## UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

Marshall County Board of Education and Wetzel County Board of Education, Individually and on Behalf of All Others Similarly Situated,

Plaintiffs,

v.

Theresa E. Sackler; Kathe A. Sackler; Mortimer D.A. Sackler; Ilene Sackler Lefcourt; Richard S. Sackler and David A. Sackler, as Executors of the Estate of Raymond R. Sackler; Richard S. Sackler and David A. Sackler, as Executors of the Estate of Beverly Sackler; Richard S. Sackler; David A. Sackler; Garrett Lynam, as Executor of the Estate of Jonathan D. Sackler.

Defendants.

ELECTRONICALLY **FILED** 10/06/2025 U.S. DISTRICT COURT Northern District of WV

No. 5:25-cv-228 Bailey

JURY TRIAL DEMANDED

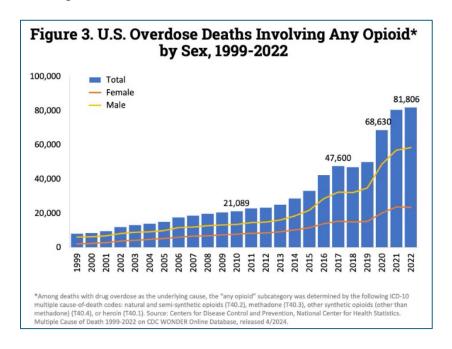
## COMPLAINT

Plaintiffs Marshall County Board of Education and Wetzel County Board of Education, individually and on behalf of all others similarly situated in West Virginia and throughout the United States, by and through its undersigned counsel, brings this civil action to rectify Defendants' violations of the federal Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1964. Defendants have unlawfully advanced an enterprise whereby they flooded Plaintiffs' communities with prescription drugs that were unlawfully marketed and distributed. In support of this action, Plaintiffs state the following:

#### I. Nature of the Case

- As a closely held corporation, Purdue Pharma L.P. ("Purdue") was owned and 1. heavily controlled by the Sackler family. In fact, eight members of the Sackler family held a majority of the seats on Purdue's Board of Directors until 2018.
- 2. For purposes of clarity, references to Purdue include Purdue Pharma L.P.; The Purdue Frederick Company; Purdue Pharma Inc.; Purdue Pharma L.P.; the Purdue Frederick Company; Purdue Pharmaceutical Products L.P.; Purdue Products L.P., Rhodes Pharmaceuticals L.P., Rhodes Technologies, Rhodes Technologies Inc., and Avrio Health Limited Partnership, and further includes any other entities or any other entities owned or controlled, in whole or in part, directly or indirectly, by or on behalf of the Sackler family, including Purdue Pharma L.P., Purdue Pharma Inc., Purdue Transdermal Technologies L.P., Purdue Pharma Manufacturing L.P., Purdue Pharmaceuticals L.P., Imbrium Therapeutics L.P., Adlon Therapeutics L.P., Greenfield BioVentures L.P., Seven Seas Hill Corp., Ophir Green Corp., Purdue Pharma of Puerto Rico, Avrio Health L.P., Purdue Pharmaceutical Products L.P., Purdue Neuroscience Company, Nayatt Cove Lifescience Inc., Button Land L.P., Rhodes Associates L.P. (N/A), Paul Land Inc., Quidnick Land L.P., Rhodes Pharmaceuticals L.P., Rhodes Technologies, UDF L.P., SVC Pharma L.P. and SVC Pharma Inc.
- 3. This is a civil action under the federal Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1964, against the estates of and other living individual members of the Sackler family for their leading roles in (a) knowingly, intentionally, willfully recklessly, and/or negligently foisting, failing to prevent, and contributing to the opioid crisis that continues to destroy families and costs lives, and (b) engaging in an unlawful enterprise to fraudulently transfer billions of dollars generated by Purdue from the opioid crisis to themselves.

- 4. As the United States Supreme Court recently noted, "[t]he opioid epidemic represents "one of the largest public health crises in this nation's history." Harrington v. Purdue Pharma L.P., 144 S.Ct. 2071, 2077 (U.S. 2023) (quoting In re Purdue Pharma L. P., 69 F. 4th 45, 56 (2d Cir. 2023).
- 5. The NIH's National Institute on Drug Abuse has tracked the steep rise in opioid overdose deaths for the period from 1999-2022:



See NIH, Drug Overdose Deaths: Facts and Figures, U.S. Overdose Deaths Involving Any Opioid by Sex, 1999-2022 (Figure 3), available at https://nida.nih.gov/research-topics/trendsstatistics/overdose-death-rates (last visited June 9, 2025). As discussed in greater detail below, it's no accident that this sickening trendline coincides with the Sackler's purposeful campaign to flood the American public with opioids.

6. Other studies have found that from 1999 to 2004, "Appalachia (primarily West Virginia) and the Southwest (primarily Utah) had the highest death rates from opioids." See Florida Atl. Univ., U.S. Drug Overdose Deaths More Than Quadrupled from 1999 to 2020

(Sept. 12, 2023), available at https://www.fau.edu/newsdesk/articles/drug-overdose-deaths.php (last visited June 9, 2025).

- 7. By controlling Purdue with an iron fist, the Sacklers' enterprise is responsible for much of that death and devastation. Through the Sacklers' direction, Purdue's sales of OxyContin, concerted efforts to push aggressive and deceptive marketing of opioid products, failure to take steps required by law to address diversion of its products, and other breaches of duty, set the opioid epidemic ablaze and stoked it for decades.
- Under the Sacklers' watchful eye, Purdue launched OxyContin in 1996. The 8. purpose of the Sacklers' enterprise was to have Purdue spread the lie far and wide that its opioids were specially formulated to be safe, not addictive, and appropriate for a far wider range of patients and pain symptoms than previously understood across the medical establishment. As part of the Sackler's aggressive campaign, Purdue (a) improperly paid doctors to promote its products; (b) targeted doctors who had well documented histories of prescribing high levels of opioids; (c) secretly sponsored astroturf and front groups, such as Partners Against Pain, that would falsely portray opioids as safe; and (d) advocated for prescribing higher doses of opioids and for longer periods of time.
- 9. In 1996, Richard Sackler – while serving as keynote speaker at Purdue's 1996 national sales meeting – gleefully proclaimed that: "the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense and white that you will never see their white flag." Sackler also told all the sales representatives and staff that Purdue "had the most powerful selling package insert in the category and in the industry." He further told the Purdue field force that the Purdue team

working on the Package Insert (of which he was a part) made the label "a more potent selling instrument." Richard Sackler would become Purdue's President three years later.

- 10. The Sacklers' enterprise succeeded beyond their wildest dreams and led to a massive wave of medically unnecessary opioid prescriptions and widespread abuse and diversion.
- 11. Purdue has twice voluntarily acknowledged that its opioid marketing and sales practices which were directed and dominated by the Sacklers constituted federal crimes:
  - a. In May 2007, Purdue confessed that, from the time of Oxycontin's launch in 1996, it falsely marketed the drug as non-addictive and pled guilty to misbranding and related crimes for which it paid a record \$600 million penalty.
  - b. In 2020, Purdue admitted to criminal misconduct by acknowledging that it conspired with others to aid and abet the dispensing of opioids without a legitimate medical purpose and outside the usual course of professional practice in violation of federal law. For these crimes, Purdue agreed a criminal fine of \$3.544 billion, plus entry of a forfeiture judgment in the amount of \$2 billion, plus allowance of a \$2.8 billion claim in the chapter 11 proceedings in the Southern District of New York to resolve civil liability asserted by the U.S. Department of Justice ("DOJ"). Purdue also specifically admitted that this opioid-related criminal misconduct dated back at least to May 2007 continued into 2017.
- 12. For approximately 70 years, Purdue founded as the Purdue Frederick Company ("Purdue Frederick") has been beneficially owned and managed by the Sackler family.
- 13. The descendants of Mortimer D. Sackler and Raymond Sackler, respectively, own the company through a web of family trusts. The two branches generally sort themselves into "Side A" (the "Mortimer side") and "Side B" (the "Raymond side"). Side A and Side B share ownership of Purdue to this day, and at all relevant times completely dominated and controlled Purdue. While only the Sackler Defendants are named Defendants in this matter, the challenged conduct includes any conduct taken by any Sackler Defendant in any capacity, including, without limitation, in his or her capacity as a trustee of any trusts that own or control any interest in

Purdue on behalf of any members of the Sackler family or any trusts for the benefit of any members of the Sackler family that have received any value from Purdue and includes any conduct by other current and former trustees of such trusts.

- 14. The Sacklers exercised such tight control over Purdue that a leading expert on corporate law concluded that "there is little to distinguish the control the Sacklers exercised over Purdue from the control that the godfather held over his Mafia family."
- 15. From the jump, the Sacklers continually pressured Purdue's sales force to drive-up OxyContin sales. The Sacklers not only closely tracked sales and marketing data, but continually demanded that management increase sales targets, tagged along on sales calls to doctors' offices, directly engaged with and gave orders to junior marketing personnel over management's objections, and contravened or countermanded executives' directives.
- 16. The Sacklers insisted that Purdue aggressively market OxyContin, including by targeting so-called "high value" prescribers that would prescribe more OxyContin prescriptions than other prescribers. This strategy made OxyContin ubiquitous, made Purdue tens of billions of dollars in sales, and transformed the Sacklers into multi-billionaires.
- 17. While the Sacklers were aware of OxyContin's addictive nature and potential for abuse and diversion, they sought to promote the impression among health care providers that it was non-addictive and to encourage providers to write OxyContin prescriptions that they otherwise would not have written.
- 18. In 2006, Purdue estimated that as much as 18.1%—or \$1.8 billion—of OxyContin sales revenue between 1996 and 2005 were "attributable to OxyContin abuse" and as much as 25% of all OxyContin kilograms were being abused. A McKinsey report provided to Purdue

concluded that, in 2007, approximately 38% of OxyContin users were dependent and/or abused the drug.

- 19. Against this backdrop, the Sackler Defendants pressured the company to seek "pediatric indications on oxycontin tablets." When asked whether promoting the use opioids by children was "desirable, appropriate or feasible," Richard Sackler said that OxyContin consumption by children was a "critically important piece of business."
- 20. The Sacklers lacked sympathy for the victims of Purdue's Oxycontin blitzkrieg. Rather, the Sacklers chose to pursue a strategy of blaming OxyContin abusers for falling into the Sacklers' trap. For example, in 2001, Richard Sackler wrote in an email that "we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are the reckless criminals."
- 21. While seeking to "turbocharge" OxyContin sales, the Sacklers failed to ensure Purdue's compliance with its anti-diversion duties under the Controlled Substances Act (the "CSA") and corresponding Drug Enforcement Administration ("DEA") regulations. Under these laws and regulations, Purdue was required to maintain effective controls against opioid diversion, including by maintaining a suspicious order monitoring ("SOM") system and an Abuse and Diversion Detection Program (the "ADD Program"). Purdue, however, failed to maintain effective diversion programs.
- 22. Rather, Purdue specifically targeted prescribers whose prescribing practices were aberrant in contravention of its own written policies.
- 23. During this period, the Sacklers also systematically moved assets out of Purdue and into their own pockets. Shortly after the guilty plea in 2007, the Sacklers panicked and asked each other, "We're rich? For how long? Until which suits get through to the family?" Shortly

thereafter, a close family advisor advised the Sacklers to "take defensive measures" against Purdue's "uncapped liabilities," including by sending assets overseas to deprive litigants of a "deep pocket."

- 24. While OxyContin was the most recognizable brand name in Purdue's stable of opioids, other opioid-related products that Purdue offered include but are not limited to MS Contin, Hysingla, Butrans, Dilaudid, Targiniq, Palladone, and Ryzolt, as well as generic versions of these drugs. Plaintiffs' use of the term "opioid" herein includes each of these drugs.
- 25. This Complaint alleges claims for violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1964 ("RICO") and public nuisance.

### II. The Parties

#### A. Plaintiffs

- 26. Plaintiffs bring this civil action against Defendants on behalf of themselves and other similarly situated public school boards in the United States, including but not limited to West Virginia, to recoup monies they have spent because of Defendants' actions and inactions and to abate the effects of the opioid epidemic on public schools caused by the Defendants.
- 27. The Marshall County Board of Education, on behalf of Marshall County Schools, an independent public school district in West Virginia, is located at 214 Middle Grave Creek Road, Moundsville, WV 26041.
- 28. The Wetzel County Board of Education, on behalf of Wetzel County Schools, an independent public school district in West Virginia, is located at 300 Foundry Street, New Martinsville, WV 26155.

#### **B.** Sackler Defendants

#### 1. Sackler Side A Defendants

- 29. Defendant Theresa E. Sackler ("Theresa Sackler") is Mortimer Sackler Sr.'s widow and was his third wife. She was a member of the Board from 1993 through 2018, a member of the MNP Board from its formation until February 19, 2019, and a member of the board (the "MNC Board") of MN Consulting LLC ("MNC") from January 17, 2019 until April 15, 2019. MNC replaced the role previously occupied by MNP in connection with management of the global Sackler enterprise. She also served as a director for at least five IACs, including but not limited to Napp Pharmaceutical Group Limited and Napp Pharmaceutical Holdings Ltd. Upon information and belief, she currently resides in the United Kingdom and resided in New York, at least part-time, through 2019.
- 30. Defendant Kathe A. Sackler ("Kathe Sackler") is Mortimer Sackler Sr.'s daughter from his first wife, Muriel. Kathe Sackler was a member of the Board from 1990 through 2018 and a member of the MNP Board from its formation until February 5, 2019. She also served as a director for at least five IACs, including but not limited to Napp Pharmaceutical Group Limited and Napp Pharmaceutical Holdings Ltd. She graduated from the New York University School of Medicine and is trained in medicine. She resides in Connecticut.
- 31. Defendant Mortimer D.A. Sackler ("Mortimer Sackler Jr.") is the son of Mortimer Sackler Sr. from Mortimer Sackler Sr.'s second wife, Gertraud Wimmer. Mortimer Sackler Jr. was a member of the Board from 1993 through 2019, a member of the MNP Board from its formation until April 1, 2019, and a member of the MNC Board from January 17, 2019 to, upon information and belief, the present. Mortimer Sackler Jr. also served as a director for at least five IACs, including but not limited to Napp Pharmaceutical Group Limited and Napp

Pharmaceutical Holdings Ltd. Upon information and belief, he resides in Switzerland and maintains a business office in New York.

32. Defendant Ilene Sackler Lefcourt ("Ilene Sackler") is another daughter of Mortimer Sackler Sr. from his first wife, Muriel. Ilene Sackler was a member of the Board between 1990 and 2018 and a member of the MNP Board from its formation until September 18, 2018. Ilene Sackler served as a director for at least four IACs, including but not limited to Napp Pharmaceutical Group Limited and Napp Pharmaceutical Holdings Ltd. She resides in New York.

#### 2. Sackler Side B Defendants

33. Estate of Raymond Sackler. Raymond R. Sackler ("Raymond Sackler"), the patriarch of "Side B" of the Sackler family, died on July 17, 2017. Defendants Richard Sackler ("Richard Sackler") and David A. Sackler ("David Sackler") are named as defendants both in their individual capacities, as noted infra, and in their capacities as executors of the Estate of Raymond Sackler, which is an estate consisting of all interests and assets owned by Raymond Sackler as of his death. Raymond Sackler was a physician and, as alleged above, acquired Purdue Frederick with his brothers Mortimer Sackler Sr. and Arthur in 1952. Raymond Sackler served on the Board (beginning October 2, 1990, including as co-Chairman until 2007) and on the MNP Board from its formation until his death in 2017. Raymond Sackler also served as a director for a number of IACs, including but not limited to Napp Pharmaceutical Group Limited. He was co-CEO of PPI at the time of OxyContin's launch in 1996 and held that position until 2003. He helped devise Purdue's business plan to preserve profit streams for the Sacklers, was involved in various operational details of Purdue's business, helped develop abuse-deterrent OxyContin formulations, consulted on high-level strategic decisions, and influenced various initiatives and programs and Purdue's support for various third parties that promoted Purdue's

interests. Raymond Sackler, his descendants, their spouses, and their affiliates are sometimes referred to by the Sacklers, and in this Complaint, as the "Side B Sacklers."

