STATE OF VERMONT

SUPERIOR COURT **CIVIL DIVISION**
CHITTENDEN UNIT **DOCKET NO.**

STATE OF VERMONT,	)
Plaintiff,	)
v.	)
RICHARD S. SACKLER, BEVERLY SACKLER, DAVID A. SACKLER, ILENE SACKLER LEFCOURT, JONATHAN D. SACKLER, KATHE SACKLER, MORTIMER D. A. SACKLER, AND THERESA SACKLER,	)
Defendants.	)

COMPLAINT

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The Vermont Attorney General brings this suit against Richard Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, Kathe Sackler, Mortimer Sackler, and Theresa Sackler (collectively, the "Sacklers" or "Defendants") for violations of Vermont's Consumer Protection Act, unjust enrichment, and creating a public nuisance. Defendants have violated the Vermont Consumer Protection Act by engaging in unfair and deceptive trade practices, Purdue unjustly enriched themselves by accepting and keeping ill-gotten gains, and created a public nuisance in the State of Vermont through the deceptive marketing of opioids, for which the Attorney General seeks civil penalties, injunctive relief, disgorgement, fees and costs, and other appropriate relief.

INTRODUCTION

A. Defendants Succeeded in Mainstreaming Opioids Prescribing

1. For 20 years, Purdue Pharma L.P. ("Purdue"),[1] a privately-held company, has been a leading force in the prescription opioid market, both nationwide and in Vermont. During this time, the pharmaceutical giant Purdue manufactured, sold, and aggressively marketed prescription opioids, including the brand-name drugs OxyContin, Butrans, and Hysingla ER.

2. Before the 1990s, opioids were not widely prescribed because it was correctly believed that their use involved serious risks—including addiction, withdrawal, and overdose—that were not justified by the benefits. Opioids typically were used only to treat short-term, acute pain (*e.g.*, trauma and post-surgical) or for palliative care (*e.g.*, end-of-life) because they were considered too addictive and debilitating for long-term use. This prevailing medical and popular understanding operated as an appropriate constraint on the market for prescription opioids.

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

3. Beginning in the late 1990s, Purdue set out to effect a sweeping change in the public and medical community's perception of opioids—by downplaying the risks and aggressively encouraging much broader use. Purdue orchestrated and enacted a plan of massive expansion—designed to change opioids' limited use from acute and palliative care to a wide-ranging and often front-line option for long-term, chronic conditions like back pain, migraines, and arthritis. Purdue executed this scheme at the direction of eight people in a single family that owned the company and controlled a majority of the seats on the company's board of directors: the Sacklers.

4. The Sacklers' ambition was to become unimaginably rich from the sale of opioids. To that end, they masterminded a strategy, carried out by Purdue, that changed the way the medical profession viewed opioid prescribing. The Sacklers exploited newly-emerging concerns in the profession that pain was an undertreated priority. Purdue helped to institutionalize this patient-centric shift, and then capitalized on the platform it had created to push its message that health care providers should prescribe more opioids to treat this undertreated chronic pain. Purdue designed an array of deceptive messages that reduced concerns about opioids generally, and that promoted Purdue's opioids specifically as safe, effective, and appropriate for long-term use and for moderate pain conditions. Purdue's massive marketing scheme, which occurred alongside similar efforts of other industry players, was profoundly successful at shifting the medical and public consensus regarding the use of opioids.

5. The Sacklers fully understood the addictive and dangerous qualities of the drugs they manufactured, but the risks presented by their drugs to individual consumers and public health did not constrain their marketing and promotional plans. The Sacklers shaped the marketing campaigns that Purdue carried out, and they set sales objectives. The Sacklers directed and approved the hiring of hundreds of workers to carry out their wishes and blanketed the country

and Vermont with disinformation about opioids. The Sacklers directed Purdue employees to get doctors to write more prescriptions for higher doses for more patients, and the company did exactly these things. And over the years, the Sacklers distributed billions of dollars earned from the sale of Purdue opioids to themselves and other family members.

6. Before the introduction of OxyContin in 1996, the opioid market was for post-surgical, end-of-life, or cancer pain. By 2012, opioids were among the most prescribed drugs; approximately 90% of prescription opioids were given for chronic pain conditions, and only 10% of prescription opioids were dispensed for post-surgical, palliative, and cancer pain treatments.[2] This was an almost complete reversal of long-standing medical practice.

7. According to the U.S. Centers for Disease Control and Prevention ("CDC"), nearly 62 million Americans received at least one opioid prescription in 2016.[3]

8. In the late 1990s, federal and state law enforcement agencies began investigating Purdue for deceptive marketing and misbranding. During the time period covered by the investigations, at least three Sackler board members were among the highest executives inside the company: Richard Sackler was Chief Executive Officer, and Jonathan and Kathe Sackler were Vice Presidents. As explained below, they were intimately involved in the launch of OxyContin and the marketing campaigns that led to the explosion of over-prescribing.

9. The investigations culminated in a series of settlements in 2007 under which Purdue and three of its executives pleaded guilty to federal criminal charges for deceptive conduct in the sale and marketing of opioids. Purdue paid more than $600 million to resolve the government

[2] Laxmaiah Manchikanti *et al.*, *Opioid Epidemic in the United States*, 15 Pain Physician ES9-ES38, at ES27 (2012).

[3] Centers for Disease Control and Prevention, Annual Surveillance Report of Drug-Related Risks and Outcomes (2017), https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf, at 7.

enforcement actions. The Sacklers decided which executives would offer guilty pleas, approved the settlement agreements, and then drew back from their roles as employees of the company to serve exclusively on the Board of Directors. As described below, in the years that followed, the Sacklers approved several large payments—in the millions of dollars—to the executives who pled guilty. At the same time, the Sacklers continued to manage the Company's core business activities: marketing, sales, and product development.

10. Although Purdue made some concessionary adjustments to the marketing statements that had prompted its prosecution, it never stopped misrepresenting the risks and benefits of its blockbuster drug, OxyContin, and other opioids. Purdue failed to correct, and actually persisted in building upon and profiting from, its earlier deceptions and the platform of misunderstanding it had created. Even worse, Purdue began directing its deceptive marketing in pursuit of new target patients: specifically, it began focusing its efforts on the elderly and patients who had not previously used these powerful drugs (labeled by Purdue as the "opioid naïve").

11. From 2007 into 2018, the Sacklers charted a new—but equally crooked—course for Purdue. The Sacklers directed and approved the hiring of—and were involved in guiding the strategic opioid marketing plans of—a large sales force, which was directed to visit health care providers nationwide and in Vermont on a frequent basis and convince them to prescribe Purdue's opioids at increasing dosages and for longer periods of time. The specific messages that Purdue's sales representatives carried changed after 2007 but were still unfair and deceptive and consistently misrepresented the risks and benefits of OxyContin and Purdue's other opioids.

12. The Sacklers also devised several additional unconscionable 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.

13. The Sacklers met regularly as the Board of Directors and received detailed briefings from the staff on not just the company's finances, but on the size, distribution, daily activities, and compensation of the sales force. Over the years 2008–2017, 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, for longer periods of use, and at increasing doses. The Sacklers' communications were not limited to quarterly Board meetings. They were in touch with Purdue marketing employees on a regular and consistent basis.

14. 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 Sacklers' 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."

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

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

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

B. Vermont Is Leading the Nation with Its Innovative and Effective Approach to Combating the Opioid Crisis

16. In 2012, Vermont passed legislation[4] authorizing its Department of Health to establish a state-wide integrated care system for opioid addiction treatment, creating the treatment "Hubs" (for high-intensity Medication Assisted Treatment and counseling) and "Spokes" (for treatment by a team consisting of Community Drug Addiction Treatment Act-waivered prescribers—which include physicians, nurse practitioners, and physician assistants—supported by a treatment team consisting of a nurse and a credentialed substance abuse counselor for every 100 persons receiving MAT).[5]

[4] Act No. 135 (available at https://legislature.vermont.gov/assets/Documents/2012/Docs/ACTS/ACT135/ACT135%20As%20Enacted.pdf).

[5] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders*, March 2017 (available at http://www.healthvermont.gov/sites/default/files/documents/2017/03/ADAP_Opioid_Strategy_Brief.pdf).

17. The Hub-and-Spoke System is unique in its comprehensiveness and has been recognized nationally as "visionary."[6] Vermont's success is the result of state and local actors working cooperatively to design and implement a multi-faceted, cutting-edge approach to addressing opioid addiction that reaches even the most rural areas in the State.[7] Despite Vermont's success in developing and administering these programs, the problem of opiate addiction is overwhelming, and the demand for these treatment programs continues to increase. Vermont's Blueprint for Health reports that more than 6,000 Vermonters are participating in the Hub-and-Spoke System through the State's Medicaid program,[8] and additional Vermonters are treated in the Hub-and-Spoke System through private insurance and Medicare. Demand for opioid treatment in Vermont has continued to rise.[9] Vermont has engaged in an ongoing effort to keep up with the need and reduce wait times for patients seeking treatment.[10]

18. Vermont has elected to invest its treatment funds in evidence-based approaches, and is the nation's most proactive state at providing buprenorphine (a key component of Medication Assisted Treatment) to patients in need. The State averages 204 buprenorphine

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[6] Vermont Opioid Coordination Council, *Initial Report of Recommended Strategies* (January 2018), http://www.healthvermont.gov/sites/default/files/documents/pdf/OCC%202018%20Report%202018-1-9.Final_.pdf, at 3.

[7] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders*, *supra* n.5.

[8] Pat Bradley, *Vermont Governor Testifies in Washington on Opioid Treatment Programs* (Feb. 7, 2018), http://wamc.org/post/vermont-governor-testifies-washington-opioid-treatment-programs; State of Vermont, *Blueprint for Health*, http://blueprintforhealth.vermont.gov/about-blueprint/hub-and-spoke.

[9] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders*, *supra* n.5.

[10] Harry Chen, MD (Commissioner, Vermont Dept. of Health), *Status of Opioid Treatment Efforts – Health Reform Oversight Committee* (October 25, 2016), http://www.leg.state.vt.us/jfo/healthcare/Health%20Reform%20Oversight%20Committee/2016_10_25/Status%20of%20Opioid%20Treatment%20Efforts%20-%20Chen.pdf, at 11 ("Hub Census and Waitlist: September 26, 2016").

prescriptions per 1,000 persons, which is 524% higher than the national average of 39 per 1,000.[11] Vermont also leads the nation in funding access to buprenorphine for its citizens. Medicaid funding is used by patients filling over 68% of the total buprenorphine prescriptions in Vermont—nearly 3x the national average of 24.2%.[12]

19. Vermont also has elevated its outreach to high-risk patients for comprehensive, specialty support. Pregnant women are eligible for not simply treatment, but also for supportive programming, including housing and transportation, which can vastly improve health outcomes for mothers and infants.[13] The State has been providing up to 120 days of addiction treatment to inmates and has pioneered efforts to divert low-level drug offenders from prosecution and incarceration if they agree to treatment shortly after arrest. As of July 1, 2018, all Vermont inmates who enter the correctional system on Medication-Assisted Treatment and/or are diagnosed with opioid use disorder will continue to be provided with Medication-Assisted Treatment while incarcerated, for as long as treatment is medically necessary.[14]

20. In December 2013, the Vermont Department of Health launched an overdose reversal pilot project to distribute naloxone to people at risk for overdose, along with their family

[11] IMS Institute for Healthcare Informatics, *Use of Opioid Recovery Medications* (September 2016), https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/use-of-opioid-recovery-medications.pdf, at 5.

[12] *Id.*

[13] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders*, *supra* n.5, at 7.

[14] S. 166, An act relating to the provision of medication-assisted treatment for inmates, https://legislature.vermont.gov/assets/Documents/2018/WorkGroups/House%20Corrections%20and%20Institutions/Bills/S.166/S.166~Ed%20Paquin%20~As%20Introduced,%201-31-2018~3-29-2018.pdf.

members and others most likely to be present in the event of an overdose.[15] To date, more than 17,000 kits have been distributed at 30 sites in Vermont—all free of charge to the recipients. [16]

21. In August 2016, the Vermont Commissioner of Health issued a statewide, standing order authorizing every pharmacy to dispense naloxone to anyone—without a prescription.[17]

22. Statewide rules and protocols for Emergency Medical Services (EMS) personnel were changed in 2013 to allow EMT providers at all license levels to administer nasal naloxone. Additional legislation passed in 2016 allowed VDH to provide all EMS agencies and law enforcement entities with naloxone at no charge.[18]

23. In June 2013, the Vermont Legislature passed Act 75 which, among other things, mandated every health care provider who prescribes or dispenses any Schedule II, III, or IV controlled substances to register for and use the Vermont Prescription Monitoring System (VPMS).[19] This law was amended in 2016, through Act 173, to increase the mandatory reporting frequency for dispensers from at least once per week to daily.[20] Today, when a prescription is

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[15] Vermont Department of Health, *Naloxone Pilot Project – Data Brief* (April 18, 2014), https://legislature.vermont.gov/assets/Documents/2014/WorkGroups/House%20Human%20Services/Bills/S.295/Witness%20Testimony/S.295~Barbara%20Cimaglio~Naloxone%20Pilot%20Project%20%E2%80%93%20Data%20Brief~4-24-2014.pdf.

[16] Vermont Opioid Coordination Council, *Initial Report of Recommended Strategies*, *supra* n.6, at 30; Naloxone Distribution and Administration in Vermont – Data Brief, updated May 2018, http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Naloxone_Data_Brief_0.pdf.

[17] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders* (March 2017), *supra* n.5.

[18] *Id*.

[19] Act No. 75. An act relating to strengthening Vermont's response to opioid addiction and methamphetamine abuse. (H. 522) (2013), http://www.leg.state.vt.us/docs/2014/Acts/Act075.PDF.

[20] Act. No. 173, An act relating to combating opioid abuse in Vermont. (S. 243) (2016), https://legislature.vermont.gov/assets/Documents/2016/Docs/ACTS/ACT173/ACT173%20As%20Enacted.

dispensed to a patient, information about the drug, recipient, prescriber, and pharmacy is uploaded into VPMS within 24 hours so that this data can be tracked and monitored, which improves a prescriber's ability to detect abuse and diversion. The Vermont Department of Health works to ensure compliance with data uploading and data quality.[21]

24. Act 75 also required professional licensing authorities for healthcare providers to develop evidence-based standards to guide them in the prescription of Schedule II, III, and IV controlled substances for the treatment of chronic pain, which was later supplemented by Act 173 to include development of guidelines for treatment of acute pain. Act 173 also created the Controlled Substances and Pain Management Advisory Council to advise the Department of Health on the drafting of guidelines for prescribing opioids for acute and chronic pain. Rules for responsible prescribing of opioids for chronic and acute pain were finalized in December 2016. The rules provide information to prescribers on appropriate treatment of pain and guidance on how to reduce the likelihood of drug dependence. Importantly, the rules require prescribers to consider non-opioid alternatives before prescribing opioids and to re-evaluate treatment at least every 90 days, if not more frequently.[22]

25. Finally, the State has undertaken many initiatives to increase public awareness and education about the dangers of opioids. The Vermont Department of Health launched Vermont's Most Dangerous Leftovers campaign in 2014, to increase awareness of the safe use, safe storage, and proper disposal of prescription drugs, including promoting the "Vermont 2-1-1" informational telephone line as a source to find local drug disposal sites. The Department of

[21] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders, supra* n.5.

[22] Vermont Department of Health, Rule Governing the Prescribing of Opioids for Pain, July 1, 2017, R. §§ 6.2, 6.2.1, 6.2.1.1, 6.2.2.

Health also produced Public Service Announcements to promote the safe use, safe storage, and safe disposal of prescription drugs and promote naloxone to prevent overdose deaths.[23]

26. Additionally, the Vermont Department of Health launched ParentUpVT.org, which provides strategies and actions for parents and caregivers to help prevent drug use among youth. And the State is establishing educational campaigns to increase the perception of risk associated with prescription pain reliever misuse and increase awareness on the responsible use of prescription pain relievers.[24]

27. Yet, much more remains to be done. The cost and effort of remediating the opioid crisis require tremendous resources and persistence. For decades, Purdue—with the Sacklers at its helm—cultivated the demand for its opioids and opioids generally, and profited from their overprescribing, misuse, and abuse. The State has filed this lawsuit to expose the misconduct of the individual members of the Sackler family—because the public deserves to know how it has been deceived, and because it is not sufficient for the corporate entity to be held accountable when individuals who steered, directed, and profited from the company's misdeeds were also personally involved in the misconduct. The Sacklers should be required to pay their share of the extraordinary costs required to abate the opioids crisis.

28. Purdue's success in promoting opioids is particularly astonishing in light of the efforts Vermont had made to curb the influence of drug manufacturers on prescribing. In 2009, Vermont passed a law banning gifts from manufacturers of prescription drugs and products to health care professionals and providers. *See* Vt. Stat. Ann. tit. 18 § 4631a. These prohibitions include a ban on any payment, food, entertainment, travel, subscription, service, or anything else

[23] Vermont Department of Health, *Public Health Strategies to Reduce Opioid Use Disorders*, *supra* n.5.

[24] *Id.*

of value with limited exceptions for things like research grants and teaching honoraria that must be disclosed to the Attorney General's Office.[25] But Purdue did not rely exclusively on gifts to persuade doctors. Purdue used front groups disguised as independent patient advocacy organizations, paid spokespeople disguised as experts, and biased studies disguised as legitimate academic research to reach doctors and patients. It is important that all of this conduct be exposed.

29. Even today, the Sacklers seek to obscure their own culpability for this crisis, as set forth in Section F. The Sacklers have tried to distance themselves from their company and have directed Purdue to distance itself from its past misconduct. Purdue attempts to portray itself as a responsible corporate citizen by falsely portraying the opioid epidemic as mainly a problem of illicit drug diversion and abuse. But the genesis of this crisis can be placed squarely on Purdue's doorstep, and more accurately, in the Sacklers' mailbox. The Sacklers directed and approved the corporate entity's efforts to change the medical consensus and public perception about the inherent dangers of opioids were tremendous in their scope, strategy, and success.

30. The Sacklers' specific unfair and deceptive conduct detailed herein, which fomented and perpetuates the opioid crisis, has violated and continues to violate Vermont law. To achieve redress for Defendants' misconduct, the Attorney General of Vermont seeks an Order requiring the Sacklers to permanently cease their unlawful promotion of opioids; to correct the deceptive statements previously made by the corporate entity at their direction or with their approval under their governance; to abate the public nuisance their conduct has created, pay civil penalties for their continuous, pervasive, deceptive and unfair business practices in connection

[25] 18 V.S.A. § 4631a.

with the marketing of opioids; and disgorge the ill-gotten gains they reaped from Purdue's opioids revenue.

PARTIES

A. Plaintiff

31. The State of Vermont brings this action by and through its Attorney General, Thomas J. Donovan Jr., who is authorized to represent the State in all civil matters at common law and as allowed by statute. 3 V.S.A. § 152. The Attorney General is charged with the responsibility of enforcing the state laws at issue, including the Consumer Protection Act ("CPA") and all regulations promulgated thereunder. 9 V.S.A. § 2458.

32. 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. Opioid use and abuse have affected a substantial segment of the population of Vermont.

B. Defendants

33. Defendant Dr. Richard S. Sackler became a member of the Purdue board in 1990 and became its Co-chair in 2003, a position in 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, 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 Vermont and gave rise to the State's claims as alleged in this Complaint. He resides in New York, Florida, and Texas.

34. Defendant Jonathan D. 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, 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 Vermont and gave rise to the State's claims as alleged in this Complaint. He resides in Connecticut.

35. Defendant Ilene Sackler Lefcourt was a member of Purdue's board from 1990 to 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, 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 Vermont and gave rise to the State's claims as alleged in this Complaint. She resides in New York.

36. Defendant Dr. Kathe A. 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, 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 Vermont and gave rise to the State's claims as alleged in this Complaint. She resides in New York and Connecticut.

37. Defendant Mortimer D.A. 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, Mortimer Sackler was personally aware of, was responsible for, engaged in, 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 Vermont and gave rise to the State's claims as alleged in this Complaint. He resides in New York.

38. 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, 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 Vermont and gave rise to the State's claims as alleged in this Complaint. She resides in Connecticut.

39. 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, 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 Vermont and gave rise to the State's claims as alleged in this Complaint. She resides in New York and the United Kingdom.

40. Defendant David A. 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, 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 Vermont and gave rise to the State's claims as alleged in this Complaint. He resides in New York.

JURISDICTION AND VENUE

41. The Court has personal jurisdiction over Defendants because they purposely directed business activities into Vermont that gave rise to the claims in this case and that resulted in unlawful practices in Vermont and against Vermont consumers.

42. Defendants generated millions of dollars of revenue through sales of Purdue opioid pain medications in Vermont. Defendants approved and participated in the marketing strategy that authorized the hiring and compensation of at least 24 different Purdue sales representatives and sales managers in Vermont between 2007 and 2018. In that period, Purdue's Vermont sales force made more than 10,000 sales visits regarding OxyContin and other Purdue opioids to Vermont health care providers.

43. Venue in this Court is proper, pursuant to 9 V.S.A. § 2458(a), because Defendants directed business into Chittenden County. Among other things, Purdue made nearly 2,000 sales visits regarding opioids to health care providers in Chittenden County during the years covered by this Complaint.

GENERAL ALLEGATIONS COMMON TO ALL COUNTS

A. Cementing the Foundation: From the Late 1990s to 2007, Purdue – with the Sacklers at Its Helm – Engaged in a Campaign of Deception to Create and Sustain a Market for Its Opioids

44. Beginning in 1996, Purdue presented OxyContin—and later its other opioids—as the solution to the problem of chronic pain. (As used in this Complaint, "chronic pain" means non-cancer pain lasting twelve weeks or longer.) Through marketing that was as pervasive as it was deceptive, Purdue convinced health care providers that the risks of long-term opioid use were overblown and also that the alleged benefits—reduced pain, improved function, and quality of

life—were proven, even though Purdue had no evidence to support these assertions.[26] By the mid-2000s, Purdue had succeeded in drastically changing medical and public opinion about opioids. Purdue's marketing convinced prescribers, educators, and patients that opioids were safe and effective for long-term use and also that they were an appropriate, first-line treatment for routine chronic pain conditions.

45. During this entire period, the Sacklers held a majority of the seats on the Board of Directors. Three of the Defendants—Richard, Kathe, and Jonathan Sackler—were high-ranking executives in the company until 2003. Richard was not only the Chief Executive Officer of the company between 1999 and 2003, but he had 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 also a senior Vice-President in the company during this time period. The other Sacklers were less visible, but no less culpable. As described below, as members of the Board they shaped the company's deceptive marketing strategies, received detailed reports on the implementation of those strategies, and continued to sanction this conduct, month after month and year after year. From these positions—as Board members and high-ranking executive employees of Purdue—the Sacklers were personally aware of, condoned and directed, and were responsible for the deceptive and unfair marketing activities described below.

1. Purdue Mainstreamed Opioids for Chronic Pain

46. Purdue marketed its opioids directly to health care providers and patients, nationwide and in Vermont. Purdue's sales representatives, also known as "detailers," made

[26] Centers for Disease Control and Prevention, *Guideline for Prescribing Opioids for Chronic Pain* (2016), https://www.cdc.gov/drugoverdose/prescribing/guideline.html (hereafter, "CDC Guideline"), at 2, 20, 25. (confirming, based on existing research and evidence, that opioid use presents a "serious risk" of addiction, use for three months or more "substantially increases" that risk, and there never has been "good evidence that opioids improve pain or function with long-term use").

thousands of in-person sales calls to Vermont healthcare providers in which they misleadingly portrayed opioids as safe, effective, and appropriate for the treatment of chronic pain. In Vermont especially, Purdue targeted generalists—primary care physicians, nurse practitioners, and physician assistants—as opposed to other healthcare professionals with specialized training and knowledge about the use and risks of opioids. Purdue's deceptive marketing created a cadre of primary care doctors, nurse practitioners, and physician assistants who were "educated" by Purdue's sales representatives and marketing literature to look for pain and to treat it with opioids. This, in turn, created a patient population that came to expect and specifically request opioids.

47. Purdue misrepresented key facts about the safety of its opioids—in particular, the risk of addiction. Purdue admitted, in 2007, that its sales representatives, as a matter of course:

- falsely told health care providers that OxyContin had a less euphoric effect, and less abuse potential, than short-acting opioids;[27]
- 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;[28]
- falsely told prescribers that patients could discontinue OxyContin therapy abruptly without experiencing withdrawal symptoms; and
- falsely told prescribers that OxyContin was more difficult to abuse intravenously than generic oxycodone.[29]

48. In addition to making deceptive claims through its sales force, Purdue also widely advertised OxyContin, including in print advertisements in medical journals and in videos

[27] Agreed Statement of Facts, *U.S. v. The Purdue Frederick Company, Inc.*, May 9, 2007, at 6; Press Release, U.S. Attorney's Office, Western District of Virginia, The Purdue Frederick Company, Inc. and Top Executives Plead Guilty to Misbranding OxyContin, Will Pay Over $600 Million (May 10, 2007), https://media.defense.gov/2007/May/10/2001711223/-1/-1/1/purdue_frederick_1.pdf, at 3.

[28] *Id*. at 6.

[29] *Id*. at 6.

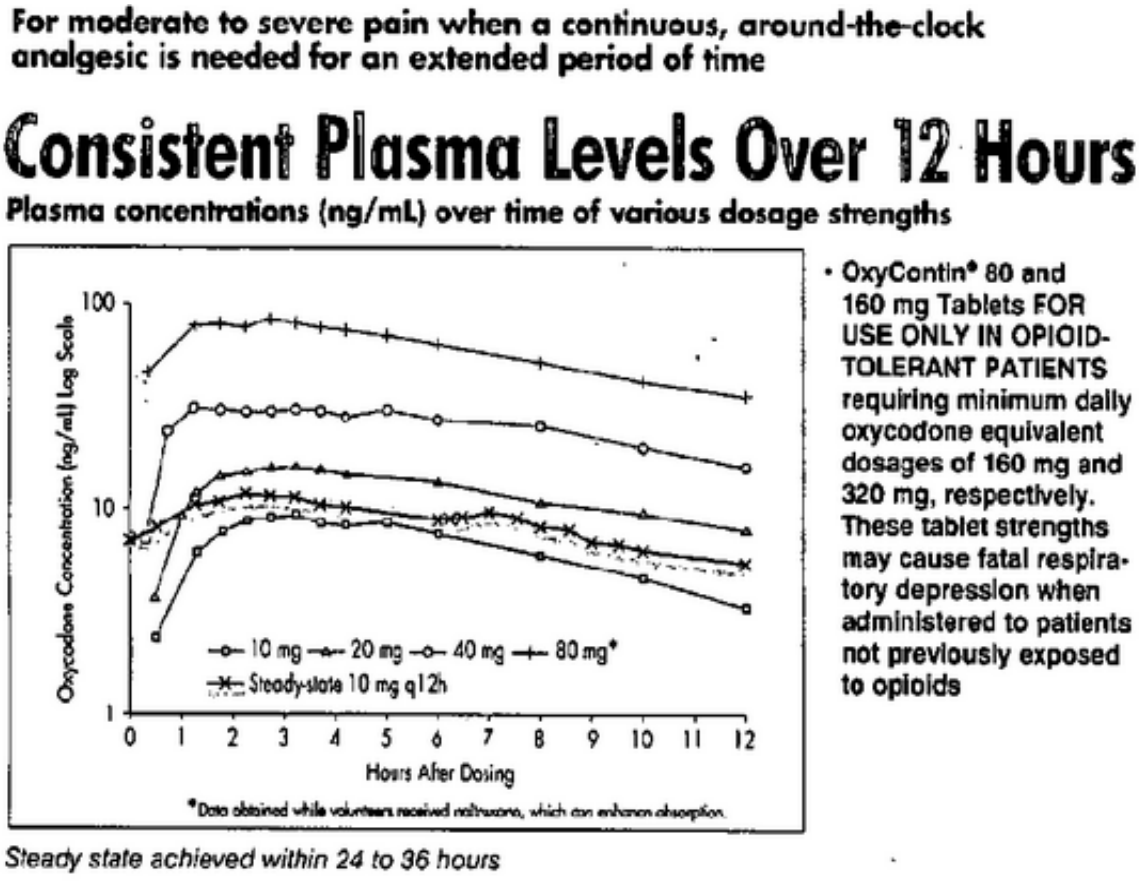
distributed directly to prescribers. These advertising campaigns deceptively underplayed the risks and overemphasized benefits of chronic opioid therapy. For example, in 1998 and 2000, Purdue distributed to doctors thousands of copies of videos, titled "I Got My Life Back," which made the unsubstantiated claim that opioid addiction occurred in less than 1% of patients.[30] In 2003, FDA warned Purdue about advertisements Purdue paid to run in the *Journal of the American Medical Association*, expressing concern that they would lead to ill-considered prescribing of OxyContin because the body of the advertisement text nowhere referred to the "serious, potentially fatal risks associated with OxyContin."[31] In 2005, Purdue also paid to run an advertisement that ran in pain journals that misleadingly implied long-term improvement in patients' pain, function and quality of life, touting OxyContin as an "around-the-clock analgesic . . . for an extended period of time" and featuring a man and a boy fishing under the tagline "There Can Be Life With Relief."

49. Purdue's advertising also included the claim that OxyContin provides "Consistent Plasma Levels Over 12 Hours."[32] That claim was accompanied by a chart, shown below, that depicted plasma levels on a logarithmic scale. However, this presentation visually distorted and obscured the steep decline in OxyContin's efficacy over 12 hours, by depicting 10 milligrams in a way that it appeared to be half of 100 milligrams in the table's y-axis, falsely making the absorption rate appear more steady or consistent over 12 hours:

[30] United States General Accounting Office Report to Congressional Requesters, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, December 2003, https://www.gao.gov/products/GAO-04-110, at 27.

[31] Letter from Thomas Abrams, Dir. FDA Div. of Drug Mktg., Advert. and Commc'n, to Michael Friedman, Exec. Vice President and Chief Operating Officer, Purdue Pharma L.P. (Jan. 17, 2003).

[32] Jim Edwards, *How Purdue Used Misleading Charts to Hide OxyContin's Addictive Power*, CBSNews.com (Sept. 28, 2011), http://www.cbsnews.com/news/how-purdue-used-misleading-charts-to-hide-oxycontins-addictive-power/.



