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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

THE PEOPLE OF THE STATE OF CALIFORNIA, Plaintiff, v. PURDUE PHARMA L.P., PURDUE PHARMA INC., THE PURDUE FREDERICK COMPANY INC., DR. RICHARD S. SACKLER, BEVERLY SACKLER, JONATHAN SACKLER, DAVID SACKLER, MARIANNA SACKLER, THERESA SACKLER, ILENE SACKLER LEFCOURT, DR. KATHE SACKLER, MORTIMER D.A. SACKLER and DOES 9 through 100, inclusive Defendants.	Case No. 19STCV19045 [JCCP No. 5029 Prescription Opioid Cases] **[PUBLIC – REDACTS MATERIALS FROM CONDITIONALLY SEALED RECORD]** **FIRST AMENDED COMPLAINT FOR PERMANENT INJUNCTION, ABATEMENT, CIVIL PENALTIES, AND OTHER EQUITABLE RELIEF** (CIVIL CODE, §3494, BUS. & PROF. CODE, §§ 17200 et seq. and 17500 et seq.) [VERIFIED ANSWER REQUIRED PURSUANT TO CODE OF CIVIL PROCEDURE §446] Judge: Hon. William F. Highberger Dept.: 10 Action Filed: June 3, 2019

Plaintiff, the People of the State of California, by and through Xavier Becerra, Attorney General of the State of California, alleges the following on information and belief:

I. INTRODUCTION

1. Plaintiff brings this action against Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company Inc. (collectively, Purdue), Dr. Richard Sackler, Beverly Sackler, Jonathan Sackler, David Sackler, Marianna Sackler, Theresa Sackler, Ilene Sackler Lefcourt, Dr. Kathe Sackler, and Mortimer D.A. Sackler (collectively, the Sacklers, and together with Purdue, Defendants) for creating a public nuisance, deceptive marketing of prescription opioid drugs, and violations of the unfair competition law. The Attorney General brings this action on behalf of the People of the State of California (the People) as the State's Chief Law Officer to protect the health and safety of the people of California.

2. In the decade between 2008 and 2017, over 14,500 Californians died due to prescription opioid drug overdoses.[1] There were over 80,000 emergency room visits and hospitalizations in California from opioid overdoses during that same time period.[2] On average, about six Californians die each day from an opioid-related overdose.[3] The opioid epidemic is estimated to have cost the United States from $294 billion to $622 billion in 2015 alone.[4]

3. The Director of the Centers for Disease Control and Prevention has explained: "We know of no other medication that's routinely used for a nonfatal condition that kills patients so frequently."[5]

4. We are in the midst of a nationwide public health crisis that Defendants helped create. Purdue's deceptive marketing of its blockbuster drug, OxyContin®, sparked the beginning of the national crisis we face today. Defendants positioned OxyContin as a safe and effective treatment

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[1] California Department of Public Health, *California Opioid Overdose Surveillance Dashboard*, at < https://discovery.cdph.ca.gov/CDIC/ODdash/ >.

[2] *Ibid.*

[3] *Ibid.*

[4] The Council of Economic Advisers, Executive Office of the President of the United States, *The Underestimated Cost of the Opioid Crisis* (Nov. 2017), p. 8, at < https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf >.

[5] Tom Frieden, Director, Centers for Disease Control and Prevention (CDC), *Press Briefing on CDC Guideline for Prescribing Opioids for Chronic Pain* (Mar. 15, 2016), at < https://www.cdc.gov/media/releases/2016/t0315-prescribing-opioids-guidelines.html >.

for non-cancer pain from the time Purdue introduced OxyContin to the market. The company and its army of sales representatives told doctors, patients, and their families that OxyContin was not addictive or subject to withdrawal symptoms, and had less potential for abuse and addiction. Defendants, however, knew these statements were not true. Indeed, in 2007, following a criminal investigation by the United States Department of Justice (USDOJ), Purdue, and a number of its executives, pleaded guilty to felony misbranding of OxyContin, admitting they illegally promoted OxyContin by falsely claiming OxyContin was less addictive, less likely to cause withdrawal symptoms, and less subject to abuse and diversion. Purdue and the executives agreed to pay over $600 million in criminal and civil penalties, fines, and forfeitures.

5. In addition to the guilty plea with the USDOJ, Purdue entered into court-ordered judgments with California and other states, agreeing not to make misrepresentations with respect to OxyContin's potential for abuse, addiction, or physical dependence. Purdue also agreed to implement and maintain an abuse and diversion detection program that required its employees and contractors to report potential activities related to abuse and diversion. Purdue was required to conduct an internal inquiry into each report of abuse or diversion, and take appropriate action as necessary. Yet it failed to do so.

6. Notwithstanding these admitted transgressions, Purdue, under the direction of the Sacklers, continued its aggressive deceptive marketing campaign and over-promotion of opioids following its 2007 guilty plea. Purdue continued to mislead healthcare providers and patients regarding the addictive nature of opioids and its potential for abuse. Purdue misleadingly told healthcare providers that obvious signs of addiction, such as intravenous drug use and deception, were instead signs of "pseudoaddiction" or "undertreated pain," which should be addressed by prescribing patients even more opioids. It misleadingly claimed that OxyContin was safe when taken as directed, and that people – not the drug themselves – were the cause of addiction. Dr. Richard Sackler himself stated that "[the abusers] are the culprits and the problem." Purdue further misled healthcare providers to prescribe higher and higher dosages of OxyContin and other opioids for longer and longer periods of time, claiming that their opioids have no dosage ceiling even though the risks of overdose and death increased with higher dosages. Purdue also

highlighted the risks of other non-opioid pain medications while downplaying the risks of its own opioids, and pushed its opioids for specific diseases they were not indicated for. The deceptive marketing and over-promotion led to the over-prescribing and over-use of Purdue's opioid products.

7. Rather than help stop the opioid problem from becoming the deadliest, costliest, and most widespread drug crisis in the United States, Defendants doubled down on their misstatements and over-promotion following the 2007 guilty plea and profited handsomely. Sales of OxyContin went from $48 million in 1996, to over $1 billion in 2000 – just four short years. By 2010, OxyContin sales were over $3 billion, and were $1.8 billion as recently as 2017.[6]

8. The Sacklers personally pocketed ***more than four billion dollars*** from the opioid crisis. They are the sole owners and beneficiaries of Purdue. They control Purdue and occupied the majority of Purdue Pharma Inc.'s board seats from its inception in 1990 until 2018. The Sacklers were not idle owners who quietly sat by, but were active participants who helped direct the actions of the company, including its marketing and sales force, and build it into a highly profitable pharmaceutical powerhouse. The Sacklers were directly involved in developing, directing, and voting on Board matters that facilitated Purdue's deceptive practices that helped create the crisis we face today.

9. Dr. Richard Sackler, in particular, drove the company's deceptive marketing practices. He was a hands-on executive who was well aware of the dangerous messages Purdue was communicating about OxyContin. Dr. Richard Sackler was so involved, even as a Board member, that Purdue employees repeatedly, over the years, expressed frustration with his micromanagement. He and the other Sacklers were also personally aware of reports of abuse and diversion of OxyContin, including through a daily news alert. Even with billions in the bank, Dr. Richard Sackler was so motivated by money that he sought to obtain non-controlled status for OxyContin in Germany, even after the medical director expressed he was "very concerned" about

[6] Hopkins, Jared S., *Pain Pill Giant Purdue to Stop Promotion of Opioids to Doctors* (Feb. 9, 2018), at < https://www.bloomberg.com/news/articles/2018-02-10/pain-pill-giant-purdue-to-stop-promotion-of-opioids-to-doctors >; Ryan, Harriet, et al., "*You Want a Description of Hell?" OxyContin's 12 Hour Problem* (May 5, 2016), at < https://www.latimes.com/projects/oxycontin-part1/ >.

the proposal because it could be viewed as "irresponsible" due to the abuse profile of the drug. One friend referred to Dr. Richard Sackler as the "Pablo Escobar of the new millennium."

10. This is a manmade epidemic that could have and should have been prevented. "[The pain will never kill you.] But if you keep these [opioids] up, it will kill you. These medications tell you to go to bed at night, 'Stop breathing. Stop breathing.' And eventually your brain listens to it, and then you don't wake up in the morning." Dr. Ahn Quan Nguyen, Kaiser Permanente.[7]

11. The People seek to hold Purdue and the Sacklers accountable for the public health crisis they helped create.

II. PARTIES

A. PLAINTIFF

12. Plaintiff is the People of the State of California. Plaintiff brings this action by and through Xavier Becerra, Attorney General and the state's chief law officer under article V, section 13 of the California Constitution. The Attorney General is authorized by California Business and Professions Code sections 17204 and 17535 to obtain injunctive relief to halt violations of, and enforce compliance with, California Business and Professions Code section 17200 et seq., and California Business and Professions Code section 17500 et seq., respectively.[8] The Attorney General is authorized by Business and Professions Code sections 17206 and 17536 to obtain civil penalties of up to $2,500 for each violation of sections 17200 and 17500, respectively. The Attorney General is authorized under Civil Code section 3494 to obtain preliminary and permanent injunctions to abate any public nuisance present in the State of California as defined by Civil Code sections 3479 and 3480.

13. Pursuant to his constitutional and statutory authority as chief law officer, including his responsibility to ensure that the laws are uniformly and adequately enforced, his supervision over District Attorneys and other law enforcement officers, and his authority to take charge of any investigation or prosecution over which the Superior Court has jurisdiction, the Attorney General,

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[7] PBS NewsHour, *How One Group of Doctors Drastically Decreased Opioid Prescriptions* (Oct. 9, 2017), at < https://www.pbs.org/newshour/show/one-group-doctors-drastically-decreased-opioid-prescriptions >.

[8] All further statutory references are to California statutes.

through the filing of this action, takes charge of any public nuisance, unfair competition law, and false advertising law claims brought on behalf of the People concerning the matters described herein. This is the People's operative complaint, and the people's operative action, concerning those claims and matters.

B. DEFENDANTS

14. Defendant Purdue Pharma L.P. is a privately held limited partnership organized under the laws of Delaware and headquartered in Connecticut. At all relevant times, Purdue Pharma L.P. has transacted and continues to transact business throughout California, including in Los Angeles County.

15. Defendant Purdue Pharma Inc. is a corporation organized under the laws of New York and headquartered in Connecticut. Purdue Pharma Inc. is the general partner of defendant Purdue Pharma L.P. At all relevant times, Purdue Pharma Inc. has transacted and continues to transact business throughout California, including in Los Angeles County.

16. Defendant The Purdue Frederick Company Inc. is a corporation organized under the laws of New York and headquartered in Connecticut. The Purdue Frederick Company Inc. has transacted business throughout California, including in Los Angeles County.

17. Defendant Dr. Richard Sackler is a natural person residing in Travis County, Texas. He is a former President of Purdue Pharma L.P. and was on the board of Purdue Pharma Inc. since its inception in 1990 through July 2018. At all relevant times, Dr. Richard Sackler, through his direction of Purdue and participation in the marketing and sales activities of Purdue, has transacted business throughout California, including in Los Angeles County.

18. Beverly Sackler, originally sued as Doe 1, is a natural person residing in Greenwich, Connecticut. She was on the board of Purdue Pharma Inc. from 1993 through 2017. At all relevant times, Beverly Sackler, through her direction of Purdue as a Board member, has transacted business throughout California, including in Los Angeles County.

19. Jonathan Sackler, originally sued as Doe 2, is a natural person residing in Greenwich, Connecticut. He was a Vice-President of The Purdue Frederick Company Inc. and on the board of Purdue Pharma Inc. since its inception in 1990 through 2019. At all relevant times, Jonathan

Sackler, through his direction of Purdue as a Board member, has transacted business throughout California, including in Los Angeles County.

