q2 2011, they visited prescribers 189,650 times.¹⁵ [REDACTED]

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

269. **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.

270. **In November**, staff told the Sacklers that Purdue still employed 640 sales representatives and, during Q3 2011, they visited prescribers 189,698 times.¹⁶ [REDACTED]

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

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

• • • 2012 • • •

272. **In January 2012**, Jonathan Sackler started the year pressing Sales VP Russell Gasdia for weekly updates on sales. A few days later, Richard Sackler corresponded with the sales staff about advertising. He noticed that online ads appeared indiscriminately on webpages with content associated with the ad—regardless of whether the association was positive or

¹⁵ Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 187,950 visits; and that representatives visited 7.2 prescribers per day, on average, compared to a target of 7.0.

¹⁶ Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 189,525 visits; and that representatives visited 7.2 prescribers per day, on average, compared to a target of 7.0.

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.”

273. That same month, staff told the Sacklers that Purdue employed 632 sales representatives and, during Q4 2011, they visited prescribers 165,994 times.¹⁷ [REDACTED]

274. 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 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 wrote: “Wouldn’t it be better to have the reps get back to work for January and back in front of doctors.” If Purdue rescheduled its meeting, “At 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.”

¹⁷ Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 166,315 visits; and that representatives visited 7.03 prescribers per day, on average, achieving the target of 7.0.

275. Meanwhile, Richard Sackler interrupted sales staff many times a day, often in a hurry: “I had hoped you would have updated this,” “Will I have it by noon?” “get 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.”

276. Also in February, [REDACTED]

[REDACTED]

[REDACTED]

277. 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.”

278. 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.

279. **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.

280. 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]

284. In April, staff told the Sacklers that Purdue employed 630 sales representatives and, during Q1 2012, they visited prescribers 179,554 times.¹⁸ [REDACTED]

285. Around this time, as discussed previously, a sales representative hired in 2011 and assigned to Purdue's Fort Wayne, Indiana territory was named Purdue's top ranked sales representative—nationwide—of the fourth quarter of 2011 and the 2012 year to date. This sales representative was ranked No. 1 out of all 525 sales representatives in the country based on sales of OxyContin and Butrans. In just the first quarter of 2012, she sold \$2,031,666 of OxyContin in her territory. Purdue rewarded her with a first quarter bonus of \$36,000, plus a trip to Aruba.

286. 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 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?"

287. Gasdia tried to assure Richard Sackler that they were 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

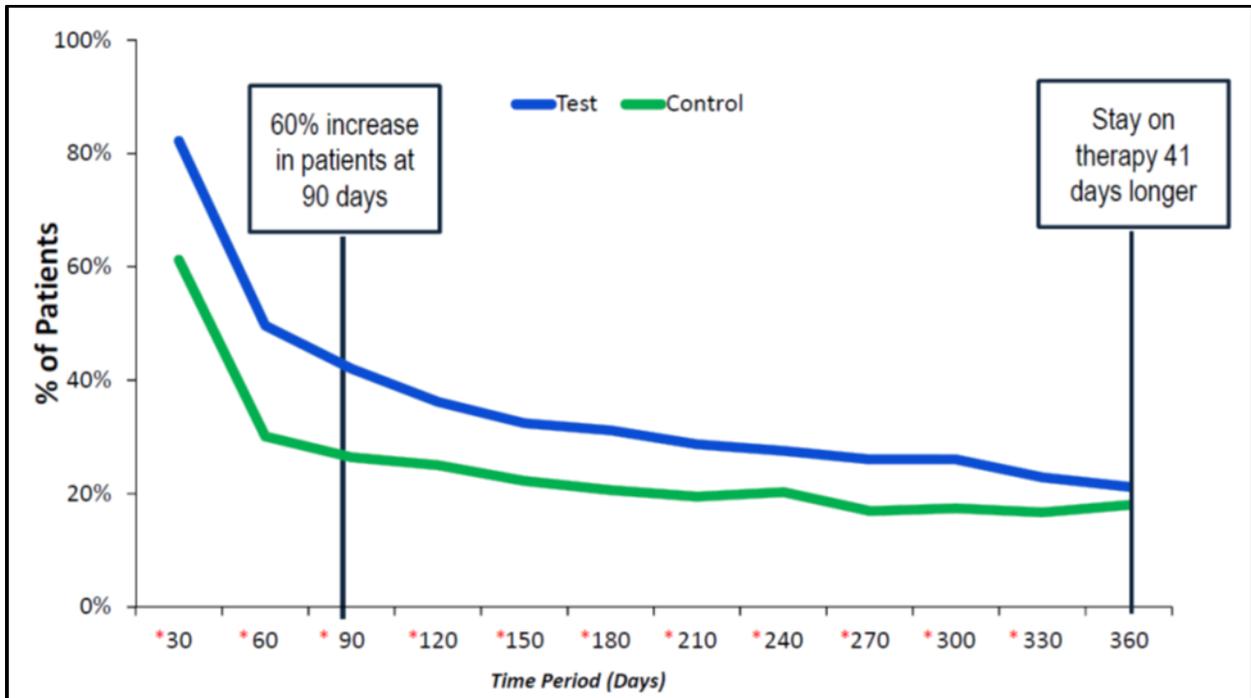
¹⁸ Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 171,024 visits; and that representatives visited 7.0 prescribers per day, on average, compared to a target of 7.1.

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?”

288. **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.

289. **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.

290. 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

As explained above, keeping patients on opioids for these lengths of time presented heightened risks of addiction and overdose.

291. Staff also told the Sacklers (as they had in 2009) that they were again targeting prescribers for OxyContin promotion through the Physicians Television Network. [REDACTED]

292. **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.”

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

294. **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.

295. **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.

296. 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.¹⁹ [REDACTED]

[REDACTED]

• • • 2013 • • •

297. **In January 2013**, Richard Sackler questioned staff about the drop in opioid prescriptions caused by Purdue sales representatives taking time off for the holidays. Richard Sackler was not satisfied: “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 returned to work, they would “boost” opioid prescriptions again.

¹⁹ Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 199,466 visits; and that representatives visited 7.0 prescribers per day, on average, compared to a target of 7.1.

298. 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 Physicians Television Network. The video urged doctors to give patients Purdue's opioid savings cards.

299. That same month, staff told the Sacklers that Purdue employed 609 sales representatives and, during Q4 2012, they visited prescribers 153,890 times.²⁰ [REDACTED]

300. **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.

301. **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

²⁰ Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 191,264 visits; and that representatives visited 7.0 prescribers per day, on average, compared to a target of 7.1.

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]

302. **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.

303. 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.”

304. The Sacklers met with Sales VP Russell Gasdia about the strategy for selling high doses. Gasdia told the Sacklers that “Titration 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.

305. Gasdia told the Sacklers that the staff would develop even more tactics to sell higher doses. They were using Purdue’s 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.”

306. That same month, staff told the Sacklers that Purdue employed 637 sales representatives and, during Q1 2013, they visited prescribers 155,354 times.²¹ [REDACTED]

[REDACTED]

307. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

²¹ Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 172,788 visits; and that representatives visited 6.8 prescribers per day, on average, compared to a target of 7.1. Staff assured the Sacklers that “call productivity is expected to increase towards the targeted goal throughout 2013.”

[REDACTED]

[REDACTED]

308. 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 representative visits to promote OxyContin 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, a strategic consulting firm, to study how to get doctors to prescribe more OxyContin.

309. 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.

310. 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.”

311. 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.²² [REDACTED]

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

312. 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. They urged the Sacklers to demand more sales visits from sales representatives, 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.

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

²² Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 191,184 visits; and that representatives visited 6.9 prescribers per day, on average, compared to a target of 7.1.

314. **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. [REDACTED]

[REDACTED] McKinsey urged the Sacklers to direct sales representatives to 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. They 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.

315. Second, McKinsey recommended that the Sacklers fight back against steps that the DEA, the U.S. Department of Justice, and others were taking to stop illegal drug sales. Two months earlier, the Walgreens pharmacy company 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 a “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.

316. 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: they reported 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.’”

317. **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 pharmacies, specialty pharmacies, or Purdue distributing opioids to patients directly.

318. 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
Calls made on physician	0 P1 1 P2	18 P1 1 P2
OxyContin scripts written during 2 nd half of year	177	344

Graphic from McKinsey presentation recommending targeting high prescribers

319. **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 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 promised to increase the budget for promoting OxyContin by \$50,000,000, and get sales representatives to generate more prescriptions with a new initiative to be presented to the Sacklers the following week.

320. 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 at 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 758,164 times in the year.

321. **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.

322. 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]

323. Staff also reported to the Sacklers that another key initiative during Q3 2013 was for sales representatives to promote OxyContin for patients who had never taken opioids before. [REDACTED]

324. Staff also told the Sacklers that analysis conducted in July 2013 showed that opioid savings cards earned the Sacklers more money by keeping patients on opioids longer; specifically, more patients stayed on OxyContin longer than 60 days. Staff reported to the Sacklers that Purdue was pushing opioid savings cards in sales representative visits, through email to tens of thousands of health care providers, and online. [REDACTED]

325. Staff reported to the Sacklers that Purdue paid their family \$399,920,000 during January–September 2013. But staff told the Sacklers that, from January to September 2013, Purdue lost hundreds of millions of dollars in potential profits because some prescribers were shifting away from higher doses of Purdue opioids.

326. Staff also reported to the Sacklers that a key initiative in 2013 was to train sales representatives to keep patients on Butrans opioids longer. They told the Sacklers that, at the same time as the initiative to keep patients on opioids longer, Purdue launched a new high dose of its Butrans opioid; sales representatives began promoting the new high dose to physicians using new 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 prescriptions and highlighted that opioid savings cards generate especially "high returns" by keeping patients on opioids longer.

327. 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.

328. 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.

329. Staff also reported results from Purdue's marketing through the "OxyContin Physicians Television Network." Purdue had selected [REDACTED] as targets for that scheme. Staff told the Sacklers that the new network increased opioid prescriptions.

330. 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.²³ [REDACTED]

331. **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 susceptible prolific prescribers.

332. 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** • • •

333. **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

²³ Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 196,845 visits; and that representatives visited 6.9 prescribers per day, on average, compared to a target of 7.1.

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.

334. **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."

335. To get higher 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]

336. 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.”

337. 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 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.

338. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

339. Staff told the Sacklers that Purdue employed 632 sales representatives and, during Q4 2013, they visited prescribers 176,227 times.²⁴ [REDACTED]

340. That February report was the last of its kind. After Q4 2013, Purdue discontinued the detailed Quarterly Reports that had created a paper trail of targets for sales visits and 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.

341. **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.²⁵

342. **In May**, 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

²⁴ Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 183,960 visits; and that representatives hit the target of visiting 7.1 prescribers per day, because managers reduced the target for visiting pharmacies to allow more visits to prescribers.

²⁵ Staff told the Sacklers that Purdue employed 643 sales representatives.

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

343. **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.” 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. The CEO 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.

344. That same month, staff sent the Sacklers an “Update on L.A. Times mitigation effort” about tactics to discourage scrutiny of Purdue’s misconduct.²⁶ 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.²⁷

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*

²⁶ A few weeks after receiving the mitigation update, Richard Sackler demanded that the *L.A. Times* send him all the paper’s correspondence with Purdue.

²⁷ Years earlier, the Sacklers had tried to influence the *New York Times* to be “less focused on OxyContin/Purdue.”

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.

345. **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.”

346. **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.”

<p>RISKS</p> <ul style="list-style-type: none">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.

347. **In August**, [REDACTED]

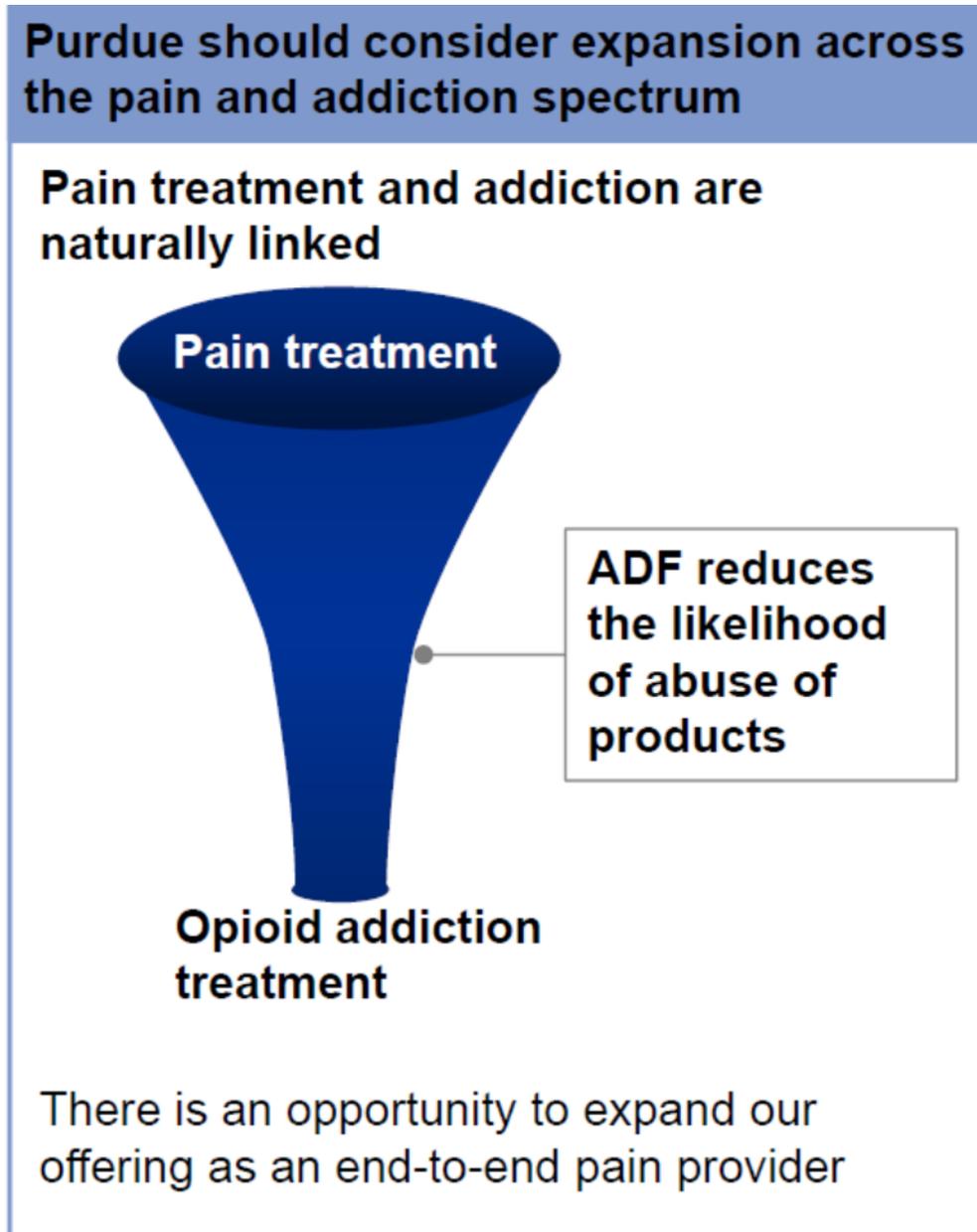
[REDACTED]

[REDACTED]

[REDACTED]

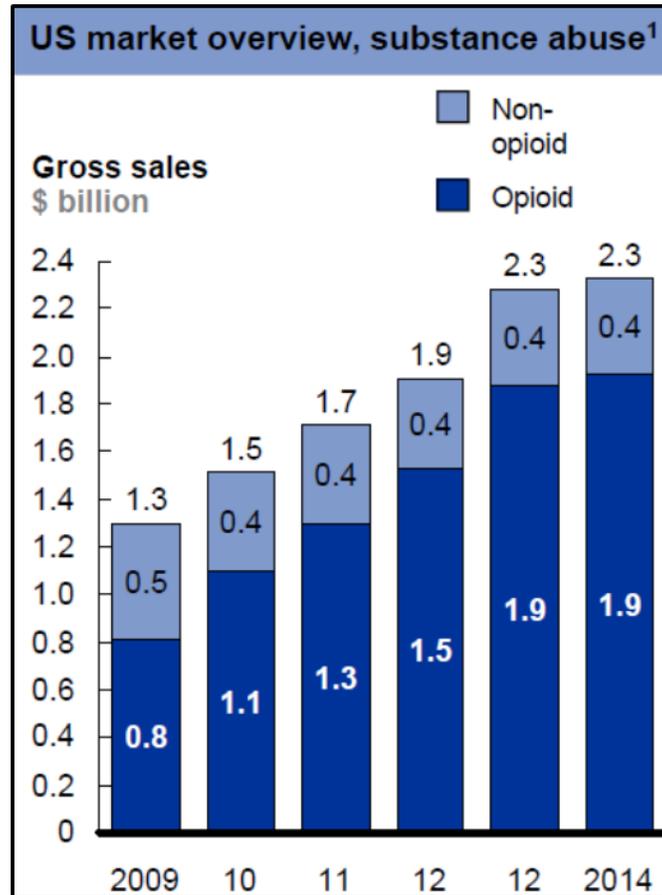
348. **Project Tango**. In September 2014, Kathe Sackler dialed in to a confidential call about *Project Tango*. *Project Tango* was a secret plan for Purdue to expand into the business of selling drugs to treat opioid addiction. In their internal documents, Purdue staff wrote down what

Purdue 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’s secret “Project Tango”²⁸

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



The presentation reviewed by Kathe Sackler and the staff showed that the addiction catastrophe provided an excellent compound annual growth rate (“CAGR”): “Opioid addiction (other than heroin) has grown by ~20% CAGR from 2000 to 2010.”²⁹

²⁸ “ADF” refers to Abuse-Deterrent Formulation, the crush-resistant version of OxyContin, which is no less addictive.