In fact, OxyContin works by releasing a greater proportion of oxycodone (about 40%) into the body when administered, followed by a steep decline over the subsequent hours.[33]

2. Purdue's Pervasive and Deceptive Unbranded Marketing

50. In addition to its branded marketing efforts that showcased specific 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 created, funded, directed, or was in any way involved with these endeavors. Purdue intended patients and prescribers to read these materials and to perceive

[33] New Zealand Ministry of Medicine Data Sheet (http://www.medsafe.govt.nz/Profs/Datasheet/o/OxyContintab.pdf); *How Purdue Used Misleading Charts to Hide OxyContin's Addictive Power*.

(incorrectly) that the materials were published by neutral researchers, clinicians, and legitimate patient advocacy groups.

51. As part of its unbranded marketing scheme, Purdue recruited and paid physicians to make presentations on opioids to their peers at lunch and dinner events. It funded the biased research that formed the basis of these presentations and sponsored Continuing Medical Education programs ("CMEs") 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.

52. Purdue had a particularly close relationship with the American Pain Foundation ("APF"), which was highly dependent on pharmaceutical company funding and produced numerous publications touting the use of opioids to treat chronic pain. Purdue was APF's second-biggest donor, with donations totaling $3.6 million between 1999 and 2012. As early as 2001, Purdue grant letters informed APF that the contributions reflected Purdue's effort to "strategically align our investments in nonprofit organizations that share our business interests," making clear that funding depended on APF continuing to support Purdue's objectives. Purdue also engaged APF as a paid consultant on various initiatives.

53. Purdue created a range of unbranded materials—from websites to glossy pamphlets—that were copyrighted by Purdue but on their face implied that the recommendations and research contained therein were the work of independent organizations with names like *Partners Against Pain*. Purdue ensured that these unbranded materials supported Purdue's branded marketing efforts to promote the use of opioids.

54. 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 Vermont: Purdue's capture, for its own ends, of healthcare providers' increased focus on pain treatment; Purdue's efforts to seed the scientific literature on chronic opioid therapy; and Purdue's corrupting influence on authoritative treatment guidelines issued by professional associations.

55. As described in more detail below, the 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]

a. Co-opting the Medical Community's Focus on Pain

56. As Purdue marketed OxyContin in the late 1990s, it both capitalized on and co-opted a movement in the medical community to make pain identification and treatment a priority for all patients. Purdue provided financial support to the organizations and people leading the

[34] [redacted]

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

57. Purdue already had laid the groundwork for this strategy by financially supporting researchers who were willing to advocate for the expanded use of opioids without adequate scientific support. Chief among these was Dr. Russell Portenoy, who wrote a seminal 1986 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.[35]

58. Dr. Portenoy's promotion of opioids for chronic pain lacked scientific support. As reported by *The Wall Street Journal* on December 17, 2012, Dr. Portenoy admitted to spreading misinformation. The article includes a quotation from a 2010 videotaped interview of Dr. Portenoy by another doctor in which he said that he gave "innumerable lectures in the late 1980s and '90s about addiction that weren't true." The assertions made by Dr. Portenoy and his followers included that opioids were easy to discontinue.

59. Beginning in 1995, the American Pain Society ("APS"), of which Dr. Portenoy later would become president, launched a national campaign to make pain a "vital sign"—an indicator doctors should monitor alongside blood pressure, temperature, heartbeat, and breathing. Purdue provided substantial funding to APS 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

[35] Russell K. Portenoy & Kathleen M. Foley, *Chronic use of opioid analgesics in non-malignant pain: report of 38 cases*, 25(2) Pain 171-86 (May 1986).

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.

60. In 2001, Joint Commission on the Accreditation of Healthcare Organizations ("JHACO") issued pain treatment standards requiring the assessment of pain in all patients and in each physician-patient interaction and made hospital accreditation decisions contingent on adherence to those standards. Purdue worked closely with JCAHO to promote the pain standards and JCAHO licensed Purdue—exclusively—to distribute educational videos about how to comply with the new pain management standards.[36] 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 . . . . <u>despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control</u>." (Emphasis added.) JCAHO distributed the book to hospital officials and physicians nationwide at a series of Purdue-sponsored "leadership summits" on pain management.[37]

61. 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 were developed to apply strictly in hospital settings, they influenced the entire medical profession through hospital-based residency training.

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[36] United States General Accounting Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, *supra* n.30, at 23.

[37] American Pain Society Press Release, 10-May-2000, *National summit on pain management to discuss new standards for pain assessment and treatment*, https://www.eurekalert.org/pub_releases/2000-05/PN-Nsop-1005100.php; United States General Accounting Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, *supra* n.30, at 23.

62. Vermont health care providers interviewed by the State recall learning about "Pain as the Fifth Vital Sign" and the importance of treating pain, through training and medical literature, during the 1990s and early 2000s. Many of these providers credit such initiatives with driving an increased focus on treatment of pain and increased use of opioids but did not know that Purdue had played a key role in launching these initiatives.

b. Corrupting the Science Regarding Opioids with Flawed and Biased Research

63. 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, were biased, and drew inappropriate conclusions from prior evidence. These studies, once published, formed a seemingly objective, research-based foundation for liberalized opioid prescribing and were cited in subsequent studies, resulting in an incomplete, inaccurate, and deceptive body of literature on which other researchers, and then ultimately physicians, relied.

64. Some of these methodologically flawed studies made unsubstantiated claims that the risk of psychological dependence or addiction is low in opioid use, absent a patient history of substance abuse.[38] One such study making this claim, published in the journal *Pain* in 2003 and widely referenced since (with more than 600 citations in Google Scholar),[39] ignored existing

[38] Seddon R. Savage *et al., Definitions related to the medical use of opioids: Evolution towards universal agreement*, 26 J. Pain and Symptom Mgmt. 1:655-667 (2003); Watson, C. Peter N., *et al., Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial in painful diabetic neuropathy*, 105 Pain 71 (2003).

[39] C. Peter N. Watson *et al., Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial in painful diabetic neuropathy*, 105 Pain 71 (2003).

research showing actual addiction rates between 8% and 13%,[40] 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:

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] 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. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

65. 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[41] and

[40] *See, e.g.*, Lawrence Robbins, *Long-Acting Opioids for Severe Chronic Daily Headache*, 10(2) Headache Q. 135 (1999); Lawrence Robbins, *Works in Progress: Oxycodone CR, a Long-Acting Opioid, for Severe Chronic Daily Headache*, 19 Headache Q. 305 (1999).

[41] NPR, *Doctor Who Wrote 1980 Letter on Painkillers Regrets That It Fed The Opioid Crisis* (June 16, 2017), http://www.npr.org/sections/health-shots/2017/06/16/533060031/doctor-who-wrote-1980-letter-on-painkillers-regrets-that-it-fed-the-opioid-crisis.

the *New England Journal of Medicine*[42] have repudiated the misuse of the Porter-Jick letter, but it became a mainstay in scientific literature in large part due to Purdue's efforts,[43] with more than 1,000 citations in Google Scholar.[44]

c. Funding and Influencing Professional Associations

66. Treatment guidelines directly inform doctors' prescribing practices, are cited throughout the scientific literature, and are referenced by third-party payors when determining which prescriptions should be covered by insurance. Purdue financed and collaborated with three groups in particular on guidelines that have been, and continue to be, broadly influential in Vermont and nationwide: the American Academy of Pain Medicine (AAPM), the American Pain Society (APS), and the Federation of State Medical Boards (FSMB).

AAPM/APS Guidelines

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

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[42] *Editor's Note* (added May 31, 2017), available at http://www.nejm.org/doi/10.1056/NEJM198001103020221.

[43] Purdue, for example, has cited it in support of Purdue's patently false marketing claim that "less than 1%" of opioid patients become addicted, most prominently in its 1998 "I Got My Life Back" video. Yet Purdue failed to disclose both the nature of the citation (a letter, not a study) and any of its serious limitations.

[44] Purdue has also relied upon the Porter-Jick letter in its marketing efforts. Purdue, for example, has cited it in support of Purdue's patently false marketing claim that "less than 1%" of opioid patients become addicted, most prominently in its 1998 "I Got My Life Back" video. Yet Purdue failed to disclose both the nature of the citation (a letter, not a study) and any of its serious limitations. *See* OxyContin Promotional Video, "I got my life back," Purdue Pharma L.P. (1998), https://www.youtube.com/watch?v=Er78Dj5hyeI.

68. 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 of patients becoming addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was, at the time, a paid speaker for Purdue and shortly thereafter became a senior executive for the company. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained, though it lingers on the Internet elsewhere.[45]

69. AAPM and APS also issued a 2001 set of recommendations, titled "Definitions Related to the Use of Opioids for the Treatment of Pain," which advanced the unsubstantiated (and since discredited) 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.[46] The 2001 AAPM/APS recommendations asserted that "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 has been definitively discredited.[47]

70. In 2009, AAPM and APS issued comprehensive opioid prescribing guidelines ("2009 AAPM/APS Guidelines"), drafted by a 21-member panel, that promoted opioids as "safe

[45] Available for purchase at http://journals.lww.com/clinicalpain/toc/1997/03000.

[46] David E.Weismann & J. David Haddox, *Opioid pseudoaddiction—an iatrogenic syndrome,* 36 Pain 363-366 (1989).

[47] The CDC Guideline makes clear that the scientific literature does not support the concept of pseudoaddiction, explaining that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," (CDC Guideline, *supra* n.26, at 13) and that physicians should "reassess[] pain and function within 1 month" to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit" (CDC Guideline, *supra* n.26, at 25).

and effective" for treating chronic pain. The panel made "strong recommendation[s]" regarding management of chronic opioid therapy, even while acknowledging "low quality evidence," to support its positions, and it 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.[48]

71. The 2009 AAPM/APS Guidelines were reprinted in the *Journal of Pain* and widely distributed nationally.[49] The guidelines have been a particularly effective channel of deception and, in addition to influencing prescribers, they have now been cited nearly 1,700 times in academic literature.

FSMB Guidelines

72. The Federation of State Medical Boards ("FSMB") is an association of the various state medical boards in the United States. The state boards that comprise the FSMB membership, including Vermont'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.

73. 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

[48] *See* John Fauber, *Chronic Pain Fuels Boom in Opioids*, Milwaukee Journal Sentinel (Feb. 19, 2012), https://www.medpagetoday.com/neurology/painmanagement/31254.

[49] Roger Chou *et al*., *Opioid Treatment Guidelines, Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, The Journal of Pain, Vol 10, No 2 (February), 2009: pp 113-130.

American Pain Society (a professional society that received funding from Purdue). The FSMB Guidelines stated that opioids "may be essential" for treatment of both acute and chronic pain, but failed to mention risks of respiratory depression and overdose death; addressed addiction only to define the term as separate from physical dependence; and stated that an "inadequate understanding" of addiction can lead to "inadequate pain control."

74. 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 stated that opioids would improve patients' function and included the now-discredited concept of pseudoaddiction, suggesting that signs of addiction may actually reflect undertreated pain that should be addressed with more opioids.

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

76. Through at least 2015, the FSMB website described the book (a Second Edition of which was republished in 2012) as the "leading continuing medical education (CME) activity for prescribers of opioid medications." Purdue provided an "educational grant" of $100,000 in 2007—

[50] [redacted]

sponsored internally by David Haddox—to support FSMB's distribution of *Responsible Opioid Prescribing* to physicians nationwide through state medical boards.

77. The FSMB Guidelines and *Responsible Opioid Prescribing* were widely distributed in Vermont. The Vermont Board of Medical Practice's first Policy for the Use of Controlled Substances for the Treatment of Pain, published in January 2006, was largely based on the 2004 FSMB model Guidelines.[51] FSMB (with the help of Purdue's grant funding) distributed *Responsible Opioid Prescribing* to 4,412 Vermont prescribers, through the Vermont Board of Medical Practice and other channels. Vermont prescribers interviewed by the State recalled receiving, reviewing, and relying upon the book well into recent years.

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

78. From the 1990s until 2007, Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler directed and sanctioned misconduct that led to criminal convictions, a judgment of the Superior Court in Washington County, Vermont, and commitments that Purdue would not deceive doctors and patients again. Their misconduct since 2007 is all the more reprehensible that background confirms that their misconduct since 2007 was knowing and intentional.

79. The Sackler family's first drug company was the Purdue Frederick Company, which they bought in 1952. In 1990, they formed Purdue Pharma Inc. and Purdue Pharma L.P. Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler took seats on the Board.

[51] Vermont Board of Medical Practice, *Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain* (2014), http://www.healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioid_Pain_Treatment_Policy_0.pdf, at 1.

For events before July 2012, this Complaint uses "the Sacklers" to refer to them. David Sackler joined the Board in July 2012. From that time forward, "the Sacklers" includes him as well.

80. The Sacklers always insisted that their family control Purdue. From 1990 through 2018, their family always held the majority of seats on the Board. In 1994, Jonathan Sackler issued a memorandum to Purdue staff requiring that the Sacklers "should receive all Quarterly Reports and any other reports directed to the Board."[52]

81. When Purdue launched OxyContin in 1996, the FDA scientist who evaluated the drug wrote in his original review: "Care should be taken to limit competitive promotion."[53] 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 [54] 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."[55] 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]

[52] 1994-04-26 memo from Jonathan Sackler, PWG004340621.

[53] 1995-10 Overall Conclusion to 1995 FDA review, Curtis Wright, PWG004340602.

[54] As used herein, the term "staff" means one or more Purdue employees.

[55] 1997-02-27 email from Walter Wimmer, PWG004340624.

[redacted] "If OxyContin is uncontrolled …, it is highly likely that it will eventually be abused."[56] Richard Sackler responded: "How substantially would it improve your sales?"[57]

82. At the OxyContin launch party, Richard Sackler spoke as the Senior Vice President responsible for sales. He asked the audience to imagine a series of natural disasters: an earthquake, a volcanic eruption, a hurricane, and a blizzard. [redacted], he said: "[T]he launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense, and white …."[58] Over the next twenty years, the Sacklers made Richard Sackler's boast come true.

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

84. From the start, the Sacklers were also the driving force behind Purdue's strategy to push opioids with the false promise that they create an enhanced "lifestyle." In 1998, Richard Sackler told Purdue's executives that OxyContin tablets provide more than merely "therapeutic" value and instead "enhance personal performance," like Viagra.[59]

[56] 1997-02-27 email from Robert Kaiko, PWG004340624.

[57] 1997-03-02 email from Richard Sackler, PWG004340624 (original in all caps).

[58] [redacted] PWG004343839.

[59] 1998-09-28 email from Richard Sackler, PWG004340622.

85. Most of all, the Sacklers cared about money. Millions of dollars were not enough. They wanted billions. 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?"[60]

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

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."[62]

A sales representative told a reporter: "We were directed to lie. Why mince words about it?

[60] 1999-06-17 email from Michael Friedman, PWG004340593.

[61] [redacted]

[62] "I Got My Life Back" video, John Christopher Prue Dep. Tr., Jan. 30, 2004, PWG004341925-26.

Greed took hold and overruled everything. They saw that potential for billions of dollars and just went after it."[63]

87. In addition to using the sales force to deceptively promote Purdue's opioids, [redacted]

88. In 2000, the Sacklers were warned that a reporter was "sniffing about the OxyContin abuse story."[64] 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."[65]

89. In January 2001, staff forwarded to Richard Sackler a plea for help from a Purdue sales representative. The sales representative described a community meeting at a local high school, organized by mothers whose children overdosed on OxyContin and died: "Statements were

[63] 2017-10-16, Christopher Glazek, "The Secretive Family Making Billions From The Opioid Crisis," *Esquire* Magazine (quoting Purdue sales representative Shelby Sherman).

[64] 2000-12-01 email from Michael Friedman, PWG004342094 (internal quotations omitted).

[65] 2000-12-01 email from Mortimer D. Sackler, PWG004342094. Defendant Mortimer Sackler's father, the late Mortimer D. Sackler, was also involved in Purdue Pharma during his lifetime.

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."[66]

90. The next month, a *New York Times* article reported on OxyContin abuse, citing a federal prosecutor who reported 59 deaths from OxyContin in a single state. Richard Sackler wrote to Purdue executives: "This is not too bad. It could have been far worse."[67]

91. That same month, Richard Sackler wrote down his solution to the overwhelming evidence of overdose and death: blame and stigmatize people who become addicted to opioids. In a confidential email, he wrote: "[W]e have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals."[68]

92. [redacted]

[66] 2001-01-26 email from Joseph Coggins, PWG004340598.

[67] 2001-02-08 email from Richard Sackler, PWG004342049.

[68] 2001-02-01 email from Richard Sackler, PWG004342047.

[69] [redacted]

93. 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."[70]

94. 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." He added: "We intend to stay the course and speak out for people in pain—who far outnumber the drug addicts abusing our product [redacted]"[71] This narrative—that escalating addiction and overdoses are a function of abuse, not overprescribing—has served as the cornerstone for Purdue's response to the opioid crisis through to the present day.

95. 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?"[72]

96. [redacted]

[70] 2001-03-05 article in *New York Times*, PWG004411394.

[71] 2001-01 letter from Richard Sackler, PWG004341421.

[72] 2001 meeting described in Barry Meier, Pain Killer (1st ed. 2003) at 158. The DEA official was Laura Nagel, head of the DEA Office of Diversion Control.

[redacted][73]

97. 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 the Sacklers nevertheless kept active control of the company. Their family owned Purdue. They controlled the Board. They paid themselves the profits. And, as alleged in detail below, they continued to direct Purdue's deceptive marketing campaign.

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

99. 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.[74] The Sacklers continued their opioid business in two other companies: Purdue Pharma Inc. and Purdue Pharma L.P.

[73] [redacted]

[74] 2007-05-03 Board minutes, PWG004343851; 2007-5-10, Purdue Frederick Company Plea Agreement, PWG003978960 at -8998.

100. 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 . . . ."[75]

101. 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 . . . ."[76] 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.

102. 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.[77]

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[75] 2007-05-09 Agreed Statement of Facts, paragraph 20, *available at* https://www.documentcloud.org/documents/279028-purdue-guilty-plea.

[76] 2007-05-09 Plea Agreement, at 2, *available at* https://www.documentcloud.org/documents/279028-purdue-guilty-plea.

[77] 2007-05-09 Plea Agreement, *available at* https://www.documentcloud.org/documents/279028-purdue-guilty-plea; 2007-05-04 Associate General Counsel's Certificate, PWG004342101; Purdue Corporate Integrity Agreement §§ III.C, III.H.

103. Finally, the Sacklers voted to enter into a Consent Judgment in Vermont, in Washington County Superior Court ("2007 Judgment"). The 2007 Judgment ordered that Purdue "shall not make any written or oral claim that is false, misleading or deceptive" in the promotion or marketing of OxyContin. The judgment further required that Purdue provide fair balance regarding risks and benefits in all promotion of OxyContin. That judgment required fair balance about the risks of taking higher doses for longer periods and the risks of addiction, overdose, and death.

104. The 2007 Judgment further required that Purdue establish and follow an abuse and diversion detection program to identify high-prescribing doctors who show signs of inappropriate prescribing, stop promoting drugs to them, and report them to the authorities:

> Upon identification of potential abuse or diversion," Purdue must conduct an inquiry and take appropriate action, "which may include ceasing to promote Purdue products to the particular Health Care Professional, providing further education to the Health Care Professional about appropriate use of opioids, or providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities."

105. The 2007 Judgment and related agreements should have ended the Sacklers' misconduct for good. Instead, the Sacklers decided to break the law again and again, expanding their deceptive sales campaign to make more money from more patients on more dangerous doses of opioids.

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

106. After the 2007 Judgment, the Sacklers could have fundamentally reformed the company. Instead, they devised and/or sanctioned new deceptive and unfair practices.

107. Continuing their pattern of deep involvement in Purdue's operations, the Sacklers directed the company to hire hundreds more sales representatives to visit doctors thousands more

times. They insisted that sales representatives repeatedly visit the most prolific prescribers. They directed representatives to encourage doctors to prescribe more of the highest doses of opioids. They studied tactics to keep patients on opioids longer—including through the use of savings cards—and then ordered staff to use them. [redacted] They asked for detailed reports about doctors suspected of misconduct, how much money Purdue made from them, and how few of them Purdue had reported to the authorities. They sometimes demanded more detail than anyone else in the entire company, so staff had to create special reports just for them. Richard Sackler even went into the field to promote opioids to doctors and supervise representatives face to face.

108. In particular, Richard Sackler's micromanagement was so intrusive that staff appealed to the CEO to intervene. 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."[78]

Richard Sackler's directions moved straight through the company. When he berated sales managers, the managers turned around and fired straight at representatives in the field. For example, when Richard Sackler wrote to managers, "This is bad,"[79] to criticize the sales of Purdue's Butrans opioid in another state, 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."[80]

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

[78] 2012-03-07 email from Russell Gasdia, PWG004335349.

[79] 2012-03-07 email from Richard Sackler, PWG004335348.

[80] 2012-03-07 email from Windell Fisher, PWG004335107.

> "I am much closer to dismissing the entire district than agreeing that they deserve a pass for poor market conditions."[81]

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

109. The Sacklers cared most of all about money. From 2007 to 2018, they voted to direct Purdue to pay their family billions of dollars, including profits earned from opioids sold in Vermont. These payments were the motivation for the Sacklers' misconduct, and the payments reflected deliberate decisions to benefit from deception in Vermont, at great cost to patients and families.

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

111. [redacted][83]

112. [redacted]

[81] 2012-03-07 email from Windell Fisher, PWG004335107.

[82] [redacted]

[83] [redacted]

[redacted][84] [redacted]

[redacted] Vermont.

113. The impact of Purdue's sales representatives in Vermont was direct and profound. [redacted]

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

115. **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— [redacted] 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.[86] Quarter after quarter, over the ensuing decade, Purdue and the

[84] [redacted]

[85] [redacted]

[86] 2007-07-15 Board report, pgs. 33, 41, 54, PWG004330365.

Sacklers would not deviate from this pattern: Staff would tell the Board that there had been hundreds of Reports of Concern; staff would further note that only a handful had been investigated, with none reported to authorities; and, on information and belief, the Board accepted this inaction.

116. Purdue's self-interested failure to report abuse and diversion continued, even though the 2007 Judgment subjected Purdue to an anti-diversion program that required it, among other steps, to report "potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities" as appropriate. 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, as described below.

117. By July of 2007, [redacted]

118. 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).[88] In FACETS, Purdue falsely instructed doctors and patients that physical dependence on opioids is not dangerous and instead improves patients' "quality of life"—just as Richard Sackler had been saying since the 1990s. In the same material,

[87] [redacted]

[88] 2007-07-15 Board report, pg. 34, PWG004330365.

Purdue also falsely told doctors and patients that signs of addiction are actually "pseudoaddiction," and that doctors should respond by prescribing more opioids.[89]

119. Purdue sent these misleading publications to doctors [redacted]

120. At the same time, staff also reported to the Sacklers that Purdue was making more money than expected. A few months earlier, they had projected a profit of $407,000,000; now they expected more than $600,000,000.[90]

121. Staff reported to the Sacklers that [redacted] were key reasons that profits were high.[91] 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.[92]

122. **August 2007:** Howard Udell was still serving as Purdue's top lawyer, even after his criminal conviction (described in paragraph 98 above). Mr. Udell 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."[93]

[89] 2007-08 FACETS Vol. 1, pgs. 51-53, PWG004327698.

[90] 2007-07-15 Board report, pg. 46, PWG004330365.

[91] 2007-07-15 Board report, pg. 46, PWG004330365.

[92] 2007-07-15 Board report, pg. 52, PWG004330365.

[93] 2007-08-30 email from Howard Udell, PWG004330084.

123. **October 2007:** 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.[94]

124. 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."[95] From 2007 into 2018, encouraging prescriptions of the highest doses of opioids—which were the most lucrative to Purdue and the Sacklers—was a primary focus of the sales force, including in Vermont, as discussed in Section D(3).

125. 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.

126. **November 2007:** 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, including in Vermont, and that those reps would pursue the objectives set by the Sacklers using the tactics on which the Sacklers had been briefed.

[94] 2007-10-15 Board report, PWG004333542 at pgs. 36, 60

[95] 2007-10-15 Board report, PWG0004333542 at pgs. 4, 58.

127. **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.[96]

128. 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.[97]

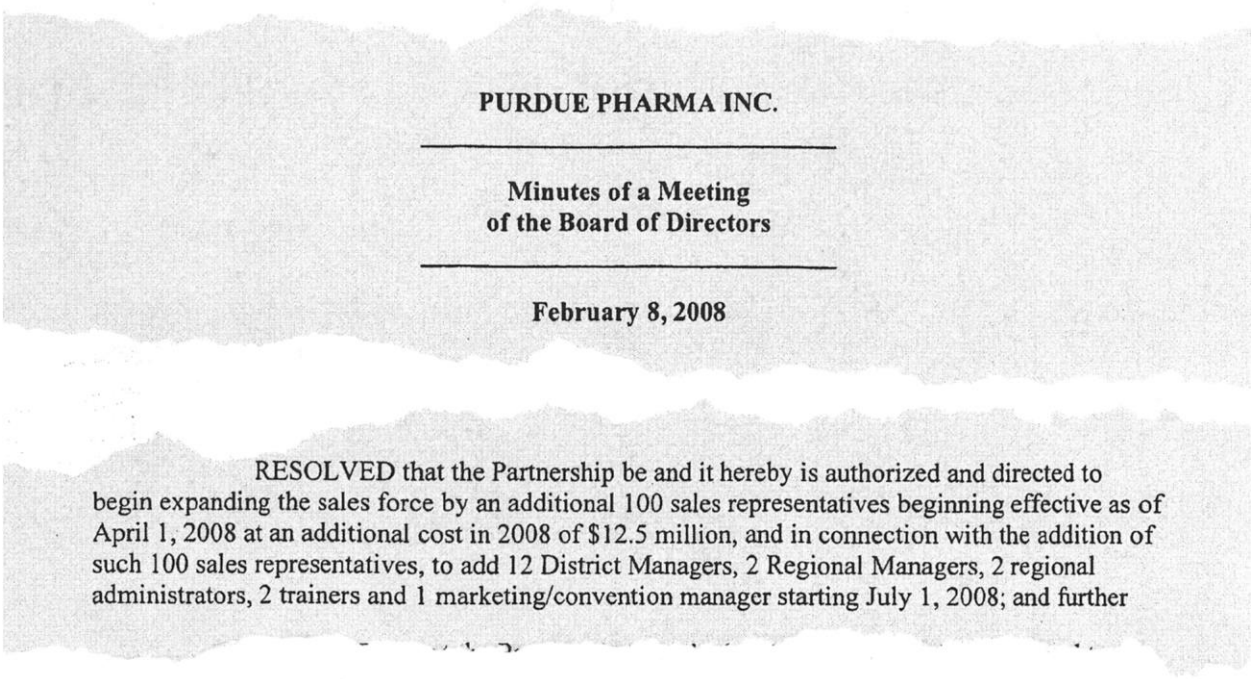
129. Despite the high sales reported to the Board, Richard Sackler wanted more details on tactics for pushing sales even higher. He wrote to Russell Gasdia, Vice President of Sales and Marketing (hereinafter "Sales VP"), demanding information about Purdue's opioid savings cards. Richard Sackler asked 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] and 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 Purdue's strategy to keep patients on opioids longer, including in Vermont, as discussed in Section D(4)(b).

[96] 2008-01-15 Board report, PWG004343257 at pgs. 4, 24.

[97] 2008-01-15 Board report, PWG004343257 at pg. 16, 24.

130. 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.

131. **February 2008:** 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."[98]



PURDUE PHARMA INC.

Minutes of a Meeting of the Board of Directors

February 8, 2008

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

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

[98] 2008-02-08 Board minutes, PWG004409681. 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. 1998-04-27 Board minutes, PWG004818005; 2007-04-26 Board minutes, PWG004339182.

adding 100 sales representatives would allow Purdue to make 12,000 more sales visits to prescribers every month, nationwide.[99]

133. From 2008 to the present, sales representatives hired in the 2008 expansion ordered by the Sacklers promoted Purdue opioids [redacted], as depicted below:

134. 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 representatives to sell more opioids.

[99] 2007-10-26 Sales & Marketing presentation, PWG004504770.

135. 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."[100] 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."[101]

136. On Valentine's Day in 2008, the Sacklers voted to pay $3 million to former CEO Michael Friedman, one of the three Purdue executives to plead guilty. It was one of several multi-million-dollar payments to the convicted executives to maintain their loyalty and protect the Sackler family.

137. Also in February, [redacted].[102] Mortimer Sackler wrote to Richard Sackler [redacted]: "Purdue should be leading the charge on this type of research and should be generating the research to support our formulation. Why are we playing catch up …? Shouldn't we have studies like this …?"[103] [redacted] Later that month, Stewart wrote to Richard Sackler that reformulating OxyContin "will not stop patients from the simple act of taking

[100] 2008-02-13 email from Richard Sackler, PWG004335364.

[101] 1997-03-12 memo from John Stewart, PWG004340626.

[102] 2008-02-07 email from Robert Kaiko, PWG004333606.

[103] 2008-02-12 email from Mortimer Sackler, PWG004333606.

too many pills."[104] As discussed in Section D(1)(c), Purdue and the Sacklers deployed the abuse-deterrent formulation ultimately developed by the company as a marketing tool, despite the fact that its efficacy in reducing abuse was unproven. Further, as discussed in Section F, Purdue—at the Sacklers' direction—used its abuse-deterrent technology to deflect blame for the opioid crisis.

138. Meanwhile, on February 26, 2008, staff gave Jonathan, Kathe, Mortimer and Richard Sackler projections indicating that OxyContin sales could plateau.[105] 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."[106] 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.

139. **March 2008:** 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 pleaded with him: "I have done as much as I can."[107] The employee explained that he needed to attend to family

[104] 2008-02-22 email from John Stewart, PWG004332845. 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." PWG004407116 at 4-11; PWG004407116 at 15. Purdue amended its OxyContin label to reference these studies in 2013.

[105] 2008-02-26 email from Edward Mahony, PWG004522170; attachment PWG004522172 at slide 17-18.

[106] 2008-02-26 email from Richard Sackler, PWG004335366.

[107] 2008-03-09 email from David Rosen, PWG004334576 at 2-3.

visiting from out of town. Richard Sackler responded by calling him at home, insisting that the sales forecast was too low, and threatening that he would have the Board reject it. On Monday, staff emailed among themselves to prepare for meeting with Richard Sackler, indicating that the results he was looking for [redacted] more sales representatives. Meanwhile, Richard Sackler met with Acting President John Stewart to discuss his analysis of the weekend's data and new graphs Richard Sackler had made.