20. David Sackler, originally sued as Doe 3, is a natural person residing in Boca Raton, Florida, and New York, New York, and owns a residence in Bel Air, California. He was on the board of Purdue Pharma Inc. from 2012 through 2018. At all relevant times, David Sackler, through his direction of Purdue as a Board member, has transacted business throughout California, including in Los Angeles County.

21. Marianna Sackler, originally sued as Doe 4, is a natural person residing in San Francisco, California, and [redacted] At all relevant times, Marianna Sackler, [redacted]., has transacted business throughout California, including in Los Angeles County.

22. Theresa Sackler, originally sued as Doe 5, is a natural person residing in New York, New York, and the United Kingdom. Theresa Sackler was on the board of Purdue Pharma Inc. from 1993 through 2018. At all relevant times, Theresa Sackler, through her direction of Purdue as a Board member, has transacted business throughout California, including in Los Angeles County.

23. Ilene Sackler Lefcourt, originally sued as Doe 6, is a natural person residing in New York, New York, and Sag Harbor, New York. She was a Vice-President of The Purdue Frederick Company Inc. and was on the board of Purdue Pharma Inc. since its inception in 1990 through 2018. At all relevant times, Ilene Sackler Lefcourt, through her direction of Purdue as a Board member, has transacted business throughout California, including in Los Angeles County.

24. Dr. Kathe Sackler, originally sued as Doe 7, is a natural person residing in New York, New York, and Westport, Connecticut. She was a Vice-President of The Purdue Frederick Company Inc. and was on the board of Purdue Pharma Inc. since its inception in 1990 through 2018. At all relevant times, Dr. Kathe Sackler, through her direction of Purdue as a Board member, has transacted business throughout California, including in Los Angeles County.

25. Mortimer D.A. Sackler, originally sued as Doe 8, is a natural person residing in New York, New York. He was a Vice-President of the Purdue Frederick Company Inc. and was on the

board of Purdue Pharma Inc. from 1993 through 2019. At all relevant times, Mortimer D.A. Sackler, through his direction of Purdue as a Board member, has transacted business throughout California, including in Los Angeles County.

26. For events prior to July 2012, "Sackler Board Members" includes Dr. Richard Sackler, Beverly Sackler, Jonathan Sackler, Theresa Sackler, Ilene Sackler Lefcourt, Dr. Kathe Sackler, and Mortimer D.A. Sackler. For events after and including July 2012, "Sackler Board Members" also includes David Sackler.

27. Plaintiff is not aware of the true names and capacities of defendants sued herein as DOES 9 through 100, inclusive, and, therefore, sues these defendants by such fictitious names. Each fictitiously named defendant is responsible in some manner for the violations of law alleged. Plaintiff will amend this Complaint to add the true names of the fictitiously named defendants once they are discovered. Whenever reference is made in this Complaint to "Defendants," such reference shall include DOES 9 through 100 as well as the named defendants.

28. At all relevant times, each Defendant acted individually and jointly with every other named Defendant in committing all acts alleged in this Complaint.

29. At all relevant times, each Defendant acted: (a) as a principal; (b) under express or implied agency; and/or (c) with actual or ostensible authority to perform the acts alleged in this Complaint on behalf of every other named Defendant.

30. At all relevant times, some or all Defendants acted as the agent of the others, and all Defendants acted within the scope of their agency if acting as an agent of another.

31. At all relevant times, each Defendant knew or realized, or should have known or realized, that the other Defendants were engaging in or planned to engage in the violations of law alleged in this Complaint. Knowing or realizing that the other Defendants were engaging in such unlawful conduct, each Defendant nevertheless facilitated the commission of those unlawful acts. Each Defendant intended to and did encourage, facilitate, or assist in the commission of the unlawful acts, and thereby aided and abetted the other Defendants in the unlawful conduct.

32. Defendants engaged in a conspiracy, common enterprise, and common course of conduct, the purpose of which is and was to engage in the violations of law alleged in this

Complaint. The conspiracy, common enterprise, and common course of conduct continue to the present.

III. JURISDICTION AND VENUE

33. This Court has original jurisdiction over this action pursuant to article vi, section 10 of the California Constitution.

34. This Court has jurisdiction over Purdue because Purdue, by marketing its opioid products and maintaining a sales force in the state of California to sell such products to hospitals, healthcare providers, and patients in this state, intentionally availed itself of the California market so as to render the exercise of jurisdiction over Purdue by the California courts consistent with traditional notions of fair play and substantial justice.

35. This Court has jurisdiction over the Sacklers pursuant to the United States Constitution, 14th Amendment, section 1, and Code of Civil Procedure section 410.10. The Sacklers, by directing, participating in, and approving of the deceptive marketing and sales of Purdue's opioid products, intentionally availed themselves of the California market so as to render the exercise of jurisdiction over the Sacklers by the California courts consistent with traditional notions of fair play and substantial justice.

36. The violations of law alleged in this Complaint occurred in the County of Los Angeles and elsewhere throughout California.

37. Venue is proper in this Court pursuant to Code of Civil Procedure section 395.5 because Defendants' marketing and sales activities included the Los Angeles region and therefore Defendants' liability arises in the County of Los Angeles.

38. Venue is also proper in this Court pursuant to Code of Civil Procedure section 393, subdivision (a), because violations of law that occurred in the County of Los Angeles are a part of the cause upon which the Plaintiff seeks the recovery of penalties imposed by statute.

IV. DISCOVERY RULE AND TOLLING

39. Defendants' unfair and deceptive conduct was well concealed. Defendants deliberately conducted much of their deception through in-person sales visits and explicitly prohibited sales representatives from communicating with healthcare providers in writing, in

order to avoid a potentially discoverable paper trail. Defendants concealed from the public their deceptive scheme, including their plans to get patients on higher and higher doses for longer and longer periods. The Sacklers further concealed their participation in the deception and did not reveal to the public their participation in the deceptive marketing scheme.

40. Discovering the nature and extent of Defendants' deceptive conduct required a costly and complex investigation. As part of the investigation, the Attorney General's Office has collected millions of pages of evidence regarding Defendants' deceptive conduct.

41. Because of Defendants' deception, any statutes of limitation otherwise applicable to any claims asserted herein against all Defendants have been tolled by the discovery rule and rules regarding fraudulent concealment and other equitable tolling doctrines.

42. In addition to the tolling provided by common law, Purdue Pharma Inc., Purdue Pharma L.P., and The Purdue Frederick Company Inc., on the one hand, and the People, on the other, entered into a written agreement tolling any applicable statutes of limitation during the period from December 23, 2016, through June 2, 2019.

V. FACTUAL ALLEGATIONS

A. PURDUE'S DECEPTIVE MARKETING CAMPAIGN AND OVER-PROMOTION OF OPIOIDS SPARKED THE BEGINNING OF THIS NATIONAL HEALTH CRISIS

43. Purdue is a privately owned company, which develops and manufactures prescription opioid drugs and other medications. Its main product is the prescription opioid OxyContin, a powerful, highly addictive pain reliever. [redacted] Purdue introduced OxyContin to the market in 1996. Its opioid product line also includes Butrans®, a long-acting buprenorphine patch approved by the United States Food and Drug Administration (FDA) in 2010, and Hysingla® ER, an extended-release hydrocodone-based pain reliever approved by the FDA in 2014.

44. Opioids are a class of drugs that are primarily used for pain relief, and include prescription drugs like morphine and codeine, as well as illicit drugs like heroin. In the past, prescription opioids were used for short-term, acute, or cancer-related pain, and for patients near

the end of life. Historically, they were not used to treat chronic, non-cancer pain because of their highly addictive nature. That all changed after Purdue brought OxyContin to market.

45. In 1994, Purdue applied to the FDA for approval of its controlled-release oxycodone-based Schedule II opioid, OxyContin. Through market research, Purdue tested the receptivity of doctors to OxyContin for non-cancer pain. The company learned that physicians were concerned about the safety and risks of OxyContin because of its addictive and abuse potential. Purdue also learned that physicians wanted a long-lasting pain reliever that was less addictive and less subject to abuse and diversion than existing drugs. The company used this information to portray OxyContin as the safe and effective, long-lasting pain reliever physicians wanted.

46. Purdue began an aggressive deceptive marketing campaign in 1996 that would completely change how physicians viewed the safety profile of opioids for chronic non-cancer pain.

Purdue Positioned OxyContin as a Safe and Effective Treatment for Non-Cancer Pain

47. Before OxyContin was approved by the FDA, Purdue conducted focus groups on primary care physicians, surgeons, and rheumatologists to determine their receptivity to using OxyContin for non-cancer pain. The physicians wanted a long-lasting pain-reliever that did not have the abuse and addiction profile of existing drugs. Purdue used this market research to position OxyContin as a long-lasting pain reliever suitable for non-cancer pain that was less addictive and less subject to abuse compared to immediate-release opioids. Purdue was also instrumental in promoting the concept of pain as the fifth vital sign, which was a core cause of the overprescribing that led to the opioid crisis. These decisions proved critical in OxyContin's success, but fatal to communities in California and the rest of the United States, both in lives lost and the costs to our economy.

Purdue Claimed that Risk of Addiction with OxyContin is Rare

48. One of Purdue's biggest obstacles in promoting OxyContin was the overwhelming risk of addiction with opioids. Rather than truthfully disclosing the known risks of addiction, Purdue misleadingly marketed the addiction risk of OxyContin as "rare" and the rate of addiction as "less than 1%."

49. In Purdue's 1998 promotional video, *I Got My Life Back*, a physician tells the audience:

> 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 . . . is much less than one percent.*** They don't wear out, they go on working, ***they do not have serious medical side effects.*** And so, these drugs, which I repeat, are ***our best, strongest pain medications, should be used much more than they are for patients in pain.***

(emphasis added). Purdue distributed 15,000 copies of *I Got My Life Back* to healthcare providers, including those in California.

50. The related brochure, *I Got My Life Back: Patients in Pain Tell Their Story*, similarly emphasized that "addiction occurs in less than 1% of patients taking opioids under a physician's care" and that "they provide a high degree of safety."

51. The promotional video featured seven patients taking OxyContin. Two of the seven were active opioid abusers when they died, and a third became addicted and quit only after she realized she was headed for an overdose.[9]

52. Years later, Purdue responded to an August 2012 email regarding a news story about the 1998 promotional video by reiterating its belief that the "incidence of developing an addictive condition is low."

53. In another promotional video, *From One Pain Patient to Another: Advice From Patients Who Have Found Relief*, Purdue similarly claimed that "[l]ess than 1% of patients taking opioids actually become addicted." Purdue distributed 14,000 copies of the video in 1999 to physicians, including healthcare providers in California. The video was also available for ordering online from June 2000 through July 2001 through Purdue's *Partners Against Pain* website.

54. In its brochure, *Dispelling the Myths About Opioids* (*Dispelling Myths*), Purdue claimed "[a]ddiction risk also appears to be low when opioids are dosed properly for chronic noncancer pain." "In a review of the records of 11,882 hospitalized patients treated with opioids,

[9] John Fauber & Ellen Gabler, *What Happened to the Poster Children of OxyContin?* (Sept. 9, 2012), at < http://archive.jsonline.com/watchdog/watchdogreports/what-happened-to-the-poster-children-of-oxycontin-r65r01o-169056206.html/ >.

there were only four cases of addiction in patients with no addiction history."

55. Similarly, in *Counseling Your Patients and Their Families Regarding the Use of Opioids to Relieve Pain* (*Counseling Your Patients*), Purdue asserted that "[t]he risk of opioid abuse or addiction in patients without prior histories of abuse is extremely rare." "[A] survey of more than 11,000 opioid-using patients, taken over several years, found only four cases of documented addiction." "Many patients – and family members – will be surprised to discover that fewer than 1% of opioid-using patients become addicted."