²⁹ The Board discussed *Project Tango* in October 2014.

350. 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.

351. 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 melts in a patient’s mouth. Staff assured Kathe Sackler that children were overdosing on pills, not films, “which is positive for *Tango*.”

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

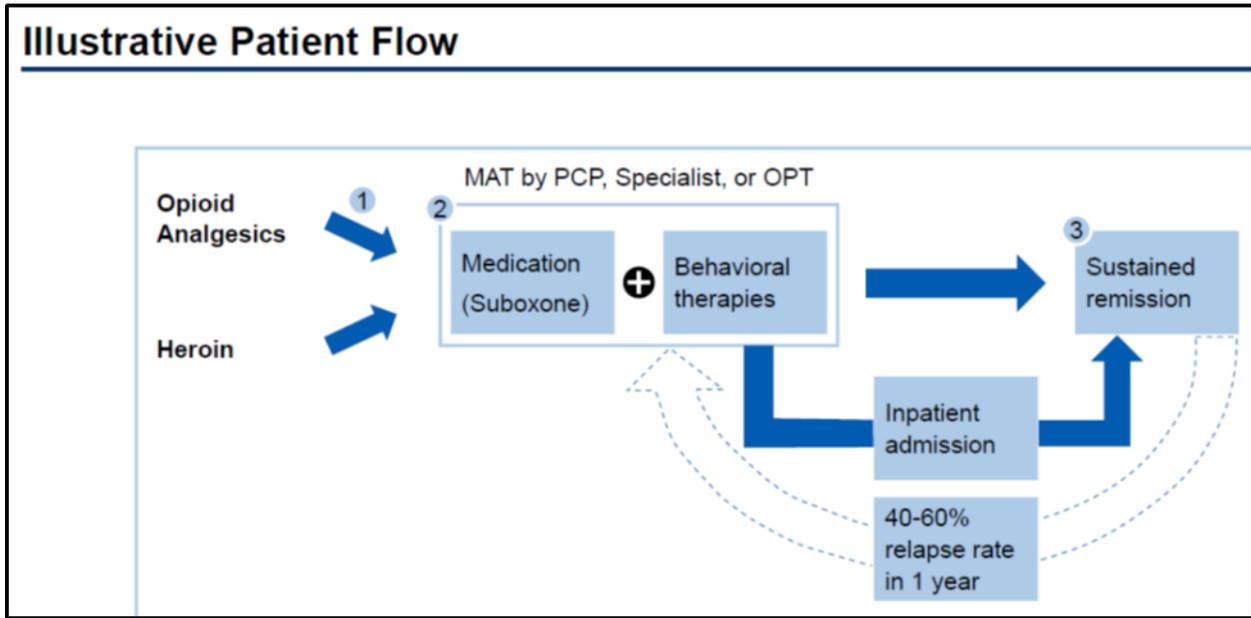
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

353. [REDACTED] 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

354. 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.

355. **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 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 “[l]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, paid an average salary of \$81,300 plus a bonus of up to an additional \$124,600 based on sales.

356. Meanwhile, sales staff exchanged news reports of a lawsuit accusing Purdue of deceptive marketing in Kentucky. They 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.” Despite that quote, because the article did not reveal the Sacklers’ role in the misconduct, Purdue’s Vice President of Corporate Affairs stated: “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]

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

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

359. 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 • • •

360. Early in the morning of **January 2**, staff began working to collect 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.³⁰

361. 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' payout would be the total amount of Purdue opioid sales.

³⁰ Mark Timney had started as CEO a year earlier with the idea that he could "separate Board interaction from the organization" so the Sacklers would stop directing sales staff. That effort failed.

362. [REDACTED]

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

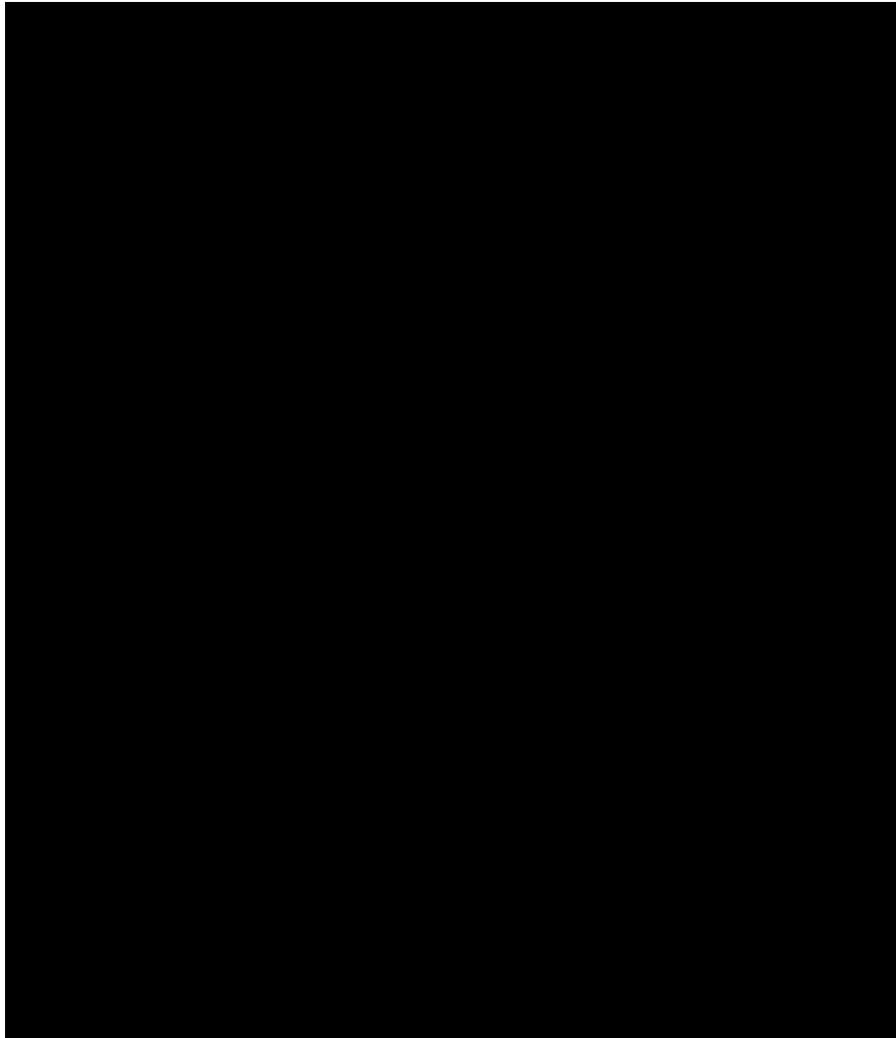
364. The Sacklers voted to expand the sales force by adding another 122 representatives.

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

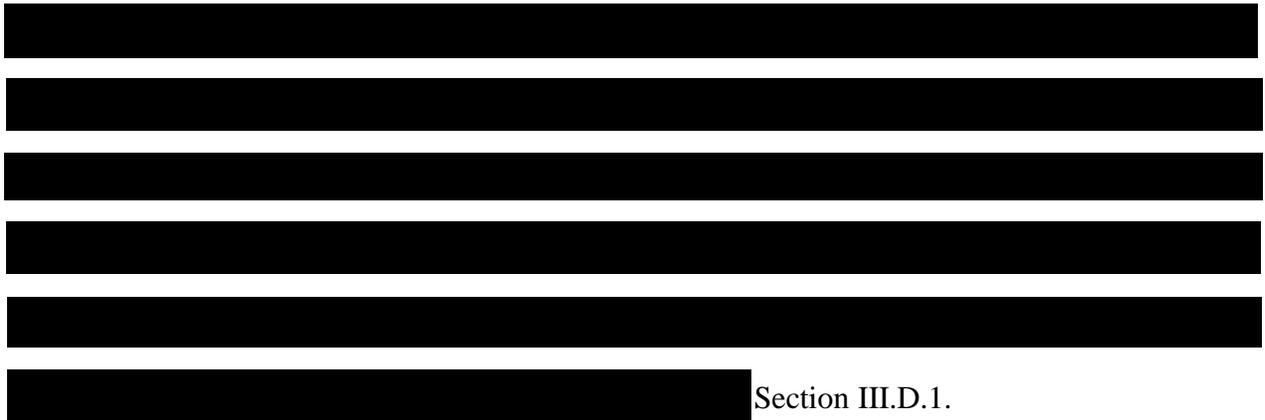
366. The Sacklers knew and intended that, because of their vote, more sales representatives would promote opioids to prescribers in Indiana. [REDACTED]

[REDACTED]³¹

³¹ Specifically, the representatives promoted Purdue opioids [REDACTED]



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



Section III.D.1.

368. **In October**, Purdue executives identified avoiding investigations of Purdue’s opioid marketing as a “Key Activity” in the company’s Operational Plan.

369. **In November**, the Sacklers voted on the budget for Purdue for 2016. Staff warned the Sacklers that public concern about opioids could get in the way of Purdue's plans. 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 million.

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

371. 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.

372. 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.

373. **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 • • •

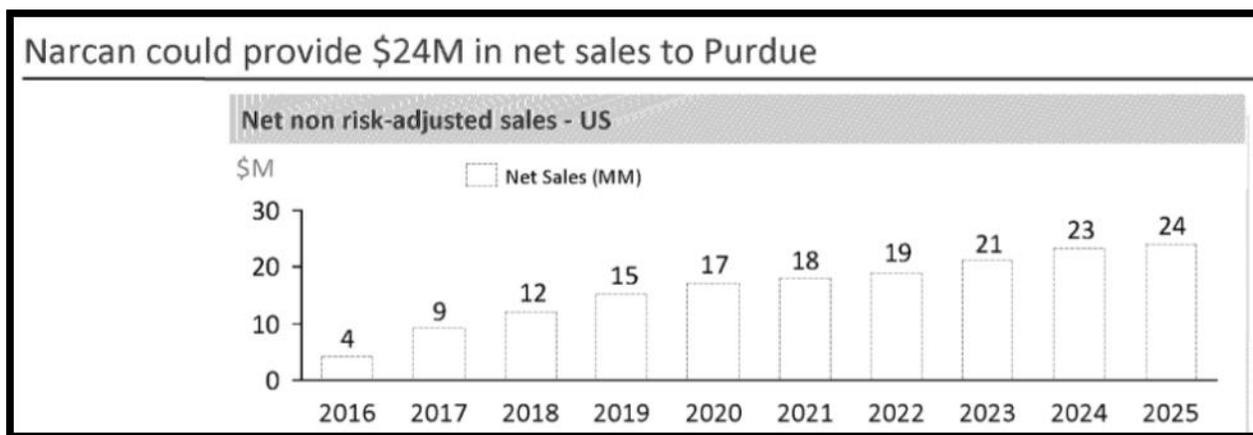
374. **In 2016**, the Sacklers met with the rest of the Board in January, March, April, June, August, October, November, and December.

375. **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 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.

376. **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 medical school program was funded by the Sacklers.

377. **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 they 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, [REDACTED]

[REDACTED] 32

378. 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:³³

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

2016 Mid-Year Board Update

379. *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”

³² They planned to “[s]egment opioid patients to better understand target end-patients (e.g., long-term script users).”

³³ “ADF” on the slide refers to abuse-deterrent formulations of opioids, such as Purdue’s crush-resistant OxyContin, which do not prevent addiction.

(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.

380. *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.

381. *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.

382. *Fourth*, the Sacklers had long sought to hide behind the FDA’s approval of Purdue’s drugs. But FDA approval does not shield the Sacklers’ deceptive marketing, which 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.

383. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

384. **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."

385. **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 • • •

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

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

387. **In May**, staff told the Sacklers that an independent nonprofit 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.

388. 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.

389. **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."

390. 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 was a problem for Purdue because it showed actual footage from Purdue's misleading advertisements next to video of people who overdosed and died.

391. 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 led Purdue so far off course 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.³⁴

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

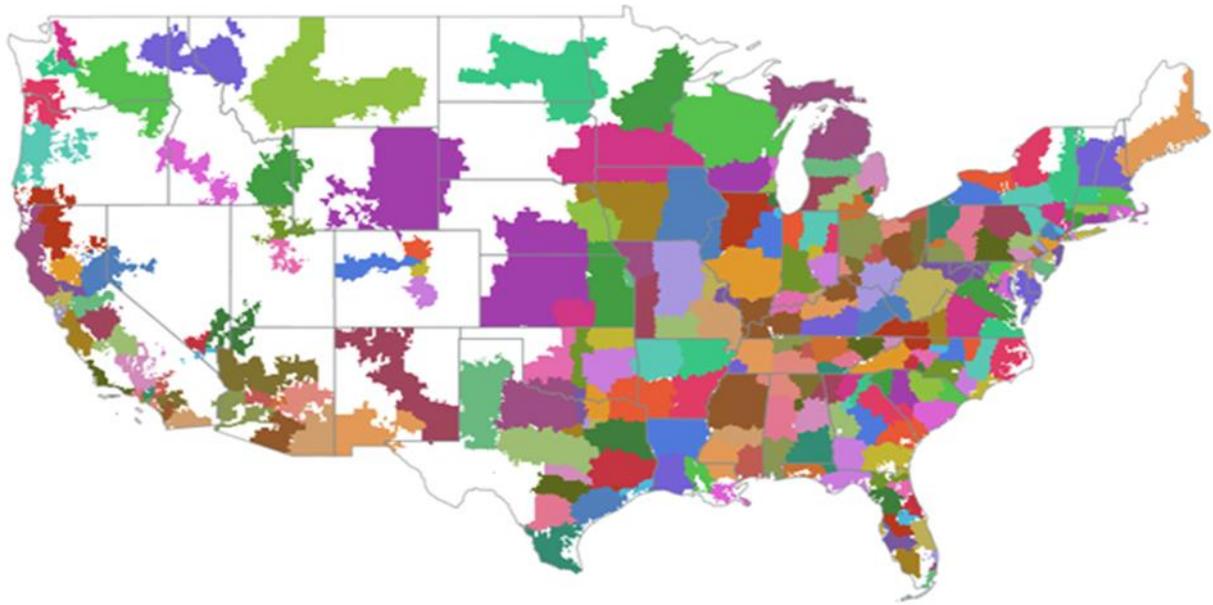
393. **In October**, Richard Sackler learned that insurance company Cigna had cut OxyContin from its list of covered drugs and replaced it with a drug from Purdue’s competitor, Collegium. Richard read that Collegium had agreed to encourage doctors to prescribe lower doses of opioids, and Collegium’s 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

³⁴ Ironically, the Sackler family members have agreed to pay \$75 million to fund an addiction research and treatment center at Oklahoma State University as part of a settlement between Oklahoma and Purdue. That amount represents approximately 2% of the over \$4 billion the Sacklers paid themselves after 2008 and after Purdue’s criminal conviction.

thought was to counterpunch. He immediately suggested that Purdue drop Cigna as the insurance provider for the company health plan.