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

> John, I know it is tricky, but Dr. Richard has to back off somewhat. He is pulling people in all directions, creating a lot of extra work and increasing pressure and stress. I will draft a response but he is not realistic in his expectations and it is very difficult to get him to understand.[108]

141. 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] for "exceeding 2007 Rx numbers on an adjusted basis (adjusted for strength and average number of tablets per Rx)."[109] The very next day, Gasdia [redacted], such as adding sales representatives, promoting Purdue's existing opioid savings cards, and promoting more intermediate doses of OxyContin.

[108] 2008-03-08 email from Russell Gasdia, PWG004335376.

[109] 2008-03-08 email from Richard Sackler, PWG004334595 at 3.

142. 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.[110]

143. 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."[111] Kathe Sackler demanded that staff identify the "pressures" and provide "quantification of their negative impact on projected sales."[112]

144. **April 2008:** 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.[113]

145. On April 18, 2008, 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

[110] 2008-03-10 email from Richard Sackler, PWG004334731 at 1-5.

[111] 2008-03-09 email from Edward Mahony, PWG004334595 at 1-2.

[112] 2008-03-11 email from Kathe Sackler, PWG004334595.

[113] 2008-04-15 Board report, pgs. 17, 23, 24, 27, PWG004410792.

can become a liability from the owners' viewpoint." Richard Sackler recommended John Stewart for CEO because of his loyalty. Richard 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.[114]

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

147. On April 18, 2008, 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

[114] 2008-04-18 email and attached memo from Richard Sackler, PWG004343783; PWG004343784 at 1-2.

times. [redacted] He requested that sales staff be assigned to answer his questions "by tomorrow morning."[115] When the sales staff asked for more time to collect the data, Richard Sackler agreed to give them until the end of the day.

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

149. 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[.]"[117] On information and belief, staff sent the proposal to the Sacklers. Richard Sackler's narrative became the underpinning for Purdue's various deceptive messages designed to minimize the risk of addiction, as discussed in Section D(1). It also was the spark for Purdue's public relations strategy to obscure its misconduct by emphasizing all the company was doing to combat the straw man of

[115] 2008-04-22 email from Richard Sackler, PWG004335363.

[116] [redacted]

[117] 2008-04-16 Executive Committee notes, PWG004332813; 2008-04-16 presentation by Luntz, Maslansky Strategic Research, slide 28, PWG004414396.

illicit drug abuse, even as it ignored the fundamental problem of marketing-driven overprescribing, as discussed in Section F.

150. **May 2008:** 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 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.[118] Jonathan Sackler, [redacted]

151. **June 2008:** 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.

152. 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.

[118] Bethany Halford, *Formulations for Fighting Abuse*, Chemical & Engineering News (Vol. 86, Issue 23), https://cen.acs.org/content/cen/articles/86/i23/Formulations-Fighting-Abuse.html.

[119] [redacted]

153. As explained above, many patients would face significant withdrawal symptoms if they tried to stop taking opioids after using five prescriptions' worth of them. Staff informed Richard, Jonathan, Kathe, and Mortimer Sackler that 27% of the savings cards had been used for all five prescriptions.

154. Also in June, [redacted] As discussed in Section D(5), 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.

155. **July 2008:** Staff 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.[121]

156. **September 2008:** The Sacklers voted to pay their family $199,012,182.

157. **October 2008:** 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

[120] [redacted]

[121] 2008-07-15 Board report, pgs. 19, 25, 27, PWG004333314.

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 received 163 tips to its compliance hotline during Q3 2008, but did not report any of them to the authorities.[122]

158. Staff also told the Sacklers that the Board-ordered sales force expansion had been implemented and Purdue now employed 414 sales representatives.[123] The Sackler-mandated reinforcements to the sales force ensured that the number of sales visits to Vermont prescribers during Q3 2008 [redacted]

159. **November 2008:** 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] 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.

160. 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.

161. **March 2009:** 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.

[122] 2008-10-15 Board report, pgs. 19, 24, 28, PWG004410762.

[123] 2008-10-15 Board report, pg. 26, PWG004410762.

162. **April 2009:** 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."[124] [redacted] a detailed conversation with Sales VP Russell Gasdia about the staffing of the sales force, how many sales representatives the company should employ, and how many prescribers each representative would visit each year. The Sacklers authorized sales executives to hire a new staff member who would contact prescribers electronically and would promote Purdue opioids through the deceptive *Partners Against Pain*, a website that misleadingly asserted a distinction between addiction and physical dependence and suggested prescribing *more* opioids as treatment for the latter.

163. 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.[125]

164. **May 2009:** 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 (there are 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.[126] Purdue management, however, did not even set up a system to track Purdue's compliance with the

[124] 2009-04-16 Board report, pgs. 5, 28, PWG004343171.

[125] 2009-04-16 Board report, pgs. 24-25, PWG004343790.

[126] Purdue Corporate Integrity Agreement section III.K, *available at* http://www.pharmacomplianceforum.org/docs/resources/PurdueCIA.pdf.

obligation. Even though Purdue executives had failed to monitor compliance with the requirement, they responded to the violation by firing three [redacted] employees in the field and letting all the executives [redacted] keep their jobs.

165. **June 2009:** Richard Sackler asked sales staff how a competing drug company had increased sales: "What is happening???"[127] 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%.[128]

166. 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.[129] Later that month, the Sacklers voted to pay their family $162,000,000.

167. **July 2009:** 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.[130]

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[127] 2009-06-12 email from Richard Sackler, PWG004334670 at 3.

[128] 2009-06-13 email from Russell Gasdia, PWG004334670 at 3.

[129] 2009-06-16 email from Pamela Taylor, PWG004455956; 2009-05-20 Executive Committee notes, PWG004332859.

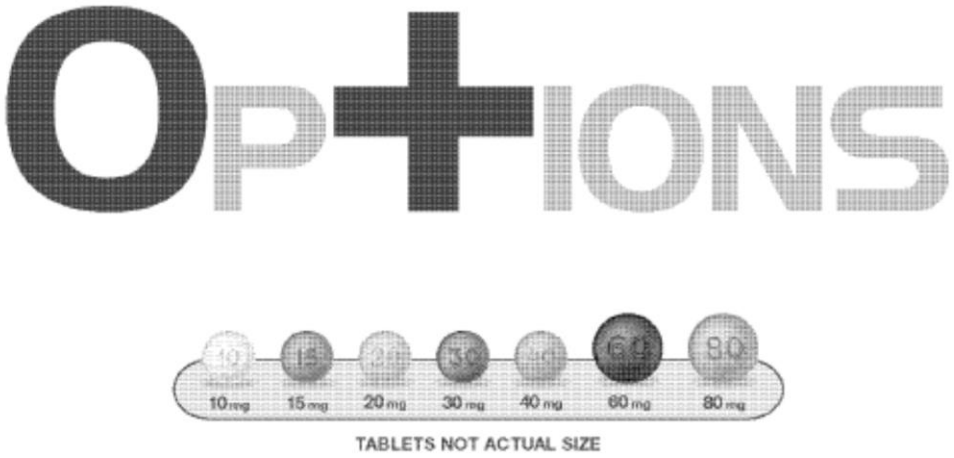
[130] 2009-07-20 email from Richard Sackler, PWG004335536 at 2.

168. **August 2009:** 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.[131] 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).

169. [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: leading 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.[132]

[131] 2009-08-12 email from Richard Sackler, PWG004447584 at 1-2; *see also* 2009-08-10 email from John Stewart, PWG004335521 ("Richard has asked me about this at least 5 times over the past few weeks ….").

[132] 2009-08-19 Board slides, slide 29, PWG004504770; *Options* marketing materials, PWG004276871, at -871.



Purdue's 2009 marketing campaign "Options"

170. Staff also reported to the Sacklers that more than 160,000 patients had used Purdue's opioid savings cards, more than doubling the result reported to the Sacklers the summer before. Staff also told the Sacklers that they would advertise OxyContin using a special television network: thousands of doctors would be given free digital video recorders for their home televisions, in exchange for watching advertisements for drugs.[133]

[133] 2009-08-19 Board slides, slide 32, PWG004504770. Purdue spent approximately $100 for each doctor who watched the advertisement, but it made the money back when the doctors prescribed Purdue's opioids. 2009-04-27 email from Lindsay Wolf, PWG004335408 at 3-4.

171. 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.

172. **September 2009:** 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.

173. Also in September, [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 D(1)(c) and F.

174. **October 2009:** Staff told the Sacklers that Purdue had expanded its sales force by an additional 50 territories and now employed 475 sales representatives.[135] 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.[136] Staff considered telling Richard Sackler that there were no weekly reports, but they decided to make a new report just for him instead.[137]

[134] [redacted]

[135] 2009-10-22 Board report, PWG004333259 at pgs. 4, 21.

[136] 2009-10-08 email from Robert Barmore, PWG004818188; *see also* PWG004334736.

[137] 2009-10-08 email from David Rosen, PWG004818189 ("Hi, guys … Someone needs to alert Dr. Richard that we no longer do a weekly report. Can either one of you help …); 2009-10-08 email from Dipti Jinwala, PWG004334408 ("we have not been providing the OxyContin weekly report since May 09"); 2009-10-08 email from Richard Sackler, PWG004334739 ("I'd like to have the weekly updates."); 2009-10-08 email from David Rosen, PWG004334739 ("If we do as dr. richard requests, we will be adding work and providing him near worthless data"); 2009-10-08 email from Russell Gasdia, PWG004334739 ("Tell her not to respond."); 2009-10-08 email from John Stewart, PWG004335532;

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

175. **November 2009:** 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.

176. 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 & Company, a worldwide management consulting firm, which Purdue had engaged to develop tactics to increase OxyContin sales and market share.[138] The McKinsey report instructed sales representatives to maximize profits by "emphasizing [the] broad range of doses" [139]—which, on information and belief, was code for promoting the doses that were highest and most profitable.

177. 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

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2009-10-09 email from Rob Barmore, PWG004334573 ("For the record, my concerns regarding workload and being able to meet demands of all the reporting, primary research, ad hocs while maintaining quality and reasonable levels of group morale remain.").

[138] 2009-11-02 budget presentation, PWG004332849 at pg. 1; 2009-12-22 email from Edward Mahony, PWG004332848 ("a list of questions raised at the November Board meeting and answers or actions on each").

[139] 2009-10-26 steering committee meeting presentation by McKinsey, PWG004334307 at slide 19.

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.

178. 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 ordered.

179. **December 2009:** 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—[redacted]. Higher doses contain more of that active ingredient and are more profitable to Purdue.

180. **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."[140] Stewart [redacted][141] Days later, Richard Sackler was writing to the sales employee on Saturday morning, ordering that [redacted] and saying it was "urgent" and should be provided "this weekend."[142]

[140] 2010-01-05 email from Russell Gasdia, PWG004334388 at pg. 2.

[141] 2010-01-08 email from John Stewart, PWG004334388 at pg. 1.

[142] 2010-01-16, email from Richard Sackler, PWG004334621 at pg. 2.

181. That same month, [redacted]

182. Also in January, [redacted]

described in Section D(2), Purdue and the Sacklers knew that promoting 12 hours of pain relief was deceptive because OxyContin does not provide 12 hours of pain relief in some patients.

183. **February 2010:** 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.[145]

184. 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.

[143] [redacted]

[144] 2010 Marketing Plan, PWG004459086.

[145] 2010-02-01 Board report, PWG004333155 at pg. 23; 2011-05-02 Board report, PWG004415402 at pgs. 3, 5; 2012-04-30 Board report, PWG004332587 at pgs. 3, 5; 2013-05-13 Board report, PWG004334509 at pg. 7.

185. 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.[146] In fact, becoming addicted to opioids makes patients more stressed, more isolated, and less likely to survive.

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

187. **March 2010:** Richard Sackler instructed sales staff to send him monthly reports on sales of OxyContin and its competitors. They complied within ten minutes.[147] The report showed that sales of Purdue's 80mg OxyContin (the highest dose) [redacted]

188. 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.[148] 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 Vermont, as discussed in Section D(5).

189. **April 2010:** The Sacklers voted to pay their family another $141,000,000.

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[146] 2009-09-11 McKinsey presentation, PWG004334759 at slide 22.

[147] 2010-03-15 emails from Richard Sackler and Mike Innaurato, PWG004335513.

[148] 2010-04-12 email from Pamela Taylor, PWG004458879; 2010-03-17 Executive Committee notes, PWG004332867 at pg. 2.

190. 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]

191. [redacted]

0

192. In Vermont, Purdue was [redacted]

193. **April 2010:** Staff gave the Sacklers one of many detailed reports on sales representatives' visits to prescribers. As with every reference to "the Sacklers" before July 2012, that includes Beverly, Ilene, Jonathan, Kathe, Mortimer, Richard, and Theresa Sackler.

194. 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

149 [redacted]

150 [redacted]

visits per day.[151] 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 to the Board.[152] The results were always close to 7 visits per day.

195. 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.[153] The Sacklers tracked the total number of sales visits per quarter, every quarter, for at least the next four years.

196. [redacted]

197. 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.[154]

198. **June 2010:** Purdue staff completed an updated 10-year plan for growing Purdue's opioid sales. On information and belief, based on distribution of other 10-year plans, this plan was presented to the Sacklers. According to the plan, the Sacklers were to receive at least $700,000,000 each year from 2010 through 2020. Beginning on page one, staff emphasized that selling this

[151] 2010-04-21 Board report, PWG004330952 at 4.

[152] 2010-04-21 Board report, PWG004330952 at -956-957; 2012-7-27 Board report, PWG004344648 at -652-653; 2014-2-4 Board report, PWG004333873 at -880-881.

[153] 2010-04-21 Board report, PWG004330952 at 4, 20. They exceeded the goal and visited prescribers 133,561 times.

[154] 2010-04-21 Board report, PWG004330952 at 4.

volume of 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, tapentadol) to Purdue's soon-to-be-released Butrans opioid, and that Butrans would become a billion-dollar drug.[155]

199. **July 2010:** 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."[156] A staff member wrote to the CEO: "Are you expecting us to provide the marketing plan by tomorrow?"[157] Richard wrote again, stating: [redacted] Staff promised to provide full details about sales and marketing at the July Board meeting.[158] Kathe Sackler then asked staff to circulate the materials before the meeting.[159]

[155] 2010-06-24 Purdue Pharma 2010 10-Year Plan, pgs. 1-15, Key Assumptions, PWG004415002 at 2-18, 65.

[156] 2010-07-01 email from Richard Sackler to multiple staff members, PWG004335504.

[157] 2010-07-01 email from Russell Gasdia, PWG004335504.

[158] 2010-07-06 email from John Stewart, PWG004335529.

[159] 2010-07-09 email from Kathe Sackler, PWG004333208.

200. At the Board meeting, 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%.[160]

201. 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,[161] even though Purdue had expressly agreed in the 2007 Judgment to stop distributing samples of OxyContin. The Board requested details about tactics Purdue sales staff used to influence doctors that Purdue viewed as "key opinion leaders," who could influence other doctors to prescribe more opioids: "Provide the Board with more information on the strategy/tactics with respect to KOL's, how they are identified, how do we plan to interact with them, how do we see them helping build appropriate utilization of Butrans - and any other relevant information that will/could influence the prescribing of the product."[162]

202. 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 didn't claim 7 days of effectiveness in its marketing.[163]

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[160] 2010-07-22 Butrans Commercial Strategy Plan Board Presentation, PWG004349737 at slides 17, 46, 49, 66, 81; 2010-06-01 email from William Mallin, PWG004465215.

[161] 2010-07-22 questions during Board meeting, PWG004333515.

[162] 2010-07-22 questions during Board meeting, PWG004333515.

[163] 2010-07-22 questions during Board meeting, PWG004333515 at 5 ("Why is there no reference to efficacy data in the marketing materials? … a specific reference or statement to Butrans providing efficacy for 7 days seems to be the desired statement … we may not have data that supports efficacy at that specific time point.").

203. 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]?"[164]

204. At the July 2010 Board meeting, 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.[165] Staff then sent the detailed data on those prescriptions written by problem prescribers to the Board.[166]

205. Also at the same July 2010 Board meeting, the Sacklers voted to [redacted]

[164] 2010-07-22 questions during Board meeting, PWG004333515 at 5.

[165] 2010-07-22 questions during Board meeting, PWG004333515 at 7.

[166] 2010-08-16 email from William Mallin, PWG004510920, at -927-928; 2010-08-11 *Region Zero* prescribers, PWG004510933.

[167] [redacted]

206. Later in July 2010, staff told the Sacklers that Purdue employed 491 sales representatives and that, during Q2 2010, they visited prescribers 135,824 times.[168] [redacted] Meanwhile, staff told the Sacklers that Purdue had paid their family $389,000,000 in the first six months of 2010.[169]

207. **August 2010:** The Sacklers continued to focus on the sales force. That month, Purdue decided not to acquire a new insomnia drug because of the risk that promoting it could distract sales representatives from selling Purdue's opioids. Richard Sackler concluded that "loss of focus" in sales representatives' meetings with prescribers was too great a risk, and Purdue decided not to go through with the deal.[170]

208. 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.[171] "Doctor-shopping" was identified as referring to a circumstance in which a patient gets opioids from multiple prescribers—an indication that the patient is at risk of addiction, overdose, and death.

209. **September 2010:** 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

[168] 2010-07-27 Board report, PWG004330924 at 5, 27. 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.

[169] 2010-07-27 Board report, PWG004330924 at 18.

[170] 2010-08-14 email from Richard Sackler, PWG004333232 at 2.

[171] 2010-08-16 email from Stuart Baker, PWG004460588; 2010-08-19 presentation by Paul Coplan, PWG004460589 at slides 7, 31.

territories.[172] The Vice President of Sales & Marketing, Russell Gasdia, also [redacted] that 82% of prescriptions for OxyContin were to "continuing" patients who were already taking the drug, [redacted].[173] The same month, the Sacklers voted to pay their family $240,000,000.

210. **October 2010:** Staff told the Sacklers that Purdue employed 506 sales representatives and, during Q3 2010, they visited prescribers 141,116 times.[174] [redacted]

211. Meanwhile, staff told the Sacklers that Purdue had paid their family $629,000,000 in the first nine months of 2010.[175]

212. **November 2010:** 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.[176] Mortimer Sackler objected to the decrease and the division into two payments, and he demanded answers from staff: "Why are you BOTH reducing the amount of the distribution and delaying it

[172] 2010-09-15 Executive Committee notes, PWG004414538.

[173] 2010-09-15 presentation by Russell Gasdia, PWG004414543 (minutes); PWG004414543 (slides) at slide 10. As discussed in Section D(4), Purdue focused much of its unfair and deceptive marketing efforts on promoting continuing, long-term use of its opioids.

[174] 2010-10-25 Board report, PWG004330897 at 3, 26. Staff told the Sacklers 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.

[175] 2010-10-25 Board report, PWG004330897 at pg. 15.

[176] 2010-11-23 email from Edward Mahony, PWG004335499.

and splitting it in two?" "Just a few weeks ago you agreed to distribute the full 320 [million dollars] in November."[177]

213. Staff also reported that the expansion of the sales force that the Sacklers had ordered was being implemented, including 125 new sales territories.[178] The Sacklers voted to spend $158,086,000 to employ sales representatives in 2011.

214. 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."[179]

215. **December 2010:** The Sacklers voted to pay their family $260,000,000.

216. 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. In September 2009, a Purdue sales manager had emailed Crowley that Purdue was promoting opioids to an illegal pill mill: "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.[180]

[177] 2010-11-23 and 2010-11-24 emails from Mortimer Sackler, PWG004335506.

[178] 2010-11-10 Executive Committee notes, PWG004414520.

[179] 2010-11-10 Executive Committee notes, PWG004463002; 2010-11-10 Slideshow presentation by Bert Weinstein, PWG004463016 at slide 7.

[180] 2016-07-10 "More than 1 Million OxyContin Pills Ended up in the Hands of Criminals and Addicts. What the Drugmaker Knew," by Harriet Ryan, Lisa Girion, and Scott Glover, *Los Angeles Times*.

217. **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.[181] [redacted]

[redacted]

218. 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.[182] 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.[183] The Sacklers faced the prospect of shrinking payouts if doctors did not prescribe more of the highest doses.

219. 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?[184]

[181] 2011-01-24 Board report, pgs. 4, 5, 35, PWG0004330861, -865, -866, 896. 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.

[182] 2011-01-24 Board report, pg. 22, PWG0004330883.

[183] 2011-01-21 email from Sharon Salwan, PWG004332955.

[184] 2011-01-30 email from Richard Sackler to Russell Gasdia, PWG004334486.

220. Richard Sackler's interventions into sales tactics made employees nervous. Two hours after sending his request, Richard Sackler asked Sales VP Russell Gasdia to call him, on a Sunday morning, on his cell phone. When [redacted], CEO John Stewart tried to slow things down, warning staff that such requests would be "never-ending."[185]

221. 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."[186] In a follow-up message, Richard Sackler asked staff to tell him the ratio of prescriptions per sales representative visit to a prescriber, divided out by the prescribers' specialties. He asked for a Board discussion of the barriers that sales representatives were encountering during promotion. After trying to answer Richard Sackler's questions and getting another dissatisfied response, [redacted] wrote to the CEO asking him to intervene. In a later message, Richard Sackler wrote to the staff again: "What do I have to do to get a weekly report on Butrans sales without having to ask for it?"[187] One staff member asked [redacted] to respond. The CEO announced that, from then on, staff would send a sales report to the Sacklers every week. When staff sent the first weekly report, Richard Sackler responded immediately: "What else more can we do to energize the sales and grow at a faster rate?"[188]

[185] 2011-01-31 email from John Stewart to Russell Gasdia and David Rosen, PWG004334486.

[186] 2011-02-15 email from Richard Sackler, PWG004335267.

[187] 2011-03-08 email from Richard Sackler, PWG004335139 at 1.

[188] 2011-03-16 email from Richard Sackler, PWG004334969 at 1.

222. 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?"[189] Staff rushed to prepare answers to share with all the Sacklers.[190]

223. 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]?"[191] Sales VP Russell Gasdia replied privately to the CEO: "as far as his disappointment, I do not share that."[192]

224. **February 2011:** Staff reported to the Sacklers that law enforcement was increasingly concerned about lawbreaking by drug companies and the resulting "danger to public safety."[193] 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

[189] 2011-04-05 and 2011-04-08 emails from Mortimer Sackler, PWG004334431 at 2-3.

[190] 2011-04-08 email from Russell Gasdia, PWG004334431 at 1-2.

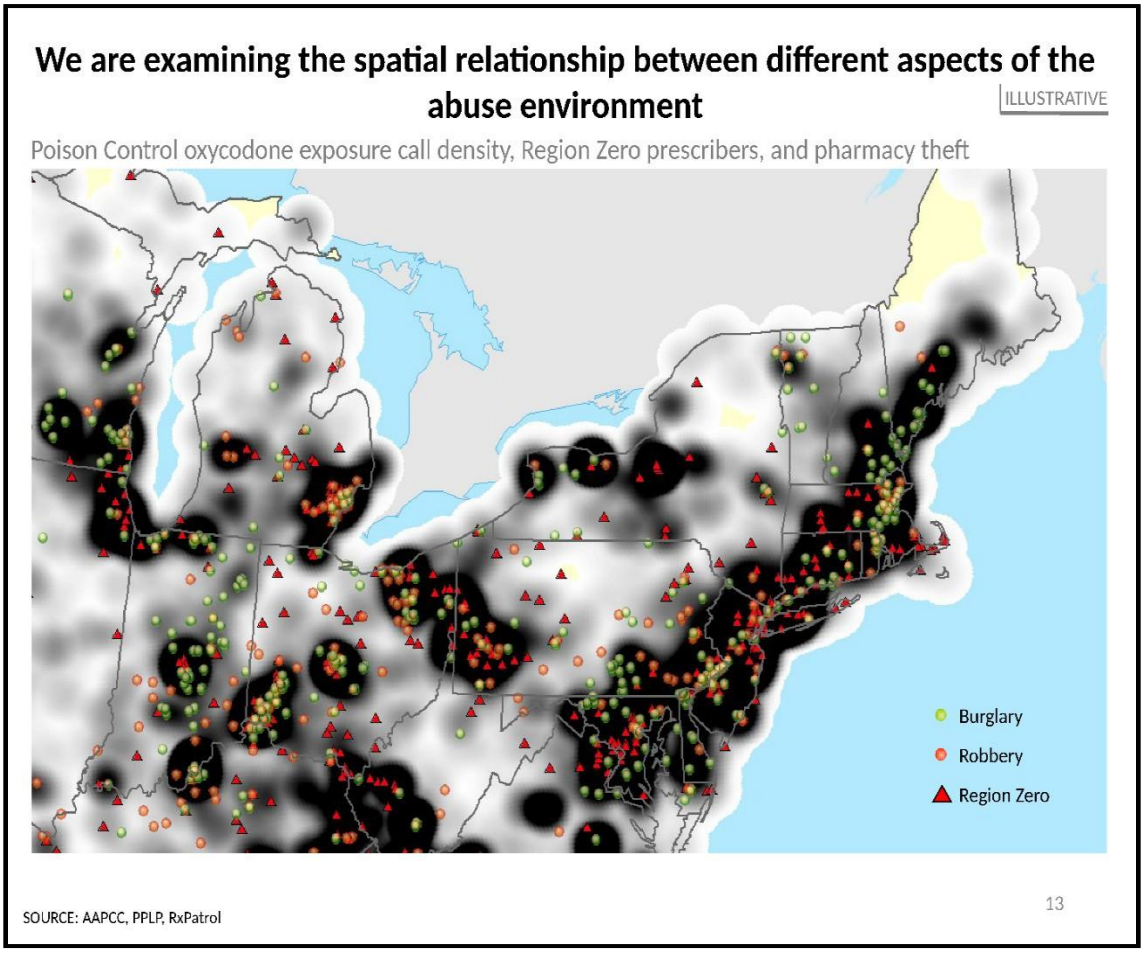
[191] 2011-03-09 email from Richard Sackler, PWG004335290 at 1.

[192] 2001-03-10 email from Russell Gasdia, PWG004335290 at 1.

[193] 2001-02-03 Board meeting materials, slide 48, PWG004343068.

the correlation between poison control calls for OxyContin overdose, pharmacy thefts, and *Region Zero* prescribers Purdue suspected of abuse and diversion.[194]

225. Staff even gave the Sacklers a map correlating dangerous prescribers in several states with reports of oxycodone poisonings, burglaries, and robberies.[195] Numerous *Region Zero* prescribers were located in New York and Massachusetts near the borders those states share with Vermont.



Map presented to the Purdue Board in 2011

[194] 2011-02-03 presentation by Bert Weinstein, slides 22-24, 86, 94-95, PWG004343068, 89-91, 161-162.

[195] 2011-02-03 presentation by Bert Weinstein, slide 95, PWG 004343161.

226. **March 2011:** 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.[196]

227. **April 2011:** 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.[197] The Sacklers voted to pay their family $189,700,000.

228. **May 2011:** In response to the Sacklers' repeated requests, staff sent Richard, Jonathan, Kathe, Mortimer, and Theresa Sackler a report on the sales tactics representatives were using to push Butrans. The first tactic reported to these Sacklers was focusing on a select "core" of physicians that Purdue calculated would be most susceptible to sales representatives lobbying to prescribe more opioids.[198]

[196] 2011-03-01 2011 OxyContin Tablets Sales Trends and Projections, PWG004337144, at 156-169.

[197] 2011-04-14 Board presentation, PWG004337213, -236.

[198] 2011-05-25 email from Russell Gasdia, PWG004332980.

[redacted]

229. 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."[199] In Vermont, promotion for "specific patient types" meant pushing opioids for elderly patients with arthritis. [redacted]

230. A third tactic reported to these five Sacklers was getting prescribers to commit to put specific patients on opioids.[200] [redacted]

231. 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."[201] Stewart and the sales team scrambled to put together a response and set up a meeting with Jonathan for the following week.

232. 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

[199] 2011-05-25 email from Russell Gasdia, PWG004332980.

[200] 2011-05-25 email from Russell Gasdia, PWG004332980.

[201] 2011-05-25 email from Jonathan Sackler, PWG004335076, -78.

sales representatives and, during Q1 2011, they visited prescribers 173,647 times.[202] [redacted]

[redacted]

233. 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.[203] Staff also told the Sacklers that they had received another 88 calls to Purdue's compliance hotline, but had not reported any of them to the authorities.[204]

234. **June 2011:** 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.[205] 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 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.[206]

235. 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

[202] 2011-05-02 Board report, pgs. 5, 6, 36, PWG004415402, -406, 407, -4437. 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.

[203] 2011-05-20 Board minutes, PWG004409681, -910PKY183212910.

[204] 2011-05-20 compliance report, PWG004337345, -388.

[205] 2011-05-12 Executive Committee notes, PWG004332957.

[206] 2011-06-21 Mid-Year Update, PWG004337450, -457-478.

day-to-day supervisors of the sales representatives. Then, having missed the meeting, he engaged Gasdia again by email, [redacted] [207] 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.[208]

236. [redacted]

237. 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. According to a district manager of the territory including Vermont, "If a rep went to see somebody who was not writing a lot of opioids, even if the doctor was new or they may be seen to have the potential to write opioids, those reps were called into question. Some of them were given warnings; others were put on probation."

238. Gasdia also told Richard Sackler that staff had initiated performance enhancement plans for sales representatives who were not generating enough opioid prescriptions. [redacted]

[207] [redacted]

[208] 2011-06-16 email from Russell Gasdia, PWG004335072.

[redacted]

239. 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 him for first thing the next morning. Richard Sackler would not wait until the morning and instructed Gasdia to call him that same day.

240. 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?"[209] He insisted that sales representatives push the doctors who prescribed the most drugs.

241. 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."[210] Compliance replied: "LOL."[211] 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.

[209] 2011-06-16 email from Richard Sackler, PWG004334785.

[210] 2011-06-16 email from Russell Gasdia, PWG004335333 ("Based on our discussions, perhaps you could sit down with JS on your thoughts. Also, I haven't spoken to him about RS going to field with reps. Perhaps you could also say something to JS and indicate I came to you for counsel as I saw this as a potential compliance risk?").

[211] 2011-06-16 email from Bert Weinstein, PWG004335245.