56. In its September 2005 continuing medication education presentation, *Principles of Pain Pharmacotherapy: Continuum of Care*, Purdue told physicians that "[a]ddiction to opioids in the context of pain treatment is reported to be rare in those with no personal or family history of addictive disorders." Similarly, in Purdue's September 2009 educational initiative, *Addressing Substance Abuse Prevention ASAP Recognition and Prevention in Clinical Practice Overview*, the company told healthcare providers "[m]ost exposures to drugs that are considered to have addiction potential do not result in the disease of addiction."

57. Purdue relied largely on a one-paragraph letter to the editor published in the *New England Journal of Medicine* in 1980 to substantiate its claim about the rarity of the incidence of addiction for patients taking opioids. This letter was specifically discussed in the *Dispelling Myths* and *Counseling Your Patients* brochures described above.

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[1] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug Surveillance Program
Waltham, MA 02154 Boston University Medical Center

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

The letter, written by Dr. Hershel Jick and Jane Porter, concluded, based on their observation of patients in a hospital setting, that "the development of addiction is rare in medical patients with no history of addiction."[10] This was not a formal peer-reviewed study or article, but merely a letter to the editor based on observations of patients who were given small, short-term doses of opioids to treat acute pain at an academic research hospital. Dr. Jick later noted that he wrote a letter to the editor instead of a peer-reviewed article because the data were not robust enough to publish as a study.[11] He also noted that the drug companies used his letter to conclude that opioids are not addictive, "[b]ut that's not in any shape or form what we suggested in our letter."[12]

58. Purdue and the Sackler Board Members knew or must have known the risk of addiction was much greater. Purdue funded a study by Dr. Lawrence Robbins in 1998, where 8% of the patients who took OxyContin to treat concurrent migraines "displayed enough addictive behavior to qualify for 'prescription opiate abuse.'" In another study from 1998, Dr. Robbins observed "[a]ddictive behavior" in 13% of patients taking OxyContin for chronic daily headache. And as early as February 1997, Purdue, Dr. Richard Sackler, Dr. Kathe Sackler, and Jonathan Sackler knew that oxycodone-containing drugs like OxyContin were among the most abused opioids in the United States.

Purdue Claimed OxyContin is Less Addictive and Less Likely to be Abused than Immediate-Release Opioids

59. Purdue also made improper and deceptive comparative claims regarding the addiction potential of OxyContin. The company told healthcare providers that OxyContin did not cause a buzz or euphoria, and therefore was less addictive and less likely to be abused and diverted than short-acting opioids.

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[10] Jane Porter & Herschel Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 New Eng. J. Med. 123 (1980).

[11] Barry Meier, *Pain Killer: An Empire of Deceit and the Origin of America's Opioid Epidemic* 174 (2d ed. 2018).

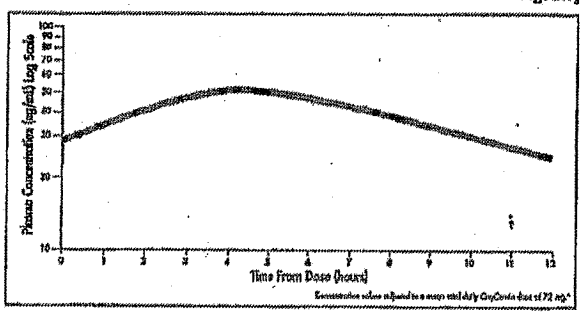
[12] Taylor Haney & Andrea Hsu, *Doctor Who Wrote 1980 Letter on Painkillers Regrets that it Fed the Opioid Crisis* (June 16, 2017), at < https://www.npr.org/sections/health-shots/2017/06/16/533060031/doctor-who-wrote-1980-letter-on-painkillers-regrets-that-it-fed-the-opioid-crisi >.

60. One way Purdue sought to demonstrate this was by showing that OxyContin purportedly had fewer peaks and troughs in blood plasma levels when compared with immediate-release opioids, resulting in less euphoria. Purdue sales representatives often provided healthcare providers a graphical demonstration of the peaks and troughs of the blood plasma levels experienced on OxyContin compared with shorter-acting opioids.

61. In October 1995, Purdue submitted its initial OxyContin launch materials to the FDA for review. As part of the package, Purdue provided a graph of blood plasma levels for OxyContin over a 12-hour period, accompanied by a statement that OxyContin's oxycodone blood plasma levels provided "fewer 'peaks and valleys' than with immediate-release oxycodone." After the FDA informed Purdue that it should include the actual blood levels in the graphs so that a reader could accurately interpret the claim, Purdue responded in January 1996 that it deleted the "fewer peaks and valleys" statement from its marketing materials.

Q12h dosing provides smooth and sustained blood levels.

[NDA ISE Vol. 96 Fig. 2.1]

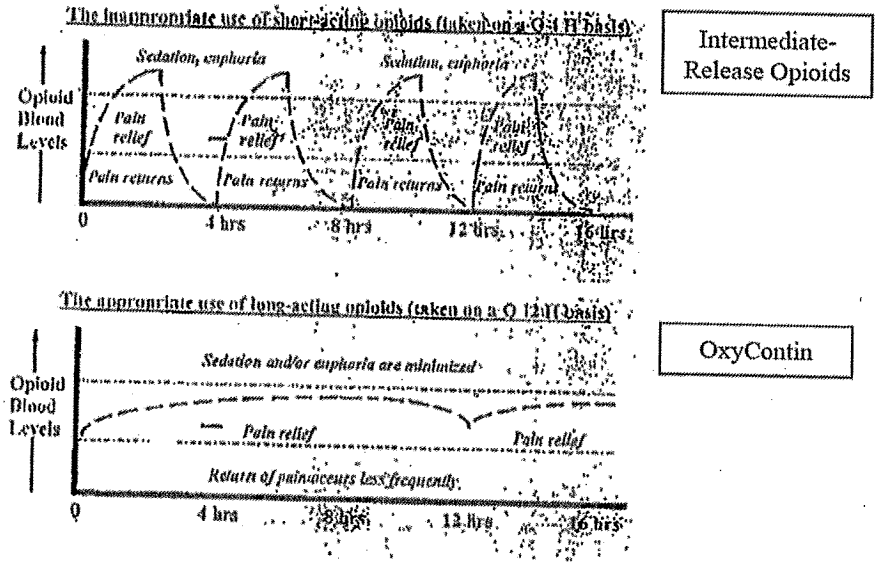


— Fewer "peaks and valleys" than with immediate-release oxycodone

[P.I.-Letter E, pp 8,14]

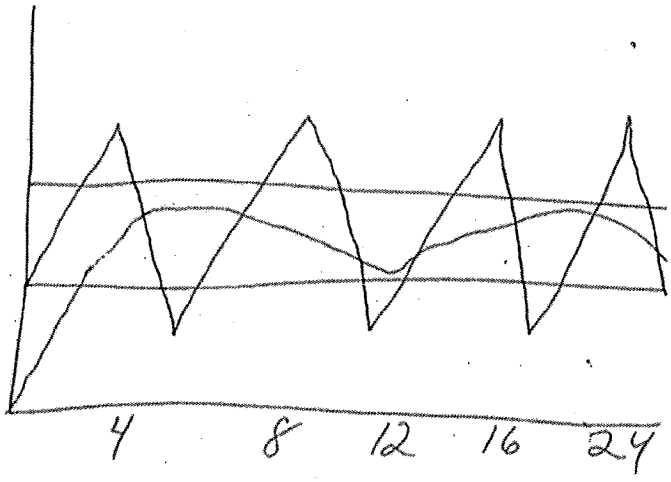
62. Nevertheless, Purdue not only continued to use the "fewer peaks and valleys" statement to promote OxyContin, but it also utilized a version of the peaks and valleys graph that was materially different, and even less accurate, than the one it submitted to the FDA. In one December 1998 sales manager training session, a pharmacist retained by Purdue used a graph showing the blood plasma levels for immediate-release opioids with significant ups and downs, and the OxyContin blood plasma levels at a steady state, to further its claim that the drug did not cause a buzz or euphoria. The pharmacist falsely told the Purdue sales managers that OxyContin

had significantly fewer peak and trough blood levels compared to immediate-release opioids, which results in less potential for abuse.



63. From 1999 through June 2001, sales representatives used this same graph to tell healthcare providers that OxyContin had less euphoric effect and therefore was less addictive and less likely to be abused than immediate-release opioids.

64. Beginning in 1999, Purdue even taught some sales representatives to draw their own blood plasma level graphs, similar to the one below, to falsely represent that OxyContin did not have the large swings in blood plasma that intermediate-release or short-acting opioids have, and therefore had less abuse potential.



65. Purdue told its sales representatives that OxyContin was less likely to be abused than immediate-release opioids because it was more difficult to extract oxycodone, the active ingredient in OxyContin, for purposes of intravenous abuse.

66. Purdue also instructed sales representatives to use the statement from the package insert that "[d]elayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug" to market and promote OxyContin. Sales representatives used this statement to falsely tell healthcare providers that OxyContin did not cause a buzz or euphoria, was less addictive, and was less likely to be abused and diverted than immediate-release opioids.

67. Purdue, however, knew that OxyContin was not less addictive and not less subject to abuse than immediate-release opioids. In October 1995, a couple months before OxyContin received FDA approval, the FDA, with Purdue's assistance, completed a medical officer review of the safety and efficacy of OxyContin. The review found, among other things, that:

a. The blood level data suggests the opioid effects of OxyContin and immediate-release oxycodone would be similar;

b. The efficacy of OxyContin is equivalent to immediate-release oxycodone, with an adverse event profile that is as good as immediate-release oxycodone; "I would not allow a 'better' claim." (emphasis in original)

c. "Withdrawal is possible in patients who have their dosage abruptly reduced or discontinued."

d. "[T]here is not enough evidence to support an [adverse event] superiority claim;" and

e. "Care should be taken to limit competitive promotion. [OxyContin] has been shown to be as good as current therapy, but has not been shown to have a significant advantage beyond reduction in frequency of dosing."

68. The FDA's medical officer review was shared with Purdue. And while the review was not binding on the company, it at minimum put Purdue on notice of the shortcomings of its product.

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69. Even Purdue's own studies showed OxyContin was not the safe, non-addictive product it misled the public to believe it was. One of Purdue's studies demonstrated OxyContin's high abuse potential. It showed that almost 68% of the oxycodone from a 10 mg OxyContin tablet could be extracted simply by crushing the tablet, stirring the powder in water, and drawing the solution through cotton into a syringe.

70. And as early as February 1997, Purdue, Dr. Richard Sackler, Dr. Kathe Sackler, and Jonathan Sackler knew that the class of drugs containing oxycodone like OxyContin was among the most abused opioids in the United States. By March 2000, Defendants were aware of specific reports of abuse and diversion involving OxyContin occurring in communities across the United States. Instead of acknowledging the highly addictive nature of OxyContin, Dr. Richard Sackler blamed the victim: "[W]e have to hammer on the abusers in every possible way. They are the culprits and the problem. They are reckless criminals."

Purdue Misleadingly Positioned OxyContin as Not as Strong as Morphine

71. Like OxyContin, morphine is a Schedule II controlled substance. Morphine is used to treat moderate to severe pain, and is often associated with end of life care. Morphine has a negative stigma attached to it that often prevents physicians from prescribing it.

72. From the start, Purdue positioned OxyContin as a safe and effective treatment for chronic non-cancer pain. Because Purdue marketed OxyContin for a broad audience that included common, everyday pain states such as back pain and arthritis, healthcare providers believed OxyContin was weaker, and therefore safer, than morphine, even though OxyContin is actually stronger on a milligram to milligram basis compared to morphine. The company did nothing to change this misperception; in fact, Purdue went out of its way to avoid correcting providers' misinformed views.