- Sackler's widow, died on October 14, 2019. Defendants Richard Sackler and David A. Sackler ("David Sackler") are named as defendants both in their individual capacities, as noted infra, and in their capacities as executors of the Estate of Beverly Sackler, which is an estate consisting of all interests and assets owned by Beverly Sackler as of her death. In life, Beverly Sackler was deeply involved in the Debtors and the Sacklers' worldwide enterprise. Beverly Sackler was a member of the Board from January 15, 1993 until October 17, 2017, and a member of the MNP Board from 1996 until October 17, 2017. Beverly Sackler also served as a director for at least three IACs, including but not limited to Napp Pharmaceutical Group Limited and Napp Pharmaceutical Holdings Ltd. Until her death in 2019, she resided in Connecticut. Upon information and belief, the Estate of Beverly Sackler that was not devised under the terms of her will is now property of the Beverly Sackler Revocable Trust.
- 35. Defendant Richard Sackler is the son of Raymond Sackler and Beverly Sackler. He became a member of the Board in 1990 and its co-chair in 2003, which position he retained until he left the Board in 2018. Richard Sackler also served on the MNP Board from its formation until October 1, 2018. He also was PPLP's head of research and development from at least 1990 through 1999, its president from 1999 through 2003, and served in other executive roles throughout the business. Richard Sackler also served as a director for at least five IACs, including but not limited to Napp Pharmaceutical Group Limited and Napp Pharmaceutical Holdings Ltd. He currently holds active licenses to practice medicine in New York and Connecticut. He resides in Florida.

- 36. Defendant David Sackler is the son of Richard Sackler and the grandson of Raymond Sackler. David Sackler was a member of the Board from 2012 through 2018, a member of the MNP Board from July 19, 2012 until April 1, 2019, and a member of the MNC Board from January 2019 to, upon information and belief, the present. David Sackler also served as a director for at least four IACs, including but not limited to Napp Pharmaceutical Group Limited and Napp Pharmaceutical Holdings Ltd. Upon information and belief, he resides in New York.
- 37. Estate of Jonathan D. Sackler ("Jonathan Sackler"), another son of Raymond Sackler and Beverly Sackler, and brother to Richard Sackler, died on June 30, 2020. Defendant Garrett Lynam is the executor of the Estate of Jonathan D. Sackler, which is an estate consisting of all interests and assets owned by Jonathan Sackler as of his death. Jonathan Sackler was a member of the Board from 1990 through 2018 and a member of the MNP Board from its formation until September 20, 2018. Jonathan Sackler also served as a director for at least six IACs, including but not limited to Napp Pharmaceutical Group Limited and Napp Pharmaceutical Holdings Ltd. He resided in Connecticut.
- 38. Defendants Theresa Sackler, Kathe Sackler, Mortimer Sackler Jr., Ilene Sackler, Estate of Raymond Sackler, Estate of Beverly Sackler, Richard Sackler, David Sackler, and Estate of Jonathan Sackler are collectively referred to as the "Sackler Defendants."

### III. Demand for Trial by Jury

39. Plaintiffs request that all claims and damages contained in and requested by this Complaint be resolved at trial by jury.

#### IV. Jurisdiction & Venue

- 40. This Court has subject matter jurisdiction under section 1331 because this matter presents a federal question under the federal Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1964 ("RICO"). 28 U.S.C. § 1331.
- 41. This Court has subject matter jurisdiction under section 1332(a), because:

  (a) Plaintiffs are all citizens of the State of West Virginia; (b) Defendants are all corporate entities that are not citizens of West Virginia; (c) there is therefore complete diversity between the parties, and (d) the amount in controversy exceeds \$75,000 exclusive of interest and costs. 28 U.S.C. § 1332(a).
- 42. This Court has subject matter jurisdiction under section 1332(d), because: (a) the amount in controversy exceeds \$5,000,000; and (b) "any member of a class of plaintiffs is a citizen of a State different from any defendant." 28 U.S.C. § 1332(d)(2)(A).
- 43. This Court has supplemental jurisdiction under 28 U.S.C. § 1367 over all other claims that are so related to claims in the action.
- 44. The U.S. District Court for the Northern District of West Virginia has personal jurisdiction over Defendants because they conduct business in West Virginia, purposefully direct or directed their actions toward West Virginia, and have the requisite minimum contacts with West Virginia necessary to constitutionally permit this Court to exercise jurisdiction.
- 45. Venue in the Northern District of West Virginia is proper under 28 U.S.C. § 1391(b)-(d), as defendants are deemed to reside in any judicial district in which they are subject to personal jurisdiction when the action is commenced, and here, the Defendants' contacts with this District are sufficient to subject them to personal jurisdiction. *Id*. §§ 1391(b)(1), (c)(2), (d). Defendants specifically conduct business in this judicial district, conducted the business activities described herein in this judicial district, and Plaintiffs incurred

damages in this judicial district. For the same reasons, a "substantial part of the events [and] omissions giving rise" to this action occurred in this judicial district. *Id.* § 1391(b)(2).

Document 1

#### V. **Facts**

- The Sacklers Owned Purdue and Exercised Complete Control Over Its A. Board
- 46. The Sacklers purchased Purdue Frederick in 1952. Purdue was not initially engaged in the sale of opioids. Purdue has, at all times, been owned, directed, and controlled by members of the Sackler family. Throughout the period relevant to this Complaint, the two sides of the Sackler family—Mortimer D. Sackler and his descendants (i.e., Side A) and Raymond Sackler and his descendants (i.e., Side B)—shared equal ownership of the company and equal rights to control the decisions of the company.<sup>1</sup>
- 47. From 1990 until January 16, 2019, members of the Sackler family served on the Board, which controlled and directed the business activities of all of Purdue. Throughout that time, the Sacklers were either the sole directors or the majority of directors on the Board.
- 48. The various Sackler Defendants served on the Board for the following periods of time:

Sackler Defendant	Total Years Served as Purdue Director (rounded to nearest year)	Years
Side A	-	
Theresa Sackler	26 years	1993–2018
Kathe Sackler	28 years	1990–2018
Mortimer Sackler Sr.	19 years	1990–2010
Ilene Sackler	28 years	1990–2018

<sup>&</sup>lt;sup>1</sup> Three brothers, Arthur, Mortimer Sackler Sr., and Raymond Sackler, purchased the company together. Arthur died in 1987. Soon after his death, and before the launch of OxyContin, Arthur's estate sold his one-third interest in Purdue to Mortimer Sackler Sr. and Raymond Sackler. Since that time, ownership of Purdue has been split equally between the two brothers and their respective families.

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Sackler Defendant	Total Years Served as Purdue Director (rounded to nearest year)	Years
Side B		
Raymond Sackler	27 years	1990–2017
Beverly Sackler	25 years	1993–2017
Richard Sackler	28 years	1990–2018
David Sackler	6 years	2012–2018
Jonathan Sackler	28 years	1990–2018
Mortimer Sackler Jr.	26 years	1993–2019

- 49. The following Sackler Defendants also held various Board positions:
  - Richard Sackler was Co-Chairman of the Board from March 6, 2003 a. through June 30, 2007; and
  - Raymond Sackler was Co-Chairman of the Board from January 1, 2004 b. through June 30, 2007, and Co- Chairman of Purdue Frederick from March 6, 2003 through December 31, 2003.
- In addition to their board positions, some of the Sackler Defendants also held 50. executive positions at Purdue for several years:
  - Richard Sackler was President of PPI from January 1, 2002, through a. March 5, 2003, and he described himself in a resume as COO from January 1, 1986, to December 1999;
  - b. Mortimer Sackler Jr. was Vice President of PPI from January 1, 2002 through April 23, 2003;
  - Raymond Sackler was President and Co-CEO of PPI from January 1, 2002 c. through March 5, 2003;
  - d. Kathe Sackler was Senior Vice President from January 1, 2002 through June 30, 2007; and
  - Ilene Sackler was a Vice President from January 1, 2002 through e. December 31, 2002. Even when they dropped these nominal officer titles, the change was entirely superficial.
- Only after Purdue pled guilty to federal crimes and settled various investigations 51. by state governments concerning its marketing and sale of opioids in 2007, the Sacklers began to

add a small number of non-Sackler members to the Board to create the appearance of some independent oversight.

- 52. Just as the Sacklers maintained total control over the Board, the Sacklers also handpicked Purdue's chief executives based on their perceived readiness to prioritize loyalty to the Sackler family over loyalty to Purdue.
- 53. The Sackler Defendants routinely injected themselves into typical management functions and made improper demands on corporate executives.
- 54. The Sackler Defendants' practices were so outside of the norms, in 2017, management identified the fact that "the Board of Directors serve[s] as the 'de facto' CEO" as one of the most pressing issues facing the company. Likewise, McKinsey & Company ("McKinsey") similarly observed that "the Board gets involved in too many decisions that it shouldn't." McKinsey further found that the Sacklers "viewed all employees like the guys who 'trim the hedges' employees should do exactly what's asked of them and not say too much."
- 55. The Sacklers themselves acknowledged that they blurred the roles between management and the Board.
- 56. In March 2007, Jonathan Sackler admonished Richard Sackler about Richard's systematic practice of assigning projects directly to Purdue employees without consulting their supervisors was improper.
- 57. While the Sackler Defendants eventually dropped their formal executive titles, they never stopped functioning as executives and micromanaging Purdue.
  - B. The Sackler Defendants Exerted Significant Control Over Purdue's Marketing Activities of OxyContin
- 58. Each Sackler Defendant took part in tightly controlling Purdue's OxyContin campaign. In 1999, for example, Richard Sackler wrote in an email, "You won't believe how

committed I am to make [sic] OxyContin a huge success. It is almost that I dedicated my live [sic] to it."

- 59. Richard Sackler and Mortimer Sackler Jr. both closely watched sales forecasts prepared by Purdue personnel and made their own demands to push OxyContin sales:
  - a. For example, on March 8, 2008, Russell Gasdia, Purdue's head of sales, informed then-CEO Stewart of a conversation he had with Richard Sackler regarding Purdue's sales forecast, writing, "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."
  - b. Either the message did not make it to Richard, or he disregarded it. The following day, on March 9, 2008, Richard engaged with Purdue's sales team in painstaking detail in an effort to prove that the team's sales forecast was too low. Richard instructed the team to revise their spreadsheets, remarking, after the changes, that "this looks very different and much more encouraging, doesn't it?" and expressing his "excite[ment] to dig into the data." After removing Richard from the chain, one of the marketing managers advised his subordinates on how to "defend[] the forecast" if "you wind up talking to Dr. Richard today without me."
  - c. But Richard preferred his own views to that of his marketing team. In a report to the Board the following day, Richard wrote that after a deep dive into "the preliminary sales forecast for 2008," he could "happily report that the 2008 forecast and sales plan [prepared by management] is almost certainly overly conservative, by which I mean it significantly understates what we may reasonably expect to be achieved in 2008." Richard concluded by recommending that the Board "have Mortimer Jr. and I work with John Stewart to re-forecast the year and also the 5 year plan for OxyContin tablets," and to create "a new and higher sales plan."
  - d. In January 2010, numerous members of Purdue's marketing team lamented receiving "more data requests from Dr. Richard . . . that will take a lot of time and not add much value," complaining that "we're getting carried away with weekly data," and querying, "[w]hat questions are we trying to answer?" Gasdia forwarded the complaints to Stewart asking for his "help with this? It seems like every week we get one off requests from Dr. Richard and now even Dr Raymond for reports tailored to their needs, which take time and effort away from other priorities. We are not even sure of the value provided once complete." After Stewart provided some advice on how to handle the Sacklers' requests, he added, "You are not alone in receiving requests for extraordinary analyses and reports."

- e. In February 2011, after Gasdia provided information to the Board regarding sales of Butrans (another opioid) compared to forecasts at Richard's request, Richard responded, "I had hoped for better results." A couple weeks later, Richard Sackler asked members of management, "What do I have to do to get a weekly report on Butrans sales without having to ask for it?" The following week, after Gasdia provided the weekly sales report that Richard requested, Richard asked Gasdia individually, "What else more can we do to energize the sales and grow at a faster rate?" Less than a week later, in response to another weekly sales report regarding Butrans sales, Richard inquired with Gasdia about the performance of a specific salesperson located in Palm Beach.
- f. In June 2011, Richard even joined sales representatives on physician sales calls in order to help the Sackler Defendants "get a sense of" what "impacts prescribing behavior" and gain "a more detailed analysis of 'where' the prescription uptake is great, and where it is poor," including "which district, which region, which types of prescribers, which types of practices etc." affected prescribing behavior—even though in private, Purdue management was wary of the "potential compliance risk" that this posed. As discussed below, Purdue's policy of targeting abnormally high-volume OxyContin prescribers for intensive marketing—enthusiastically endorsed by the Sackler Defendants—is at the heart of the criminal conduct to which Purdue confessed, and is closely related to the Sackler civil settlement they reached with the DOJ in 2020.
- g. In February 2012, Mortimer Sackler Jr. intervened on the timing of Purdue's annual sales meeting, arguing that Purdue should "not plan the national sales meeting" after "the winter break as it extends the period of time since the doctor[s] last saw our rep." As a result, Mortimer Sackler Jr. was accused by lower-level sales managers of "micromanagement beyond belief."
- h. In March 2012, after Richard was provided with a report regarding sales of Butrans, Richard remarked, "This is bad," and asked a marketing executive to make edits to the report. Gasdia forwarded the email to Stewart, writing, "This is taking a lot of David's energy, almost every day. . . . It isn't constructive to spend too much time on this as opposed to expending energy within my department of identifying the problem, developing the solutions and gaining implementation. Anything you can do to reduce the direct contact of Richard into the organization is appreciated."
- i. In 2013, Baker reported that during "a recent conversation with Dr. Richard, he outlined what he would tell [incoming CEO] Mark [Timney] he had to do to do [sic] with the US business in the short run," despite Baker imploring Richard "to leave the new executive to consider and make recommendations to the board without prior direction."

- In June 2014, after Richard posed questions to then-CEO Timney and j. Saeed Motahari, a new sales executive, aimed at boosting sales of Butrans, Timney cautioned that it was "a little early" to be pushing Motahari since he was "only 2 weeks into the role." Seemingly disregarding Timney's words of caution, Richard responded, "I'm looking for the difficult task of changing the trajectory very significantly. What can be done that gives a relaunch a chance?"
- 60. In 2015, MNP's Governance Committee actually drafted a resolution in an attempt to curb the Sackler's meddling. This effort met some resistance and the Governance Committee was unable adopt the measure.
  - C. At the Sacklers' Direction, Purdue Launched OxyContin and Undertook an Aggressive—and Criminal—Marketing Scheme
- 61. Purdue's entry into the opioid market occurred when it acquired a Scottish drug producer in the 1980s.
- 62. In 1996, Purdue launched "OxyContin." The drug was designed to release oxycodone into the user's bloodstream over 12 hours. Because it contained far more oxycodone than comparable "immediate-release" prescription pills OxyContin had enormous potential for abuse. In its original formulation, OxyContin easily could be crushed or dissolved in water to cause the release of all 12 hours' worth of opioids at once, producing an intense high and increasing the risk of overdose and addiction.
- Although oxycodone is substantially more powerful than morphine, the Sacklers 63. sought to ensure that OxyContin would not be limited like morphine to only treating cancer and palliative care. To further this goal, the Sackler Defendants caused the company to engage in improper and illegal marketing campaigns designed to mislead medical professionals and patients. For example, Purdue hired amassed a large sales force to falsely claim that OxyContin could be prescribed safely in high doses for a broad variety of pain ailments, could improve

patients' quality of life, could provide 12 hours of continuous pain relief, and had a lower addiction risk than other opioids.

- 64. The Sackler Defendants were well aware that Purdue was misleading prescribers to achieve higher sales. For example, Richard Sackler and then-CEO Friedman celebrated that Purdue's campaign had succeeded in cementing the mistaken view "held by many physicians, that oxycodone is weaker than morphine."
- 65. From OxyContin's launch, the Sackler Defendants made decisions intended to limit their potential exposure of their misrepresentations concerning the abuse-potential of OxyContin. The Sackler Defendants, for example, deliberately limited Purdue's marketing efforts to states that lacked certain regulations aimed at reducing medically unnecessary prescriptions of controlled substances like opioids.
- 66. As a result, OxyContin prescribing was more than twice as high in states that did not require pharmacists to report Schedule II prescriptions to a state-monitoring agency than the ones that did have such a requirement.
- 67. The National Bureau of Economic Research published a working paper and concluded had non-reporting states implemented a reporting regime at the time OxyContin had launched, there would have had an average of 36% fewer drug overdose deaths and 44% fewer opioid overdose deaths in those states between 1996 and 2017.
- 68. Purdue regularly distributed "educational materials" that made misleading statements to physicians across the country. For example, in a pamphlet entitled Providing Relief, Preventing Abuse: A Reference Guide to Controlled Substance Prescribing Practices, Purdue stated that addiction "is not caused by drugs." Another entitled Resource Guide for People with Pain, Purdue stated that, when properly prescribed and taken as directed, opioids do

not lead to addiction or cause a "high." The materials were distributed under the Sacklers' watchful eyes even though they knew of the high potential for abuse.