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

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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

242. A number of 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.[212]

[212] 2011-07-17 email from Bert Weinstein, PWG004335262.

243. 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.[213]

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

245. 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.[214]

246. 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

[213] 2011-07-20 email from Richard Sackler, PWG004415795, -797.

[214] PWG004335281.

> OxyContin. Finally, you could observe the Product Theaters we are implementing.[215]

247. **August 2011:** Staff told the Sacklers that Purdue employed 640 sales representatives and, during Q2 2011, they visited prescribers 189,650 times.[216] [redacted]

248. Meanwhile, staff reported to the Sacklers that, in the first seven months of 2011, Purdue paid the family $211,000,000.[217]

249. **September 2011:** 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.[218] That same month, the Sacklers voted to pay their family $140,800,000 more.

250. **November 2011:** Staff told the Sacklers that Purdue still employed 640 sales representatives and, during Q3 2011, they visited prescribers 189,698 times.[219] [redacted] Looking ahead, the Sacklers voted to spend $162,682,000 to employ sales representatives in 2012.

251. Meanwhile, staff told the Sacklers that, in the first nine months of 2011, Purdue paid their family $551,000,000.[220]

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[215] 2011-07-26 email from Russell Gasdia, PWG004335243.

[216] 2011-08-03 Board report, pgs. 6, 42, PWG004330818, -823, -859. 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.

[217] 2011-08-03 Board report, pg. 29, PWG004330818.

[218] 2011-09-28 email from Richard Sackler to John Stewart, PWG004334870.

[219] 2011-11-09 Board report, pgs. 5, 41, PWG004330776, -781, -817. 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.

[220] 2011-11-09 Board report, pg. 26, PWG004330776, -802.

252. **January 2012:** Jonathan Sackler started the year pressing Sales VP Russell Gasdia for weekly updates on sales. A few days later, Richard Sackler interjected himself further into the details surrounding Purdue's advertising with the sales staff. He had noticed that online advertisements appeared indiscriminately on webpages with content associated with the advertisement—regardless of whether the association was positive or negative. Staff assured Richard Sackler that, when Purdue bought online advertising for opioids, it specified that the advertisements 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."[221]

253. That same month, staff told the Sacklers that Purdue employed 632 sales representatives and, during Q4 2011, they visited prescribers 165,994 times.[222] [redacted]

254. The Sacklers were not satisfied with the sales effort. **In February 2012**, 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.[223] Mortimer Sackler was not pleased. He suggested that, "in future years we should not plan the national sales meeting so close following the winter break as it extends the period of time since the doctor last saw our rep." Mortimer Sackler wrote: "Wouldn't

[221] 2012-01-26 email from Russell Gasdia, PWG004335285.

[222] 2012-01-25 Board report, pgs. 7, 48, PWG004334921, -927. -968. 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.

[223] 2012-02-07 email from Russell Gasdia, PWG004334192.

it be better to have the reps get back to work for January and back in front of doctors."[224] Mortimer Sackler was agitated by the thought of doctors going too many days without a sales representative visiting to promote Purdue opioids. If Purdue rescheduled its meeting, "[a]t least then the doctors will have gotten at least one reminder visit from our reps in the last month whereas now they might go two months without seeing one of our reps??" Staff replied to Mortimer Sackler, arguing for "balance."[225] Richard Sackler replied within minutes that, since the National Sales Meeting prevented sales representatives from visiting doctors, "[m]aybe the thing to have done was not have the meeting at all."[226] Purdue's compliance officer forwarded the exchange to his staff, commenting: "Oh dear."[227]

255. 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."[228] Staff advised each other: "avoid as much e mail with dr. r as you can."[229] Sales VP Gasdia wrote to the CEO in exasperation: "I'm not sure what we can do about Dr. Richard."[230]

256. Also in February, [redacted][231]

[224] 2012-02-07 email from Mortimer Sackler, PWG004334192.

[225] 2012-02-08 email from Russell Gasdia, PWG004334191.

[226] 2012-02-08 email from Richard Sackler, PWG004334191.

[227] 2012-02-08 email from Bert Weinstein, PWG004334191.

[228] 2012-02-02 and 2012-02-03 emails from Richard Sackler, PWG004521501; *see also* 2012-02-22 emails from Richard Sackler, PWG004334404.

[229] 2012-01-09 email from William Mallin, PWG004336654.

[230] 2012-02-01 email from Russell Gasdia, PWG004334724.

[231] [redacted]

257. 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."[232] When sales dropped for one week on account of the Presidents' Day holiday, Richard Sackler wrote to sales management: "This is bad."[233] 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."[234]

258. 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."[235] A week later, Richard wrote to sales management again to criticize them for U.S. sales being "among the worst" in the world.[236]

259. **March 2012:** Staff sent the Sacklers a revised 2012 budget that cut the proposed payout to their family from $472,500,000 to $418,200,000.[237]

260. 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.[238] Gasdia [redacted] Do let us know how this

[232] 2012-02-07 email from Russell Gasdia, PWG004335301.

[233] 2012-02-07 email from Richard Sackler, PWG004335348.

[234] 2012-02-07 email from Russell Gasdia, PWG004335348.

[235] 2012-02-07 email from Russell Gasdia, PWG004335349.

[236] 2012-02-10 email from Richard Sackler, PWG004334401.

[237] 2012-03-05 email from Edward Mahony, PWG004333513.

[238] 2012-03-17 email from Richard Sackler to David Rosen, PWG004334669.

goes."[239] Later that month, staff created for Richard Sackler a historical summary of key events determining OxyContin sales.[240] Eleven of the key events in sales history were changes in the size of the Purdue sales force—all known to Richard Sackler because the Sacklers had ordered them.

261. A few days later, staff sent Richard Sackler an assessment of recently improved opioid sales. Staff told Richard that the increase in prescriptions was caused by tactics that Purdue taught sales representatives: pushing opioids for elderly patients with arthritis ("proper patient selection") and encouraging doctors to use higher doses of opioids ("quick titration").[241] In the coming months, Purdue would study, document, and expand the use of higher doses to increase sales.

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

263. Richard Sackler was not satisfied. Days later, after sales did not increase, staff told him that they were starting quantitative research to determine why patients stay on opioids, so they could find ways to sell more opioids at higher doses for longer.[242]

[239] 2012-03-18 email from Russell Gasdia, PWG004334669.

[240] 2012-03-28 presentation, PWG004334222.

[241] 2012-03-28 email from David Rosen, PWG004334209.

[242] 2012-04-20 email from David Rosen, PWG004334403.

264. **April 2012:** Staff told the Sacklers that Purdue employed 630 sales representatives and, during Q1 2012, they visited prescribers 179,554 times.[243] [redacted]

265. 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?"[244] A colleague replied incredulously to Gasdia: "Is there any question of your commitment?"[245]

266. 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."[246] Richard Sackler wanted more. He wanted to know what tactics sales staff would use to get more prescriptions, and he wanted to talk about it right away. First he wrote: "give me the table of weekly Rx plan and the actual. Then show how you plan to make up the current shortfall."[247] 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?"[248]

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[243] 2012-04-30 Board report, pgs. 6, 33, PWG004332587, -592, -619. 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.

[244] 2012-04-11 email from Richard Sackler, PWG004335340, -41.

[245] 2012-04-11 email from David Rosen, PWG004334387.

[246] 2012-04-12 email from Russell Gasdia, PWG004335341.

[247] 2012-04-12 email from Richard Sackler, PWG004335340-41.

[248] 2012-04-12 email from Richard Sackler, PWG004335340-41.

267. **May 2012:** Executives emphasized to 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.[249]

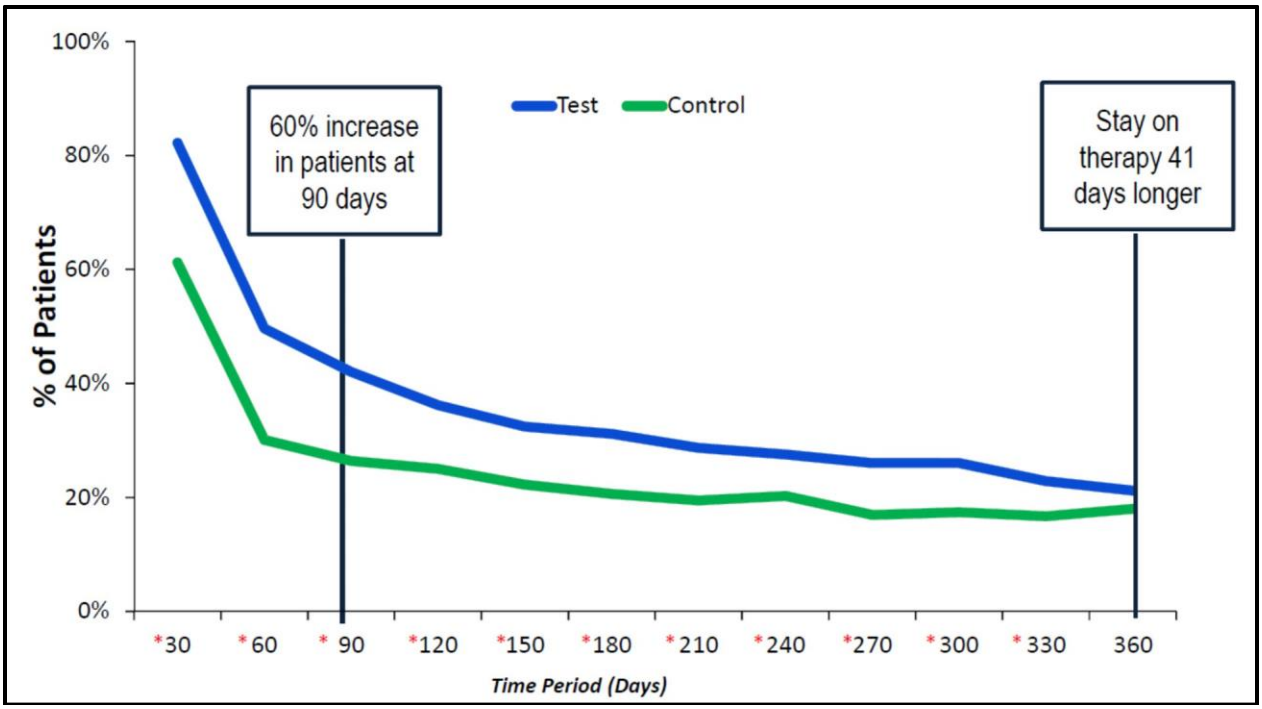
268. **June 2012:** The Sacklers discussed sales and marketing again. Staff reported to the Sacklers that they had added 120,000 sales visits to drive sales of OxyContin.[250]

269. 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.[251]

[249] 2012-05-15 email from Gary Lewandowski, PWG004336403.

[250] 2012-06-18 Mid Year Sales and Marketing Board Update, slide 10, PWG004335279.

[251] 2012-06-18 Mid Year Sales and Marketing Board Update, slides 11-12, PWG004335279.



Purdue internal analysis linking increased savings card utilization with increased duration of opioid use

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

270. **July 2012:** David Sackler (Richard Sackler's son) took a seat on the Board. For events after July 2012, this Complaint includes David in "the Sacklers."

271. Staff told the Sacklers that Purdue employed 633 sales representatives and, during Q2 2012, they visited prescribers 183,636 times.[252] [redacted]

272. **August 2012:** The Sacklers voted to direct Purdue to recruit an additional marketing executive and make candidates available to meet with members of the Board.

273. **November 2012:** Staff provided the Sacklers with the results of [redacted] study of 57,000 patients that Purdue performed explicitly to determine how opioid dose "influences

[252] 2012-07-23 Board report, PWG004344648 at -653, -690. Staff told the Sacklers that the sales representative visits compared to a target for the quarter of 190,662 visits; and that representatives visited 7.0 prescribers per day, on average, compared to a target of 7.1.

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.[253]

274. 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.[254] [redacted]

275. **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?"[255] Staff assured him that doctors were "sensitive" to sales representative visits and, as soon as the representatives went back into the field, they would "boost" opioid prescriptions again.[256]

276. 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

[253] 2012-11-01 Board report, pgs. 18, 30, PWG004415673, -690, -702.

[254] 2012-11-01 Board report, pgs. 15, 54, PWG004330717, -731. PWG000414901, -940. 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.

[255] 2013-01-07 email from Richard Sackler, PWG004334613.

[256] 2013-01-07 email from David Rosen, PWG004334613.

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.

277. That same month, staff told the Sacklers that Purdue employed 609 sales representatives and, during Q4 2012, they visited prescribers 153,890 times.[257] [redacted]

278. **February 2013:** 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.

279. **March 2013:** Staff reported to the Sacklers on the devastation caused by prescription opioids. [redacted] staff told the Sacklers that drug overdose deaths had more than tripled since 1990—the period during which Purdue had made OxyContin the best-selling painkiller. Staff told the Sacklers that tens of thousands of deaths were only the "tip of the iceberg." Staff reported that, for every death, there were more than a hundred people suffering from prescription opioid dependence or abuse.[258] For the Sacklers, however, the opioid epidemic was simply another opportunity to sell more opioids: [redacted]

[257] 2013-01-28 Board report, pgs. 10, 56, PWG004415259 at 268, 314. 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.

[258] 2013-03-21 Board presentation, PWG004337710 at 746-48.

[redacted][259]

280. **May 2013:** 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.[260]

281. 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."[261]

282. The Sacklers met with Sales VP Russell Gasdia about the strategy for selling high doses. Gasdia told the Sacklers that "[t]itration up to higher strengths, especially the 40mg and 80mg strengths is declining." He analyzed the "Causes of OxyContin's Decline in Higher

[259] [redacted]

[260] 2013-05-13 Board report, pg. 18, PWG004334509 at 526.

[261] 2013-05-13 Board report, pg. 8, PWG004334509 at 516.

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.[262]

283. 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."[263]

284. That same month, staff told the Sacklers that Purdue employed 637 sales representatives and, during Q1 2013, they visited prescribers 155,354 times.[264] [redacted]

285. **July 2013:** 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.[265] 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

[262] 2013-05 Board presentation by Russell Gasdia, PWG004337835 at 854-55.

[263] 2013-05 Board presentation by Russell Gasdia, PWG004337835 at 856.

[264] 2013-05-13 Board report, pgs. 12, 62, PWG004334509 at 520. 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."

[265] 2013-07-24 Communications and External Affairs Committee minutes, PWG004329632 at -635.

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 retained McKinsey & Company to study how to get doctors to prescribe more OxyContin.[266]

286. 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.[267]

287. 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."[268]

288. 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

[266] 2013-07-05 email from Edward Mahony, PWG004334598 at 600-02.

[267] 2013-07-23 Board report, pg. 25, PWG004414544 at 568.

[268] 2013-07-07 email from John Stewart, PWG004334492; attachment PWG004334496-508.

longer periods. Staff told the Sacklers that Purdue employed 634 sales representatives and, during Q2 2013, they visited prescribers 177,773 times.[269] Staff assured the Sacklers that they were trying to achieve even more sales visits by monitoring the representatives.[270]

289. 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.[271]

290. Days later, staff told the Sacklers that Purdue paid their family $42,000,000.[272]

291. **August 2013:** 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

[269] 2013-07-23 Board report, pgs. 11, 12, 59, PWG004414544 at 554, 556, 602. 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.

[270] 2013-07-23 Board report, pgs. 10-11, PWG004414544 at 553-54.

[271] 2013-07-18 Identifying Granular Growth Opportunities for OxyContin: First Board Update, PWG004337901 at 7991-8009.

[272] 2013-08-06 email from Edward Mahony, PWG004333602.

actions to increase sales. McKinsey urged the Sacklers to direct sales representatives to visit the most prolific opioid prescribers. McKinsey 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.[273]

292. 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 "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.[274]

293. 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

[273] 2013-08-08 Identifying Granular Growth Opportunities for OxyContin: Addendum to July 18th and August 5th Updates, PWG004338010.

[274] 2013-08-08 Identifying Granular Growth Opportunities for OxyContin: Addendum to July 18th and August 5th Updates, PWG004338010 at 15-17.

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." McKinsey urged the Sacklers to make "a clear go-no go decision to 'Turbocharge the Sales Engine.'"[275]

294. **October 2013:** 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.

295. 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.[276]

296. **October 2013:** Mortimer Sackler pressed for more information on dosing and "the breakdown of OxyContin market share by strength."[277] 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."[278] 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.[279] Staff promised to increase the budget for

[275] 2013-08-08 Identifying Granular Growth Opportunities for OxyContin: Addendum to July 18th and August 5th Updates, PWG004338010 at 17-18.

[276] 2013-08-22 McKinsey presentation, slide 10, PWG004335592.

[277] 2013-10-28 email from Mortimer Sackler, PWG004334213.

[278] 2013-10-28 email from David Rosen, PWG004334210-011.

[279] 2013-10-28 email from David Rosen, PWG004334211.

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.[280]

297. At the end of the month, the Sacklers met to discuss Purdue's budget for sales and marketing for 2014. Staff again told the Sacklers that Purdue's opioid savings cards kept patients on opioids longer.[281] 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.[282] To fight against that threat, staff told the Sacklers that they would increase the sales visits by each representative to 7.3 visits per day and visit prescribers a total of 758,164 times.[283]

298. **November 2013:** 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?"[284] Staff immediately offered to replace Richard Sackler's alert with a service that provided more flattering stories.[285]

299. 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.[286] [redacted]

[redacted]

[280] 2013-10-23 email from Edward Mahony, PWG004334218.

[281] 2013-10-29 OxyContin 2014 Budget Proposal to the Board, PWG004338136.

[282] 2013-10-29 Sales & Marketing presentation to the Board, PWG004338063.

[283] 2013-10-29 Sales Force 2014 Objectives presented to the Board, PWG004338073.

[284] 2013-11-18 email from Richard Sackler, PWG004336630.

[285] 2013-11-18 email from Raul Damas, PWG004336630.

[286] 2013-11-01 Board report, pg. 15, PWG004334067.

[redacted]

300. 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.[287] [redacted]

301. 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.[288] [redacted]

302. Staff reported to the Sacklers that Purdue paid their family $399,920,000 during January-September 2013. But staff told the Sacklers that, during the same period, Purdue lost hundreds of millions of dollars in potential profits because some prescribers were shifting away from higher doses of Purdue opioids.[289]

[287] 2013-11-01 Board report, pg. 14, PWG004334066.

[288] 2013-11-01 Board report, pgs. 15-16, 23-24, PWG004334067-068, -075-076.

[289] 2013-11-01 Board report, pgs. 3, 6, PWG004334055, -058.

303. 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.[290]

304. 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.[291] On information and belief, these communications were disseminated to Vermont prescribers.

305. 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.[292]

[290] 2013-11-01 Board report, pgs. 11-13, 27, PWG004334063-065, -079.

[291] 2013-11-01 Board report, pgs. 14, 16, PWG004334066, -68.

[292] 2013-11-01 Board report, pgs. 20-23, PWG004334072-75.

306. 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,[293] [redacted]

307. **December 2013:** 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.[294]

308. 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.[295] 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.[296]

309. **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"

[293] 2013-11-01 Board report, pgs. 11, 52, 55, PWG004334063, -104, -107. 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.

[294] 2013-12-04 email from David Rosen, PWG004334232.

[295] 2014-01-03 email from Burt Rosen, PWG004332488 ("I spoke to Richard just before the year end and raised concerns over our internal documents.").

[296] 2014-01-02 email from Jonathan Sackler, PWG004332488.

policies so that executives would forfeit bonuses they earned from misconduct, but Purdue had not. The boards of other companies passed resolutions each quarter certifying their oversight of the companies' compliance with the law, but the Sacklers did not.[297]

310. **February 2014:** Staff sent the Sacklers the final results from 2013.[298] 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.[299] 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."[300]

311. 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.[301]

[297] 2014-01-16 quarterly compliance report to the Board, PWG004338834.

[298] 2014-02-03 email from Edward Mahony, PWG004332207.

[299] 2014-01-30 memo from Edward Mahony, PWG004332208.

[300] 2014-02-27 email from Russell Gasdia, PWG004335682.

[301] 2014-01-30 memo from Edward Mahony, PWG004332209.

[302]

[redacted]

312. Also in February 2014, 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."[303]

313. 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.[304] 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

[303] 2014-02-04 Board report, pgs. 3, 5, 9, 22, PWG004333875, -877, -881, 894.

[304] 2014-02-04 Board report pgs. 13-14, PWG004333885-886.

compliance concerns with Purdue's speaker programs, in which the company paid doctors to promote Purdue opioids to other doctors.[305]

314. [redacted]

315. Staff told the Sacklers that Purdue employed 632 sales representatives and, during Q4 2013, they visited prescribers 176,227 times,[307] [redacted]

316. 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.

317. **March and April 2014:** 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

[305] 2014-02-04 Board report pgs. 15, 39-40, PWG004333887, -911-912.

[306] [redacted]

[307] 2014-02-04 Board report, pgs. 9, 47, PWG004333881, -919. 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.

sales representative visits promoting that opioid.[308] The Sacklers had assumed prescriptions would fall, but staff were concerned that the effect could be greater than anticipated.

318. **May 2014:** Richard and Jonathan Sackler's father, Raymond Sackler, sent David, Jonathan, and Richard Sackler a confidential memo about Purdue's strategy [redacted] The memo recounted that some physicians had argued that patients should not be given high doses of Purdue opioids, or kept on Purdue opioids for long periods of time, but Purdue had defeated efforts to impose a maximum dose limit or a maximum duration of use. Raymond Sackler asked David, Jonathan, and Richard Sackler to talk with him about the memo.

319. **June 2014:** 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."[309] Sure enough, Richard Sackler told Gasdia's replacement that he would be given little time to show that he could increase opioid sales: "it is very late in the day to rescue the failed launch" of Butrans, which was not making as much money as Richard Sackler desired.[310] CEO Mark Timney tried to caution Richard that it was "a little early" to be attacking the new sales leader, since he'd been at Purdue only two weeks.[311]

[308] 2014-03-07 email from Edward Mahony, PWG004524096-097; 2014-04-06 email from Edward Mahony, PWG004335566.

[309] 2014-06-10 email from Russell Gasdia, PWG004335670.

[310] 2014-06-10 email from Richard Sackler, PWG004335674.

[311] 2014-06-10 email from Mark Timney, PWG004335674.

320. That same month, staff sent the Sacklers an "Update on L.A. Times mitigation effort" about tactics to discourage scrutiny of Purdue's misconduct.[312] 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.[313]

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 don't get addicted and die.[314] The next year, the *Los Angeles Times* revealed that Purdue tracked suspicious prescribing of OxyContin with a secret list of 1,800 doctors code-named *Region Zero*, but did not report them to the authorities.[315]

321. **July 2014:** 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."[316]

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[312] 2014-06-30 email from Raul Damas, PWG004336634. 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. 2014-08-14 email from Scott Glover, PWG004332246.

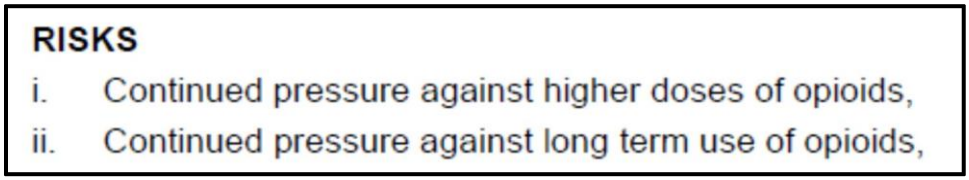
[313] 2014-06-30 email from Raul Damas, PWG004336634. Years earlier, the Sacklers had tried to influence the *New York Times* to be "less focused on OxyContin/Purdue." 2011-04-22 email from John Stewart, PWG004332542.

[314] 2012-11-11 "Legal drugs, deadly outcomes," by Scott Glover and Lisa Girion.

[315] 2013-08-11 "OxyContin maker closely guards its list of suspect doctors," by Scott Glover and Lisa Girion.

[316] 2014-07-22 email from Todd Baumgartner, PWG004334051-052.

322. **In July** and again in **August**, **September**, and **October 2014:** 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."[317]



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.[318]

323. **In August**, [redacted][319]

324. **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 internal documents, Purdue staff wrote down what it had publicly denied for decades: that addictive opioids and opioid addiction are "naturally linked." Staff proposed that Purdue should expand across "the pain and addiction spectrum," to become "an end-to-end pain

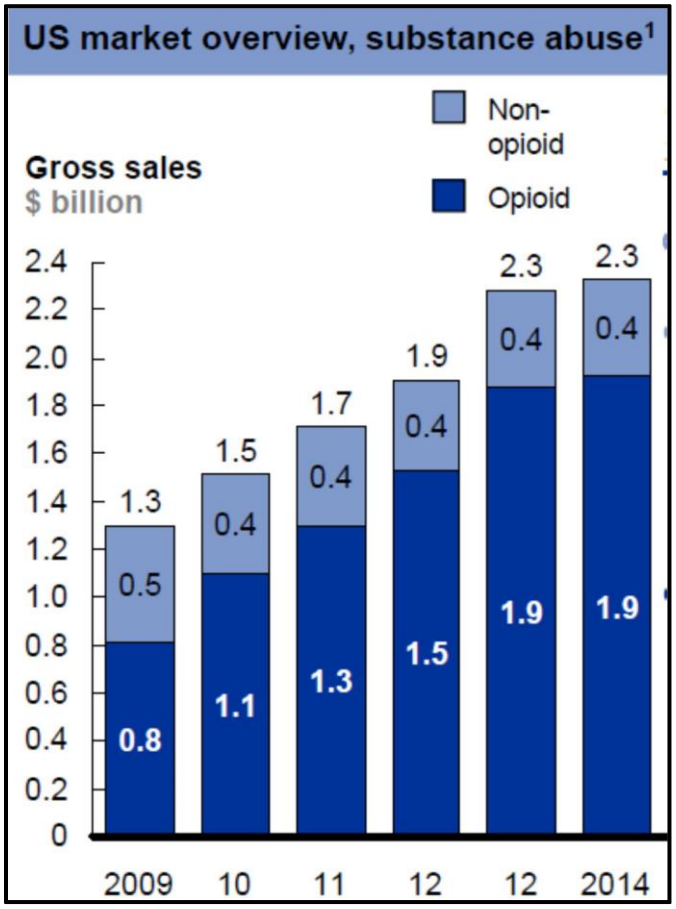
[317] 2014-07-01 Board Flash Report, slide 5, PWG004336412; 2014-08-05 Board Flash Report, slide 6, PWG004334424; 2014-09-05 Board Flash Report, slide 6, PWG004334661; 2014-10-15 Board Flash Report, slide 7, PWG004334293.

[318] 2014-07-01 Board Flash Report, slide 5, PWG004336412; 2014-08-05 Board Flash Report, slide 6, PWG004334424; 2014-09-05 Board Flash Report, slide 6, PWG004334661.

[319] [redacted]

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.[320]

325. Kathe Sackler and the *Project Tango* team reviewed their findings that the "market" of people addicted to opioids—measured in billions of dollars, rather than human lives—had doubled from 2009 to 2014.

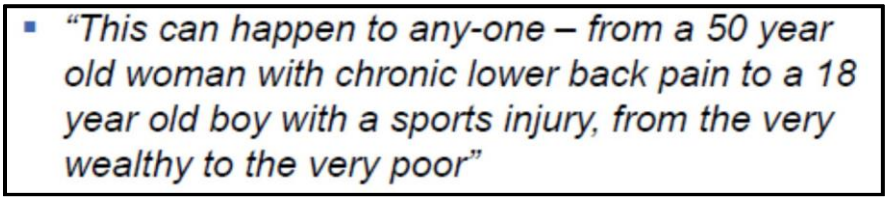


Purdue's Measure of the Opioid Addiction "Market"

[320] 2014-09-10 email from Brian Meltzer, PWG004490064; 2014-09-12 presentation, PWG004415180.

The presentation reviewed by Kathe Sackler and the staff showed that the catastrophic trend of addiction rates provided an excellent compound annual growth rate ("CAGR"): "Opioid addiction (other than heroin) has grown by ~20% CAGR from 2000 to 2010."[321]

326. 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:



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.[322]

327. 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*

[321] 2014-09-10 presentation, slide 4, PWG004415175. The Board discussed *Project Tango* in October 2014. 2014-10-01 Board meeting materials, PWG004338853.

[322] 2014-09-10 presentation, slides 2, 4, PWG4415175.

Tango, in a film that melts in a patient's mouth.[323] Staff assured Kathe Sackler that children were overdosing on pills, not films, "which is a positive for *Tango*."[324]

328.

[redacted]

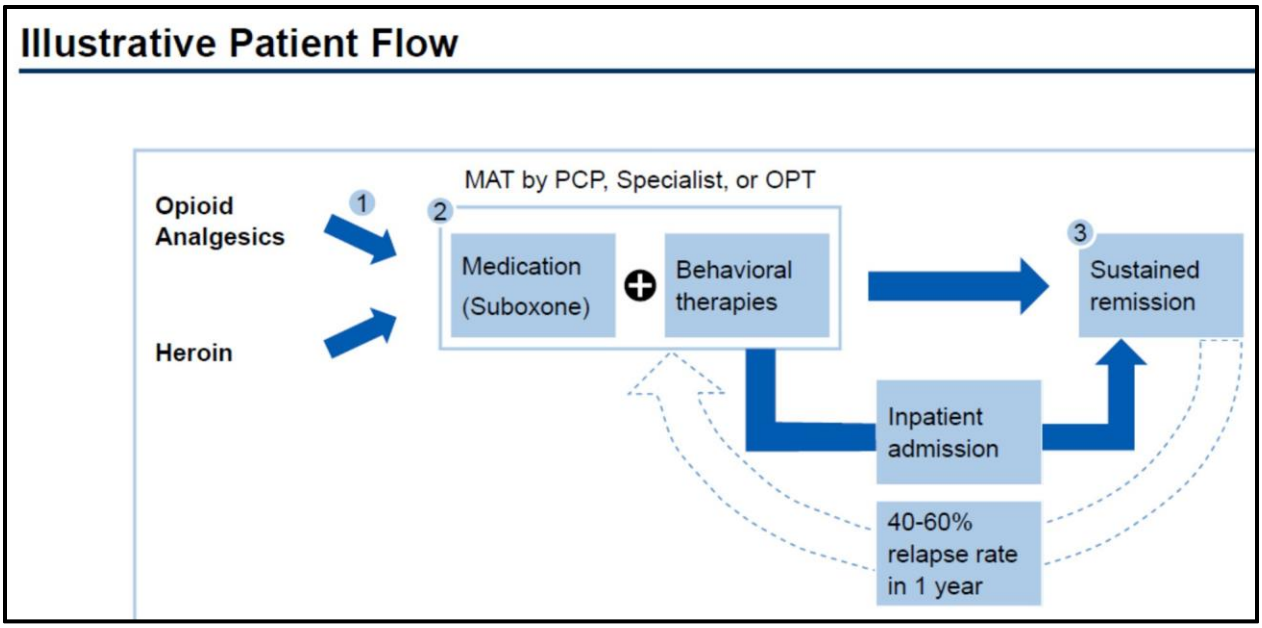
329. [redacted] The *Tango* team mapped how patients could get addicted to opioids through prescription opioid analgesics (such as Purdue's OxyContin) or heroin, and then become consumers of the new company's Suboxone. The team noted the opportunity to capture repeat customers: even after patients were done buying Suboxone the first time, between 40-60% would relapse and need it again.[326]

[323] 2014-09-16 email from Kathe Sackler, PWG004331682.

