CONSUMER PROTECTION DIVISION, OFFICE OF THE ATTORNEY GENERAL 200 St. Paul Place, 16th Floor Baltimore, Maryland 21202, Proponent, v. PURDUE PHARMA, L.P., THE PURDUE FREDERICK COMPANY, INC., PURDUE PHARMA INC., PURDUE PHARMACEUTICAL PRODUCTS L.P., AVRIO HEALTH LIMITED PARTNERSHIP (f/k/a PURDUE PRODUCTS L.P.), RHODES PHARMACEUTICALS L.P., RICHARD S. SACKLER, JONATHAN D. SACKLER, MORTIMER D.A. SACKLER, KATHE A. SACKLER, ILENE SACKLER LEFCOURT, THERESA SACKLER, and DAVID A. SACKLER, Respondents.	*	IN THE CONSUMER PROTECTION DIVISION OF THE OFFICE OF THE ATTORNEY GENERAL CPD Case No: 311366 OAH Case No.:

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AMENDED STATEMENT OF CHARGES

The Consumer Protection Division of the Office of the Attorney General of Maryland (the "Division") hereby institutes this proceeding on behalf of the State of Maryland to enjoin Purdue Pharma, L.P., The Purdue Frederick Company, Inc., Purdue Pharma Inc., Purdue Pharmaceutical Products L.P., Avrio Health Limited Partnership (f/k/a Purdue Products L.P.), Rhodes Pharmaceuticals L.P., Richard S. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Kathe A. Sackler, Ilene Sackler Lefcourt, Theresa Sackler, and David A. Sackler (collectively, "Respondents") from engaging in unfair and deceptive trade practices and to obtain relief for consumers victimized by Respondents' unfair and deceptive trade practices.

For decades, Respondents have repeatedly engaged in unfair, abusive, and deceptive trade practices in violation of the Maryland Consumer Protection Act, Md. Code Ann. §§ 13-101 *et seq.*, by marketing and selling opioids – which comprise a dangerous, highly addictive, and often lethal class of natural, synthetic, and semi-synthetic painkillers – for conditions for which they are neither safe nor effective and which they, in fact, often exacerbate. Respondents disseminated to Maryland prescribers, consumers, and others, false and misleading information concerning the purported safety and efficacy of opioid use for the treatment of chronic pain. Respondents omitted material facts regarding the chemical properties of opioids and minimized or failed to disclose the attendant risks of addiction, respiratory depression, and worsening pain (opioid-induced hyperalgesia). Respondents falsely marketed and sold opioids to at-risk Marylanders, who, because of their addiction, were unable to control or reduce their opioid use. Similarly, Respondents failed to report suspicious orders to regulators as required by law. Respondents' practices, as set forth in further detail herein, fueled the epidemic. They fed the addiction of a generation of Marylanders and, in so doing, have caused tremendous harm to the State and its citizens.

I. INTRODUCTION

1. Maryland, like other states across the country, faces an unprecedented opioid epidemic caused by Respondents' unfair, abusive, and deceptive misconduct. The opioid crisis has left a devastating wake of addiction and death in Maryland while Respondents have profited handsomely from their misconduct.

2. Opioids are powerful narcotic painkillers derived from opium poppy plants, although most prescription opioids today are actually synthetic or semi-synthetic derivatives of opium. When introduced into the central nervous system, opioids, like opium, bind to opioid receptors on neurons that control dopamine release. According to the Surgeon General, opioids,

like other addictive substances, have powerful effects on the brain. They "hijack" the brain's reward system by inducing feelings that motivate people to use them repeatedly, despite associated risks. With continued exposure, progressive changes occur in the structure and function of the brain, compromising brain function and driving chronic misuse. Addiction is now understood to be a chronic disease that is subject to relapse and is characterized by clinically significant impairments in health, social function, and voluntary control over substance use.[1]

3. Between doses of opioids, patients can suffer body aches, nausea, sweats, racing heart, hypertension, insomnia, anxiety, agitation, opioid cravings, opioid-induced hyperalgesia (increased pain), and other symptoms of withdrawal. When the agony of withdrawal is relieved by the next dose, it creates a cycle of euphoria and dysphoria that fosters addiction and dependence. Even when prescribed for a legitimate pain condition, prescription opioids are as addictive as heroin because they have exactly the same addictive effects on the neurocircuitry of the brain. Additionally, the chronic use of opioids has been shown to increase pain rather than reduce it, due to opioid-induced hyperalgesia.

4. Prior to 1980, out of appropriate concern that patients would become addicted, doctors prescribed opioid pain relievers sparingly, only for short-term use in cases of severe injury, surgery, or at the end of life, such as with cancer patients. Although there has never been any evidence to justify widespread opioid prescribing or to support a conclusion that long-term opioid use reduces pain or improves function, Respondents perpetuated misconceptions regarding the

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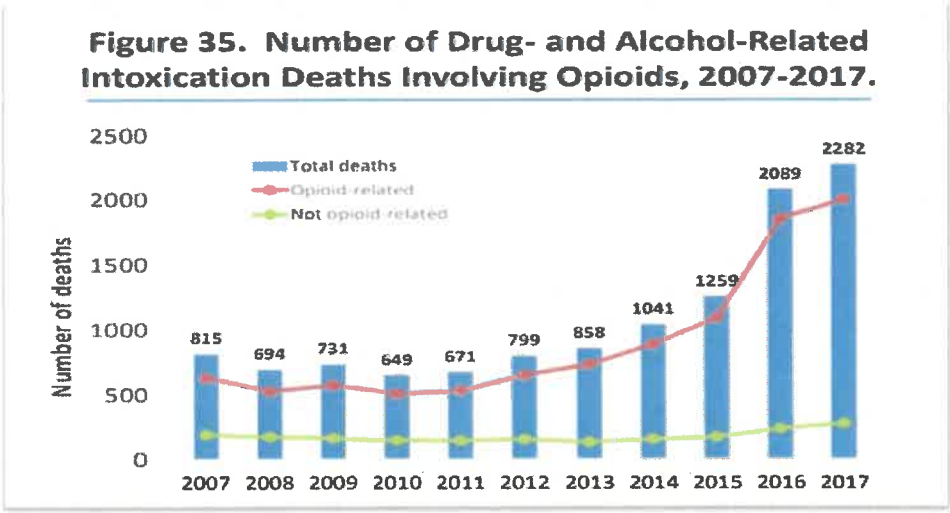
[1] *Facing Addiction in America, The Surgeon General's Spotlight on Opioids*, U.S. Department of Health & Human Services Substance Abuse and Mental Health Services Administration at 12 (Sept. 2018), https://addiction.surgeongeneral.gov/sites/default/files/OC_SpotlightOnOpioids.pdf.

safety and efficacy of opioids for chronic pain so as to effect a paradigm shift in the thinking on, and prescribing of, opioids – all to maximize sales.

5. According to the Maryland Department of Health ("MDH"), opioid-related fatalities increased in Maryland in 2017 for the seventh year in a row, reaching an all-time high of 2,009 deaths.[2] This represents an increase of nearly 300% since 2010, when there were 504 reported opioid-related deaths.[3] Because not all opioid-related deaths are reported or detected, these figures may be understated.



6. While the final tally of 2018 opioid-related deaths in Maryland is not yet available, preliminary data found 2,114 opioid-related deaths in Maryland, a 5.2% increase over the prior

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[2] *Unintentional Drug- and Alcohol-Related Intoxication Deaths in Maryland, Annual Report, 2017*, Maryland Department of Health, at 15 (June 2018), https://bha.health.maryland.gov/OVERDOSE_PREVENTION/Documents/Drug_Intox_Report_2017.pdf (hereinafter, "*Unintentional Drug-and Alcohol-Related*").

[3] *Id.*

year.[4] For the first nine months of 2018, which is the most recent data for which the MDH has published statistics, the number of opioid-related deaths in Maryland climbed by 10%, with 1,648 deaths reported from January through September 2018, compared to 1,502 in 2017.[5]

7. Maryland ranks among the top five states for the highest rates of opioid-related overdose deaths.[6] The death rate in Maryland has consistently been above the national average since 1999, ranging from roughly 1.5 to 3 times that average. Baltimore City, for example, had an overdose death rate of 45 per 100,000 residents in 2016, compared with the national overdose death rate of 13.3 per 100,000 persons.[7]

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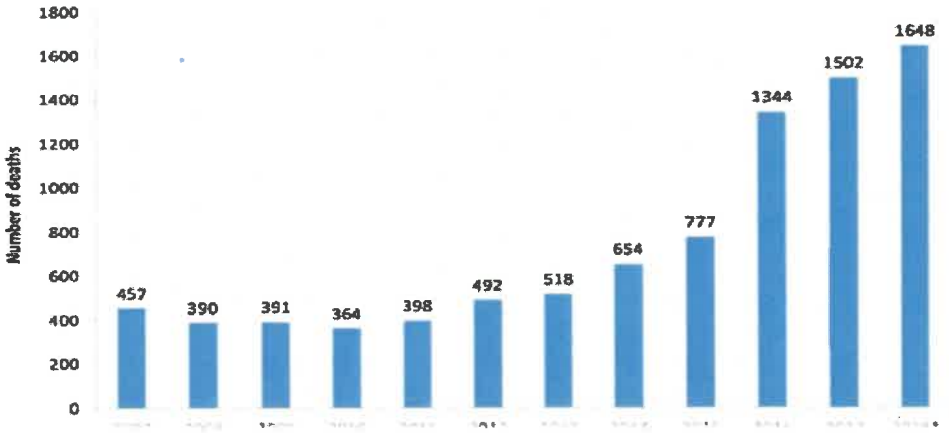
[4] *Annual Report*, Opioid Operational Command Center at 2 (May 9, 2019), https://beforeitstoolate.maryland.gov/wp-content/uploads/sites/34/2019/05/OOCC-Final-Annual-Report-2018.pdf

[5] Dandan Zou, *Opioid overdose death rate stabilizes in region as statewide trend continues to surge*, The Calvert Recorder (Jan. 17, 2019), https://www.somdnews.com/recorder/spotlight/opioid-overdose-death-rate-stabilizes-in-region-as-statewide-trend/article_a166907d-8aad-5c87-a666-1ea0e6e1de73.html.

[6] *Maryland Opioid Summary, Opioid-Related Overdose Deaths*, National Institute on Drug Abuse, https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/maryland-opioid-summary (last visited May 14, 2019) (hereinafter, "*Maryland Opioid Summary*").

[7] *Unintentional Drug-and Alcohol-Related*, *supra* n.2, at 44; *Maryland Opioid Summary*, *supra* n.6.

Figure 2. Number of Opioid-Related Deaths Occurring in Maryland from January through September of Each Year.*



8. The trend in opioid-related overdose deaths is not limited to Maryland. In 2014, more than 47,000 people died in the United States from lethal drug overdoses, the majority of which involved opioids. The total has risen each year since. The number of overdose deaths in 2017 is estimated to have been more than 72,000.

9. More than three out of five of those deaths involve opioids, and nearly half of those involve legal opioids prescribed by doctors to treat pain. In all, more than 200,000 people died in the United States between 1999 and 2017 from overdoses directly related to prescription opioids.[8]

10. Moreover, most illicit drug users, including those who die from illicit opioid overdoses, suffer addictions that are directly linked to their use of legally manufactured prescription opioids. According to the National Institutes of Health, more than 80% of heroin users reported using prescription opioids before initiating heroin use.[9]

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[8] *Prescription Opioid Data*, Centers for Disease Control and Prevention: Opioid Overdose, https://www.cdc.gov/drugoverdose/data/overdose.html (last visited May 14, 2019).

[9] *Prescription Opioids and Heroin*, National Institute on Drug Abuse (January 2018), https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use; *see also* Wilson M. Compton,

11. Public health officials have called the current opioid epidemic the worst drug crisis in American history.[10] According to Robert Anderson, Chief of the Mortality Statistics Branch of the National Center for Health Statistics, "I don't think we've ever seen anything like this. Certainly not in modern times."[11]

12. On March 1, 2017, Governor Hogan declared a state of emergency "in response to the heroin, opioid, and fentanyl crisis ravaging communities in Maryland and across the country."[12] On October 26, 2017, the federal government designated the opioid crisis a national public health emergency. According to recent estimates, as many as 145 people in the United States continue to die every day from opioid overdoses.[13]

13. The cost of the country's opioid crisis is estimated to have exceeded $1 trillion from 2001 to 2017 and is projected to cost an additional $500 billion by 2020:[14]

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et al., *Relationship between Nonmedical Prescription-Opioid Use and Heroin Use*, 374 N. Eng. J. Med 154-63 (2016), https://www.nejm.org/doi/full/10.1056/NEJMra1508490.

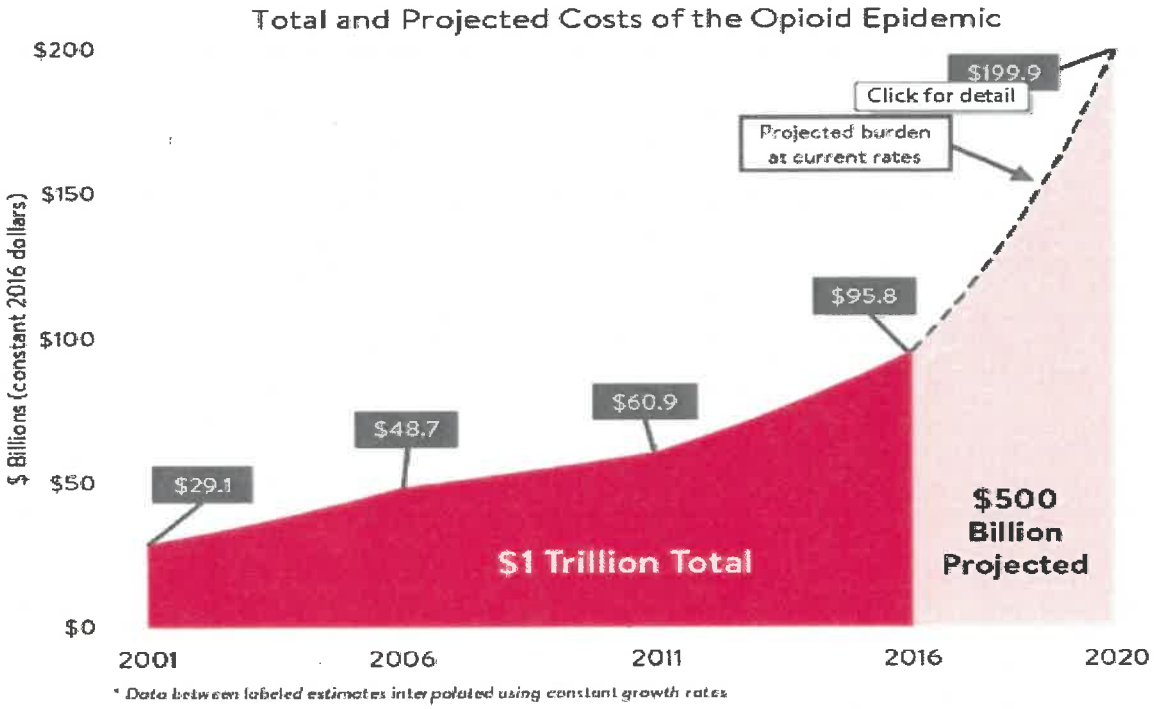
[10] Julie Bosman, *Inside a Killer Drug Epidemic: A Look at America's Opioid Crisis*, N.Y. Times (Jan. 6, 2017), https://www.nytimes.com/2017/01/06/us/opioid-crisis-epidemic.html.

[11] *Drug overdoses now kill more Americans than guns*, CBS News (Dec. 9, 2016), https://www.cbsnews.com/news/drug-overdose-deaths-heroin-opioid-prescription-painkillers-more-than-guns/.

[12] Press Release, Office of Governor Larry Hogan, Hogan-Rutherford Administration Declares State of Emergency, Announces Major Funding to Combat Heroin and Opioid Crisis in Maryland (Mar. 1, 2017), http://governor.maryland.gov/2017/03/01/hogan-rutherford-administration-declares-state-of-emergency-announces-major-funding-to-combat-heroin-and-opioid-crisis-in-maryland/.

[13] Patrick R. Keefe, *The Family that Built an Empire of Pain*, The New Yorker (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain (hereinafter, "Keefe, *Empire of Pain*").

[14] *Economic Toll of Opioid Crisis in U.S. Exceeded $1 Trillion Since 2001*, Altarum (Feb. 13, 2018), https://altarum.org/about/news-and-events/economic-toll-of-opioid-crisis-in-u-s-exceeded-1-trillion-since-2001.



According to the Council of Economic Advisers, the economic cost of the opioid crisis was $504 billion in 2015 alone – 2.8% of the 2015 gross domestic product.[15]

14. As reported in a study published in *Medical Care* in March 2019, the latest statistics show the opioid epidemic collectively cost state governments $11.8 billion in lost tax revenue between 2000 and 2016.[16] The study reported that Maryland lost a total of more than $344 million in lost tax revenue alone.

15. The deceptive marketing and sale of opioids to treat chronic pain by drug manufacturers like Purdue has been one of the main drivers of the opioid epidemic. Purdue

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[15] The Council of Economic Advisors, *The Underestimated Cost of the Opioid Crisis* at 1 (Nov. 2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf.

[16] Joel E. Segel, Ph.D, *et al.*, *Revenue Losses to State and Federal Government from Opioid-related Employment Reductions*, Medical Care (Mar. 5, 2019) (published ahead-of-print), https://journals.lww.com/lww-medicalcare/Abstract/publishahead/Revenue_Losses_to_State_and_Federal_Government.98477.aspx#pdf-link.

manufactures prescription opioids, including brand-name medications like OxyContin, MS Contin, Dilaudid, Hysingla, Ryzolt, and Butrans, as well as generics like oxycodone, morphine sulfate, and hydrocodone.

16. Prior to 1980, prescription opioids had been used for short-term, post-surgical, and trauma-related pain, and for palliative end-of-life care primarily in cancer patients. Because opioids are highly addictive and dangerous, the U.S. Drug Enforcement Administration ("DEA") has generally regulated them as Schedule II Controlled Substances, *i.e.*, drugs that have a high potential for abuse and that may lead to severe psychological or physical dependence.

17. This demonstrated need for caution comports with the historical understanding of both the medical community and American culture at large regarding the serious consequences of opioid use and misuse. Thousands of years of experience have taught that opioids' ability to relieve pain comes at a steep price; opioids are dangerously addictive and often lethal substances. For generations, physicians were taught that opioid painkillers were highly addictive and should be used sparingly and primarily for patients near death.[17] The medical community also understood that opioids were poorly suited for long-term use because tolerance would require escalating doses and dependence would make it extremely difficult to discontinue their use.

18. This prevailing and accurate understanding of the enormous risks and illusory benefits of long-term opioid use constrained drug manufacturers' ability to drive sales. In order to decrease accepted concerns about opioids and to increase profits, opioid manufacturers, including Purdue, engaged in a concerted, coordinated strategy to shift the way in which doctors and patients think about pain and, specifically, to encourage the use of opioids to treat not just the

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[17] Harriet Ryan, *et al.*, *OxyContin goes global – "We're only just getting started,"* L.A. Times (Dec. 18, 2016), http://www.latimes.com/projects/la-me-oxycontin-part3/ (hereinafter, "Ryan, *OxyContin goes global*").

relative few who suffer from acute post-surgical pain and end-stage cancer pain, but the masses who suffer from common chronic pain conditions.

19. To this end, as set forth below, Respondents employed a multiplicity of nefarious marketing strategies designed to "reeducate" the public and prescribers about the risks and benefits of opioids. Respondents' goal was to create an entirely new "health care" narrative – one in which opioids are considered safe and effective for long-term use and any pain is aggressively treated with opioids regardless of their inappropriateness and long-term costs. According to this newly-fabricated narrative, pain existed and was seriously undertreated throughout the United States because opioids were underprescribed, and doctors came under enormous pressure to treat all kinds of pain with opioids. The effort to establish this false narrative was successful.

20. Respondents' intent was to normalize aggressive prescribing of opioids for various kinds of pain by downplaying the very real risks of opioids, especially the risk of addiction, and by exaggerating the benefits of opioid use. To accomplish this goal, Respondents intentionally misled doctors and patients about the appropriate uses, risks, safety, and efficacy of prescription opioids. They misled doctors, patients, and insurers directly through sales representatives and marketing materials and indirectly through financial relationships with academic physicians, professional societies, trade associations for state medical boards, and seemingly neutral third-party foundations, whose deceptive messages Respondents controlled.

21. Respondents aggressively targeted prescribers in Maryland with their false and misleading messaging. Based on notes of sales calls by Purdue sales representatives, between 2006 and 2016, Purdue sales representatives visited Maryland healthcare providers more than [redacted] times to promote OxyContin and other opioid painkillers. During these calls, Purdue sales representatives made false and misleading claims about opioids and distributed thousands of

copies of false and misleading marketing materials to Maryland prescribers, while failing to inform them of the risks of addiction, death, and opioid-induced hyperalgesia.

22. Purdue trained its Maryland sales representatives using materials that downplayed risks associated with opioids. Purdue compensated its sales representatives with modest base compensation and substantial bonuses based on the volume of product the staff convinced doctors to prescribe, giving them a massive incentive to omit or minimize such risks. [redacted]

23. Purdue sales representatives and their managers were each paid tens of thousands of dollars per year in bonuses based on their success in marketing the company's drugs. In 2014, the Purdue sales representative for Prince Georges, Charles, Saint Mary's, and Calvert counties received an additional bonus and was made a member of the "Toppers Club" at Purdue for outstanding performance in sales. According to the sales representative, the Toppers Club was reserved for the top 10% of sales representatives in the United States.