73. By May 1997, Purdue, including Dr. Richard Sackler and Dr. Kathe Sackler, was well aware that many physicians wrongly believed that OxyContin was weaker than morphine. Purdue marketed OxyContin in a way that would allow sales representatives to sell OxyContin for a number of different pain states, "intentionally avoid[ing] a promotional theme that would link OxyContin to cancer pain." Purdue knew doctors used OxyContin because they wrongly

believed the "'personality' of OxyContin is less threatening to them and their patients than that of the morphine alternatives."

74. In a May 1997 email from Michael Friedman, head of sales and marketing who would ultimately become CEO and plead guilty to misbranding of OxyContin, to Dr. Richard Sackler discussing physicians' misconception of OxyContin when compared to morphine, Mr. Friedman stated "it would be extremely dangerous, at this early stage in the life of this product, to tamper with this 'personality' to make physicians think the drug is stronger or equal to morphine. We are better off expanding use of OxyContin, in the non-malignant pain states" since OxyContin was "successful beyond our expectations in the non-malignant pain market."

75. In a June 1997 email from Michael Cullen, Senior District Manager, to Dr. Richard Sackler, Dr. Kathe Sackler, and others, Mr. Cullen noted that in recent meetings the teams discussed "the issue that OxyContin is perceived by some physicians, particularly Oncologists, as not being as strong as MS Contin" (Purdue's morphine-based opioid). "Since oxycodone is perceived as being a 'weaker' opioid than morphine, it has resulted in OxyContin being used much earlier for non-cancer pain. Physicians are positioning this product where [weaker opioids] have been traditionally used." Mr. Cullen went on to state that "it is important that we allow this product to be positioned where it currently is in the physician's mind. If we stress the 'Power of OxyContin' versus morphine, it may help us in the smaller cancer pain market, but hurt us in the larger potential non-cancer pain market. Some physicians may start positioning this product where morphine is used and wait until the pain is severe before using it."

Purdue Claimed OxyContin is Not Subject to Withdrawal Symptoms

76. Purdue also told healthcare providers that patients would not develop tolerance to OxyContin and could abruptly stop therapy without experiencing withdrawal symptoms, misleadingly citing a 2000 study on osteoarthritis that it sponsored and helped author as support.

77. Dr. Peter G. Lacouture, Purdue's Senior Director of Clinical Research, was one of the authors of a study on the use of low-dose OxyContin by osteoarthritis patients. The study, "Around-the-Clock, Controlled-Release Oxycodone Therapy for Osteoarthritis-Related Pain," was published in March 2000 in the Archives of Internal Medicine. The results section of the

study noted: 1) one patient, who was receiving 70 mg oxycodone, was hospitalized with withdrawal symptoms that resolved after three days; 2) a second patient, who was receiving 60 mg oxycodone, experienced withdrawal symptoms after running out of medication but did not experience such symptoms during scheduled respites from doses at 30 mg or 40 mg; and 3) withdrawal syndrome was not reported as an adverse event during any scheduled respites. Taking into account these results, the study indicated that patients taking OxyContin at doses below 60 mg (which is 90 morphine milligram equivalent (MMEs)) can discontinue use without tapering the dose. This number is significant because 90 MMEs is the ***maximum*** daily dosage recommended by the Centers for Disease Control and Prevention (CDC).[13] Even at 50 MMEs, the CDC warns that extra precautions should be taken, and that a prescription for naloxone, the overdose reversal drug, should also be considered.[14]

78. In June 2000, Purdue sent the full text of the osteoarthritis article to its entire sales force, including sales representatives in California, with a marketing tip that stated the article was available for use in achieving sales success. The marketing tip listed as one of the article's key points: "There were 2 reports of withdrawal symptoms after patients abruptly stopped taking CR oxycodone at doses of 60 or 70 mg/d. Withdrawal syndrome was not reported as an adverse event during scheduled respites indicating that CR oxycodone at doses below 60 mg/d can be discontinued without tapering the dose if the patient condition so warrants."

79. Between June 2000 and June 2001, Purdue distributed reprints of the osteoarthritis study to all of the company's sales representatives, including its California sales representatives, for purposes of promoting OxyContin to healthcare providers. During that same time period, Purdue's sales representatives shared reprints of the osteoarthritis study with healthcare providers and told them that patients taking OxyContin at doses below 60 milligrams a day will not develop tolerance and can discontinue therapy abruptly without withdrawal symptoms.

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[13] Centers for Disease Control and Prevention (CDC), *Calculating Total Daily Dose of Opioids for Safer Dosage*, at <https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf>.

[14] Centers for Disease Control and Prevention (CDC), *Calculating Total Daily Dose of Opioids for Safer Dosage*, at <https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf>.

80. Purdue distributed the osteoarthritis study to its entire sales force, knowing that its sales representatives, including those in California, would provide the study and make misleading statements to healthcare providers about OxyContin's purported lack of withdrawal symptoms. The company, however, knew that the underlying data from the osteoarthritis study showed that some patients had withdrawal symptoms, and the company separately received reports of patients experiencing withdrawal symptoms.

81. In February 1999, Napp Laboratories, a United Kingdom company related to Purdue provided the company with an analysis of the osteoarthritis study and another clinical study that showed 19 patients, including eight from the osteoarthritis study, who had symptoms that may have been related to opioid withdrawal. The analysis stated the symptoms may have simply resulted from the return of pain, but nonetheless noted "the incidence of withdrawal syndromes in patients treated with OxyContin tablets is a concern." The analysis went on to conclude that "[a]s expected, some patients did become physically dependent on OxyContin tablets but this is not expected to be a clinical problem so long as abrupt withdrawal of [the] drug is avoided."

82. In May 2000, Purdue's Medical Services Department learned of a patient who was unable to stop taking 10 mg OxyContin every 12 hours without experiencing symptoms of withdrawal. The Medical Services Department commented that "[t]his type of question, patients not being able to stop OxyContin without withdrawal symptoms, has come up quite a bit here . . . (at least 3 calls in the last 2 days)."

83. In February 2001, Purdue received a review of the accuracy of the withdrawal data in the osteoarthritis study. The review stated that there were multiple comments for enrolled patients that "directly stated or implied that an adverse experience was due to possible withdrawal symptoms." In March 2001, a Purdue employee emailed a supervisor regarding the withdrawal data review and asked whether it was worth drafting an abstract, "[o]r would this add to the current negative press and should be deferred?" The supervisor replied, "I would not write it up at this point," and no abstract was ever written.

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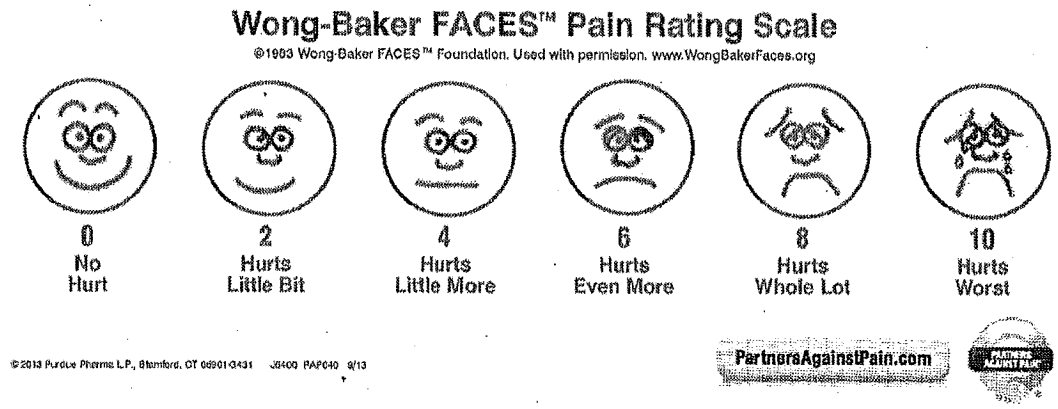
Purdue Was Instrumental in Promoting the Concept of Pain as the Fifth Vital Sign

84. In the mid-1990s, the American Pain Society, with the support of Purdue, recommended that pain be treated as the fifth vital sign to ensure that pain would be a regular part of a patient's health evaluation. In 2001, the Joint Commission, which accredits hospitals and other health care organizations, with the assistance of Purdue, adopted the fifth vital sign concept purportedly to ensure that patients would receive appropriate pain treatment. Hospitals and other health facilities were required to assess pain as a critical factor, alongside blood pressure, heart rate, respiratory rate, and temperature, in the evaluation of a patient's overall health.



85. Purdue was instrumental in the pain as the fifth vital sign movement, "supporting the American Pain Society's program designating pain as the 'Fifth Vital Sign'" and providing grants to the Joint Commission to support the fifth vital sign concept.

86. And "[e]xpand[ing] the concept of *Pain – The Fifth Vital Sign*" was part of Purdue's marketing strategy. Purdue pushed the concept through promotional materials, such as fifth vital sign wall posters, clipboards, and watches, which were provided to hospitals, and other healthcare facilities. Sales representative trainings included discussions of the fifth vital sign and the sales force implemented the fifth vital sign concept onto the field. Purdue even registered the domain name www.5thvitalsign.com.

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87. Unfortunately, the concept of pain as the fifth vital sign has been recognized as a core cause of the opioid epidemic.[15] Its promotion led to the over-prescription of Purdue's opioids, flooding our communities with the drugs, resulting in opioid over-use, and ultimately leading to the public health crisis we face today.

Purdue Used Hundreds of Sales Representatives to Deceptively Promote OxyContin

88. Purdue used a variety of avenues to promote OxyContin, including through branded written materials, unbranded materials, websites, promotional videos, speakers' bureau programs, and continuing medical education presentations. Its most effective marketing tools, however, were its sales representatives. Between 1996 and 2002, Purdue more than doubled its sales force in the United States, from 318 sales representatives in 1996 to 767 in 2002.[16] And together with sales representatives from Abbott Laboratories, with which Purdue had a copromotion agreement, sales representatives promoting OxyContin numbered over 1,000 by 2002.[17] The number of prescriptions written grew exponentially with the number of sales representatives. From 1997 to 2002, the number of prescriptions increased from approximately 920,000 to over 7 million.[18] And sales increased from $48 million in 1996 to nearly $2 billion in 2002.

89. Purdue's sales representatives made false and misleading statements directly to physicians, nurses, and other healthcare providers, including those in California. Purdue sales representatives targeted not only pain specialists, but also primary care physicians, psychiatrists, rheumatologists, and other doctors who may not have adequate training in pain management. Purdue sales representatives promoted OxyContin as the drug "to start with and to stay with,"[19] and peddled the deceptive marketing messages described above.

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[15] President's Com. on Combating Drug Addiction and the Opioid Crisis, Rep. (Nov. 1, 2017), pp. 9, 21, at < https://www.whitehouse.gov/sites/whitehouse.gov/files/images >.

[16] U.S. General Accounting Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem* (Dec. 2003), at < https://www.gao.gov/assets/250/240884.pdf >.

[17] *Ibid.*

[18] *Ibid.*

[19] *Ibid.*

B. PURDUE AND THE SACKLERS WERE SUBSTANTIAL FACTORS IN CAUSING AND MAINTAINING THE OPIOID EPIDEMIC

90. Purdue and the Sacklers were well aware that OxyContin was not safer than other opioids. Nevertheless, through active promotion, Defendants positioned OxyContin as a safe and effective pain-reliever for non-cancer pain that was less addictive and less subject to abuse than immediate-release opioids, and not subject to withdrawal symptoms. Purdue and the Sacklers knew – through the medical literature, news media, the FDA medical officer review, and Purdue's own studies and reports – that OxyContin was not less addictive or less subject to abuse and diversion and that people who took OxyContin would be subject to withdrawal symptoms. They regularly received reports of abuse and diversion and of people suffering withdrawal. Defendants nevertheless continued deceptively promoting and over-promoting OxyContin. As the number of people dying and hospitalized due to OxyContin continued increasing over the years, so too did Purdue's revenues and the Sacklers' bank accounts, well into the billions of dollars.