394. 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: “[T]he 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.”

395. **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 Indiana. Staff even gave Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler a map of where the remaining sales representatives worked, with Indiana shaded to show that Purdue would keep visiting prescribers here.



Purdue internal map of planned sales representative territories for 2018

• • • 2018 • • •

396. 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.

397. [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.

398. **By April**, 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.

399. **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.

400. **On November 14, 2018**, the Indiana Attorney General filed suit to hold Purdue accountable. But just as their employees predicted, the Sacklers tried to obfuscate their involvement. 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.

III. In Carrying Out Marketing Strategies Devised and Approved By the Sackler Defendants, Purdue’s Sales Force Misrepresented the Risks and Benefits of Opioids in Numerous Ways.

A. Purdue failed to correct its previous false and misleading marketing messages.

401. In the 2007 Settlements, Purdue entered into consent decrees with the federal government and numerous states to resolve investigations into its marketing of OxyContin between 1996 and 2007. As part of these settlements, Purdue admitted that it had misrepresented key facts about the safety of its opioids—particularly about the risk of addiction. The Purdue Frederick Company and its top representatives plead guilty to federal crimes related to these misrepresentations. Purdue admitted that its sales representatives, as a matter of course:

- falsely told some health care providers that OxyContin had “less euphoric effect, and less abuse potential than short-acting opioids”;

- falsely told prescribers that OxyContin—the first “extended release” a/k/a “long-acting” (“ER/LA”) opioid—had fewer “peak and trough” effects than short-acting opioids, also known as immediate release (IR) opioids;
- falsely told prescribers that patients could discontinue OxyContin therapy without experiencing withdrawal symptoms; and
- falsely told prescribers that OxyContin was more difficult to intravenously abuse than generic oxycodone.

The Sackler Defendants reviewed and approved the company’s guilty pleas admitting this conduct.

402. In addition to making these deceptive claims through its sales force, Purdue also deceptively advertised OxyContin in print advertisements in medical journals and in videos distributed directly to physicians:

- 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
- Purdue print advertising claimed that OxyContin provides “Consistent Plasma Levels Over 12 Hours” and depicted plasma levels on a logarithmic scale. The graph however, visually distorted and intentionally obscured the steep decline in OxyContin’s efficacy over 12 hours, falsely 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.

403. The 2007 Settlements required Purdue to cease 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. The Sackler Defendants, as members of the Board, were covered persons responsible for complying with the settlements terms on reporting any violations.

404. Had Purdue ceased its marketing efforts after the 2007 Settlements, it may not have had a duty to affirmatively correct these past misrepresentations. But Purdue neither ceased its deceptive marketing nor corrected its past misrepresentations. Instead, Purdue intensified its marketing efforts and built upon the deceptive messaging that had established chronic opioid therapy as a first-line option for treatment of routine, moderate pain. In failing to affirmatively correct the statements already deemed—and in some cases admitted—to be false and misleading, Purdue engaged in material omissions.

405. Through its sales force and deceptive promotional materials, Purdue continued, from 2010 through at least 2017, to omit, understate, and misrepresent the serious risks posed by opioids and to overstate the benefits of chronic opioid therapy, while failing to disclose the lack of evidence supporting long-term use.

406. 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 helped to create or were aware of and authorized and approved 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.

B. Purdue minimized or omitted the known and serious risks of addiction and overdose.

407. As explained above, the Sackler Defendants directed Purdue employees to minimize the risk of addiction by promoting a narrative in which opioid deaths and disability

were attributed to abuse and abusers, not to prescribed use and foreseeable addiction. This messaging was implemented through several sales pitches: (1) baldly understating addiction risk; (2) re-casting “addiction” as a benign condition, like tolerance or pseudo-addiction; (3) convincing prescribers that addiction could be prevented by screening likely abusers from treatment.

408. To convince Indiana prescribers and patients that opioids are safe, Purdue has deceptively minimized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction. Purdue trained its sales representatives to overemphasize the technical distinctions between dependence and addiction in order to convey the deceptive message that “dependence” was a benign consequence of opioid use and that “addiction” was a rare outcome of opioid use that could be easily anticipated and prevented.

409. Purdue’s misrepresentations and omissions, which are described below, have reinforced each other to create the dangerously misleading impressions that:

- 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 pain that requires **more** or **higher doses** of opioids;
- 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;
- The abuse-deterrent formulations of Purdue’s opioids both prevent abuse and are inherently less addictive; and
- Physicians can prescribe steadily higher doses of opioids without added risk of dependence or addiction.

Each of these misrepresentations is contrary to FDA and CDC scientific conclusions, as well as a substantial body of scientific literature regarding the limitations, disadvantages, and risks of long-term opioid use.

410. These core messages on addiction risk flowed directly from the strategy devised 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. 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.

1. Omitting, trivializing, and mischaracterizing addiction risk.

411. In furtherance of the strategic narrative set by the Sackler Defendants—to deny addiction risk or deflect addiction concerns—throughout the time period covered by this Complaint, Purdue’s Indiana sales representatives regularly omitted from their sales conversations any discussion of the risk of addiction from long-term use of opioids. As part of the State’s investigation, Purdue produced a total of 270,071 Indiana call notes (each representing a single sales representative visit to an Indiana prescriber), dated January 3, 2006 through December 22, 2017. Of the 270,071 call notes memorializing Purdue sales representative visits to Indiana prescribers over this 10-year period, there are only 416 instances—approximately 0.1% (one-tenth of one percent)—mentioning “addiction,” “addicted,” or any variation thereof.

412. These omissions are material and rendered even facially truthful statements about opioids false and misleading because they were incomplete in light of Purdue’s prior misrepresentations regarding the risk of addiction. By failing to correct earlier false statements,

Purdue's sales representatives let stand the dangerous and incorrect impression that patients who receive chronic opioid therapy for legitimate pain conditions are unlikely to become addicted.

413. Even when Purdue's sales representatives mentioned addiction, they emphasized that Purdue's ER/LA opioids (OxyContin, Butrans, and Hysingla) provide a slow-onset, stable dose with "steady-state" blood plasma levels—encouraging Indiana prescribers to take away the misleading message that these particular opioids were safer because they do not produce the euphoric high that fosters addiction.

414. One Indiana prescriber recalls a Purdue employee telling her—approximately within the last two years—that extended release opioids [*e.g.*, OxyContin, Butrans, and Hysingla] were less addictive because they provide a more steady, stable relief without an immediate rush.

415. Another Indiana prescriber remembers that the Purdue sales representative who visited him approximately within the last two years explained that extended release opioids do not provide the highs that can cause people to become addicted.

416. Yet another Indiana prescriber was told by a Purdue detailer—approximately within the last three to five years—that continuous release opioids have no peaks and valleys.

417. Promotional materials and other publications Purdue disseminated or made available in Indiana during the relevant time period have included similar, mutually reinforcing messages minimizing the risk of addiction.

418. In 2011, for example, Purdue published an unbranded pamphlet, *Providing Relief, Preventing Abuse*, for prescribers that misleadingly depicted the signs of addiction. The pamphlet showed graphic pictures of the stigmata of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa—and promoted the scientifically discredited concept of

pseudoaddiction. Purdue sales representatives regularly distributed *Providing Relief, Preventing Abuse* to Indiana prescribers for years. At least one former Purdue sales representative in Indiana was handing this pamphlet out “on a daily basis” in 2015. She described the indications that someone may be abusing opioids identified in *Providing Relief, Preventing Abuse* as “pictures of like pupils and things, if a patient is, I guess, abusing, how their pupils might look ... track marks, just behavior that seemed a little erratic, like calling the doctor 20 times in a two-hour period.”

419. [REDACTED] Purdue created and promoted an unbranded campaign, *Partners Against Pain*, to distribute medical education resources and information, which included a website styled as an “advocacy community” for better pain care. Purdue sales representatives widely showed and disseminated *Partners Against Pain* materials to Indiana prescribers and encouraged prescribers to use the *Partners Against Pain* website as a resource as recently as 2015. Indiana residents accessed the *Partners Against Pain* website 10,093 times between 2012 and 2016.

- (a) One early *Partners Against Pain* pamphlet 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.”
- (b) Through 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.
- (c) Purdue sales representatives also distributed a pamphlet called “Clinical Issues in Opioid Prescribing,” which made similar claims about drug-seeking behaviors. It 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. This document was available on the *Partners Against Pain* website until at least 2016.

- (d) A *Partners Against Pain* “Pain Management Kit” likewise promoted the pseudoaddiction concept, referring prescribers to the 2001 AAPM/APS “Definitions Related to the Use of Opioids for the Treatment of Pain.” The *Partners Against Pain* “Pain Management Kit” was distributed in Indiana from at least 2006 through 2012.

420. Purdue also created, funded, and controlled a website targeted at patients, caregivers, and prescribers: *In the Face of Pain* (www.inthefaceofpain.com), which was publicly accessible until it was deactivated in October 2015, following an investigation by the New York Attorney General. Upon information and belief, this website was promoted to Indiana prescribers and patients. Indiana residents accessed the *In the Face of Pain* website 7,913 times between 2010 and October 2015.

421. The *In the Face of Pain* website is another example of Purdue’s “unbranded” marketing; although it featured the Purdue copyright at the bottom of each page, the site was designed to cultivate the “impression that it [was] neutral and unbiased.”

- (a) The *In the Face of Pain* website asserted that policies limiting access to opioids are “at odds” with best medical practices, and encouraged patients to be “persistent” in finding doctors who will treat their pain—but contained **no mention** of the risk of addiction. Instead, the website contained a single link, that if followed, took the consumer to a separate document that briefly mentioned opioid abuse, but not addiction.
- (b) At the same time, *In the Face of Pain* contained testimonials from several dozen physician “advocates” speaking positively about opioids but failed to disclose that from 2008 to 2013 (the years for which this partial financial information is available), Purdue paid 11 of these advocates a total of \$231,000.

422. Purdue’s misrepresentations regarding the addictive properties of OxyContin and the risk of 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.

423. Purdue pleaded guilty to federal charges of misbranding under the Federal Food, Drug, and Cosmetic Act for deceptively claiming that patients taking OxyContin would not

experience peaks and valleys. Moreover, Purdue was aware that for many patients, OxyContin does not provide even 12 hours of pain relief and will cause patients to experience a crash (or valley) hours before they are due to take their next pill.

424. Purdue’s other statements regarding addiction are also indefensible. Studies have shown that at least 8 to 12%—and as many as 30% or even 40%—of patients on long-term opioid therapy experience problems with addiction. At the conclusion of its evidence review in 2016, the CDC found that “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder,” the diagnostic term for addiction. The CDC also emphasized that “continuing opioid therapy for 3 months substantially increases risk for opioid use disorder.”

425. Purdue’s depiction of opioid addiction as manifesting in only the most extreme methods of abuse—methods associated with illegal street drugs—is also contrary to fact. Opioid addicts who snort and inject crushed prescription pills are uncommon; the far more typical reality is that patients become addicted and maintain that addiction through oral use. These depictions were harmful because they reassured doctors that as long as they were not observing those more extreme signs of abuse, they did not need to worry that their patients were abusing or addicted to opioids.

2. Exaggerating the efficacy of “abuse-deterrent” properties.

426. In 2010, Purdue developed an abuse-deterrent formulation for OxyContin and Hysingla ER—a new coating and elements to make these pills more difficult to crush or inject.

427. Purdue regularly cites its introduction of abuse-deterrent opioids as evidence of its commitment to addressing the opioid crisis. 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 original patent was set to expire.

428. In furtherance of the strategic narrative set by the Sackler Defendants to deny addiction risk or deflect addiction concerns, Purdue used the abuse-deterrent reformulation of its opioids as a primary selling point to differentiate its products from its competitors, especially generic opioids. In delivering this sales message, Purdue sales representatives falsely claimed or implied to Indiana 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.

429. Multiple Indiana prescribers recall Purdue sales representatives telling them that the abuse-deterrent properties of Purdue drugs made them safer than generics, that abuse potential was greatly decreased, and—as recently as late 2017—that the way to prevent addiction was to use an abuse-deterrent formulation.

430. An Indiana doctor specifically recalled that, between 2012 and 2015, a Purdue representative told him that when drugs were diverted to the streets, they were only taken in crushed form, not swallowed whole.

431. Another Indiana doctor recalled being told by a Purdue sales representative in the last two years that the ER formulation was less addictive because it did not offer the same immediate high as the IR products, and the formulation changes for OxyContin ER made it more difficult to abuse and therefore less subject to abuse or diversion.

432. Purdue's internal documents confirm that it was well aware that prescribers who were detailed about the abuse-deterrent properties of Purdue's opioids were likely to come away with the misimpression that those opioids had a "safer formulation," were reformulated in a manner that would "prevent abuse," and had less potential for "abuse and diversion." The majority of those prescribers considered abuse-deterrent technology to be "an advantage" and

said it had “a favorable impact on their perception of opioids.” Purdue also knew that prescribers detailed on the abuse-deterrent properties of OxyContin were significantly more likely to increase their prescribing of that drug compared to prescribers who had not been detailed with that message.

433. Data from inVentiv Health, a market research and analytics company that tracks promotional messaging in the pharmaceutical industry, further demonstrate that Purdue’s sales representatives made these deceptive statements to prescribers. Practitioners in the Midwest Region—which includes Indiana—received messages from Purdue sales representatives that OxyContin has “less potential for abuse,” has been found “abuse preventative in clinical trials,” and that the drug is abused “only when used incorrectly.”

434. Indiana prescribers’ recollections are also consistent with a 2014 national survey of 1,000 primary care physicians—in which nearly half reported that they believed abuse-deterrent formulations of opioids are inherently less addictive. One-third of the doctors in that same study had the mistaken impression that most prescription drug abuse is by means other than swallowing the pills as intended.

435. Purdue’s misrepresentations were deceptive and misleading for several reasons:

- **First**, they were inconsistent with the FDA-approved labels for OxyContin and Hysingla ER, which affirmatively indicate that their abuse-deterrent properties can be defeated, state that the drugs can be abused orally notwithstanding the abuse-deterrent properties, and do not indicate that the drugs prevent or reduce abuse, misuse, or diversion.
- **Second**, prescription opioid abuse takes several forms, the most common of which is oral abuse, which includes not only using the drugs without a prescription, but also taking higher or more frequent doses than prescribed. When the FDA reviewed Purdue’s application for approval of the abuse-deterrent reformulation, the agency 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” (emphasis added).

- **Third**, 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 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. Of the survey respondents who continued to abuse the drug, most either continued with or switched to oral abuse, while about a third found various methods to continue snorting or injecting the drug.

436. It appears from contemporaneous correspondence that the Sacklers knew that the abuse-deterrent formulation would not actually deter abuse, let alone prevent addiction, **before** they brought the abuse-deterrent formulation drug to market in 2010. And yet, abuse deterrence became a point of product differentiation and a key marketing message after OxyContin was reformulated, with approval of the Sackler Defendants. [REDACTED]

[REDACTED]

[REDACTED]

437. Purdue knew that its marketing should not go beyond the words “abuse-deterrent properties” to claim that OxyContin and Hysingla actually deter abuse. The FDA was aware that the abuse-deterrent formulation of OxyContin required more “effort, time, experience and tools to create a fine powder for intranasal abuse,” but could still be crushed and abused in this manner.

438. Purdue’s deceptive marketing of the benefits of its abuse-deterrent formulations was particularly dangerous because it overcomes the very risk that doctors and patients are concerned about. 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.