24. Respondents caused false messages about the safety and efficacy of prescription opioids to be disseminated in Maryland also by purportedly neutral professional medical associations and organizations that were, in fact, funded and influenced by Respondents. Such entities drafted materials and prescribing guidelines in order to disseminate false and deceptive pro-opioid communiques under the guise of science and truth. [redacted] Purdue sales representatives during their sales calls on Maryland healthcare providers. Indeed, opioid manufacturers, including Purdue, paid nearly $9 million

between 2012 and 2017 to advocacy groups and professional societies operating in the area of opioids policy.[18] The manufacturers got their money's worth:

> Initiatives ***from the groups . . . often echoed and amplified messages favorable to increased opioid use*** – and ultimately, the financial interests of opioid manufacturers. ***These groups have issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids*** for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for overprescription and misbranding. . . .[19]

25. The purportedly neutral medical societies also "strongly criticized 2016 guidelines from the Centers for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain," which has been described as "a key federal response to the ongoing epidemic." There has been "a direct link between corporate donations and the advancement of opioids-friendly messaging."[20]

26. Among their most pernicious unfair, abusive, and deceptive trade practices in Maryland and nationwide, Respondents assured the public and prescribers in Maryland that the risk of becoming addicted to prescription opioids among patients being treated for pain was less than 1% and that evidence to the contrary was merely what Respondents deceptively dubbed "pseudoaddiction." In reality, many people with no addiction history became addicted after just

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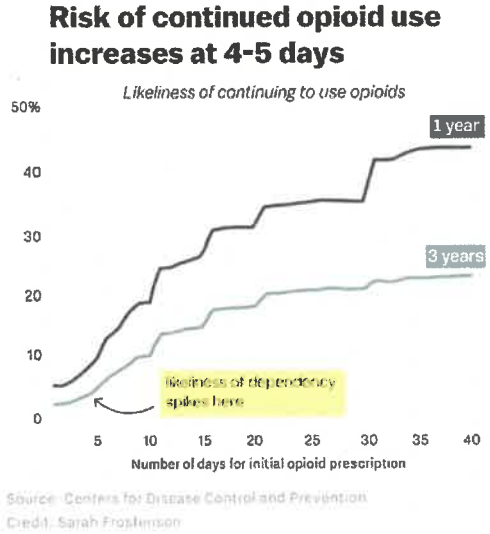
[18] *Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third-Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office at 1 (Feb. 13, 2018), https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf (hereinafter, "*February 2018 Report*").

[19] *Id.* Emphasis is added and citations and footnotes are omitted throughout unless otherwise noted.

[20] *Id.*

weeks or even days of use.[21] According to some estimates, as many as 56% of patients receiving long-term prescription opioid painkillers become addicted.[22] Indeed, almost one in five patients who receive an opioid prescription with ten days' supply will still be taking opioids one year later.[23] The following chart illustrates the degree to which the risk of dependency escalates based on the length of time for which the patient receives an initial opioid prescription:[24]



27. Put simply, Respondents manipulated and misrepresented medical science to serve their own agenda at great human cost. Indeed, as set forth in further detail below, in a study

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[21] Anna Lembke, *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop* 22 (Johns Hopkins University Press 2016) (hereinafter, "Lembke (2016)").

[22] Bridget A. Martell, *et al.*, *Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction*, 146(2) Ann. Intern. Med. 116-27 (2007), http://annals.org/aim/article/732048/systematic-review-opioid-treatment-chronic-back-pain-prevalence-efficacy-association (hereinafter, "Martell, *Systematic Review*").

[23] Sarah Frostenson, *The risk of a single 5-day opioid prescription, in one chart*, Vox (Mar. 18, 2017, 7:30 AM), www.vox.com/2017/3/18/14954626/one-simple-way-to-curb-opioid-overuse-prescribe-them-for-3-days-or-less.

[24] German Lopez & Sarah Frostenson, *How the opioid epidemic became America's worst drug crisis ever, in 15 maps and charts*, Vox (Mar. 29, 2017), http://www.vox.com/science-and-health/2017/3/23/14987892/opioid-heroin-epidemic-charts.

published on March 6, 2018, in the *Journal of the American Medical Association* ("*JAMA*"),[25] researchers who conducted the first randomized clinical trial designed to compare the efficacy of opioids and non-opioids (including acetaminophen, ibuprofen, and lidocaine) for the treatment of moderate to severe back pain, hip pain, or knee osteoarthritis pain concluded that patients who took opioids over the long term experienced improvements in pain-related function no better than patients who used safer alternatives. In short, opioids were no more effective for the treatment of chronic pain than the active ingredients in Tylenol and Advil.

28. Further, Purdue was required by state and federal law to report and halt suspicious orders it received for opioids. Under the direct supervision of the Sackler Respondents (defined below), however, Purdue utterly failed to do so. Despite the fact that Purdue had a practice of tracking and targeting the highest prescribers of opioids, staggering amounts of opioids were shipped to particular localities in Maryland, in quantities that common sense dictates could not possibly be justified by medical necessity. In 2016, for example, enough opioids were distributed in four of Maryland's 24 counties to provide an opioid prescription to every adult and child, and then some. In Washington County, pharmacies dispensed enough opioids to fill 170,000 prescriptions for approximately 150,000 adults and children. In Kent County, pharmacies dispensed almost 23,000 opioid prescriptions for about 19,700 adults and children. And in Allegany County, the prescription rate was about 92,000 prescriptions for roughly 72,000 people.[26]

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[25] Erin E. Krebs, *et al.*, *Effect of Opioid vs. Nonopioid Medications on Pain-Related Function in Patients with Chronic Back Pain or Hip or Knee Osteoarthritis Pain, The SPACE Randomized Clinical Trial*, 319(9) JAMA 872-82 (2018) (hereinafter, "Krebs, *Effect of Opioid vs. Nonopioid Medications*").

[26] U.S. Centers for Disease Control and Prevention, *U.S. County Prescribing Rates, 2016*, https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html (last visited May 14, 2019); U.S. Census Bureau, *American Factfinder Data*, https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml (last visited May 14, 2019).

Moreover, various pill mills went unreported in Maryland and thus continued to operate at great human cost. It was not until there was a multi-agency crackdown on pill mill operators in Maryland that certain pill-mill physicians were criminally prosecuted for dispensing opioids without a legitimate medical purpose.[27] Had Respondents reported suspicious orders as required, the breathtaking over-distribution of opioids in Maryland could have been mitigated or avoided. Respondents, however, did not report suspicious orders; they encouraged them.

29. Purdue, for example, provided its Maryland sales representatives with detailed data on all prescribers they were assigned to visit, showing whether the prescribers wrote prescriptions for Purdue opioids or for its competitors' opioids, as well as their volume and history. Purdue compensated the sales staff based on the volume of product the staff convinced doctors to prescribe. Purdue, however, also relied on its sales staff as the sole means of reporting any suspicious activities about the prescribers they visited, in the form of "reports of concern" that were sent to the company's legal department. Sales representatives were therefore faced with declining income if they reported prescribers as suspicious.

30. Even when sales representatives transmitted such "reports of concern" to Purdue, however, in numerous cases the company took no action to stop the prescribers from prescribing

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[27] For example, Dr. Kofi Shaw-Taylor and nine co-conspirators were convicted for the alleged unlawful distribution of controlled dangerous substances, and operating as pill mills, (that is, a physician's office, clinic, or health care facility that routinely engages in the practice of prescribing and dispensing controlled dangerous substances outside the scope of professional practice and without legitimate medical purpose), from June 2015 through April 2017. Saliqa A. Khan, *Maryland AG announces pill mill indictments*, WBALTV.com (Aug. 10, 2017), http://www.wbaltv.com/article/maryland-ag-announces-pill-mill-indictments/11665042. Shaw-Taylor pled guilty to Medicaid fraud and was sentenced to two concurrent sentences of five years each. Similarly, Dr. Hasan Babaturk was indicted on 21 drug charges based on allegations that he unlawfully distributed, dispensed, and prescribed controlled dangerous substances, including oxycodone, oxymorphone, and fentanyl over the course of four months, from December 2015 to March 2016. *Id.* Babaturk pleaded guilty to distribution and received a prison sentence.

more opioids, or took months or years to act on the reports. For example, in one case a sales representative reported that a prescriber's office was locked with no cars in the parking lot and that nobody had seen the prescriber for more than three months. Yet Purdue did nothing to stop the prescriber from writing more prescriptions for more than two years, and then only after two more reports by the sales representative about the prescriber not being present at the practice but still being an active prescriber.

31. Purdue instructed its Maryland sales representatives to use numerous other pernicious ways to increase sales, without regard to patient safety. For example, the Maryland sales representatives were instructed to make sure prescribers were fully supplied with "savings cards" that would pay some or all of patients' out-of-pocket expenses for the first few prescriptions. As noted herein, Purdue had developed the cards with the goal of having patients "remain on therapy longer." Further, Purdue's marketing department gave the Maryland sales representatives detailed reports on the use of the cards, allowing the representatives to further hone their sales pitches to doctors.

II. PARTIES

32. The proponent in this proceeding is the Consumer Protection Division of the Office of the Attorney General of Maryland ("Proponent"). Proponent has brought this proceeding to require Respondents to cease and desist from violating the Consumer Protection Act, Md. Code Ann., Com. Law §§ 13-101 *et seq.*, to prevent future violations, and to redress all past violations, to provide relief to the State of Maryland, the citizens of Maryland, and other parties within the State.

33. Respondent Purdue Pharma L.P. is a Delaware limited partnership formed in 1991 with headquarters located in Stamford, Connecticut.

34. Respondent Purdue Pharma Inc. is incorporated in New York with its principal place of business in Stamford, Connecticut. It is the general partner of Respondent Purdue Pharma L.P.

35. Respondent The Purdue Frederick Company, Inc. is incorporated in New York with its headquarters in Stamford, Connecticut.

36. Respondent Purdue Pharmaceutical Products L.P. is incorporated in Delaware with its headquarters in Stamford, Connecticut.

37. Respondent Avrio Health Limited Partnership (f/k/a Purdue Products L.P.) is incorporated in Delaware with its headquarters in Stamford, Connecticut.

38. Respondent Rhodes Pharmaceuticals L.P. ("Rhodes") is a Delaware limited partnership formed in or around 2007 with headquarters located in Coventry, Rhode Island.

39. Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Inc., Purdue Pharmaceutical Products L.P., Purdue Products L.P., and Rhodes are referred to collectively herein as "Purdue."

40. Respondent Richard S. Sackler is a natural person residing in Travis County, Texas. "Dr. Richard" has served as a member of the Board of Directors of Purdue since the 1990s. Richard Sackler is one of the six inventors listed on the original patent for OxyContin. He began working for Purdue in the 1970s as an assistant to his father, Raymond Sackler, who served as the president of the company at that time. Richard Sackler rose through leadership in the subsequent decades, serving as President of Purdue from 1999 to 2003. He resigned from his role in 2003 over apparent worry that executive officers of Purdue would be held personally liable for any opioid-related liabilities.

41. Richard Sackler continued to serve as co-chair of Purdue's board with his uncle, Mortimer Sackler, and as chair after the latter's death in 2010. Service on Purdue's very active board, including Richard Sackler's service as chair, allowed Respondents to retain control of the company regardless of whether they also served as executives.

42. During his executive tenure at Purdue and after, Richard Sackler actively participated in every aspect of the company's opioid business, from invention to marketing to sale. With the assistance of his father, Raymond, and his uncle, Mortimer, Richard Sackler introduced OxyContin to the market with one of the largest pharmaceutical advertising campaigns in history. Within five years, OxyContin was earning Purdue $1 billion a year.

43. Further, at all relevant times, Richard Sackler served as trustee of one or more trusts that own and control Purdue. He is the direct or indirect beneficiary of some portion of 25% of the profits earned from the sale of opioids by Purdue.

44. Notably, when Richard Sackler spoke at the launch party for OxyContin while serving as Purdue's Senior Vice President responsible for sales, he instructed the audience to imagine a series of natural disasters: an earthquake, a volcanic eruption, a hurricane, and a blizzard. He said, "the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense, and white."

45. According to Richard Sackler's publicly disclosed emails, in 1999, when employee Michael Friedman reported to Richard Sackler that Purdue was making more than $20,000,000 per week, Richard replied immediately, at midnight, that the sales were "not so great." "After all, if we are to do 900M this year, we should be running at 75M/month. So it looks like this month could be 80 or 90M. Blah, humbug. Yawn. Where was I?" Richard Sackler also personally

directed his sales reps not to tell doctors the truth about Respondents' opioids because the truth could hurt sales.

46. In or about 2001, Richard Sackler wrote down his solution to the overwhelming evidence of overdose and death; blame and stigmatize people who become addicted to opioids. "[W]e have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals." When *TIME* began reporting on OxyContin deaths in 2001, Richard Sackler responded to employee concerns that *TIME*'s coverage of people who lost their lives to OxyContin was not "balanced," and that the deaths were the fault of "the drug addicts," instead of Purdue. "We intend to stay the course and speak out for people in pain – who far outnumber the drug addicts abusing our product." That spring, Purdue executives met with the DEA. A senior DEA official sat across from Richard Sackler. Before the meeting ended, she leaned over the table and told Richard: "People are dying. Do you understand that?"[28]

47. Richard Sackler also stated in the early 2000s: "Abusers aren't victims; they are the victimizers" to an unidentified friend, who responded, "Abusers die, well that is the choice they made, I doubt a single one didn't know of the risks." If people die because they abuse OxyContin, "then good riddance." Richard Sackler further stated, "Unfortunately, when I'm ambushed by 60 Minutes, I can't easily get this concept across . . . . Calling drug addicts 'scum of the earth' will guarantee that I become the poster child for liberals."[29]

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[28] 2001 meeting described in *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* by Barry Meier, p. 158 (2003). The DEA official was Laura Nagel, head of the DEA Office of Diversion Control.

[29] Erik Larson & Jeff Feeley, *Purdue's Richard Sackler Allegedly Called Opioid Addicts 'Victimizers'*, Bloomberg (May 7, 2019), https://www.bloomberg.com/news/articles/2019-05-07/purdue-s-sackler-allegedly-called-opioid-addicts-victimizers.

48. Respondent Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut. He has served as a member of the Board of Directors of Purdue since the 1990s. Jonathan Sackler served as Senior Vice President of Purdue starting in or around 2000. Like his brother Richard, Jonathan Sackler resigned from his position in or after 2003, due to concerns that the executive officers of Purdue would be personally liable for crimes and litigation stemming from Purdue's opioid products. He continued to serve on Purdue's board after his resignation. At all relevant times, Jonathan Sackler served as trustee of one or more trusts that own and control Purdue. He is the direct or indirect beneficiary of some portion of 25% of the profits earned from the sale of opioids by Purdue. Jonathan Sackler regularly attended business meetings and business dinners with Purdue employees.

49. Respondent Mortimer D.A. Sackler is a natural person residing in New York County, New York. He has served as a member of the Board of Directors of Purdue since the 1990s. Mortimer D.A. Sackler was previously a board member of Purdue and is the direct or indirect beneficiary of 7.14% of the profits earned from the sale of opioids by Purdue. Mortimer participated actively in the management of the opioids business, including in sales and marketing. For example, in 2011, as states were looking for ways to curb opioid prescriptions, Mortimer D.A. Sackler sent an email asking if Purdue could sell a generic version of OxyContin in order to "capture more cost sensitive patients." In 2013, Mortimer told the other members of the board that

[redacted]

In 2016, Mortimer Sackler was involved in discussions with Richard

Sackler and Jonathan Sackler about acquiring a company that used implantable drug pumps to treat opioid addiction.[30]

50. Respondent Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut. She has served as a member of the Board of Directors of Purdue since the 1990s. "Dr. Kathe" began serving as Senior Vice President of Purdue in or around 2000. She resigned from her position in or about 2003 due to concerns that the executive officers of Purdue could be held personally liable for crimes and litigation stemming from Purdue's opioid products. She continued to serve on Purdue's board. She is the direct or indirect beneficiary of 7.14% of the profits earned from the sale of opioids by Purdue. As a member of the board, Kathe Sackler participated in and directed the affairs of Purdue. For example, in 2009, Kathe Sackler directed executives to [redacted] She also regularly attended business meetings and business dinners with company employees.

51. In September 2014, Kathe Sackler dialed in to a confidential call about *Project Tango*, which was a secret plan for Purdue to expand into the business of selling drugs to treat opioid addiction. In their now publicly disclosed internal documents, Kathe and staff wrote down what Purdue had publicly denied for years: that addictive opioids and opioid addiction are "naturally linked." They determined that Purdue should expand across "the pain and addiction spectrum," to become "an end-to-end pain provider." Purdue illustrated the end-to-end business model with a picture of a dark hole labeled "Pain treatment" that a patient could fall into – and "Opioid addiction treatment" waiting at the bottom.

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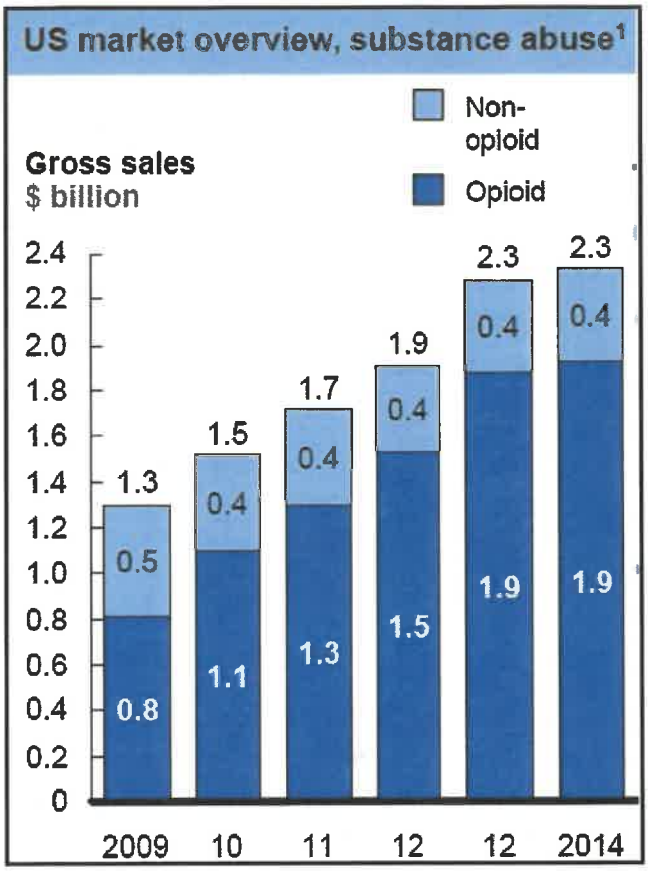
[30] Danny Hakim, Roni Caryn Rabin & William K. Rashbaum, *Lawsuits Lay Bare Sackler Family's Role in Opioid Crisis*, The New York Times (Apr. 1, 2019), https://www.nytimes.com/2019/04/01/ health/sacklers-oxycontin-lawsuits.html.

52. Kathe Sackler and the *Project Tango* team reviewed their findings that the "market" of people addicted to opioids, measured coldly in billions of dollars, had doubled from 2009 to 2014. Kathe and the staff found that the catastrophe provided an excellent compound annual growth rate ("CAGR"): "Opioid addiction (other than heroin) has grown by ~20% CAGR from 2000 to 2010."



53. Kathe Sackler and the staff revealed in their internal documents that Purdue's tactic of blaming addiction on untrustworthy patients was a lie, admitting the truth is that opioid addiction can happen to anyone who is prescribed opioids:

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

Purdue's "Project Tango" patient and clinical rationale

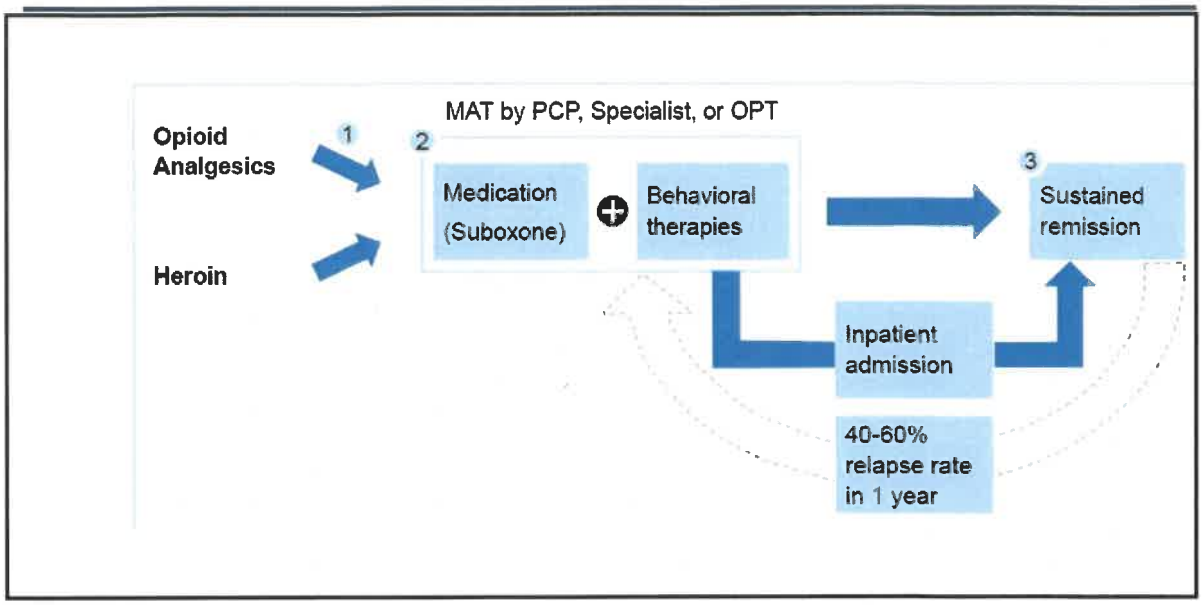
54. Kathe and the staff concluded that millions of people who became addicted to opioids were Respondents' next business opportunity. Staff wrote: "It is an attractive market. Large unmet need for vulnerable, underserved, and stigmatized patient population suffering from

substance abuse, dependence and addiction." The team identified eight ways that Purdue's experience getting patients ***on*** opioids could now be used to sell treatment for opioid addiction.