[324] 2014-09-17 email from Mark Timney, PWG004331681-682.

[325] [redacted]

[326] 2015-02-24 *Project Tango* presentation, PWG004334111.



Purdue presentation explaining "Project Tango" patient flow

330. 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.

331. **October 2014:** Staff sent the Sacklers a Proposed Operating Plan and Budget to be approved by the Board for 2015.[327] 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

[327] 2014-10-24 email from Edward Mahoney, PWG004336423.

"[a]dd additional contract sales force capacity at launch to drive uptake."[328] 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.[329]

332. Meanwhile, sales staff exchanged news reports of a lawsuit accusing Purdue of deceptive marketing in Kentucky.[330] 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."[331] Purdue's Vice President of Corporate Affairs was delighted by the article, because it did not reveal the Sacklers' role in the misconduct. "I'm quite pleased with where we ended up. There's almost nothing on the Sacklers and what is there is minimal and buried in the back."[332] [redacted][333]

[328] 2015 Commercial Budget Review, slides 19, 26, 31, 38, 51, 67, PWG004336456, -463, -468, , -475, -488, -504.

[329] 2015 Budget Submission, slides 13, 56, PWG004336544, -587.

[330] 2014-10-20 email from John Axelson, PWG004336379.

[331] 2014-10-20 Bloomberg Businessweek report, PWG004336386.

[332] 2014-10-20 email from Raul Damas, PWG004415329.

[333] [redacted]

333. **November 2014:** Staff reported to the Sacklers that their sales tactics were working, and the shift away from higher doses of OxyContin had slowed.[334]

334. **December 2014:** Staff told the Sacklers that Purdue would pay their family $163,000,000 in 2014 and projected $350,000,000 in 2015.[335]

335. **New Year's Eve 2014:** 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.[336]

336. Early in the morning of **January 2, 2015**, staff started collecting sales data for Richard Sackler.[337] They didn't 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:

> [U]nit 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.[338]

The CEO stepped in to say the work would have to wait three weeks [redacted]. Richard let him know that wasn't a great response—"That's longer than I had hoped for"—and directed marketing staff to start sending him materials immediately.[339]

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[334] 2014-11 OxyContin Brand Strategy and Forecast for 2015, PWG004338984 ("Strength mix shifting toward lower strengths has slowed with 40-80mg share going from 29% in the 10 Year Plan to 33% in the Budget").

[335] November 2014 report slide 8, PWG004334630.

[336] 2014-12-31 email from Richard Sackler, PWG004334464-465.

[337] 2015-01-02 email from Saeed Motahari, PWG004334463.

[338] 2015-01-07 email from Richard Sackler, PWG004334459-460.

[339] 2015-01-08 email from Richard Sackler, PWG004334459. Mark Timney had started as CEO a year earlier with the idea that he could "separate Board interaction from the organization" so the

337. 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.

338. **April 2015:** Staff told the Sacklers that sales of Purdue's highest dose 80mg OxyContin were down 20% and that the average prescription had declined by eight pills since 2011.

339. The Sacklers voted to expand the sales force by adding another 122 representatives.[340] As with every reference to "the Sacklers" after July 2012, that includes Beverly, David, Ilene, Jonathan, Kathe, Mortimer, Richard, and Theresa Sackler.

340. Staff told the Sacklers the additional representatives would increase net sales of opioids by $59 million.[341]

341. **June 2015**: After the City of Chicago sued Purdue Pharma for deceptive advertising, [redacted][342]

Sacklers would stop directing sales staff. 2014-01-29 email from Mark Timney, PWG004334456. That effort failed.

[340] 2015-04-21 Board materials, PWG004330062 ("It was decided to move forward with an expansion of the sales force by 122 reps"); 2015-05-04 Strategic Plan Update, slide 5, PWG004332262; 2015-04-21 Board decision, PWG004340515.

[341] 2015-04-21 Board materials, PWG004330058.

[342] [redacted]

[redacted] as discussed in Section A.

342. **October 2015:** Purdue executives identified avoiding investigations of Purdue's opioid marketing as a "Key Activity" in the company's Operational Plan.[343]

343. **November 2015:** 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.[344]

344. Staff proposed to the Sacklers that, for 2016, Purdue would plan for prescribers to average 60 pills of Purdue opioids per prescription. They told the Sacklers that they would aim to make enough of those pills be high doses to make the average per pill 33 milligrams of oxycodone.[345] That way, Purdue could hit its target for the total kilograms of oxycodone it wanted to sell.

345. 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

[343] 2015-10-27 Executive Operating Committee presentation, slide 16, PWG004329881.

[344] 2015-11 budget for 2016, slides 16, 28, 44, PWG004336046, -058, -074.

[345] 2015-11 budget for 2016, slide 41, PWG004336071.

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.[346]

346. 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.[347] 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.[348]

347. **December 2015:** 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.

348. **2016:** The Sacklers participated in regular meetings with the rest of the Board throughout 2016: in January, March, April, June, August, October, November, and December.

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[346] 2015-11 budget for 2016, slides 7, 39, PWG004336037, -069. Purdue fired 107 sales representatives in 2015.

[347] 2015-11 budget for 2016, slides 24, 26, 49, PWG004336054, -056, -079.

[348] 2015-11-03 email from Zach Perlman, Executive Committee materials, slide 36, PWG004335977.

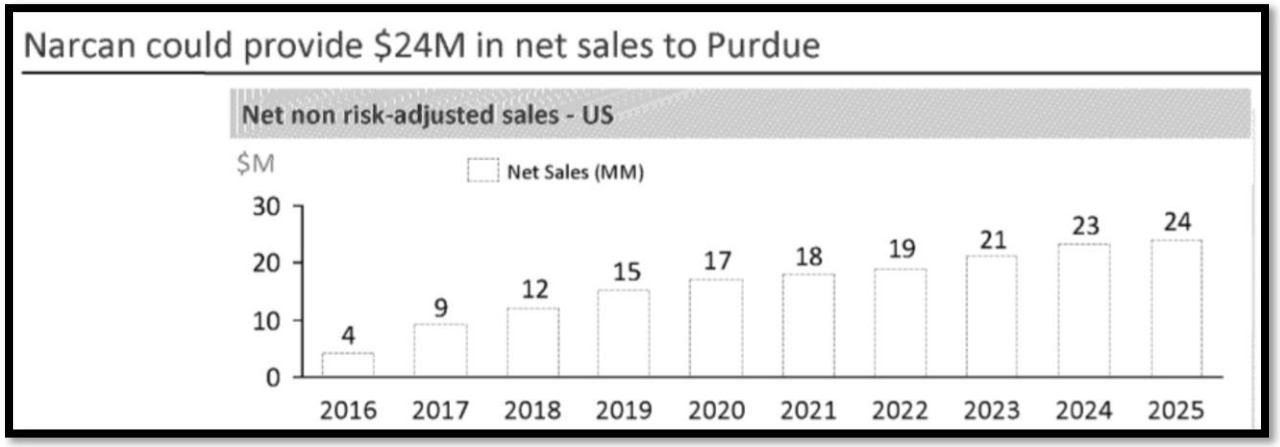
349. **April 2016:** The Sacklers considered exactly how much money was riding on their strategy of pushing higher doses of opioids. The month before, the CDC announced guidelines to try to slow the epidemic of opioid overdose and death. The CDC urged prescribers to avoid doses higher than 30mg of Purdue's 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 the amount at risk on a state-by-state basis. In Vermont, [redacted].[349]

350. **May 2016:** Richard Sackler told staff to circulate a *New York Times* story reporting that opioid prescriptions were dropping for the first time since Purdue launched OxyContin twenty years earlier. The *Times* wrote: "Experts say the drop is an important early signal that the long-running prescription opioid epidemic may be peaking, that doctors have begun heeding a drumbeat of warnings about the highly addictive nature of the drugs." The only person quoted in favor of *more* opioid prescribing was a professor whose program at his university was funded by the Sacklers.[350]

351. **June 2016:** The Sacklers met to discuss a revised version of *Project Tango*—another attempt to profit 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.

[349] PWG003976914.

[350] 2016-05-21 email from Richard Sackler, PWG004527906; 2016-05-20 "Opioid Prescriptions Drop for First Time in Two Decades," by Abby Goodnough and Sabrina Tavernise. The opioid advocate was Dr. Daniel B. Carr, director of Tufts Medical School's program on pain research education and policy.



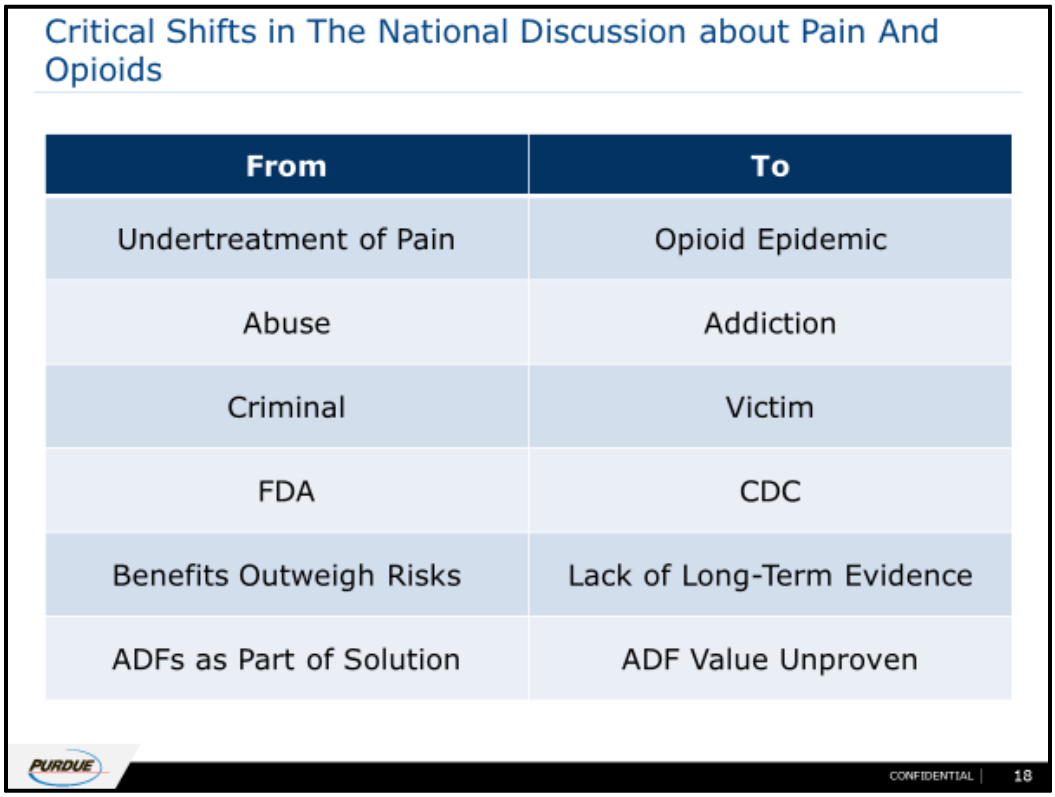
Board presentation showing potential sales from acquiring NARCAN

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].[351]

352. 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

[351] 2016-06 Board Book slides 46-49, 114, PWG004335773-776, -841. They planned to "Segment opioid patients to better understand target end-patients (e.g., long-term script users)."

Purdue had used to conceal the risks of opioids was being exposed. Staff summarized the problems on a slide:[352]



2016 Mid-Year Board Update

353. First, to convince doctors to prescribe dangerous opioids, Purdue had promoted its drugs as the solution to "undertreatment of pain." Richard Sackler had made sure that Purdue bought the internet address 5thvitalsign.com so it could promote pain as the "fifth vital sign" (along with temperature, blood pressure, pulse, and breathing rate) to expand the market for opioids. But now, staff reported to the Sacklers, doctors and patients were starting to worry more about the epidemic of opioid addiction.[353]

[352] 2016-06-08 Mid-Year Update, slide 18, PWG004335859. "ADF" on the slide refers to abuse-deterrent formulations of opioids, such as Purdue's crush-resistant OxyContin, which do not prevent addiction.

[353] 2016-06-08 Mid-Year Update, slide 18, PWG004335859.

354. 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."[354] But now, staff reported to the Sacklers, doctors and patients were realizing that addiction was a true danger.[355]

355. 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.[356] 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.[357]

356. Fourth, the Sacklers had long sought to hide behind the approval of Purdue's drugs by the FDA. But FDA approval could not protect the Sacklers when their deceptive marketing led thousands of patients to become addicted and die. The 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."[358] The 2016 Mid-Year Update warned that the truth was threatening Purdue.

357. [redacted]

[redacted]

[354] 2008-05-16 email from Pamela Taylor, PWG004445356; 2008-04-16 Executive Committee notes, PWG004332813; 2008-04-16 presentation by Luntz, Maslansky Strategic Research, slide 28, PWG004414396.

[355] 2016-06-08 Mid-Year Update, slide 18, PWG004335859.

[356] 2001-02-01 email from Richard Sackler, PWG004342047 ("we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals.").

[357] 2016-06-08 Mid-Year Update, slides 18, 20, PWG004335859, -861.

[358] 2016-03-15 briefing by CDC Director Tom Frieden.

[redacted]

358. **November 2016:** Staff prepared draft 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."[359] 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."[360] Staff eventually told the press: "Sackler family members hold no management positions."[361]

359. **December 2016:** 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."[362] The Sacklers kept searching for a way to expand their business by selling both addictive opioids and treatment for opioid addiction.

[359] 2016-11-03 email from Robert Josephson, PWG004336632.

[360] 2016-11-03 email from Raul Damas, PWG004336632 ("Love the second statement" – it was the second of two statements in the draft).

[361] 2016-11-28 email from Robert Josephson, PWG004331703.

[362] 2016-12-22 Braeburn Pharmaceuticals: Structuring Analysis, slide 3, PWG004336600.

360. **In April 2017**, [redacted][363]

361. **May 2017:** Staff told the Sacklers that the independent nonprofit's final report had concluded that Purdue's reformulation of OxyContin was not a cost-effective way to prevent opioid abuse.[364] Theresa Sackler asked staff what they were doing to fight back to convince doctors and patients to keep using the drug.[365]

362. 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."[366] The Sacklers made him CEO a few weeks later.

363. **June 2017:** 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

[363] [redacted]

[364] 2017-05-06 email from Gail Cawkwell, PWG004333152.

[365] 2017-05-06 email from Theresa Sackler, PWG004333152.

[366] 2017-05-02 Landau presentation, PWG004415342.

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."[367]

364. 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*."[368] 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.

365. 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 as a "new narrative" to reinvent the company. Staff also suggested that the Sacklers create a family foundation to help solve the opioid crisis.[369]

[367] 2017-06 Board of Directors: Purdue Mid-Year Pre-Read, slides 2, 152, PWG004333346, -496.

[368] 2017-06 Board of Directors: Purdue Mid-Year Pre-Read, slide 6, PWG004333350.

[369] 2017-06 Board of Directors: Purdue Mid-Year Pre-Read, slides 36-38, PWG004333380-382.

366. The Sacklers did not redirect the company toward appropriate use or create the suggested family foundation. Instead, they approved a 2018 target of [redacted]—more than the number of sales visits they had ordered for OxyContin in 2010.

367. **October 2017:** Richard Sackler learned that insurance company Cigna had cut OxyContin from its list of covered drugs and replaced it with a drug from Purdue's competitor, Collegium. Richard read that Collegium had agreed to encourage doctors to prescribe lower doses of opioids, and Collegium's contract with Cigna was designed so Collegium would earn *less* money if doctors prescribed high doses. Cigna announced that opioid companies influence dosing: "While drug companies don't control prescriptions, they can help influence patient and doctor conversations by educating people about their medications." Richard Sackler's first thought was to counterpunch. He immediately suggested that Purdue drop Cigna as the insurance provider for the company health plan.

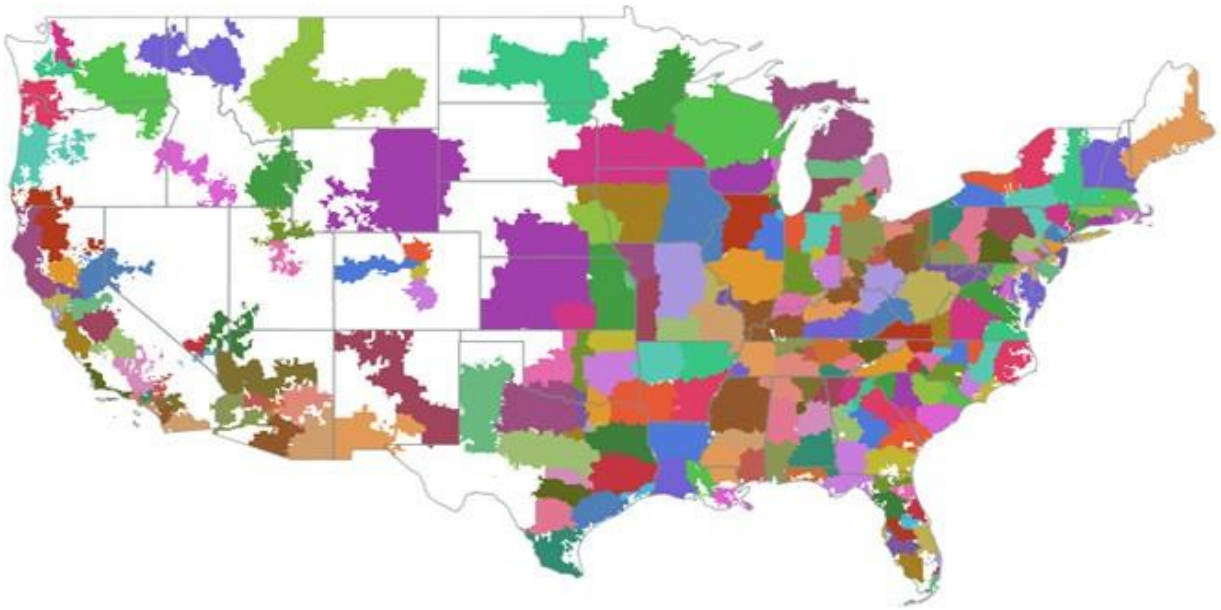
368. On October 17, Beverly Sackler served her last day on the Board. A week later, the *New Yorker* published an article entitled "The Family That Built an Empire of Pain." The story quoted a former FDA Commissioner: "the goal should have been to sell the least dose of the drug to the smallest number of patients." The reporter concluded: "Purdue set out to do exactly the opposite."[370]

369. **November 2017:** 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.[371] At the Board meeting that month, the remaining Sackler Board members (Richard, David, Ilene,

[370] 2017-10-23 email from Robert Josephson, PWG004332511.

[371] 2017-11-21 email from Craig Landau, PWG004333245.

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 Vermont. Staff even gave Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler a map of where the remaining sales representatives worked, with Vermont shaded to show that Purdue would keep visiting prescribers here.[372]



Purdue internal map of planned sales representative territories for 2018

370. **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.[373]

[372] 2017-11 Board budget, slides 47, 51, PWG004333838, -842.

[373] 2018-01-09, U.S. Patent No. 9,861,628 ("a method of medication-assisted treatment for opioid addiction"); 2007-08-29, international patent publication no. WO 2008/025791 Al.

371. In January, [redacted][374] 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.

372. **By April 2018**, staff were scared. Richard Sackler was again asking questions about sales. Staff prepared a presentation for the Board of Directors ("BoD"). One employee suggested that they add more information about the company's problems. Another cautioned against that:

> "I think we need to find a balance between being clear about what reality looks like – which I certainly support in [this] situation – and just giving so much bad news about the future that it just makes things look hopeless. Let's not give the BoD a reason to just walk away."[375]

373. **On May 3** and again on **June 6 and 8**, **2018:** all seven remaining Sacklers attended meetings of the Board: Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler. But just as their employees predicted, the Sacklers attempted to walk away. Richard Sackler was the first to go; he resigned from the Board in July 2018. By April 2019, the other six had left, too, leaving no Sackler family members on the Board – for the first time in Purdue Pharma history.

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

374. In 2007, Purdue entered into consent decrees with the federal government and numerous states, including Vermont, to resolve investigations into its marketing of OxyContin.

[374] [redacted]

[375] 2018-04-10 email from Paul Medeiros, PWG004335698.

As reported by USDOJ, those investigations centered on misrepresentations that OxyContin was less addictive and had less abuse potential than IR opioids, and that patients taking OxyContin could discontinue the drug without withdrawal symptoms. Prospectively, the decrees required Purdue more generally to discontinue all deceptive marketing, including any misrepresentations regarding OxyContin's potential for abuse, addiction, or physical dependence, and to provide a fair balance of risk and benefit information as required by FDA regulations. Specifically, the Vermont Consent Judgment required that all material used in promoting OxyContin be "not inconsistent with the Package Insert, contain only information that is truthful, balanced, accurately communicated, and not minimize the risk of abuse, addiction or physical dependence associated with the use of OxyContin." The Vermont Consent Judgment also required Purdue to disseminate "written, non-branded educational information related to detecting and preventing abuse and diversion of opioid analgesics," the intended purpose of which was to enlist Purdue's considerable financial resources to set the record straight on the abuse and diversion potential of opioids. Instead, Purdue seized a new opportunity to continue deceiving the public regarding the broader risks of dependence and addiction.

375. As part of Purdue's agreement with the United States, the Sacklers, as members of the Board of Directors, were required to undergo training to understand the terms of the corporate integrity agreement and to verify their agreement to comply with its terms.[376] This training was to include "the proper methods of promoting, marketing, selling, and disseminating information about Purdue's products in accordance with … FDA requirements."[377]

[376] Purdue Corporate Integrity Agreement § III.C.1.

[377] Purdue Corporate Integrity Agreement § III.C.1.

376. Notwithstanding its legal commitments to the State of Vermont, Purdue failed to correct its misrepresentations or actually reform its conduct. Instead, Purdue—at the direction of the Sacklers (as described in Sections B and C herein)—built upon its decades-long foundation of deceptive messaging that had established chronic opioid therapy as commonplace and generated billions of dollars in profit for Purdue. Purdue has continued to omit discussion of the serious risks of opioids and lack of evidence supporting long-term opioid use—thereby failing to correct its prior deceptions—and to affirmatively under-represent the serious risks and over-represent the benefits of opioids for the treatment of chronic pain. Purdue also pursued new, unfair marketing tactics to expand and preserve its customer base—and therefore the Sacklers' profits.

377. 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 duration of opioid treatment, and to increase the dosages of opioids prescribed. The Sacklers helped to create or were aware of and sanctioned marketing messages that Purdue sales representatives were trained to convey: that pain was undertreated, that opioids were preferable to over-the-counter and milder combination drugs, that the benefits of opioids greatly outweighed the risks, and that the risks of addiction and death were minimal and attached to very particular types of undesirable persons and behavior.

378. Purdue accomplished much of this through its sales force: the messages they verbally conveyed to healthcare providers, and the materials they showed or distributed to prescribers, or directed prescribers to review online. Since the launch of OxyContin, Purdue relied heavily on its sales representatives to market its opioids directly to prescribers, and that practice continued into 2018. For example, of the $167 million Purdue spent on promoting opioids

nationwide in 2016, $156 million—93.4%—was spent on detailing. By establishing personal relationships with doctors, Purdue's sales representatives were able to disseminate their misrepresentations in targeted, one-on-one settings.

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

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

381. At least 26 different Purdue sales representatives have detailed Vermont prescribers since 2006. Each of those representatives was expected to make seven to eight in-person sales calls to prescribers per day. Purdue's own records indicate that its representatives detailed at least 645 Vermont prescribers (a very significant percentage of the several thousand physicians, nurse practitioners, and physician's assistants practicing in the State) between 2006 and 2017. Many of

these prescribers were visited repeatedly. Indeed, in that same period, Purdue sales representatives made in excess of 11,000 unique sales visits in Vermont. Purdue assessed sales representatives' performance based on their ability to drive prescribing of its opioids; for example, one former Purdue detailer in Vermont had a sales goal of 1,100 OxyContin prescriptions per month.

382. The content of these sales calls was documented in "call notes," which Purdue expected to be detailed, thorough, and accurate. According to internal sales training documents, sales representatives were instructed to "[p]repare a concise call note that captures the key points of the dialogue between the Representative and the Customer," "ensure that call reporting clearly reflects the sales presentation," "[r]e-read every word of your call report to make sure that it is clear and accurate," "[a]lways review a call note before saving the record to ensure that it accurately reflects the important events that took place during the call," and complete the call note shortly after the sales call to ensure accuracy.

383. Purdue developed sophisticated plans to select prescribers for sales visits based on their prescribing habits. It purchased and closely analyzed prescription sales data that allowed the company to track prescribing of its opioids and those of its competitors. According to a former Purdue employee who trained and supervised Vermont sales representatives, any prescribing of an opioid—whether Purdue's or a competitor's—could land a prescriber on a detailing target list.

384. Purdue employed the same marketing tactics and messages in Vermont as it did nationwide, using uniform marketing materials and national and regional sales training. Purdue carefully trained its sales representatives to deliver company-approved sales messages. The company exactingly directed and monitored its sales representatives—through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' "call notes" from each visit—to ensure that individual detailers actually delivered the company's

desired messages. Purdue likewise required its sales representatives to deploy sales aids reviewed, approved, and supplied by the company.

385. As set forth below, through its sales force and deceptive promotional materials, Purdue misrepresented the serious risk of addiction posed by its opioids and misleadingly promoted OxyContin as effective for 12 hours. Purdue also deceptively and unfairly promoted its opioids in news ways and to new groups, by (a) targeting the elderly and the opioid-naïve with false claims about the safety and efficacy of low doses; (b) pushing physicians to prescribe the highest strengths of Purdue's opioids without disclosing the risks attendant to higher dosing; and (c) scheming to keep patients on opioids for longer periods, including offering innocuous-seeming savings cards, even though Purdue knew both that there was no good science supporting the efficacy of long-term opioid therapy and that the serious risks of addiction, overdose, and death increased with duration of use. The Sacklers approved or sanctioned all of this conduct, both by (a) ordering certain strategies and (b) being fully apprised of others, then directing Purdue to implement those strategies with more sales representatives making more visits to more prescribers.

1. To Fulfill the Sacklers' Directions and With the Sacklers' Awareness and Approval, Purdue Falsely Minimized or Failed to Disclose the Known, Serious Risk of Addiction

386. As explained above, the Sacklers 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 benign condition, like tolerance or pseudo-addiction; (3) convincing prescribers that addiction could be prevented by screening likely abusers from treatment.

387. To convince Vermont prescribers and patients that opioids were safe, Purdue built upon its extensive and effective foundation of deceptive marketing and deceptively minimized and

failed to disclose the risks of long-term opioid use, particularly the risk of addiction. Purdue trained its sales representatives to deflect questions about addiction into discussions of how to identify "appropriate patients," and to draw distinctions between "physical dependence" and "addiction" to allay prescribers' concerns about addiction risks. This strategy has been crucial to Purdue's business model, because the vast majority of Purdue's OxyContin sales are for patients who are continuing users of the drug (as opposed to new prescriptions). Deceptively minimizing the risk of addiction also was critical to Purdue's efforts to encourage new prescriptions, as prescribers and consumers have become more aware of the opioid epidemic over the last ten years.

388. These misrepresentations and omissions, described further below, reinforced each other to create the dangerously misleading impressions that:

(a) Purdue's ER/LA opioids present a reduced risk of addiction, and even patients who present symptoms of addiction may simply be physically dependent on the drug or have undertreated pain that should be treated with more opioids;

(b) patients at greatest risk of addiction can be identified and vetted out, allowing doctors to confidently prescribe opioids to all other patients and even prescribe to high-risk patients, provided they are closely managed;

(c) the abuse-deterrent formulations of Purdue's opioids both prevent abuse and are inherently less addictive; and

(d) physicians can prescribe steadily higher doses of opioids without added risk.

These deceptive messages often were delivered in combination and had a cumulative impact. Each of them has now been debunked by FDA and the CDC.

389. These core messages on addiction risk flowed directly from the strategy devised by Dr. Richard Sackler, who had previously served as Purdue's President and CEO from 1999 to 2003. Dr. Sackler directed Purdue to characterize the growing opioid problem as one of "abuse" rather than "addiction." Thus, according to Purdue's misrepresentations, doctors had no reason to fear that legitimate pain patients would become addicted, and screening tools and abuse-deterrent

formulations could keep the abusers at bay. As described in Section C, in 2016, when the tide of public opinion regarding opioids had turned, the staff reported to the Sacklers that the concepts of undertreatment and abuse—which had long been successful parts of Purdue's marketing—were no longer accepted as plausible explanations for an epidemic of addiction linked tightly to overprescribing.

390. Purdue's marketing strategy to increase opioid prescriptions focused on two distinct patient groups: keeping existing patients with "continuing" opioid prescriptions, which constituted over 80% of Purdue's sales, and identifying and gaining new patients who were not yet on opioid therapy or were new to the Purdue brand. To maintain and expand "continuing" prescription patients, Purdue built on its prior deceptions and persisted in misleading prescribers and the public about the benefits of opioids and of its specific opioid products, especially for long-term use, while minimizing the serious risks associated with these drugs, including addiction and overdose. To expand its reach and generate new prescriptions, Purdue took additional steps to expand the market for its opioids.