C. Purdue failed to disclose the increased risks of higher doses of opioids.

439. Purdue falsely told Indiana 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 dosages as a clear pathway to increased sales and revenue.

440. 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—because chronic opioid patients develop a tolerance to the drugs, requiring the dose to be increased over time. 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.” These materials were presented to the Sacklers for their approval and, on information and belief, were approved.

441. Purdue’s sales representatives omitted from their sales conversations any discussion of increased risks associated with 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, non-opioid pain relievers to the lowest dose of OxyContin, without discussing that the dose would need to be increased over time. Indiana sales representatives used the patient vignette of Sam, an elderly patient on non-steroidal anti-inflammatory drugs (“NSAIDs”) to gain a prescriber’s commitment to convert patients from non-opioid medications to the lowest dose of OxyContin:

I mentioned Oxycontin to physician with indication and the seven tablet strengths. I mentioned Sam in Sales Aid (OP0560) who has osteoarthritis of the knee and has taken different NSAIDS and he was having a hard time tolerating them. I discussed with physicians [sic] would prescribe after this scenario for Sam and physician mentioned if he has insurance could prescribe low dose Oxycontin as 10mgs. Q12H. I mentioned good answer and that Oxycontin would be appropriate for this patient and can increase the Q12H dose if [sic] needed.

442. Purdue and Purdue-sponsored publications and CMEs available in Indiana also misleadingly suggested that higher opioid doses carried no added risk. 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 advice provided to the Sacklers by McKinsey in 2013: to use “patient pushback” to influence hesitant prescribers.

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

444. Even where Purdue marketing pieces acknowledged that certain serious risks rose with increasing the opioids' dose, they failed to disclose the dramatically 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.

445. There is no substantial scientific evidence that doses of opioids can be continuously titrated upward without significant added risk. On the contrary, 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. Patients receiving high doses of opioids as part of long-term opioid therapy are 3 times to 9 times more likely to suffer overdose from opioid-related causes than those on low doses.

446. 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. The CDC has published that “higher dosages haven’t been shown to reduce pain over the long term. One randomized trial found no difference in pain or function between a more liberal opioid dose escalation strategy (with average final dosage 52 MME) and maintenance of current dosage (average final dosage 40 MME).”

447. More specifically, the CDC explains that “there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages.” The CDC also states that there are “increased risks for opioid use disorder, respiratory depression, and death at higher dosages.”

448. Because of these risks, the 2016 CDC Guideline advises doctors to “avoid increasing dosage” above 90 morphine milligram equivalents (MME) per day. 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, and the 30 milligram dose equals the 90 MME limit when taken twice daily as directed. Yet, many patients have continued to receive dangerously high doses of opioids. Among Indiana patients insured by Medicaid, for example, 49% of patients taking OxyContin between 2012 and July 2018 ultimately were prescribed doses exceeding the CDC’s recommended limit of 90 MME.

D. Purdue promoted the long-term use of opioids despite the lack of supporting evidence.

449. To convince Indiana prescribers and patients that opioids should be used to treat chronic pain despite the unavoidable risk of addiction, Purdue had to persuade them that there were significant benefits to long-term opioid use.

1. Overstating pain control and improvement in function.

450. Purdue promoted the purported benefits of long-term opioid use—pain control and improved function—while falsely and misleadingly implying that these benefits are supported by scientific evidence. In their sales conversations with Indiana prescribers, Purdue sales representatives who worked in Indiana between 1997 and 2016 failed to disclose the lack of evidence supporting long-term use. Purdue promotional materials shown and distributed to Indiana prescribers by Purdue detailers likewise promoted long-term use without disclosing the absence of long-term studies.

451. For example, the OxyContin “Conversion and Titration Guide,” which sales representatives widely distributed in Indiana, 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”—implying that use for a period of years was appropriate without disclosing the absence of any evidence showing that therapeutic benefits existed for use lasting 6 months, 12 months, or longer. Purdue detailers showed this guide to prescribers across the country, including in Indiana, for years. Even after removing the specific references to periodic annual and semi-annual reviews, Purdue still trained its detailers to recommend semi-annual or annual medication reviews.

452. Purdue specifically has claimed—also without evidence—that long-term opioid use will improve patients’ daily function and quality of life. Purdue’s sales representatives active

in Indiana between at least 1992 and 2013 have delivered this unsubstantiated and deceptive message in their Indiana sales visits, and Indiana prescribers recall hearing this deceptive marketing message as recently as 2015.

453. On information and belief, materials written or sponsored and influenced by Purdue were distributed or available in Indiana to reinforce this message. The APF book *Exit Wounds* asserted unequivocally: “The bottom line with opioids is that these are very valuable pain-relievers when used correctly and responsibly and can really help improve your functioning in daily life.” APF’s *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.”

454. Purdue knew better. The FDA has cautioned 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.

455. In internal correspondence from 2011, Purdue acknowledged that it needed evidence to support these claims. It is impossible to believe that Purdue was not aware of available and growing evidence indicating that opioids do not improve patient function, and, in fact, may worsen patients’ health over a long-term course of therapy.

- A 2006 academic review of studies found that “[f]or functional outcomes, ... other [non-addictive] analgesics were significantly more effective than were opioids.”³⁵
- A 2011 study concluded that increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic

³⁵ Andrea D. Furlan et al., “Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects,” 174(11) *Can. Med. Ass’n J.*, 1589–94 (2006).

stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.³⁶

- Studies from 2007, 2008, 2012, 2013, and 2014 of patients using opioids to treat lower back pain and migraine headaches, for example, consistently showed that patients experienced deteriorating function over time, as measured by ability to return to work or physical activity, pain relief, rates of depression, and subjective quality-of-life measures.³⁷
- Studies analyzing workers' compensation claims in 2008 and 2012 found that (a) workers who take opioids are almost four times more likely to reach costs over \$100,000, owing to greater side effects and slower returns to work;³⁸ (b) receiving an opioid for more than seven days increased patients' risk of being on work disability one year later;³⁹ and (c) an opioid prescription as the first treatment for a workplace injury doubled the average length of the claim.⁴⁰

456. These findings are consistent with the CDC's exhaustive review of the literature, concluded in 2016. The CDC summarized: "there is **no good evidence** that opioids improve pain or function with long-term use" (emphasis added). Specifically, the CDC noted that "evidence is

³⁶ Richard A. Deyo et al., "Opioids for Back Pain Patients: Primary Care Prescribing Patterns and Use of Services," 24 *J. Am. Bd. Fam. Prac.*, 717–27 (2011).

³⁷ Luis E. Chaparro et al., "Opioids Compared to Placebo or Other Treatments for Chronic Low-Back Pain," 8 *Cochrane Database of Systematic Reviews* (Aug. 27, 2013); Jeffrey Dersh et al., "Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders," 33(20) *Spine*, 2219–27 (Sept. 15, 2008); Dawn C. Buse, "Opioid Use and Dependence Among Persons With Migraine: Results of the AMPP Study," 52 *Headache: The J. of Head & Face Pain*, 18-36 (Jan. 2012); Nat'l Headache Found., *Opioid Treatment of Migraine is Associated with Multiple Risks*, News Briefs, June 15, 2012, <http://www.headaches.org/2012/06/15/opioid-treatment-of-migraine-is-associated-with-multiple-risks/>; Nat'l Headache Found., "Migraine Patients Taking Addictive Or Non Approved FDA Migraine Treatment, Press Kits," May 15, 2007, http://www.headaches.org/press/NHF_Press_Kits/Press_Kits/Press_Kits_Migraine_Patients_Taking_Addictive_Or_Non_Approved_FDA_Migraine_Treatments (last visited Apr. 15, 2014).

³⁸ Jeffrey A. White et al., "The Effect of Opioid Use on Workers' Compensation Claim Cost in the State of Michigan," 54(8) *J. of Occupational & Environ. Med.*, 948–53 (2012).

³⁹ Gary M. Franklin et al., "Early Opioid Prescription and Subsequent Disability Among Workers with Back Injuries: The Disability Risk Identification Study Cohort," 33(2) *Spine*, 199–204 (2008).

⁴⁰ Dongchun Wang et al., "Longer-Term Use of Opioids," *Workers Comp. Res. Inst.* (Oct. 2012).

limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia.” In addition, the CDC observed that the risks of addiction and death “can cause distress and inability to fulfill major role obligations.” Purdue’s claims that patients will experience functional improvement, in addition to lacking evidence, also ignore these very serious consequences.

2. Overstating the efficacy of screening tools.

457. In furtherance of the strategic narrative set by the Sackler Defendants to deny addiction risk or deflect addiction concerns, Purdue falsely instructed Indiana prescribers and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to reliably identify and safely prescribe opioids to patients, including patients predisposed to addiction.

458. Purdue conveyed these messages in its in-person detailer visits in Indiana, where sales representatives discussed with health care providers ways to screen patients at high risk for addiction through urine tests and patient contracts. When Indiana prescribers expressed hesitance about prescribing a Purdue opioid for fear of attracting drug seekers, internal Purdue records from 2011 and 2012 reflect that the sales representative did not address the concern, but rather parroted inapplicable responses like, “prescribe[e] for appropriate [sic] patients within guidelines, using INSPECT, and urine drug screens” or only give the drug “to patients she knows and trusts”—advice that relates to diversion, not to dependence or addiction. These prescribers told the Purdue representative they would consider prescribing the drug.

459. Sales representatives in Indiana used and disseminated the *Partners Against Pain* “Pain Management Kit,” which contained several drug abuse screening tools. The Pain

Management Kit included the “Opioid Risk Tool” created by opioid advocate Dr. Lynn Webster, who received research funding from Purdue. The Opioid Risk Tool is a five-question, one-minute screening tool that assumes honest and accurate patient self-reporting (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.

460. One former Purdue sales representative who detailed Indiana prescribers from 2009 until 2015 described the *Partners Against Pain* material (including the kit and screening tool) as something she used with Indiana prescribers because it contained “tools and resources for physicians ... [to] help identify appropriate [opioid] patients.”

461. Purdue also deceptively promoted screening tools in CMEs and at scientific conferences as reliable means for predicting and managing addiction risk. For example, Purdue sponsored a 2011 web-based CME taught by Dr. Lynn Webster titled “Managing Patient’s Opioid Use: Balancing the Need and Risk.” Upon information and belief, this webinar was available to Indiana prescribers. Dr. Webster’s webinar deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented “overuse of prescriptions” and “overdose deaths”—providing the type of false assurance designed to encourage opioid prescribing. This CME was offered online as late as 2017.

462. Purdue also funded a deceptive 2012 symposium titled “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.

463. 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 2016 CDC Guideline notes that there are **no studies** assessing the effectiveness of risk mitigation strategies such as screening tools, patient contracts, urine drug testing, or pill counts—all widely believed by doctors to detect and deter abuse. As a result, the 2016 CDC 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.”

464. Such misrepresentations made health care providers more comfortable prescribing opioids to their patients, and patients more comfortable starting on chronic opioid therapy. Purdue’s misrepresentations were critical to assuring doctors—who were beginning to see or hear about rising 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.

3. Promoting OxyContin as safer than NSAIDs and other OTCs.

465. One of Purdue’s main selling points for its opioids—including but not limited to OxyContin—was that unlike NSAIDs and other pain relievers (*e.g.*, Advil or Tylenol), there is no maximum dose for opioids. This gave the **false impression** that opioids were **safer than Advil or Tylenol**. Purdue also deceptively presented the risks of opioids in comparison to the risks presented by over-the-counter pain relievers like NSAIDs—containing ibuprofen (*e.g.*, Advil or Motrin), which can cause gastrointestinal bleeding at high doses—and acetaminophen (*e.g.*, Tylenol), which can cause liver toxicity at high doses.

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

increased risk from using high doses of opioids. The CME was edited by Dr. Russell Portenoy, who received research support, honoraria, and consulting fees from Purdue. Issued by the American Medical Association (AMA) in 2013, the CME remains available online to Indiana prescribers from the AMA. Purdue also sponsored a pain pamphlet for physician assistants that 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.

467. Former Purdue sales representatives who were detailing Indiana prescribers as recently as 2015 confirmed that they told Indiana prescribers that acetaminophen and ibuprofen posed risks to patients, while simultaneously explaining that Purdue's opioids do not contain the allegedly dangerous chemical compounds found in Advil and Tylenol. They also promoted Purdue's opioids in comparison with popular, short-acting "combination opioids" like Vicodin. As one former Indiana Purdue sales representative explained, because short-acting opioids often contain acetaminophen, there was a ceiling dose, "strictly because of the acetaminophen ... the ceiling dose really comes into play when you have the acetaminophen." The sales representative went on to say, "Probably one of the biggest as far as deaths is liver toxicity with acetaminophen."

4. Equating 12-hour dosing with 12-hour pain relief.

468. To convince Indiana prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. While the product labeling specifies 12-hour dosing, Purdue's marketing went well beyond the label's limited instructions to **take** OxyContin every 12 hours by (1) affirmatively claiming that OxyContin **lasts** for 12 hours; and (2) by failing to disclose the material fact that OxyContin

does not provide 12 hours of pain relief for a significant percentage of patients. Purdue has known this since 1996. There is even a name for it: “end-of-dose failure.”

469. The Sacklers [REDACTED] As described in Section II.B,

[REDACTED]

470. [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, [REDACTED] 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 the 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.

471. Purdue’s decision to seek FDA approval for 12-hour dosing (“Q12”) when the drug was introduced in 1996 was a business decision. Internal Purdue marketing documents show that Purdue considered 12-hour dosing the key to distinguishing OxyContin from its competition—short-acting, generic opioids (like Percocet and Vicodin) that require patients to wake in the middle of the night to take the next dose in order to maintain adequate pain control. Purdue has held tight to this perceived market advantage, which explains why Purdue has never

pursued FDA approval for more frequent dosing on the OxyContin label (e.g., every 8 hours). In Purdue's own words, 12-hour dosing was "a significant competitive advantage."

472. 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 in the middle of the night to take another dose. 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 this marketing claim.

473. 12-hour dosing has remained a principal feature of Purdue's marketing and has been featured in most OxyContin promotional pieces.

- A 2012 version of Purdue's Conversion and Titration Guide—which was distributed nationally (including in Indiana) through 2017—for example, contains the tag line: "Because each patient's treatment is personal / Individualize the dose / Q12 OxyContin Tablets."
- A 2014 visual aid used by sales representatives refers not merely to OxyContin, but to "every 12-hour OxyContin" and "Every-12-Hour OxyContin Tablets."
- The 2017 Conversion and Titration Guide advises prescribers that they can increase the dosage to achieve adequate pain relief "as clinical need dictates, while maintaining every 12-hour dosing."

None of these pieces discloses that the pain relief from each 12-hour dose will not last 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.

474. Indiana health care providers complained to Purdue sales representatives that OxyContin was not giving 12 hours of pain relief to a significant number of their patients. One Indiana doctor told the State that he complained to Purdue for years about the fact that a 12-hour dose only lasts for eight hours. He said that he repeatedly brought this up with the Purdue sales

representative who visited him over the past 6 years, and the representative's response was to encourage higher dosing of OxyContin.

475. When Purdue sales representatives were asked whether Indiana doctors raised this concern, a district manager who worked in Indiana until 2016 replied, “[w]e heard it all the time.”

476. Instead of addressing the real problem, Purdue trained sales representatives who worked in Indiana between 1997 and 2016 to tell prescribers to increase the patient's OxyContin dose as a way to compensate for end-of-dose failure. As one district manager explained, “Our FDA approved labeling was only for q12 hour dosing, so that's all we could talk about.” Thus, she trained her Indiana detailers to “encourage the doctor to maybe titrate the patient [increase the dose] instead of adding a third dose.” Purdue's constant suggestion to increase the dose was not accompanied by appropriate warnings regarding increased risk of addiction associated with increased doses, as discussed in Sections III.B.1 and III.C. During the State's investigation of Purdue, an Indiana district manager confirmed that she reported to her superiors at Purdue—multiple times and over a span of years—that she was frequently hearing that 12-hour OxyContin dosing did not work.