55. Kathe Sackler instructed staff that *Project Tango* required their "immediate attention." She pressed staff to look into reports of children requiring hospitalization after swallowing buprenorphine – the active ingredient in both Purdue's Butrans opioid and the opioid addiction treatment that Respondents wanted to sell, through *Project Tango*, in a film that melts in one's mouth. Staff assured Dr.Sackler that children were overdosing on pills, not films, "which is a positive for *Tango*."

56. In February 2015, staff presented Kathe Sackler's work on *Project Tango* to the Board. The plan was for a Joint Venture controlled by Respondents to sell buprenorphine as addiction medication.

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



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

59. Respondent Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She has served as a member of the Board of Directors of Purdue since the 1990s. Ilene Sackler Lefcourt served as Vice President of Purdue during the initial development and launch of OxyContin. She, too, resigned from her position around 2003 due to concerns of personal liability for executive officers of Purdue for opioid-related crime and litigation but continued to serve on the Board. As a member of the Board, Ilene Sackler Lefcourt participated, among other things, in formulating policies related to Purdue's marketing and increasing its sales.

60. Respondent Theresa Sackler is a natural person residing in New York County, New York. She has served as a member of the Board of Directors of Purdue since the 1990s. She is the direct or indirect beneficiary of some portion of the 50% of profits earned by Purdue through

the sale of opioids. As a member of the board, Theresa Sackler has participated in and directed Purdue's public messaging.

61. Respondent David A. Sackler is a natural person residing in New York County, New York. He has served as a member of the Board of Directors of Purdue since 2012. He has also served on the Business Development Committee of Rhodes and was intimately involved in overseeing and approving Rhodes' business activities. He is the direct or indirect beneficiary of some portion of 25% of the profits earned by Purdue through the sale of opioids. As a member of the board, David Sackler has participated in and directed policies designed to increase Purdue's sales.

62. Collectively, the parties listed in ¶¶33-61 are the Respondents. Richard Sackler, Jonathan Sackler, Mortimer Sackler, Kathe Sackler, Ilene Sackler Lefcourt, Theresa Sackler, and David Sackler (collectively, the "Sackler Respondents" or the "Sackler Families") each knowingly aided, participated in and benefited from the unlawful conduct of Purdue. They were deeply and personally involved. Purdue is the family business. One Maryland employee could not help but refer to the "board" as "the family."

63. At the direction of the Sackler Respondents, Purdue has in the last two decades manufactured, marketed, sold, and distributed opioids in Maryland and nationwide, including the following:

Drug Name/Chemical Name	**Description**	**CSA Category**
OxyContin (oxycodone hydrochloride extended release)	Opioid indicated for pain severe enough to require daily, around-the-clock, long-term opioid treatment; not indicated as an as-needed (p.r.n.) analgesic. It was first approved by the FDA in December 1995.	Schedule II

Drug Name/Chemical Name	Description	CSA Category
MS Contin (morphine sulfate extended release)	Controlled-release tablet form of morphine sulfate indicated for the management of severe pain; not intended for use as a p.r.n. analgesic; first approved in May 1987 as the first formulation of an opioid pain medicine that allowed dosing every 12 hours.	Schedule II
Dilaudid (hydromorphone hydrochloride)	Opioid analgesic; injectable and oral formulation; eight times more potent than morphine.[31]	Schedule II
Dilaudid-HP (hydromorphone hydrochloride)	Opioid analgesic; injectable and oral high-potency and highly concentrated formulation indicated for relief of moderate-to-severe pain in opioid-tolerant patients.	Schedule II
Hysingla ER (hydrocodone bitrate)	Brand-name extended-release form of hydrocodone bitrate indicated for the management of severe pain.	Schedule II
Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride)	Brand-name extended-release opioid analgesic made of a combination of oxycodone hydrochloride and naloxone hydrochloride. It was approved by the FDA on July 23, 2013.	Schedule II
Butrans (buprenorphine)	Opioid analgesic; transdermal skin patch indicated for the management of moderate to severe pain	Schedule III

64. Purdue's Area Manager at relevant times resided and worked in Maryland. The Area Manager supervised regional managers, district managers, and sale representatives in approximately half the states in the United States, including in Maryland. The Area Manager was aware of and directed their conduct, which included misconduct set forth in this Statement of Charges.

III. STATEMENT OF FACTS

65. The Sackler Respondents were chief architects and beneficiaries of Purdue's false marketing and deception and failure to report suspicious orders. Prior to Purdue's entry into the opioid market, the general standard use of opioids was for short-term periods, for example: acute

[31] *Dilaudid Addiction*, Suboxone California, https://www.suboxonecalifornia.com/suboxone-treatment/dilaudid-addiction (last visited May 14, 2019).

pain, surgery recovery, cancer, and palliative care. Chances of opioid abuse are low when applied in this manner. Purdue went to great effort to influence public perception of the perceived benefits and risks of long-term opioid use.

66. Arthur Sackler, the brother of Raymond and Mortimer Sackler, is largely responsible for this change in public perception, effectively creating the pharmaceutical advertising industry. He realized that direct advertising to doctors and prescribers would be the most effective means of turning a profit. He paid prominent doctors to endorse his products, offered physicians perks and benefits, published marketing material disguised as neutral medical journal articles, and funded "education" seminars that extolled the virtues of his drug products. His deceptive and unethical marketing techniques led to Valium becoming the first hundred-million-dollar, and the first billion-dollar, prescription drug. In 1998, the Medical Advertising Hall of Fame lauded: "No single individual did more to shape the character of medical advertising than the multi-talented Dr. Arthur Sackler. His seminal contribution was bringing the full power of advertising and promotion to pharmaceutical marketing." To maximize their sales of opioid products, Respondents used many of Arthur Sackler's techniques to blur the lines between promotion and journalism and infiltrate all aspects of medical education.

67. Purdue launched and promoted OxyContin with one of the largest pharmaceutical marketing campaigns in history. The Sackler Respondents controlled and directed all of the misconduct described herein; including knowingly and intentionally directing sales representatives to promote Purdue's addictive and lethal narcotics and failing to report suspicious orders.

68. Despite the prescription opioids' highly addictive qualities, Respondents launched aggressive pro-opioid marketing efforts that caused a dramatic shift in the public's and prescribers' perception of the safety and efficacy of opioids for chronic long-term pain and everyday use.

Contrary to what doctors had previously understood about opioid risks and benefits, they were encouraged for the last three decades by Respondents and other opioid manufacturers to prescribe opioids aggressively and were assured, based on false evidence provided directly by Purdue and numerous medical entities funded by Purdue, that: (a) the risk of becoming addicted to prescription opioids among patients being treated for pain was low, even as low as less than 1%; and (b) great harm was caused by "under-treated pain," for which opioids were the most effective treatment. These two foundational falsehoods, which Respondents and other opioid manufacturers systematically and repeatedly peddled to healthcare providers, patients, insurers, and officials throughout the United States, led directly to Maryland's current opioid crisis.

A. Background on Opioid Overprescribing

69. For decades, Respondents schemed to drive demand for opioids artificially higher by overstating their benefits and minimizing their risks.

70. Respondents' scheme to drive rapid and dramatic expansion of prescription opioids was rooted in two pieces of so-called "evidence," *i.e.*, articles that they coopted to use opportunistically as support for the premise that opioids are non-addictive and safe and effective for chronic pain.

71. The first of these was a 100-word letter to the editor (***not*** a clinical study) published in 1980 in the *New England Journal of Medicine* ("1980 Letter to the Editor").[32] The 1980 Letter to the Editor by Jane Porter ("Porter") and Dr. Herschel Jick ("Jick") reported that less than 1% of patients at Boston University Medical Center who received narcotics while hospitalized became

[32] Jane Porter & Hershel Jick, *Addiction rate in patients treated with narcotics*, 302(2) New Eng. J. Med. 123 (Jan. 10, 1980); Harrison Jacobs, *This one-paragraph letter may have launched the opioid epidemic*, Bus. Insider (May 26, 2016), http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5 (hereinafter, "Jacobs, *One-paragraph letter*").

addicted. Purdue improperly cited this letter as purported "evidence" supporting its claims that opioids were safe and non-addictive when used for the treatment of chronic pain conditions.

72. The letter, however, did not support the conclusion for which Purdue repeatedly referenced it thereafter. The letter was neither a clinical study nor a scientific research article but merely a short note about a relatively small number of patients prescribed opioids in a supervised hospital setting. A recent article about the 1980 Letter to the Editor, titled, "A 5-sentence letter helped trigger America's deadliest drug overdose crisis ever," quoted a 2017 study in the *New England Journal of Medicine*, in which researchers concluded:

> "[W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy."[33]

73. The second piece of so-called evidence was a single medical study summarized in an article by Drs. Russell Portenoy ("Portenoy") and Kathleen Foley ("Foley") that was published in 1986 by the medical journal *Pain* ("Portenoy Publication").[34] The Portenoy Publication summarized the results of a "study" of 38 chronic non-cancer pain patients who had been treated with opioid painkillers. Portenoy and Foley concluded that, for non-cancer pain, opioids "can be safely and effectively prescribed to selected patients with relatively little risk of producing the maladaptive behaviors which define opioid abuse."[35] Again, Purdue improperly cited this article as purported "evidence" supporting its claims that opioids were safe and effective for chronic pain.

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[33] German Lopez, *A 5-sentence letter helped trigger America's deadliest drug overdose crisis ever*, Vox (June 1, 2017), https://www.vox.com/science-and-health/2017/6/1/15723034/opioid-epidemic-letter-1980-study.

[34] *Pain* later became the official journal of the American Pain Society ("APS").

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

74. The Foley and Portenoy study was not scientific and did not meet the rigorous standards commonly used to evaluate the validity and strength of such studies in the medical community. For instance, there was no placebo control group, and the results were retroactive (asking patients to describe prior experiences with opioid treatment rather than less biased, in-the-moment reports). Even the authors advised caution, stating that the drugs should be used as an "alternative therapy" and recognizing that longer-term studies of patients on opioids would have to be performed. None was. As noted in a May 31, 2016 article entitled "The Ongoing Opioid Prescription Epidemic: Historical Context," published in the *American Journal of Public Health*, at the time of the Foley article, "there had been in fact no long-term controlled studies of opioids for chronic pain at all."[36]

75. In the wake of the study, Portenoy emerged as one of the industry's most vocal proponents of long-term opioid use. Portenoy essentially made it his life's work to campaign for the pharmaceutical industry's movement to increase the use of prescription opioids. He became one of Big Pharma's[37] "thought leaders" and was paid to travel the country to promote more liberal opioid prescribing for many types of pain. His talks were sponsored by Purdue and organizations it funded, to provide continuing medical education ("CME") programs required for doctors. Portenoy had financial relationships with at least a dozen pharmaceutical companies, most of which produced prescription opioids, including Purdue.[38]

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[36] Marcia L. Meldrum, *The Ongoing Opioid Prescription Epidemic: Historical Context*, 108(6) American Journal of Public Health 1365-66 (Aug. 2016).

[37] "Big Pharma" is used herein to refer to large pharmaceutical companies, including, but not limited to, Purdue, considered a politically influential group.

[38] Lembke (2016), *supra* n.21, at 59 (citing Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* (St. Martin's Press 2003)).

76. On November 1, 2017, the President's Commission on Combating Drug Addiction and the Opioid Crisis noted the important and detrimental role played by the 1980 Letter to the Editor and the Portenoy Publication. In a section of the Commission's Report with the header "Contributors to the Current Crisis," the Commission wrote the following:

> **Unsubstantiated claims:** One early catalyst can be traced to a single letter to the Editor of the New England Journal of Medicine published in 1980, that was then cited by over 600 subsequent articles. With the headline "Addiction Rare in Patients Treated with Narcotics," the flawed conclusion of the five-sentence letter was based on scrutiny of records of hospitalized patients administered an opioid. It offered no information on opioid dose, number of doses, the duration of opioid treatment, whether opioids were consumed after hospital discharge, or long-term follow-up, nor a description of criteria used to designate opioid addiction. Six years later, another problematic study concluded that "opioid maintenance therapy can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse." High quality evidence demonstrating that opioids can be used safely for chronic non-terminal pain did not exist at that time. These reports eroded the historical evidence (see Appendix 2) of iatrogenic addiction and aversion to opioids, with the poor-quality evidence that was unfortunately accepted by federal agencies and other oversight organizations.[39]

77. Portenoy has since admitted that he minimized the risks of opioids.[40] In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not "real" and left real evidence behind:

> I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, ***none of which represented real evidence***, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. ***In essence this was***

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[39] *The President's Commission on Combating Drug Addiction and the Opioid Crisis* at 20 (Nov. 1, 2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

[40] Celine Gounder, *Who Is Responsible for the Pain-Pill Epidemic?*, New Yorker (Nov. 8, 2013), http://www.newyorker.com/business/currency/who-is-responsible-for-the-pain-pill-epidemic (hereinafter, "Gounder, *Who Is Responsible*").

education to destigmatize [opioids] and because the primary goal was to destigmatize, we often left evidence behind.[41]

78. While Portenoy's admission is helpful, the damage had already been done. By 1997, the APS and the American Academy of Pain Medicine ("AAPM") (both funded by Purdue) issued a "landmark consensus," co-authored by Portenoy, stating there is little risk of addiction or overdose in pain patients.[42] In the years following publication of the 1980 Letter to the Editor and the Portenoy Publication, Respondents introduced two powerful prescription brand-name opioids into the market: MS Contin in 1987 and OxyContin in 1995. To sell these and other drugs, Purdue went on to use these two publications, the 1980 Letter to the Editor and the Portenoy Publication, as the foundation for a massive, far-reaching campaign to dramatically shift the thinking of healthcare providers, patients, policymakers, and the public on the risk of addiction presented by opioid therapy.

79. Respondents' strategies have been, and continue to be, a brilliant marketing success. Among other things, through their misinformation campaigns, Respondents redefined back pain, neck pain, headaches, arthritis, fibromyalgia, and other common conditions suffered by most of the population at some point to be a distinct malady – chronic pain – for which opioids became an appropriate, successful, and low-risk treatment. Indeed, studies now show more than 85% of patients taking OxyContin at common doses are doing so for chronic, non-cancer pain, despite the absence of reliable evidence supporting the safety and efficacy of opioids for chronic pain.[43]

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[41] Jacobs, *One-paragraph letter*, *supra* n.32; Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be.

[42] Jacobs, *One-paragraph letter*, *supra* n.32.

[43] Ryan, *OxyContin goes global*, *supra* n.17.

80. Respondents' strategies have continued despite studies revealing that up to 56% of patients receiving long-term prescription opioid painkillers for chronic back pain progress to addictive opioid use, including patients with no prior history of addiction.[44]

81. Despite Purdue's representations to the contrary, there has never been any reliable evidence that opioids are safe and effective for the treatment of chronic pain. In fact, the first randomized clinical trial designed to make head-to-head comparisons between opioids and other kinds of pain medications had not been conducted until recently, with results published on March 6, 2018 in *JAMA*. The trial, sponsored by the U.S. Department of Veterans Affairs ("Veterans Affairs"), was a randomized, 12-month study of 240 patients at Veterans Affairs primary care clinics. Each of the eligible patients had moderate to severe chronic back pain or hip or knee osteoarthritis despite the use of analgesic drugs.

82. The researchers began by noting that the "[r]ising rates of opioid overdose deaths have raised questions about prescribing opioids for chronic pain management." They acknowledged the "risk for serious harms without sufficient evidence for benefits" and ultimately reported that "[t]here was no significant difference in pain-related function between the 2 groups" – those whose pain was treated with opioids and those whose pain was treated with non-opioids, including acetaminophen and other non-steroidal anti-inflammatory drugs ("NSAIDs") like ibuprofen. They further found that "[o]verall, opioids did not demonstrate any advantage over nonopioid medications that could potentially outweigh their greater risk of harms." As such, they concluded: "***Treatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months.***"[45]

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[44] Lembke (2016), *supra* n.21, at 22 (citing Martell, *Systematic Review*, *supra* n.22).

[45] Krebs, *Effect of Opioid vs. Nonopioid Medications*, *supra* n.25.

83. Respondents, who had no scientific support, used false and misleading statements to expand the prescription opioid market exponentially from patients with end-stage cancer and acute pain, an obviously limited customer base, to anyone suffering from chronic pain, which, according to messaging promoted by Respondents and other opioid manufacturers, conveniently included approximately 100 million Americans – nearly one-third of the country's population and 40% of American adults.[46] The promotion, distribution, and rampant sale of non-medically necessary opioids without the reporting of suspicious orders required by federal and state law has made Respondents billions of dollars. It has also led to widespread, debilitating opioid addiction and death in Maryland.

B. The Sackler Respondents Directed Purdue to Falsely Market Extended-Release Drugs as Safer and More Effective than Regular-Release Drugs

84. Respondents launched OxyContin in 1995 with a bold marketing claim: "One dose relieves pain for 12 hours, more than twice as long as generic medications."[47] Prior to the launch, Respondents conducted focus groups with doctors and "learned that the 'biggest negative' that might prevent widespread use of the drug was ingrained concern regarding the 'abuse potential' of opioids."[48] In their initial press release launching OxyContin, Respondents told doctors that one OxyContin dose would provide "smooth and sustained pain control all day and all night." Based in large part on this message and on Respondents' other assurances that their opioids were

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[46] AAPM Facts and Figures on Pain, The American Academy of Pain Medicine, https://web.archive.org/web/20181213051417/http://www.painmed.org/patientcenter/facts_on_pain.aspx (last visited May 14, 2019).

[47] Harriet Ryan, *et al.*, *"You Want A Description of Hell?" OxyContin's 12-Hour Problem*, L.A. Times (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/ (hereinafter, "Ryan, *Description of Hell*")

[48] Keefe, *Empire of Pain*, *supra* n.13.

effective, safe, and necessary to relieve undertreated pain, OxyContin became America's best-selling painkiller.[49] Yet Respondents had no scientific basis for their claims.[50]

85. The idea behind these long-acting opioids – Respondents told Maryland prescribers, patients, and others – was that short acting opioids caused greater highs when initially taken and deeper lows as the body eliminated them, so longer-acting drugs would be more steady. According to Respondents, the extended dosing provided by long acting opioids – which are designed so that they are absorbed over time – enables patients to take them without highs (which cause addicting euphoria) or lows (which cause debilitating symptoms of withdrawal) associated traditionally with opioids.

86. But Respondents' claims about the safety of these opioids were deliberately misleading. They were designed to overcome objections to prescribing opioids, not to be accurate. Contrary to their claims, Respondents' products did not eliminate highs or lows or abuse or addiction. Rather, Purdue products were designed to continue to deliver both highs and lows.

87. While touting the supposed benefits of extended-release dosing, Respondents deliberately misled Maryland prescribers about the pharmacokinetics and pharmacodynamics of their products in at least two ways.

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[49] Press Release, Purdue Pharma L.P., New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain (May 31, 1996), https://www.freelibrary.com/NEW+HOPE+FOR+MILLIONS+OF+AMERICANS+SUFFERING+FROM+PERSISTENT+PAIN%3A...-a018343260.

[50] Though the FDA's 1995 approval allowed Purdue to include a package insert for OxyContin declaring the drug to be safer than its competitors due to its delayed release design, Purdue had in fact "conducted no clinical studies on how addictive or prone to abuse the drug might be. . . . The F.D.A. examiner who oversaw the process, Dr. Curtis Wright, left the agency shortly afterward. Within two years, he had taken a job at Purdue." Keefe, *Empire of Pain*, *supra* n.13.

88. First, contrary to the claims of eliminating highs, Purdue designed OxyContin to continue to deliver them by means of a bolus effect. In designing a long-acting product, through beading, coating, and other design features, manufacturers can control the rate at which the opioid molecule is delivered over time, making it theoretically steady and smooth. But manufacturers can also choose to distort the delivery of the drug so that more is delivered early (to produce a high) and less is delivered late (to create withdrawal). While representing that it was delivering smooth and steady pain relief, Purdue did exactly that.

89. Purdue designed OxyContin to have a "bolus effect." What this means is that OxyContin was designed to deliver earlier a higher percentage of the oxycodone in the pill than it delivered later, to produce the high that satisfied patients. Purdue misled prescribers about OxyContin's "front-loaded" delivery, resulting in patients experiencing greater highs than their providers understood. Because of the bolus effect, Purdue's long-acting opioids in fact produced the very highs that Purdue claimed they were designed to eliminate. At the same time, at least in part because of the bolus effect, Purdue's claims about its long-acting drugs' extended release properties were equally false. Purdue, for example, marketed OxyContin to Maryland prescribers as requiring dosing every 12 hours and discouraged physicians from prescribing it more frequently.

90. The truth, however, was that the marketing claims Respondents made in Maryland were false and highly deceptive. OxyContin was not superior to immediate-release opioids. It did not relieve pain for 12 hours. And it most certainly was addictive.