- 69. Purdue also paid high profile physicians it identified as "Key Opinion Leaders" and purportedly "independent" third-party organizations to promote misinformation about the benefits and safety of OxyContin. Purdue also ran a shadow campaign through unbranded websites to achieve the same objectives.
- 70. Purdue exercised significant direct control over the non-profit American Pain Foundation, an organization that depended entirely on incoming grants from (and was controlled by) pharmaceutical companies such as Purdue. The American Pain Foundation assisted with the design and promotion of the website for Partners Against Pain, which reached nearly 39 million people "with key messages about pain and overcoming barriers to treatment through print, television, radio, and online placements as a part of Purdue's local market media outreach grant."
- 71. Additionally, the American Pain Foundation established the Pain Care Forum in 2004 to "promote and support taking collaborative action regarding federal pain policy issues." Despite this admirable aim, the Pain Care Forum actually frustrated legislative, regulatory, and educational measures aimed at mitigating the opioid crisis.
- 72. Purdue also exercised control over the American Academy of Pain Medicine and the American Society, which Purdue paid millions of dollars to help fund. Each of these entities worked on behalf of Purdue to increase opioid prescribing.
- 73. As a result of Purdue's multi-pronged approach, OxyContin generated \$3.5 billion in revenue for Purdue between 1996 to 2001 and almost immediately accounted for 90% of the company's sales.

- 74. This uncontrolled growth, spurred on by Purdue's illegal marketing practices, led to a flood of medically inappropriate and unnecessary prescriptions, which then caused significant overdose deaths and addiction in others.
- 75. The resulting government investigations concluded in a series of settlements with Purdue in 2007 where it confessed to criminal misconduct. In May 2007, Purdue Frederick and its top three executives—CEO Friedman, General Counsel Howard Udell, and former Chief Medical Officer Goldenheim—entered into the 2007 DOJ Criminal Plea and Settlement and pled guilty to criminal misdemeanor charges of misbranding OxyContin. In entering the agreement, the DOJ noted, among other things, that (a) Purdue had falsely marketed OxyContin as a "miracle drug—a low risk drug that could provide long acting pain relief but was less addictive and less subject to abuse"; (b) OxyContin had become "the new pain medication of choice for many doctors and patients" due to Purdue's "aggressive marketing campaign"; (c) sales for OxyContin had "skyrocketed— making billions for Purdue and millions for its top executives"; (d) "Purdue's claims that OxyContin was less addictive and less subject to abuse and diversion were false—and Purdue knew its claims were false"; and (e) "OxyContin is nothing more than pure oxycodone—a habit forming narcotic derived from the opium poppy."
- 76. In connection with its 2007 plea agreement, Purdue admitted to criminal misbranding of OxyContin by making false and misleading statements for use in distribution and sale of the drug. Among other things, Purdue admitted that, "with intent to defraud or mislead," it falsely claimed that OxyContin was "less addictive, less subject to abuse and diversion and less likely to cause tolerance and withdrawal than other pain medications." Purdue paid a settlement of \$600 million—at the time, the largest a pharmaceutical company had ever paid—consisting of criminal and civil penalties, fines, and forfeitures, and its three executives paid an additional

\$34.5 million (which was reimbursed by Purdue). In connection with the 2007 DOJ Criminal Plea and Settlement, Purdue admitted that it had illegally promoted OxyContin and trained sales representatives to misrepresent the risks of OxyContin. As the plea agreement plainly stated, "Purdue is pleading guilty as described above because Purdue is in fact guilty."

- 77. Purdue also entered into agreements with multiple state governments in connection with the 2007 DOJ Criminal Plea and Settlement. First, a number of states entered into settlement agreements with Purdue Frederick resolving certain Medicaid-related claims for \$59.4 million (collectively, the "Medicaid Settlements"). Separately, Purdue entered into consent judgments with 26 states and the District of Columbia concerning their Medicaid programs or, in some cases, investigations of claims arising under their respective consumer protection laws during the covered period (from 1995 to 2005) (together with the Medicaid Settlements, the "State Released Claims").
- 78. These settlements did not release any other state claims against Purdue or claims that may have arisen in any other periods.
  - D. Following Purdue's Pre-2008 Settlements, It Continued to Engage in Similar **Unlawful Tactics**
- 79. In the wake of settlings for its pre-2008 actions, Purdue later admitted that its crime spree resumed in May 2007, the same month it entered into its last guilty plea. As became clear through further investigation, the Sackler Defendants' and Purdue's efforts to increase OxyContin resumed using the same types of unlawful strategies.
- 80. In 2007, the Sacklers were specifically aware that profits and other assets held at Purdue were vulnerable to litigation and that OxyContin's patent protection would expire. At this time, the Sackler Defendants began considering strategies to effectively extend OxyContin's exclusivity and retained outside consultants to help "turbocharge" OxyContin sales.

- 81. These continued efforts would eventually lead to Purdue pleading guilty to multiple charges in October 2020. In the 2020 Purdue-DOJ Plea Agreement, Purdue admitted to a three-count felony information and agreed to a criminal fine of \$3.544 billion and an additional \$2 billion in criminal forfeitures. Purdue admitted it was guilty of engaging in a (1) conspiracy to defraud the United States and to violate the Federal Food, Drug, and Cosmetic Act, including by continuing to market opioids to healthcare providers ("providers," "doctors," and "HCPs") despite having information showing that such providers were prescribing opioids without a legitimate medical purpose; (2) conspiracy to violate the Federal Anti-Kickback Statute through improper payments to doctors; and (3) conspiracy to violate the Federal Anti-Kickback Statute related to Purdue's payments to Practice Fusion Inc. ("Practice Fusion"), a cloud-based electronic health records organization.
- 82. The 2020 Purdue-DOJ Plea Agreement set forth the following counts to which Purdue stipulated and agreed:
  - a. "Purdue knowingly and intentionally conspired and agreed with others to defraud the DEA by impeding its lawful governmental functions and rights by: failing to maintain effective controls against diversion in that, with respect to more than one hundred HCPs, including ten of the HCPs the United States has identified for Purdue in the course of plea negotiations, Purdue, inter alia, failed to: (1) report and provide complete and accurate information to DEA about HCPs after the HCPs were flagged by internal anti-diversion programs, in situations in which the Company possessed sufficient information that should have led to a report; and (2) cease detailing HCPs after receiving information suggesting that those HCPs were prescribing opioid products without a legitimate medical purpose and outside the usual course of professional practice, in situations in which Purdue possessed sufficient information that a decision should have been made to cease detailing. Moreover, Purdue knowingly and intentionally conspired and agreed with others to impede the lawful function of the DEA by failing to account for potential downstream diversion of its products in reporting sales numbers to DEA as part of its quota requests."
  - b. "Purdue knowingly and intentionally conspired and agreed with others to aid and abet HCPs' dispensing, without a legitimate medical purpose and outside the usual course of professional practice (and thus without a valid

- prescription), prescription drugs held for sale after shipment in interstate commerce, thereby rendering the dispensed drugs misbranded in violation of the Federal Food, Drug, and Cosmetic Act."
- Purdue "knowingly and willfully offer[ed] payments in the form of c. speakers fees and other payments (e.g., travel, lodging, consulting fees) to two HCPs with at least one purpose to induce those HCPs to write more prescriptions of Purdue opioid products, for which payment was made in whole or in part under a Federal healthcare program."
- d. Certain "remuneration paid by Purdue to Practice Fusion was done in return for Practice Fusion including in its [electronic health records] platform" an alert to prompt HCPs to conduct pain assessments in order to influence prescriptions of Purdue's opioid products, "portions of which were paid for by federal health care programs, in violation of the Anti-Kickback Statute. . . . Purdue and Practice Fusion's agreement was a conspiracy to violate the Anti- Kickback Statute."
- 83. Also in October 2020, Purdue and the Sacklers entered into separate settlement agreements with the DOJ resolving certain civil claims against them based on their misconduct in connection with their marketing and sale of opioids following the Pre-2008 DOJ/State Resolutions. Purdue agreed to a \$2.8 billion civil settlement to resolve its civil liability under the False Claims Act. Additionally, the Sacklers agreed to pay another \$225 million to resolve False Claims Act claims against Richard Sackler, David Sackler, Mortimer Sackler Jr., Kathe Sackler, and the Estate of Jonathan Sackler (collectively referred to as the "Named Sacklers").
- 84. Through these agreements, the DOJ concluded that the Board, and the Sackler Defendants in particular, orchestrated, implemented, and micromanaged an aggressive marketing scheme that, among other things, targeted high "decile" HCPs and pharmacies that dispensed opioids at an alarmingly high rate, and at the same time failed to satisfy its anti-diversion and SOM obligations under federal law.

- Ε. Purdue Knowingly Employed Improper Sales and Marketing Tactics That Resulted in Staggering Numbers of Medically Unnecessary Prescriptions
  - 1. Purdue Continued to Detail Suspicious HCPs and Pharmacies and Provide "Speaker Fees" to High-Prescribing HCPs, All of Which Caused Them to Prescribe and Dispense More of Purdue's Opioids than Were Medically Necessary
- 85. Under the CSA, opioid manufacturers such as Purdue are required to monitor, flag, and report any suspected abuse and diversion of their opioid products. Rather than flag suspected abuse and diversion, Purdue continued to make sales calls on, or "detail," a significant number of prescribers whom it suspected were involved in the abuse and diversion of its products.
- 86. Even after pleading guilty in 2007, Purdue continued to detail providers with suspicious prescribing habits with the aim of promoting Purdue's opioid products.
- 87. In October 2010, at a presentation to Purdue's sales supervisors, a Purdue executive explained: "As I have stated several times, we know increases in the prescriber call average will have the single largest impact of anything you can do to increase prescriptions of Purdue products with our core and super core prescribers." The Sackler Defendants knew of the connection between detailing providers and prescriptions. The Sackler Defendants routinely received ROI analyses demonstrating that Purdue's efforts to detail providers materially increased OxyContin prescriptions.
- 88. Purdue also implemented a savings card program where its sales representatives provided doctors with savings cards to defray the costs of Purdue opioid prescriptions. This program was a key component of Purdue's strategy for prolonging patients' use of OxyContin. Purdue's internal analyses showed that (a) patients who redeemed savings cards stayed on OxyContin longer; and (b) the use of savings cards led more providers to prescribe OxyContin.

- 89. Likewise, Purdue's sales representatives regularly provided physicians, and their patients, with coupons that patients could redeem for a week to a month supply of free OxyContin, with the promise that it was generally safe and useful to treat a variety of non-cancer pain conditions. Purdue specifically "trained its sales representatives to carry the message that the risk of addiction was 'less than one percent,'" and "[a] consistent feature in the promotion and marketing of OxyContin was a systematic effort to minimize the risk of addiction in the use of opioids for the treatment of chronic non-cancer-related pain." Purdue's free product coupons were distributed in and redeemed in West Virginia and throughout the United States resulting in medically unnecessary treatment for patients suffering from common pain.
- 90. Purdue also organized speaker programs in which it "recruited and paid HCPs to educate other HCPs about Purdue opioid products." Drug manufacturers are prohibited from sponsoring speaker programs if, among other things, the program involves kickbacks or otherwise incentivizes fraud and abuse, such as payments made to induce the speaker to write additional prescriptions. In the 2020 settlement, Purdue admitted that it offered payments in the form of speaker fees and other payments to providers "with at least one purpose to induce those HCPs to write more prescriptions of Purdue opioid products."

# 2. By Targeting High-Decile Prescribers, Purdue Turned Its Professed Anti- Diversion Strategy on Its Head

91. Purdue's ADD Program was meant to be in place from 2002 to 2018 and was to give Purdue the ability to identify prescribers engaged in abuse and diversion. For much of that time, the ADD Program was governed by Purdue's Standard Operating Procedure ("SOP") 1.7.1, which was supposed to minimize improper prescribing of opioids by requiring Purdue personnel to report any HCP engaged in certain kinds of suspicious activity, including when an HCP was engaged "in an atypical pattern of prescribing."

- 92. These "ADD Reports" were meant to be reviewed by senior Purdue employees to consider whether such providers were enabling the diversion of opioids. Among other things, Purdue was to determine whether such HCPs should be placed on the so-called Region Zero (i.e., "do not call") list.
- 93. Instead, Purdue functionally used one of the primary "red flags" under its SOP 1.7.1 as a marketing list to drive opioid sales. Under the Sackler Defendants' direction, Purdue deliberately identified providers who were prone to prescribing OxyContin at higher rates.
- 94. Through its systematic efforts, Purdue learned that high-prescribing doctors were the most responsive to the practice of provider detailing. A July 2012 Purdue PowerPoint entitled "OxyContin Marketing Mix Modeling Result," included a chart showing a clear correlation between deciles and the impact of detailing. Extreme high-volume prescribers (top 40%) were the most responsive to detailing—with the top 20% demonstrating the greatest level responsiveness to Purdue's marketing push.
- 95. Purdue's Board and the Sackler Defendants were well aware of the Company's improper detailing strategy and its impact on OxyContin sales. In October 2012, Mahony emailed the Board a "Sales & Marketing" presentation that highlighted why Purdue focused on targeting high-decile prescribers: "OxyContin is still promotionally sensitive to sales calls. For every \$1 spent on a decile 7-10 HCP, an[] average of \$3.70 is returned."
  - F. The Sackler Defendants Failed to Ensure That Purdue Met Its Legal **Obligations to Maintain Effective Diversion Controls**
- 96. While pressing Purdue's unlawful marketing campaign, the Sackler Defendants failed to prevent opioid diversion into illegal drug markets. As a result, during relevant times, millions of OxyContin pills have been diverted into illegal channels where they fueled a crisis of

abuse of, and addiction to, illegally dispensed opioids, compounding the crisis of abuse and addiction in patients using legally dispensed opioids.

- 97. While under the Sackler Defendants' control, Purdue admitted that it violated its duties under the CSA and related DEA regulations. These duties required Purdue to maintain effective controls against the diversion of its opioid products into illegal drug markets, including by maintaining a SOM system able to (i) identify wholesaler and pharmacy orders that indicated a risk of diversion due to some irregularity in size, frequency, or pattern—so-called "suspicious orders"—and (ii) report suspicious orders to the DEA when they were identified. Purdue failed to maintain such controls—and, indeed, actually encouraged suspicious orders in order to increase sales of its opioid products.
- 98. While Purdue maintained certain SOM systems and a semblance of an ADD Program, its programs failed to control diversion of its opioid products and did not meet its legal obligations. In addition, Purdue's Order Monitoring System Committee (previously defined as the "OMS Committee")—which was nominally responsible for Purdue's SOM operations for more than eight years between March 2009 and September 2017 failed to report numerous suspicious orders to the DEA despite clear evidence of diversion.
- 99. Purdue's ADD Program failed to report countless diversion-prone prescribers to authorities and, in many cases, the company permitted and even encouraged sales representatives to continue promoting opioid products to these prescribers.

# 1. Purdue's Anti-Diversion and SOM Duties under the CSA and Corresponding DEA Regulations

100. The CSA regulates the manufacturing, distribution, and use of substances that may have a detrimental effect on public health and welfare. Under 21 U.S.C. § 841(a)(1), it is illegal to manufacture a controlled substance except where an individual or entity is expressly

authorized to "possess, manufacture, distribute, or dispense [controlled] substances . . . in conformity with the other provisions" of the CSA. This express authority comes in the form of DEA licensure and is required for doctors, pharmacists, manufacturers, distributors, and other practitioners to prescribe or otherwise handle controlled substances, including opioids. As a manufacturer of opioids, Purdue was required to be a DEA registrant.

- 101. Under 21 U.S.C. § 823(b)(1), DEA registrants have a general duty to maintain "effective control[s] against the diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." In other words, DEA registrants must act to prevent the diversion of controlled substances into illegal drug markets. Additionally, under 21 C.F.R. § 1301.74(b), DEA registrants have a specific duty to "design and operate a system to disclose . . . suspicious orders of controlled substances" and "inform the Field Division Office of the [DEA] in [the relevant area] of suspicious orders when discovered."
- 102. As defined in 21 C.F.R. § 1301.74(b), "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." Under 21 U.S.C. § 842(c)(B)(ii), each violation "related to the reporting of suspicious orders for opioids" or "failing to maintain effective controls against diversion of opioids" is subject to a civil penalty of as much as \$100,000. Under 21 U.S.C. § 842(c)(D), each violation "that relates to the reporting of suspicious orders for opioids" or "failing to maintain effective controls against diversion of opioids" is subject to a criminal fine of as much as \$500,000.
- 103. On September 27, 2006, the DEA issued the first (the "2006 SOM Letter") of a series of general guidance letters (the "SOM Letters") explaining that the reporting requirement set forth in 21 C.F.R. § 1301.74(b) is "in addition to, and not in lieu of, the general requirement

under [the CSA] that a [DEA registrant] maintain effective controls against diversion." This has been widely interpreted—critically, by the DEA itself—as requiring opioid manufacturers to monitor not only their own customers—*i.e.*, the wholesalers that purchase products directly from the manufacturers—but also their customers' customers—*i.e.*, the pharmacies and retailers that purchase the manufacturers' products from the wholesalers—to inhibit the so-called "downstream distribution" of opioids. Indeed, the 2006 SOM Letter sets forth a list of ten questions for a manufacturer or distributor to pose to a pharmacy in order "to determine whether a suspicious order is indicative of diversion of controlled substances to other than legitimate medical channels."