477. Despite their training to give a non-responsive, scripted answer to prescriber concerns about OxyContin's 12-hour duration, Purdue sales representatives also hinted at or outright told Indiana prescribers that prescribing OxyContin 3 times a day was an option. According to one Indiana health care provider, when she informed a Purdue detailer that her patients were not getting 12 hours of relief from OxyContin, the detailer told her that she had heard this from other doctors' offices, and that those other offices were writing the prescription for 8-hour (3 times a day) dosing. The prescriber inferred that the detailer was implicitly

encouraging her to write the prescription for 8-hour dosing. Another prescriber also told Purdue sales representatives that “lots” of her patients were not getting 12 hours of relief from OxyContin. The sales representative acknowledged that they heard the same thing from other doctors and told her to try prescribing every 8 hours (3 times a day).

478. 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, one-third of the patients dropped out because the treatment was ineffective. Purdue’s researchers changed the rules to allow patients to take supplemental immediate release/short-acting opioids—referred to as “rescue medication”—between OxyContin twice-daily doses. In another OxyContin study conducted by Purdue, the majority of patients used rescue medication, and 95% resorted to it at least once.

479. 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.” End-of-dose failure causes patients to 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. This exacerbates the risks of addiction, overdose, and death. With a higher dose, the pain relief does not last 12 hours—patients experiencing end-of-dose failure will simply experience higher highs and lower lows, increasing their craving for their next pill.

480. “Titrating up” to cover the end-of-dose failure also means that health care providers routinely prescribe OxyContin in doses that exceed the maximum recommended daily limit of 60mg (90 MME). Based on a nationwide analysis by the *Los Angeles Times* in 2014,

more than 52% of patients taking OxyContin longer than three months were on doses greater than the 60mg that the 2016 CDC Guideline urges prescribers to “avoid” or “carefully justify.”

These high doses of OxyContin are similarly prevalent in Indiana. About 59% of OxyContin and Hysingla prescriptions covered by Medicaid in Indiana in the last decade exceeded the CDC threshold.

5. Purdue used savings cards to initiate and encourage long-term use of opioids.

481. Purdue’s distribution of prescription discount “Savings Cards” for OxyContin, Butrans, and Hysingla was part of its deliberate marketing strategy to encourage, initiate, and extend long-term use of these drugs. Purdue carried out this strategy at the direction of the Sacklers, who had studied the use of savings cards and urged Purdue to optimize their use to meet long-term sales goals.

482. Purdue promoted, marketed, advertised, or distributed Savings Cards in Indiana that offered patients discounts on their out-of-pocket costs for OxyContin, Butrans, and Hysingla and encouraged long-term use of these drugs. Examples of the Savings Cards that Purdue promoted, marketed, advertised, or distributed include:

The OxyContin Savings Card

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

Prescription Savings Card

OXYCONTIN[®] II
(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–5:00 pm EST Mon.–Fri.

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

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

- 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}
[Ethinamate Bitartrate] (C)
OPREVEKIN-KYOWA PHARMACEUTICAL

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. See Hysingla ER Trial Offer website 01/9/2016.

Only paying patients and patients whose prescriptions are covered under Medicare, Medicaid, or other government programs are eligible.

For health questions, please call 1-800-396-2622 800 am - 8:00 pm EST, Monday through Friday.

Please read accompanying Full Prescribing Information including Basic Warning on the cover of box and the Medication Guide.

©2014 Purdue Pharma L.P., Deerfield, IL 06/14/14 014801-ETC - 1/14

Pharmacist: Please be informed when working with us. **LoopyScriptSM**
Rx BIN: XXXXXX Rx PCN: Loyalty
Rx GRP: XXXXXXXX ISSUER: OXXXXX
ID#: XXXXXXXX
Other coverage restrictions apply.



Hysingla^{ER}
[Ethinamate Bitartrate] (C)
OPREVEKIN-KYOWA PHARMACEUTICAL

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

Patients must obtain Hysingla ER Savings Card for further savings. Savings Card can only be used when accompanied by a valid prescription for Hysingla ER (hydrocodone bitartrate) bitartrate (Purdue). Other restrictions apply. Patients whose prescriptions are covered under Medicare, Medicaid, or other government programs are not eligible.

Patients with questions, please call 1-855-396-2622 8:00 am - 8:00 pm EST, Monday through Friday.

Please read accompanying Full Prescribing Information, including Basic Warning on the cover of box and the Medication Guide.

©2014 Purdue Pharma L.P., Deerfield, IL 06/14/14 014801-ETC - 1/14

Pharmacist: Please be informed when working with us. **LoopyScriptSM**
Rx BIN: XXXXXX Rx PCN: Loyalty
Rx GRP: XXXXXXXX ISSUER: OXXXXX
ID#: XXXXXXXX
Other coverage restrictions apply.

To learn more and download cards visit [Hysingla ER.com](http://HysinglaER.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 payor" 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 eVoucherRxSM 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

483. The State alleges, on information and belief, that the Savings Cards for OxyContin, Butrans, and Hysingla that Purdue promoted, marketed, advertised, or distributed in Indiana do not bear prominent disclosures—as required by Indiana law—that the benefits offered are not insurance. A disclaimer sometimes appeared in the “terms and conditions” language in pamphlets or other material accompanying Savings Cards, but it did not appear on the Savings Cards themselves, nor did it appear in a prominent place in bold and prominent type.

484. Purdue trained sales representatives to discuss Savings Cards on every sales call. Purdue tracked the redemption of these cards and evaluated detailers' "sales skills" based, in part, on how many Savings Cards were redeemed in their territory.

485. 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. In 2013, Purdue identified the need to "drive appropriate titration and length of therapy ... with continuing patients" as a "critical success factor[]" for the OxyContin brand.

486. 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." Internal Purdue business plan documents separately confirm that the Savings Card Program "has consistently shown a positive [return on investment]" and that "patients who receive these cards have up to a 49% increase in their likelihood to remain on OxyContin after 90 days."

487. Purdue also used Savings Cards to encourage new patients to try its opioids, by making the drugs significantly cheaper. 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."

488. Purdue marketed, promoted, advertised, or distributed Savings Cards to Indiana prescribers and pharmacies for use by Indiana patients, who could present the cards at participating pharmacies for discounts on out-of-pocket pharmacy costs. Detailers met with prescribers and pharmacists and advised them to inform their opioid patients / customers about available discounts that would reduce the out-of-pocket price.

489. 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), and Purdue call notes show that detailers in Indiana instructed prescribers on how to download savings cards. Purdue sales representatives in Indiana also 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.

490. In the 2007 Settlements, Purdue expressly agreed to stop distributing samples of OxyContin. Indiana, moreover, strictly regulates the distribution of free narcotic samples. Nonetheless, Purdue used the promotion of Savings Cards to eliminate or steeply discount patient co-payments—effectively making these drugs free (or very inexpensive) to patients—as a way to drive long-term use.

491. As discussed in Section II.B, Purdue’s staff kept the Sacklers apprised of the status of Purdue’s savings card program. In June 2008, for example, staff explained to Richard, Jonathan, Kathe, and Mortimer how many of Purdue’s opioids savings cards had been used and what percentage of those cards had been redeemed for all five purchases. The following year, staff reported to the Sacklers that the number of savings cards that had been used had doubled. Staff also reported to the Sacklers on more than one occasion that Purdue was successfully using savings cards to keep patients on opioids longer. Richard Sackler, in particular, took an interest in Purdue’s use of opioid savings cards and sent staff [REDACTED] emails seeking to expand Purdue’s use of them.

E. Purdue targeted the elderly and opioid-naïve patients to expand its market.

492. Part of Purdue’s strategy to continue expanding its market share, and hence its revenue, has been to target two overlapping markets: **the elderly**, a demographic that has seen an explosion in opioid prescribing in recent years, and **opioid-naïve patients**, those who previously had not taken opioids.

493. Training materials and sales goals for Purdue’s sales representatives, as well as Indiana detailer call notes and sales manager “ride-along” reports from 2011 through 2014, include multiple references to Purdue’s efforts to persuade doctors to start prescribing OxyContin and Purdue’s other ER/LA opioids to elderly patients. As one former Indiana sales representative stated, Purdue encouraged its representatives to remind all Indiana prescribers that OxyContin was covered for Medicare part D patients: “[the elderly was] an approved ... patient population to go after.” Call notes from Indiana also show that detailers told prescribers that OxyContin was “safe in the elderly” while simultaneously reminding them of all OxyContin dosage levels available. Managers evaluating the performance of sales representatives in Indiana noted favorably when sales representatives “Bridged to Oxycontin and asked for those med d pts [Medicare part D patients].”

494. There is ample evidence from former Indiana detailers to demonstrate the extent of Purdue’s efforts to persuade doctors who were prescribing immediate release opioids such as Percocet (a Schedule II opioid that combines oxycodone and acetaminophen) to prescribe OxyContin instead, by emphasizing the dangers of liver toxicity from acetaminophen. This practice of using ER rather than IR opioids 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.

495. When Indiana sales representatives were confronted by a reluctant prescriber, they were trained to promote (and did, in fact, promote) 10mg and 15mg OxyContin to allay the prescriber's concerns. As one Indiana detailer recorded in her call notes, "Shared the Oxycontin med D grid and asked for consideration for 65+ patients with chronic pain. Discussed Nursing home patients too. Noel said she shy [sic] away from C2 products. But she likes the idea of Oxycontin lower doses with Q12h control."

496. Purdue detailers in Indiana also specifically targeted nursing home residents through their physicians. In 2016, one-third of 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 maximum threshold that the CDC has set. These high doses underscore the reality that even elderly patients do not simply remain on OxyContin 10mg—their doses escalate too, along with the concomitant increased risks.

497. Purdue's targeting of elderly patients overlapped with Purdue's broad marketing push to persuade doctors to prescribe OxyContin and Butrans to opioid-naïve patients—even when faced with reluctant practitioners. For example, an October 2012 sales representative training bulletin provided suggested questions for prescribers designed to elicit their commitment to converting opioid-naïve patients to OxyContin. Manager ride-along notes from detailing visits made in Indiana during 2014 reflect Purdue's focus on expanding prescriptions through the conversion of opioid-naïve patients to OxyContin. One manager praised a sales representative for getting a prescriber to try Butrans for a particular patient after challenging the prescriber with: "when was the last time you initiated a new start for an opioid?" Another manager praised

his detailer in 2012 when he “positioned Butrans for the opioid naïve,” and obtained the Indiana doctor’s prescribing “commitment for these types of patients.”

498. Purdue’s decisions to target the elderly and opioid-naïve patients reflect a business strategy that placed little value on the well-being and safety of consumers. Elderly patients are at higher risk for the most dangerous side effect of opioids—respiratory depression. They also are likely to experience more severe consequences from falls (fractures and hospitalizations) caused by the cognitive impairment that is associated with opioid use.⁴¹ A 2010 paper reported that elderly patients who used opioids had a significantly higher rate of deaths, heart attacks, and strokes than users of NSAIDs.⁴²

499. For opioid-naïve patients, the unproven benefits of long-term opioid therapy are not justified by the known and serious risks—particularly when safe and effective alternative treatments for their conditions exist. As the CDC summarized in 2016, “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. Purdue targeted this population to enrich itself.

500. Part and parcel of marketing to the elderly and opioid-naïve was Purdue pitching ineffective low doses. Purdue long-ago recognized that it would need to overcome the reservations of prescribers who preferred to treat chronic pain with NSAIDs, combination acetaminophen-low dose opioid products (such as Percocet), and non-pharmacologic therapies (*e.g.*, exercise, improved ergonomics, and physical therapy) rather than expose their patients to the risks of addiction and overdose associated with opioids. Purdue marketed the lowest doses of

⁴¹ Saunders, Dunn et al., “Relationship of opioid use and dosage levels to fractures in older chronic pain patients,” *J. Gen. Intern. Med.*, 2010;25:310-5.

⁴² Kathleen W. Saunders et al., “Relationship of opioid use and dosage levels to fractures in older chronic pain patients,” 2010(25) *J. Gen. Intern. Med.*, 310–15 (Jan. 2009).

OxyContin—the 10mg and 15mg pills—as safe **and** effective for treating pain to assuage concerns about opioid side effects and addiction risks when Purdue had no scientific evidence demonstrating that those low doses provide any analgesic relief.

501. Purdue call notes from Indiana detailers show that sales representatives regularly promoted the 10mg and 15mg doses of OxyContin to Indiana prescribers until at least 2015—without disclosing the lack of evidence of efficacy or distinguishing them as merely “starter doses” that would require escalation for effective analgesia. Compensation documents for Indiana detailers show that Purdue specifically encouraged promotion of these doses, by using a multiplier for any growth in sales of the 10mg and 15mg doses when calculating bonus compensation. Sales of these low doses were worth 20% more than sales of the 20mg, 30mg, or 40mg tablets. Nothing in the call notes from Indiana detailers suggests that sales representatives advised prescribers that clinical research showed that 10mg OxyContin was ineffective. Interviews of Indiana prescribers and depositions of former Purdue sales representatives confirm that this critical information was neither delivered nor received.

502. 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 20 and 80 milligrams. At the same time, Purdue knew that once patients started on OxyContin, dose escalation (“titrating up”)—with the attendant increased risks of dependence and addiction—was likely, if not inevitable.

503. 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 20 mg, but not 10mg, was statistically significant in pain reduction compared with placebo.”

504. 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 “The 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 “Close observation and frequent titration are warranted until pain management is stable on the new opioid.”

505. 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.

506. 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 were specifically labeled as “retained” and “not for distribution.” On information and belief, this visual aid was sent by Purdue to sales representatives in Indiana.

Because each patient's treatment is personal
Individualize the dose



Tablets not actual size. Not actual patients.

Q12h OxyContin Tablets

Available in 7 tablet strengths to meet the individual therapeutic needs of your appropriate patient

507. 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.

508. 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.

509. 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.

510. Purdue also knew that the risks of dependence, overdose, and addiction rise with the dose. 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. This consequence is particularly disturbing when many of the patients targeted for 10mg and 15mg OxyContin were, as explained below, prime candidates for safer and more effective non-opioid therapies.

511. The Sacklers were aware of and approved the *Individualize The Dose* campaign. The marketing materials related to these messages were presented to the Sacklers on more than one occasion. As discussed in Section II.B, staff reported to the Sacklers in January 2013 that Purdue continued to reinforce the *Individualize The Dose* campaign. In May 2013, staff again reported to the Sacklers that the *Individualize The Dose* campaign was a marketing initiative. The campaign achieved two goals: it created a new population of users starting with low doses

and created a pipeline for escalation to higher doses—a sales goal that the Sacklers reinforced continuously.