91. It is now recognized that OxyContin's stunning success masked a fundamental problem: as a *Los Angeles Times* investigation uncovered, the drug wears off hours early in many

people. OxyContin is a chemical cousin of heroin, and when it doesn't last, patients can experience excruciating symptoms of withdrawal, including an intense craving for the drug.[51]

92. Experts therefore have called 12-hour dosing of OxyContin "an addiction producing machine."[52] Respondents have known for decades that 12-hour relief was a false promise but nevertheless mobilized hundreds of sales representatives to "refocus" physicians on 12-hour dosing.

93. Even before OxyContin went on the market, Respondents knew that Purdue's claims about 12-hour dosing were deceptive. The clinical trials for OxyContin demonstrated that many patients simply were not getting the 12 hours of relief that Respondents would soon promise. Since the drug's debut in 1995, Respondents have been confronted with additional evidence, undermining repeated claims of 12-hour pain relief including complaints from doctors, reports from sales representatives, and Purdue's own independent research.[53]

94. Nevertheless, Purdue has chosen to hold fast to the claim of 12-hour relief, in order to protect its revenue. Even as recently as 2015, for example, Purdue instructed its sales representatives to continue to reassure prescribers worried by the opioid crisis that OxyContin provided 12-hour relief. OxyContin's market dominance and its high price – up to hundreds of

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[51] The *Los Angeles Times* investigation, reported in three parts on May 5, July 10, and December 18, 2016, included the review of thousands of pages of confidential Purdue documents and court and other records. They span three decades, from the conception of OxyContin in the mid-1980s to 2011, and include emails, memoranda, meeting minutes, and sales reports, as well as sworn testimony by executives, sales representatives, and other employees. Ryan, *Description of Hell*, *supra* n.47. The *Los Angeles Times* reporters also examined FDA records, Patent Office files, and medical journal articles, and interviewed experts in pain treatment, addiction medicine, and pharmacology. *Id.*

[52] Kathleen Frydl, *Purdue Pharma: Corporate Fraud With a Body Count*, Alternet (May 18, 2016), http://www.alternet.org/drugs/purdue-pharma-corporate-fraud-body-count.

[53] Ryan, *Description of Hell*, *supra* n.47.

dollars per bottle – hinge on its supposed 12-hour duration. Without this claim, OxyContin loses its advantage over less expensive painkillers.[54]

95. To make matters worse, when doctors began prescribing OxyContin at shorter intervals in the late 1990s, Purdue executives mobilized hundreds of sales representatives to "refocus" physicians on 12-hour dosing. Anything shorter "needs to be nipped in the bud. NOW!!" one manager wrote to her staff.[55]

96. Purdue instructed doctors to remedy the problem by prescribing stronger doses, instead of more frequent ones. That approach creates other risks. Stronger doses create greater highs and lower lows. Research shows that the more potent the dose of an opioid such as OxyContin, the greater the possibility of overdose, respiratory depression, and death, and the greater the risk of addiction.[56]

97. Purdue sales representatives regularly encouraged Maryland healthcare providers to increase the dose of OxyContin without discussing the risks associated with dose increases. For example, according to notes from sales calls made in Maryland between 2006 and 2016, a Purdue sales representative noted of his call on a prescriber in [redacted]:

[redacted]

54 *Id.*

55 *Id.*

56 *Id.*

98. Additionally, one Purdue sales representative noted in her follow-up comments after a call with a [redacted]:

[redacted]

99. And a Purdue sales representative noted of her call on a [redacted]:

[redacted]

100. The company line, confirmed by one Maryland sales manager in testimony under oath to the Division, was that OxyContin lasted 12 hours if "dosed correctly." Respondents directed their sales representatives to constantly encourage higher doses and incentivized their doing so. Due largely to the success of these efforts, more than half of long-term OxyContin users are on doses that public health officials consider dangerously high, according to an analysis of nationwide prescription data conducted for the *Los Angeles Times*.[57]

101. As reported by *The New York Times*, "internal Purdue Pharma documents show that company officials recognized even before the drug was marketed that they would face stiff resistance from doctors who were concerned about the potential of a high-powered narcotic like OxyContin to be abused by patients or cause addiction."[58] To combat this resistance, Respondents

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[57] *Id.*

[58] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. Times (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html (hereinafter, "Meier, *Guilty Plea*").

promised the long-acting, extended-release formulation as safer and "less prone to such problems."[59]

102. Purdue's sales culture required aggressive sales of its opioids and embraced the sell-at-any-cost notion: sell or be gone. Aggressive quotas were put into place for opioids including OxyContin and Hysingla, at all dosage levels. The highest dosage for OxyContin was referred to by Purdue sales representatives as "hillbilly heroin." When sales representatives failed to meet their quotas, they were placed on performance employment plans and/or terminated. When they were successful, they were richly rewarded with extravagant bonuses and prizes. There was so much money to be made, and so much pressure to meet quotas, that sales representatives became desensitized to what they were selling.

C. The Sackler Respondents Directed Purdue to Falsely Claim Low Addiction Risk, and Market Opioids to Patients for Whom Opioids Were Unnecessary, Inappropriate, Ineffective, and Dangerous

103. As noted above, prior to 1980, physicians correctly understood opioids as being appropriately reserved only for rare cases, such as in late-stage cancer patients. They were perceived as ineffective, inappropriate, and too dangerous for other types of patients, who should be treated for pain with other therapies.

104. To overcome these limitations on the size of its market for opioids and to drive profits ever higher, Respondents increasingly marketed their opioids for use in non-cancer patients to whom opioids previously would not ordinarily have been prescribed. These patients today make up 86% of the total opioid market.[60]

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[59] *Id.*

[60] Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012, 8:57 PM),

105. To reach these patients, rather than targeting merely those physicians treating acute severe short-term pain, like post-operative pain physicians or oncologists treating end-stage cancer pain, reports indicate that Purdue heavily promoted OxyContin in Maryland and nationwide to doctors such as general practitioners, who often had little training in the treatment of serious pain or in recognizing signs of drug abuse in patients.[61] According to a report in *The New Yorker*, "[a] major thrust of the sales campaign was that OxyContin should be prescribed not merely for the kind of severe short-term pain associated with surgery or cancer but also for less acute, longer-lasting pain: arthritis, back pain, sports injuries, fibromyalgia," such that "[t]he number of conditions that OxyContin could treat seemed almost unlimited."[62]

106. Purdue also trained its Maryland sales representatives to call upon psychiatrists – physicians who treat patients with mental health disorders that place them at greater risk for opioid use disorders.

107. Sales representatives plied these and other physicians, and their patients, with coupons that patients could redeem for a 7- to 30-day supplies of free OxyContin, with the promise that OxyContin was generally safe and useful to treat a variety of non-cancer pain conditions. Purdue "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

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https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups/ (hereinafter, "Ornstein, *American Pain Foundation*").

[61] Meier, *Guilty Plea*, *supra* n.58.

[62] Keefe, *Empire of Pain*, *supra* n.13.

chronic non-cancer-related pain."[63] Thousands of Purdue's free product coupons were distributed in Maryland through prescribers who treated common pain conditions for which Purdue's opioids were medically unnecessary.

108. At the Sackler Respondents' direction, Purdue managers hired and trained a sales force comprised of hundreds of sales reps. Purdue managers tested the sales reps on the most important false statements during training at headquarters – specifically that the risk of addiction was "less than one percent." Purdue mailed promotional videos to thousands of doctors with the same false claim:

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

109. Additionally, sales representatives were directed to market OxyContin as a product "'to start with and to stay with,'" and Respondents deliberately exploited a misconception they knew many doctors held that oxycodone was less potent than morphine.[64] Sales representatives also received training in overcoming doctors' concerns about addiction with talking points Respondents knew to be untrue about the drug's abuse potential. *The New Yorker* reported that "[i]n 2002, a sales manager from the company, William Gergely, told a state investigator in Florida that Purdue executives 'told us to say things like it is "virtually" non-addicting.'"[65]

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[63] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am. J. Pub. Health 221-27 (Feb. 2009) (hereinafter, "Van Zee, *Promotion and Marketing*").

[64] Keefe, *Empire of Pain*, *supra* n.13.

[65] *Id.*

110. Further, to overcome objections about using dangerous opioids in an ever-broadening class of patients, "[a]ccording to training materials, Purdue instructed sales representatives to assure doctors – repeatedly and without evidence – that 'fewer than one per cent' of patients who took OxyContin became addicted." But "[i]n 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent."[66] Regardless, even as late as 2015, if not later, Purdue sales representatives were telling physicians OxyContin was addiction resistant and had abuse-deterrent properties. Indeed, according to notes from sales calls made in Maryland, [redacted].

111. Respondent David Sackler was deeply involved in the development of Purdue's public messaging regarding the abuse-deterrent formulation of OxyContin that it launched in 2010, messaging that was ultimately disseminated throughout Maryland. Respondents' claims that OxyContin was abuse-deterrent were deceptive. In reality, the claims were designed to falsely reassure public and prevent the erosion of OxyContin's dominance in the market.

112. According to notes from Purdue sales representatives' calls on Maryland healthcare providers, Purdue sales representatives [redacted].

113. [redacted] *Providing Relief, Preventing Abuse: A Reference Guide to Control*

[66] *Id.*

Substance Prescribing Practices (2008), falsely informed Maryland prescribers that addiction "is not caused by drugs." Instead, Purdue assured Maryland healthcare providers that addiction occurs when the wrong patients get drugs and abuse them: "it is triggered in a susceptible individual by exposure to drugs, most commonly through abuse." This is incorrect. In fact, "many people with no addiction history can become addicted to opioid painkillers in the course of routine medical treatment. Furthermore, they can become addicted quickly, in a matter of days to weeks."[67] Moreover, Purdue's assurances encouraged these prescribers to believe that these physicians would be able to detect which patients were more susceptible to addiction, which in many cases was beyond the specialization and training that many of the recipients of these messages possessed.

114. Another Purdue publication [redacted], the *Resource Guide for People with Pain* (2010), falsely assured patients that opioid medications are not addictive:

> "Many people living with pain and even some healthcare providers believe that opioid medications are addictive. The truth is that when properly prescribed by a healthcare professional and taken as directed, these medications give relief – not a 'high.'"

These statements are not true.

115. Yet another Purdue publication [redacted], *Clinical Issues in Opioid Prescribing*, informed doctors that signs of addiction may be indicative of "pseudoaddiction," which can be treated by prescribing more or more powerful opioids:

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[67] Lembke (2016), *supra* n.21, at 22 (citing Gillian A. Beauchamp, Erin L. Winstanley, Shawn A. Ryan & Michael S. Lyons, *Moving beyond misuse and diversion: the urgent need to consider the role of iatrogenic addiction in the current opioid epidemic*, 104(11) Am. J. Public Health 2023 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4202970/.

> "A term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may 'clock watch' and may otherwise seem inappropriately 'drug-seeking.' Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated."

116. Purdue's Maryland sales force told Maryland prescribers to ignore clear warning signs that their patients were addicted by deceptively dubbing the symptoms of real addiction to be pseudoaddiction. As one of Respondents' district managers in charge of sales in Maryland testified under oath to the Division, Maryland prescribers were informed that inappropriate drug-seeking behaviors, including even lying to physicians about their pain itself to obtain opioids, and the illegal use of heroin and cocaine – which are clear signs of addiction – were merely signs of pseudoaddiction and needed a higher dose. The solution to many of the problems Maryland prescribers identified with Respondents' opioids was often predictably that the patient simply needed a higher dose.

117. Respondents also promoted their opioids directly to Maryland patients with marketing that was designed to obscure the risk of addiction and even the fact that Purdue was behind the campaign. Purdue created a website, *In the Face of Pain*, that promoted pain treatment by urging patients to "overcome" their "concerns about addiction." Testimonials on the website that were presented as personal stories were in fact stories by Purdue consultants, whom Purdue had paid tens of thousands to promote its drugs. Purdue sales representatives [redacted].

118. Through another unbranded consumer website *Partners Against Pain*,[68] Purdue stated the following: "Current Myth: Opioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids." It further reads: "Addiction risk also appears to be low when opioids are dosed properly for chronic, noncancer pain." Purdue sales representatives [redacted].

119. The marketing worked. Keith Humphreys, professor of psychiatry at Stanford University and drug-policy adviser to the Obama Administration, said, "'[t]hat's the real Greek tragedy of this – that so many well-meaning doctors got co-opted. The level of influence is just mind-boggling. Purdue gave money to continuing medical education, to state medical boards, to faux grassroots organizations.'"[69] Purdue's payments were made at Respondents' direction. Maryland prescribers and patients were deceived.

120. At the Sackler Respondents' direction, Purdue also tracked physicians' prescribing practices by reviewing pharmacy prescription data it obtained from IMS Health (now known as IQVIA), a company that buys bulk prescription data from pharmacies and resells it to drug makers

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[68] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for better pain care, and a set of medical education resources distributed to prescribers by sales representatives. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."

[69] Keefe, *Empire of Pain*, *supra* n.13.

for marketing purposes. (Notably, Arthur Sackler co-founded IMS Health.) Rather than reporting the highly suspicious prescribing practices this information divulged, Purdue used the data to track physicians who prescribed some opioids and might be persuaded to prescribe more opioids. Purdue also could identify physicians writing large numbers of prescriptions, and particularly for high-dose 80 mg pills – potential signs of diversion and drug dealing.[70] But instead of reporting and ceasing sales to these high prescribers, Purdue targeted them for additional sales, Internally, it called these high-prescribing doctors "whales."[71]

121. Respondents knew about many suspicious doctors and pharmacies from prescribing records, pharmacy orders, field reports from sales representatives and, in some instances, its own surveillance operations.[72] Since 2002, Purdue maintained a confidential roster of suspected reckless prescribers known as "Region Zero." By 2013, although there were more than 1,800 doctors in Region Zero, Purdue had reported only 8% of them to authorities. Maryland prescribers were among those listed in Region Zero. The *Los Angeles Times* reported that "[a] former Purdue

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[70] An 80 mg tablet is equivalent in strength to 16 Vicodin tablets, and was generally reserved by doctors for patients with severe, chronic pain who had built up a tolerance over months or years. In the illegal drug trade, however, "80s" were the most in demand. For those attempting to detect how OxyContin was getting onto the black market, a physician writing a high volume of 80s was a red flag. Harriet Ryan, *et al.*, *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, L.A. Times (July 10, 2016), http://www.latimes.com/ projects/la-me-oxycontin-part2/ (hereinafter, "Ryan, *More than 1 million*").

[71] Keefe, *Empire of Pain*, *supra* n.13.

[72] Purdue's "Abuse and Diversion Detection" program requires its sales representatives to report to the company any facts that suggest a health care provider to whom it markets opioids may be involved in the abuse or illegal diversion of opioid products. When a provider is reported under the program, Purdue [purportedly] conducts an internal inquiry regarding the provider to determine whether he or she should be placed on a "no-call" list. If a provider is placed on this list, Purdue sales representatives may no longer contact the provider to promote the company's opioid products. Bill Fallon, *Purdue Pharma agrees to restrict marketing of opioids*, Stamford Advocate (Aug. 25, 2015, 3:32 PM), http://www.stamfordadvocate.com/ business/article/Purdue-Pharma-agrees-to-restrict-marketing-of-6464800.php.

executive, who monitored pharmacies for criminal activity, acknowledged that even when the company had evidence pharmacies were colluding with drug dealers, it did not stop supplying distributors selling to those stores."[73]

D. At the Sackler Respondents' Direction, Purdue Falsely Marketed Progressively Higher Doses

122. For patients, taking higher doses of opioids increases the risk of addiction and death. But for Purdue, higher doses mean higher profits. Purdue aggressively marketed doctors to get patients on higher and higher doses.

123. Purdue earns more money every time a patient's dose is increased. In 2015, Purdue's prices increased dramatically at higher dosages. Purdue makes $38 for each patient taking the lowest dose pill twice a day for a week. Purdue's profits increase 450% to $210 if the patient is given the highest dose instead.

OxyContin Prices

bottle of 100 tablets (10 mg) $269.17
bottle of 100 tablets (15 mg) $396.28
bottle of 100 tablets (20 mg) $501.99
bottle of 100 tablets (30 mg) $698.15
bottle of 100 tablets (40 mg) $859.72
bottle of 100 tablets (60 mg) $1,217.22
bottle of 100 tablets (80 mg) $1,500.18

124. To increase profits, Purdue designed its sales tactics to increase doses. Purdue created a campaign for OxyContin with the slogan, "*Individualize The Dose*." Purdue's CEO gave a presentation to the Sackler Respondents explaining that Purdue would use *Individualize the Dose* to sell more of its highest doses. When Purdue decided to refresh the campaign with a new slogan, it hired consultants to study what would increase doses the most.

125. Purdue trained its sales force on "titration" (escalating doses), a tactic it determined was key to making more money. Purdue pushed a one-way path of increasing doses and specifically cited "clinical need."

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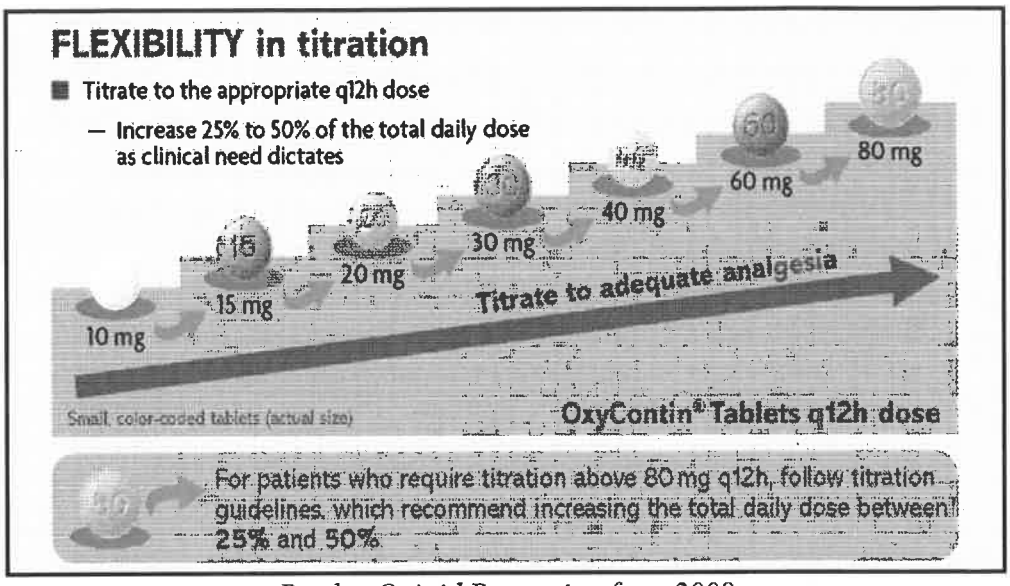
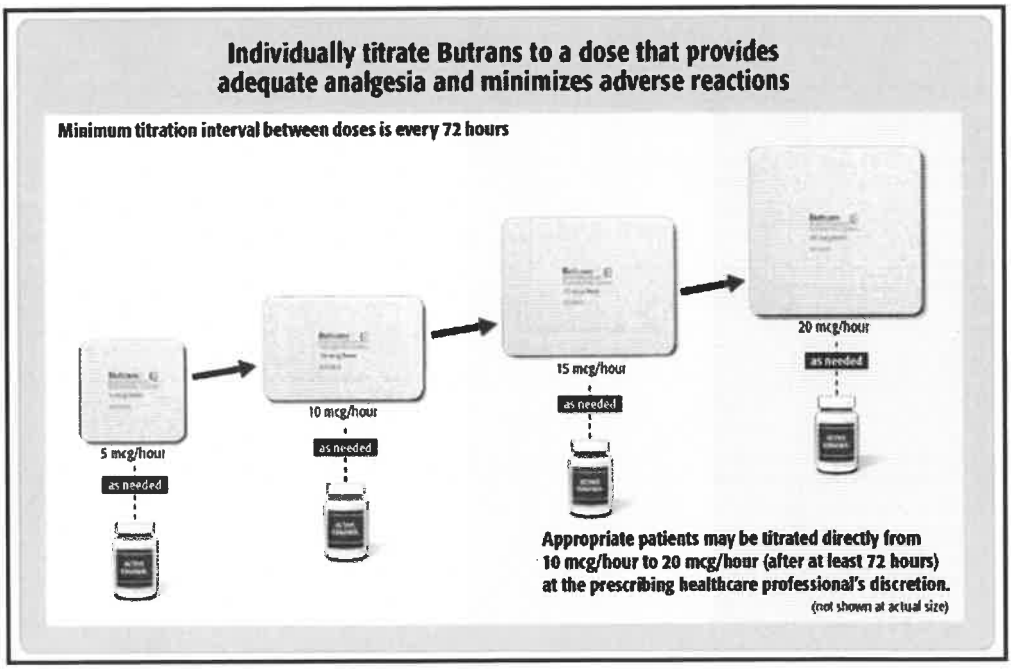
[73] Ryan, *More than 1 million*, *supra* n.70.