91. Defendants' active promotion of OxyContin sparked the beginning of the public health crisis we face today.

C. PURDUE PLEADED GUILTY TO FELONY MISBRANDING OF OXYCONTIN

92. In the mid-2000s, the United States, led by the United States Attorney's Office for the Western District of Virginia, began a criminal investigation into Purdue's promotion and marketing to determine whether Purdue was misbranding OxyContin. In May 2007, defendants Purdue Pharma L.P. and The Purdue Frederick Company Inc. entered into a settlement agreement and non-prosecution agreement to resolve the investigation.[20]

93. On May 10, 2007, The Purdue Frederick Company Inc. pleaded guilty to felony misbranding of a drug with the intent to defraud or mislead. Purdue admitted that beginning in December 1995 and continuing through at least June 2001, Purdue, "with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications." Purdue admitted

[20] *United States v. The Purdue Frederick Company, Inc., et al*, Case No. 1:07CR00029, Plea Agreement, Dist. of Va., May 2007.

that it directed its sales representatives that they could market OxyContin as less addictive than immediate-release opioids. Purdue also falsely told healthcare providers that OxyContin did not cause euphoria and had less abuse potential than immediate-release opioids.[21]

94. Three high-level executives, including a former president, former general counsel, and former chief medical officer, also pleaded guilty to misbranding. The company, together with the executives, were fined $634.5 million.[22]

95. The Sackler Board Members voted unanimously in favor of defendant The Purdue Frederick Company Inc. and the three high-level executives pleading guilty to misbranding of OxyContin. The Sackler Board Members also voted in favor of admitting in the Agreed Statement of Facts of the plea agreement that from December 1995 through June 2000, The Purdue Frederick Company Inc. employees intentionally misled healthcare providers about OxyContin. During this timeframe, Dr. Richard Sackler was President of The Purdue Frederick Company Inc., Dr. Kathe Sackler, Mortimer D.A. Sackler, Jonathan Sackler, and Ilene Sackler Lefcourt were vice-presidents of The Purdue Frederick Company Inc., and the Sackler Board Members all sat on the board of Purdue Pharma L.P.

96. The Sackler Board Members also entered into a Corporate Integrity Agreement with the U.S. Government, which contained a number of rules that prohibited deception about Purdue opioids, as well as training and reporting requirements. Dr. Richard Sackler, Dr. Kathe Sackler, Mortimer D.A. Sackler, Jonathan Sackler, Ilene Sackler Lefcourt, Beverly Sackler, and Theresa Sackler each certified that he or she would follow the rules and requirements.

D. PURDUE ENTERED INTO A STIPULATED JUDGMENT WITH CALIFORNIA

97. A multistate group of state attorneys general was also investigating Purdue in the mid-2000s for deceptive marketing practices related to OxyContin. On May 8, 2007, California Attorney General Edmund G. Brown Jr., on behalf of the People of the State of California, filed suit against Purdue for violations of California consumer protection laws.[23] On the same day,

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[21] *Ibid.*

[22] *United States v. The Purdue Frederick Company, Inc., et al*, Case No. 1:07CR00029, Plea Agreement, Dist. of Va., May 2007.

[23] *People v. Purdue Pharma L.P., et al*, No. 37-2007-00066353, Los Angeles Super. Ct.,

Purdue and the California Attorney General entered into an agreed-upon consent judgment (California Consent Judgment).[24] Purdue entered into similar consent judgments with 26 other Attorneys General, and agreed to pay the States and the District of Columbia $19.5 million.[25]

98. The California Consent Judgment prohibits Purdue from, among other things:

a. Marketing or promoting OxyContin in a manner that is directly or indirectly inconsistent with the "Indication and Usage" section of the package insert for OxyContin;

b. Making misrepresentations with respect to OxyContin's potential for abuse, addiction, or physical dependence as set forth in the Package Insert, including claims that OxyContin is "nonaddictive" or that addiction occurs in "less than 1%" of patients being treated with OxyContin;

c. Providing healthcare providers with written materials describing off-label use of OxyContin that have not appeared in a scientific or medical journal or reference publication; and

d. Misrepresenting the existence, non-existence, or findings of any medical or scientific evidence, including anecdotal evidence, relating to off-label uses of OxyContin.[26]

99. The California Consent Judgment required Purdue to implement and follow an OxyContin abuse and diversion detection program. The program was to consist of internal procedures designed to identify potential abuse or diversion of OxyContin. As part of that program, Purdue was required to conduct an internal inquiry following any report of potential abuse or diversion, and take further steps as appropriate, including ceasing to promote Purdue products to particular healthcare providers.[27]

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Complaint for Injunction, Civil Penalties, and Other Equitable Relief, May 8, 2017.

[24] *People v. Purdue Pharma L.P., et al*, No. 37-2007-00066353, Los Angeles Super. Ct., Final Judgment, May 8, 2017 (California Consent Judgment).

[25] *Ibid.*

[26] *Ibid.*

[27] *Ibid.*

100. Purdue was also required to monitor and review news stories regarding abuse and diversion of OxyContin, and take action as necessary to address any abuse and diversion identified in the media, including by correcting any misinformation.[28]

E. THE DECEPTIVE MARKETING CAMPAIGN AND OVER-PROMOTION OF OPIOIDS CONTINUES FOLLOWING PURDUE'S GUILTY PLEA

101. Notwithstanding the guilty plea to felony misbranding, the $600 million fine, and the many lives lost and ruined as a result of OxyContin that should have caused Defendants to stop their lies, Purdue and the Sacklers instead doubled down and continued the deceptive marketing campaign to healthcare providers, patients, and the public about Purdue's extended-release opioid drugs, by now including Butrans (FDA approved in 2010) and Hysingla ER (FDA approved in 2014) on top of OxyContin. Defendants came up with new and creative ways to deceptively promote Purdue's opioid products. Rather than correct their prior misstatements, Defendants carefully spun their old lies and came up with new ones. These misrepresentations and omissions were material and likely to deceive the reasonable healthcare professional and/or the reasonable patient. These misrepresentations and omissions, and over-promotion of opioids, poured more fuel onto the crisis that exists today.

102. As part of its aggressive deceptive marketing campaign, Purdue made the following types of misrepresentations to healthcare providers and patients in California and elsewhere. These statements were disseminated via multiple avenues, including through Purdue-branded publications, nonbranded publications, websites, sales representative statements, Purdue-sponsored or Purdue-funded continuing medical education, and third-party materials sponsored and paid for by Purdue. Purdue sent tens of thousands of publications into California. Its websites received tens of thousands of visits from Californians. Purdue sales representatives contacted California medical providers hundreds of thousands of times.

Purdue Misrepresented the Signs of Addiction as "Pseudoaddiction"

103. After Purdue's guilty plea in 2007, Purdue and the Sacklers had to come up with new and creative ways to market and promote OxyContin. The medical community continued to be

[28] *California Consent Judgment.*

hesitant to prescribe OxyContin because of the potential for addiction. Defendants downplayed this fear by claiming the medical community had been confusing signs of addiction, like tolerance and even intravenous drug use and deception, with simple physical dependence, which they called "pseudoaddiction" and distinguished from "true" addiction.

104. From 2007 through at least 2017, Purdue distributed a pamphlet for doctors called *Providing Relief, Preventing Abuse: A Reference Guide to Controlled Substances Prescribing Practices* (*Providing Relief*). *Providing Relief* claims physical dependence and withdrawal are not reliable signs of addiction: "Confusing physical dependence with addiction is a common error, caused by the fact that most people that health care or law enforcement providers encounter with addiction are also physically dependent to the substance(s) they are abusing. Thus, withdrawal is frequently seen in these people, and it is easy to think that withdrawal equals addiction." *Providing Relief* fails to mention that dependence is dangerous even if it does not turn into addiction.

105. In *Providing Relief*, Purdue also misleadingly and deceptively describes "tolerance" as if it were a normal and expected effect of certain medications: "Tolerance to the respiratory depressant effects of opioids is what allows a patient with pain to regularly take a dose of medicine that would be fatal for someone who wasn't taking the same medicine on a regular basis." Purdue fails to explain that tolerance can drive up dosage, and higher dosages are associated with a greater risk of overdose and death. *Providing Relief* also describes "drug seeking" and "clock watching" patients as simply needing more pain medication, suggesting that pain was being undertreated, rather than acknowledging the risk of addiction.

106. Purdue distributed at least 22,832 copies of *Providing Relief* to California healthcare providers between 2007 and 2017.

107. In Purdue's September 2009 educational initiative, *Addressing Substance Abuse Prevention ASAP Recognition and Prevention in Clinical Practice Overview*, the company told healthcare providers "[a]ddiction involves innate and biological factors. Each person has a particular underlying genetic risk for developing addiction if exposed to a certain type of drug in a certain environment." "Most exposures to drugs that are considered to have addiction potential

do not result in the disease of addiction."

108. Purdue funded a number of publications by third-party, purportedly independent pain groups, including the American Academy of Pain Medicine. The American Academy of Pain Medicine monograph, *Opioid Prescribing: Clinical Tools*, sponsored by Purdue, told healthcare providers that "behaviors that suggest abuse may only reflect a patient's attempt to feel normal."

109. Even widely accepted addiction indicators such as illicit drug use and deception were downplayed by Purdue. In its brochure, *Clinical Issues in Opioid Prescribing* (*Clinical Issues*), Purdue claims that opioids are frequently underdosed or withheld due to a widespread lack of information. *Clinical Issues* describes patients who display drug-seeking behavior, such as those who watch the clock, as people with unrelieved pain. It goes as far as to say that "[e]ven such behaviors as illicit drug use and deception" can be signs of "pseudoaddiction."

110. Similarly, in a 2013 presentation to healthcare providers, "Is it Pain?," Purdue claimed that widely accepted indicators of addiction such as illicit drug use and deception were "not necessarily a result of addiction" and "can occur in the patient's efforts to obtain relief." The presentation went on to state that stealing, forging prescriptions, injecting oral formulations, and prostitution "may occur from time to time in patients being treated for chronic pain" and may be the result of an "unresolved family issue" or "criminal intention" rather than addiction.

111. Purdue even downplayed the risks of addiction in its promotion to consumers. On its patient-focused website, www.inthefaceofpain.com, Purdue told consumers to "overcome" their concerns about addiction. The website also described "concern about the development of tolerance" to medication as a barrier to "effective pain assessment and treatment." The www.inthefaceofpain.com website was visited by Californians from 2010 through October 2015 at least 36,000 times.

112. Addiction, however, does not only develop through the misuse of opioids. Simply using opioids as prescribed can lead to addiction. The probability of continuing use of opioids at one year is significant, even after just five days of use.[29] One of Purdue's own key opinion

[29] Anuj Shah, et al., *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015* (May 17, 2017), Centers for Diseases Control

leaders admitted that what Purdue mischaracterized as "pseudoaddiction" describes "behaviors that are clearly characterized as drug abuse" and put Purdue at risk of "ignoring" addiction and "sanctioning abuse."

Purdue Misrepresented that Opioids Are Safe When Used as Directed

113. Purdue misrepresented to healthcare providers and patients, that people – not drugs – are the root cause of addiction. Purdue led healthcare providers and patients to believe that OxyContin is safe when used as directed and addiction only occurs in people who are susceptible to it, such as people with mental health issues or a history of drug use. Purdue misrepresented to healthcare providers that "trusted" patients could be prescribed opioids without fear of addiction. But opioids like OxyContin are by nature highly addictive, and therefore the drugs themselves, even when used as directed, can lead to addiction.

114. In *Providing Relief*, Purdue states addiction "is not caused by drugs; it is triggered in a susceptible individual by exposure to drugs, most commonly, though not always, through abuse." *Providing Relief* includes photos of people with marks caused by needles, with the caption: "Look for signs of drug abuse. Marks caused by injections," implying that abuse is associated with intravenous drug use. *Providing Relief* also suggests looking out for: "Possession of paraphernalia: syringes, bent spoons, needles."