IV. The Sackler Defendants Have Caused Significant Harm to Public Health, Welfare, and Finances in Indiana.

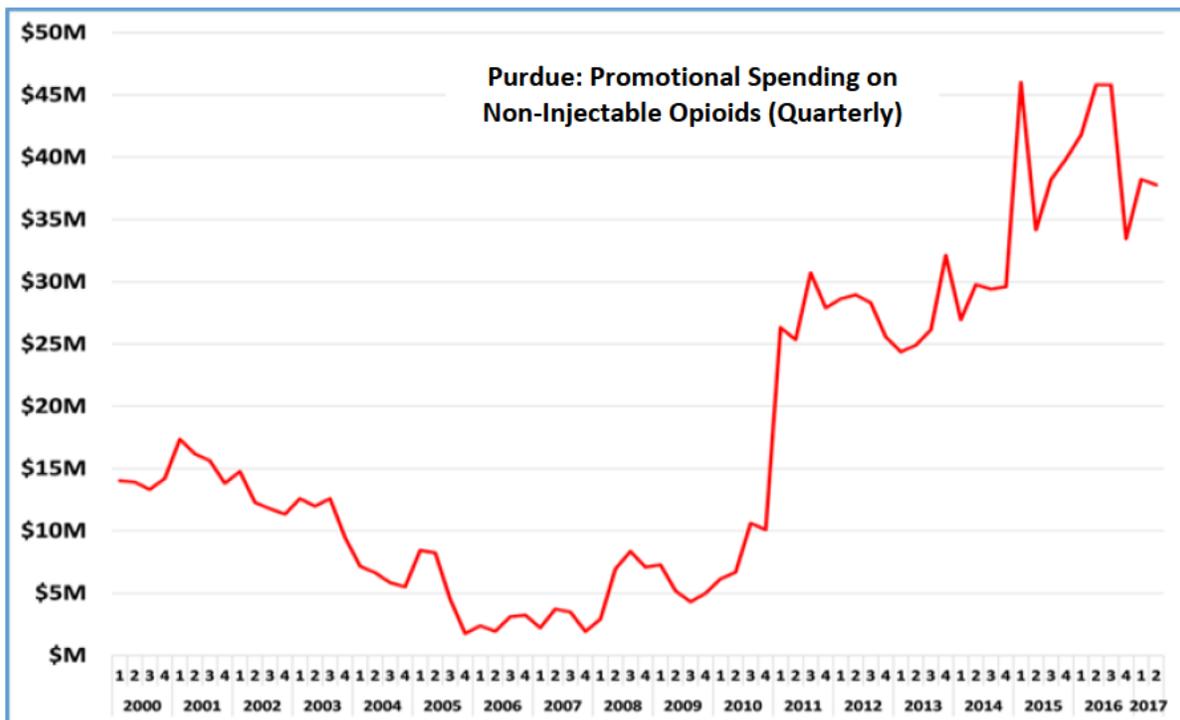
512. Indiana and its citizens are suffering an epidemic of opioid addiction, abuse, overdose, and other injuries—with their attendant societal costs—as a result of the Purdue-driven overprescribing of, and increased patient demand for, opioids. Through State-funded health programs, more than two hundred million dollars has been spent for opioid prescriptions and related treatment. Many of these opioid prescriptions were not medically necessary or appropriate and would not have been written but for Purdue’s fraudulent scheme.

A. Purdue’s deceptive marketing fueled opioid prescribing in Indiana.

513. Purdue’s misrepresentations have prompted Indiana health care providers to prescribe, patients to take, and the State to reimburse the cost of opioid prescriptions for the treatment of chronic pain—directly contributing to an explosion in opioid use. Opioids are the most common treatment for chronic pain in the United States. The CDC has reported that, by 2012, healthcare providers were writing 259 million opioid prescriptions annually—“enough for every adult in the United States to have a bottle of pills.”

514. Purdue accounts for the lion’s share of these prescriptions. Nationwide in 2013, there were 6 million prescriptions of OxyContin, resulting in \$2.6 billion in sales—giving Purdue 44% of the ER/LA opioid market and 24% of the overall opioid market (which includes generics). In Indiana, from 2012 to the present, Purdue accounted for 53.93% of branded opioid prescriptions paid by the State’s Medicaid programs, and 50.31% of those paid by the State’s Employee Health Plans and Workers’ Compensation Program.

515. Nationwide, opioid prescribing has quadrupled since 2000, a gigantic increase that corresponds to Purdue’s equally massive marketing push. As depicted below, Purdue’s national spending on opioid marketing stood at \$15 million per quarter in 2000. Its spending decreased from 2000 to 2007, as the company came under investigation by the U.S. Department of Justice and state attorneys general. But by 2010, with the introduction of Butrans and the reformulated “abuse-deterrent” OxyContin, Purdue redoubled its marketing investment, spiking to \$25 million per quarter in 2011. By 2016, with the introduction of Hysingla, it soared to more than \$40 million per quarter.



516. The largest component of this spending was the cost of sales representatives who were responsible for meeting with prescribers. Annual detailing expenditures nationwide rose from \$45 million in 2000 to \$156 million in 2014.

517. While many physicians may not readily acknowledge the significant impact of pharmaceutical detailing on their prescribing, the Sackler Defendants knew that detailing is a

powerful way to influence prescribing. The vast budget Purdue has devoted to detailing—hundreds of millions of dollars since the launch of “abuse-deterrent” OxyContin in 2010—is a testament to the success of this model and was reviewed, increased, and approved by the Sackler Defendants year after year.

518. The effects of detailer sales calls on prescribing are well documented. A 2009 study correlates 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.⁴³ Over a long period of time, the lockstep pattern is apparent, with spending and prescribing rising together: between 2007 and 2016, Purdue’s spending quadrupled while prescribing trebled.

519. The aggressive marketing approved and directed by the Sackler Defendants affected even those health care providers whom Purdue did not aggressively target directly. Purdue’s long-running marketing scheme entrenched opioids as a routine treatment for chronic pain, despite their serious risks and the absence of evidence that they improve patients’ pain and quality of life over the long term. Purdue’s marketing of opioids as the best, first-choice answer to chronic pain reinforced the psychological incentives for doctors who want to make their patients feel better: if they provide opioids, the patient is satisfied; if they do not, the patient feels underserved and may, with Purdue’s encouragement, seek another doctor who will.

B. The Purdue-driven increase in opioid prescribing has placed devastating social and economic burdens on Indiana.

520. Purdue’s success in expanding the market for opioids fueled the opioid epidemic in Indiana and nationally. In August 2016, the U.S. Surgeon General published an open letter to physicians, enlisting their help in combating this “urgent health crisis”—and linking that crisis to

⁴³ Art Van Zee, “The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy,” 99(2) *Am. J. Pub. Health*, 221 (2009).

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.”

521. The leading cause of drug overdoses in Indiana is prescription opioids: Indiana loses more citizens to prescription opioid overdoses annually than to cocaine and heroin combined. In Indiana, there were 757 opioid-overdose deaths in 2016—reflecting a 73% rise since just 2014. Year-over-year increases are continuing despite efforts by the State and the CDC to reduce prescribing and educate consumers.

522. Scientific evidence demonstrates the close link between opioid prescriptions and opioid abuse. A 2007 study found “a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse,” with compelling data for extended release oxycodone (i.e., OxyContin).⁴⁴ An estimated 60% of the opioids that are abused come, directly or indirectly, through physicians’ prescriptions.⁴⁵

523. Opioid prescribing and opioid-related overdoses have risen in tandem since 1999. Both have quadrupled. According to the CDC, patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC has 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.”

⁴⁴ Theodore J. Cicero et al., “Relationship between therapeutic use and abuse of opioid analgesics in rural, suburban, and urban locations in the United States,” 16 (8) *Pharmacoepidemiology and Drug Safety*, 827–40 (Aug. 2007).

⁴⁵ N. Katz, “Prescription Opioid Abuse: Challenges and Opportunities for Payers,” *Am. J. Manag. Care*, Apr. 19, 2013, at 5, <http://www.ajmc.com/publications/issue/2013/2013-1-vol19-n4/Prescription-Opioid-Abuse-Challenges-and-Opportunities-for-Payers>.

524. Opioid overdose deaths are only the tip of the iceberg, according to national data analyzed by the National Institute on Drug Abuse. For every overdose death in 2009, for example, 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.

525. The number of people in Indiana seeking treatment for opioid addiction also has risen. In 2000, of all Indiana admissions for substance abuse and addiction treatment, 5.5% reported prescription opioid misuse or abuse; by 2012, this number rose to 22%. According to public health experts' estimates, as many as 89,000 people in Indiana are currently struggling with opioid use, misuse, and addiction.

526. Opioids harm not only those who take them. Infants exposed to opioids in utero are at increased risk for Neonatal Abstinence Syndrome (“NAS”)—with 60–80% experiencing withdrawal symptoms upon birth including tremors, difficulty eating, vomiting, seizures, and respiratory distress. When untreated, NAS can be life-threatening. Research shows these children are likely to suffer serious neurologic and cognitive impacts.

527. Infants with NAS face more difficult and more expensive hospital stays. In 2014, the average length of a hospital stay in Indiana for infants without NAS was 2.24 days at an average cost of \$4,167, compared to 17.88 days at an average cost of \$97,555 for an infant with NAS. The total hospital cost for 657 infants with NAS in Indiana in 2014 was \$64 million.

528. Opioid abuse has impacted hospital emergency departments. An Indiana University report identified 641,940 visits to Indiana emergency departments due to non-fatal poisonings in 2010 alone, 90% of which were due to drug abuse. Non-fatal emergency room visits due to opioid overdoses increased 60% from 2011 to 2015, per the State Department of

Health. These visits represent not simply a health care cost, but a diversion of resources that affects the ability of emergency departments to deliver timely care.

529. More than 7,000 naloxone kits were distributed in 2016 and 2017 by treatment facilities, local health departments, schools, prisons, and jails through a State initiative to broaden the availability of this overdose-reversal drug.

530. Indiana's health care costs attributable to opioids totaled \$650 million in 2007 according to a Matrix Global Advisors report. This figure is 12th highest among all U.S. states and places Indiana even higher—8th—among all 50 states on a per capita basis with a cost of \$99 per citizen. This figure is certain to have risen as the opioid crisis has worsened.

531. In addition to its impact on Indiana's health care system, Purdue's conduct has led to other substantial costs for the State, in the form of social welfare spending, law enforcement costs, and lost productivity.

532. More than 60% of children removed from homes by Indiana's Department of Child Services come from families with parental drug use. Roughly one in four teenagers has abused prescription drugs, according to 2012 data. In 2015, 16.8% of Indiana teens had abused prescription drugs, including prescription opioids.

533. The proliferation of opioids has increased drug-related crime, requiring additional law enforcement resources. From 2013 through May 2016, Indiana led the nation in pharmacy robberies, with 367 reported. By contrast, California—with a population six times as large—had 47 fewer robberies during the same time period.

534. Prescription opioid addiction functions as a gateway to heroin addiction. Those addicted to prescription opioids are 40 times more likely to be addicted to heroin, and 45% of heroin users were also addicted to prescription opioids. Studies report that as many as 80% of

heroin addicts used prescription opioids before turning to heroin. Heroin overdose deaths in Indiana have risen dramatically, by more than 300%, from 54 in 2010 to 239 in 2015. And the rates of heroin dependence reported by people seeking treatment in Indiana have risen from 1.8% in 2001 to 7.9% in 2012.

535. A litany of adverse health outcomes is associated with heroin, including spontaneous abortions, chronic infections, liver disease, pulmonary complication, and death. When heroin is administered by injection, needle-sharing puts users at increased risk for HIV and Hepatitis B and C.⁴⁶ Ten Indiana counties have been recognized by the CDC as among the U.S. counties most vulnerable to HIV outbreaks due to injection drug use.

536. Fentanyl, an opioid even more dangerous than heroin because it is more potent, is becoming more prevalent. Indiana forensics labs recorded 600 cases of seized fentanyl in 2016, compared to 27 in 2013.

537. The severity of the epidemic is also reflected in the State's prison population. More than 50% of the State's prison population have reported substance use disorders. Of those incarcerated two or more times, 75% have substance abuse disorders.

538. Finally, the impact of opioid over-prescribing and misuse has seeped into Indiana businesses. As many as 80% of Indiana's employers have observed prescription drug misuse by their employees, according to a survey by the National Safety Council and the Indiana Attorney General. Almost two-thirds of Indiana employers surveyed perceived that prescription drugs present bigger problems in the workplace than illegal substances.

⁴⁶ Increased risk of HIV and Hepatitis is not limited to heroin users. In fact, one of the worst recent outbreaks of these diseases is attributable to prescription opioid abuse via needle injections. In Austin, Indiana, there were only five reported cases of HIV between 2004 and 2014. In late 2014, three individuals were diagnosed with HIV. By April 2016, there were 191 cases, half of which were located within a half-square-mile area. Ninety-percent of those infected with HIV were also infected with Hepatitis C.

539. Not surprisingly, drug overdoses are harming Indiana in terms of work loss. Data from the CDC show that the estimated lifetime medical and work loss costs in Indiana of drug overdose fatalities occurring in 2014 were \$1.4 billion, while costs incurred for non-fatal drug overdose emergency room visits were \$31.9 million. Over a four-year period from 2007 to 2010, hospitalizations for all non-fatal poisonings led to lifetime medical and work loss costs totaling \$350 million.

540. Indiana has taken numerous steps to stop over-prescribing in the State and reduce the harms caused by opioids:

- Setting restrictions on opioid coverage under the Medicaid program;
- Setting a new, seven-day supply limit on all initial opioid prescriptions;
- Improving INSPECT, the State's prescription drug monitoring program, to help providers determine what other opioids a patient has been prescribed;
- Requiring State health care professional licensing boards to review and revise their prescribing guidelines;
- Funding OB/GYN training on medication-assisted treatment (MAT) for opioid addiction to improve maternal health and reduce the incidence of NAS; and
- Passing legislation that provides funding and authority for first responders and laypersons to obtain and administer overdose-reversal drugs.

C. Purdue's conduct has burdened Indiana's health insurance and Workers' Compensation Programs with substantial direct costs.

541. Indiana has incurred significant costs due to the payment of false claims for chronic opioid therapy under the State's (a) Medicaid programs; (b) Employee Health Plans; and (c) 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.

1. State's Medicaid Programs.

542. The State provides comprehensive health care benefits—including prescription drug coverage—to low- and moderate-income residents through its Medicaid programs. These programs, which include Traditional Medicaid, the Healthy Indiana Plan, Hoosier Healthwise, and others, operate under the Indiana Health Coverage Programs—the single State agency designated to administer the Medicaid program in Indiana under Title XIX of the Social Security Act (collectively with its vendors, agents, and contractors, “IHCP”). Approximately 1.44 million Indiana residents are enrolled in these programs, which are administered through four managed care entities: Anthem, MDwise, MHS, and CareSource (“Medicaid Contractors”). The State pays the Medicaid Contractors a capitated rate—per beneficiary, per month—to provide the services covered under the IHCP.

543. The Medicaid Contractors enlist health care providers (“Medicaid Providers”)—including doctors and pharmacies—to provide services to beneficiaries. To uphold their responsibilities to the State, each Medicaid Contractor requires its Medicaid Providers to deliver medically necessary services. The Indiana Administrative Code defines a “medically reasonable and necessary service” as “a covered service ... that is required for the care or well-being of the patient and is provided in accordance with generally accepted standards of medical or professional practice.”

544. Separately, each Medicaid Provider enters a Provider Agreement with the State, under which they agree to provide covered services to program beneficiaries and to only submit claims for reimbursement “that can be documented by Provider as being strictly for medically necessary medical assistance services.” Each of the four Medicaid Contractors’ policies substantially reflects the Indiana Administrative Code’s definition of medical necessity.

545. 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. Medicaid Providers are required to submit information regarding the specific services provided to their patients to their corresponding Medicaid Contractor in order to be compensated. In submitting such information, Medicaid Providers certify the medical necessity of the services for which they seek reimbursement. The Medicaid Contractor audits and monitors these submissions for accuracy, completeness, and timeliness, and provides the data to the State. Pharmacy data is likewise provided to the State by the Medicaid Contractors. The State uses this to calculate and adjust, on an annual basis, the capitated rates that the State pays its Medicaid Contractors. Where utilization rates or costs rise, the State's capitated rates rise, too.

2. State's Employee Health Plans.

546. The State provides comprehensive health care benefits ("Employee Health Plans")—including prescription drug coverage—to its active, full-time employees and their dependents. These Employee Health Plans are self-funded, meaning the State bears the charges for all services and products used by beneficiaries.

547. The State's four Employee Health Plans all offer a variety of premium costs, deductibles, and out of pocket maximums, but coverage under each plan is restricted to medically necessary care. Each plan defines "medically necessary" as an intervention determined to be, among other things:

- Medically appropriate for and consistent with the symptoms and proper diagnosis or treatment of the beneficiary's condition, illness, disease, or injury;
- Provided in accordance with applicable medical and/or professional standards;
- Known to be effective, as proven by scientific evidence, in materially improving health outcomes; or

- Not more costly than an alternative service that is medically appropriate, or the service is performed in the least costly setting that is medically appropriate.

548. As of 2018, State employees' drug benefits are administered by CVS/Caremark. In order for prescription drugs to be covered by CVS/Caremark, they must be "medically necessary and not experimental or investigative." Prior to 2018, State employees' drug benefits were administered by Express Scripts and its predecessor Medco, which applied identical requirements and limitations to its prescription drug coverage.