Purdue Opioid Promotion from 2008



Purdue Opioid Promotion from 2013

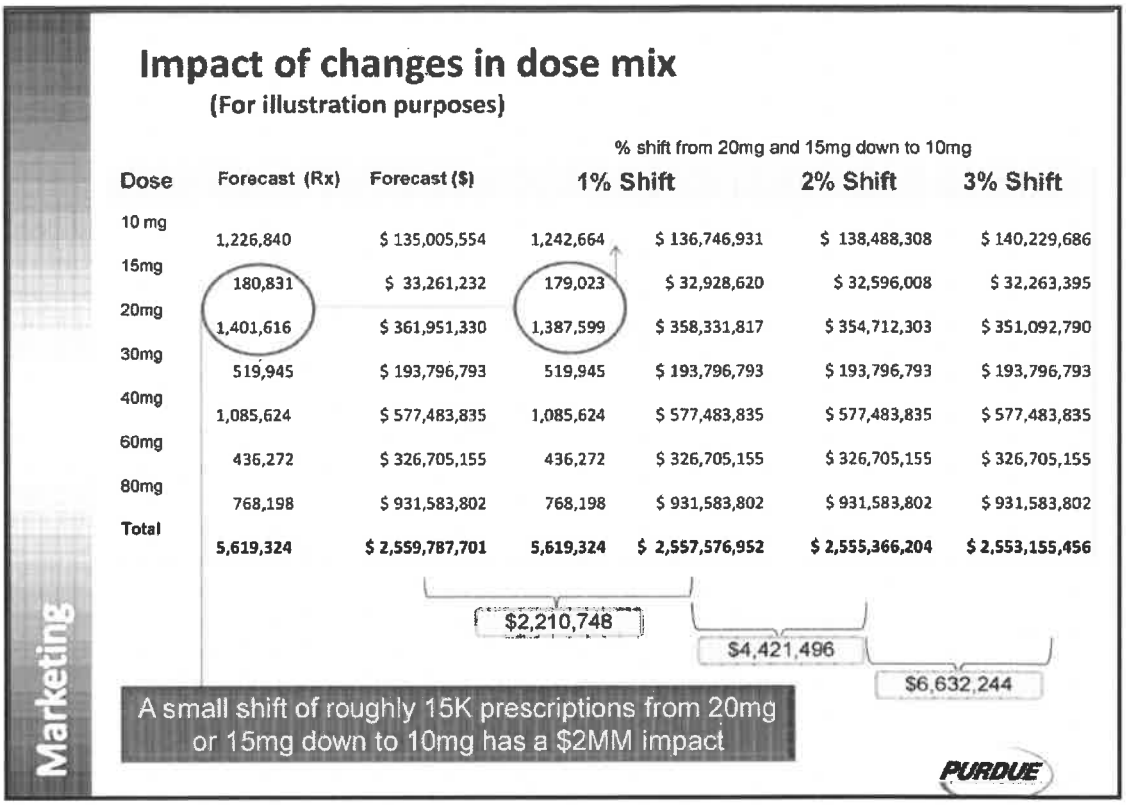
126. Purdue tracked whether sales reps were effectively getting patients on higher doses and warned staff when they were not successful that "titration up to higher strengths, especially the 40mg and 80mg strengths, is declining." Purdue required sales reps to "practice verbalizing the titration message" to get patients on higher doses.

127. Respondents knew that Purdue's promotion drove patients to higher doses. Purdue's internal analysis "found that there is greater loss in the 60mg and 80mg strengths (compared to other strengths) when we don't make primary sales calls." Purdue's business plans emphasized that "OxyContin is promotionally sensitive, specifically with the higher doses, and recent research findings reinforce the value of sales calls." In 2014, when public health experts tried to save patients' lives by warning against high doses of opioids, Purdue pursued a "strategic initiative" to fight back and "maintain 2013 dose mix."

128. At the Sackler Respondents' direction, Purdue encouraged doctors to prescribe high doses and failed to warn that higher doses carry heightened risk of addiction, overdose, and death. Purdue further concealed risks from its own sales force.

129. The deception was deliberate. Purdue claimed that "dose was not a risk factor for opioid overdose," even while it admitted in internal documents that it was "very likely" that patients face "dose-related overdose risk."

130. Respondents analyzed, down to the last dollar, how much of Purdue's profit depended on patients taking higher doses of opioids. In the slide below, Purdue reminded staff that a shift to lower doses, which reduces danger to patients, would be bad for Purdue's bottom line.



Purdue Internal Strategy Presentation from 2012

131. When the CDC issued a national warning against the highest and most dangerous doses of opioids, Purdue's response was to analyze prescription data to calculate how much profit it would lose if doctors followed the CDC's advice.

E. The Sackler Respondents Directed Purdue to Fund Publications and Presentations That Inundated Prescribers and Patients with False and Misleading Messaging

132. Respondents' false marketing scheme was not limited to misrepresentations made by Purdue's own sales representatives and branded marketing materials. In addition, in a carefully orchestrated scheme, Respondents employed a variety of strategies to normalize the use of opioids for chronic long-term pain without informing the public and prescribers about the very significant risk of addiction, overdose, and death. Essentially coopting science with money, Respondents sponsored purportedly neutral medical boards and foundations in order to promote the liberal

prescribing of opioids for chronic pain. Furthering Respondents' unfair and deceptive scheme to market opioids, the following organizations, funded by Purdue, advised doctors that liberal prescribing of opioids was both safe and effective. In truth, it was neither.

133. **Federation of State Medical Boards**: The Federation of State Medical Boards ("FSMB") is a national organization that functions as a trade group representing the 70 medical and osteopathic boards in the United States. Among the FSMB's members is the Maryland Board of Physicians.

134. The FSMB often develops guidelines that serve as the basis for model policies with the stated goal of improving medical practice. Since 1998, the FSMB has been developing treatment guides for the use of opioids for the treatment of pain. The 1998 version, *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies," including Purdue. These 1998 Guidelines that Respondents helped author taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were "essential" for the treatment of chronic pain, including as a first prescription option." Both a 2004 revision of the 1998 Guidelines and a 2007 guide by Dr. Scott Fishman ("Fishman") titled "Responsible Opioid Prescribing" (in the form of a book, still available for sale on Amazon) made the same claims as the 1998 Guidelines. (Fishman has had relationships with at least eight pharmaceutical companies, including Purdue, for which he was a consultant, paid speaker, and recipient of research support.[74]) Purdue sales representatives [redacted]

[74] Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 9:14 AM), https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry (hereinafter, "Weber, *Two Leaders in Pain*").

[redacted]. Respondents thereby used FSMB as a front to add legitimacy to what were in fact deceptive marketing claims.

135. After adopting Fishman's "Responsible Opioid Prescribing: A Physician's Guide," the FSMB reportedly asked Purdue for $100,000 to help pay for printing and distribution.[75] Ultimately, with Respondents' sponsorship, the guide was disseminated by the FSMB to 700,000 practicing physicians.

136. The guide's clear purpose is to focus prescribers on the purported undertreatment of pain and falsely assure them that opioid therapy is an appropriate treatment for chronic, non-cancer pain. Among other things, it states the following:

- Pain management is integral to good medical practice and for all patients;
- Opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins;
- Patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.

* * *

Four key factors contribute to the ongoing problem of under-treated pain:

1. Lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment;
2. The perception that prescribing adequate amounts of opioids will result in unnecessary scrutiny by regulatory authorities;
3. ***Misunderstanding of addiction and dependence***; and
4. Lack of understanding of regulatory policies and processes.[76]

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[75] John Fauber, *Follow the Money: Pain, Policy, and Profit*, MedPage Today (Feb. 19, 2012), https://www.medpagetoday.com/neurology/painmanagement/31256.

[76] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide* 8-9 (Waterford Life Sciences 2007).

137. While the guide acknowledges the risk of "abuse and diversion" (with little attention to addiction), it purports to offer "professional guidelines" that will "easily and efficiently" allow physicians to manage that risk and "minimize the potential for [such] abuse."[77] Indeed, it encourages the use of opioids even in patients who are at risk for substance abuse, suggesting that this risk "does not mean that opioid use will become problematic or that opioids are contraindicated," but only requires that physicians use additional care in prescribing. These statements deceptively minimize the risk of addiction.

138. The guide further warns physicians to "[b]e aware of the distinction between pseudoaddiction and addiction" and teaches that behaviors such as "[r]equesting [drugs] by name," "[d]emanding or manipulative behavior," "[o]btaining opioid drugs from more than one physician" and "[h]oarding opioids" – all red flag signs of genuine addiction – are merely signs of "pseudoaddiction."[78] The guide defines "Physical Dependence" as an acceptable result of opioid therapy, not to be equated with addiction and states that while "[i]t may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications," there could be other acceptable reasons for non-adherence.[79]

139. Purdue sales representatives [redacted]. For example, according to notes from a sales call to a doctor in [redacted], a Purdue sales representative noted the following communication:

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[77] *Id.* at 9.

[78] *Id.* at 62.

[79] *Id.*

[redacted]

140. Additionally, a sales representative's notes concerning a sales call to a doctor in [redacted], provided:

[redacted]

141. Further, in follow-up comments regarding a sales call, the sales representative commented [redacted].

142. With Respondents' sponsorship and active support, the FSMB guide became the seminal authority on opioid prescribing for the medical profession. It dramatically overstated the safety and efficacy of opioids and understated the risk of opioid addiction. According to notes of sales calls made to Maryland prescribers by Purdue sales representatives between 2006 and 2016, the [redacted].

143. In 2012, Fishman updated the guide and continued emphasizing the "catastrophic" "under-treatment" of pain and the "crisis" such under treatment created:

> Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, ***it's critical to remember that the problem of unrelieved pain remains as urgent as ever.***[80]

[80] Scott M. Fishman, *Responsible Opioid Prescribing: A Clinician's Guide* 10-11 (Waterford Life Sciences 2012).

144. The updated guide still assures that "***[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and noncancer origins.***"[81]

145. In yet another 2012 guide, Responsible Opioid Prescribing: A Physician's Guide, Fishman continues to downplay the risk of addiction: "***I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a 'chemical coper' and an addict.***"[82] The guide also continues to present symptoms of addiction as symptoms of "pseudoaddiction."

146. The heightened focus on the undertreatment of pain was a concept designed by Respondents and other manufacturers to sell opioids. Indeed, Purdue sales representatives [redacted]. With Respondents' support, ***the FSMB issued a report calling on medical boards to punish doctors for inadequately treating pain.***[83] Among the drafters of this policy was Dr. J. David Haddox ("Haddox"), who coined the term "pseudoaddiction," which wholly lacked scientific evidence but quickly became a common way for Respondents and their allies to promote the use of opioids even to patients displaying addiction symptoms. Respondent Richard Sackler later hired Haddox as a Purdue vice president. Haddox has likened OxyContin to a vegetable, stating at a 2003 conference at Columbia University,[84] "If I gave you a stalk of celery and you ate

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[81] *Id.* at 11.

[82] Scott M. Fishman, *Listening to Pain: A Physician's Guide to Improving Pain Management Through Better Communication* 45 (Oxford University Press 2012).

[83] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts* at A1, Wall St. J. (Dec. 17, 2012).

[84] Gounder, *Who Is Responsible*, *supra* n.40.

that, it would be healthy. But if you put it in a blender and tried to shoot it into your veins, it would not be good."[85]

147. As noted in section III.I. *infra*, in 2012 and again in 2017, the guides and the sources of their funding became the subject of a Senate investigation.

148. On June 8, 2012, the FSMB submitted a letter to the Senate Finance Committee concerning the committee's investigation into the abuse and misuse of opioids.[86] While the letter acknowledged the escalation of drug abuse and related deaths resulting from prescription painkillers, the FSMB continued to focus on the "serious and related problem" that "[m]illions of Americans suffer from debilitating pain – a condition that, for some, can be relieved through the use of opioids." Among other things, the letter stated that "[s]tudies have concluded that both acute pain and chronic pain are often under-treated in the United States, creating serious repercussions that include the loss of productivity and quality of life." But the letter cited no such studies. The letter also confirmed that the FSMB's "Responsible Opioid Prescribing: A Physician's Guide" had been distributed in each of the 50 states and the District of Columbia.

149. In addition, the FSMB letter disclosed payments the FSMB received from organizations that develop, manufacture, produce, market, or promote the use of opioid-based drugs from 1997 through 2012. Included are the following payments from Purdue:

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[85] Keefe, *Empire of Pain*, *supra* n.13.

[86] Letter from Federation of State Medical Boards to U.S. Senators Max Baucus and Charles Grassley (June 8, 2012).

Company	*Fiscal Year*	*Amount*
Purdue	2001	$38,324.56
	2002	$10,000.00
	2003	$85,180.50
	2004	$87,895.00
	2005	$244,000.00
	2006	$207,000.00
	2007	$50,000.00
	2008	$100,000.00
	Total Purdue Payments	***$822,400.06***

150. The letter also disclosed payments of $50,000 by Purdue to directly fund the production of "Responsible Opioid Prescribing" and disclosed that sales of "Responsible Opioid Prescribing" in Maryland generated more than $51,000 in revenues.[87]

151. **The Joint Commission**: The Joint Commission is an organization that establishes standards for treatment and accredits healthcare organizations in the United States. Respondents contributed misleading and groundless teaching materials and videos to the Joint Commission, which emphasized what Purdue and other opioid manufacturers coined the "under-treatment of pain," referenced pain as the "fifth vital sign" (the first and only unmeasurable/subjective vital sign) that must be monitored and treated and encouraged the use of prescription opioids for chronic pain while minimizing the danger of addiction. It also called doctors' concerns about addiction "inaccurate and exaggerated." Notably, Richard Sackler made sure that Purdue bought the internet address 5thvitalsign.com so it could promote pain as the "fifth vital sign."

152. In 2000, the Joint Commission printed a book for purchase by doctors as part of required continuing education seminars that cited studies falsely claiming "***there is no evidence that addiction is a significant issue when persons are given opioids for pain control.***" The book was sponsored by Purdue.

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[87] *Id.* at 11-12, 15.

153. In 2001, the Joint Commission and the National Pharmaceutical Council (founded in 1953 and supported by the nation's major research-based biopharmaceutical companies)[88] collaborated to issue a 101-page monograph titled, "Pain: Current understanding of assessment, management, and treatments." The monograph states falsely that beliefs about opioids being addictive are "erroneous":

> Societal issues that contribute to the undertreatment of pain include drug abuse programs and erroneous beliefs about tolerance, physical dependence, and addiction (*see* I.E.5). ***For example, some clinicians incorrectly assume that exposure to an addictive drug usually results in addiction.***
>
> * * *
>
> **b. Etiology, issues, and concerns**
>
> Many medications produce tolerance and physical dependence, and some (*e.g.*, opioids, sedatives, stimulants, anxiolytics, some muscle relaxants) may cause addiction in vulnerable individuals. Most experts agree that patients who undergo prolonged opioid therapy usually develop physical dependence but do not develop addictive disorders. ***In general, patients in pain do not become addicted to opioids. Although the actual risk of addiction is unknown, it is thought to be quite low.*** A recent study of opioid analgesic use revealed "low and stable" abuse of opioids between 1990 and 1996 despite significant increases in opioids prescribed. . . .
>
> ***Fear of causing addiction (i.e., iatrogenic addiction), particularly with opioid use, is a major barrier to appropriate pain management.*** This fear sometimes reflects a lack of understanding of the risk of addiction with therapeutic drug use. Although studies suggest that the risk of iatrogenic addiction is quite low (*e.g.*, Perry and Heidrich, Zenz *et al.*), surveys indicate that clinicians often overestimate this risk.[89]

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[88] Currently funded by Purdue, among others.

[89] National Pharmaceutical Council, Inc., *Pain: Current Understanding of Assessment, Management, and Treatments* at 16-17 (Dec. 2001), http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf.

154. Additionally, the monograph recommends that "[p]ain . . . is assessed in all patients" and suggests that long-acting (*i.e.*, extended release) pain medications are superior and should be used whenever possible:

> ***Long-acting and sustained-release opioids are useful for patients with continuous pain, as they lessen the severity of end-of-dose pain*** and often allow the patient to sleep through the night.
>
> * * *
>
> - Administer opioids primarily via oral or transdermal routes, using long-acting medications when possible.[90]

155. In truth, long-acting opioids often do not work for the full period stated and require additional doses for what is described as "breakthrough pain," and "the higher the dose, the worse the side effects, including the risks of addiction and death due to accidental overdose."[91]

156. Purdue's infiltration of and influence over the Joint Commission's standards and literature exerted overwhelming pressure on doctors to treat and eliminate pain. As more and more doctors migrated from private practice to integrated healthcare systems in the 2000s, treatment options were dictated by, among other things, the Joint Commission's guidelines.[92] Consistent with the guidelines, doctors who left pain untreated were viewed as demonstrating poor clinical skills and/or being morally compromised.[93]

157. The U.S. General Accounting Office's December 2003 Report to Congressional Requesters confirms that Purdue funded the "pain management educational courses" that taught the new standard of care for treating pain. It further revealed that Purdue disseminated educational

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[90] *Id.* at 67 (Table 38).

[91] Lembke (2016), *supra* n.21, at 60.

[92] *Id.* at 119.

[93] *Id.* at 42.

materials on pain management, which "'facilitated [Purdue's] access to hospitals to promote OxyContin.'"[94]

158. **The American Pain Foundation**: The American Pain Foundation ("APF"), headquartered in Baltimore through its dissolution in 2012, described itself as the nation's largest organization for pain patients.[95] While APF held itself out as an independent patient advocacy organization, in reality it received more than $10 million in funding from opioid manufacturers from 2007 to 2012, when it shut down only days after the U.S. Senate Committee on Finance ("Senate Finance Committee") launched an investigation of the APF's promotion of prescription opioids.

159. Payments to the APF were made with strings attached. Respondents, along with other members of the industry, were actively involved in the planning of the APF's campaigns.

160. The APF published guides for patients, journalists and policymakers that trivialized the risk of addiction and greatly exaggerated the benefits associated with opioid painkillers.[96]

161. For example, in 2001, the APF published "Treatment Options: A Guide for People Living with Pain,"[97] which it disseminated throughout the United States, including in Maryland. The guide, which was produced with financial support from companies including Purdue, misrepresented the risks associated with opioid use. Among other things, the guide:

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[94] Gounder, *Who Is Responsible*, *supra* n.40; U.S. General Accounting Office, GAO-04-110, *Prescription Drugs, OxyContin Abuse and Diversion and Efforts to Address the Problem* (Dec. 2003), http://www.gao.gov/new.items/d04110.pdf.

[95] The APF was the focus of a December investigation by ProPublica in *The Washington Post* that detailed its close ties to drugmakers.

[96] Ornstein, *American Pain Foundation*, *supra* n.60.

[97] *Treatment Options: A Guide for People Living with Pain*, American Pain Foundation, https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (last visited May 14, 2019).

- lamented that opioids were sometimes called narcotics because "***[c]alling opioid analgesics 'narcotics' reinforces myths and misunderstandings*** as it places emphasis on their potential abuse rather than on the importance of their use as pain medicines";[98]

- stated that "[o]pioids are an essential option for treating ***moderate*** to severe pain associated with surgery or trauma";[99] and

- opined that "[r]estricting access to the most effective medications for treating pain [opioids] is not the solution to drug abuse or addiction."[100]

The guide included blurbs from Portenoy, who is quoted as saying "[t]his is a very good resource for the pain patient," and Fishman, who is quoted as saying, "[w]hat a great job! Finally, a pill consumer resource created for patients with pain. A 'must have' for every physician's waiting room."

162. In 2003, the APF published a newsletter titled, "Best of . . . The Pain Community News" that purported to clarify any confusion over addiction and opioids and emphasized the "tragic consequence of leaving many people with severe pain under-treated because they – or their doctors – fear that opioids will cause addiction." The guide was disseminated in Maryland with funding provided by Purdue.

163. In 2009, the APF played a central role in a first-of-its-kind, web-based series called, "Let's Talk Pain," hosted by veteran TV journalist Carol Martin. The series brought together healthcare providers and "people with pain to discuss a host of issues from managing health care for pain to exploring integrative treatment approaches to addressing the psychological aspects associated with pain." The "Let's Talk Pain" talk show is still available online. In the very first episode of this talk show, the following exchange took place:

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98 *Id.* at 11.

99 *Id.*

100 *Id.* at 15.

> **[Teresa Shaffer (APF Action Network Leader):]** As a person who has been living with pain for over 20 years, opioids are a big part of my pain treatment. And I have been hearing such negative things about opioids and the risk factors of opioids. Could you talk with me a little bit about that?
>
> **[Dr. Al Anderson (AAPM Board of Directors):]** The general belief system in the public is that the opioids are a bad thing to be giving a patient. Unfortunately, it's also prevalent in the medical profession, so patients have difficulty finding a doctor ***when they are suffering from pain for a long period of time***, especially ***moderate*** to severe pain. And ***that's the patients that we really need to use the opioids*** methods of treatment, because they are the ones who need to have some help with the function and they're the ones that need to be controlled enough so that they can increase their quality of life.[101]

164. Opioids, however, do not improve function, and there is no evidence substantiating that the chronic use of opioids improves the quality of patients' lives.[102] To the contrary, there is ample evidence that opioids impose significant risks and adverse outcomes on long-term users and that they may actually reduce function. As a recent article in the *New England Journal of Medicine* concluded: "Although opioid analgesics rapidly relieve many types of acute pain and improve function, the benefits of opioids when prescribed for chronic pain are much more questionable." The article continues, "opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions."[103] More recent still, a study published in *JAMA* concluded that "[t]reatment with

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[101] *Episode 1: Safe Use of Opioids (PainSAFE)*, Let's Talk Pain (Sept. 28, 2010), https://www.youtube.com/watch?v=zeAlVAMRgsk.

[102] Lembke (2016), *supra* n.21, at 59 (citing Richard Chou, *et al.*, Evidence Report/Technology Assessment: *The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain*, 218 Agency for Healthcare Research and Quality (Sept. 2014), https://effectivehealthcare.ahrq.gov/sites/default/files/related_files/chronic-pain-opioid-treatment_executive.pdf).