115. Purdue funded American Pain Foundation's signature patient-directed book: *Treatment Options: A Guide for People Living with Pain* (*Treatment Options*), which Purdue disseminated through its website, www.inthefaceofpain.com. *Treatment Options* falsely states that people suffering from addiction use illicit means to obtain opioids, suggesting that those who are prescribed opioids are not at risk of addiction: "Opioids get into the hands of drug dealers and persons with an addictive disease as a result of pharmacy theft, forged prescriptions, Internet sales, and even from other people with pain." Similarly, the Federation of State Medical Boards' publication, *Responsible Opioid Prescribing*, which Purdue funded, states that only "a small minority of people seeking treatment may not be reliable or trustworthy."

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and Prevention, MMWR Morb Mortal Wkly Rep 2017; 66:265-269, at < https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm >.

116. In its patient-focused *Resource Guide for People with Pain*, Purdue states: "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.'" The American Pain Foundation's publication, *Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families* (*Exit Wounds*), which Purdue helped fund and was on Purdue's consumer-facing website www.inthefaceofpain.com, states: "Long experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medication."

117. In its sales representative trainings, Purdue taught sales representatives to respond to objections about the difficulty patients encounter when stopping OxyContin by emphasizing that patients with personal and family histories of substance abuse and mental illness are more likely to abuse opioids. One presentation noted that all patients "should be routinely monitored for signs of misuse, abuse and addiction." But the presentation also instructed sales representatives to minimize the risk of addiction caused by OxyContin by challenging health care providers' objections and suggesting that the patients themselves, and not the drug, were responsible for addiction. Dr. Richard Sackler similarly blamed patients for their OxyContin addiction. He called people who were addicted to OxyContin "criminals" and "the problem." He believed "we have to hammer on the abusers in every way possible." Sales representatives similarly blamed the victims, noting "the problem being a patient problem, not a drug problem."

118. Purdue sales representatives also pushed physicians to prescribe opioids to "trusted" patients, implying healthcare providers could screen out potential addicts through urine tests and patient contracts. Healthcare providers were told to focus on patients that could be trusted to take the drugs purportedly without risk of addiction, including older, trustworthy patients.

119. Simply using opioids as prescribed, however, can lead to addiction. "The very way most opioids are prescribed for outpatients is potentially addicting[.]" It is well known that prescription opioids and overdoses are linked.[30] The company recognized opioid addiction "can

[30] Deborah Dowell, et al., *Opioid Analgesics—Risky Drugs, Not Risky Patients* (May 9, 2013), Journal of the American Medical Association (JAMA), pp. E1-E2, at < http://cpsa.ca/wp-content/uploads/2015/07/opioid-analgesics.pdf >.

happen to any-one [sic]." Purdue also knew "the original formulation of OxyContin was subject to significant abuse and diversion[,]" including both "intentional abuse" and "inadvertent[] misuse[] by legitimate patients."

120. Last year, Purdue acknowledged opioids can be addictive even when taken as directed, in a full-page Washington Post advertisement: "We are acutely aware of the public health risks opioid analgesics can create, even when taken as prescribed."[31]

Purdue Misled Prescribers to Believe that Opioids Have No Dosage Ceiling

121. Purdue pushed healthcare providers to prescribe higher and higher dosages over time, affirming and reaffirming that there is no limit to the amount of OxyContin a physician could prescribe. Purdue told doctors to titrate up quickly, as often as every one to two days, to higher and higher dosages, and that the only ceiling imposed is by any side effects. And the higher dosages led patients to stay on Purdue's opioids for longer periods of time. However, the clinical evidence shows there is a higher likelihood of overdose and death with increased dosage and longer length of therapy.

122. The American Pain Foundation's *Treatment Options*, which Purdue distributed through its website, www.inthefaceofpain.com, recklessly and dangerously states that with opioids "[t]here is no ceiling dose as there is with the NSAIDs" (nonsteroidal anti-inflammatory drugs like over-the-counter aspirin and ibuprofen) and that doses of opioids can continue to increase over time, despite the fact that the medical literature showed that high doses of opioids increased the risk of addiction and death.

123. Purdue communicated its "no dosage ceiling" message primarily through sales representatives who had direct contact with the healthcare providers prescribing OxyContin. At various national sales representative trainings and in sales representative training materials, Purdue told sales representatives to encourage healthcare providers to titrate up often because the dosage ceiling is imposed only by side effects. At a National Sales Meeting Follow-Up

[31] Just five days later, Purdue took out another full-page advertisement in the Washington Post; however, this time they took out the phrase "even when taken as prescribed." Compare https://kaiserhealthnews.files.wordpress.com/2018/07/july19_purdue.pdf with https://kaiserhealthnews.files.wordpress.com/2018/07/july24_purdue.pdf.

presentation in 2012, the company stated: "With pure opioid agonist analgesics, there is no defined maximum daily dose. The ceiling to analgesic effectiveness is imposed only by side effects . . . . If tolerance develops, or if pain severity increases, a gradual increase in dose may be required." In another sales representative training from April 2014, "OxyContin: The 'Reassess at Every Step' Campaign," Purdue told its sales representatives that they should "point out that the ceiling to analgesic effectiveness is imposed only by adverse reactions."

124. Sales representatives were also taught to encourage healthcare providers to titrate up, and often. At the National Sales Meeting Follow-Up in 2012, sales representatives were told that OxyContin could be increased by 25-50% every one to two days. Purdue encouraged sales representatives to "practice verbalizing the titration message." Sales representatives were told to ask healthcare providers whether some of their "patients [are] appropriate for a dose adjustment/titration due to lack of analgesia on their current dose." Presentations often included a vignette with a hypothetical patient. In one training, sales representatives were encouraged to "discuss how a [hypothetical] patient like Michael may be appropriate for a dose adjustment."

125. Purdue relied heavily on sales representatives to push the titration up and no dosage ceiling messages because it knew "OxyContin is promotionally sensitive, specifically with the higher doses, and recent research findings reinforce the value of sales calls." Purdue "found that there is greater loss in [prescriptions written for] the 60mg and 80mg strengths (compared to other strengths) when we don't make primary sales calls."

126. California sales representatives consistently told physicians, pharmacists, and other healthcare providers that there is no ceiling dose:

a. "oxycontin has no ceiling dose and can be titrated to provide adequate analgesia and tolerability" (family medicine[32]);

b. "no ceiling dose with Oxycontin as long as the [patient] has adequate analgesia and tolerability" (internal medicine);

c. "oxycontin has no ceiling dose" (pharmacist);

[32] Indicates type of prescriber or specialty.

d. "no ceiling dose of [single entity opioids] except for side effects" (internal medicine);

e. "no dose limit with OxyContin, that she can titrate patients to effect as long as the adverse events are manageable" (pharmacist).

The sales representatives' written notes of their meetings with healthcare providers fail to mention there are greater risks of overdose and death with higher doses.

127. When a pain specialist told a sales representative "400 mg is his daily limit," the representative "mentioned oxycotn [sic] studies of 640 mg as dosing," suggesting the doctor could go much higher. A dose of 640 mg/day translates to over 960 MMEs, over ten times the maximum dosage of 90 MMEs recommended by the CDC.[33]

128. Dosage level is highly significant because of the direct relationship between dosage and the length of time patients remain on opioids. The higher the dosage, the longer a patient typically stays on opioids. And the longer a patient stays on opioids, the more money Purdue makes. Purdue gave its sale representatives explicit instructions to "extend average treatment duration." This overpromotion of higher dosages and longer length of therapy led to the over-prescribing and over-use of Purdue's opioids that flooded California communities.

129. In 2013, when public health experts began an initiative to warn against high doses of opioids and long treatment periods ("limiting total daily dose and length of therapy"), Purdue believed it would "negatively impact business" and pursued "strategic initiatives" to fight back. Purdue analyzed down to the dollar how much of its profit depended on patients taking higher doses. For example, a 2014 presentation showed that "[a] small shift of roughly 15[,000] prescriptions from 20mg or 15mg down to 10mg has a $2 [million] impact."

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[33] Centers for Disease Control and Prevention (CDC), *Calculating Total Daily Dose of Opioids for Safer Dosage*, at <https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf>.

Impact of changes in dose mix

(For Illustration purposes)

% shift from 20mg and 15mg down to 10mg

Dose	Forecast (Rx)	Forecast ($)	1% Shift		2% Shift	3% Shift
10 mg	1,226,840	$ 135,005,554	1,242,664	$ 136,746,931	$ 138,488,308	$ 140,229,686
15mg	180,831	$ 33,261,232	179,023	$ 32,928,620	$ 32,596,008	$ 32,263,395
20mg	1,401,616	$ 361,951,330	1,387,599	$ 358,331,817	$ 354,712,303	$ 351,092,790
30mg	519,945	$ 193,796,793	519,945	$ 193,796,793	$ 193,796,793	$ 193,796,793
40mg	1,085,624	$ 577,483,835	1,085,624	$ 577,483,835	$ 577,483,835	$ 577,483,835
60mg	436,272	$ 326,705,155	436,272	$ 326,705,155	$ 326,705,155	$ 326,705,155
80mg	768,198	$ 931,583,802	768,198	$ 931,583,802	$ 931,583,802	$ 931,583,802
Total	5,619,324	$ 2,559,787,701	5,619,324	$ 2,557,576,952	$ 2,555,366,204	$ 2,553,155,456

$2,210,748 | $4,421,496 | $6,632,244

A small shift of roughly 15K prescriptions from 20mg or 15mg down to 10mg has a $2MM impact

Marketing

PURDUE

DRAFT | For Internal Use Only | Not for Dissemination or Promotion

28

130. Purdue's deceptive sales representative training paid off: Purdue's success at keeping patients on high dose opioids for longer than 90 days was one of its "2011 Highlights."

131. The dosage level was also important because of the substantial difference in price. For example, in 2015, Purdue made $38 per week for a patient taking the lowest dose (10 mg) twice daily, but could make over five times more – $210 per week – at the highest dose (80 mg). Over the course of a year, this amounts to about $1,950 for a patient on the 10 mg dose, but nearly $11,000 for a patient on the 80 mg dose.

132. Higher dosages do in fact come with greater risks. A 2013 article in the Journal of the American Medical Association stated, "contrary to the view that there is no maximum safe dose if opioids are increased gradually over time, death from opioid overdose becomes more likely at higher doses."[34] A 2011 Archives of Internal Medicine study found "a significant relationship between the average daily opioid dose and opioid-related mortality . . . . Compared with patients

[34] Deborah Dowell, et al., *Opioid Analgesics—Risky Drugs, Not Risky Patients* (May 9, 2013), Journal of the American Medical Association (JAMA), pp. E1-E2, at < http://cpsa.ca/wp-content/uploads/2015/07/opioid-analgesics.pdf >.

receiving less than 20 mg/d, those prescribed opioids at daily doses of 200 mg or more of morphine (or equivalent) had a much higher risk of opioid-related mortality[.]"[35] Similarly, a 2011 study in Journal of the American Medical Association found "[a]mong patients receiving opioid prescriptions for pain, higher opioid doses were associated with increased risk of opioid overdose death."[36] Even Purdue acknowledged in internal documents that "it is very likely" that there is a "dose-related overdose risk."

133. In California, Purdue's stronger dosages were prevalent. Between 2006 and 2014, over 355 million doses of Purdue's opioids were distributed in California, consisting of over 20 billion morphine milligram equivalents (MME). This amounts to an average dosage of over 58 MME, which level is above the 50 MME the CDC warns should only be prescribed with extra precautions and potentially with naloxone, the overdose reversal drug.[37]

134. Unfortunately, Purdue's over-promotion of opioids led to more and more Californians on higher and higher dosages, for longer periods of time, resulting in the public health crisis we face today.