3. State's Workers' Compensation Program.

549. 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 covering the employee's medical costs and lost wages. Indiana law prohibits the State from purchasing workers' compensation insurance, so its liability is covered through self-insurance.

550. The purpose of providing medical care as part of workers' compensation is "to treat the injury and bring the employee to" the point at which his or her condition "will no longer improve." The State is required to provide the employee with a "physician for the treatment of the employee's injuries, and in addition thereto, such services and products as the attending physician or the workers' compensation board may deem necessary."

4. False and material claims against the above State-funded programs.

551. Coverage under each of the above State-funded programs includes opioids, when prescribed by a doctor as medically necessary, as well as office visits for pain management (including toxicology screens), and treatments related to any adverse outcomes from chronic opioid therapy (such as overdose or addiction).

552. Most long-term use of opioids to treat chronic pain is not medically necessary or appropriate, as defined by the programs above. As set forth in Section III.B–D, long-term opioid

therapy for chronic moderate pain is not medically appropriate because the risks of long-term use generally outweigh the benefits. In fact, long-term use can cause hyperalgesia (increased sensitivity to pain), and cognitive impairment without improving physiological function. Yet, Purdue undertook a systematic marketing campaign to encourage prescribers to use opioids as the first line of treatment for chronic pain. In doing so, the Sacklers caused prescribers and pharmacies to submit, and the State to pay, claims to the State's Medicaid program, Employee Health Plans, and Workers' Compensation Program that were false by:

- (a) causing prescribers to write, and pharmacies to fill, prescriptions for chronic opioid therapy supported by Purdue's deceptive, false, and incomplete representations regarding the risks, benefits, and superiority of those drugs; and
- (b) causing prescribers to certify that these prescriptions were "medically necessary" and causing pharmacies to fill such prescriptions 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 medically appropriate for long-term, chronic use.

These false claims subsequently caused prescribers to write continuing opioid prescriptions when long-term opioid use renders patients dependent upon the continued and increased use of the drugs.

553. 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 from the late 1990s onward, that medical consensus existed only because standards of practice had been re-written to conform to the false reality created by Purdue. Purdue engineered that medical consensus, causing prescribers to believe that long-term use of opioids to treat chronic pain was not simply permissible or appropriate but required.

554. The State would not have knowingly reimbursed claims for prescription drugs that were not eligible for coverage. For example, the State paid the following claims:

- (a) Indiana Medicaid Patient A was diagnosed with unspecified joint pain and osteoarthritis. Patient A received 59 opioid prescriptions (38 OxyContin prescriptions, 6 oxycodone prescriptions, 6 Nucynta ER prescriptions, 8 morphine sulfate prescriptions, and 1 methadone prescription)—totaling a 1,626 day supply—between January of 2012 and April of 2018. These prescriptions resulted in \$26,589.73 in claims paid through the IHCP. The prescriptions were written by a practitioner who received 360 visits from Purdue detailers from 2006 to 2017. Five of those visits (including one at which the Purdue representative provided lunch to the practitioner) occurred in the two months prior to writing Patient A’s first opioid prescription, including one at which the Purdue detailer explicitly discussed Medicaid coverage for OxyContin with the practitioner.
- (b) Indiana Medicaid Patient B was diagnosed with abdominal pain, a backache, and a diaphragmatic hernia. Patient B received 62 opioid prescriptions (35 OxyContin prescriptions, 19 oxycodone prescriptions, 5 morphine sulfate ER prescriptions, and 3 Tramadol prescriptions)—totaling a 1,783 day supply—between August of 2013 and April of 2017. These prescriptions resulted in \$26,419.80 in claims paid through the IHCP. The prescriptions were written by a practitioner who received 140 visits from Purdue detailers from 2007 to 2017. Two of those visits occurred in the two months prior to writing Patient B’s first opioid prescription. At one visit, which occurred two days prior to Patient B’s first prescription, the Purdue detailer reviewed the abuse deterrent properties of OxyContin and went over the appropriate patient profile for the drug, and the practitioner responded that he would make an effort to try OxyContin with his patients.
- (c) Indiana Medicaid Patient C was diagnosed with myalgia and myositis (muscle pain and inflammation) and central pain syndrome. Patient C received 53 opioid prescriptions (34 OxyContin prescriptions and 19 Opana ER prescriptions)—totaling a 1,589 day supply—between January of 2012 and February of 2017. These prescriptions resulted in \$34,360 in claims paid through the IHCP. The prescriptions were written by a practitioner who received 159 visits from Purdue detailers from 2011 to 2017. Three of those visits occurred in the two months prior to writing Patient C’s first opioid prescription, and the Purdue detailer noted that he encouraged the practitioner multiple times during those visits to start new patients on OxyContin.
- (d) Indiana Medicaid Patient D was diagnosed with acute cholecystitis (gallbladder inflammation). Patient D received 74 opioid prescriptions (37 OxyContin prescriptions and 37 oxycodone prescriptions)—totaling a 2,220 day supply—between June of 2015 and June of 2018. These prescriptions resulted in \$17,796.69 in claims paid through the IHCP. The prescriptions were written by a practitioner who received 243 visits from Purdue detailers between 2006 and 2017. Seven of those visits (including one at which the Purdue detailer provided lunch to the practitioner) occurred in the two months prior to writing Patient D’s first opioid prescription. The Purdue detailer noted that, at the lunch visit that occurred 10 days prior to the prescription, the practitioner committed to continue trying OxyContin with patients.
- (e) Indiana Employee Plan Patient E was diagnosed with an ankle fracture and ankle, foot, and joint pain. Patient E received 9 OxyContin prescriptions—totaling a 270 day

supply—between March of 2014 and November of 2014. These prescriptions resulted in \$2,356.63 in claims paid through the State Employee Health Plans. The prescriptions were written by a practitioner who received 159 visits from Purdue detailers between 2011 and 2017, including one visit (at which the Purdue detailer provided lunch to the practitioner) that occurred in the two months prior to writing Patient E’s first opioid prescription.

- (f) Indiana Employee Plan Patient F was diagnosed with osteoarthritis and received a hip joint replacement. Patient F received 34 OxyContin prescriptions—totaling a 954 day supply—between September of 2011 and December of 2017. These prescriptions resulted in \$12,147.65 in claims paid through the State Employee Health Plans. The prescriptions were written by a practitioner who received 232 visits from Purdue detailers between 2001 and 2017. Two of those visits (including one at which the Purdue detailer provided lunch to the practitioner) occurred in the two months prior to writing Patient F’s first opioid prescription.
- (g) Indiana Employee Plan Patient G was a passenger in a van that collided with a fixed object and was diagnosed with pain in the soft tissues of the limbs. Patient G received 8 OxyContin prescriptions—totaling a 240 day supply—between June of 2010 and November of 2010. These prescriptions resulted in \$9,140.28 in claims paid through the State Employee Health Plans. The prescriptions were written by a practitioner who received 427 visits from Purdue detailers between 2006 and 2017. Five of those visits (including one at which the Purdue detailer provided lunch to the practitioner) occurred in the two months prior to writing Patient G’s first opioid prescription.

555. During the years 2012-2018, the State paid substantial funds for prescription opioids: more than \$100 million for opioids covered through Medicaid; more than \$8 million for opioids covered by State employee insurance programs, and workers’ compensation for State employees. For the reasons stated above, the State believes that a significant percentage of these prescriptions were not medically necessary or appropriate as defined by the relevant plans and should not have been covered 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 pain less severe than indicated in the package insert; or (c) without exploration of alternative therapies like non-opioid medication and physical therapy.

556. As described above, Purdue at the direction of the Sackler Defendants set out to change the medical consensus supporting chronic opioid therapy **so that** prescribers would

prescribe—and **so that** government payors such as the State would pay for—long-term prescriptions to treat moderate, chronic pain in the absence of scientific evidence showing that the benefits outweigh the risks. Purdue’s actions were all in furtherance of the Sackler Defendants’ objectives and were carried out at the direction of and for the benefit of the Sackler Defendants.

557. In addition to these prescription costs, the State has paid for services and supplies necessitated by long-term opioid use abuse—office visits, toxicology screens, hospitalization for overdoses and infection, rehabilitation and addiction-related therapy, and other treatments.

558. 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. But for Purdue’s unfair and deceptive marketing campaign, the State would not have been presented with, or paid, claims for opioids to treat chronic, moderate pain. That the State would pay for these ineligible prescriptions was a foreseeable and intended consequence of Purdue’s intentionally misleading marketing scheme.

559. 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 above State-funded programs. Misrepresentations as to, for example, whether patients were likely to become addicted, would be able to resume life activities, and would experience long-term relief were not minor; they went to the core of a prescriber’s decision-making.

V. The Sacklers Knew That Purdue’s Marketing of Opioids Was False and Misleading and Instructed Purdue to Fraudulently Conceal Its Misconduct and Hid Their Own Involvement.

560. As explained above, Purdue knowingly made deceptive and misleading statements about OxyContin—and opioids generally—for more than two decades. Under the

terms of the 2007 Settlements, Purdue publicly agreed that it would stop all deceptive and misleading marketing related to OxyContin’s potential for abuse, addiction, and physical dependence. Purdue publicly committed to marketing its drugs in a manner consistent with the “Indication and Usage” section of the Package Insert and to providing “fair balance” in its marketing of OxyContin and other opioids.

561. The Sackler Defendants were obligated to comply with these commitments and report any breaches. They were deeply involved in the running of Purdue, were highly knowledgeable about Purdue products, and were knowledgeable about what types of statements and practices were lawful. Notwithstanding this knowledge, the Sacklers directed Purdue to continue to deceive and mislead prescribers and patients. In addition, the Sacklers directed and/or sanctioned the steps taken by Purdue to avoid detection of—and to fraudulently conceal—its deceptive marketing and unlawful and deceptive conduct from regulators and law enforcement.

562. After 2007, Purdue continued to disguise its own role in the deceptive marketing of chronic opioid therapy by funding and promoting unbranded marketing, third-party advocates, and professional associations. Purdue purposefully hid behind the assumed credibility of these sources and relied on them to disseminate and establish 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 conclusions of the studies it cited and deceptively offered them as evidence for propositions the studies did not support.

563. Further, Purdue 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.

564. Purdue worked hard to obfuscate the origin of the opioid crisis—unprecedented overprescribing in response to Purdue’s assurances that opioids are the proper treatment for routine, moderate pain because their benefits vastly outweigh their risks. Instead, Purdue has spent considerable resources to publicly ascribe widespread abuse, addiction, and death to patients who deliberately misuse opioids and the diversion of pills to illicit secondary channels. Richard Sackler devised this narrative and memorialized it in a marketing memo in 2001, and it has been the foundation for Purdue’s approach to the opioid crisis ever since.

565. Purdue has engaged in a public relations campaign to publicize its purported efforts to work 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.

566. These public pronouncements have created the impression that Purdue is proactively working with law enforcement and government authorities, nationwide and in Indiana, to root out drug diversion, including the illicit prescribing that can lead to diversion. They aimed to distance Purdue from its past publicly admonished conduct in deceptively marketing opioids—which gave rise to its 2007 criminal pleas—and to make its current marketing seem more trustworthy and truthful. In fact, Purdue 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.

567. For almost 20 years, Purdue has maintained a database of health care providers that Purdue itself has flagged as inappropriately prescribing OxyContin or other opioids. According to Purdue, providers 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 were detailed, and sales representatives received no compensation tied to these providers’ prescriptions.

568. Yet, Purdue did not report suspicious prescribing or suspicious prescribers to law enforcement agencies. Despite its knowledge of illicit prescribing in other jurisdictions, 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. The Sacklers either received reports that Region Zero prescribers were not being referred to law enforcement or elected not to inquire. Purdue did not report any suspicious prescribing or suspicious prescribers to the Indiana Attorney General’s Office, the Professional Licensing Agency, or the Medical Licensing Board.

569. In Indiana, Purdue seemed to see law enforcement as an obstacle to its mission to expanding the opioids market. As discussed in Section II.B, one of the most notorious pill mills in the country—the Wagoner Clinic located in Kokomo, Indiana—operated for years under Purdue’s indulgent gaze. For a number of years, the clinic was within the territory of one of Purdue’s top salespeople nationwide, and at times Purdue’s sales representatives visited it as often as twice a week. At its peak, the small family medicine practice was writing **hundreds** of

opioid prescriptions **weekly**. By the time its four doctors were arrested in 2013, they had written more than 125,000 prescriptions, and the overdose deaths of more than two dozen patients had been traced to their reckless prescribing.

570. Purdue detailers, despite their regular visits, did not report any suspicious activity to the State.

571. Purdue did not instruct its detailers to stop visiting the Wagoner Clinic even after the Attorney General's Office suspended the licenses of four physicians in the practice on March 18, 2013. Instead, more than a week later, Purdue informed its sales representatives not to visit specific prescribers at that clinic, while continuing to allow them to visit others. Purdue did not instruct its sales representatives to stop visiting one prescriber who had been arrested and charged with dealing narcotics until six months later.

572. Purdue similarly turned a blind eye to misconduct by Dr. Tristan Stonger, who was indicted by the State in 2016 for improperly prescribing vast quantities of opioids through three pain clinics he operated in Indiana. In just four years (2012–2015), Dr. Stonger wrote at least 48,000 prescriptions for controlled substances. Stonger was routinely “seeing” as many as 100 patients a day; his waiting rooms were filled beyond seating capacity, and large numbers of vehicles and people gathered in the clinic parking lots. Despite all of these questionable signs, Purdue detailers visited Dr. Stonger, listed in Purdue call notes as a plastic surgeon, 86 times between December 2010 and January 2015. Purdue never reported any suspicious conduct to the appropriate state licensing authorities.

573. Nor did Purdue cut off improper prescribing at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions. 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 conduct emblematic of illicit prescribing and drug diversion.

574. 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.

575. The Sacklers sought to hide their role as well. After vacating executive positions within the company before the 2007 Settlements, they served on the Board of Directors. 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 representatives 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 Corporate Integrity Agreement. In 2017, Purdue drafted a statement that attempted to erase the Sacklers' minute direction of Purdue by disclaiming their leadership of the company that was characterized as "owned by the family trust."

CAUSES OF ACTION

COUNT ONE: Unjust Enrichment

576. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

577. Under Indiana law, unjust enrichment exists where a measurable benefit has been conferred on the defendant under such circumstances that the defendant's retention of the benefit without payment would be unjust.

578. The Sacklers engaged in wrongdoing by authorizing or directing Purdue to promote the use of opioids in Indiana.

579. The State has conferred measurable benefits on the Sacklers that it would not have but for that wrongdoing by, among other things:

- (a) allowing Purdue to promote opioids in Indiana;
- (b) using hundreds of millions of dollars in public funds to reimburse prescriptions for Purdue's opioid products covered by the State's Medicaid programs, employee insurance plans, and Workers' Compensation Program; and
- (c) attempting to address all aspects of the opioid epidemic in Indiana. To do so, it has increased spending on healthcare, social welfare, law enforcement, and other services. The Sacklers have profited from the State's remedial expenditures. Had Purdue and the Sackler Defendants been bearing these costs, there would not have been a profitable market for Purdue's dangerous and addictive opioid products.

580. By engaging in the wrongdoing set forth in this Complaint, the Sacklers impliedly requested the benefits conferred on them by the State.

581. The Sacklers have reaped income from the benefits conferred on them by the State by awarding themselves billions of dollars in distributions from Purdue, which came in part from Indiana, enriching themselves at the State's expense.

582. It would be wrong and unjust for the Sacklers to retain the benefits conferred on them by the State. But for the wrongdoing set forth in this Complaint, the State would not have conferred those benefits on the Sacklers.

583. The State seeks restitution of the sum, to be determined at trial, by which the Sacklers have been unjustly enriched.

COUNT TWO: Violations of the DCSA

584. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

585. The Deceptive Consumer Sales Act makes it unlawful for a supplier to engage in an “unfair, abusive, or deceptive act, omission, or practice” in connection with a consumer transaction. Ind. Code § 24-5-0.5-3(a).