[103] Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, 374 New Eng. J. Med. 1253-63 (Mar. 31, 2016), http://www.nejm.org/doi/full/10.1056/NEJMra1507771#t=article.

opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months."[104]

165. The APF also developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website, www.painknowledge.org. NIPC promoted itself as an education initiative and promoted its expert leadership team, including purported experts in the pain management field. The website painknowledge.org provided that, on opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life and "improved function" as benefits of opioid therapy. In the brochure *Pain: Opioid Facts*, available on painknowledge.org, the NIPC misleadingly stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted."[105]

166. In or around 2011, the APF published "A Policymaker's Guide to Understanding Pain & Its Management," sponsored by Respondents, which dispelled the notion that "strong pain medication leads to addiction" by characterizing it as a "***common misconception***[]":

> ***Many people living with pain, and even some health care practitioners, falsely believe that opioid pain medicines are universally addictive.*** As with any medication, there are risks, but these risks can be managed when these medicines are properly prescribed and taken as directed. For more information about safety issues related to opioids and other pain therapies, visit http://www.painsafe.org.[106]

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[104] Krebs, *Effect of Opioid vs. Nonopioid Medications*, *supra* n.25.

[105] *Pain: Opioid Facts*, Pain Knowledge (2007), https://web.archive.org/web/20101007102042/http://painknowledge.org/patiented/pdf/Patient%20Education%20b380_b385%20%20pf%20opiod. pdf (last visited May 14, 2019).

[106] *A Policymaker's Guide to Understanding Pain & Its Management*, American Pain Foundation at 5 (Oct. 2011), http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

167. The guide describes "pain in America" – instead of addiction to Respondents' opioids – as "an evolving public health crisis" and characterizes concerns about opioid addiction as misconceptions: "Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include: . . . ***Misconceptions about opioid addiction.***"[107] It even characterizes as a "***myth***" that "***[c]hildren can easily become addicted to pain medications.***"[108] The guide further asserts that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health and health-related quality of life for chronic pain patients, claims that are simply false.[109]

168. In December 2011, *The Washington Post* reported on ProPublica's investigation of the APF, which detailed the APF's close ties to drugmakers:

> [T]he pills continue to have an influential champion in the American Pain Foundation, which describes itself as the nation's largest advocacy group for pain patients. ***Its message: The risk of addiction is overblown, and the drugs are underused.***
>
> ***What the nonprofit organization doesn't highlight is the money behind that message.***

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[107] *Id.* at 6.

[108] *Id.* at 40.

[109] The "Policymaker's Guide" cites for support "Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects," a review published in 2006 in the *Canadian Medical Association Journal*. *Id.* at 34. However, the review concludes: "For functional outcomes, ***the other analgesics were significantly more effective than were opioids***." Andrea D. Furlan, *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Canadian Med. Assoc. J. 1589-94 (May 23, 2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1459894/. The Purdue-sponsored guide failed to disclose both this conclusion and the fact that the review analyzed studies that lasted, on average, five weeks and therefore could not support the long-term use of opioids.

> ***The foundation collected nearly 90 percent of its $5 million in funding last year from the drug and medical-device industry – and closely mirrors its positions***, an examination by ProPublica found.[110]

169. In 2010 alone, the APF received 90% of its funding from drug and medical device companies. At the Sackler Respondents' direction, Purdue paid the APF unspecified amounts in 2008 and 2009 and between $100,000 and $499,999 in 2010.[111]

170. **American Academy of Pain Medicine and American Pain Society**: Respondents contributed funding to the AAPM and the APS for decades.

171. In 1997, the AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. At the time, the chairman of the committee that issued the statement, Haddox, was a paid speaker for Purdue. Haddox later became a vice president for health policy at Purdue, where he was employed between September 1999 and October 2018. The consensus statement, which also formed the foundation of the 1998 guidelines, was published on the AAPM's website. AAPM's corporate council includes Purdue, Depomed, Inc. ("Depomed"), Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Fishman (2005), Dr. Perry G. Fine ("Fine") (2011) and Lynn R. Webster (2013), all of whose connections to opioid manufacturers are well documented.

172. At or about the same time, the APS introduced the "Pain As the 5th Vital Sign" campaign, to require doctors to ask patients about their level of pain at every visit, despite the fact

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[110] Charles Ornstein & Tracy Weber, *Patient advocacy group funded by success of painkiller drugs, probe finds*, Wash. Post (Dec. 23, 2011), https://www.washingtonpost.com/national/health-science/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probe-finds/2011/12/20/gIQAgvczDP_story.html?utm_term=.22049984c606.

[111] American Pain Foundation, 2010 Annual Report at 16-19, https://www.documentcloud.org/documents/277604-apf-2010-annual-report#document/ (last visited May 14, 2019).

that pain is a symptom that cannot be measured objectively, unlike the four objectively observable vital signs: body temperature, pulse rate, respiration rate, and blood pressure. The campaign successfully influenced prescribers and organizations throughout the United States to prescribe opioids in ways that were not supported by science. The campaign influenced the addition of pain-related questions to patient satisfaction surveys used by CMS to determine hospital reimbursement rates, thereby linking reimbursement to patient satisfaction with pain treatment.

173. The AAPM and APS issued *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain* (the "Clinical Guidelines") in 2009 that continued to recommend the use of opioids to treat chronic pain.[112] Fourteen of the 21 panel members who drafted the 2009 Guidelines received funding from drug manufacturers. Four of the 21, Fine, Steven D. Passik, Portenoy, and Ben A. Rich, received direct funding from Purdue. The Clinical Guidelines were published in *The Journal of Pain*, published by Elsevier on behalf of APS, distributed nationwide in print and internationally via the Internet. The Clinical Guidelines, still available online, have been cited hundreds of times.

174. The *Clinical Guidelines* were published, in their own words:

> to provide evidence-based recommendations for use of COT [chronic opioid therapy] for CNCP [chronic non cancer pain] in both primary care and specialty settings. The target audience is all clinicians who provide care for adults with CNCP, including cancer survivors with chronic pain due to their cancer or its treatment.

Despite conceding that there is limited evidence – indeed, despite conceding that "the panel did not rate any of its 25 recommendations as supported by high quality evidence" – the Clinical Guidelines continued to falsely state that chronic opioid therapy is effective for the treatment of

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[112] Roger Chou, *et al.*, *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10(2) J. of Pain 113-30 (Feb. 2009), http://www.jpain.org/article/S1526-5900(08)00831-6/pdf (hereinafter, "*Clinical Guidelines*").

chronic noncancer pain: "Although evidence is limited, an expert panel convened by [the American Pain Society] and [the American Association for Pain Management] concludes that COT can be an effective therapy for carefully selected and monitored patients with CNCP." Among the unsupported claims nevertheless recounted, the Clinical Guidelines opined that the "[p]roposed benefits of transitioning to long-acting opioids with around-the-clock dosing include more consistent control of pain, improved adherence, and lower risk of addiction or abuse."

175. Reaping the benefit from its contributions, Purdue widely cited and promoted the Clinical Guidelines in Maryland and nationally despite their being misleading and unsubstantiated by scientific evidence.

176. **The Alliance for Patient Access**: Founded in 2006, the Alliance for Patient Access ("APA") is a self-described patient advocacy and health professional organization that styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care."[113] It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.[114] As of June 2017, the APA listed 30 "Associate Members and Financial Supporters," Purdue among them.

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[113] *About AfPA*, The Alliance for Patient Access, http://allianceforpatientaccess.org/about-afpa/ (last visited Jan. 30, 2019). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

[114] Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma's agenda*, Health News Review (Oct. 2, 2017), https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/ (hereinafter, "Jaklevic, *Non-profit Alliance for Patient Access*").

177. APA's board members have also directly received substantial funding from pharmaceutical companies.[115] For instance, board vice president Dr. Srinivas Nalamachu ("Nalamachu"), who practices in Kansas, received more than $800,000 from 2013 through 2015 from pharmaceutical companies – nearly all of it from manufacturers of opioids or drugs that treat opioids' side-effects, including more than $150,000 in consulting and speaking payments from Purdue. Nalamachu's clinic was raided by Federal Bureau of Investigation ("FBI") agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys.[116] Dr. Howard Hoffberg from Maryland was also a board member of the APA, but his now-closed practice also was raided by the FBI in March 2018, Dr. Hoffberg received $153,000 between 2013 and 2015 from pharmaceutical companies, including Purdue, which recruited Dr. Hoffberg as a paid speaker and paid him more than $20,000 in 2015 and 2016.

178. Among its activities, the APA issued a white paper titled, "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse." The white paper expresses concern about policies that have been enacted in response to the prevalence of pill mills:

> Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management] centers must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.[117]

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[115] All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica's Dollars for Docs database, available at https://projects.propublica.org/docdollars/.

[116] Andy Marso, *FBI seizes records of Overland Park pain doctor tied to Insys*, Kansas City Star (July 20, 2017), http://www.kansascity.com/news/business/health-care/article162569383.html.

[117] *Id.* at 5-6.

179. In addition, in an echo of earlier industry efforts to push back against what they termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication:

> Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management – a situation fueled by the numerous regulations and fines that surround prescription pain medications.[118]

180. In conclusion, the white paper states that "[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs."[119] Again, there exists no reliable evidence that opioids are safe and effective for the treatment of chronic pain.

181. ***The Financial Ties Between Opioid Manufacturers and Third-Party Groups***: A February 12, 2018 report titled, "Fueling an Epidemic Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups" issued by then-U.S. Senator Claire McCaskill sheds additional light on the financial connections between opioid manufacturers and purportedly neutral patient advocacy organizations and medical professional societies that, unsurprisingly, have "echoed and amplified messages favorable to increased opioid use – and ultimately the financial interests of opioid manufacturers."[120]

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[118] *Id.* at 6.

[119] *Id.* at 7.

[120] *February 2018 Report*, *supra* n.18, at 1.

182. The report details findings resulting from subpoenas issued by then-Senator McCaskill to 5 opioid manufacturers, including Purdue, and to 15 purportedly neutral patient advocacy organizations and medical professional societies. "The information produced to the Committee demonstrates that many patient advocacy organizations and professional societies focusing on opioids policy have promoted messages and policies favorable to opioid use while receiving millions of dollars in payments from opioid manufacturers," the report found. It continued: "Through criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy organizations have often supported industry interests at the expense of their own constituencies."[121]

183. According to the report, the five manufacturers whose information was subpoenaed by Senator McCaskill alone contributed almost $9 million combined to patient advocacy organizations and professional societies operating in the opioids policy area, including the APA, AAPM, the American Geriatrics Society, the APF, and the APS, among others. Payments from Purdue alone totaled over ***$4 million***.

184. In addition to the nearly $9 million in payments to purportedly neutral patient advocacy organizations and medical professional societies, the five subpoenaed opioid manufacturers made an additional $1.6 million in payments to the organizations' and societies' group executives, staff members, board members, and advisory board members. When payments from all five opioid manufacturers are tabulated, more than $10.6 million was paid to individuals affiliated with such organizations and societies from 2013 through the date of the report.

185. Included in the above-referenced payments were payments of more than $140,000 from opioid manufacturers, including Purdue, to ten members of the American Chronic Pain

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[121] *Id.* at 3.

Association Advisory Board, and more than $950,000 to members of The National Pain Foundation board of directors from various opioid manufacturers.

186. Most importantly, many of the groups investigated "amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain." Several of the groups "also lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescription and misbranding."[122]

187. The report found that, while health advocacy organizations are "'among the most influential and trusted stakeholders in U.S. health policy,'" the reality is that their "'positions closely correspond to the marketing aims of pharmaceutical and device companies,'" including in the area of opioids policy. "The findings in this report indicate that this tension exists in the area of opioids policy – that organizations receiving substantial funding from manufacturers have, in fact, amplified and reinforced messages favoring increased opioid use." This amplification "may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic."[123]

F. At the Sackler Respondents' Direction, Purdue Paid Key Opinion Leaders and Sponsored Speakers' Bureaus to Disseminate False and Misleading Messaging

188. Purdue has made tens of thousands of payments to physicians nationwide, including in Maryland, to promote aggressive prescribing of opioids for chronic pain. Recently released federal data shows that Purdue increased such payments to physicians who treat chronic pain even

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[122] *Id.* at 12.

[123] *Id.* at 17.

while the opioid crisis accelerated and overdose deaths from prescription opioids and related illicit drugs, such as heroin, soared to record rates.[124] According to data that began to be made publicly available in 2013 through the Center for Medicare and Medicaid Services, Purdue's payments to Maryland doctors increased from just over $16,000 in 2013, to nearly $76,000 in 2014, to more than $189,000 in 2015. These payments come in the form of consulting and speaking fees, free food and beverages, discount coupons for drugs, and other gifts. For example, Purdue paid Dr. William Tham approximately $19,600 in 2014 and 2015, and paid Dr. Howard Hoffberg more than $26,700 between 2013 and 2016, for "[p]romotional [s]peaking/[o]ther" related to Purdue opioids. This is true even though Dr. Hoffberg's practice had been recognized as a problem practice and briefly removed from Purdue's call list in 2012 only to be later reinstated. Purdue removed problem prescribers from the call lists while they were under investigation; a Maryland sales manager could not recall a prescriber being removed due to Respondents' identification of problems. The subsequent disciplinary or criminal action against prescribers upon whom Purdue called demonstrates that Respondents blithely ignored blazing red flags that placed Maryland patients in extreme danger.

189. Both Dr. Tham and Dr. Hoffberg have come under fire or investigation for inappropriate opioid prescribing. Dr. Tham was named in a lawsuit filed by Anne Arundel County. The lawsuit alleges that he received more than $100,000 from pharmaceutical companies between August 2013 and December 2015, and that payments to Dr. Tham from Purdue and other opioid manufacturers (specifically, Teva, Janssen, Endo, and Insys) comprised more than 80% of

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[124] Joe Lawlor, *Even amid crisis, opioid makers plied doctors with perks*, Portland Press Herald (Dec. 25, 2016), http://www.pressherald.com/2016/12/25/even-amid-crisis-opioid-makers-plied-doctors-with-perks/.

payments to all doctors during that time frame.[125] According to another lawsuit, Dr. Tham also prescribed a single patient the equivalent of 5,000 Percocet pills per day.[126] Dr. Hoffberg's two clinics were raided in February 2018 by federal and state agents, including officials associated with the Attorney General's Medicaid Fraud Control Unit. He and his partner, Dr. Norman Rosen, were named in a lawsuit by Baltimore County alleging that their practice operated "as a pill mill that supplied individuals with massive quantities of prescription opioids with few questions asked" for their role in "exacerbat[ing] the opioid crisis in Baltimore."[127] The Division has noted issues with both prescribers and their practices in an enforcement action against another opioid manufacturer widely accused of paying kickbacks to prescribers.

190. According to public records collected by ProPublica, in 2015 alone, Medicare Part D paid over $19 million for claims arising from Maryland physicians' OxyContin prescriptions.[128]

191. The total payments from opioid manufacturers, including Purdue, to doctors related to opioids doubled from 2014 to 2015. Moreover, according to experts, research shows even small amounts of money can have large effects on doctors' prescribing practices.[129] Physicians who are high prescribers are more likely to be invited to participate in manufacturers' speakers' bureaus.

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[125] Phil Davis, *Anne Arundel sues opioid manufacturers, distributors and local prescribers*, Capital Gazette (Jan. 3, 2018), https://www.capitalgazette.com/news/for_the_record/ac-cn-opioid-lawsuit-0104-story.html.

[126] John Pacenti, *Veteran, would-be lawyer, mom left dead or addicted after Subsys*, The Palm Beach Post (Apr. 11, 2018), https://www.palmbeachpost.com/news/20180404/veteran-would-be-lawyer-mom-left-dead-or-addicted-after-subsys.

[127] Alison Knezevich, *Federal search warrants executed at pain clinics in Baltimore County*, The Baltimore Sun (Feb. 27, 2018), https://www.baltimoresun.com/news/maryland/baltimore-county/bs-md-co-clinics-searched-20180227-story.html.

[128] *Prescribers of OXYCONTIN in Maryland*, ProPublica, https://projects.propublica.org/checkup/states/maryland (last visited May 14, 2019).

[129] *Id.*

According to a study published by the National Institutes of Health, "[i]n the speakers' bureau system, physicians are recruited and trained by pharmaceutical, biotechnology, and medical device companies to deliver information about products to other physicians, in exchange for a fee."[130]

192. According to a research letter published in *JAMA Internal Medicine* on May 14, 2018, doctors who had just one extra meal paid for by an opioid company were more likely to prescribe opioids than doctors who received fewer free meals.[131]

193. The use of speakers' bureaus has led to substantial ethical concerns within the medical field. As summarized in a 2013 publication by the Institute on Medicine as a Profession:

> **The Problem:**
>
> ***Pharmaceutical companies often recruit physicians to perform speeches or presentations for the purpose of marketing a specific drug.*** In 2010, 8.6% of physicians reported having received payments for participating in speakers' bureaus. These speakers' bureaus leverage the credibility of physicians in order to promote the use of pharmaceutical products. The physicians are generally trained to present a certain message, or are provided with pre-produced slides. ***The audience may assume that these presentations are objective, when in fact they are heavily biased towards the interests of the industry sponsor.***
>
> ***Speakers' bureaus may lead to the dissemination of false or biased information.*** Exposure to industry-sponsored speaking events is associated with decreased quality of prescribing. Additionally, the compensation provided for these engagements may influence the attitudes or judgment of the presenter.[132]

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[130] Lynette Reid & Matthew Herder, *The speakers' bureau system: a form of peer selling*, 7(2) Open Med. e31-e39 (Apr. 2, 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3863750/.

[131] Scott E. Hadland, *et al.*, *Association of Pharmaceutical Industry Marketing of Opioid Products to Physicians With Subsequent Opioid Prescribing*, JAMA Intern. Med. (May 14, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6145750/. The study looked at the Open Payments database, which was used to pull out non-research payments to doctors in 2014. It then compared that data to claims in the Medicare Part D Opioid Prescriber Summary File from doctors who wrote opioid prescriptions in 2015, leaving in "all physicians with complete, nonduplicate information who had at least 10 opioid claims during 2015."

[132] *Speakers' Bureaus: Best Practices for Academic Medical Centers*, IMAP (Oct. 10, 2013), http://imapny.org/wp-content/themes/imapny/File%20Library/Best%20Practice%20toolkits/

194. For example, Fishman is a physician whose ties to the opioid drug industry, and Purdue in particular, are legion. He has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received "market rate honoraria." As discussed above, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Purdue and other opioid manufacturers. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in *JAMA* titled, "Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion."[133]

195. Similarly, Fine's ties to opioid manufacturers, including Purdue, have been well documented.[134] He has authored articles and testified in court cases and before state and federal committees, and he, too, has served as president of the AAPM and argued against legislation restricting high-dose opioid prescription for non-cancer patients. Multiple videos available online feature Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith for pain did not make her an addict before her death.[135] He has also acknowledged having failed to disclose numerous conflicts of interest.

Best-Practices_Speakers--bureaus.pdf (citing research in *JAMA*, *The Journal of Law, Medicine & Ethics* and *Academic Psychiatry*).

[133] Scott M. Fishman, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306(13) JAMA 1445 (2011); Weber, *Two Leaders in Pain*, *supra* n.74.

[134] Weber, *Two Leaders in Pain*, *supra* n.74.

[135] Linda Deutsch, *Doctor: 1,500 pills don't prove Smith was addicted*, Seattle Times (Sept. 22, 2010, 5:16 PM), http://www.seattletimes.com/entertainment/doctor-1500-pills-dont-prove-smith-was-addicted/.

196. Fishman and Fine are only two of the many physicians whom Purdue paid to present false or biased information on the use of opioids for chronic pain.

G. Purdue's Guilty Pleas

197. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin for falsely marketing and promoting OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal symptoms than other pain medications in what the company acknowledged was an attempt to mislead doctors. Purdue was ordered to pay $600 million in fines and fees. Purdue also entered into settlements with several states, including Maryland, relating to this misconduct.

198. In its federal plea agreement, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction, and was unsupported by science. Additionally, Michael Friedman, the company's president, pled guilty to a misbranding charge and agreed to pay $19 million in fines; Howard R. Udell ("Udell"), Purdue's top lawyer, pled guilty and agreed to pay $8 million in fines; and Paul D. Goldenheim ("Goldenheim"), its former medical director, pled guilty and agreed to pay $7.5 million in fines. Specifically, Purdue pled guilty to illegally misbranding OxyContin in an effort to mislead and defraud physicians and consumers, while Michael Friedman, Udell, and Goldenheim pled guilty to the misdemeanor charge of misbranding OxyContin by introducing it into interstate commerce in violation of 21 U.S.C. §§331(a), 333(a)(1)-(2), and 352(a).

199. In a statement announcing the guilty plea, John Brownlee, the U.S. Attorney for the Western District of Virginia, stated:

> Purdue claimed it had created the miracle drug – a low risk drug that could provide long acting pain relief but was less addictive and less subject to abuse. ***Purdue's marketing campaign worked, and sales for OxyContin skyrocketed – making billions for Purdue and millions for its top executives.***

> But OxyContin offered no miracles to those suffering in pain. ***Purdue's claims that OxyContin was less addictive and less subject to abuse and diversion were false – and Purdue knew its claims were false. The result of their misrepresentations and crimes sparked one of our nation's greatest prescription drug failures....*** OxyContin was the child of marketeers and bottom line financial decision making.[136]

200. Even after this guilty plea, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund seemingly neutral organizations to disseminate the message that opioids were effective and non-addictive, and continued to aggressively market the liberal prescribing of opioids for chronic pain while diminishing the associated dangers of addiction.

201. Since 1995, Purdue has earned more than $31 billion from OxyContin, the nation's best-selling painkiller, which constitutes approximately 30% of the United States market for painkillers.[137] Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up threefold from 2006 sales of $800 million.[138] According to data for the years 2006 through 2014 provided by the U.S. Drug Enforcement Agency, Purdue sold [redacted] dosage units of opioids containing more than [redacted] in Maryland.