391. Overall, Purdue's marketing strategy created the impression that opioids were an ordinary and appropriate treatment for many kinds of people, that opioids generally (and OxyContin, specifically) provided meaningful benefits that justified their use, and that the risks of these drugs were minimal (and outweighed by the benefits).

a. Omitting, trivializing, and mischaracterizing addiction risk

392. In furtherance of the strategic narrative set by the Sacklers—to deny addiction risk or deflect addiction concerns—Purdue's sales representatives regularly omitted from their visits to Vermont prescribers any discussion of the addiction risks that are plainly associated with long-term use of opioids. Given that Purdue admitted that it had made misrepresentations between 1996 and 2007, these material omissions were particularly damaging. Purdue did not train its sales force

to correct the company's historic, deeply misleading—but highly profitable—message that patients who receive chronic opioid therapy for legitimate pain conditions face only a very small risk of becoming addicted.

393. These omissions, where were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading, especially in light of Purdue's prior misrepresentations regarding the risk of addition. In addition, by failing to correct this earlier misinformation, Purdue's representatives let stand the dangerous impression that patients who receive chronic opioid therapy for legitimate pain conditions are unlikely to become addicted.

394. The messages delivered in Vermont by detailers to prescribers were, as Purdue intended, passed on to patients. Patients receiving substance abuse treatment and whose addiction began with prescriptions for chronic pain often report that they were not warned of the risk they might become addicted to opioids. This is confirmed by national research: A 2015 survey of more than 1,000 opioid patients found that 40% were not told opioids were potentially addictive.[378]

"Pseudoaddiction"

395. In furtherance of the strategic narrative set by the Sacklers to deny addiction risk or deflect addiction concerns, Purdue represented to Vermont prescribers that red-flag signs of addiction may simply be indicators of medically undertreated pain that should be treated with higher doses. This concept was dubbed "pseudoaddiction" in earlier marketing, and the term persisted in marketing to Vermont prescribers until at least 2014. Even after Purdue stopped calling it "pseudoaddiction," Purdue continued to advance this unsubstantiated and misleading concept. Purdue consistently used this concept to suggest to prescribers that they should prescribe

[378] Hazelden Betty Ford Foundation, *Missed Questions, Missed Opportunities* (Jan. 27, 2016), http://www.hazeldenbettyford.org/about-us/news-and-media/press-release/doctors-missing-questions-that-could-prevent-opioid-addiction.

higher doses of opioids when presented with patients who quite clearly exhibit drug-seeking behaviors.

396. As discussed above, the concept of "pseudoaddiction" was developed by Dr. Haddox, a paid Purdue speaker in the 1990s who went on to become a high-level Purdue executive. Purdue ensured that the term and concept of "pseudoaddiction" appeared in *Responsible Opioid Prescribing*, a reference book that was distributed through the Vermont Board of Medical Practice to prescribers in Vermont. The concept has since been discredited. Nonetheless, Vermont prescribers interviewed during the State's investigation of Purdue's deceptive marketing scheme stated that they currently have in their possession, continue to reference, and rely upon copies of this book.

397. Purdue promoted the fallacy of pseudoaddiction in "*Providing Relief, Preventing Abuse*." This pamphlet was distributed for the purpose of fulfilling Purdue's obligation under the 2007 Vermont Consent Judgment to provide "written, non-branded educational information related to detecting and preventing abuse and diversion of opioid analgesics," and it was broadly disseminated in Vermont. But rather than provide accurate, non-deceptive information about the risk of abuse and diversion, this pamphlet reinforced the misleading message that drug-seeking behaviors—commonly understood to be symptoms of addiction—are instead signs of benign "pseudoaddiction."

398. Purdue promoted the concept of "pseudoaddiction" through other extensive, unbranded marketing that it funded or controlled. *Partners Against Pain* is a Purdue marketing imprint consisting of both medical education resources, distributed to prescribers (including Vermont prescribers) by the sales force, and a now-defunct website that, before Purdue shut it down in 2016, was styled as an "advocacy community" for better pain care. *Partners Against Pain*

existed since at least the early 2000s and served as a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. Through at least 2013, the *Partners Against Pain* website relied on and directed users to the 2001 Guideline from American Academy of Pain Medicine and American Pain Society, which endorsed the concept of "pseudoaddiction."

399. A *Partners Against Pain* "Pain Management Kit" that debuted in 2009 likewise advocated the "pseudoaddiction" concept, referring prescribers to the 2001 AAPM/APS "Definitions Related to the Use of Opioids for the Treatment of Pain." The kit also introduced another resource—a set of drug abuse screening tools (discussed in Section D(1)(b))—by stating that "[b]ehaviors that are suggestive of drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior." Purdue sales representatives have regularly directed Vermont prescribers to the *Partners Against Pain* website and distributed the Pain Management Kit to Vermont prescribers, and Vermont prescribers have used the *Partners Against Pain* website as a prescribing resource.

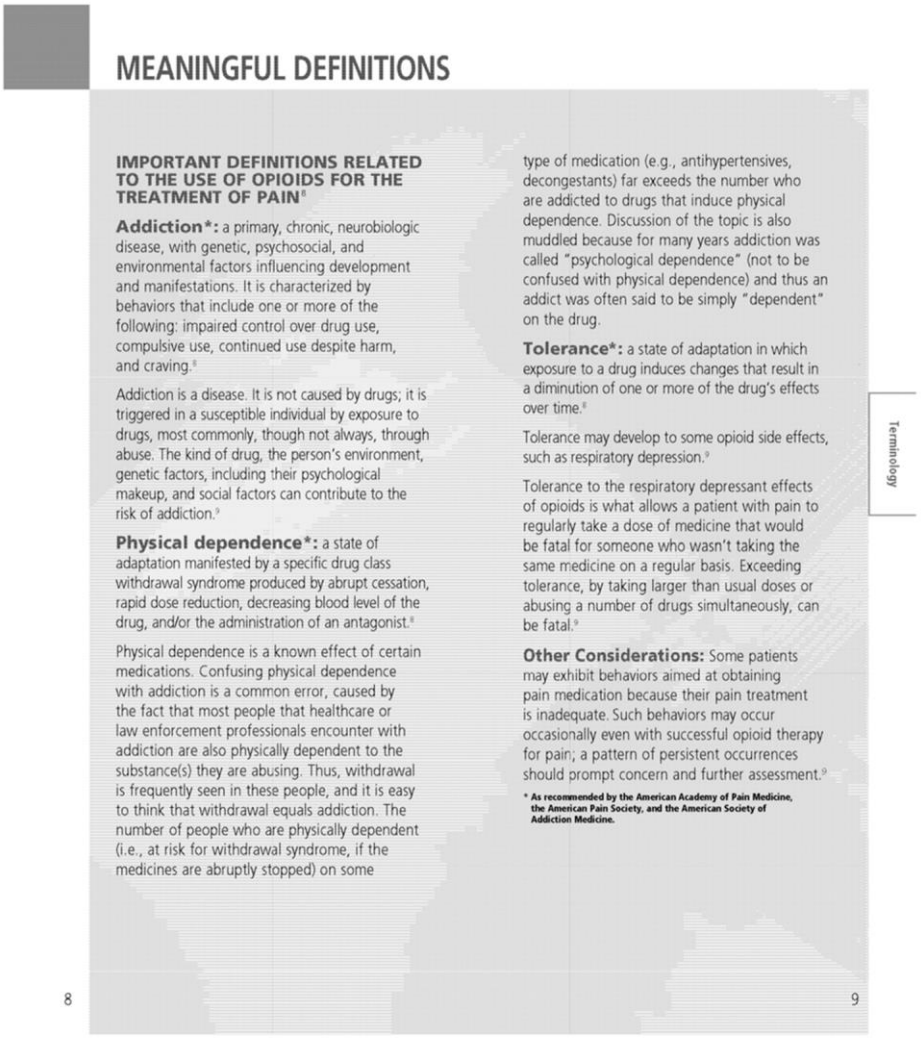
Distinction between "Physical Dependence" and Addiction

400. In furtherance of the strategic narrative set by the Sackler Defendants to deny addiction risk or deflect addiction concerns, Purdue also attempted to assuage prescribers' concerns about its products by distinguishing between "addiction" (dependence that results in compulsive drug use despite harmful consequences) and "physical dependence" (the body's need for higher doses of the opioid over time and withdrawal symptoms if opioids are discontinued). Purdue described "physical dependence" as a normal consequence of extended opioid use, but failed to disclose the serious risks and problems associated with physical dependence. Purdue misled prescribers when it drew a distinction between "physical dependence" and "addiction" without fully explaining the risks associated with both conditions—deliberately creating the

impression that the negative consequences prescribers (and patients) were worried about would only occur in the context of "addiction."

401. Purdue's omissions about the risks of physical dependence are all the more glaring because the risks are expressly included in the label. The 2013 version of the OxyContin label describes the risk that a patient will experience withdrawal symptoms if OxyContin is discontinued or reduced in dose. The label also states that infants born to mothers physically dependent on opioids will be physically dependent and may experience withdrawal themselves.

402. This misleading and incomplete message minimizing the risks of "physical dependence" was delivered through both sales calls and in written advertising materials. Purdue sales representatives were trained to differentiate between "physical dependence" and "addiction," and sales representatives delivered this message in sales calls to prescribers. Promotional materials and other publications Purdue disseminated or made available in Vermont have included similar, mutually reinforcing messages minimizing the risk of addiction by distinguishing it from "physical dependence."



MEANINGFUL DEFINITIONS

IMPORTANT DEFINITIONS RELATED TO THE USE OF OPIOIDS FOR THE TREATMENT OF PAIN[8]

Addiction*: a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.[8]

Addiction is a disease. It is not caused by drugs; it is triggered in a susceptible individual by exposure to drugs, most commonly, though not always, through abuse. The kind of drug, the person's environment, genetic factors, including their psychological makeup, and social factors can contribute to the risk of addiction.[9]

Physical dependence*: a state of adaptation manifested by a specific drug class withdrawal syndrome produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or the administration of an antagonist.[8]

Physical dependence is a known effect of certain medications. Confusing physical dependence with addiction is a common error, caused by the fact that most people that healthcare or law enforcement professionals encounter with addiction are also physically dependent to the substance(s) they are abusing. Thus, withdrawal is frequently seen in these people, and it is easy to think that withdrawal equals addiction. The number of people who are physically dependent (i.e., at risk for withdrawal syndrome, if the medicines are abruptly stopped) on some type of medication (e.g., antihypertensives, decongestants) far exceeds the number who are addicted to drugs that induce physical dependence. Discussion of the topic is also muddled because for many years addiction was called "psychological dependence" (not to be confused with physical dependence) and thus an addict was often said to be simply "dependent" on the drug.

Tolerance*: a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.[8]

Tolerance may develop to some opioid side effects, such as respiratory depression.[9]

Tolerance to the respiratory depressant effects of opioids is what allows a patient with pain to regularly take a dose of medicine that would be fatal for someone who wasn't taking the same medicine on a regular basis. Exceeding tolerance, by taking larger than usual doses or abusing a number of drugs simultaneously, can be fatal.[9]

Other Considerations: Some patients may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate. Such behaviors may occur occasionally even with successful opioid therapy for pain; a pattern of persistent occurrences should prompt concern and further assessment.[9]

* As recommended by the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine.

Terminology

8

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403. The *Providing Relief, Preventing Abuse* pamphlet included similar deceptions. It downplayed "physical dependence" as "a known effect of certain medications," citing benign blood pressure medications and decongestants as analogous examples. It also asserted that "physical dependence" and "addiction" are commonly confused.

404. Purdue's distinction between "physical dependence" and "addiction" was especially deceptive in the context of increasing public awareness of the risks of opioid addiction, because it implied that "physical dependence" was less harmful than "addiction." These messages also implied that physical dependence on OxyContin was no more problematic than physical

dependence on blood pressure medication. *Providing Relief, Preventing Abuse* also showed graphic pictures of the stigmata of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa—to illustrate "potential signs consistent with drug abuse." In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients becoming addicted through oral use. These depictions deceptively reassured doctors that, as long as they do not observe physical signs of snorting or injecting, they need not worry that their patients are abusing or addicted to opioids.

405. Purdue's *Partners Against Pain* website likewise offered misleading and deceptively reassuring distinctions between addiction and physical dependence, presenting addiction as a neurobiological disease and physical dependence as a benign "state of adaptation."

406. In disseminating such messages, Purdue was attempting to avoid associations with addiction. This failed to acknowledge the very serious reality that Vermont consumers faced: that no matter what definitions and labels are applied, patients taking opioids are at serious risk of becoming "hooked," needing ever-increasing doses to avoid withdrawal symptoms, and being unable to stop taking opioids.

Other Unbranded Marketing Minimizing the Risk of Addiction

407. In furtherance of the strategic narrative set by the Sackler Defendants to deny addiction risk or deflect addiction concerns, Purdue disseminated or supported the dissemination of unbranded marketing materials that also minimized the risk of addiction associated with opioids generally.

408. Purdue maintained an online "interactive toolkit" for patients, caregivers, and prescribers—*In the Face of Pain* (www.inthefaceofpain.com)—that deceptively downplayed the risks of chronic opioid therapy. *In the Face of Pain*, which Purdue deactivated in October 2015 following an investigation by the New York Attorney General, was another example of

"unbranded" marketing. Although it featured the Purdue copyright at the bottom of each page, the site did not refer to Purdue products in particular and cultivated the impression that it was neutral and unbiased.[379] As of 2010, the "In the Face of Pain Toolkit" was also available on the *Partners Against Pain* website, which detailers frequently referenced during Vermont sales calls.

409. *In the Face of Pain* 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. As of 2015, while a document linked from the *In the Face of Pain* website briefly mentioned opioid abuse, the site itself did not—even once—mention the risk of addiction, a risk so significant that it requires a black box warning on all opioid drug labels. At the same time, the website contained testimonials from several dozen physician "advocates" speaking positively about opioids. The website failed to disclose that, from 2008 to 2013, Purdue paid 11 of these advocates a total of $231,000.[380]

410. Purdue also continued working closely with allies, such as the American Pain Foundation ("APF")—a group that, as discussed above, was heavily dependent on funding from Purdue and other pharmaceutical companies—to disseminate misleading, unbranded messages about the risks of opioids.

411. APF's *Exit Wounds* described opioids as the "'gold standard' of pain medications" and minimized the risk of addiction. It emphasized that physical dependence often is mistaken for addiction and claimed 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."

[379] *In the Matter of Purdue Pharma L.P.*, Assurance No. 15-151, Assurance of Discontinuance (signed August 19, 2015).

[380] *Id.*

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

The True Risks of Opioids

413. Purdue's claims regarding addiction are contrary to longstanding scientific evidence, and its failures to address the risk of addiction when promoting the use of these drugs are material omissions, given both the magnitude of the risk and the grave consequences of addiction. As confirmed by the CDC in its 2016 Guideline, "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])" exists. The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder." (Emphasis added.)

414. Studies have shown that at least 8-12%, and as many as 30% or even 40%, of long-term users of opioids experience problems with addiction.[381] In requiring a new black-box warning on the labels of all IR opioids in March 2016, similar to the warning already required for ER/LA

[381] Joseph A. Boscarino *et al*., *Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system*, 105(10) Addiction 1776-82 (Oct. 2010); Joseph A. Boscarino *et al., Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM5 vs. DSM-4 Diagnostic Criteria*, 30(3) J. of Addictive Diseases 185-94 (July-Sept. 2011); Vowles, Kevin E. *et al*., *Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis*, Pain 156.4 (2015): 569-576.

opioids, FDA emphasized the known, "serious risks of misuse, abuse, [and] addiction . . . . across all prescription opioid products."[382] That same month, after a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC published its *Guideline for Prescribing Opioids for Chronic Pain*.[383] The CDC found that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder."[384] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[385]

b. Overstating the efficacy of screening tools

415. In furtherance of the strategic narrative set by the Sackler Defendants to deny addiction risk or deflect addiction concerns, Purdue deceptively promoted screening tools—such as drug testing, pill counts, and patient contracts—as reliable ways to prevent addiction and safely prescribe long-term opioids. While screening tools may help doctors identify the most susceptible patients and identify diversion, and patient contracts convey the gravity of risks and establish protocols to stop diversion, they cannot prevent dependence or addiction from occurring. These misrepresentations provided false assurances to healthcare providers and patients that addiction was avoidable and largely the result of other prescribers' failure to rigorously manage and weed out problem patients who could have been easily identified with screening tools.

416. Purdue conveyed these messages during in-person sales calls in Vermont. For example, when one prescriber discussed with the Purdue sales representative the increasingly

[382] Food and Drug Administration, *FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death* (Mar. 22, 2016), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

[383] CDC Guideline, *supra* n.26, at 2.

[384] CDC Guideline, *supra* n.26, at 2.

[385] CDC Guideline, *supra* n.26, at 25.

aggressive behavior of his opioid patients and his fears for his staff's safety, the representative emphasized the importance of continuing to prescribe OxyContin for "appropriate patients": *e.g.*, ones who attended scheduled appointments, signed and abided by patient contracts, and complied with urine screens and pill checks.

417. Purdue also promoted the "Opioid Risk Tool" created by opioid advocate Dr. Lynn Webster, who received research funding from Purdue, as part of its *Partners Against Pain* "Pain Management Kit." This "Opioid Risk Tool" is a five-question, one-minute screening tool that relies on honest 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. Sales representatives distributed the kit in CD ROM format to prescribers in Vermont, and frequently directed prescribers to the *Partners Against Pain* site throughout recent years.

418. Purdue promoted screening tools as a reliable means to manage addiction risk in CME and scientific conferences available to Vermont prescribers. In 2011, Purdue sponsored a CME taught by Dr. Lynn Webster via webinar titled "Managing Patient's Opioid Use: Balancing the Need and Risk." This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths." Purdue also funded a 2012 symposium called "Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes," which taught doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addictive behavior could be safely treated with opioids.

419. The 2016 CDC *Guideline for Prescribing Opioids for Chronic Pain—United States* ("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. There are no studies assessing the effectiveness of screening tools, patient contracts, urine drug testing, or pill counts—all which were widely promoted by Purdue and believed by doctors in Vermont—"for improving outcomes related to overdose, addiction, abuse, or misuse."[386] In fact, the CDC Guideline recognizes that risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy." (Emphasis added.)[387]

c. Overstating the efficacy of "abuse-deterrent" properties

420. In furtherance of the strategic narrative set by the Sacklers to deny addiction risk or deflect addiction concerns, Purdue deceptively marketed its abuse-deterrent opioids—a reformulated version of OxyContin and Hysingla ER—to Vermont prescribers in a manner that falsely implies that these abuse-deterrent drugs can curb abuse and even addiction. As explained above, the Sacklers were advised, even before the abuse-deterrent formulation was brought to market in 2010, that Purdue's reformulation would not prevent addiction—or even abuse. In truth, all these reformulations do is make it harder to crush the pill. This does nothing to protect against the most common form of abuse, which is via oral ingestion.

421. Oral abuse of prescription opioids includes not only taking the drugs without a prescription, but also taking higher or more frequent doses than prescribed. Rather than focus on the oral abuse associated with the widespread prescribing of OxyContin for chronic pain, Purdue

[386] 2016 CDC Guideline, *supra* n.26, at 11.

[387] 2016 CDC Guideline, *supra* n.26, at 18. These screening tools may serve different purposes: they can assist doctors in identifying diversion, and they can convey to patients the gravity of the risks of opioid use.

tied abuse and addiction to less common illegal product diversion and abuse via snorting or injecting the drug. Purdue's proffered solution—introduced as an abuse-deterrent formulation in 2010—was a new pill coating and other elements to make its opioids more difficult to crush or inject (*i.e.*, making it tamper-resistant). Purdue misleadingly assured prescribers that they could prescribe Purdue's opioids without contributing to the epidemic of misuse and abuse.

422. FDA approved the reformulated OxyContin in 2010.[388] In its medical review of Purdue's application, however, FDA found that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)" and that "[w]hile the reformulation is harder to crush or chew, possibly mitigating some accidental misuse, oxycodone HCI is still relatively easily extracted."[389] (Emphasis added.)

423. Purdue regularly cited its introduction of abuse-deterrent opioids as evidence of its commitment to addressing the opioid crisis, as described in Section F. In fact, the tamper-resistant reformulation, and the change in labeling, made Purdue richer by solving an inconvenient business problem: how to keep the money flowing after April 2013, when OxyContin's patent was set to expire. Generic versions of OxyContin had become available in February 2011, threatening to erode Purdue's share of the long-acting opioid market and decrease the price Purdue could charge. However, Purdue convinced FDA in April 2013 that original OxyContin—which Purdue had designed and promoted for years—should be removed from the market as unsafe because it lacked abuse-deterrent properties. The impact was that generic equivalents of the old formulation could not be sold, once again securing brand exclusivity for OxyContin and Purdue through at least 2017.

[388] Center for Drug Evaluation and Research Approval Package for NDA 22-272, Apr. 5, 2010, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/ 022272s000Approv.pdf.

[389] Center for Drug Evaluation and Research, NDA 22-272, *Summary Review for Regulatory Action* (Dec. 30, 2009), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022272s000MedR.pdf, at 7.

424. Purdue also used the abuse-deterrent properties of its opioids as a primary selling point to differentiate its products from its competitors, including generic short-acting opioids. As recently as 2015, internal sales training documents characterize the "abuse-deterrence labeling" as one of four "Strategic Pillars" for achieving OxyContin sales goals, directing Purdue employees to "[e]levate the importance of abuse deterrence as a key driver for [extended-release opioid] prescribing."

425. However, 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 roughly one-third found various methods to continue snorting or injecting it.[390]

426. As discussed in Section C, it appears from contemporaneous correspondence that [redacted]. And yet, abuse deterrence because a point of product differentiation and a key marketing message as soon as OxyContin was re-formulated. [redacted]

[390] Theodore J. Cicero & Matthew J. Ellis, *Abuse-Deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States: Lessons Learned from OxyContin*, 72(5) JAMA Psychiatry 424-430 (May 2015).

427. There remains no substantial scientific evidence that Purdue's abuse-deterrent opioids actually reduce opioid abuse. As the CDC Guideline states, "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," and the technologies—even when they work—"do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."

428. Because of their questionable benefits, any discussion of abuse-deterrent technologies has a high potential to mislead practitioners and patients and create a false sense of security about prescribing opioids, particularly for long-term use. In a 2014 survey of 1,000 primary care physicians, nearly 50% reported that they believed abuse-deterrent formulations of opioids are inherently less addictive.[391] One-third of the doctors in that same study had the mistaken impression that most prescription pill abuse is by means other than swallowing the pills.

429. Purdue's deceptive marketing of the benefits of its abuse-deterrent formulations was particularly dangerous because it persuaded doctors—who might otherwise have curtailed their opioid prescribing—to continue prescribing Purdue's opioids based on misleading assurances and deceptive implications that they are safer. It also allowed prescribers and patients to discount evidence of opioid addiction and attribute it to other opioids that don't have tamper-resistant properties—*i.e.*, to believe that while patients might abuse or overdose on non-abuse-deterrent opioids, Purdue's opioids do not carry that risk.

2. Purdue Misleadingly Promoted OxyContin as Supplying 12 Hours of Pain Relief.

430. As explained above, the Sacklers were keenly aware that Purdue's key point of differentiation between OxyContin and other opioid pain relievers on the market is its extended-

[391] Catherine S. Hwang *et al.*, *Primary Care Physicians' Knowledge and Attitudes Regarding Prescription Opioid Abuse and Diversion*, 32(4) Clinical J. Pain 279-284 (Apr. 2016).

release formulation and "Q12"—or every 12 hour—dosing. The Sacklers were also aware that the OxyContin did not, in fact, deliver 12 hours of pain relief to a large number of users. Nevertheless, the Sacklers knew about and approved Purdue's efforts to promote the drug as a Q12/12 hour drug. Therefore, Purdue consistently overstated the efficacy of this dosing interval while omitting the serious risks associated with it, compared to other alternative pain relievers.

431. Purdue sought FDA approval for OxyContin's 12-hour dosing schedule to maintain a competitive business advantage over more-frequently dosed (*e.g.*, every 8 hours, or as needed) opioids, despite knowing that OxyContin does not provide pain relief for 12 hours in many patients, a phenomenon known as "end of dose failure." Internal Purdue marketing documents indicate that 12-hour dosing was considered key to differentiating the drug from the competition—generic, short-acting opioids that require patients to wake in the middle of the night to take the next dose.[392]

432. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. Purdue relied on labeling that it sought from FDA, and for which the company is legally responsible, directing 12-hour dosing. However, Purdue went well beyond the label's limited instructions to take OxyContin every 12 hours by affirmatively advertising that OxyContin lasts for 12 hours—and by failing to disclose that OxyContin does not provide 12 hours of pain relief to many patients.

433. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, around-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as

[392] Memo to OxyContin Launch Team (April 4, 1995), available at http://documents.latimes.com/oxycontin-launch-1995/.

providing "smooth and sustained pain control all day and all night."[393] But FDA has never approved such a marketing claim. To the contrary, FDA found in 2008, in response to a citizen petition by the Connecticut Attorney General, that a "substantial proportion" of chronic pain patients taking OxyContin experienced "end of dose failure."[394]

434. Sales representatives frequently referenced "Q12" dosing as a benefit of OxyContin during sales visits in Vermont. These misrepresentations continued into recent years in Vermont. Purdue trained its sales representatives to deliver the message of "[p]roven relief with Q12h dosing" to prescribers during sales calls.

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

436. Purdue has known, since the launch of OxyContin, that the drug often wears off well short of 12 hours. 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

[393] Purdue Pharma L.P., *New Hope for Millions of Americans Suffering from Persistent Pain*, PR Newswire (May 31, 1996), https://assets.documentcloud.org/documents/2815975/Pressreleaseversionone.pdf.

[394] FDA response letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation and Research, to Richard Blumenthal, Conn. Att'y Gen. (Sept. 8, 2008), http://www.purduepharma.com/wp-content/pdfs/fda_response_blumenthal_oxycontin.pdf, at 5.

one clinical trial, one-third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental short-acting opioids—"rescue medication"—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once.[395] Prescribers, including prescribers in Vermont, likewise have observed and complained to Purdue sales representatives that OxyContin does not supply 12 hours of pain relief in a significant number of the prescribers' patients. And it was well-known to Purdue that OxyContin was routinely prescribed (including in Vermont) every 8 hours—rather than every 12 hours, as directed. One former Purdue employee, who trained and supervised sales representatives in Vermont, said Purdue knew providers frequently prescribed OxyContin for every 8 hours, tracked statistics on such prescribing, and sought to change it: "We talked about that in almost every meeting, how we were going to try and get people to buy [the 12-hour dosing]."

437. Purdue's solution to the end-of-dose failure experienced by many patients was to advise prescribers to maintain the 12-hour dosing schedule but to increase the dose of OxyContin. Purdue's sales representatives routinely told doctors in Vermont that, if the Q12 dose didn't last the full 12 hours, the doctor should increase—or "titrate"—the dose, rather than increasing the frequency of dosing. The OxyContin label and the *Conversion and Titration Guide* also advise prescribers that they can increase the dosage to achieve adequate pain relief "as clinical need dictates, while maintaining every 12-hour dosing." Increased opioid dosing poses greater risks, as discussed in Section D(3). However, Purdue's advice to "titrate up" when a patient experienced

[395] Harriet Ryan, Lisa Girion & Scott Glover, *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, Los Angeles Times (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/.

end-of-dose failure was not accompanied by appropriate warnings regarding the increased risk of addiction associated with higher doses.

438. Purdue's misrepresentations regarding 12-hour dosing—which Purdue has made since 1996 and continued to make at least until 2018, when it stopped promotion of opioids to prescribers through sales representatives—are particularly dangerous because the inadequate dosing helps fuel 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. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[396]

439. The Sacklers [redacted]

440. Yet the Sacklers also had long known that OxyContin did not last 12 hours in some patients. Richard Sackler admitted in his 2015 deposition that Purdue's own clinical studies had shown that some patients complained they were "back in pain" after 8 or 9 hours.[397] 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, the other Sacklers knew about the end-of-dose failure problem as well. That petition complained that many patients were being

[396] Harriet Ryan, Lisa Girion & Scott Glover, *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, Los Angeles Times (May 5, 2016), http://www.latimes.com/ projects/oxycontin-partl.

[397] Richard Sackler Dep. Tr. 145:14-146:22, *Kentucky v. Purdue*, No. 07-CI-01303, Aug. 28, 2015.