586. Defendants are “suppliers” as defined by Ind. Code § 24-5-0.5-2(3).

587. The purchase and sale of opioid products are “consumer transactions” as defined by Ind. Code § 24-5-0.5-2(1).

588. Pharmaceutical manufacturers are required to comply with the provisions of the DCSA in their marketing, promotion, sale, and distribution of prescription drugs.

589. Defendants, by authorizing or directing Purdue to cause its sales force to make or disseminate false or misleading statements about the long-term use of opioids to treat chronic pain, violated Ind. Code § 24-5-0.5-3(a) and § 24-5-0.5-3(b)(1) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions, and by misrepresenting that such subject of a consumer transaction had uses or benefits that it did not have which Defendants knew or reasonably should have known that it does not have.

590. Defendants, by authorizing or directing Purdue to cause false or misleading statements about opioids to be made or disseminated, violated Ind. Code § 24-5-0.5-3(a) and § 24-5-0.5-3(b)(1) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions, and by misrepresenting that such subject of a consumer transaction had uses or benefits that it did not have which Defendants knew or reasonably should have known that it does not have.

591. Defendants, by authorizing or directing Purdue to cause its sales force to make statements to promote the use of opioids to treat chronic pain that omitted or concealed material facts, violated Ind. Code § 24-5-0.5-3(a) and § 24-5-0.5-3(b)(1) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions, and by misrepresenting that such subject of a consumer transaction had uses or benefits that it did not have which Defendants knew or reasonably should have known that it does not have.

592. Defendants, by failing to direct Purdue to cause its sales force to correct prior misrepresentations and omissions about the risks and benefits of opioids, violated Ind. Code § 24-5-0.5-3(a) and § 24-5-0.5-3(b)(1) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions, and by misrepresenting that such subject of a consumer transaction had uses or benefits that it did not have which the Defendants knew or reasonably should have known that it does not have.

593. Defendants, by authorizing or directing Purdue to cause its sales force to claim or imply that long-term use of opioids would improve patients' function and quality of life, violated Ind. Code § 24-5-0.5-3(a) and § 24-5-0.5-3(b)(1) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions, and by misrepresenting that such subject of a consumer transaction had uses or benefits that it did not have which the Defendants knew or reasonably should have known that it does not have.

594. Defendants, by authorizing or directing Purdue to cause its sales force to mischaracterize the risk of opioid addiction and abuse, including by stating or implying that abuse-deterrent properties meant the drugs were less likely to be addictive or abused, and that specific opioid drugs were less addictive or less likely to be abused than other opioids, violated Ind. Code § 24-5-0.5-3(a) and § 24-5-0.5-3(b)(1) by committing unfair, abusive, and deceptive

acts, omissions, and practices in connection with consumer transactions, and by misrepresenting that such subject of a consumer transaction had uses or benefits that it did not have which the Defendants knew or reasonably should have known that it does not have.

595. Defendants, by authorizing or directing Purdue to cause its sales force to claim or imply that addiction can be avoided or successfully managed through the use of screening and other tools, violated Ind. Code § 24-5-0.5-3(a) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions.

596. Defendants, by authorizing or directing Purdue to cause its sales force to promote the misleading and discredited concept of pseudoaddiction and emphasizing the prevalence of dependence to conceal and distract from the true risk of addiction, violated Ind. Code § 24-5-0.5-3(a) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions.

597. Defendants, by authorizing or directing Purdue to cause its sales force to claim or imply that increasing the dose of opioids (titrating up) poses no significant additional risk, violated Ind. Code § 24-5-0.5-3(a) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions.

598. Defendants, by authorizing or directing Purdue to cause its sales force to misleadingly depict the safety profile of opioids by minimizing their risks and adverse effects while emphasizing the risks of competing products, violated Ind. Code § 24-5-0.5-3(a) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions.

599. Defendants, by authorizing or directing Purdue to cause its sales force to misleadingly market 10mg and 15mg doses of OxyContin for the treatment of pain when Purdue

knew that those dosages provide no therapeutic benefit, violated Ind. Code § 24-5-0.5-3(a) and § 24-5-0.5-3(b)(1) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions, and by misrepresenting that such subject of a consumer transaction had uses or benefits that it did not have which Defendants knew or reasonably should have known that it does not have.

600. Defendants, by authorizing or directing Purdue to cause its sales force to engage in deceptive, false, and misleading marketing that was unsupported by substantial scientific evidence to support its product claims as required by 21 C.F.R. § 202.1(e), violated Ind. Code § 24-5-0.5-3(a) and § 24-5-0.5-3(b)(1) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions, and by misrepresenting that such subject of a consumer transaction had uses or benefits that it did not have which Defendants knew or reasonably should have known that it does not have.

601. Defendants, by authorizing or directing Purdue to engage 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, contravening FDA regulations, including 21 C.F.R. § 202.1(e), violated Ind. Code § 24-5-0.5-3(a) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions.

602. Defendants, by authorizing or directing Purdue to cause its sales force to promote 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 competing products without substantial scientific evidence to support those claims, contravening FDA regulations, including 21 C.F.R. § 202.1(e), violated Ind. Code § 24-5-0.5-3(a) and § 24-5-0.5-3(b)(1) by committing unfair,

abusive, and deceptive acts, omissions, and practices in connection with consumer transactions, and by misrepresenting that such subject of a consumer transaction had uses or benefits that it did not have which Defendants knew or reasonably should have known that it does not have.

603. Defendants, by authorizing or directing Purdue to cause its sales force to promote 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, violated Ind. Code § 24-5-0.5-3(a) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions.

604. Defendants, by authorizing or directing Purdue to cause its sales force to target a vulnerable population—senior consumers, as defined by Ind. Code § 24-5-0.5-2(a)(9)—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, violated Ind. Code § 24-5-0.5-3(a) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions.

605. Defendants, by authorizing or directing Purdue to cause its sales force to target opioid naïve patients and patients using other competing products, violated Ind. Code § 24-5-0.5-3(a) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions.

606. Defendants, by authorizing or directing Purdue to use unbranded marketing, front groups, and key opinion leaders to evade FDA oversight and rules prohibiting deceptive marketing and to deceive prescribers and consumers regarding the impartiality of the information conveyed, violated Ind. Code § 24-5-0.5-3(a) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions.

607. Defendants, by authorizing or directing Purdue to cause its sales force to market, promote, advertise, or distribute in Indiana savings cards that purported to offer discounts or access to discounts from a pharmacy for the prescription drugs OxyContin, Butrans, and Hysingla—where the card did not expressly state in bold and prominent type, which was prominently placed, that the discounts were not insurance—violated the Prescription Drug Discount and Benefit Cards Statute (Ind. Code § 24-5-21) and thereby violated Ind. Code § 24-5-0.5-3(b)(32).

608. WHEREFORE the State requests an order under Ind. Code § 24-5-0.5-4: permanently enjoining Defendants from engaging in these unfair and abusive acts and practices; directing disgorgement of any ill-gotten gains; directing the payment of civil penalties for each violation of the DCSA; awarding attorneys' fees and costs to the State, and any other just and proper relief.

COUNT THREE: Knowing Violations of the DCSA

609. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

610. The deceptive acts asserted in Count Two were committed by Defendants with knowledge of their deceptive acts.

COUNT FOUR: Incurable Deceptive Acts

611. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

612. The deceptive acts asserted in Count Two are incurable deceptive acts and were committed by Defendants as part of a scheme, artifice, or device with intent to defraud or mislead.

COUNT FIVE: Violations of Prescription Drug Discount and Benefit Card Statute

613. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

614. The Prescription Drug Discount and Benefit Cards Statute makes it unlawful for a non-exempt business to sell, market, promote, advertise, or distribute a card that purports to offer discounts or access to discounts from a pharmacy for prescription drug purchases where the card does not expressly state in bold and prominent type, which is prominently placed, that the discounts are not insurance. Ind. Code § 24-5-21-3.

615. At all times relevant to this Complaint, Defendants violated Ind. Code § 24-5-21-3 by authorizing or directing Purdue to engage in the following acts and practices:

- (a) Marketing, promoting, advertising, or distributing in Indiana savings cards that purported to offer discounts or access to discounts from a pharmacy for the prescription drug OxyContin where the card did not expressly state in bold and prominent type, which was prominently placed, that the discounts were not insurance;
- (b) Marketing, promoting, advertising, or distributing in Indiana savings cards that purported to offer discounts or access to discounts from a pharmacy for the prescription drug Butrans where the card did not expressly state in bold and prominent type, which was prominently placed, that the discounts were not insurance; and
- (c) Marketing, promoting, advertising, or distributing in Indiana savings cards that purported to offer discounts or access to discounts from a pharmacy for the prescription drug Hysingla where the cards did not expressly state in bold and prominent type, which was prominently placed, that the discounts were not insurance.

616. WHEREFORE the State requests an order under Ind. Code § 24-5-21-6 permanently enjoining Defendants from marketing, promoting, advertising, or distributing savings cards in Indiana in violation of Ind. Code § 24-5-21-3; directing the payment of civil penalties of a sum equal to one hundred dollars (\$100) per card distributed in Indiana or ten thousand dollars (\$10,000), whichever is greater; awarding attorneys' fees and costs to the State; and providing any other relief that the Court considers proper.

COUNT SIX: Violations of the False Claims Act

617. The State realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

618. A person is liable under the Indiana False Claims Act, Ind. Code § 5-11-5.5-2(b)(8), when that person knowingly or intentionally causes or induces another person to present a false claim to the State for payment or approval **or** to make or use a false record or statement to obtain payment or approval of a false claim from the State.

619. Ind. Code § 5-11-5.5-1(1) defines a “claim” as:

a request or demand for money or property that is made to a contractor, grantee, or other recipient if the state (a) provides any part of the money or property that is requested or demanded; or (b) will reimburse the contractor, grantee, or other recipient for any part of the money or property that is requested or demanded.

620. Each Defendant is a “person” within the meaning of the Indiana False Claims Act. Defendants’ practices, as described in the Complaint, violated Ind. Code § 5-11-5.5-2(b). By authorizing or directing Purdue to engage in deceptive marketing of opioids, Defendants caused to be presented false or fraudulent claims and knowingly caused false statements to be used to get false or fraudulent claims paid or approved by the State.

621. Defendants knew, deliberately ignored, or recklessly disregarded, at the time of causing these statements to be made or disseminated, that such 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.

622. Defendants' authorization or direction of Purdue's scheme caused doctors and other prescribers to write prescriptions for opioids to treat chronic pain, resulting in claims paid through the IHCP or "Medicaid," and the State employee health and workers' compensation plans. Doctors, pharmacists, other health care providers, and/or other agents participating in these programs 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 through the marketing campaign described in Sections I–III above. 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.

623. Defendants knew or should have known that, as a foreseeable consequence of their actions, 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 Purdue's deceptions. The misrepresentations Purdue caused to be made, at the authorization or direction of Defendants, 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.

624. Through the IHCP and State employee health and workers' compensation plans, more than a hundred million dollars has been paid for opioid prescriptions that were represented to the State as medically necessary. These prescriptions would not have been prescribed or covered but for Purdue's deceptive, fraudulent, and unlawful marketing practices—conduct that Defendants authorized or directed.

625. The State has paid and will continue to pay consequential health care costs necessitated by Defendant's authorization or direction of Purdue's deceptive, fraudulent, and

unlawful marketing practices, including drugs for persons dependent upon and addicted to opioids and treatment costs for those dealing with addiction, overdose, and other adverse effects.

WHEREFORE Plaintiff, the State of Indiana, respectfully requests that this Court enter an order enjoining Defendants from engaging in conduct that violates Ind. Code § 5-11-5.5; requiring Defendants to pay the maximum civil penalty for each false or fraudulent claim Defendants caused to be presented to an official, employee, or contractor of the State for payment or approval; requiring Defendants to pay three times the amount of damages, including consequential damages, sustained by the State for each violation of this section; compelling Defendants to pay the cost of the suit, including attorneys' fees under Ind. Code § 5-11-5.5-2(b)(8); and awarding the State such other, further, and different relief as this Court may deem just.

COUNT SEVEN: Violations of the Medicaid False Claims Act

626. The State realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

627. A person is liable under the Indiana Medicaid False Claims Act, Ind. Code § 5-11-5.7-2(a)(1), when that person knowingly causes to be presented a false claim to the State for payment or approval *or* causes to be made or used a false record or statement to obtain payment or approval of a false claim from the State.

628. Ind. Code § 5-11-5.7-1(b)(1) defines a "claim" as:

[A] request or demand for money or property, whether under a contract or otherwise, and whether the state has title to the money or property that: (A) is presented to an officer, employee, or agent of the state; or (B) is made to a contractor, grantee, or other recipient if the money or property is to be spent or used on the state's behalf or to advance a state program or interest, and if the state: (i) provides or has provided any part of the money or property that is requested or demanded; or, (ii) will reimburse the contractor, grantee, or other recipient for any part of the money or property that is requested or demanded.

629. Defendants' practices, as described in the Complaint, violated Ind. Code § 5-11-5.7-2. By authorizing or directing Purdue to engage in deceptive marketing of opioids, 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.

630. Defendants knew, deliberately ignored, or recklessly disregarded, at the time of causing these statements to be made or disseminated, that such 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.

631. Defendants' authorization or direction of Purdue's scheme caused doctors and other prescribers to write prescriptions for opioids to treat chronic pain, resulting in claims paid through the IHCP. Doctors, pharmacists, other health care providers, and/or other agents participating in the IHCP 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 through the marketing campaign described in Sections I–III above. 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.

632. Defendants knew or should have known that, as a foreseeable consequence of its actions, 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 Purdue's deceptions.

The misrepresentations Purdue made and caused to be made, at the authorization or direction of Defendants, 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.

633. Through the IHCP, more than a hundred million dollars has been paid for opioid prescriptions that were represented to the State as medically necessary. These prescriptions would not have been prescribed or covered but for Defendants' authorization or direction of Purdue's deceptive, fraudulent, and unlawful marketing practices.

634. The State has paid and will continue to pay consequential health care costs necessitated by Defendants' authorization or direction of Purdue's deceptive, fraudulent, and unlawful marketing practices, including drugs for persons dependent upon and addicted to opioids, and treatment costs for those dealing with addiction, overdose, and other adverse effects.

WHEREFORE Plaintiff, the State of Indiana, respectfully requests that this Court enter an order enjoining Defendants from engaging in conduct that violates Ind. Code § 5-11-5.7; requiring Defendants to pay the maximum civil penalty for each false or fraudulent claim Defendants caused to be presented to an official, employee, or contractor of the State for payment or approval; requiring Defendants to pay three times the amount of damages, including consequential damages, sustained by the State for each violation of this section; compelling Defendants to pay the cost of the suit, including attorneys' fees under Ind. Code § 5-11-5.7-2(a)(8); and awarding the State such other, further, and different relief as this Court may deem just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the Court enter judgment against

Defendants:

- (a) awarding judgment in its favor and against Defendants on each cause of action asserted in the Complaint;
- (b) directing Defendants to disgorge any benefits unjustly retained at a cost the State;
- (c) assessing treble damages for the payments made by or on behalf of the State for opioid prescriptions covered by the IHCP, the State Employee Health Plans, and the State Workers' Compensation Program;
- (d) assessing the maximum statutory civil penalties for each violation of the Indiana False Claims Act and the Indiana Medicaid False Claims Act;
- (e) permanently enjoining Defendants from engaging in the deceptive, unfair, and abusive acts and practices described in the Complaint, including by directing Defendants to disgorge any ill-gotten gains acquired by virtue of the conduct described in the Complaint;
- (f) assessing maximum statutory civil penalties for each violation of the Deceptive Consumer Sales Act;
- (g) assessing maximum statutory civil penalties for each violation of the Prescription Drug Discount and Benefit Cards Statute;
- (h) requiring Defendants to pay the costs of the suit, including attorneys' fees; and
- (i) awarding such other, further, and different relief as this Court may deem just.

JURY DEMAND

The State demands a trial by jury on all issues properly so tried.

Dated: May 21, 2019
Indianapolis, IN

Respectfully submitted,

By: 
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