- 104. Thus, under the CSA and relevant DEA regulations, Purdue had legal obligations not only to report suspicious orders, but also to ensure that it maintained systems capable of preventing actual diversion of its drugs. Purdue understood this very well. The company's standing operating procedure titled GC-SOP-0007 (Order Management System) mirrored the language of C.F.R. § 1301, 74(b) and the guidance set forth in the 2006 SOM Letter, explaining, "As a DEA registrant, Purdue is charged with maintaining effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels," and "recognizes that pertinent regulations require that registrants inform the local DEA Field Division Office of suspicious orders when discovered by the registrant (21 CFR § 1301.74(b))."
- 105. Purdue was aware of and understood its legal duties to monitor wholesalers and pharmacies to ensure that it was not shipping orders that could be diverted downstream. Pursuant to GC-SOP- 0007, Purdue recognized that its regulatory obligations "include[d] reasonable efforts to 'know our customers' as well as aiding in the efforts of our distributors to ensure that they take reasonable steps to 'know their customers.'"

- C.F.R. § 1301.74(b) is individual, not joint, and so a manufacturer may not decline to report a suspicious order to the DEA simply because it expects that a wholesaler will do so. Again, Purdue's GC-SOP-0007 memorialized this obligation, stating, "We recognize as a manufacturer and distributor we may not simply rely on the fact that the person placing the order is a DEA registrant and fail to scrutinize what may be suspicious circumstances. Rather we must exercise due care in confirming the legitimacy of all orders prior to filling." Despite understanding its individual reporting obligation, Purdue routinely failed to report suspicious orders made by pharmacies, supposedly because Purdue expected that wholesalers would do so instead. Each time Purdue deferred to wholesalers in this way, it violated its obligation under 21 C.F.R. § 1301.74(b) to report suspicious orders "when discovered."
- 107. The 2006 SOM Letter also identifies "circumstances that might be indicative of diversion" and instructs DEA registrants not to rely on any single factor or subset of factors when evaluating orders but instead to "consider the totality of the circumstances when evaluating an order for controlled substances, just as DEA will do when determining whether the filling of an order is consistent with the public interest within the meaning of 21 U.S.C. § 823(e)." As described in further detail in the section that follows, Purdue did not abide by this guidance, as its OMS relied on rigid algorithms to detect possible suspicious orders for review and follow-up, and failed to consider the "totality of the circumstances" when evaluating orders.
- 108. The DEA issued another guidance letter on December 27, 2007 (the "2007 SOM Letter"), after the Pre-2008 DOJ/State Resolutions, that further explained its interpretation of 21 U.S.C. § 823(b)(1) and 21 C.F.R. § 1301.74(b). As the 2007 SOM Letter states, DEA registrants must "inform the local DEA Division Office of suspicious orders when discovered," and so

periodic reports of completed transactions involving suspicious orders are inadequate. As noted above and explained in detail below, Purdue violated this requirement whenever it deferred to wholesalers to report suspicious pharmacy orders. Moreover, Purdue arguably failed to satisfy this reporting requirement by definition because its practice was to investigate orders that were flagged as suspicious and then, only after failing to eliminate the suspicion, report to the DEA.

109. The 2007 SOM Letter also discusses the definition of "suspicious order" stated in 21 C.F.R. § 1301.74(b) and clarifies the practical significance of that definition. As the 2007 SOM Letter states, the elements of a "suspicious order" set forth in 21 C.F.R. § 1301.74(b)—"orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency"—are "disjunctive" and "not all inclusive." Thus, "if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious." Similarly, the size of an order alone, whether or not it deviates from a normal pattern, is "enough to trigger the responsibility to report the order as suspicious." For these reasons, the 2007 SOM Letter warns DEA registrants not to rely on "rigid formulas to define whether an order is suspicious" due to the risk that such formulas may fail "to detect suspicious orders."

110. Purdue's SOM operations violated the plain meaning of 21 U.S.C. § 823(b)(1) and 21 C.F.R. § 1301.74(b) and flouted the explicit guidance provided by the DEA in the SOM Letters. Among other things, Purdue's SOM systems relied on rigid algorithms that were divorced from the DEA's definition of "suspicious order," failed to report suspicious orders and suspicious activity generally when discovered, unlawfully relied on wholesalers to report suspicious orders in violation of Purdue's individual obligations to report such orders, and failed to fulfill Purdue's legal obligation to prevent diversion.

# 2. Purdue's SOM Systems

- 111. In essence, Purdue maintained two largely parallel SOM systems. One of these systems monitored wholesaler orders (the "Wholesaler SOM"), while the other monitored pharmacy orders (the "Pharmacy SOM"). The procedures of each system, and the various iterations of each, were established under a specific SOP or a collection of SOPs.
- 112. An outside consultant with expertise in CSA compliance audited Purdue's SOM systems in 2016 (the "SOM Audit"). The compliance consultant criticized Purdue's wholesaler and pharmacy SOM systems. Based on its findings, the compliance consultant recommended that Purdue overhaul these systems substantially to enable Purdue to comply with its duties under 21 U.S.C. § 823(b)(1) and 21 C.F.R. § 1301.74(b). "At a high level," the SOM Audit "found that the firm's SOM activities are at times poorly organized, fragmented and difficult to understand."
- other things, Purdue's SOP 7.7, which was published to monitor suspicious wholesaler orders, charged Customer Service Representatives ("CSRs") with identifying suspicious orders from wholesalers in the first instance. This created an inherent conflict of interest, because CSRs were compensated based on the volume of opioids that they sold, and therefore CSRs' primary function and concern was to fill orders—not to investigate and, if necessary, stop suspicious orders, as required under SOP 7.7. In addition, CSRs lacked sufficient training to discharge their SOM responsibilities adequately and were provided with stale empirical data that prevented them from identifying suspicious orders until "well after the shipment."
- 114. Even when a CSR managed to identify a suspicious order, the order would then have to undergo several additional levels of review before it was finally recognized by Purdue as a "suspicious order" for purposes of 21 C.F.R. § 1301.74(b) and reported to the DEA, and thus was not reported when discovered. The teams that were tasked with monitoring and reviewing

suspicious orders were woefully understaffed, as evidenced by the fact that Purdue tasked only three employees with reviewing possible suspicious orders made by Purdue's three largest wholesalers—Cardinal, McKesson, and AmerisourceBergen.

- 115. Purdue did not maintain a SOM system to monitor orders for generic opioid products manufactured and distributed by Rhodes, Purdue's affiliate. Indeed, at the time of the SOM Audit, Purdue staff reported to the compliance consultant that there was "no electronic analysis of orders" submitted to Rhodes, that staff "perform[ed] manual calculations . . . to look for suspicious orders," and that "no [Rhodes] order has ever been reported to the DEA."
- 116. In addition, the SOM Audit found that its Wholesaler SOM was deficient because it relied on rigid computer algorithms to identify possible suspicious orders in the first instance. Specifically, these algorithms were largely based on order volume and would flag an order for follow-up if it was either 33% or 50% over the wholesaler's average. The SOM Audit found that these rigid thresholds were "arbitrary in nature," "penalize[d] all small wholesalers" that submitted orders in lower quantities than the big three wholesalers, were "not appropriate given Purdue's disparate customer base," and did "not provide Purdue with the ability to track the deviation from normal ordering trends." Moreover, the algorithm did not track either a change in order frequency or any significant deviation from normal patterns even though these "two specific factors [were] identified in the regulatory definition of a suspicious order." Thus, by definition, Purdue's Wholesaler SOM was not equipped to flag categories of "suspicious orders" explicitly set forth in 21 C.F.R. § 1301.74(b). As a result, Purdue's Wholesaler SOM system was woefully insufficient to meet Purdue's legal obligations under the CSA.
- 117. The SOM Audit identified similar shortcomings in Purdue's Pharmacy SOM. GC-SOP-0007 established an OMS Committee to oversee Purdue's SOM operations and empowered

the OMS Committee to decide when to report pharmacies or pharmacy orders to the DEA as suspicious. However, the OMS Committee routinely deferred to wholesalers to make this decision. This practice was deficient for several reasons. First, Purdue failed to satisfy its individual affirmative duty to report suspicious orders to the DEA itself rather than rely on other DEA registrants to do so. Purdue's unlawful deference was particularly egregious because Purdue knew that many of its wholesalers themselves lacked adequate order monitoring systems or otherwise could not be trusted to provide complete and accurate information about their customers' (*i.e.*, pharmacies') orders.

- 118. Purdue also failed to report pharmacies to the DEA when suspicious orders were discovered, which is an express requirement under 21 C.F.R. § 13.01.74(b) and was reiterated explicitly in the SOM Letters. Instead, Purdue allowed the pharmacies to go unreported while waiting to confer with the pharmacy's wholesaler. Third, multiple wholesalers did not enter into any Fee for Service Agreements ("FFSAs") with Purdue, which meant that Purdue did not have access to "chargeback data" necessary for it to evaluate pharmacy orders submitted to those wholesalers. With respect to pharmacies that were customers of wholesalers without FFSAs, by definition, Purdue lacked the information necessary to monitor their orders in clear violation of Purdue's SOM duties under 21 C.F.R. § 1301.74(b).
- 119. Moreover, Purdue knew that wholesalers and pharmacies were financially incentivized to ensure that the gusher of opioid sales continued unabated and should not be relied on to provide complete and accurate suspicious order reporting. Indeed, Purdue actively and knowingly worked with these wholesalers and pharmacies to maximize sales of Purdue's opioid products. As examples, Purdue worked with CVS, Walgreens, and Rite Aid to exaggerate the

benefits of OxyContin, downplay its risks, and train pharmacists (using Purdue-designed continuing education programs) to ignore red flags for diversion and abuse.

- 120. In addition, even when the OMS Committee met periodically to discuss reports concerning distributors and pharmacies whose orders or other behavior indicated a risk of diversion ("OMS Reports"), the OMS Committee failed to ensure that Purdue satisfied its duty to report suspicious pharmacy activity to the DEA.
- 121. Furthermore, in numerous cases, while the OMS Committee waited to confer with a wholesaler about reporting a pharmacy to the DEA, the OMS Committee recommended that sales representatives continue promoting opioids to the pharmacy.
- 122. Finally, even though Purdue was responsible for implementing and overseeing SOM systems for Rhodes given Rhodes' manufacture of generic opioids, the SOM Audit found that (i) Rhodes's orders were monitored for suspicious activity manually, which "could be considered arbitrary[,]" (ii) Rhodes does not conduct "any SOM activity relating to 'downstream distribution'" and therefore did not comply with its obligation to monitor and report suspicious orders placed by pharmacies, and (iii) "no [Rhodes] order ha[d] ever been reported" to the DEA.
- 123. Despite Purdue's well-known statutory and regulatory obligations to maintain an effective SOM program, the Board appears to have taken no steps to oversee or establish oversight controls regarding Purdue's SOM systems, let alone any steps to address the manifest failures of these systems.

## 3. Purdue's ADD Program

Program was supposed to "ensure that Purdue's interactions with Prescribers or Pharmacists that reveal observations or circumstances that suggest potential concerns generate appropriate review and follow up," and "preclude promotion of Purdue's opioid products in circumstances where

there is a concern about potential abuse or diversion." The ADD Program failed to achieve these objectives.

- organization, medical science liaisons, and other Purdue employees and contract or third party representatives" to report prescribers and pharmacies suspected of diversion to Purdue's law department "promptly, ideally within 48 hours of when the Reporter learns of a circumstance or makes an observation that may be indicative of potential abuse or diversion." As laid out in SOP 1.7.1, "red flags" that would trigger an obligation to file a report with Purdue's law department included, inter alia, excessive numbers of patients, short patient visits, patients paying HCPs for opioids with cash, unexplained changes in prescribing behavior, patients overdosing, and reports of suspicious activity from pharmacists or law enforcement, among others.
- 126. If the answer was "no," the HCP was required to be placed in "Region Zero"—the "no call" list containing prescribers Purdue suspected of intentionally or recklessly prescribing controlled substances to drug dealers and abusers or otherwise facilitating diversion. In addition, the HCP was required to be reported to appropriate medical, regulatory, or law enforcement authorities (including the DEA) consistent with the ADD Program's parameters and Purdue's regulatory obligations under the CSA. Purdue's Associate General Counsel from 2002 to 2016, Defendant Abrams, once described the law department's decision-making process as "essentially a judgment call," but did not explain exactly how the law department arrived at its decisions.
- 127. Despite the opacity of the decision-making process, it is clear that Purdue and its law department prioritized Purdue's sales performance at the expense of the ADD Program's stated objectives. Even though the ADD Program regularly surfaced alarming information suggesting that prescribers were likely sources of diversion, the law department continued to

allow sales representatives to promote Purdue opioid products to these prescribers rather than place them on the Region Zero list and report them to the DEA and other relevant authorities, as required. Indeed, in some instances where Purdue identified particular "high value" doctors, managers ordered representatives to keep promoting opioids to these doctors even after these representatives warned their supervisors that the doctors were involved in diversion and abuse.

- 128. In other situations, the law department would place a prescriber on the Region Zero list but fail to report them to the DEA even after receiving numerous reports about suspected diversion.
- 129. There are many more examples of Purdue placing a prescriber on the Region Zero list for improper prescribing but deciding not to report the prescriber to the DEA or other authorities. For instance, in response to an information request from the Medical Board of California, Purdue represented that it placed more than 110 California doctors on the Region Zero list through September 2013, in many cases for improper prescribing. Yet, Purdue's response to the Medical Board of California indicates that no more than 20 of these prescribers were actually reported by Purdue to the DEA or other authorities.
- Purdue's own employees acknowledged the failure of Purdue's law department to 130. administer the ADD Program effectively. For example, in March 2013, sales representatives learned that a prescriber named Christopher Huntington had committed suicide after losing his license for improper prescribing of opioids, including OxyContin. Purdue began investigating Huntington in 2011 after sales representatives informed the law department about his suspicious prescribing practices. But the law department decided not to designate Huntington as a Region Zero prescriber or report him to the DEA or other authorities. After learning that Huntington finally had lost his license, sales representatives deflected blame from themselves and criticized

the law department for not taking action. As one sales representative wrote, the law department had "goofed and missed this . . . NOT us. When an HCP is reported to legal and he then has his license taken away . . . it should NOT impact the rep in any way. Legal missed something."

- 131. As part of its drive toward selling as many opioids as possible, Purdue adopted a cavalier attitude toward important regulatory limits designed to crack down on improper prescribing. For example, in 2013, a sales representative complained to her supervisor that she was having issues with a pharmacist being unable to purchase more OxyContin because of a DEA SOP that placed limits on the amount of oxycodone a pharmacy can purchase based on the pharmacy's previous buying patterns. Her supervisor responded by congratulating the representative on selling such high amounts of opioids and instructed the representative that when "customer (prescribers)" express concern about pharmacies being unable to supply OxyContin due to exceeding the DEA limit, representatives should tell the prescriber that their patient "will simply need to fill the RX at another store."
- department not only failed to report prescribers suspected of diversion and abuse to the appropriate authorities but also continued to allow Purdue to promote them. The Board did nothing to address the law department's shortcomings. For example, at the July 2010 Board meeting, the Board asked staff about opioid sales and revenue generated by doctors on the Region Zero list and was assured that prescription information existed at the doctor level (indeed, prescription level), and that data was then shared with the Board. The Board also was given a list of the problem prescribers by name, along with the exact number of prescriptions and dollars of revenue each prescriber's practice provided to Purdue. Despite possessing this wealth of knowledge of suspected abuse and diversion, the Board did not halt the promotion of Purdue's

products to these problematic prescribers and failed to ensure the prescribers were reported to the DEA. Nor did they ensure proper response by management.