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[136] Press Release, U.S. Department of Justice, Statement of United States Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and Its Executives for Illegally Misbranding OxyContin (May 10, 2007), http://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf.

[137] MME stands for morphine milligram equivalent, the standard measure for opioid dosage potency. CDC guidelines state that dosages above 50 MME per day increase risks for overdose by at least two times more than 20 MME dosages. For example, each milligram of oxycodone, the opioid in OxyContin, is equivalent to 1.25 milligrams of morphine.

[138] Katherin Eban, *OxyContin: Purdue Pharma's painful medicine*, FORTUNE (Nov. 9, 2011), http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/ (hereinafter, Eban, *Purdue Pharma's painful medicine*").

H. The Sackler Respondents Establish Rhodes as a "Landing Pad" from Purdue

202. In or around November 2007, in the immediate aftermath of the guilty plea by Purdue and its executives regarding the company's false and misleading marketing of OxyContin, the Sackler Respondents established Rhodes. According to a former senior manager at Purdue, "Rhodes was set up as a 'landing pad' for the Sackler Respondents in 2007, to prepare for the possibility that they would need to start afresh following the crisis then engulfing OxyContin."[139]

203. In other words, fearful that their ability to make money from Purdue would be negatively impacted or imperiled by Purdue's guilty plea, the Sackler Respondents quietly established a new company, seemingly unrelated to Purdue, through which they could continue to extract billions from the sale of opioids. While the Sackler Respondents' concern over Purdue was ultimately unfounded – the company continued to profit handsomely through the sale of opioids – they were correct that Rhodes would provide an additional source of opioid revenues for the family. In 2016, Rhodes' market share for opioids was three-and-one-half times larger than Purdue's.[140]

204. The Sackler Respondents' involvement in Rhodes and its relationship to Purdue were not publicly known until the September 9, 2018 publication of an article in the *Financial Times*. According to the article, "Rhodes has not been publicly connected to the Sackler family before, and their ownership of the company may weaken one of their longstanding defences: that

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[139] David Crow, *How Purdue's 'one-two' punch fuelled the market for opioids*, Financial Times (Sept. 9, 2018), https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c.

[140] *Id.*

they cannot be held responsible for the opioid crisis because Purdue accounts for a small fraction of the overall prescriptions."[141]

205. Despite being registered as a separate company from Purdue, employees at Rhodes and Purdue use the same employee handbook, and "little distinction is made internally between the two companies."[142]

206. Rhodes manufactures, markets, sells, and distributes the following opioids in Maryland and nationwide:

Drug Name/Chemical Name	Description	CSA Category
Hydromorphone hydrochloride	Generic opioid agonist.	Schedule II
Hydrocodone bitartrate and acetaminophen	Generic opioid agonist.	Schedule II
Oxycodone and acetaminophen	Generic opioid agonist.	Schedule II
Buprenorphine hydrochloride	Generic opioid agonist indicated for the treatment of opioid dependence.	Schedule III
Morphine sulfate	Generic opioid agonist.	Schedule II
Oxycodone hydrochloride	Generic opioid agonist.	Schedule II
Tapentadol hydrochloride	Generic opioid agonist.	Schedule II

207. According to public records collected by ProPublica, in 2015 alone, Medicare Part D paid over $570,000 for claims arising from Maryland physicians' generic hydromorphone hydrochloride prescriptions, $3.6 million for claims arising from Maryland physicians' generic hydrocodone bitartrate/acetaminophen prescriptions, $8 million for claims arising from Maryland physicians' generic oxycodone/acetaminophen prescriptions, $124,1323 for Maryland physicians' generic buprenorphine hydrochloride, $5.1 million for claims arising from Maryland physicians' generic extended release morphine sulfate prescriptions, and $7.35 million for claims arising from Maryland physicians' generic oxycodone hydrochloride prescriptions.

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[141] *Id.*

[142] *Id.*

I. Senate Investigations of Purdue

208. In May 2012, the Chair and Ranking Member of the Senate Finance Committee launched an investigation into makers of narcotic painkillers and groups that champion them. The investigation was triggered by "an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers," including popular brand names like OxyContin, Vicodin and Opana.

209. The committee sent letters to Purdue, Endo, and Johnson & Johnson, as well as five groups that support pain patients, physicians, or research, including the APF, AAPM, APS, University of Wisconsin Pain & Policy Studies Group, and the Center for Practical Bioethics. Letters also went to the FSMB and the Joint Commission.

210. As shown below in an excerpt from the Senators' letter to the APF, the Senators addressed the magnitude of the epidemic and asserted that mounting evidence supports that the pharmaceutical companies may be responsible:

> ***It is clear that the United States is suffering from an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers [such as Oxycontin (oxycodone), Vicodin (hydrocodone), Opana (oxymorphone)].*** According to CDC data, "more than 40% (14,800)" of the "36,500 drug poisoning deaths in 2008" were related to opioid-based prescription painkillers. Deaths from these drugs rose more rapidly, "from about 4,000 to 14,800" between 1999 and 2008, than any other class of drugs, killing more people than heroin and cocaine combined. ***More people in the United States now die from drugs than car accidents as a result of this new epidemic. Additionally, the CDC reports that improper "use of prescription painkillers costs health insurers up to $72.5 billion annually in direct health care costs.***"
>
> * * *
>
> Concurrent with the growing epidemic, the New York Times reports that, based on federal data, "***over the last decade, the number of prescriptions for the strongest opioids has increased nearly fourfold, with only limited evidence of their long-term effectiveness or risks" while "[d]ata suggest that hundreds of thousands of patients nationwide may be on potentially dangerous doses.***"
>
> * * *

There is growing evidence pharmaceutical companies that manufacture and market opioids may be responsible, at least in part, for this epidemic by promoting misleading information about the drugs' safety and effectiveness.

Recent investigative reporting from the *Milwaukee Journal Sentinel/MedPage Today* and *ProPublica* revealed extensive ties between companies that manufacture and market opioids and non-profit organizations such as the American Pain Foundation, the American Pain Society, the American Academy of Pain Medicine, the Federation of State Medical Boards, and the University of Wisconsin Pain and Policy Study Group.

According to the *Milwaukee Journal Sentinel/MedPage Today*, ***a "network of national organizations and researchers with financial connections to the makers of narcotic painkillers . . . helped create a body of dubious information" favoring opioids "that can be found in prescribing guidelines, patient literature, position statements, books and doctor education courses.***"[143]

In a *ProPublica* story published in the Washington Post, the watchdog organization examined the ***American Pain Foundation, a "health advocacy" organization that received "nearly 90 percent of its $5 million funding from the drug and medical device industry.***" *ProPublica* wrote that its review of the American Pain Foundation's "guides for patients, journalists, and policymakers ***play down the risks associated with opioids and exaggerate their benefits.*** Some of the foundation's materials on the drugs include statements that are misleading or based on scant or disputed research."

Although it is critical that patients continue to have access to opioids to treat serious pain, ***pharmaceutical companies and health care organizations must distribute accurate and unbiased information about these drugs in order to prevent improper use and diversion to drug abusers.***[144]

211. The Senators demanded substantial documents, such as payment information from the companies to various groups, including the front organizations identified above, and to physicians including Portenoy, Fishman, and Fine. They asked about any influence the companies

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[143] For example, the *Sentinel* reported that the FSMB, with financial support from opioid manufacturers, distributed "'more than 160,000 copies'" of a model policy book that drew criticism from doctors because "'it failed to point out the lack of science supporting the use of opioids for chronic, non cancer pain.'" John Fauber, *Follow the Money: Pain, Policy, and Profit*, MedPage Today (Feb. 19, 2012), http://www.medpagetoday.com/Neurology/PainManagement/31256.

[144] Letter from U.S. Senators Charles E. Grassley and Max Baucus to Catherine Underwood, Executive Director, American Pain Society (May 8, 2012) (footnote added).

had on a 2004 pain guide for physicians that was distributed by the FSMB, on the APS' guidelines, and on the APF's Military/Veterans Pain Initiative. Almost immediately upon the launch of the Senate investigation, the APF shut down "'due to irreparable economic circumstances.'" The opioid report resulting from this investigation has not been released.[145]

212. On March 29, 2017, it was widely reported[146] that yet another Senate investigation had been launched:

> Missouri Senator Claire McCaskill has launched an investigation into some of the country's leading prescription drug manufacturers, demanding documents and records dating back the past five years which indicate just what the companies knew of the drugs' risk for abuse as well as documents detailing marketing practices and sales presentations. Her office has sent letters to the heads of Purdue, Janssen/Johnson & Johnson, Insys, Mylan, and Depomed.

The above-referenced companies were reportedly targeted based on their role in manufacturing some of the opioid painkillers with the highest sales in 2015.

213. On September 12, 2017, then-Senator McCaskill convened a Roundtable Discussion on Opioid Marketing. During the hearing, Senator McCaskill stated:

> The opioid epidemic is the direct result of a calculated marketing and sales strategy developed in the 90's, which delivered three simple messages to physicians. First, that chronic pain was severely undertreated in the United States. Second, that opioids were the best tool to address that pain. And third, that opioids could treat pain without risk of serious addiction. As it turns out, these messages were exaggerations at best and outright lies at worst.
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> * * *
>
> Our national opioid epidemic is complex, but one explanation for this crisis is simple, pure greed.

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[145] Paul D. Thacker, *Senators Hatch and Wyden: Do your jobs and release the sealed opioids report*, Stat News (June 27, 2016), https://www.statnews.com/2016/06/27/opioid-addiction-orrin-hatch-ron-wyden/; *see also* Ornstein, *American Pain Foundation*, *supra* n.60.

[146] Nadia Kounang, *Senator opens investigation into opioid manufacturers*, CNN (Mar. 29, 2017, 11:06 AM), http://www.cnn.com/2017/03/28/health/senate-opioid-manufacturer-investigation/index.html.

214. Professor Adriane Fugh-Berman ("Fugh-Berman"), Associate Professor at Georgetown University Medical Center and director of the Georgetown program Pharmed Out, which conducts research on and educates the public about inappropriate pharmaceutical company marketing, also testified during the hearing. She, too, blamed pharmaceutical companies for the opioid crisis:

> Since the 1990's, pharmaceutical companies have stealthily distorted the perceptions of consumers and healthcare providers about pain and opioids. Opioid manufacturers use drug reps, physicians, consumer groups, medical groups, accreditation and licensing bodies, legislators, medical boards and the federal government to advance marketing goals to sell more opioids. This aggressive marketing pushes resulted in hundreds of thousands of deaths from the overprescribing of opioids. The U.S. is about – comprises about five percent of the world population, but we use about two-thirds of the world supply of opioids.

215. Fugh-Berman also provided insight regarding why doctors were able to be convinced by pharmaceutical companies' marketing efforts:

> Why do physicians fall for this? Well, physicians are overworked, overwhelmed, buried in paperwork and they feel unappreciated. Drug reps are cheerful. They're charming. They provide both appreciation and information. Unfortunately, the information they provide is innately unreliable.
>
> Pharmaceutical companies influence healthcare providers' attitudes and their therapeutic choices through financial incentives that include research grants, educational grants, consulting fees, speaking fees, gifts and meals.

216. Fugh-Berman further described the false information provided by pharmaceutical companies and the industry creation of front organizations, including the APF, to pass industry-influenced regulations and policies:

> Pharmaceutical companies convinced healthcare providers that they were opiophobic and that they were causing suffering to their patients by denying opioids to patients with back pain or arthritis. They persuaded prescribers that patients with pain were somehow immune to addiction. Even when addiction was suspected, physicians were taught that it might not really be addiction, it might be pseudo-addiction, an invented condition that's treated by increasing opioid dosages.
>
> Industry created the American Pain Foundation co-opted other groups including medical organizations, and they change state laws to eliminate curbs on opioid

> prescribing. Between 2006 and 2015, pharmaceutical companies and the advocacy groups they control employ 1,350 lobbyists a year in legislative hubs. Industry-influenced regulations and policies ensure that hospitalized patients were and are berated constantly about their level of pain and overmedicated with opioids for that pain. Even a week of opioids can lead a patient into addiction so many patients are discharged from hospitals already dependent on opioids.

217. In addition, Fugh-Berman pointed out that promotion of opioids remains ongoing despite increasing public concern about their use:

> Promotion of opioids is not in the past. Between 2013 and 2015, one in 12 physicians took out money from opioid manufacturers, a total of more than $46 million. Industry-friendly messages that pharmaceutical companies are currently perpetuating reassure physicians that prescribing opioids is safe as long as patients do not have a history of substance abuse or mental illness.

218. Fugh-Berman concluded by stating: "It is a misperception to think that most opioid deaths are caused by misuse of opioids or overdoses. In fact, many deaths occur when people are using opioids in exactly the way they were prescribed. Misuse isn't the problem; use is the problem."

J. Respondents Failed to Report Suspicious Sales as Required

219. The Controlled Substances Act ("CSA"), and the regulations promulgated thereunder, 21 C.F.R. §§1300 *et seq*., imposes on all "[r]egistrant[s]" the obligation to design and operate a system to disclose to the registrant suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b). Maryland law also provides for the same reporting. Md. Code Ann., Crim. Law. § 5-303(e); COMAR 10.19.03 *et seq*.

220. Purdue is a "[r]egistrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

221. Purdue, which has at all times represented to consumers that it has been compliant with regulatory requirements, was required by federal and state law to set up a system to prevent diversion, including excessive volume and other suspicious orders. This includes reviewing Purdue's own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. Despite having specialized and detailed knowledge of potential suspicious prescribing and dispensing of opioids through Maryland sales representatives' visits to healthcare providers, and Purdue's purchase of data from commercial sources, Respondents failed in Purdue's obligation to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division or state authorities of suspicious orders, as required by state and federal law.

K. The Sackler Respondents Oversaw and Directed Purdue's Unlawful Conduct

222. The Sackler Respondents helped direct Purdue's unlawful marketing techniques, using many of the same unethical techniques developed by Arthur Sackler, to maximize their sales of opioid products. The Sackler Respondents worked hard to ensure that Purdue succeeded financially.

223. OxyContin was launched with one of the largest pharmaceutical marketing campaigns in history. Purdue paid thousands of physicians to present to medical conferences on the benefits of OxyContin.

224. Sales representatives touted the drug's benefits, recommending OxyContin as the solution not just for acute, short-term pain but also for less-acute, longer-lasting pain. Sales training included lessons in overcoming doctors' concerns about health and addiction by minimizing or downplaying OxyContin's addictive qualities.

225. The Sackler Respondents were deeply involved in OxyContin's marketing campaign. Family members were on site at Purdue's headquarters daily, controlling the management of the family business. According to a former sales representative who was talking about OxyContin's sales success, Richard Sackler was "'the dude that made it happen.'" In response to the concerns of benefit plans that OxyContin was ripe for addictive use, Richard sent an email to sales representatives, asserting that "'addiction' may be a convenient way to just say 'NO.'"[147]

226. The Sackler Respondents considered whether they could sell OxyContin as "non-narcotic," without the safeguards that protect patients from addictive drugs, which would result in a "vast increase of the market potential." The inventor of OxyContin, Robert Kaiko ("Kaiko"), wrote to Richard Sackler in 1997 that he was "very concerned" about the danger of selling OxyContin without strict controls. Kaiko warned: "I don't believe we have a sufficiently strong case to argue that OxyContin has minimal or no abuse liability." To the contrary, Kaiko wrote, "oxycodone containing products are still among the most abused opioids in the U.S." Kaiko predicted: "If OxyContin is uncontrolled, . . . it is highly likely that it will eventually be abused." Nevertheless, Richard Sackler responded: "How substantially would it improve your sales?"

227. In 1997, Richard and Kathe Sackler took part in a conspiracy to mislead doctors by claiming oxycodone was half as strong as morphine. The truth was precisely the opposite. Purdue engaged in this deception in the attempt to alleviate healthcare providers fears in prescribing the drug for non-acute pain. As recorded in internal correspondence, Richard Sackler directed Purdue staff not to tell doctors the truth because the truth could reduce OxyContin sales.

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[147] Keefe, *Empire of Pain*, *supra* n.13.

228. Around 1999 to 2003, Purdue had a system whereby company emails would self-erase after pre-determined times. This policy created a system whereby potentially incriminating documents would be automatically erased even if received by third parties. Richard, Jonathan, and Kathe Sackler were all aware and supportive of this system.

L. The Sackler Respondents Were Aware of the Abuse Potential of OxyContin from at Least Summer 1999

229. The Sackler Respondents were aware that OxyContin and other prescription medication could lead to addiction. An internal memo prepared by Purdue employee Maureen Sara in 1999, for example, described the abuse and recreational use of OxyContin. The memo was sent directly to Purdue's board members, including Richard, Jonathan, and Kathe Sackler.

230. The Sackler Respondents were thus aware of potential liability for Purdue since at least 1999 due to OxyContin's addictive nature. Around this time, the Sackler Respondents began to transfer profits from Purdue to their own private trusts and accounts in order to shield their funds from creditors. In 2015, for example, the Sackler Respondents removed $700 million from their privately held companies, two-thirds of which came from Purdue. These transfers of ill-gotten gains were done for the purpose of protecting the money from any civil or criminal judgment against Purdue for its participation in the opioid crisis. These transfers also left Purdue undercapitalized and potentially unable to compensate for the staggering injuries that its illegal conduct has created.

231. Rather than protect the public's health, at every turn, the Sackler Respondents protected – and sought to increase – their own wealth.

M. The Sackler Respondents Continued to Oversee Purdue's Wrongdoing Even After Repeated Warnings and Fines

232. The Sackler Respondents participated in the unfair and deceptive trade practices engaged in by Purdue. The Sackler Respondents either participated directly in or knew about the

unfair and deceptive trade practices and had authority to stop them, but, instead of stopping them, promoted their use.

233. The Sackler Respondents' liability extends beyond their leadership of Purdue. They were aware of, participated in, approved of, and were obligated to address, Purdue's conduct due to previous investigations into the company's deceptive practices.

234. Purdue was under investigation by 26 states and the U.S. Department of Justice from 2001 to 2017. In 2003, on the advice of legal counsel, each Sackler who held an executive role at Purdue resigned from his or her executive positions to avoid personal liability for the conduct in which they had engaged and continued to engage prior to and after their resignations.

235. In 2007, the directors of Purdue declared that it would pay roughly $700 million in connection with the guilty plea for misleading patients about OxyContin. (The entity that paid the money, The Purdue Frederick Company, Inc., was a separate corporate entity that was controlled by the same people and shared the same headquarters as Purdue Pharma L.P.). Purdue acknowledged that its supervisors and employees had fraudulently promoted OxyContin as safer and less addictive than other pain medications.

236. Michael Friedman, the Chief Executive Officer ("CEO") of Purdue, pled guilty to criminal charges of fraudulent marketing. Udell, Purdue's chief lawyer, and Goldenheim, Purdue's chief medical officer, pled guilty to the same crime. The directors, including the Sackler Respondents, were forced to choose a new CEO; and the felony convictions resulted in mass-scale retraining of company employees.

237. The 2007 convictions warned Respondents against any further deception.

238. Respondents also agreed to a Consent Judgment that ordered Purdue not to make any false or misleading oral or written claims about OxyContin, including concerning the risk of

addiction. The Consent Judgment also required Purdue to establish a program that would identify high-prescribing doctors, stop promoting OxyContin to them, and report them. This program was to last from 2007 to 2017.

239. The directors also entered a Corporate Integrity Agreement with the U.S. government, wherein Purdue would appoint a compliance officer to a senior management position at Purdue. The officer would make periodic reports on compliance matters to the Board to ensure no deception took place again. Under the agreement, the directors and CEO were "Covered Persons" who had to comply with rules prohibiting deception regarding Purdue's products. This status lasted from 2007 to 2012 and required that leadership report all rule violations and undergo hours of compliance training. The directors and CEO were warned of consequences in case of a violation and certified that they understood their new status.

240. Purdue's directors were clearly aware of their obligations under the above agreements. In 2009, Purdue had to report to the Inspector General of the U.S. Department of Health and Human Services ("HHS") that it had not immediately trained a new director on the terms of the Corporate Integrity Agreement. Purdue assured HHS that the director had undergone the training the day after Corporate Compliance had learned of the issue.

241. The years after the 2007 guilty plea and Corporate Integrity Agreement were filled with alarming reports and stories about the opioid crisis. However, in spite of these widespread warnings, Purdue's directors, including the Sackler Respondents, did nothing to stop Purdue's misconduct. Instead, they continued to concern themselves with how to protect and increase their wealth.

242. In April 2008, Richard Sackler sent Kathe, Ilene, David, Jonathan, and Mortimer Sackler a secret memo about how to keep money flowing to their family. Richard wrote that it

was crucial to install a CEO who would be loyal to the family: "People who will shift their loyalties rapidly under stress and temptation can become a liability from the owners' viewpoint." Richard Sackler recommended John Stewart for the position because of his loyalty. He also proposed that the family should either sell Purdue in 2008 or, if they could not find a buyer, milk the profits out of the business, and "distribute more free cash flow" to themselves.

243. That month, the Sackler Respondents voted to have Purdue pay them $50,000,000. From the 2007 convictions until 2018, the Sackler Respondents voted dozens of times to pay out billions of dollars in Purdue's opioid profits to themselves.

244. In 2008, opioid overdoses killed more Americans than any previous year, a record that would continue to be broken each subsequent year through the present.

245. In 2009, the *American Journal of Public Health* published "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy."[148] The article detailed the misleading and deceptive nature of Purdue's opioid marketing, including the misuse of sales representatives, the targeting of high-prescribing practitioners, and deception about the potential rates of abuse. The CDC reported that deaths stemming from opioid use had tripled in the preceding year.