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.[398] 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.[399]

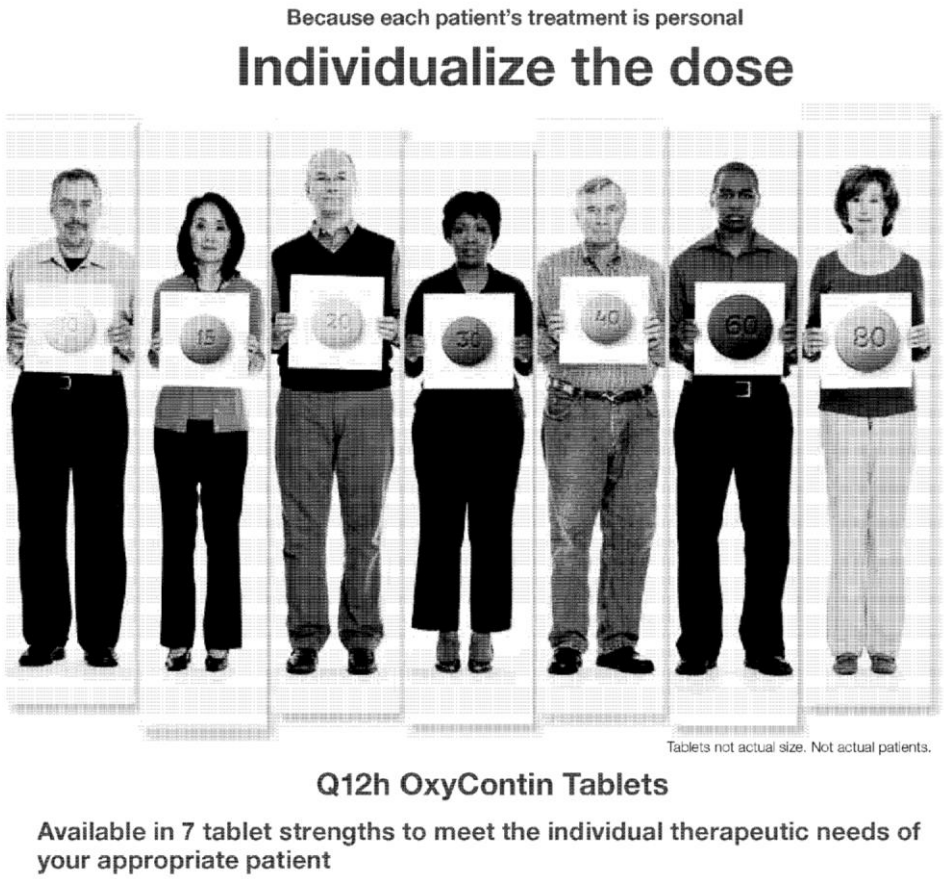
3. Purdue Pushed Higher and Higher Doses of Opioids Without Disclosing the Risks

441. Although Purdue used the lowest strengths of OxyContin to expand its captive customer base, the Sacklers' ultimate goal was to move more and more patients up the dose "ladder" of its opioids, including to the 60mg and 80mg OxyContin pills—the most lucrative strengths for both the company and its owners. The Sacklers repeatedly, over the course of many years, directed Purdue executives to pursue and achieve this goal. As described in Section C, Purdue extensively tracked prescriptions of its highest-strength pills in particular. [redacted]

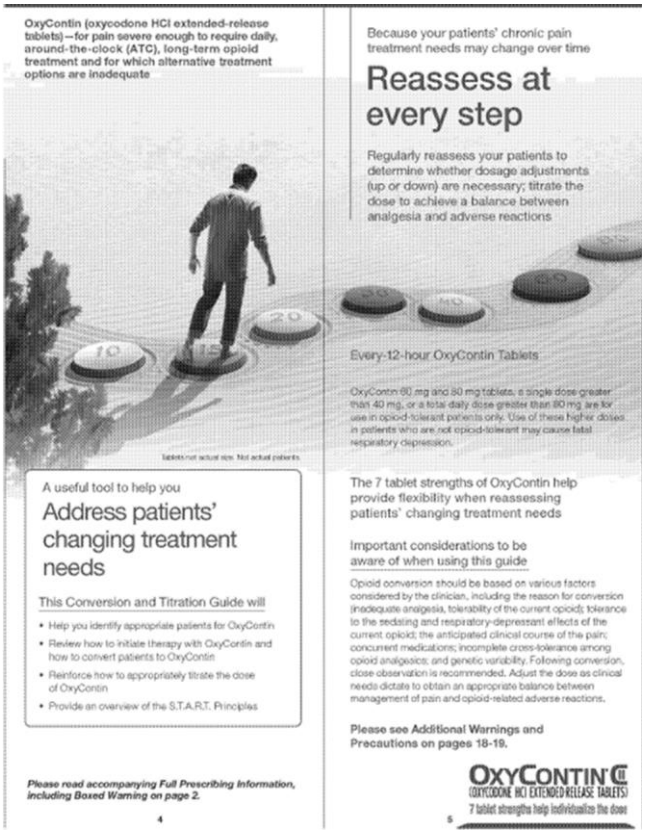
442. To sell more and more of the highest doses, Purdue falsely claimed to Vermont prescribers and consumers that opioids can be taken at ever-increasing doses for better pain relief, without disclosing that higher doses carry greater risk of addiction and overdose. They did so to fulfill the express expectations of the Sacklers, who viewed higher dosages as a clear pathway to increased sales and revenue.

[398] Connecticut Attorney General Citizen Petition to FDA, Jan. 7, 2004, *available at* http://documents.latimes.com/fda-filing-2004/.

[399] FDA response letter from Janet Woodcock, Director, Center for Drug Evaluation and Research, to Richard Blumenthal, Connecticut Attorney General (Sept. 8, 2008), *supra* n.394. at 5.



443. The ability to escalate doses ("titrating up") was critical to Purdue's efforts to market opioids for long-term use to treat chronic pain. Unless doctors felt comfortable prescribing increasingly higher doses of opioids to counter tolerance to the drugs' effects, they may not have chosen to initiate opioid therapy at all. Numerous Purdue marketing materials depict the seven OxyContin tablet strengths—in a line or even a series of steps—and instruct prescribers that they can titrate, *i.e.*, increase the dose, "as clinical need dictates." These materials also conveyed the message that there was "no defined maximum daily dose" for OxyContin. The Sacklers, who were extensively briefed on these materials (from the *Options* and *Individualize the Dose* campaigns), were aware that the sales force would use them to promote higher doses and were responsible for that action.



444. Through at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a doctor did not prescribe, in the patient's opinion, a sufficiently high 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.

445. *A Policymaker's Guide* asserted that dose escalations—even when unlimited—are "sometimes necessary." The publication did not disclose the risks from high doses of opioids.

446. Purdue also deceptively compared the risks of opioids to the risks of other pain relievers, like non-steroidal anti-inflammatory drugs ("NSAIDs" like Advil or Motrin) and acetaminophen (Tylenol). The company sponsored a 2013 CME titled "Overview of Management Options" that highlighted the evidence of adverse effects from high doses of NSAIDs but did not discuss the increased risk from using high doses of opioids. The CME was edited by Dr. Russell Portenoy, who received research support, honoraria, and consulting fees from Purdue. Issued by

the American Medical Association in 2013, the CME remains available from the American Medical Association ("AMA") online.[400] 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.

447. Even where Purdue marketing materials acknowledged that certain serious risks rose with the dose, they failed to disclose the increased risk of addiction. For example, the *Conversion and Titration Guide* stated that "the ceiling to analgesic effectiveness is imposed only by side effects, the more serious of which may include somnolence and respiratory depression."

448. There is no valid scientific evidence that doses of opioids can be continuously titrated upward without significant added risk. On the contrary, the risk of addiction, overdose, and death are increased when patients are prescribed higher doses of prescription opioids.[401] Patients receiving high doses of opioids as part of long-term opioid therapy are 3x to 9x more likely to suffer overdose than those on low doses.[402] For example, in 2015 in Vermont, over 80% of individuals with opioid prescription histories who suffered opioid-related accidental fatalities had received high dose (at least 90 MME) analgesics in the five years prior to death.[403]

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[400] American Medical Association, *Pain Management – Overview of Management Options*, https://cme.ama-assn.org/activity/1296783/detail.aspx (last visited 8/3/18).

[401] National Institute on Drug Abuse, *Improving Opioid Prescribing*, last updated March 2017, https://www.drugabuse.gov/publications/improving-opioid-prescribing/improving-opioid-prescribing; Centers for Disease Control and Prevention, *Calculating Total Daily Dose of Opioids for Safer Dosage*, last visited Aug. 6, 2018, https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.

[402] Kate M. Dunn *et al.*, *Opioid prescriptions for chronic pain and overdose: a cohort study*, 152(2) Annals of Internal Med. 85-92 (Jan. 19, 2010). Most overdoses were medically serious and 12% were fatal.

[403] Anne VanDonsel, Shayla Livingston, and John Searles (Vermont Department of Health), *Opioids in Vermont: Prevalence, Risk, and Impact* (October 27, 2016), http://www.healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioids_Prevalence_Risk_Impact.pdf, at 31.

449. As compared to non-opioid pain remedies, patients develop a tolerance to opioids' analgesic effects more quickly 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 accidental overdose even where opioids are taken as recommended.[404]

450. As confirmed by the CDC in its Guideline, research published over the past decade has consistently found that the "[b]enefits of high-dose opioids for chronic pain are not established," while the risks for serious harms are clear and dose-dependent. More specifically, the CDC explains—citing research dating back to 2010—that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid doses." The CDC also states that there are "increased risks for opioid use disorder, respiratory depression, and death at higher dosages."

451. The CDC Guideline reinforces earlier findings announced by FDA. In 2013, FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."[405]

452. Because of these risks, the CDC Guideline advises doctors to "avoid increasing doses" above 90 morphine milligram equivalents (MME) per day. Yet, many patients have received dangerously high doses of opioids, and every dosage of OxyContin available on the market imposes increased risks (compared to lower-dose analgesics) on patients. Of the seven

[404] *See* Laxmaiah Manchikanti *et al.*, *Opioid Epidemic in the United States*, *supra* n.2 (60% of opioid overdoses prescribed were within guidelines).

[405] Letter from Janet Woodcock, M.D., Dir., FDA Ctr. for Drug Evaluation and Research, to Andrew Kolodny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013) https://www.regulations.gov/document?D=FDA-2012-P-0818-0793, at 13-14.

available OxyContin tablet strengths, the three strongest all exceed the CDC guideline limit when taken (as directed) twice daily: 40-mg (120 MME per day), 60-mg (180 MME per day), and 80-mg (240 MME per day). Patients on the twice-daily 80-mg dose receive nearly 3x the recommended ceiling of 90 MME. Even patients taking 30-mg of OxyContin twice daily reach the CDC daily maximum of 90 MME. Moreover, the CDC has made it clear that even much lower daily doses—exceeding just 20 MME per day—put patients at increased risk.[406] The lowest strength of OxyContin—the 10-mg tablet strength—exceeds this amount when taken twice daily as prescribed.[407] However, despite the known and growing body of research on the risks of these high-dose opioids, Purdue marketed OxyContin, and advocated for doctors to prescribe higher and higher doses to patients, without providing adequate disclosures of the risks these drugs posed.

4. Purdue Encouraged Long-term Use of Opioids—Including With Savings Cards—Despite the Known Risks and Absence of Benefits of Such Use.

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

[406] Centers for Disease Control and Prevention, *Calculating Total Daily Dose of Opioids for Safer Dosage*, https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.

[407] *Id*.

454. Purdue's deceptive marketing about the benefits of its products focused on a particular goal: reinforcing the supposed benefits of long-term opioid use, so that Purdue could derive revenue—and the Sacklers could derive profits—from long-term increased sales. Purdue's marketing messages lacked scientific support and were, in many cases, false.

455. To convince Vermont 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 was a significant upside to long-term opioid use. But as the 2016 CDC Guideline made clear, there was "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." (Emphasis added.) In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[408] (Emphasis added.) FDA similarly recognized the lack of scientific support for long-term opioid use, stating in a 2013 letter to Dr. Kolodny that the FDA was "not aware of adequate and well-controlled studies of opioid use longer than 12 weeks."[409] Thus, Purdue's ongoing representations, to prescribers and consumers, regarding the benefits of long-term opioid therapy have continued to be misleading and deceptive.

456. It is well established that long-term opioid use harms, rather than helps, patient health and wellbeing. Purdue's marketing scheme ran contrary to the real science on the known risks and unproven benefits of long-term opioid use.

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[408] CDC Guideline, *supra* n.26, at 9, 15.

[409] Letter from Janet Woodcock, M.D., Dir., FDA Ctr. for Drug Evaluation and Research, to Andrew Kolodny, M.D., President, Physicians for Responsible Opioid Prescribing, *supra* n.405, at 10.

457. The available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health. As early as 2006, numerous peer-reviewed studies conducted by independent researchers have concluded that: (1) "[f]or functional outcomes, . . . other [non-addictive] analgesics were significantly more effective than were opioids,"[410] (2) increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater healthcare utilization,[411] and (3) "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[412] More recently, the CDC Guideline, approved by FDA, concluded that "there is no good evidence that opioids improve pain or function with long-term use."[413] (Emphasis added.) The CDC reinforced this conclusion throughout the CDC Guideline, finding that (a) "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later";[414] (b) "[a]lthough opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy";[415] and (c) "evidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for

[410] 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. 1589-1594 (2006).

[411] 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).

[412] Andrea Rubenstein, *Are we making pain patients worse?* Sonoma Medicine (Fall 2009).

[413] CDC Guideline, *supra* n.26, at 20.

[414] *Id*. at 15.

[415] *Id*. at 18.

which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."[416] The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[417] As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life spent cycling through periods of addiction, abuse, and recovery do not improve their function and quality of life.

458. Purdue and the Sacklers who have served on its Board of Directors cannot have been unaware of the disconnection between the academic literature, which has never assessed efficacy beyond 12 weeks, and the prescribing reality—which Purdue was instrumental in shaping—that many patients use OxyContin and other opioids for many months or years. For example, a 2011 internal email among Purdue researchers discussed the need for "new research studies of not less than 12 months duration to determine the long-term effectiveness of opioids for chronic non-cancer pain"—an acknowledgement that such evidence did not exist.

a. Material Misrepresentations and Omissions Regarding Long-Term Use of Opioids

459. The FDA-approved labeling of Purdue's ER/LA opioids does not address long-term use (*i.e.*, beyond 12 weeks). Relied upon in the first OxyContin label—and still, to this day, the only clinical study Purdue has cited for OxyContin's efficacy in adults—is a two-week study of a scant 133 patients. Yet, Purdue marketed OxyContin with the expectation that health care providers—believing the drug to be appropriate for long-term use—would prescribe it to their chronic pain patients over periods of months or years. The State of Vermont did not uncover, in its review of call notes reflecting thousands of sales visits to prescribers, that detailers disclosed Purdue's lack of evidence supporting the use of opioids for more than 90 days.

[416] *Id*. at 18-19.

[417] *Id*. at 20.

460. Routine, chronic pain conditions—like osteoarthritis and lower back pain—continued to be a focus of Purdue's marketing efforts for OxyContin and Butrans. In more recent years, sales representatives have used "patient vignettes" or "patient profiles"—brief summaries of the background and medical needs of fictional patients—to illustrate the kinds of patients who should be identified as "good" (according to Purdue) candidates for drugs like OxyContin and Butrans. These vignettes typically featured chronic, long-term health problems as indications appropriate for opioid use. For example, the "Carol" and "Maggie" patient profiles, used to market OxyContin, featured osteoarthritis of the hip and chronic low back pain. The "Scott" and "Pam" patient profiles, used to market Butrans, both featured chronic low back pain due to osteoarthritis. Purdue provided its sales representatives with these and other patient profiles, along with training on their use, and Vermont sales representatives used them in sales calls to Vermont healthcare providers.

461. In Vermont, Purdue sales representatives positioned Purdue's opioid products—namely OxyContin and Butrans—*specifically for* long-term pain relief, to encourage healthcare providers to convert patients from short-acting opioids or other pain relievers to Purdue's extended-release opioid products. For example, sales representatives asked prescribers how long they typically wait before transitioning patients from short-acting opioids to an extended-release product, like OxyContin. During one Vermont sales call, for example, the sales representative initiated this discussion, and the prescriber agreed that "he would think about some patients who have been on an IRO [immediate release opioid] way too long."

462. Upon information and belief, sales representatives in Vermont also delivered a national "insight message" crafted by Purdue specifically for use in sales calls—that "according to IMS, a 3rd party prescription data source, 41% of IR hydrocodone/APAP combination

prescriptions were associated with a length of therapy lasting 90 days or longer. Of these prescriptions lasting at least 90 days, the average number of days until a patient was converted to an extended- release opioid was 287." This message implied that long-term use was inappropriate for short-acting opioids, but not so for extended-release opioids, and that such patients should be transitioned to an extended-release opioid like OxyContin.

463. Purdue also reinforced the appropriateness of OxyContin for long-term use through written materials it distributed in Vermont. For example, Purdue's OxyContin *Conversion and Titration Guide*, which sales representatives widely referred to during sales visits and distributed in Vermont, implied that use could continue safely for years. A 2007 version of that guide recommended that "the need for around-the-clock opioid therapy should be reassessed periodically (*e.g.*, every 6 to 12 months) as appropriate for patients on chronic therapy," but did not disclose the absence of evidence supporting safety and efficacy of use for 6 to 12 months. Later versions of this *Guide* omit the parenthetical "(*e.g.*, every 6 to 12 months)" and simply state that prescribers should "periodically reassess the continued need for opioid analgesics." However, Purdue continued to train sales representatives to tell prescribers to periodically reassess "every 6 to 12 months," when prescribing OxyContin, even after this language had been removed from the printed marketing materials, but they did not train representatives to disclose that Purdue had no studies supporting efficacy of use beyond 12 weeks.

464. Purdue and Purdue-sponsored materials distributed nationally reinforced the message that opioids offer benefits to the patient with use that lasts months or even years. The APF-published *Exit Wounds*, a book written as a personal narrative of one veteran recovering from war injuries, asserted unequivocally that "[w]hen used correctly, opioid pain medications increase

[a person's] level of functioning" and that opioids "can really help improve your functioning in daily life." APF promoted this book until at least 2011.

465. Purdue also sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, a 2011 publication that falsely claimed that "multiple clinical studies have shown that long-acting opioids, in particular, are effective in improving [d]aily function . . . [and] quality of life for people with chronic pain." *A Policymaker's Guide* cited a single study for this claim – which, upon examination, expressly noted the absence of long-term studies and actually found that "[f]or functional outcomes, . . . other analgesics were significantly more effective than were opioids."[418]

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

467. FDA has said for years that opioid manufacturers should not make claims regarding functional improvement and ability to perform daily activities, and FDA has warned Purdue competitors in public letters that such claims lacked substantial scientific evidence.[419]

[418] 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. 1589-1594 (2006).

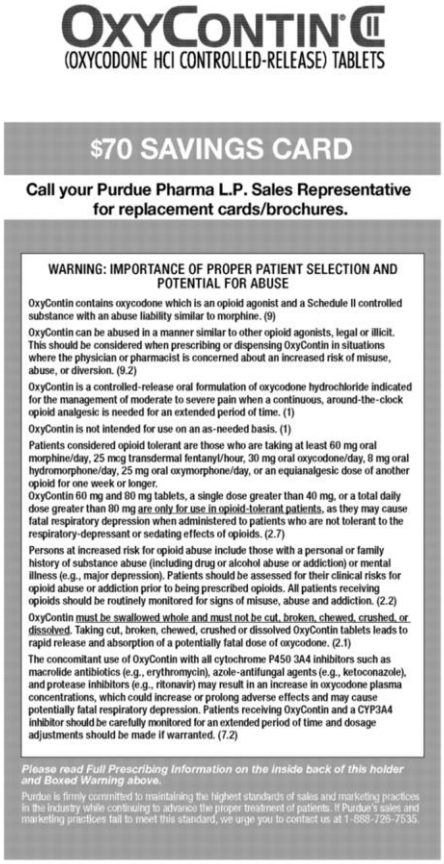
[419] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf; Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008).

468. These unsubstantiated and deceptive statements regarding the benefits of long-term opioid therapy misled prescribers and patients into believing that there were advantages to continuing opioid use over many months or even years.

b. Use of Savings Cards to Encourage Long-Term Use of Opioids

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

470. Purdue promoted "Savings Cards" in Vermont to provide patients with a Purdue-funded discount on their out-of-pocket cost for OxyContin and encourage long-term use of OxyContin:



471. Purdue trained sales representatives to discuss Savings Cards on every sales call. The company also carefully tracked redemption of Savings Cards and evaluated sales representatives on the number of Savings Cards redeemed in their districts.

472. The purpose behind Purdue's emphasis on Savings Cards was to boost the "continuing prescriptions" group of patients—which constituted 80% of its OxyContin sales—beyond 90 days of use. In a 2012 sales training document, Purdue explained that "market research has shown that ~60% more patients stay on therapy >90 days if a savings card is redeemed." Purdue had no research showing the benefits of OxyContin for these longer durations of treatment.

473. Purdue also used Savings Cards to encourage initiation of new patients on its opioids, lowering the barrier of entry by making the drugs cheaper to try. In a 2012 sales training

presentation, Purdue described its rationale for subsidizing a $0 (*i.e.*, free) copayment through Savings Cards for new Butrans patients: that a Savings Card was "effectively acting as a sample."

474. Sales representatives routinely distributed OxyContin Savings Cards during their sales visits to Vermont prescribers and pharmacies. Some Vermont healthcare providers declined Savings Cards, expressly referencing concerns about OxyContin use.

475. But Purdue continued to distribute the Savings Cards through marketing efforts in Vermont pharmacies, instructing pharmacists to inform opioid patients about available discounts for OxyContin that would bring the out-of-pocket price down significantly. 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"—or healthcare providers, but Purdue sales representatives seem to have encouraged pharmacists to tell *patients* to download the cards directly, as a workaround when prescribers chose not to offer them. In one 2012 sales call to a pharmacy, the Purdue detailer advised the pharmacy techs about how patients can go online to obtain savings cards "[s]ince the p[re]scribers in town are changing policies about cards."

476. Purdue has long been aware of the State of Vermont's concern that offering free or heavily subsidized opioids to consumers was an unfair business practice. In the 2007 Consent Judgment, Purdue expressly agreed to stop distributing samples of OxyContin in Vermont. Nonetheless, Purdue used the promotion of Savings Cards to eliminate or steeply discount patient co-payments—effectively making these drugs free to patients—as a way to drive long-term use.

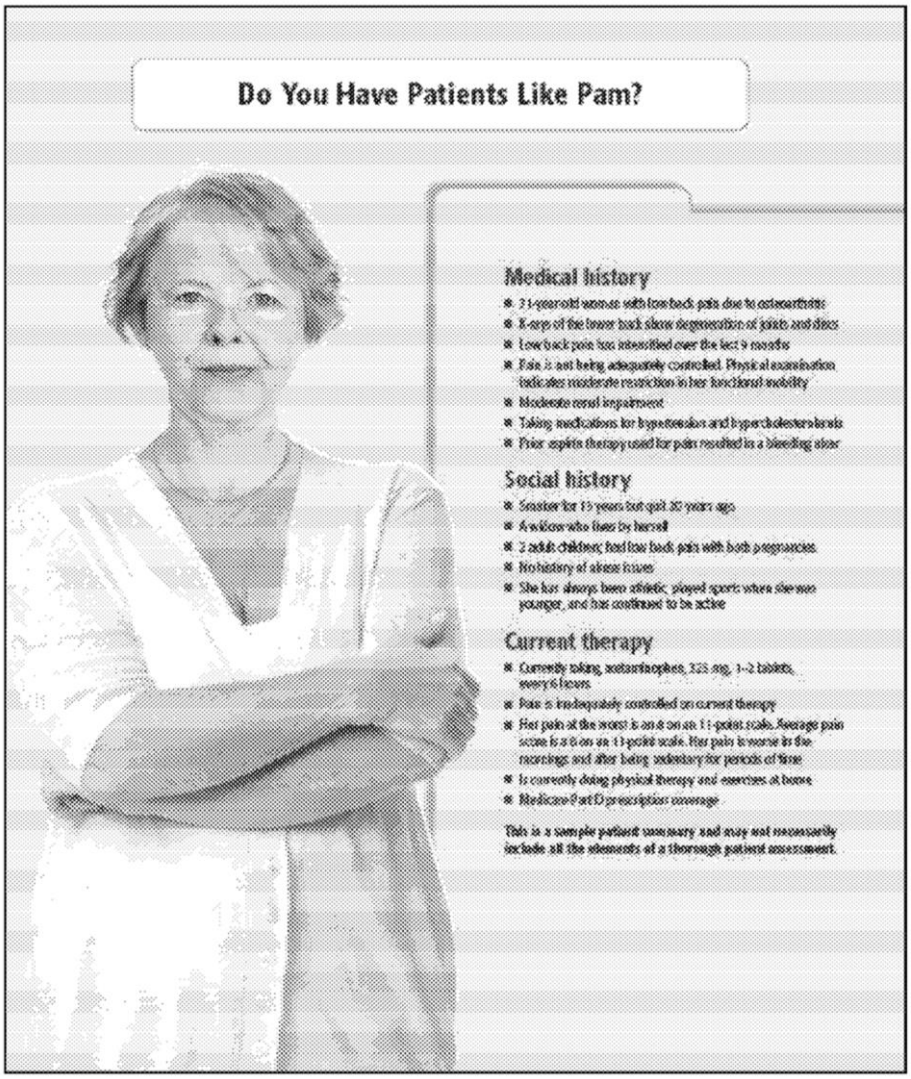
5. Purdue Targeted Elderly and Opioid-Naïve Patients

477. Part of Purdue's strategy to continue expanding its market share, and hence its revenue, has been to target two overlapping markets in particular: the elderly, a demographic that

has seen an explosion in opioid prescribing in recent years, and opioid-naïve patients—those who had not previously taken opioids. As discussed in greater detail above, Purdue staff purposefully targeted marketing efforts to increase opioid prescribing to elderly and opioid-naïve patients—and kept the Purdue Board and the Sacklers informed about these efforts—in their pursuit of the increased sales and market share the Sacklers directed staff to obtain.

478. Training materials, reviews of sales representatives, and Vermont detailer call notes include multiple references to Purdue's efforts to persuade doctors to start prescribing its ER/LA opioids to elderly patients.

479. Purdue also used its "patient vignettes" or "patient profiles" to subtly persuade doctors that OxyContin and Butrans were appropriate for their elderly patients, by featuring fictional patients who were older and/or who suffered from conditions like osteoarthritis that are common in older patients.



480. Purdue's unbranded marketing efforts also targeted elderly patients. For example, *In the Face of Pain*'s publication "The Handbook for People with Pain: A Resource Guide (5th Edition"), available through *In the Face of Pain*'s website, included a section entitled "Special Considerations for Seniors." This section identified "pain in the absence of disease" as a major problem affecting seniors "experienced daily by a majority of older adults in the United States." It goes on to list problems associated with pain, including "decreased mobility" and "increased risk for falls and weight loss." It highlights the fact that "most pain can improve with treatment," instructing seniors to speak to their healthcare providers and develop a treatment plan. These

unbranded marketing materials were intended to drive demand among elderly consumers for pharmacological pain treatment, including opioid therapy. However, they omit any reference to the risks and side effects of such treatments.

481. Purdue focused heavily on marketing its opioids in Vermont as medications that were covered by insurance plans, with a focus on educating physicians about Medicare Part D (prescription benefit) coverage for opioids, including OxyContin in particular. Sales representatives frequently wrote in call notes that they talked to prescribers about Medicare Part D coverage for OxyContin.

482. Purdue managers and sales representatives also focused detailing efforts on the nursing home market. For example, a call note from a visit to a Vermont pharmacy in May 2010 reflects the pharmacist's suggestion that the sales representative bring copies of the *Conversion and Titration Guide* to area nursing homes. In response text from the sales representative's supervisor, the supervisor stated "Good Call...you were given the names of two homes to focus on, lets [sic] talk about plans for these on our next work session." Other Vermont call notes from 2011 and 2012 discuss sales representatives' efforts to identify and gain access to providers at nursing homes and senior/assisted living facilities.

483. Purdue has targeted seniors for a reason: they have been an important growth sector for the opioid industry. In 2016, one-third of all enrollees in Medicare Part D—over 14.5 million beneficiaries, nationwide—received at least one opioid prescription.[420] And more than 500,000 enrollees nationwide were on a high dose of at least 120 MME—well above the CDC's

[420] U.S. Department of Health & Human Services Office of the Inspector General, *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing*, HHS OIG Issue Brief (July 2017), https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf, at 1.

recommended maximum dosage of 90 MME.[421] These high doses underscore the eventuality that elderly patients will not simply remain on OxyContin 10-mg but will require escalating amounts—which come with escalating dangers and side effects that are particularly acute in the elderly.

484. Purdue's targeting of elderly patients overlapped with Purdue's broad marketing push to persuade doctors to prescribe OxyContin to opioid-naïve patients—even when faced with reluctant practitioners.

485. Sales representatives regularly suggested 10- and 15-mg OxyContin for elderly and opioid-naïve patients, without disclosing that Purdue had no evidence of efficacy at those doses. For example, during one sales call in April 2010 in Vermont, a sales representative wrote that she "[r]eviewed [OxyContin] newer strengths and IR to ER conversion guide, explained 10mg q12h is indicated for op[i]oid naive pts and well covered on part d. He will consider for his elderly." Another sales representative wrote in call notes in 2013 that he would ask providers about initiating opioid-naïve patients at the 10-mg dose: "Would it surprise you to know that an opioid naïve patient could be started on OxyContin 10 mg Q 12.?" None of these call notes indicate that sales representatives disclosed that OxyContin was no more effective than placebo at that dose.

486. 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. For patients in these populations, opioid treatment generally—and especially OxyContin treatment—imposes significant risks and should be undertaken only if less-risky analgesics prove ineffective.

487. Elderly patients taking opioids are at greater risk for fracture and hospitalization, and they have increased vulnerability to adverse drug effects such as respiratory depression, which

[421] *Id*.

Purdue acknowledges in its opioids' labels (but not in its marketing).[422] Elderly patients who use opioids also have a significantly higher rate of death, heart attacks, and strokes than users of NSAIDs.[423] The severity of these risks is increased with OxyContin treatment—which involves a higher opioid dose than as-needed opioids or opioid combination drugs—because the risks associated with opioids are dose-dependent. (*See* Section D(3).)

488. Purdue's specific focus on opioid-naïve patients was likewise unwarranted, in light of the steady stream of information over the past decade emphasizing (as the CDC summarized in 2016), that "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[424] Such risks are simply not warranted for most opioid-naïve patients. Other, less-risky analgesics are available on the market for opioid-naïve patients needing pain relief, including non-opioid pain relievers.

489. Nonetheless, through its marketing efforts, Purdue sought to capture elderly and opioid-naïve patients as a critical customer base that would grow Purdue's profits by continuing to require opioids as they became dependent on and/or addicted to these dangerous drugs.

[422] OxyContin ER Full Prescribing Information (last revised 12/2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022272s034lbl.pdf; OxyContin & Hysingla labels; Hysingla ER Full Prescribing Information (revised 12/2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/206627s004lbl.pdf; Kathleen W. Saunders, *et al*., *Relationship of opioid use and dosage levels to fractures in older chronic pain patients*, J Gen Intern Med 2010; 25:310-5 (April 2010).

[423] *Relationship of opioid use and dosage levels to fractures in older chronic pain patients*, *supra* n.422.

[424] Thomas R. Frieden & Debra Howry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline,* 374 New Eng. J. Med. 1501, 1503 (Apr. 21, 2016).

E. The Proliferation of Prescription Opioids Has Been Devastating to Vermont

Increased Opioid Abuse and Addiction

490. Purdue's deceptive marketing has reaped Purdue and the Sacklers massive profits but has been catastrophic for the State and its citizens. In 2010, 482,572 opioid prescriptions were dispensed in Vermont, a state with a population of just over 625,000. [425] That number continued to rise. In 2015, the number of opioid prescriptions increased to 498,973[426]—the equivalent of giving a prescription to every 1.3 people living in Vermont, including infants.