Purdue Misleadingly Positioned Opioids as Superior to Other Pain Medications

135. Purdue misrepresented the safety and effectiveness of its controlled-release opioids by positioning them as the "first line" of therapy and emphasizing the risks and lack of effectiveness of safer alternatives, such as nonsteroidal anti-inflammatory drugs (NSAIDs) like over-the-counter Tylenol®, aspirin, and ibuprofen.

136. In a 2009 sales representative training presentation, "Osteoarthritis – Diagnosis and Treatment," Purdue claims some of the pharmacologic options to treat osteoarthritis include NSAIDs, tramadol, and opioids. The sales representative training dedicates four full slides to the side effects and risk factors of NSAIDs, including gastrointestinal bleed, cardiac issues,

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[35] Tara Gomes, et al., *Opioid Dose and Drug-Related Mortality in Patients with Nonmalignant Pain* (April 11, 2011), Arch Intern Med., 171(7):686-691.

[36] Amy S. B. Bohnert, et al., *Association Between Opioid Prescribing Patterns and Opioid Overdose-Related Deaths* (April 6, 2011), Journal of the American Medical Association (JAMA), 305(13):1315-1321.

[37] Centers for Disease Control and Prevention (CDC), *Calculating Total Daily Dose of Opioids for Safer Dosage*, at <https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf>.

abdominal pain, peptic ulcers, and hypertension. In the one slide for opioids, the side effects mentioned are respiratory, gastrointestinal, and central nervous system.

137. The American Pain Foundation's signature patient-directed book *Treatment Options*, which Purdue funded and disseminated through its website, www.inthefaceofpain.com, emphasizes the "serious" and "life-threatening" side effects of NSAIDs, including heart attack, stroke, decreased kidney function, and gastrointestinal complications including heartburn, ulcers, and bleeding, but minimizes the risks associated with opioids. Respiratory depression is mentioned as a potential risk of opioids only in passing, blithely described as "a decreased rate and depth of breathing" which is "associated with overdose." The book otherwise focuses on opioids' minor side effects like "constipation, nausea and vomiting, sedation (sleepiness), mental clouding and itching," which the authors assured would either go away with time or could be treated easily with additional medications.

138. *Treatment Options* also states that "[d]espite the great benefits of opioids, they are often under-used," while also mentioning that NSAIDs are overused. An entire section called "Should I take these pain medicines?" appears in the discussion of NSAIDs, but the question is never raised in the book's discussion of opioids.

139. Purdue also provided a $115,000 grant to American Pain Foundation in part to support the writing and publication of *Exit Wounds*. *Exit Wounds* downplays the effectiveness of NSAIDs, while pushing the use of opioids. *Exit Wounds* claims that NSAIDs "alone are not effective treatments for chronic pain." "The pain-relieving properties of opioids are unsurpassed; they are today considered the 'gold standard' of pain medications, and so are often the main medications used in the treatment of chronic pain. Yet, despite their great benefits, opioids are often underused."

140. But Purdue knew its opioids were not safer or more effective than other pain-relievers. In fact, year after year, Purdue acknowledged in various sales representative trainings that they could not make such comparative and superiority claims. Purdue told its sales representatives that "[c]omparisons cannot represent or suggest a drug is safer/more effective unless there is substantial evidence/clinical trials. ***We have no drugs that satisfy this standard.***" (emphasis

added). Indeed, Purdue received a significant number of Warning and Untitled Letters from the FDA regarding unsubstantiated superiority claims.

Purdue Misrepresented the Appropriateness of Opioids for Specific Pain Conditions

141. Purdue's opioids were not indicated for specific pain conditions, but the company nevertheless trained its sales representatives to recommend its opioids for specific disease states. For example, in one 2012 training guide, "A Managed Care Playbook for Sales Representatives," Purdue told its sales representatives that the number one core message that will resonate with healthcare providers who delayed prescribing opioids was to tell them "OxyContin may be appropriate for use in patients with around-the-clock moderate to severe pain associated with conditions such as low back pain, osteoarthritis pain, and cancer pain." Purdue essentially told its sales representatives that the best way to get physicians who were reluctant to prescribe opioids was to conveniently tell them that opioids are appropriate for some of the most common diseases that have associated pain.

142. These lies continued in other sales representatives trainings. In a 2012 National Sales Meeting Follow-Up presentation, sales representatives were told that OxyContin may be appropriate for "patients with moderate to severe pain associated with conditions such as low back pain, osteoarthritis, and cancer pain."

143. Purdue often used vignettes showing people with back pain or osteoarthritis as appropriate patients. In one sales representative training, all of the hypothetical patients suffered from back pain or arthritis. In another training presentation, Purdue suggested that OxyContin "may be appropriate" for a 55-year-old man suffering from osteoarthritis of the knee. This was notwithstanding the fact that a 2014 study of the efficacy of opioids on osteoarthritis of the knee and hip concluded that the "small mean benefit of non-tramadol opioids are contrasted by significant increases in the risk of adverse events." The presentation also failed to mention that studies showed increased risk of falls, fractures, and death resulting from opioid use in older individuals.

144. The sales force, including California sales representatives, told healthcare providers that Purdue's opioids were appropriate for specific disease states such as osteoarthritis,

fibromyalgia, cancer, and back pain. For example, California sales representatives "[a]sked provider[s] to prescribe OxyContin for patients with osteoarthritis," "[d]iscussed using OxyContin for osteoarthritis patients," and reviewed the use of OxyContin for "use for patients with osteoarthritis, low back pain and cancer."

145. In one call note, the sales representative noted the "Dr. looked at the OxyContin vis[ual] aid with osteoarthritis listed as a disease state that warrants OxyContin."

146. In another call note, the district manager suggested a sales representative steer the internal medicine doctor to prescribe OxyContin for osteoarthritis and lower back pain, notwithstanding the physician's concerns of stated abuse with stronger opioids like OxyContin.

147. During one call, the sales representative asked the endocrinologist, "How about fibromyalgia?" and then stated that "[a]s long as these [patients] meet [the] OxyContin indication they could be appropriate." The endocrinologist commented she did not want to prescribe Schedule II controlled substances like OxyContin. The physician was right to be concerned. Purdue acknowledged in its 2012 Business Strategy that "[f]or some etiologies of pain (e.g. fibromyalgia) opioids do not seem to produce pain relief that is consistent with the magnitude of response they produce in other pain etiologies – so given concerns over abuse liability and other adverse events, they are not highly recommended for use in these conditions."

148. Purdue noted that its representatives were "identifying appropriate patients" when promoting its opioids because osteoarthritis was specifically mentioned during 35% of sales visits.

149. However, Purdue knew its opioids are "not indicated for a specific disease state." "[I]t is very important that you never suggest to your [healthcare professional] that OxyContin is indicated for the treatment of a specific disease state such as Rheumatoid Arthritis or Osteoarthritis."

Purdue Misrepresented that Opioids Improve Function and Quality of Life

150. Purdue told healthcare providers and patients that long-term opioid use improves functional outcomes for patients, but failed to mention there is a greater chance of addiction and abuse with long-term use. In Purdue's most widely distributed marketing piece, *Focused and*

Customized Education Topic Selections in Pain Management (*FACETS*), the company instructed doctors and patients that physical dependence on opioids is not dangerous and instead improves patients' "quality of life." However, the medical literature showed opioids were ineffective at improving patient function.

151. In its September 2005 continuing medication education presentation, *Principles of Pain Pharmacotherapy: Continuum of Care*, Purdue told physicians that the potential benefits of long-term opioid therapy include "[f]unctional improvement: and "[i]mproved quality of life."

152. Similarly, in a 2007 presentation, "Pain Management and Pharmaceutical Care," Purdue's Area Director stated that opioids' side effects "improve over time, except constipation."

153. The American Pain Foundation's *Exit Wounds*, which was available on Purdue's consumer website, www.inthefaceofpain.com, stated "[w]hen used correctly, opioid pain medications increase a person's level of functioning[.]" "The bottom line with opioids is that these are very valuable pain relievers when used correctly and responsibly, and they can go a long way toward improving your functioning in daily life."

154. *Responsible Opioid Prescribing*, which Purdue sponsored, states: "Opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain[.]"

155. But Purdue had no evidence that its opioids improved patients' quality of life. In internal training materials, Purdue conceded it has "no drugs with clinical studies" showing improvements in patients' well-being. "Purdue has no clinical studies or other substantial evidence demonstrating that a Purdue Product will improve the quality of a person's life." One 2008 study reported that "higher dose opioids do not necessarily contribute to overall improvement in physical health quality of life in chronic pain patients." The study went on to state that "quality of life scores remained significantly lower across physical health and bodily pain domains for those using daily opioids >40 mg/d of morphine equivalents."[38] Another journal concluded that "opioid treatment of long-term/chronic non-cancer pain does not seem to fulfil[l] any of the key outcome opioid treatment goals: pain relief, improved quality of life and

[38] Katherin Dillie, et al., *Quality of Life Associated with Daily Opioid Therapy in a Primary Care Chronic Pain Sample*, J Am Board Fam Med 2008, 21:108-117.

improved functional capacity."[39]

Purdue Misrepresented the Safety of its Abuse-Deterrent Formulations

156. Purdue developed an abuse-deterrent formulation of OxyContin in the late 2000s in response to the serious abuse and diversion problem associated with its opioids. The OxyContin abuse-deterrent formulation (OxyContin ADF), [redacted] was approved by the FDA in April 2010.[40] In April 2013, the FDA approved new labeling for OxyContin ADF.[41] In November 2013, the FDA approved Hysingla with similar abuse-deterrent labeling.[42]

157. Purdue deceptively marketed OxyContin ADF and Hysingla, implying they are safer and more effective at stopping and even preventing abuse compared to non-abuse-deterrent formulations, even though Defendants had no evidence that the purported "abuse-deterrent" formulas were less subject to misuse.

158. Purdue sponsored a website at http://www.responsibleopioidrx.com that discussed the "importance of developing formulations with abuse-deterrent properties."[43] The website touted the FDA's stance regarding the development of abuse-deterrent formulations as a "public health priority."[44] Purdue claimed abuse-deterrent opioids are "intended to help deter the abuse, misuse, and diversion these products are subject to, while ensuring that patients in pain continue to have appropriate access to these important agents."[45]

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[39] Jorgen Eriksen, et al., *Critical Issues on Opioids in Chronic Non-Cancer Pain: An Epidemiological Study*, Pain (November 2006), 125(1-2):172-179. Epub 2006 Jul 13.

[40] U.S. Food & Drug Administration, *Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse* (current as of September 25, 2019), at < https://www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-opioid-misuse-and-abuse >.

[41] *Ibid.*

[42] *Ibid.*

[43] http://www.responsibleopioidrx.com accessed via Wayback Machine – Internet Archive, *available at* https://web.archive.org/web/20150715042638/http://www.responsibleopioidrx.com/, captured May 25, 2019.

[44] *Ibid.*

[45] *Ibid.*

159. The http://www.responsibleopioidrx.com website was promoted in various materials and at continuing medical education presentations [redacted]

160. In training materials, sales representatives were told that [redacted]

161. Purdue also told its sales representatives [redacted]

162. In Purdue-sponsored content in *The Atlantic*, Purdue key opinion leader Dr. Gerald Aranoff claimed abuse-deterrent formulations were "safer alternatives" that made "certain forms of abuse much more difficult."[46]

163. However, there is no scientific evidence that abuse-deterrent formulations reduce the risk of misuse or abuse compared to non-abuse deterrent formulas. The CDC guidelines state abuse-deterrent formulations "do not prevent opiate abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes."[47] The CDC further concluded that no reliable studies have established that abuse-deterrent formulations of extended-release or long-acting opioids (like OxyContin ADF and Hysingla) are effective as risk mitigation for deterring or preventing abuse.