- 133. The Board knew that Region Zero prescribers accounted for a meaningful portion of Purdue's proceeds from OxyContin. For example, in March 2011, staff told the Board that if Region Zero doctors stopped prescribing opioids, Purdue would lose almost 10% of its sales. By failing to report Region Zero prescribers to authorities, the Sackler-dominated Board ensured that revenue generated by such suspect prescribers would continue to flow, and that the Sackler Defendants would continue to profit from their non-medically necessary prescriptions.
- 134. Unsurprisingly, a number of Region Zero prescribers ultimately lost their licenses or were criminally convicted for improper opioid prescribing. By then, Purdue and the Sacklers had collected a vast amount of money from their dangerous prescriptions and poured medically unnecessary opioids into communities around the country. Notably, presumably aware that top prescribers could face liability, Mortimer Sackler Jr. suggested in 2005 that Purdue lobby Congress to shield doctors from liability when prescribing opioids in order to "eliminate doctors needing to play Russian roulette each time they write a prescription for an opioid."
- 135. Despite Purdue's well-known anti-diversion obligations, including and in addition to the obligations arising from the Pre-2008 DOJ/State Resolutions, the Sackler and Non-Sackler Defendants, and the Non-Sackler Officers, took insufficient steps to oversee or establish oversight controls regarding the ADD Program, let alone to address its manifest failures. The Board's failure to take steps to ensure adequate oversight of the ADD Program is especially remarkable given how assiduously they monitored Region Zero sales data and other activity indicating diversion of Purdue's opioid products.

- G. Purdue Desperately Attempted to "Turbocharge" Sales after the Reformulation Made Some Methods of Abuse More Difficult
  - 1. Seeking to Extend Their Monopoly, the Sacklers Reformulated OxyContin and Successfully Lobbied to Have the Original Formula Declared Unsafe
- Defendants spent years coming up with ideas for new products or new formulations of OxyContin in order to preserve Purdue's exclusive OxyContin revenue stream. They reaped the fruits of their labor in April 2010, when Purdue received approval from the U.S. Food and Drug Administration (the "FDA") to begin marketing a reformulated, purportedly abuse-deterrent version of OxyContin ("ADF OxyContin"). ADF OxyContin was more difficult to crush or dissolve for purposes of snorting or injecting. As the FDA warned, however, the reformulation was "not completely tamper-resistant." Moreover, "the product can still be misused or abused and result in overdose by simply administering or ingesting larger than recommended oral doses." The Sacklers remained callously indifferent towards the FDA's concerns of ongoing abuse, even with the new formulation. For example, in May 2008, Jonathan Sackler "joked" about possible ways "abusers" would react to ADF OxyContin, suggesting that "[m]aybe they'll dissolve it in battery acid and pour it into their ears," or "[m]aybe they'll take an ice pick and stab a hole in their sternums and plunge the tablets into their hearts."
- 137. Purdue and the Sackler Defendants maintained close ties to current and former FDA employees as it navigated the regulatory waters surrounding production, marketing, and distribution of opioids. For example, Purdue hired Dr. Curtis Wright in October 1998 upon his retirement a year earlier from the FDA. Dr. Wright was the FDA Medical Officer tasked with reviewing the OxyContin applications submitted by Purdue to the FDA. As part of his review of OxyContin, Dr. Wright concluded that that OxyContin was "as good as current therapy, but has

not been shown to have a significant advantage beyond reduction in frequency of dosing." Based on this, Dr. Wright founds claims that OxyContin was less likely to produce addiction were unsupportable. In his workup, however, Dr. Wright also included two key and misleading statements that became the foundations of Purdue's aggressive marketing campaigns surrounding its opioids. Specifically, these statements were (a) "Delayed absorption. As provided by OxyContin tablets, is believed to reduce the abuse liability of a drug"; and (2) "When the patient no longer requires therapy with OxyContin tablets, patients receiving doses of 20-60 mg/day can usually have the therapy stopped abruptly without incident." There is evidence to suggest that Purdue was directly involved and had a hand in drafting Dr. Wright's approval submission. In March 1995, nine months before OxyContin was approved, a Purdue employee advised a Purdue executive that Dr. Wright "has confirmed that we will receive an APPROVAL letter for OxyContin (NDA 20-553) by the end of December 1995."

138. Incredibly, to extend their monopoly, the Sackler Defendants and Purdue then campaigned to have the original formula for OxyContin deemed unsafe. That's right: despite having aggressively marketed OxyContin in its original form in the United States for fifteen years, and despite continuing to sell OxyContin in its original form in foreign markets, Purdue petitioned the FDA to refuse to accept generic versions of the original formulation because it was too dangerous to be sold in the United States. In April 2013, Purdue's shameless about-face paid off, with the FDA deciding to withdraw the original formulation from the market "for reasons of safety." In a presentation to the Sacklers, Defendant Stewart credited a "company-wide, sustained effort" that "[a]voided what would, in all likelihood, have been a 'patent cliff' event."

- 2. After Reformulation Made Some Forms of Abuse More Challenging, the Sackler Defendants Pushed Management to Fill the Sales Gap
- 139. Following the introduction of the new formulation designed to make it less prone to abuse, Purdue saw a substantial drop in original-formula OxyContin sales. In December 2010, Purdue management informed the Board and the Sackler Defendants that the total weekly kilograms dispensed of branded OxyContin declined from August to November 2010, and that the Region Zero prescribers accounted "for much of the [prescription] decline at the regional level."
- 140. In a June 2011 presentation, Defendant Mahony, Purdue's then-CFO, informed the Board that "[s]ince the transition, 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." The presentation included a revised forecast of projected OxyContin sales for 2011 of \$2.8 billion, down from \$3.9 billion.

  OxyContin sales dropped from \$2.31 billion in 2009 to \$2.26 billion in 2010, then to \$2.1 billion in 2011, and continued to decline thereafter.
- 141. Purdue studied the post-reformulation decline in OxyContin sales and determined that the decline was largely attributable to a reduction in prescriptions written for individuals who abused OxyContin by crushing, and then snorting or injecting the drug. Purdue also conducted post-marketing studies of ADF OxyContin, which showed that the decline in OxyContin prescriptions was most pronounced among high-volume opioid prescribers and 40 mg and 80 mg tablets, Purdue's highest and most profitable dosages that were most popular among those who used the drug for non-medical purposes.
- 142. This sales drop was not celebrated by the Sackler Defendants but instead led to even more aggressive marketing efforts.

- 3. The Sackler Defendants Continued to Press for More Aggressive Sales Targets and Tactics
- 143. The Sackler Defendants focused on increasing sales even with the imminent launch of ADF OxyContin that was approved for sale in April 2010. On January 25, 2010, Richard Sackler emailed the other members of the Board regarding the importance of OxyContin sales, reminding them that "the most important driver of our sales growth or decline is the performance of all the oxycodone extended-release forms in the market (called OER); this is comprised of OxyContin tablets plus all the generics in the space."
- 144. The Sackler Defendants pressured executives to meet aggressive OxyContin sales goals, despite knowing that ADF OxyContin would necessarily lead to decline in sales.
- 145. The 2010 budget prepared by Purdue management pegged OxyContin prescription growth at 3%. Richard Sackler felt that 3% growth was unacceptably low and would "lead to an OxyContin[] tablets forecast that is almost the same as our sales in 2009." Then-CEO Stewart informed Richard that more significant growth was unrealistic: "I know that you have been advocating for an increase in the top line, but in looking at the recent OER prescription growth trends and knowing the overall dynamics of the market OxyContin competes in I just can't see a way of the prescription growth tracking to a level substantially higher than the 3% on which this budget is based." Stewart stressed to Richard that the higher target Richard wanted would "be interpreted as an imposition as opposed to an action that will stimulate the type of business building behaviors we want to encourage."
- 146. Unsatisfied with Stewart's response, Richard Sackler replied, "I'm disappointed and don't agree with you. This is a matter that the Board will have to take up and give you a settled direction." While management targeted 3% growth, Richard Sackler was convinced that

growth of up to 12% was reasonable. Mortimer Sackler Jr. followed up with Theresa Sackler regarding Richard's email, stating, "we should push management to agree to a higher target."

- beginning in 2010 was attributable to reduced diversion due to the reformulation, they nevertheless continued to insist that Purdue work to recapture the lost medically unnecessary sales. In April 2012, Richard Sackler emailed Russell Gasdia, Purdue's head of sales, writing, "We should . . . discuss the sudden decline in [OxyContin] sales in the past year or two. What are we doing to identify corrective actions?" The following day, Purdue's Vice President of Sales forwarded Richard Sackler's email to Purdue's CEO, among others, stating, "I am surprised that Dr. Richard is asking this . . . Since the decline is related to reformulation I'm not sure how to proceed with him."
- leadership. On July 17, 2012, he emailed Board members to discuss a "search asap for a new CEO." He also suggested that they consider "replacing the head of sales and marketing." In October 2013, Mortimer Sackler Jr. requested additional data concerning the downward trend in sales by dosage, including a chart that "show[s] the breakdown of OxyContin market share by strength against competitors. I would like to understand more the recent dynamics of the market and where the patients are shifting to that we are losing." Later that same day, responses to his questions explained that the loss of sales was due to "the recent dynamics of the market," the pressures of increased government regulation, and "fewer patients titrating to the higher strengths from the lower ones." Ultimately, Mortimer Sackler Jr. exclaimed that it "[s]eems like the organization has just fully given up" and that the Sackler Defendants "would be better off laying everyone off and milking the business than doing this!"

# 4. Purdue Engaged Consultants to "Turbocharge" OxyContin Sales

- 149. In 2013, hoping to make up for lost black market sales following the introduction of ADF OxyContin, Purdue hired McKinsey to help "turbocharge" sales. McKinsey ultimately agreed to resolve criminal proceedings with a \$650 million settlement with the DOJ.
- 150. McKinsey was first retained by Purdue in 2004 to provide consulting services, including analyses focused on assessing the abuse potential of OxyContin, and adverse reports resulting from the use of OxyContin. In February 2009, McKinsey drafted a PowerPoint for Purdue entitled "Evaluating Abuse Potential: Risk Mitigation in Developing Products for Pain Management," and one of its core findings was that OxyContin was a "perfect storm" for abuse potential.
- 151. In June 2009, McKinsey drafted a PowerPoint regarding "[p]hysician survey results," which found that opioids were "the leading source of abuse and diversion issues for physicians." Less than two weeks later, McKinsey presented a strategy to Purdue called "OxyContin: Driving Growth Through Stronger Brand Loyalty," which analyzed drivers of prescription decline and sensitivity to detailing and used that prescriber-level detail to devise ways that Purdue could increase brand loyalty to OxyContin, even though its prior analyses had shown the drug was one of the opioids of "greatest concern."
- 152. McKinsey continued to develop strategies focused on increasing OxyContin prescriptions throughout 2009. Among other things, McKinsey recommended convincing doctors that opioids provide "freedom" and "peace of mind" and give patients "the best possible chance to live a full and active life." At a Purdue Steering Committee meeting, McKinsey recommended that Purdue use "messages and tactics" that would increase sales among "loyalist prescribers and 'fence sitters.'"

- 153. As OxyContin sales predictably fell following the introduction of ADF OxyContin, the Sackler Defendants turned to McKinsey for help. On or around May 25, 2013, Richard Sackler had a call with a senior executive from McKinsey and, three days later, Purdue entered into another contract with McKinsey to "conduct a rapid assessment of the underlying drivers of current OxyContin performance, identify key opportunities to increase near-term OxyContin performance, and build plans to capture priority opportunities."
- and that "this downshift primarily reflects reduced demand among abusers for the new abuseresistant formulation." McKinsey also highlighted the "intense scrutiny" faced by "[t]he retail
  channel, both pharmacies and distributors," as an impediment to opioid sales. McKinsey
  explained that "[t]here are reports of wholesalers stopping shipments entirely to an increasing
  number of pharmacies," that "[m]any wholesalers are also imposing hard quantity limits on
  orders based on prior purchase levels," and that "[p]harmacy chains are implementing guidelines
  for which patients can fill opioid prescriptions." McKinsey identified these policies to address
  mass opioid abuse as obstacles that Purdue and the Sackler Defendants would need to overcome
  in their desire to boost sales of OxyContin. McKinsey concluded that, "despite strong trends that
  may be making the opioid marketplace challenging for the foreseeable future," its findings
  indicated that "there [was] significant opportunity to improve OxyContin performance" and that
  "OxyContin remain[ed] quite promotionally sensitive." McKinsey encouraged Purdue to
  "aggressively seize these opportunities and begin action immediately."
- 155. Despite clear indications of abuse and diversion, McKinsey recommended that Purdue take actions to "Turbocharge Purdue's Sales Engine" by focusing sales efforts on doctors who were highly inclined to prescribe OxyContin. This turbocharging focused on what

McKinsey saw as a "significant opportunity to improve sales through better targeting." Specifically, McKinsey opined that "better targeting" of HCPs could result in greater than \$100 million in sales "upside," noting that "the average prescriber in decile 5-10 writes 25 times as many OxyContin scripts as prescribers in decile 0-4"—even though the HCPs in deciles 5-10 comprised less than 7% of all prescribers nationwide—and recommending "shift[ing] calls to higher potential prescribers."

- 156. In August 2013, McKinsey's progress on evaluating growth opportunities for OxyContin was discussed with the Board, including certain Sackler Defendants. The presentation noted that the analysis would include an examination of "[r]elatively more sudden declines in: [t]ablets per prescription and [p]rescriptions for 40mg & 80mg strengths" and "[p]rescriber segmentation and targeting." Later that same day, Richard Sackler emailed Mortimer Sackler Jr.: "The 'discoveries' of McKinsey are astonishing." Richard Sackler subsequently arranged for a face-to-face meeting for the Board.
- examined its "unvarnished" findings and recommendations. Following the meeting, one of McKinsey's partners that led the meeting memorialized in an email, "[T]he room was filled with only family, including the elder statesman Dr. Raymond [Sackler] . . . We went through exhibit by exhibit for about 2 hrs . . . They were extremely supportive of the findings and our recommendations . . . and wanted to strongly endorse getting going on our recommendations." Another McKinsey partner remarked that their "findings were crystal clear" to the Sacklers "and [the Sacklers] gave a ringing endorsement of 'moving forward fast."

- 5. Purdue Implemented McKinsey's "Evolve to Excellence" Program to Target High Volume, High Value Prescribers
- 158. Purdue implemented McKinsey's recommendations through a program called "Evolve to Excellence" ("E2E"). The core focus of the E2E program was developing mechanisms to target the highest-volume prescribers, including through increased call frequency and minimized sales representative discretion in choosing which prescribers to target. E2E placed a "heavy emphasis on target physicians" and tied sales representative incentive plans to their adherence to the plan's sales structure.
- 159. In July 2013, Purdue's Board met to discuss the first report on sales tactics that McKinsey had prepared for them called *Identifying Granular Growth Opportunities for OxyContin: First Board Update*. McKinsey confirmed that Purdue's direct sales visits increased the rate of opioid prescriptions. McKinsey recommended that the Board requires its sales representatives' quotas for in-person sales visits be increased from 1,400 to 1,700. McKinsey also advised the Board to control the sales representatives' target lists more closely, focusing on high-prescribing doctors to generate more revenue. To facilitate this recommendation, McKinsey asked the Board to obtain "prescriber level milligram dosing data" so they could analyze the doses prescribed by individual doctors.
- 160. In an August addendum to the July report, McKinsey recommended that "Purdue make[] a clear go/no go decision to 'Turbocharge the Sales Engine.'" In September 2013, McKinsey provided two final reports in connection with its "OxyContin Growth Project." McKinsey's "OxyContin growth opportunities Phase I Final Report: Diagnostic" proposed measures to address decreasing OxyContin prescriptions. It found that "increased [sales] calls have a significant impact on OxyContin" prescriptions, provided an overview of effective sales programs including "dinner programs," and estimated that "revenue upside from sales re-

targeting and adherence could be up to \$235M." McKinsey's "OxyContin growth opportunities

Phase II Final Report: Recommendations" made a variety of recommendations, including hiring

more sales representatives to hit target goals, examining their compensation structure, and

turbocharging the sales force.

- the broad range of doses," which would have the intended effect of increasing the sales of the highest (and most profitable) doses of OxyContin. Indeed, evidence indicates that the 80-milligram pill of OxyContin—the highest dosage strength—was the most popular and profitable in illicit sales of the product. Of course, higher dosage strength, particularly for longer periods of use, also contributes to and accelerates opioid dependency, addiction, and abuse. Purdue implemented McKinsey's suggestions by adopting the marketing slogan, "Individualize the Dose," and initiating the S.T.A.R.T. (Supplement, Titrate, Adjust, Reassess, Tailor) initiative, which was meant to focus sales conversations with HCPs on titrating patients to higher dosages. The goal of the program was to discourage patients' discontinuation of OxyContin due to a perceived lack of pain relief by encouraging HCPs to increase the OxyContin dosage, or "titrate up." In other words, Purdue trained its sales representatives to "[o]vercome . . . objection[s]" from HCPs whose patients complained that they still felt pain by encouraging the HCPs to "titrate up" to higher dosages.
- 162. Specifically, sales representatives were trained to pivot from legitimate concerns about addiction voiced by HCPs to statements about "dependence" and opioid "tolerance." In fact, when asked about the safety of high dosages, representatives were instructed to respond that OxyContin "does not have a ceiling dose." On their sales calls, sales representatives also were

trained to discuss initiating opioid naïve patients (*i.e.*, patients not already taking opioids) on opioid therapy and switching patients from immediate release opioids to ADF OxyContin.