246. In 2010, *TIME* magazine published "The New Drug Crisis: Addiction by Prescription."[149] The article focused extensively on Purdue's line of opioid products. Overdoses were the number one cause of accidental death in 15 states that year, and Purdue's directors were informed that Purdue would not be able to get product liability insurance to cover OxyContin.

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[148] Van Zee, *Promotion and Marketing*, *supra* n.63.

[149] Jeffrey Kluger, *The New Drug Crisis: Addiction by Prescription*, TIME (Sept. 13, 2010), http://content.time.com/time/magazine/article/0,9171,2015763,00.html.

247. In 2011, the White House announced that prescription drug abuse was the nation's fastest-growing drug problem and called for educating healthcare providers about prescription drug abuse to prevent overprescription. The CDC announced that prescription opioid overdoses had reached never-before-seen levels and specifically called out Purdue's line of opioid products. *Fortune* magazine published an article that same year where Purdue executives were interviewed about the ongoing crisis and the involvement of the company and the Sackler Respondents. The interviewees included Purdue Vice President Alan Must, who admitted that Purdue was "well aware" of concerns about its conduct: "We are well aware of detractors. . . . For those individuals who think we're evil . . . I don't think there's anything we can do that is going to change their opinion."[150]

248. In 2012, the U.S. Senate announced an investigation into Purdue's unlawful deception of doctors and patients about the nature of its opioid products. The Senators warned of "an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers" in a letter to the CEO of Purdue Pharma, Inc. and Purdue Pharma L.P.[151] The Senate letter specifically warned of the danger of higher levels of opioid dosage: "'over the last decade, the number of prescriptions for the strongest opioids has increased nearly fourfold, with only limited evidence of their long-term effectiveness or risks' while '[d]ata suggest that hundreds of thousands of patients nationwide may be on potentially dangerous doses.'"[152] The Senate letter also warned about Purdue's deceptive tactics with doctors and patients: "There is growing evidence pharmaceutical companies that manufacture and market opioids may be

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[150] Eban, *Purdue Pharma's painful medicine*, *supra* n.138.

[151] Letter from U.S. Senate Finance Committee to John H. Stewart, President and CEO of Purdue Pharma L.P. (May 8, 2012), https://www.finance.senate.gov/imo/media/doc/ Purdue_May_8.pdf.

[152] *Id.*

responsible, at least in part, for this epidemic by promoting misleading information about the drugs' safety and effectiveness."[153] The Senate specifically warned the directors and CEO that they were under scrutiny, demanding that Purdue present a set of "presentations, reports, and communications to Purdue's management team or board of directors from 2007 to the present."[154]

249. In 2013, the *Los Angeles Times* reported that Purdue had created a list of 1,800 doctors suspected of recklessly prescribing its opioids over the past decade but had reported only 8% of them to authorities. Purdue attorney Robin Abrams ("Abrams") gave multiple interviews to the newspaper. Abrams was a Vice President of Purdue, and she signed Purdue's 2007 settlement agreement. In 2013, she admitted that Purdue had the list and said with regard to Purdue's unwillingness to disclose the list: "'I don't really want to open up an opportunity for folks [to] come in here and start looking and second-guessing.'"[155]

250. Abrams and Purdue's directors had good reason to be concerned: the Commonwealth of Kentucky had brought a lawsuit against Purdue for deceiving doctors and patients about the nature of its opioid products. When Purdue's lawyers surveyed the local residents for potential jury service, one-third of respondents said they knew someone who had been hurt or had overdosed taking Purdue opioids, and 29% knew someone who had died. Purdue itself filed these findings in court.

251. In 2014, Edward Mahony, the Executive Vice President, Chief Financial Officer, and Treasurer of Purdue, announced that the Kentucky lawsuit was noteworthy enough to

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[153] *Id.*

[154] *Id.*

[155] Scott Glover & Lisa Girion, *OxyContin maker closely guards its list of suspect doctors*, Los Angeles Times (Aug. 11, 2013), https://www.latimes.com/local/la-me-rx-purdue-20130811-story.html.

"'jeopardize Purdue's long-term viability.'"[156] The Governor of Massachusetts declared the opioid crisis a public health emergency in the same year.

252. In 2016, in an attempt to stop the threatening spread of opioid overprescribing, the CDC published the *CDC Guideline for Prescribing Opioids for Chronic Pain*. The 2016 CDC Guideline provides recommendations for primary care clinicians who prescribe opioids for chronic pain outside of cancer treatment, palliative care, or end-of-life care. It was intended to "offer[] clarity on recommendations based on the most recent scientific evidence, informed by expert opinion and stakeholder and public input." In summary, the CDC concluded that "evidence on long-term opioid therapy for chronic pain outside of end-of-life care remains limited, with insufficient evidence to determine long-term benefits versus no opioid therapy, though evidence suggests risk for serious harms that appears to be dose-dependent." Among the CDC's recommendations are that "[n]onpharmacologic therapy and nonopoid pharmacologic therapy are preferred for chronic pain."[157]

253. The Sackler Respondents, in their capacities as directors and executives, controlled the operation of Purdue's sales representatives. Richard Sackler has testified that Purdue primarily promoted its opioids through its sales representatives and that regular visits from representatives were the key to get doctors to continue to prescribe the drugs. The Board knew which drugs the sales representatives were to promote, the number of visits representatives made to doctors, how much each visit cost the company and the quarterly plans for sales visits. The Board approved

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[156] Tracy Staton, *Addiction-riddled Kentucky out for blood in $1B suit against OxyContin-maker Purdue*, FiercePharma (Oct. 20, 2014, 9:00 AM), https://www.fiercepharma.com/pharma/addiction-riddled-kentucky-out-for-blood-1b-suit-against-oxycontin-maker-purdue.

[157] Deborah Dowell, MD, *et al.*, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, Centers for Disease Control and Prevention, https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm (last visited May 14, 2019).

specific hiring plans for their sales representatives, hiring directors and regional managers and creating sales territories for representatives to target doctors.

254. In April 2010, staff gave Ilene, Jonathan, Kathe, Mortimer, Richard, and Theresa Sackler one of many detailed reports on sales representatives' visits to prescribers. And in April 2015, David, Ilene, Jonathan, Kathe, Mortimer, Richard, and Theresa Sackler voted to expand the salesforce by adding another 122 representatives.

255. Richard Sackler was intensely involved in Purdue's day-to-day operations. For example, in January 2010, he asked sales staff for new customized reports. Staff complained to each other until Sales Vice President Russell Gasdia ("Gasdia") asked Stewart to intervene: "Can you help with this? It seems like every week we get one off requests from Dr. Richard." But neither Stewart nor anyone else could keep Richard out of sales. Days later, Richard was writing to a sales employee on a Saturday morning, ordering that his need to review the sales plan was "urgent" and should be satisfied "this weekend."

256. The Sackler Respondents oversaw the specific tactics used by sales representatives to sell opioids. For example, a board report encouraged the use of iPads during sales visits, which increased the average length of sales calls to 16.7 minutes.

257. According to internal correspondence, at a 2011 Launch Meeting for Butrans, an opioid introduced by Purdue that releases opioids into the body via skin patch, Richard Sackler met with sales representatives for several days to discuss how they would promote the new product. Richard Sackler followed up with sales management to demand a briefing on how the sales visits were going in the field:

> "I'd like a briefing on the field experience and intelligence regarding Butrans. How are we doing, are we encountering the resistance that we expected and how well are we overcoming it, and are the responses similar to, better, or worse than when we marketed OxyContin tablets?"

258. The Sackler Respondents oversaw the promotional claims representatives used during sales visits. The directors and CEO, reviewed reports that Purdue sales representatives were deceptively promoting opioids as an appropriate treatment for minor pain, among hundreds of other examples of unlawful marketing techniques in need of correction.

259. According to internal correspondence, Richard Sackler demanded that he be sent into the field with sales representatives. Richard wanted to shadow two Purdue sales representatives per day for a week. Gasdia reportedly appealed to Purdue's Chief Compliance Officer in horror, warning that Richard Sackler promoting opioids was "a potential compliance risk." The Compliance Officer replied: "LOL." To make sure the Sackler Respondents' involvement in marketing remained secret, staff instructed: "Richard needs to be mum and be anonymous."

260. Richard Sackler indeed went into the field to promote opioids to doctors alongside a sales representative. When he returned, Richard reportedly argued to Gasdia that a legally required warning about Purdue's opioids was not needed. He asserted that the warning "implies a danger of untoward reactions and hazards that simply aren't there." Richard insisted there should be "less threatening ways to describe Purdue opioids."

261. Additionally, the Sackler Respondents oversaw Purdue's research, which in some cases contradicted Purdue's marketing. The Sackler Respondents received detailed and specific reports concerning Purdue opioids being used for "opioid-naïve" patients and patients with osteoarthritis. Yet Purdue has continued to promote the use of opioids in opioid-naïve patients, expanding its customer base to the detriment of these new opioid users.

262. According to internal correspondence, during a 2010 Purdue Board of Directors meeting, the Sackler Respondents inquired whether sales representatives could sell more Butrans

if they remained silent about failed clinical trials testing Butrans for patients with osteoarthritis: "What can be said in response to a prescriber who asks directly or indirectly, 'can this product be prescribed for my patient with [osteoarthritis]?' In responding are we required to specifically mention the failed trials in [osteoarthritis]?"

263. The Sackler Respondents supervised sales representatives' communications with healthcare providers. Purdue had a policy of prohibiting sales representatives from communicating with doctors via email; when Purdue found that some representatives had in fact emailed doctors, Purdue "investigated" the matter and told the Board that the representatives had been disciplined and the matter would be discussed at the next Board meeting.

264. The Sackler Respondents oversaw Purdue's strategy to pay high-prescribing doctors to promote its opioids. The Board was aware of the amount paid to specific high prescribers and the return on investment it received from these payments. The Board knew that Purdue allowed a gift spending limit of $750 per doctor per year and was told specifically that paying doctors was a high-risk activity that could result in improper off-label use or other promotional activity for opioids. Nevertheless, it continued to authorize these payments.

265. The Sackler Respondents managed Purdue's focus on encouraging patients to use higher and higher doses of opioids, leading to health issues, addiction, and greater profits for Purdue. Upon learning that sales of 40mg and 80mg strengths of OxyContin had fallen below sales targets, the Board received multiple reports that public health authority initiatives to have doctors consult with pain specialists before prescribing high opioid doses were a "threat." The Board oversaw measures to oppose these initiatives and received reports in 2013 that attempts to encourage increased total daily doses had had a positive impact on Purdue's bottom line.

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

267. The Sackler Respondents oversaw Purdue's plan to keep patients hooked on opioids for longer periods of time through higher doses. The Board received thorough reports of how many patients remained on Purdue opioids for extended lengths of time, as well as internal documents that indicated patients on higher doses used the product for longer amounts of time, creating greater chances of addiction and abuse. The Board was presented with a plan to create workshops and give specific direction to representatives about this link, and that increasing opioid use was a focus point of the company. The Board was told in writing that encouraging higher doses "is a focal point of our promotion" and that sales representatives should push doctors to increase patient doses as soon as three days after initial treatment. The Board knew or should have known that this sales tactic was both deceptive and placing patients at high risk of addiction and overdose.

268. In January 2018, Richard Sackler received a patent for a drug to treat opioid addiction for which he had applied in 2007. He assigned it to a different company controlled by the Sackler Respondents instead of Purdue. Notably, Richard Sackler's patent application says

opioids ***are*** addictive. The application calls the people who become addicted to opioids "junkies" and asks for a monopoly on a method of treating addiction.

269. The Sackler Respondents oversaw Purdue's use of "savings cards" to get patients on Purdue opioids for longer periods of time. The Board knew exactly how many thousands of cards were used each quarter, the return on investment, and the goal of the program: for patients "to remain on therapy longer."

270. The Sackler Respondents oversaw Purdue's targeting of prescribers without special knowledge of opioids, as they were the most likely to respond to Purdue's sales techniques. Purdue proceeded with this strategy despite the DEA expressing concern that Purdue was marketing its opioids to doctors who were not appropriately trained in pain management.

271. The Sackler Respondents oversaw a strategy of targeting elderly patients, using images of older patients to target healthcare providers who practiced in long-term care. The Sackler Respondents knew or should have known both that this strategy was deceptive and that targeting doctors who lacked special training in pain management and elderly patients increased the risk of addiction and overdose.

272. The Sackler Respondents were aware of a plan to steer patients away from less dangerous pain-management medicines, which involved efforts to emphasize the danger of acetaminophen-based pain medication to the liver. These efforts included deceptive websites that the New York Attorney General specifically determined to be misleading in specific sections.

273. The Sackler Respondents oversaw the response to thousands of harm reports from patients, in one case receiving over 5,000 complaints in a single quarter.

274. Proponent is informed and believes, and thereupon alleges, that Purdue possesses documents that show each of the reports mentioned above was sent to every individual respondent on the Board, including each Sackler Respondent with a board position.

IV. IMPACT

275. The impact of Purdue's false messaging has been profound. Respondents have profited handsomely as more and more people became addicted to opioids and died of overdoses.[158] Its opioid sales grew from $48 million per year in 1996, to over $1 billion per year in 2000, to $3.1 billion per year ten years later.

276. By 2002, "[l]ifetime ***nonmedical*** use of OxyContin increased from 1.9 million to 3.1 million people between 2002 and 2004, and in 2004 there were 615,000 new nonmedical users of OxyContin."[159]

277. By 2004, OxyContin had "become the most prevalent prescription opioid abused in the United States."[160]

278. As OxyContin sales grew between 1999 and 2002, so did sales of other opioids, including fentanyl (226%), morphine (73%), and oxycodone (402%). And, as prescriptions surged between 1999 and 2010, so did deaths from opioid overdoses (from about 4,000 to almost 17,000). Purdue's sales and marketing in Maryland was so successful that during at least one year (2011-2012), Purdue's Maryland District Sales Manager was rewarded as a top performer nationally with a "President's Club" trip to South Beach, Florida.

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[158] German Lopez, *How big pharma got people hooked on dangerous opioids – and made tons of money off it*, Vox (Sept. 22, 2016, 3:00 PM), http://www.vox.com/2016/2/5/10919360/opioid-epidemic-chart.

[159] Van Zee, *Promotion and Marketing*, *supra* n.63.

[160] *Id.*

279. Maryland, like the rest of the United States, is experiencing an unprecedented opioid addiction and overdose epidemic, costing millions in health insurance and public safety, as well as lost productivity in the workforce. In 2012 alone, an estimated 259 million opioid prescriptions were filled, enough to medicate every adult in the United States for a month on a round-the-clock basis.[161] In 2014, there were more than 47,000 drug overdose deaths nationwide, 61% involving a prescription or illicit opioid.[162] The use of prescription painkillers costs health insurers up to $72.5 billion annually in direct healthcare costs.[163] According to a research paper published in 2018 by the American Enterprise Institute that set out to determine geographic variation in the costs of the opioid crisis, estimated total per-capita costs of the opioid crisis in Maryland during 2015 were $3,337.[164] Because Maryland's total population was approximately 5,987,000 in 2015, that figure indicates that ***the total costs of the opioid crisis in Maryland were in excess of $19.97 billion in 2015 alone.***

280. Respondents' duplicitous and unlawful acts have damaged, and continue to damage, Maryland and Maryland residents. Damages incurred by Maryland include: (a) the costs of treating opioid addiction, including addiction treatment, emergency room visits and inpatient and outpatient treatment; (b) the costs of maintaining harm reduction, overdose prevention and education on the dangers of opioid use; (c) special costs incurred by Maryland for the public safety,

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[161] *Opioid Painkiller Prescribing*, Centers for Disease Control and Prevention: Vital Signs (July 2014), https://www.cdc.gov/vitalsigns/opioid-prescribing/.

[162] Rudd, *Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010-2015*, Centers for Disease Control and Prevention (Dec. 30, 2016), https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm.

[163] Eban, *Purdue Pharma's painful medicine*, *supra* n.138.

[164] Alex Brill & Scott Ganz, *The geographic variation in the cost of the opioid crisis*, AEI Economics Working Paper 2018-03, at Table 1 (March 20, 2018), https://www.aei.org/wp-content/ uploads/2018/03/Geographic_Variation_in_Cost_of_Opioid_Crisis.pdf.

health and welfare of its citizens; and (d) the economic harm to Maryland resulting from the addiction epidemic.

V. VIOLATIONS OF THE CONSUMER PROTECTION ACT

281. Proponent incorporates by reference and realleges each and every allegation contained in this Statement of Charges.

282. The Consumer Protection Act prohibits any unfair, abusive, or deceptive trade practices. Md. Code Ann., Com. Law §§13-301 *et seq.* It expressly designates the following such practices as unlawful:

- Representations that have "the capacity, tendency, or effect of deceiving or misleading consumers" (Md. Code Ann., Com. Law §13-301(1));
- Representations that consumer goods have a sponsorship, approval, characteristic, use or benefit that they do not have (Md. Code Ann., Com. Law §13-301(2)(i));
- Representations that fail to "state a material fact if the failure deceives or tends to deceive" (Md. Code Ann., Com. Law §13-301(3)); and
- Any "[d]eception, fraud, false pretense, false premise, misrepresentation, or knowing concealment, suppression, or omission of any material fact with the intent that the consumer rely on the same in connection with . . . [t]he promotion or sale of any consumer goods" (Md. Code Ann., Com. Law §13-301(9)).

283. During the relevant period and as detailed further herein, Respondents have each engaged repeatedly in such practices in violation of the Consumer Protection Act by actively promoting and marketing the use of opioids for indications not federally approved, circulating false and misleading information concerning opioids' safety and efficacy, downplaying or omitting the risk of addiction arising from their use, and failing to comply with the Controlled Substances Act, as well as failing to disclose this noncompliance to consumers.

284. Respondents' false and misleading statements and representations, including those regarding the appropriateness of opioids for particular conditions, in certain amounts and doses, and/or for specific patients, or as to opioids' benefits and risks, have had the capacity, tendency,

and/or effect of deceiving and misleading consumers and constitute unfair or deceptive trade practices as defined in §13-301(1) of the Consumer Protection Act.

285. Respondents' false and misleading representations, including those regarding the sponsorship, approval, characteristics, uses, or benefits of opioids, *e.g.*, that they are safe, effective, and appropriate for particular conditions and/or specific patients induced prescribers to prescribe Respondents' opioids by deception and constitute unfair or deceptive trade practices as defined in §13-301(2)(i) of the Consumer Protection Act.

286. Respondents' failure to disclose material of facts, the omission of which deceived or tended to deceive consumers, including their failure to disclose their marketing practices, the purpose of which was to induce prescribers to prescribe Respondents' opioids regardless of their safety, efficacy, and/or appropriateness, purpose, or associated risks, failure to disclose that Purdue opioids were not safe, effective, appropriate, and/or medically necessary in the amounts or for the conditions or patients for which they had been prescribed, and failure to disclose their lack of compliance with legal requirements designed to protect consumers from improper prescribing, constitute unfair, abusive, or deceptive trade practices as defined in §13-301(3) of the Consumer Protection Act.

287. Respondents' failure to design and operate a system to disclose suspicious orders of controlled substances, as well as the failure to actually disclose such suspicious orders, as required of "registrants" by the federal CSA, 21 C.F.R. §1301.74(b), which is incorporated into Maryland law, *see* COMAR 10.19.03.01 *et seq.*, constitutes unfair, abusive, or deceptive trade practices, including under §13-301(9).

288. In marketing and selling their opioids, Respondents devised and knowingly carried out a scheme and artifice to defraud by means of materially false or fraudulent pretenses,

representations, promises, or omissions of material facts regarding suspicious sales and the safe, non-addictive, and effective use of opioids for long-term chronic, non-acute, and non-cancer pain. Respondents intended that Proponent, Proponent's agents, prescribers, the public, and persons on whom Proponent and its agents relied would rely on deceptive conduct undertaken at the Sackler Respondents' direction. Such acts and omissions constitute an unfair, abusive, or deceptive trade practice as defined by §13-301(9) of the Consumer Protection Act.

289. Respondents engaged in unfair practices in violation of §13-303 by engaging in the practices alleged above, which caused significant consumer harm; consumers could not reasonably avoid that harm; and the harm had no countervailing benefit to consumers or competition that outweighed it.

290. In selling and offering for sale opioids to at risk populations of medical patients, while in flagrant violation of federal and state law, under circumstances in which consumers became dependent and addicted, Respondents engaged in abusive trade practices prohibited by §13-303 of the Consumer Protection Act.

291. Respondents' unfair, abusive, or deceptive acts or practices in violation of the Consumer Protection Act offend Maryland public policy, are immoral, unethical, oppressive, or unscrupulous, as well as malicious, wanton, and manifesting ill will, and caused substantial injury to the State of Maryland.

WHEREFORE, pursuant to the Consumer Protection Act §13-403(b)(1), Proponent respectfully requests that the Consumer Protection Division issue an Order:

A. requiring Respondents to cease and desist from engaging in unfair or deceptive trade practices in violation of the Consumer Protection Act;

B. requiring Respondents to take affirmative actions, including, but not limited to, the restitution and disgorgement of all moneys that it received in connection with their unfair or deceptive trade practices and the creation of an adequate addiction treatment program available to all individuals in Maryland who received Respondents' opioids;

C. awarding economic damages;

D. requiring Respondents to pay the costs of this proceeding, including all costs of investigation;

E. requiring Respondents to pay civil penalties pursuant to §13-410 for each violation of the Consumer Protection Act; and

F. granting such other and further relief as is appropriate and necessary.

Respectfully submitted,

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