491. There is no question that this volume of opioids leads to increased incidence of dependence and addiction. In a 2014 survey by the U.S. Department of Health and Human Services, more than three percent of Vermonters—approximately 18,000 people—reported a dependence on a controlled substance.[427] Vermont ranks as the 8th-highest state for drug dependence nationwide,[428] despite other favorable health indicators like better access to health care and insurance coverage as compared to other states.[429]

492. Opioids are killing Vermont citizens at a skyrocketing rate, and a common origin is prescription opioids. Drug-related fatalities involving opioids nearly tripled between 2010 and

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[425] *Opioids in Vermont: Prevalence, Risk, and Impact*, *supra* n.403, at 30 ("Number of Prescriptions by Drug Type and Year"); Vermont Department of Health, *Special Report: Opioid Prescriptions and Benzodiazepines, 2014* (February 2016), http://www.healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioids_Benzodiazepenes_Report.pdf, at 3.

[426] *Id.*

[427] amfAR Opioid & Health Indicators Database, *Percent of people 12+ Reporting Drug Dependence*, http://opioid.amfar.org/indicator/drugdep.

[428] *Id*.

[429] *See State Health Assessment Plan - Healthy Vermonters 2020* (December 2012), http://www.healthvermont.gov/sites/default/files/documents/2016/11/Healthy%20Vermonters%202020%20Report.pdf, at 13, 5, 27.

2018.[430] While the national average of opioid-related overdose deaths in 2017 was 14.6 per 100,000 persons, the rate in Vermont was 20.0 – 37% higher than the national average.[431] And these overdose deaths have a broad impact. In a state like Vermont, there are no anonymous deaths.

493. The link between prescription opioids and "street drugs" like heroin and fentanyl fuels the opioid crisis. Many addicts begin with a legal opioid prescription from their doctor or by taking a pill from a prescription bottle belonging to a family member or friend.[432] Prescription opioid users also are far likelier to use illegal opioids like heroin and fentanyl. CDC statistics show that people addicted to prescription opioids are 40x more likely also to be addicted to heroin. The same CDC report shows that nearly half (45%) of people who used heroin also were addicted to prescription opioid painkillers.[433] In 2017, the Vermont Department of Health reported that 80% of new heroin users also had a history of misusing prescription opioids.[434]

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[430] Vermont Department of Health, *Opioid-Related Fatalities Among Vermonters* (updated February 2019), http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Data_Brief_Opioid_Related_Fatalities.pdf.

[431] National Institute on Drug Abuse, *Vermont Opioid Summary* (revised March 2019), https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/vermont-opioid-summary.

[432] Nora Volkow and Francis Collins, National Institute on Drug Abuse, *"All Scientific Hands On Deck" to End the Opioid Crisis*, May 31, 2017, https://www.drugabuse.gov/about-nida/noras-blog/2017/05/all-scientific-hands-deck-to-end-opioid-crisis ("While there were nearly 20,000 overdoses in 2015 due to heroin or fentanyl, the trajectory of opioid addiction usually begins with prescription opioid misuse. Some people with opioid addiction began by taking diverted pills from friends and family members, but others began with an opioid prescription of their own").

[433] Centers for Disease Control and Prevention, *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/.

[434] Vermont Department of Health, *Opioid Misuse, Abuse & Dependence in Vermont Data Brief, April 2017*, http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_data_brief_opiodmisuse.pdf.

494. The heroin/fentanyl problem in Vermont is acute—in 2018, fentanyl was involved in three-quarters of all opiate-related fatalities, and heroin was involved in over half of all opiate-related fatalities.[435] The number of fatal overdoses involving fentanyl, in particular, has skyrocketed in recent years—a fourteenfold increase from 6 fatalities in 2012 to 83 fatalities in 2018.[436]

495. Beyond just addiction, there are additional and serious health dangers associated with illicit heroin and fentanyl use, including collapsed veins, bacterial infections of the blood and heart, lung complications, and depression. When heroin is administered by injection, the sharing of needles or bodily fluids puts users at heightened risk for HIV and Hepatitis B and C—serious diseases that can be transmitted to sexual partners and children.[437] The concern about rising rates of HIV and Hepatitis C is very real in Vermont: in 2016, the CDC identified two Vermont counties—Essex and Windham—out of the more than 3,100 counties across the entire United States as among those in the 95th percentile (top 5% nationwide) at greatest risk for outbreaks of HIV and Hepatitis C.[438]

496. While heroin and fentanyl have contributed to the increasing number of opioid deaths in Vermont, the majority of opioid fatalities are causally linked to opioid prescriptions—which many heroin and fentanyl abusers have in their system at the time of their fatal overdose

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[435] *Opioid-Related Fatalities Among Vermonters*, *supra* n.430, at 1.

[436] *Id*. at 2.

[437] National Institute on Drug Abuse, *What are the medical complications of chronic heroin use?* (March 28, 2018) at 11, https://www.drugabuse.gov/publications/research-reports/heroin/what-are-medical-complications-chronic-heroin-use.

[438] Michelle M. Van Handel et al., *County-level Vulnerability Assessment for Rapid Dissemination of HIV or HCV Infects among Persons who Inject Drugs, United States*, Journal of Acquired Immune Deficiency Syndromes, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5479631/; American Foundation for AIDS Research, *Vermont Opioid Epidemic*, http://opioid.amfar.org/VT.

or have used at some point prior to their fatal overdose. A study by the Vermont Prescription Monitoring System found that 85% of opioid-related accidental fatalities in Vermont had received an opioid prescription within the last five years[439] and that 25% percent had received an opioid prescription within 30 days prior to their death.[440]

497. In Vermont, 90.6% of opioid-related fatalities in 2015 occurred in people who had controlled substance prescription histories. Of the decedents who had been given an opioid prescription during the year prior to their death, the average opioid prescription supply was 261 days.[441]

498. In the most recent years for which data from the Vermont Department of Health is available (2015, 2016, 2017, and 2018), prescription opioids have been involved in roughly one-third of opioid-related deaths in Vermont.[442]

499. The demand for opioid addiction treatment has risen dramatically. In 2008, 2,272 Vermonters were treated for opioid use in state-funded treatment facilities. By 2017, that number had tripled, to 6,605.[443]

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[439] Vermont Prescription Monitoring System, *Controlled Substance Prescription Histories for Opioid-Related Accidental Fatalities in 2015* at 3, http://www.healthvermont.gov/sites/default/files/documents/2017/01/HSRV_VPMS_10_28_16_opioid_related_accidental_fatality_brief.pdf.

[440] *Id*.

[441] *Opioids in Vermont: Prevalence, Risk, and Impact, supra* n.403, at 31 ("Prescription History of Individuals with Opioid-related Accidental Fatalities").

[442] *Opioid-Related Fatalities Among Vermonters, supra* n.430, at 1.

[443] Vermont Department of Health, *2017 Treatment Data*, http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Treatment_Data_by_Age_Gender_County_Total.pdf.

500. The effects of the opioid epidemic are widely felt in Vermont. In a 2016 poll commissioned by Vermont Public Radio, 53% of respondents said that they or someone they knew had been personally affected by opiate addiction.[444]

The devastating effects on infants and young children

501. Opioid use disorder in pregnant women has become prevalent in Vermont, as opioid use has proliferated more broadly, with potentially devastating health consequences for them and their infants. The number of women with diagnosed opioid use disorder at the time of delivery has increased dramatically over time in Vermont: from 0.5 per 1,000 deliveries in 2001 to 48.6 per 1,000 deliveries in 2014—over seven times the national average, and the highest among the 30 states that have compiled this data.[445] This widespread prevalence of opioid use disorder in pregnant Vermonters is a major public health concern, because of the serious potential adverse maternal and neonatal outcomes associated with opioid use during pregnancy: preterm labor, stillbirth, neonatal abstinence syndrome, and maternal mortality.[446]

502. The number of infants born in Vermont who are diagnosed with Neonatal Abstinence Syndrome ("NAS")—a condition in which a newborn baby suffers withdrawal symptoms—also far exceeds the national average. Based on available data from 2012, the Vermont Department of Health estimated that the rate of NAS in Vermont was five times higher than the national average, and the Vermont statistics have continued to rise.[447]

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[444] Vermont Public Radio, *The VPR Poll: The Issues, The Races and The Full Results* (July 27, 2016), http://digital.vpr.net/post/vpr-poll-issues-races-and-full-results#stream/0.

[445] *Opioid Use Disorder Documented at Delivery Hospitalization—United States, 1999-2014*, CDC Morbidity and Mortality Weekly Report (August 10, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/mm6731a1.htm?s_cid=mm6731a1_e, at 847.

[446] *Id*. at 845.

[447] *Opioids in Vermont: Prevalence, Risk, and Impact*, *supra* n.403, at 44 ("Improved treatment and screening have helped to identify more infants exposed to opioids").

503. In 2008, there were 17.0 infants with NAS per 1,000 live births (to Vermont residents in Vermont hospitals). By comparison, in 2014, that number had more than doubled to 35.3 per 1,000 live births (to Vermont residents in Vermont hospitals).[448]

504. Infants exposed to opioids *in utero* also face serious health consequences. At least 60–80% of these babies will experience symptoms such as seizures, respiratory distress, diarrhea, hypertonia, feeding intolerance, tremors, and vomiting because of their exposure to opioids in the womb.[449]

505. Infants born with NAS require longer and costlier hospital stays than those who are born without exposure to opioids. In 2012, the average length of hospital stay for non-NAS infants born to Vermont residents in Vermont hospitals was 3.0 days, at a cost of $5,590. But Vermont infants with NAS faced hospital stays more than 2x longer and nearly 3x more expensive, averaging 7.4 days and $15,456 (respectively).[450]

506. More than 50% of Vermont children under the age of five who have been taken into the custody of the Vermont Department of Children and Families (DCF) have been removed from their homes because of opioid-related issues.[451] As reported in 2016, the reporting of incidences to DCF's Child Protection Line have increased by 30%—from 15,760 reports in 2012

[448] Vermont Department of Health, *Neonates Exposed to Opioids in Vermont* (April 2017), http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Opioids_Neonate_Exposure.pdf, at 1.

[449] Stephen W. Patrick *et al.*, *Neonatal Abstinence Syndrome and Associated Health Care Expenditures*, Journal of the American Medical Association (2012), https://www.ncbi.nlm.nih.gov/pubmed/ 22546608.

[450] Vermont Department of Health, *Neonates Exposed to Opioids in Vermont*, *supra* n.448, at 2.

[451] Vermont Opioid Coordination Council, *Initial Report of Recommended Strategies*, *supra* n.6, at 3 n.1.

to 20,583 in 2016—and during those same years, approximately 30% of the calls related to substance abuse.[452]

The financial cost to our communities

507. Opioid overprescribing, misuse, and prescription diversion are draining Vermont's health care system. For example, one study estimated the 2007 total health care spending associated with opioid abuse in Vermont as exceeding $38 million.[453] From 2007 to 2018, opioid prescribing rose dramatically, as did the numbers of persons using, misusing, and abusing both prescription and illegal opioids.

508. The health care costs associated with opioid overprescribing, addiction, and abuse are crushing. Vermont consumers—individuals, employers, and private insurers—have paid millions for opioid prescriptions. Vermont's opioid treatment programs cost more than $70 million between 2012 and 2017 alone.[454] Vermont consumers have likewise borne substantial healthcare costs due to this epidemic of addiction.

509. It is well-established that health care costs for persons addicted to opioids are much higher than health care costs for the general population. For example, overall health care costs are approximately 3x higher among patients receiving Medication Assisted Treatment for

[452] Howard Weiss-Tisman, *Opioid Abuse Continues to Strain Vermont's Child Welfare System*, Vermont Public Radio (December 5, 2017), http://digital.vpr.net/post/opioid-abuse-continues-strain-vermonts-child-welfare-system#stream/0; Vermont Dept. for Children and Families Family Services Div., *2016 Report on Child Protection in Vermont*, http://legislature.vermont.gov/assets/Legislative-Reports/Child-Protection-Report-2016.pdf.

[453] Matrix Global Advisors, *Health Care Costs from Opioid Abuse: A State-by-State Analysis* (April 2015), https://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf, at 5.

[454] Chen (Vermont Department of Health), *Status of Opioid Treatment Efforts*, *supra* n.10, at 22.

opioid addiction than is true for the general Medicaid population.[455] The average national private payer cost per person with opioid use disorder was $63,356 (in 2015). [456]

510. The prevalence of opioids in Vermont also places a greater burden on law enforcement—increased costs associated with investigating and prosecuting crimes related to opioid use and abuse, as well as increased costs for treating incarcerated residents for opioid use disorder.

511. The costs of incarceration—which include Medication Assisted Treatment for addiction and other related costs—are largely paid by the State. Crimes associated with prescription drugs—chiefly robbery and burglary—have risen.[457] Data collected by the Vermont Intelligence Center show that law enforcement consistently averages between one and two seizures of illicit opioids per day.[458] In a small state like Vermont, this steady drumbeat of opioid seizures has become a focal point of police time and attention.

512. Purdue's prescription opioids continue to be a central cause of the opioid crisis in Vermont, and Purdue also has retained a significant market share of the dollars spent by the State on opioid prescriptions. Using the Vermont State Employees' health plan data as just one example, Purdue's opioids alone account for more than 55% of the State of Vermont's total opioid prescription spending, from April 2010 to June 2018.

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[455] Vermont Department of Health, *The Opioid Addiction Treatment System* (January 13, 2013), http://www.leg.state.vt.us/reports/2013externalreports/285154.pdf, at 9.

[456] Chen (Vermont Department of Health), *Status of Opioid Treatment Efforts*, *supra* n.10.

[457] Vermont Department of Health, *Issue Brief: Prescription Drug Misuse in Vermont,* at 12 (Feb. 12, 2013), http://thehungryheartmovie.org/wp-content/uploads/2013/09/SEOW_Rx_Issue_Brief_Final_02_12_13.pdf.

[458] *Opioid Seizures: Number of Opioid Seizures as Reported by Vermont Law Enforcement*, Vermont Intelligence Center (January 2017), last updated June 2015, last on website May 18, 2018 (available at https://webcache.googleusercontent.com/search?q=cache:u92N642SthsJ:https://app.resultsscorecard.com/perfmeasure/embed/101519+&cd=2&hl=en&ct=clnk&gl=us).

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

513. Purdue made, promoted, and profited from its misrepresentations about the risks and benefits of opioids for chronic pain, even though it knew that its marketing was false and misleading. Purdue also actively concealed its unfair and deceptive conduct from regulators and others who were working to curb the growing opioid epidemic.

514. The medical profession's historic understanding of the risks that opioids pose, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of serious adverse outcomes. FDA and other regulators warned Purdue of this, and Purdue entered into settlements in the hundreds of millions of dollars with the United States and numerous states (including Vermont) in 2007 to address similar misconduct. Purdue had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients were suffering from addiction, overdose, and death in alarming numbers.

515. The Sacklers knew all of this, too. They were not merely passive overseers who met yearly, approved budgets, and took distributions. The Sacklers were deeply involved in the running of Purdue, were highly knowledgeable about Purdue products and sales tactics, and were knowledgeable about what types of statements and practices were lawful. In addition, as discussed in Section B, the Corporate Integrity Agreement they approved in 2007 required them to be trained on marketing rules and report violations.

516. Notwithstanding this knowledge, at all times relevant to this Complaint, the Sacklers either directed Purdue to engage in the deceptive and unconscionable practices described herein or were aware of the conduct and responsible for it. They then took the additional step of

directing or sanctioning the steps taken by Purdue to avoid detection of and to conceal Purdue's wrongful conduct.

517. In the 2007 settlement with Vermont, Purdue committed that it would not make written or oral claims about OxyContin that were deceptive, and that it would not market OxyContin in a way that was inconsistent with the "Indication and Usage" section of the Package Insert. Purdue also promised to provide "fair balance" statements in its marketing of OxyContin, including statements regarding OxyContin's potential for abuse, addiction, or physical dependence, and that it would not make misrepresentations about OxyContin's potential for abuse, addiction, or physical dependence.

518. However, unbeknownst to the State, Purdue continued its deceptive and misleading marketing. As alleged in greater detail above, Purdue sales representatives rarely discussed the risks of addiction during sales calls, and instead were trained to distinguish it from physical dependence (while omitting key information about the risks of physical dependence) and "appropriate patient selection" (implying that the risks of dependence and addiction can be avoided through prescriber vigilance). These deflections misleadingly reassured doctors that they could safely prescribe Purdue's opioids long-term for chronic pain without fear of addiction.

519. In fact, only when Purdue was being investigated a second time by the State, did it make an attempt to educate prescribers about the risk of addiction posed by its drugs. There are zero references in the call note records to any addiction materials or handouts provided by Purdue sales representatives to Vermont prescribers prior to October 26, 2016. Yet, suddenly, in the fourteen-month period between October 26, 2016 and December 6, 2017 (the last date for which the State received call note records from Purdue), there are 62 references to a "Risk of Addiction"

handout provided to prescribers (the handout was provided in approximately 47% of the 131 Vermont detailer visits that occurred between October 26, 2016 and December 6, 2017).

520. Purdue also disguised its own role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded marketing, third-party advocates, and professional associations. Purdue purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of Purdue's false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Purdue masked or never disclosed its role in shaping, editing, and approving the content of this information. Purdue also distorted the meaning or import of studies it cited and offered them as evidence for propositions the studies did not support.

521. 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."[459] 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.

522. Purdue's public stance long has been that opioid abuse and diversion to illicit secondary channels are to blame for widespread addiction and deaths. But Purdue has consistently failed to address the problems caused by over-prescribing opioids. Instead, Purdue funded various drug abuse prevention programs nationwide and introduced abuse-deterrent opioids reformulated to make non-oral ingestion more difficult. Purdue also generated papers for presentation at

[459] Purdue Pharma L.P., "Setting The Record Straight On OxyContin's FDA-Approved Label" (May 5, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/; Purdue Pharma L.P., "Setting The Record Straight On Our Anti-Diversion Programs" (July 11, 2016), http://www.purduepharma.com/ news-media/ get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

conferences of addiction prevention professionals that stressed the importance of patient selection and touted the efficacy of its "abuse deterrent" opioids. Depicting the opioid crisis as a problem of misuse and diversion, and promoting its pills as solutions, allowed Purdue to present itself as a responsible corporate citizen while continuing to profit from the commonplace prescribing of its drugs, even at high doses for long-term use. 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, as directed and sanctioned by the Sacklers.

523. At the heart of Purdue's public outreach has been its claim that the Company works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation features in virtually all of Purdue's recent pronouncements in response to public scrutiny of opioid abuse: "[W]e are acutely aware of the public health risks these powerful medications create . . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . . ."[460]

524. Purdue's statement on "Opioids Corporate Responsibility" likewise stated, until recently, that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government." But Purdue has failed to accurately and diligently report to authorities illicit or suspicious prescribing of its opioids, even as it publicly and repeatedly touted its "constructive role in the fight against opioid abuse" and "strong record of coordination with law enforcement." In responding to criticism of its failure to report suspicious prescribing to government regulatory and enforcement authorities,

[460] Purdue Pharma L.P., *Opioids With Abuse-Deterrent Properties*, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/ (last visited Aug. 6, 2018).

Purdue's website similarly proclaimed that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."

525. These public pronouncements created the misimpression that Purdue is proactively working with law enforcement and government authorities, nationwide and in Vermont, 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 2007 criminal pleas, and to make its current marketing seem more trustworthy and truthful. In fact, Purdue has consistently failed to report suspicious prescribing to authorities, despite having all the necessary tools—detailed prescribing data and the eyes and ears of its sales force—to observe such practices.

526. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. According to Purdue, physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing volume. Purdue has said publicly that "[o]ur procedures help ensure that whenever we observe potential abuse or diversion activity, we discontinue our company's interaction with the prescriber or pharmacist and initiate an investigation." According to Purdue, it prohibits the detailing of health care providers added to the database, and sales representatives receive no compensation tied to these providers' prescriptions.

527. Yet, according to a 2016 investigation by the *Los Angeles Times*, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. In an interview with the *Los Angeles Times*, Purdue's former

senior compliance officer acknowledged that, in five years of investigating suspicious pharmacies, Purdue consistently failed to report suspicious dispensing or to stop supplies to the pharmacy, even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers. Despite its knowledge of illicit prescribing, Purdue did not report its suspicions, for example, until years after law enforcement shut down a Los Angeles clinic that Purdue's district manager described internally as "an organized drug ring" and that had prescribed more than 1.1 million OxyContin tablets.[461] The New York Attorney General's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. As described in Section C, the Sacklers were briefed in detail on Purdue's efforts to blunt the impact of the *Times'* story, including by collaborating on more favorable reporting by a *Times* competitor. After receiving that briefing, Richard Sackler went so far as to demand from the *Times* that it send him all the paper's correspondence with Purdue.

528. 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 was unaware of the existence or scope of Purdue's unlawful conduct and reasonable diligence would not have revealed this information at the time it was occurring. Only by conducting a second investigation of Purdue's marketing conduct, beginning in 2016, was the State able to gain access to information about Purdue's continued deceptive and misleading marketing conduct.

529. The Sacklers sought to hide their role as well. After vacating executive positions within the company before 2007, they continued to serve on the Board of Directors. On information and belief, they did so recognizing that it was crucial to install a CEO who would be

[461] Harriet Ryan *et al., More than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/

loyal to the family. The Sacklers also hid behind the façade that they operated as a normal board, approving high-level strategy and budgets but no more, as discussed in Section C above. When Dr. 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 federal Corporate Integrity Agreement. Most shocking of the Sacklers' efforts to erase their comprehensive direction of Purdue was the 2017 statement—which disclaimed any leadership of a company that was characterized as "owned by the family trust."

CAUSES OF ACTION

COUNT ONE
DECEPTIVE ACTS AND PRACTICES
VIOLATIONS OF THE VERMONT CONSUMER PROTECTION ACT

The State realleges and incorporates by reference each of the allegations contained in all paragraphs of this Complaint as though fully set forth herein.

530. Each Defendant engaged in deceptive practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), by causing material misrepresentations and omissions regarding the risks and benefits of their opioid products to be made to Vermont prescribers and consumers. Through this deception, Defendants succeeded in getting many Vermont doctors to prescribe and Vermont patients to take and remain on Purdue's opioids.

531. Defendants are personally liable for the conduct described herein because each of Purdue's misrepresentations and omissions was either undertaken at Defendants' explicit direction, undertaken to fulfill Defendants' explicit directions, or was conduct that Defendants were personally aware of and responsible for. Defendants approved the hiring of sales representatives, targets for volume of sales representative activity, and sales objectives with the

knowledge that Purdue would engage in the misrepresentations and omissions described in this Complaint.

532. The material misrepresentations and omissions about the use of opioids to treat chronic pain that are the subject of this Complaint were not supported by or were contrary to scientific evidence, as confirmed by recent pronouncements of the CDC and FDA based on that evidence, and the material omissions (which were false and misleading in their own right) which rendered even seemingly truthful statements about opioids false and misleading because they were materially incomplete.

533. These misrepresentations and omissions were likely to mislead prescribers and consumers, affecting their decisions regarding the prescribing and use of opioids. The meaning Plaintiff ascribes to these misrepresentations and omissions herein is reasonable, given the nature thereof.

534. Defendants also engaged in deceptive practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), because the representations caused by them were not substantiated by competent and reliable scientific evidence.

COUNT TWO
UNFAIR ACTS AND PRACTICES
VIOLATIONS OF THE VERMONT CONSUMER PROTECTION ACT

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

535. Each Defendant engaged in unfair practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), by: causing material misrepresentations and omissions regarding the risks and benefits of their opioid products to be made to Vermont prescribers and consumers; causing Purdue to target a vulnerable population—the elderly—for

promotion of opioids to treat chronic pain in the face of the known, heightened risks of opioid use to that population, including risks of addiction, adverse effects, hospitalization, and death; causing Purdue to target opioid-naïve patients and patients using IR or weaker (Schedule III) opioids for conversion to Purdue's ER/LA opioid products; authorizing and approving 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; and directing Purdue to offer Savings Cards as an incentive to use Purdue's prescription opioids. Through this conduct, Defendants succeeded in getting many Vermont doctors to prescribe and Vermont patients to take and remain on their opioids.

536. Defendants are personally liable for the unfair acts and practices described herein because the conduct was either undertaken at Defendants' explicit direction, was undertaken to fulfill Defendants' explicit directions, or was conduct that Defendants were personally aware of, condoned, and were responsible for. Defendants approved the hiring of sales representatives, targets for volume of sales representative activity, and sales objectives with the knowledge that Purdue would engage in the unfair acts and practices described in this Complaint.

537. These acts or practices may be deemed unfair in that they offend public policy reflected in (a) the CPA, which protects consumers and competitors from deceptive marketing and to ensure an honest marketplace, and (b) federal law, which requires the truthful and balanced marketing of prescription drugs, 21 C.F.R. § 202.1(e).

538. These acts or practices were unfair because they unethically deprived prescribers of the information they needed to appropriately prescribe-or not prescribe-these dangerous drugs. Patients who use opioids can quickly become dependent and addicted, such

that neither the patient nor the prescriber can avoid injury by simply stopping or choosing an alternate treatment.

539. Because of Defendants' conduct, Vermont consumers have suffered substantial injury by reason of the health risks associated with opioid use, including the pain, and suffering associated with opioid addiction, injury, disability, overdose, and death, as well as the associated financial costs.

COUNT THREE
PUBLIC NUISANCE

540. The Defendants, through the actions described in the Complaint, have created—or were a substantial factor in creating— a public nuisance by causing an unreasonable interference with a right that is common to the general public and that harms the health, safety, peace, comfort, or convenience of the general community.

541. The State and its citizens have a public right to be free from the substantial injury to public health, safety, peace, comfort, and convenience that has resulted from the Defendants' conduct in causing the illegal and deceptive marketing of opioids for the treatment of chronic pain.

542. This injury to the public includes, but is not limited to (a) widespread dissemination of false and misleading information regarding the risks and benefits of opioids to treat chronic pain; (b) a distortion of the medical standard of care for treating chronic pain, resulting in pervasive overprescribing of opioids and the failure to provide more appropriate pain treatment; (c) high rates of opioid abuse, injury, overdose, and death, and their impact on Vermont families and communities; (d) increased health care costs for individuals, families, employers, and the State; (e) lost employee productivity resulting from the cumulative effects of long-term opioid use, addiction, and death; (f) the creation and maintenance of a secondary, criminal market for opioids;

and (g) greater demand for emergency services and law enforcement paid for by the State at the ultimate cost of taxpayers.

543. At all times relevant to the Complaint, the Defendants' conduct substantially and unreasonably interfered in the enjoyment of this public right by the State and its citizens. Purdue engaged in a pattern of conduct that (a) overstated the benefits of chronic opioid therapy, including by misrepresenting OxyContin's duration of efficacy and by failing to disclose the lack of evidence supporting long-term use of opioids; and (b) obscured or omitted the serious risk of addiction arising from such use. This conduct was either undertaken at Defendants' explicit direction, was undertaken to fulfill Defendants' explicit directions, or was conduct that Defendants were personally aware of and responsible for. This conduct effected and maintained a shift in health care providers' willingness to prescribe opioids for chronic pain, resulting in a dramatic increase in opioid prescribing and the injuries described above.

544. At all times relevant to the Complaint, Defendants exercised control over the instrumentalities constituting the nuisance—i.e., Purdue's marketing as conveyed through sales representatives, other speakers, and publications, and its program to identify suspicious prescribing. As alleged herein, Defendants created, or were a substantial factor in creating, the nuisance through multiple vehicles, including (a) Purdue's in-person sales calls that contained false or misleading statements or material omissions; (b) Purdue's dissemination of deceptive advertisements and publications; (c) Purdue's sponsorship and creation of flawed and biased scientific research and prescribing guidelines; and (d) Purdue's sponsorship of and collaboration with third parties to disseminate false and misleading messages about opioids.

545. Defendants' actions were a substantial factor in creating the public nuisance because it caused prescribers and patients to be deceived about the risks and benefits of opioids

and distorted the medical standard of care for treating chronic pain. Without Defendants' actions, opioid use would not have become so widespread, and the opioid epidemic that now exists in Vermont would have been averted or would be much less severe.

546. The public nuisance was foreseeable to Defendants. As alleged herein, Purdue engaged in widespread promotion of opioids in which it misrepresented the risks and benefits of opioids to treat chronic pain. Defendants knew that there was no evidence showing a long-term benefit of opioids on pain and function, and that opioids carried serious risks of addiction, injury overdose, and death. Defendants were positioned to foresee not only a vastly expanded market for chronic opioid therapy as the likely result of Purdue's conduct, but also the widespread problems of opioid addiction and abuse that have, in fact, materialized. Defendants were on notice and aware of signs that the broader use of opioids was causing just the kinds of injuries described in this Complaint.

547. This public nuisance can be abated—in part—through health care provider and consumer education on appropriate prescribing, honest marketing of the risks and benefits of long-term opioid use, addiction treatment, disposal of unused opioids, and other means.

COUNT FOUR
UNJUST ENRICHMENT

548. The State realleges and incorporates by reference each of the allegations contained in all paragraphs of this Complaint as if set forth fully herein.

549. As an expected and intended result of their wrongdoing as set forth in this Complaint, each Defendant has profited and benefited from the sale of their opioids within the State.

550. Each Defendant has accepted the profits and benefits conferred on them through the sale of their opioids within the State, including by accepting disbursements from Purdue which included funds that came from Vermont.

551. Each Defendant's retention of the profits and benefits conferred on them through the increased sales of their opioids within the State is inequitable. Each Defendant has unjustly enriched themselves at the State's expense, while the State has borne the cost of remedying and mitigating the harms caused by Defendants' conduct.

PRAYER FOR RELIEF

WHEREFORE, the State respectfully requests that this Court grant the following relief after a trial on the merits:

A. Determine that all Defendants engaged in unfair and deceptive acts and practices in violation of 9 V.S.A. § 2453, and the regulations promulgated thereunder;

B. Permanently enjoin all Defendants from engaging in unfair and deceptive acts and practices;

C. Order all Defendants to disgorge all payments received as a result of their unlawful conduct;

D. Order all Defendants to pay civil penalties of up to $10,000 for each and every violation of the Vermont Consumer Protection Act;

E. Award the State of Vermont all investigative and litigation costs and fees;

F. Determine that all Defendants created a public nuisance;

G. Order all Defendants to abate the nuisance, to reimburse the cost of the State's abatement efforts, and to pay compensatory damages for harms caused by the nuisance; and

H. Grant all other relief as the Court may deem just and proper.

JURY DEMAND

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

Dated: May 21, 2019

Respectfully submitted,

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