- 163. Purdue's Board received a presentation on E2E's implementation at the September 12, 2013 Board meeting. The implementation of the E2E program was overseen by McKinsey and some of Purdue's top executives through the creation of the E2E Executive Oversight Team and Project Management Office and was an immediate success. In December 2013, a Purdue executive told the Board that "[t]he E2E sales force focus/effectiveness initiatives [that] are being implemented starting October 2013 through April 2014 are already showing positive results." By April 2014, Purdue's CFO Mahony was able to report to the Board that "[t]he E2E effort has resulted in significant improvement" in sales of opioids.
- had already established to increase prescriptions from high-value, high-volume opioid prescribers. Then-CEO Timney explained to the Board in a May 2014 memorandum titled "Rebuilding Purdue to Compete, Win & Grow," that Purdue shifted to a "tiered" structure for sales calls, targeting the highest volume prescribers at 24 sales calls per year. As a Purdue executive emphasized during a national sales meeting: "[T]he single core objective of E2E... is to make sure that we're making calls on the highest potential customers with the right frequency to maximize prescribing potential." As part of that initiative, Purdue made sure to reward sales representatives for "[c]alling on the right physicians with the right frequency" via a sales bonus. Identifying "the right physicians" depended solely on the physician's opioid prescribing volume, not his or her area of medical specialty. Given the Sackler Defendants' high level of engagement in Purdue's day-to-day operations, they were surely aware of these recommendations.

- A 2014 budget presentation to the Board explicitly referencing Purdue's work with McKinsey reflected that the extreme high-volume prescribers Purdue was targeting through E2E were the most sensitive to Purdue's marketing. The presentation noted: "Increased calls with decile 8-10 prescribers have a significant impact on OxyContin TRx growth"—an over 39% increase as compared to a decline of approximately 17% among HCPs receiving fewer calls. Astonishingly, on average, more prescriptions were written by the high-decile HCPs whom Purdue targeted through E2E than even Region Zero doctors—i.e., doctors on Purdue's "do not call" list due to suspected overprescribing and diversion.
- 166. Not only did he Sackler Defendants met personally with McKinsey to learn about their "astonishing" findings, the expanded Board also received budget presentations reviewing E2E's implementation and discussed ensuring E2E's funding at Board meetings. The Board approved of the program, which was designed to increase OxyContin sales despite the welldocuments issued of addiction and abuse.
  - Purdue Should Have Considered High Decile Prescribers for 6. Inclusion on the Region Zero List, but Instead Focused on Driving **Them to Still More Prescriptions**
- 167. Purdue knew, or reasonably should have known, that the top prescribers it was targeting were potential candidates for the Region Zero list.
- 168. The prescribing patterns of high-decile prescribers after ADF OxyContin was introduced also were similar to Region Zero doctors. Purdue learned that much of the fall off in following the introduction of ADF OxyContin was due to Region Zero doctors writing fewer prescriptions, presumably because their customers disproportionately had been crushing or dissolving the original formular of OxyContin for abuse. Prescriptions from high decile prescribers exhibited the same pattern. A report supplied to the Sackler Defendants and other Board members in August 2013 indicated that "[t]wo thirds of th[e] decline [in OxyContin sales]

comes from prescribers in [the highest prescribing] deciles 5-10." This is another reason Purdue should have investigated high decile prescribers for inclusion on the Region Zero list, rather than targeting them for more sales.

- OxyContin, others skyrocketed, and Purdue's own studies indicated that such abuse and diversion was concentrated among patients of high-volume prescribers. On October 25, 2011, the Board received a study that found that there was a "[d]ecline in 80 mg prescriptions, esp[ecially] among [Region Zero] doctors," and "[s]hifts in routes of abuse, especially injecting and snorting." Notably, the study indicated that the percentage of abusers who reported abusing OxyContin orally increased from 52% to 75% following the introduction of ADF OxyContin. Abuse via snorting or injection also continued, albeit at lower rates. The same Board materials indicated that a comparatively "small number of prescribers contribute to a large proportion of potential diversions of opioids from legal to illegal channels," and "there were doctors in the [Purdue] datebase [sic] who were prescribing painkillers 'for what appears to be the wrong reasons.""
- 170. Despite these damning findings, Purdue to no steps to determine why their high-volume doctors were writing so many prescriptions even though McKinsey's previous reports linked high-volume doctors to abuse and diversion.
  - 7. Purdue Detailed the Pharmacies of Region Zero Doctors Resulting in More Medically Unnecessary Prescriptions to Be Written and Filled
- 171. In 2013, McKinsey identified pharmacist scrutiny as a hurdle to sales and told the Board: "Access to OxyContin for some patients has become quite challenging in specific local markets. This is due to a combination of factors including: regulations, DEA initiatives, [Physicians for Responsible Opioid Prescribing], wholesaler initiatives and local pharmacist

perceptions. . . . While the wholesaler issues are quite visible and real, we believe the daily decisions being made at local pharmacies, while less publicly visible, are in fact creating far greater access issues."

- 172. On November 18, 2013, Purdue received a presentation from a vendor that identified the top 20 OxyContin prescribers whose OxyContin prescriptions had declined as a result of a pharmacy's "good faith dispensing" policy designed to hinder the dispensing of medically unnecessary prescriptions. In 2014, a Purdue regional manager similarly wrote that "[t]he retail pharmacist is an integral part of our business. As the old adage in pharmaceutical sales goes, 'The pharmacist isn't likely to generate business, but they sure can kill it."
- 173. To ensure that prescriptions from extreme high-volume prescribers would be filled, Purdue engaged in a variety of strategies, including instructing its sales representatives to detail pharmacies to fill "red flag" prescriptions. For example, Purdue sales representatives also encouraged pharmacists to "reach out to a [p]rescriber to recommend that a patient be switched from immediate release oxycodone to OxyContin." These pharmacy calls, at times, effectively functioned to bypass safeguards such as the Region Zero list, which forbade Purdue's sales force from contacting certain prescribers directly. In a similar vein, Purdue also trained its sales force to call on pharmacies that dispensed a "high volume of opioid scripts" and were near a "[1]arge pain practice."
- 174. Despite Purdue's knowledge of the red flags indicating the pharmacy was engaged in abuse and diversion, the OMS Committee voted to "continue to monitor" the pharmacy and allowed the sales representatives to continue to call on the pharmacy for the next five years.

- 8. To Circumvent Safeguards against the Dispensation of Suspicious Prescriptions, the Sackler Defendants Caused Purdue to Enter Into Distribution Agreements with Specialty Pharmacies to Fill OxyContin Prescriptions That Traditional Pharmacies Had Rejected
- 175. In McKinsey's *Identifying Granular Growth Opportunities for OxyContin: First Board Update*, it informed the Board that part of the reason for declining OxyContin sales was that "both pharmacies and distributors" were "under intense scrutiny and direct risk," causing a "clear disruption impacting patients." In particular, McKinsey noted a "range of obstacles" to patients' access to OxyContin, including "entire pharmacies being shut off by distributors, pharmacies themselves imposing tablet limits, decreases in channel inventory leading to greater stockouts, and pharmacies choosing to not stock OxyContin." To address this issue, McKinsey proposed creating an "alternative model for how patients receive OxyContin" that would "bypass retail, likely through a third party vendor who would provide [] direct distribution to patients."
- Stewart soliciting ideas for a new distribution system "to help relieve this problem of product access" and asking whether they were pursuing the strategy proposed by McKinsey "or an alternate." Mortimer Sackler Jr. shared his own vision for a new distribution system in which Purdue "would directly ship" patients OxyContin prescriptions "after using an independent service to verify the legitimacy of their prescriptions." Stewart responded that Purdue was "considering/evaluating many options," including "shipping directly to pharmacies who can't get supply from their regular wholesalers" and finding a way "to provide guidance to patients who call [Purdue] with respect to their personal problem in filling a prescription." To this, Mortimer Sackler Jr. responded, copying additional members of Purdue's management and the entire MNP Board, "I do think there may be an opportunity here for us to set up a complimentary [sic] business to handle this for Purdue as well as other controlled drug manufacturers."

- 177. Responding to Mortimer Sackler Jr., Richard Sackler claimed to have had the same idea and expressed it to Stewart. In turn, Stewart confirmed Mortimer Sackler Jr.'s interest in exploring an "alternative distribution process for all or essentially all opioid formulations" that would "supply pharmacies, clinics and perhaps also patients (eg mail order)," and possibly even hospitals. Mortimer Sackler Jr. responded, "To be clear, I was thinking about selling to pharmacies," and noted his belief that "McKinsey was talking about our fulfilling [prescriptions] to the consumer."
- 178. Not long after these exchanges—and as explained in an update about the implementation of E2E prepared by members of Purdue's management—Purdue proceeded to develop "multiple tactics to address [distribution] issues," including "alternative [supply] channels." By October 2013, Purdue approached at least six potential partners for its alternative distribution strategies, but all of them rejected Purdue's offer because they were "not comfortable with mail fulfillment" and were concerned with the "risk associated with dispensing OxyContin" under Purdue's proposed distribution models. Despite these setbacks, Purdue continued to explore alternative distribution strategies and, in October 2013, members of Purdue's management updated the Board on the status of these strategies: "What is Purdue Considering? Includes exploring opportunity to distribute directly; exploring existing channels (Specialty pharmacies, independent pharmacy networks)."
- 179. Purdue eventually realized its goal of establishing "alternative distribution" channels. In 2015, Purdue entered into distribution agreements with three specialty pharmacies, which proceeded to fill numerous prescriptions that (1) had been rejected by traditional retail pharmacies based on indications of diversion; (2) were for uses that were unsafe, ineffective, and medically unnecessary; and (3) were often diverted into illegal drug markets. Indeed, the

findings of Purdue's own ADD Program show that many of these prescriptions were medically unnecessary. In particular, the specialty pharmacies filled Medicare prescriptions for Purdue opioids written by approximately 100 prescribers, nearly one-fourth of whom were referred to the ADD Program on suspicion of diverting opioids into illegal markets. Between 2015 and 2018, Purdue paid these specialty pharmacies more than \$100,000 in kickbacks to fill prescriptions that other traditional pharmacies had rejected.

- 180. When prescribers and patients experienced difficulty filling prescriptions for Purdue's opioid products, including OxyContin, Purdue's sales representatives and employees in its Medical Affairs department referred them to the specialty pharmacies with which Purdue had contracted.
  - 9. Purdue Paid Practice Fusion to Design an Online Pain Platform to Increase Purdue's Extended-Release Opioid Sales
- 181. As acknowledged in separate criminal plea agreements, Purdue and Practice Fusion conspired to drive medically unnecessary sales of opioids. Practice Fusion is a web-based electronic health record company that provided electronic health record services to tens of thousands of HCPs in the United States, and its software was used during millions of patient encounters each month. Practice Fusion received payments from pharmaceutical companies in exchange for creating a clinical decision support ("CDS") alert in its electronic health records program. The CDS generated treatment recommendations using the patient information entered into the system by providers.
- 182. Beginning in or around spring 2014, Purdue discussed paying Practice Fusion to implement a "Pain CDS." The Pain CDS would prompt doctors to focus on assessing and treating a patient's pain systems and suggesting treatments, including the prescription of extended-release opioid medications such as Purdue's products.

- 183. The Pain CDS was presented as a neutral medical standard, but Purdue's primary objective was increasing sales of its extended-released opioids ("ERO"). As a Purdue executive wrote on May 4, 2014, regarding a potential deal with Practice Fusion, "[t]he key is understanding how it grows or protects [prescriptions]." A Purdue presentation from March 2016 similarly noted that the primary goal of the collaboration with Practice Fusion was "to increase Rx [prescriptions] for Purdue's medications," and a Practice Fusion employee remarked in May 2016, "I keep hearing the client revert back to 'Rx lift' as the primary objective of the program[.]"
- 184. On March 23, 2015, a Practice Fusion employee emailed colleagues in preparation for an upcoming meeting at Purdue and described the opportunity to sell the CDS program to Purdue. The Practice Fusion employee explained that Purdue "has communicated that the average dosage of OxyContin is declining," and that "[p]roviders are hesitant about using high dosages to combat pain." The Practice Fusion employee further explained that, "[a]s a result, Purdue is toying with the idea of using Pain Assessment tools with the provider at every visit and before every [prescription]."
- 185. In a September 2015 presentation to Purdue's marketing personnel, Practice Fusion touted that the Pain CDS would increase Purdue's prescriptions of OxyContin, Butrans, and Hysingla by delivering "clinical patient-centric provider messages" targeted at HCPs with "opioid naïve patients with chronic pain"—meaning patients who had not been prescribed opioids recently and/or were not receiving opioids on a regular basis—and with patients currently receiving immediate release oxycodone and hydrocodone.
- 186. Purdue directly participated in the design of the Pain CDS alert and approved the types of patients it would target and what guidance the alert would provide to providers. The

Pain CDS was presented to providers as a neutral medical standard, but a look under the hood revealed it was actually designed to increase sales of Purdue's opioid products. Moreover, the Pain CDS directly violated medically accepted standards, CDC guidelines, and FDA-approved labels for Purdue's EROs.

- 187. From 2015 to 2016, Purdue spent approximately \$1 million working with Practice Fusion "to add reminder[s] for healthcare professionals prescribing opioid medications to conduct interim pain assessments." Purdue now admits that "[t]he remuneration [it] paid . . . to Practice Fusion was done in return for Practice Fusion including in its [electronic health record] platform a CDS with one of its purposes to increase Purdue's ERO sales, portions of which were paid for by federal health care programs, in violation of the Anti-Kickback Statute."
- 188. The CDS alerts were live on Practice Fusion's platform from at least on or about July 6, 2016 to the spring of 2019, and more than 230 million alerts were generated during that period. Doctors who received the Pain CDS alerts prescribed extended-release opioid prescriptions such as Purdue's ERO products at a higher rate than those who did not.
- Fusion project. On July 21, 2017, the head of Purdue's Medical Affairs Strategic Research department, wrote Gail Cawkwell, then Chief Medical Officer, expressing "significant discomfort about the Practice Fusion Project." As she noted, there had been "an explicit (in writing) goal at the beginning of increasing opioid scripts," which put Purdue in "a precarious position." They were right—Practice Fusion's Pain CDS directly contributed to an increase in unnecessary opioid prescriptions and the steadily mounting opioid liability that Purdue faced. Indeed, in January 2020, Practice Fusion executed a deferred prosecution agreement with the

DOJ in which it admitted to conspiring with Purdue to drive medically unnecessary opioid prescriptions and paid \$145 million in fines.

# H. Purdue and the Sackler Defendants Actively Sought to Deflect and Conceal Their Misconduct

- 190. While Purdue was knowingly engaged in aggressive mismarketing of its dangerous drugs, Purdue and the Sackler Defendants publicly promoted the false notion that opioid abuse and addiction was the result of the moral failings of the victims of drug addiction.
  - a. In May 2008, Purdue personnel sent the Board a proposal of "KEY MESSAGES THAT WORK"—one of which Richard Sackler had long subscribed to: Deflect blame from Purdue's addictive drugs by stigmatizing people who become addicted. The tag line the staff proposed did just that: "It's not addiction, it's abuse. It's about personal responsibility."
  - b. In 2010, Dr. Portenoy—a doctor who "led the charge for mass prescribing of opioids in the US, and was then paid by Purdue Pharma to help drive sales of OxyContin"—said on Good Morning America that "[a]ddiction, when treating pain, is distinctly uncommon" and "most doctors can feel very assured that that person is not going to become addicted." Dr. Portenoy later admitted in an interview that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true" because the primary goal was to "destignatize" opioids. In an interview with the Wall Street Journal he said: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."
  - c. In September 2011, CEO Stewart gave a speech in Connecticut titled Providing Relief, Preventing Abuse, which deceptively blamed addiction, overdose, and death on "abuse"—deploying Richard Sackler's time-worn strategy to "hammer on the abusers in every way possible"—to draw attention away from how dangerous Purdue opioids were for everyone.
  - d. On October 4, 2018, after reviewing an article suggesting that low-income people are more prone to opioid abuse because they cannot afford alternative care or surgery, Mortimer Sackler Jr. continued his victimblaming, asking, "Is that the reason or is it because lower income households are more prone to drug abuse (to escape the difficulties of their lives) and hence seek out opioid prescriptions as a means of getting high and so their prescriptions are not legitimate pain prescriptions?"

- 191. After Purdue and the Sackler Defendants spent years blaming opioid addicts, the Business Development Committee led by Kathe Sackler sought to further profit from the "market" of individuals addicted to opioids, rationalizing that "[a]ddiction treatment is a good fit and next natural step for Purdue," because "[p]ain treatment and addiction are naturally linked" and there is a "[l]arge, unmet need for vulnerable, underserved and stigmatized patient population." In 2014, the Business Development team, led by Kathe Sackler, pitched "Project Tango"—a plan to expand across "the pain and addiction spectrum" to become an "end-to-end pain provider" by treating addiction with Suboxone. Purdue illustrated this marketing strategy internally with a picture of a funnel guiding patients down the funnel from pain treatment to opioid addiction treatment.
- 192. The Sackler Defendants and Purdue took great pains to ensure that they were not associated with any written evidence of Purdue's criminal conduct. Purdue's internal documents from before and after 2007 are filled with examples of Purdue leadership, including the Sackler Defendants, discouraging written communications about topics that could raise potential liability issues for Purdue. For example:
  - a. In 2001, a regional manager sent his sales representatives a reminder of the types of information that is "okay to communicate" but "should never ever go on e-mail." Instead, he advised that negative comments "should be placed on voicemail or typed in a hard copy memo and sent via U.S. mail or fax, so there is no permanent electronic record." The manager told his team to "[i]magine if each of these messages was displayed on an overhead projector in a court of law accusing Purdue of unethical or inappropriate marketing."
  - b. Purdue's strictest policy against written communications prohibited sales representatives from recording details about their sales pitches to doctors in emails. The Board knew about and approved this policy, and staff assured the Board that the policy was enforced. Purdue instructed its sales representatives to avoid using words like "Meal ticket" or "I pushed her to write more OxyContin" in their call notes "Work to remove this language from you[r] written and oral communications!" Its training presentations also advised sales representatives to "not include adverse

events" - defined as "any undesirable event . . . associated with the use of a drug" – "in your call notes." Purdue required that sales representatives discuss opioids only in face-to-face oral conversations to avoid generating discoverable evidence of its misconduct. As the top sales and marketing executive in the company, Russell Gasdia personally enforced the rule. When Gasdia learned that a sales representative had sent a doctor emails about Purdue opioids, he ordered: "Fire her now! We can't afford this."

- This, of course, was consistent with Gasdia's email playbook. For c. example, when staff emailed Russell Gasdia a detailed report of illegal OxyContin trafficking, he responded: "These should not be on email." When the Northeast Regional Manager emailed Gasdia about the arrest of a profitable "core physician" in Massachusetts, Gasdia ordered: "Discontinue use of email on this subject." When sales staff emailed each other about how to "push" doctors to prescribe more opioids, Gasdia instructed: "Please take this off line. I would prefer a face to face discussion on this."
- d. In 2014, Purdue abolished the issuance of detailed Quarterly Reports that had created a paper trail of targets for sales visits and been emailed among the Board and staff, as a result of a subpoena that the City of Chicago served on Purdue in 2013 seeking internal documents about Purdue's marketing of opioids. The subpoena provoked a flurry of activity, including discussion among the Board. Purdue fought the subpoena, and eventually it was withdrawn. But as a result of this incident, from 2014 and onward, the Board decided to limit many of Purdue's official Board reports to numbers and graphs and relayed other information orally only.
- Throughout 2018, Josephine Martin, Purdue's Senior Vice President of e. Corporate Affairs and Communications, was the center of several email exchanges concerning public affairs issues. Martin frequently ended electronic conversations and insisted on continuing them offline, for example, writing: "Happy to discuss offline." After such messages, the electronic communications usually ended.
- 193. Purdue's status as a privately held corporation enhanced the Sacklers' ability to conceal their wrongdoing. As a privately held corporation, Purdue was not subject to same reporting or disclosure obligations imposed on public companies by the U.S. Securities and Exchange Commission and other state and federal regulators. Richard Sackler commented that the lack of a disclosure requirement was a "definite advantage of our private status."

### I. The Sacklers Implemented a Scheme to Transfer Assets Out of Purdue to **Prevent Them from Falling into the Hands of Creditors**

- As Mortimer Sackler Jr. explained in a February 2008 email to Side B's Richard 194. Sackler, "Fundamentally we don't want to stay in this business anymore (given the horrible risks, outlooks, difficulties, etc.) and I think the majority of your family feels the same way." He went on to note that a sale could "once and for all eliminate the great risks we have and continue to take and secure our families' current and future financial security."
- 195. The Sackler Defendants soon recognized, however, that selling the company would not be easy because of significant liability that Purdue was facing. As David Sackler noted, Purdue's "future liabilities" stood in the way of any potential transaction because they threatened to "decimate" any prospective merger partner's stock price. The Sacklers instead focused on transferring cash and other value out of Purdue, just as Boer had recommended. Indeed, during the 10 years following the 2007 DOJ Criminal Plea and Settlement (and the Boer Memo), the Sacklers transferred more than \$10 billion in cash out of Purdue, as well as more than \$1.5 billion more in non-cash assets, all to themselves and their trusts and entities, or otherwise for the family's ultimate benefit.

### 1. The Sackler Defendants Shared a Common Purpose and Scheme in **Unlawfully Marketing and Selling Opioids**

196. Despite knowing that their opioid products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, the Sackler Defendants participated in the marketing and sale of opioids as described in this complaint, along with other non-Defendants described herein, such as Project Fusion and McKinsey, formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic

misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain ("Enterprise").

- 197. In order to unlawfully increase the demand for opioids, the Sackler Defendants through the Enterprise formed an association-in-fact enterprise. Through their personal relationships, the members of the Enterprise had the opportunity to form and take actions in furtherance of the Enterprise's common purpose.
- 198. The Sackler Defendants, through the Enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including Plaintiffs, and made or caused to be made numerous misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included: (a) that addiction is rare among patients taking opioids for pain; (b) that addiction risk can be effectively managed; (c) that withdrawal is easily managed; (d) that increased dosing presents no significant risks; (e) that long-term use of opioids improves function; (f) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (g) that use of time-released dosing prevents addiction; (h) that abuse-deterrent formulations provide a solution to opioid abuse; and (i) that opioids would bring patients freedom and peace of mind.
- 199. The Sackler Defendants' scheme devised, implemented and conducted by the Enterprise was a common course of conduct designed to ensure that Purdue (and therefore the Sackler Defendants) unlawfully increased their sales and profits through concealment and misrepresentations about the addictive nature and effective use of the Purdue's opioids. The Sacker Defendants acted together for a common purpose and perpetuated the Enterprise's scheme as described above.

- 200. There were regular communications between and among the Sackler Defendants in which information was shared and misrepresentations were coordinated. The Sackler Defendants functioned as a continuing unit for the purpose of implementing the Enterprise's scheme and common purpose, and each agreed and took actions to hide the true nature and scope of scheme and continue its existence.
- 201. As public scrutiny and media coverage focused on how opioids ravaged communities throughout the United States, neither Purdue nor the Sackler Defendants sought to correct their previous misrepresentations or discontinue their role in the Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence. Instead, the Sackler Defendants continued to participate in the Enterprise for financial gain, even well beyond the Purdue's criminal guilty plea in 2007.
- 202. The Sackler Defendants engaged in certain discrete categories of activities in furtherance of the common purpose of the Enterprise. The Enterprise's conduct in furtherance of the common purpose of the Enterprise involved misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain.
- 203. The impact of the Sackler Defendant's scheme is still being felt—*i.e.*, the opioids continue to be prescribed and used for chronic pain throughout United States, and the opioid epidemic they unleashed continues to injure Plaintiff, and consume Plaintiffs' resources.
- 204. As a result, it is clear that the each of the Sackler Defendants were willing participants in the Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

#### 2. The Conduct of the Enterprise Violated Civil RICO

- 205. From at least 2004 to the present, each of the Sackler Defendants exerted varying levels of control over the Enterprise and participated in the operation or management of the affairs of the Enterprise, directly or indirectly, in the following ways:
  - Creating and providing a body of deceptive, misleading and unsupported a. medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
  - b. Creating and providing a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
  - Creating and providing a body of deceptive, misleading and unsupported c. sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
  - d. Devised and implemented marketing schemes that included targeting and misleading physicians, unlawfully incentivizing sales representatives to maximize prescriptions and dosages, and evading regulatory constraints.
  - Disseminating many of their false, misleading, imbalanced, and e. unsupported statements through unbranded materials that appeared to be independent publications; and
  - f. Using front groups and key opinion leaders ("KOLs") to mislead the public about opioids.
- 206. The scheme devised and implemented by the Enterprise Members and the Sackler Defendants amounted to a common course of conduct intended to increase the Enterprise Members' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

# 3. Pattern of Racketeering Activity

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- 207. The Opioid Members' scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of racketeering activity as described herein.
- 208. The pattern of racketeering activity used by the Enterprise Members to unlawfully market opioids likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Enterprise, including essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain, with the goal of profiting from increased sales of the Opioid
- 209. Enterprise Members' drugs induced by consumers, prescribers, regulators and Plaintiff's reliance on the their statements and the statements they caused to occur.
- 210. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity, through which the Enterprise Members and the Sackler Defendants defrauded and intended to defraud Plaintiff, and other intended victims.
- 211. The Members devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive and effective use of opioids for long-term chronic, non-acute and non-cancer pain. The Enterprise Members and Sackler Defendants knew that these representations violated the FDA approved use these drugs, and were not supported by actual evidence. The Enterprise Members and Sackler Defendants intended that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate

wire facilities, intentionally and knowingly with the specific intent to advance, and for the purpose of executing, their illegal scheme.

- 212. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain to prescribers, regulators and the public, including Plaintiffs, the Enterprise Members and Sackler Defendants engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.
- 213. The Enterprise Members' and Sackler Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, inter alia:
  - a. Marketing materials about opioids, and their risks and benefits, which the Enterprise Members sent or caused to be sent to health care providers, transmitted through the internet and television, published, and transmitted to front groups and KOLs located across the country, including in Plaintiffs' Communities;
  - b. Written representations and telephone calls between and among the Enterprise Members, and between and among the Sackler Defendants and front groups, regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
  - c. Written representations and telephone calls between and among the Enterprise Members, and between and among the Sackler Defendants and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
  - d. E-mails, telephone and written communications between and among the Enterprise Members, and between and among the Sackler Defendants and the front groups agreeing to or implementing the opioids marketing scheme;
  - e. E-mails, telephone and written communications between and among the Enterprise Members, and between and among the Sackler Defendants and the KOLs agreeing to or implementing the opioids marketing scheme;

- f. Communications between and among the Enterprise Members, and between and among the Sackler Defendants, front groups and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same to the public;
- Communications between and among the Enterprise Members, and g. between and among the Sackler Defendants, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same to the public;
- h. Written and oral communications directed to Plaintiffs and/or Plaintiffs' Communities that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and
- i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme.
- In addition to the above-referenced predicate acts, it was intended by and 214. foreseeable to the Enterprise Members and Sackler Defendants that the front groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.
- 215. To achieve the common goal and purpose of the Enterprise, the Enterprise Members and Sackler Defendants hid from the consumers, prescribers, regulators and the Plaintiff: (a) the fraudulent nature of the Enterprise Members' and Sackler Defendants' marketing scheme; (b) the fraudulent nature of statements made by the Enterprise Members and Sackler Defendants and by their KOLs, front groups and other third parties regarding the safety and efficacy of prescription opioids; and (c) the true nature of the relationship between the members of the Enterprise and Sackler Defendants.
- 216. The Enterprise Members and Sackler Defendants, with knowledge and intent, to the overall objective of the Enterprise Members' and Sackler Defendants' fraudulent scheme and

participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

- For the Enterprise Members' and Sackler Defendants' fraudulent scheme to work, 217. each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that Purdue and Sackler Defendants supported, and worked through the same KOLs and front groups, and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines.
- The Enterprise Members' and Sackler Defendants' predicate acts all had the 218. purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the Enterprise Members and Sackler Defendants. The predicate acts were committed or caused to be committed by the Enterprise Members and Sackler Defendants through their participation in the Enterprise and in furtherance of its fraudulent scheme.

#### VI. **Class Action Allegations**

219. Plaintiffs bring this case on behalf of themselves and those similarly situated school districts identified in the Settlement Agreement under Fed. R. Civ. P. 23(a), 23(b)(2) and 23(b)(3). All class members bear the steadily rising costs of providing special education and related supports and services and diversion of resources to their states to provide for (a) children exposed to opioids in utero, which makes those children about twice as likely to exhibit learning and developmental disabilities than children who were not exposed,<sup>2</sup> and (b) children presenting emotional and behavioral challenges in schools because of their family members' use of opioids.

<sup>&</sup>lt;sup>2</sup> Paul Morgan and Yangyang Wang, The Opioid Epidemic, Neonatal Abstinence Syndrome, and Estimated Costs for Special Education Services, 25 Am. Journal of Managed Care 13 (2019).

- 220. Plaintiffs and the School District Classes will continue to incur significant costs in the years to come as the current and future cohorts of adversely impacted children come of school age and move from lower school to high school with special needs all along the way.
  - 221. Plaintiffs' School District Classes are defined as follows:

The Class shall consist of elementary, middle, and secondary public school districts in the United States (a) with enrollments of more than 5,000 students,

- (b) that have filed proofs of claim in the Bankruptcy Case, or (c) that are Litigating School Districts.
- 222. Plaintiffs reserve the right to amend or modify the class definitions with greater specificity or further division into subclasses or limitation to particular issues.
- 223. Numerosity. The potential members of the State Classes as defined as so numerous that joinder of all members is unfeasible and not practicable.
- Commonality and Predominance. There are questions of law and fact common to 224. the School District Classes, which predominate over any questions affecting only individual School District Class members. These common questions of law and fact include, without limitation:
  - a. The Sackler Defendants' conduct in creating, recommending, and implementing marketing, promotion, distribution, and sales strategies for opioids after Purdue's first guilty plea in 2007;
  - b. Whether the Sackler Defendants disregarded the risks associated with its strategies for maximizing sales and return on investment for opioid products;
  - Whether the Sackler Defendants' conduct in creating, recommending, and c. implementing nationwide opioid sales strategies for numerous opioid manufacturers caused or contributed to an increase in opioid addiction and abuse and the effect alleged;
  - Whether the Sackler Defendants' predicate acts amount to a conspiracy d. under RICO;

- Whether the Sackler Defendants' conduct caused or contributed to a e. public nuisance;
- f. Whether the Sackler Defendants' conduct resulted in false misrepresentations to prescribers, including those within each Scool District Class Member's state, regarding opioids;
- Whether the Sackler Defendants' conduct caused an increase in the g. number of children born with in utero opioid exposure;
- Whether children affected by opioid usage in utero require special h. education services and other supports in public schools; and
- i. Whether opioid addiction or use disorder in the family home increases the risk that a student will present emotional and behavioral difficulties in school.
- 225. Typicality. The claims of the named Plaintiffs are typical of the claims of each of their School District Classes and Subclasses. Plaintiffs and the School District Class and Subclass Member sustained damages as aforesaid arising out of and caused by the Sackler Defendants' unlawful conduct as alleged herein.
- 226. Adequacy of Representation. Plaintiffs will fairly and adequately represent and protect the interests of the members of School District Class. Counsel representing Plaintiffs are competent and experienced in litigation class actions.
- 227. Superiority of Class Action. A class action is superior to other available methods for the fair and efficient adjudication of this controversy since joinder of all the members of the State Classes is impracticable. Furthermore, the adjudication of this controversy through a class action will avoid the possibility of inconsistent and potentially conflicting adjudication of the claims asserted. A class action would provide a superior vehicle for resolving the issues for all similarly affected and situated. There will be no difficulty in the management of this action as a class action.

### **CAUSES OF ACTION**

### **Count I:** Racketeer Influenced and Corrupt Organizations (RICO) 18 U.S.C. § 1961, et. seq.

- Plaintiff incorporates by reference the allegations in paragraphs 1 through 227 of 228. this complaint as if fully set forth herein, and further allege as follows:
- 229. This claim is brought by Plaintiff against the Sackler Defendants for actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964, for violations of 18 U.S.C. § 1961, et seq.
- At all relevant times, each of the Sackler Defendants is and has been a "person" 230. under 18 U.S.C. § 1961(3) because it is capable of holding, and does hold, "a legal or beneficial interest in property."
- 231. Each Plaintiff is a "person," as that term is defined in 18 U.S.C. § 1961(3) and has standing to sue as it was and is injured in its business and/or property as a result of Defendant's wrongful conduct described herein.
- 232. The Enterprise conducted an association-in-fact enterprise, and/or participated in the conduct of an enterprise through a pattern of illegal activities (the predicate racketeering acts of mail and wire fraud) to carry-out the common purpose of the Enterprise, i.e., to unlawfully increase profits and revenues from the continued prescription and use of opioids for long-term chronic pain. Through the racketeering activities of the Enterprise, Enterprise Members and Sackler Defendants sought to further the common purpose of the enterprise through a fraudulent scheme to change prescriber habits and public perception about the safety and efficacy of opioid use. In so doing, each of the Enterprise Members and Sackler Defendants knowingly conducted and participated in the conduct of the marketing activities described herein by engaging in mail and wire fraud in violation of 18 U.S.C. §§ 1962(c) and (d).

- 233. The Enterprise is an association-in-fact enterprise that consists of the Enterprise Members and Sackler Defendants.
- 234. Each of the Enterprise Members and Sackler Defendants conducted and participated in the conduct of the Enterprise by playing a distinct role in furthering the Enterprise's common purpose of increasing profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use, and the risks and symptoms of addiction, in order to increase the market for prescription opioids by changing prescriber habits and public perceptions.
- 235. Specifically, the Enterprise Members and Sackler Defendants each worked together to coordinate the Enterprise's goals and conceal their role, and the Enterprise's existence, from the public by, among other things, (a) funding, editing and distributing publications that supported and advanced their false messages; and (b) funding KOLs to further promote their false messages.
- 236. Further, each of the Enterprise Members and Sackler Defendants had systematic links to and personal relationships with each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities.
- 237. The Enterprise Members and Sackler Defendants conducted and participated in the conduct of the Enterprise through a pattern of racketeering activity that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase profits and revenue by changing prescriber habits and public perceptions in order to increase the prescription and use of prescription opioids and expand the market for opioids.
- 238. The Enterprise Members and Sackler Defendants each committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering

activity (*i.e.*, violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the Enterprise Members and Sackler Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the Enterprise Members' and Sackler Defendants' regular use of the facilities, services, distribution channels, the U.S. Mail and interstate wire facilities. The Enterprise Members and Sackler Defendants participated in the scheme to defraud by using mail, telephones and the Internet to transmit mailings and wires in interstate or foreign commerce.

- 239. The Enterprise Members' and Sackler Defendants' predicate acts of racketeering, (18 U.S.C. § 1961(1), include but are not limited to:
  - a. Mail Fraud: The Enterprise Members and Sackler Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
  - b. Wire Fraud: The Enterprise Members and Sackler Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- 240. As summarized herein, the Enterprise Members and Sackler Defendants used the mail and wires to send or receive thousands of communications, publications, representations, statements, electronic transmissions and payments to carry-out the Enterprise's fraudulent scheme.
- 241. Because the Enterprise Members and Sackler Defendants disguised their participation in the enterprise, and worked to keep even the enterprise's existence secret so as to

- 242. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers, prescribers, regulators and Plaintiffs. The Enterprise Members calculated and intentionally crafted the scheme and common purpose of the Enterprise to ensure their own profits remained high.
- 243. The Enterprise Members' and Sackler Defendants' pattern of racketeering activity alleged herein and the Enterprise are separate and distinct from each other.
- 244. The racketeering activities conducted by the Enterprise Members and Sackler Defendants amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive consumers, prescribers, regulators and the Plaintiffs. Each separate use of the U.S. Mail and/or interstate wire facilities employed by the Enterprise Members and Sackler Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including consumers, prescribers, regulators and the Plaintiff.
- 245. Each of the Enterprise Members and Sackler Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

- 246. As described herein, the Enterprise Members and Sackler Defendants engaged in
- a pattern of related and continuous predicate acts for years. The predicate acts constituted a

variety of unlawful activities, each conducted with the common purpose of obtaining significant

money and revenue from the marketing and sale of their highly addictive and dangerous drugs.

The predicate acts also had the same or similar results, participants, victims, and methods of

commission. The predicate acts were related and not isolated events.

247. The Enterprise Members' and Sackler Defendants' violations of law and their

pattern of racketeering activity directly and proximately caused Plaintiff's injury in their business

and property.

248. It was foreseeable and expected that the Enterprise Members and Sackler

Defendants creation and subsequent participation in the Enterprise through a pattern of

racketeering activities to carry-out their fraudulent scheme would lead to a nationwide opioid

epidemic, including increased opioid addiction and overdose.

249. The Sackler Defendants' misleading marketing and failure to prevent prescription

opioid diversion damaged Plaintiffs and Plaintiffs' Communities. The Sackler Defendants'

misconduct has contributed to a range of social problems, including addiction, violence and

delinquency.

250. Specifically, the Enterprise Members' and Sackler Defendants creation of, and

then participation in, the Enterprise through a pattern of racketeering activities to carry-out their

fraudulent scheme has injured Plaintiffs in the form of substantial losses of money and property

that logically, directly and foreseeably arise from the opioid-addiction epidemic, such as

damages including, but not limited to, significant expenses for special education programs for

(a) students exposed to opioids in utero (NOWS), (b) students with emotional and behavioral

damages resulting from living in households afflicted by opioids, and (c) students addicted to opioids themselves, for which Plaintiffs and the Class demand compensatory and punitive damages and all damages and relief allowed by law.

- Plaintiffs' and the Class's injuries were directly and thus proximately caused by 251. these racketeering activities because they were the logical, substantial and foreseeable cause of Plaintiffs' and the Class's injuries. But for the opioid-addiction epidemic the Enterprise Members and Sackler Defendants created through their Enterprise, Plaintiff would need to spend resources on addressing the impacts of the opioid epidemic as described herein.
- 252. Plaintiffs and the Class are the most directly harmed entity and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.
- 253. Plaintiff seeks all legal and equitable relief as allowed by law, including, inter alia, actual damages; treble damages; equitable and/or injunctive relief in the form of courtsupervised corrective communication, actions and programs; forfeiture as deemed proper by the Court; attorneys' fees; all costs and expenses of suit; and pre- and post-judgment interest, including, inter alia: (a) actual damages and treble damages, including pre-suit and postjudgment interest; (b) an order enjoining any further violations of RICO; (c) an order enjoining any further violations of any statutes alleged to have been violated in this Complaint; (d) an order enjoining the commission of any tortious conduct, as alleged in this Complaint; and (e) attorneys' fees and all costs and expenses of suit.

### **Count II: Public Nuisance**

Plaintiff incorporates by reference the allegations in paragraphs 1 through 227 of 254. this complaint as if fully set forth herein, and further allege as follows:

- 255. The Sackler Defendants' conduct has created a foreseeable, ongoing, significant, unlawful, and unreasonable interference with rights common to the general public, including public health, welfare, safety, peace, comfort, and convenience of the Plaintiffs' and their School District Class Members' and Subclass Members' communities through their work in marketing, promoting, distributing, and selling massive doses of opioids throughout the states where Plaintiffs and the School District Class and Subclass Members are located, fueling and opioid epidemic in those communities.
- By their conduct, the Sackler Defendants knowingly exacerbated an opioid 256. epidemic that affects entire communities, municipalities, towns, school districts, and states, including Plaintiffs' and the School District Class and Subclass Members' communities. The Sackler Defendants knew, or reasonably should have known, that opioids would be used, possessed, and/or diverted unlawfully nationwide, including in and around Plaintiffs' and School District Class and Subclass Members' communities.
- The Sackler Defendants nuisance-creating conduct has been intentional and 257. unreasonable and/or violated statutes imposing specific legal requirements for the protection of others.
- 258. As a direct and proximate result of the Sackler Defendants' intentional, unreasonable, and unlawful conduct, the Plaintiffs and School District Class and Subclass Members have suffered damages including, but not limited to, expenditures to provide special education and other supports and services because of learning disabilities after children's damaging exposure in utero to opioids and direct costs to Plaintiff and the School District Class and Subclass Members for health care, disability benefits and workers' compensation.

- 259. By incurring pecuniary losses as a result of the increase in children born with NOWS who qualify for special education services due in part to Defendants' conduct, the Plaintiffs and the School District Class and Subclass Members have suffered harm that is different in kind to the harm suffered by the general public in their respective states.
- 260. By the marketing of and efforts to boost sales of opioids in Plaintiffs' and their State Class's and Subclass's communities, Defendants violated federal law including, but not limited to, 18 USC § 2 and 21 U.S.C. § 846 with respect to Purdue's violation of 21 U.S.C.A. § 823 and 21 C.F.R. § 1301.74.
- 261. The Sackler Defendants' conduct, if unabated, will continue to threaten the health, safety, and welfare of students and staff and taxpayers of the schools of the Plaintiffs and the School District Class Members. The Plaintiffs and the School District Class and Subclass Members have a clearly ascertainable right to abate this nuisance and its effects and seek relief from it.

### PRAYER FOR RELIEF

**WHEREFORE**, Plaintiffs, on behalf of themselves and the putative class, pray that this Court enter judgment against Defendants:

- past, present, and future costs associated with increased educational services,
   including but not limited to special education needs, services, and programs for
   children with opioid-related learning disabilities or needs;
- b. disgorgement of profits;
- c. all of the hundreds of millions of dollars in costs and means to abate the effects in public school districts caused by the opioid epidemic created by Defendants' wrongful and/or unlawful conduct;

- d. all other costs and damages, including treble damages, specified herein;
- e. attorneys' fees, costs, and expenses of suit;
- f. pre- and post- judgment interest; and
- g. such other relief as the Court deems appropriate.

Dated: October 6, 2025 Respectfully submitted,

Wayne Hogan
TERREL HOGAN YEGELWEL, P.A.
233 East Bay Street, 8th Floor
Jacksonville, FL 32202
T: 904.722.2228
hogan@terrellhogan.com

Neil Henrichsen Austin Griffin HENRICHSEN LAW GROUP, PLLC 655 15th Street, N.W., Suite 800 Washington, DC 20005 T: 202.423.3649 nhenrichsen@hslawyers.com agriffin@hslawyers.com /s/ Benajmin L. Bailey
Benjamin L. Bailey
John W. Barrett
BAILEY & GLASSER, LLP
209 Capitol Street
Charleston, WV 25301
T: 304.345.6555
bbailey@baileyglasser.com
jbarrett@baileyglasser.com

Cyrus Mehri
MEHRI & SKALET, PLLC
2000 K Street, N.W., Suite 325
Washington, DC 20006
T: 202.822.5100
cmehri@findjustice.com

Michael Murphy
BAILEY & GLASSER, LLP
1055 Thomas Jefferson St. NW, Suite 540
Washington, DC 20007
T: 202.463.2101
mmurphy@baileyglasser.com

## JS 44 (Rev. 03/2) Case 5:25-cv-00228-JPB DOTWIENCOVERIISHED POR 15-2025 - 125-20-2028-JPB

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS				DEFENDAN	TS					
Marshall County Board of Education, et al.				Theresa E. Sackler, et al.						
(b) County of Residence of First Listed Plaintiff Marshall Cty., WV				County of Residence of First Listed Defendant						
(EXCEPT IN U.S. PLAINTIFF CASES)				(IN U.S. PLAINTIFF CASES ONLY)  NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.						
(c) Attorneys (Firm Name, Address, and Telephone Number)				Attorneys (If Known)						
See Attachment	A									
II. BASIS OF JURISDICTION (Place an "X" in One Box Only)  III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Place (For Diversity Cases Only) and One Box for Defendant)										
1 U.S. Government Plaintiff	3 Federal Question (U.S. Government Not a Party)			Citizen of This State X		F DEF PTF DE			DEF 4	
2 U.S. Government Defendant	x 4 Diversity (Indicate Citizenship of Parties in Item III)		Citize	en of Another State	2	2 Incorporated and of Business In A		5	<b>X</b> 5	
				zen or Subject of a 3 Foreign Nation oreign Country				<u> </u>	<u></u> 6	
IV. NATURE OF SUIT (Place an "X" in One Box Only)				Click here for: Nature of Suit Code Descriptions.						
CONTRACT  110 Insurance	TORTS  PERSONAL INJURY PERSONAL INJURY			FORFEITURE/PENALTY 625 Drug Related Seizure		BANKRUPTCY 422 Appeal 28 USC 158		375 False Claims Act		
120 Marine   130 Miller Act   140 Negotiable Instrument   150 Recovery of Overpayment & Enforcement of Judgment   151 Medicare Act   152 Recovery of Defaulted Student Loans (Excludes Veterans)   153 Recovery of Overpayment of Veteran's Benefits   160 Stockholders' Suits   190 Other Contract   195 Contract Product Liability   196 Franchise	330 Federal Employers' Liability 340 Marine 345 Marine Product Liability 350 Motor Vehicle 355 Motor Vehicle Product Liability 360 Other Personal Injury 362 Personal Injury - Medical Malpractice  CIVIL RIGHTS 440 Other Civil Rights 441 Voting	365 Personal Injury - Product Liability 367 Health Care/ Pharmaceutical Personal Injury Product Liability 368 Asbestos Personal Injury Product Liability PERSONAL PROPERT 370 Other Fraud 371 Truth in Lending 380 Other Personal Property Damage Product Liability PRISONER PETITIONS Habeas Corpus: 463 Alien Detainee	71	LABOR 710 Fair Labor Standards Act 720 Labor/Management Relations 740 Railway Labor Act 751 Family and Medical Leave Act 790 Other Labor Litigation 791 Employee Retirement Income Security Act		423 Withdrawal 28 USC 157  INTELLECTUAL PROPERTY RIGHTS  820 Copyrights 830 Patent 835 Patent - Abbreviated New Drug Application 840 Trademark 880 Defend Trade Secrets Act of 2016  SOCIAL SECURITY  861 HIA (1395ff) 862 Black Lung (923) 863 DIWC/DIWW (405(g)) 864 SSID Title XVI 865 RSI (405(g))  FEDERAL TAX SUITS  870 Taxes (U.S. Plaintiff	Corrupt Organizations 480 Consumer Credit (15 USC 1681 or 1692) 485 Telephone Consumer Protection Act 490 Cable/Sat TV 850 Securities/Commodities/ Exchange 890 Other Statutory Actions 891 Agricultural Acts 893 Environmental Matters 895 Freedom of Information			
240 Torts to Land 245 Tort Product Liability 290 All Other Real Property	442 Employment 443 Housing/ Accommodations  445 Amer. w/Disabilities - Employment 446 Amer. w/Disabilities - Other  448 Education	ilities - 535 Death Penalty Other:		IMMIGRATION 462 Naturalization Application 465 Other Immigration Actions		or Defendant) 871 IRS—Third Party 26 USC 7609	Act 896 Arbitration 899 Administrative Procedure Act/Review or Appeal of Agency Decision 950 Constitutionality of State Statutes			
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	Cite the U.S. Civil Stat 18 U.S.C. § 1964	ute under which you ar	e filing (L	Oo not cite jurisdictiona	l statute:	s unless diversity):				
VI. CAUSE OF ACTIO	Brief description of cau Conspiracy to violate sta									
VII. REQUESTED IN COMPLAINT:	( D)	DEMAND \$ CHECK YES only if demanded in complaint:  JURY DEMAND: Yes No								
VIII. RELATED CASE IF ANY	(See instructions):	JUDGE Honorable	John Pre	ston Bailey		_ DOCKET NUMBER _5:	24-cv-00207			
DATE										
10/06/2025		/s/Benjanin L. Bailey								
FOR OFFICE USE ONLY  RECEIPT # AM	MOUNT	APPLYING IFP		JUDG	Е	MAG. JU	DGE			

## UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF WEST VIRGINIA

# MARSHALL COUNTY BOARD OF EDUCATION, ET AL.

v.

### THERESA E. SACKLER, ET AL.

### ATTACHMENT A

Benjamin L. Bailey (WVSB No. 200) John W. Barrett (WVSB No. 7289) BAILEY & GLASSER, LLP 209 Capitol Street Charleston, West Virginia 25301 (304) 345-6555 (phone) (304) 342-1110 (fax) bbailey@baileyglasser.com jbarrett@baileyglasser.com

Michael Murphy
BAILEY & GLASSER, LLP
1055 Thomas Jefferson St. NW, Suite 540
Washington, DC 20007
T: 202.463.2101
mmurphy@baileyglasser.com

Cyrus Mehri Mehri & Skalet, PLLC 2000 K Street NW, Suite 325 Washington, DC 20006 Telephone: (202) 822-5100 cmehri@findjustice.com

Neil Henrichsen Henrichsen Law Group, PLLC 655 15th Street, N.W. Suite 800 Washington, DC 20005 Telephone: (202) 423-3649 nhenrichsen@hslawyers.com Wayne Hogan Terrell Hogan Yegelwel, P.A. 233 East Bay Street, 8th Floor Jacksonville, FL 32202 Telephone: (904) 722-2228 hogan@terrellhogan.com