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[46] Gerald Aronoff, *Take My Pain Away: A Physician's Perspective of Prescription Opioids and Pain Management*, THE ATLANTIC (Jan. 9, 2015), at < https://www.scribd.com/document/347236217/take-my-pain-away >.

[47] Deborah Dowell, Tamara M. Haegerich & Roger Chou, CDC Guideline for Prescribing Opioids for Chronic Pain —United States, 2016, 65 CDC MORBIDITY & MORTALITY WKLY REP.: RECOMMENDATIONS & REPS., March 18, 2016, at 1, 10–11, 31, at < https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf >.

164. Even Purdue recognized [redacted] In fact, Purdue's own research identified 32 publicly circulated "recipes" to effectively defeat the abuse-deterrent characteristics of OxyContin ADF.[48]

165. Purdue's lies and misrepresentations, in particular regarding the lack of dosage ceiling, the superiority of opioids over safer alternatives like NSAIDs, and their effectiveness in improving quality of life, led to over-promotion and over-prescribing of opioids as a safe and effective treatment for chronic non-cancer pain. This led to over-use by our families, friends, neighbors, and coworkers, and ultimately led to the opioid epidemic we face today.

F. PURDUE UTILIZED ITS SALES REPRESENTATIVES AND THIRD-PARTY ORGANIZATIONS TO DECEPTIVELY MARKET ITS OPIOID PRODUCTS

166. After the 2007 guilty plea, Purdue continued to use a variety of avenues to promote OxyContin, including through written materials, websites, and continuing medical education presentations; however, its most effective marketing tool continued to be its sales representatives.

167. Purdue implemented formal rules and procedures that helped the company keep its lies off the radar and from leaving a paper trail. Sales representatives were prohibited from communicating with healthcare providers in writing other than to arrange or confirm a visit, and were explicitly told they "must avoid any mention of product, product attributes, competitor products, disease states, and/or specific patients." Of course, they could verbally communicate whatever they wanted. As one former sales representative admitted: "We were directed to lie. Why mince words about it?"[49]

168. Purdue continued to target a variety of specialties and healthcare providers, including primary care physicians, psychiatrists, surgeons, nurses, and physician assistants, to prescribe OxyContin and its other opioid products. Knowing the additional value sales representatives

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[48] Emily C McNaughton et al., *Monitoring of Internet Forums to Evaluate Reactions to the Introduction of Reformulated OxyContin to Deter Abuse*, 16 J. OF MED. INTERNET RES. e119 (2014), at < https://pdfs.semanticscholar.org/7fda/f3fc9b7c0c5b42c516cc5bf9cd5fef89e9fe.pdf?_ga=2.226492122.131622791.1569452983-1740149820.1568927208 >.

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

brought to the bottom line, the Board of Directors of Purdue Pharma Inc. (Board), including the Sackler Board Members, voted on February 8, 2008, just nine months after Purdue pleaded guilty to illegally marketing and promoting OxyContin, to expand the sales force by an additional 100 sales representatives by April 1, 2008. This would increase the sales force by a whopping 40%, bringing the total number of sales representatives to 350 by July 1, 2008. The expanded sales force would "allow[ ] us to cover an additional 10,000 – 12,000 high prescribers of [OxyContin]." The 2008 revised budget for Purdue Pharma L.P., included over $155 million for sales and promotion alone, over 20% more than the amount budgeted for research and development.

169. Purdue fully understood the value of direct personal communications. According to a 2014 Purdue analysis, "Data confirms that OxyContin is promotionally sensitive, specifically at the higher doses, and recent research findings reinforce the value of sales calls." Purdue's research showed that "[f]or the 1,950 [health care providers] who went from no calls a quarter to at least one primary call in the latter quarter it resulted in a 29.0% growth in [total prescriptions] across all strengths [of OxyContin] and a 27% increase in the 60 and 80 mg strengths," the two highest-strength tablets. The research also showed that "there is greater loss in the 60mg and 80mg strengths (compared to the other strengths) where we don't make primary sales calls or stop making primary sales calls."

170. The company's internal research showed that sales calls were particularly effective with healthcare providers who were already prescribing the greatest amounts of opioids. A 2013 OxyContin presentation called for increased sales calls on high-prescribing health care providers. Purdue's 2015 commercial strategy for OxyContin called for prioritizing health care providers "who prescribe high volumes of branded [extended release opioids] and have high but declining OxyContin prescriptions." Purdue conducted research to determine characteristics of low-prescribers to weed out physicians who were reluctant to prescribe its products. Purdue targeted high-prescribing healthcare providers, including those in California.

171. Savings cards were an integral part of sales representatives' promotional arsenal and one of the keys to increasing prescriptions. The savings card had "the highest [return on investment]" in the entire "OxyContin Marketing Mix." For every million dollars Purdue gave

away in savings cards, Purdue got back $4.28 million, or over four times its investment. Purdue's savings cards were not for one-time use. The savings card could be used every 7 or 14 days, ensuring that patients kept coming back for more. Purdue's "10-year plan" highlighted that the patient savings card program resulted in "more patients remain[ing] on OxyContin after 90 days." In 2011 alone, Purdue shipped approximately 800,000 savings cards into the field. These savings cards were distributed by sales representatives to California healthcare providers.

172. Purdue employed between 31 and 92 sales representatives in California between 2007 and 2017.

173. During that same decade, between June 2007 and December 2017, Purdue sales representatives contacted California doctors and other medical providers over 750,000 times. This amounts to over 285 visits to California medical providers each and every work day over the ten-year period. And these visits were not cheap. On average, each sales visit cost the company more than $200. Purdue more than made up for these costs in the number of prescriptions these healthcare providers wrote. Purdue employees benefited greatly, from the sales representatives who could make almost a quarter of a million dollars in bonuses in just one year, to the Sacklers who received hundreds of millions to over a billion dollars each year in distributions from the company.

174. Purdue also leveraged third-party pain organizations to communicate its deceptive statements about opioids. Purdue poured millions of dollars and other support into purported independent pain advocacy groups, such as the American Pain Foundation, American Academy of Pain Management, the Alliance for Patient Access, the U.S. Pain Foundation, the Pain Care Forum, the American Chronic Pain Association, American Pain Society, American Academy of Pain Medicine, and the Federation of State Medical Boards. Purdue stacked the boards of many of these pain advocacy groups with its employees, consultants, and key opinion leaders.

175. Purdue noted that the basis of Purdue's grants to these organizations was the company's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

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176. These groups advocated for more aggressive treatment of pain, especially through the use of opioids. They repeated many of the false and misleading statements Purdue peddled, including promoting "pseudoaddiction" and minimizing the risks of opioids while exaggerating the risks of other non-opioid pain-relievers. The pain advocacy groups were also key players in the pain as fifth vital sign concept.

177. Purdue provided general funding to the organizations as well as financial and editorial support for special projects. For example, Purdue provided funding for the American Pain Foundation's publications *Exit Wounds* and *Treatment Options*, patient-oriented publications that Purdue included on its consumer-facing website, www.inthefaceofpain.com. Purdue funded the American Academy of Pain Management's *Opioid Prescribing*. Purdue also provided monetary as well as editorial support for the Federation of State Medical Boards' publication *Responsible Opioid Prescribing*. These third-party publications were disseminated by Purdue to healthcare providers and patients in California.

178. Purdue also supported local California organizations and programs, including the American Chronic Pain Foundation, based in Rocklin, and For Grace, based in Valley Village. For Grace's founder, Cynthia Toussaint, sponsored Assembly Bill (AB) 369, which would have allowed easier access to potent opioids by requiring health plans to cover medications such as OxyContin without first requiring patients to try safer, less potent medications. The bill, which was vetoed by former California Governor Edmund G. Brown Jr., also would have allowed prescribers free reign on the length of treatment.[50]

G. PURDUE AND THE SACKLERS KNEW THE COMPANY WAS SUPPLYING OPIOIDS THAT WERE BEING ABUSED AND DIVERTED

179. As early as February 1997, Purdue and certain of the Sacklers knew that oxycodone-containing drugs like OxyContin were among the most abused opioids in the United States. Defendants were well aware of the abuse and diversion of OxyContin taking place in California and across the country because they kept apprised of stories related to OxyContin through *daily*

[50] Rob O'Neil, *California Governor Vetoes Step Therapy Bill*, Nat. Pain Rep. (Oct. 1, 2012), at < http://www.nationalpainreport.com/california-governor-vetoes-step-therapy-bill-8816005.html >.

news alerts, the vast majority of which involved reports of abuse, diversion, and opioid-induced deaths and overdoses. This was in addition to reports and complaints of abuse and diversion that the company directly received. Purdue also kept a secret list of prescribers suspected of abuse and diversion, code-named "Region Zero."

180. Purdue has a team dedicated to reviewing news stories regarding the company and OxyContin, and many individual employees and Board members, including Dr. Richard Sackler, Dr. Kathe Sackler, Jonathan Sackler, and Mortimer D.A. Sackler, also received daily news alerts, including through Google alerts, Competitive Daily News, and PR News. Dr. Richard Sackler acknowledged in a February 2007 email, responding to a forwarded Google alert regarding college students abusing OxyContin, that "[w]e monitor these items routinely. So you don't have to send them." Similarly, in response to a forwarded March 2013 Google alert containing news stories regarding the rising number of deaths due to painkillers like OxyContin and the growing danger of prescription drug abuse, CEO John Stewart noted that "[a]ll such alerts and stories are picked-up by the organization, and are [ ] vetted." In 2007, Purdue's top lawyer specifically wrote to Dr. Richard Sackler, Mortimer D.A. Sackler, Dr. Kathe Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, and Theresa Sackler informing them of numerous news stories suggesting overpromotion and increasing abuse and diversion of opioid products.

181. Indeed, as part of the 2007 California Consent Judgment with former Attorney General Edmund G. Brown Jr., Purdue was *required* to continue to monitor news stories regarding abuse and diversion of its opioid products.

182. Defendants also had knowledge of abuse and diversion through Purdue's maintenance of a list, known as "Region Zero," that kept track of prescribers suspected of abuse and diversion. Sales representatives were supposed to cease calling on prescribers once on the "Region Zero" list, but they nevertheless continued to do so because they were often high-prescribers. Defendants, in fact, continued to track "Region Zero" prescribers, including total prescriptions written and the dollar value of these prescriptions, among other statistics. Over 650 California prescribers are on Purdue's "Region Zero" list.

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183. In addition, Defendants had knowledge of abuse and diversion through various communications and events. In a February 1997 email, Defendants were told that "oxycodone containing products are still among the most abused in the U.S." OxyContin creator Dr. Robert Kaiko further noted in the email that included Dr. Richard Sackler, Dr. Kathe Sackler, Jonathan Sackler and other Purdue executives and Board members that a number of patients in the company's research program "were suspect in terms of their drug accountability."

184. One September 1999 email that included Dr. Richard Sackler forwarded a posting from an online message board about abusing OxyContin, describing how to "feel the rush" by chewing the pills and how the best ones "are the 40-milligram ones cuz [sic] you're not snorting lots of filler."

185. By March 2000, Purdue was aware of specific reports of abuse and diversion involving OxyContin occurring in communities across the United States. The media were reporting that people were crushing OxyContin tables and snorting the powder or dissolving the powder in water and injecting the solution in order to attain a rush or high. Indeed, in a 2001 letter sent to healthcare providers, Purdue acknowledged "the diversion and abuse of OxyContin Tablets and other analgesics in some regions of the country."

186. Congressional hearings took place in late 2001 and early 2002 to discuss the growing problem of abuse and diversion of OxyContin and how to address it. In 2001, Purdue, in conjunction with the FDA, developed and implemented a risk management plan to help detect and prevent abuse and diversion of OxyContin. And in 2002, Purdue began using physician prescribing practices and other information to identify potential improper sales promotion and abuse and diversion of OxyContin.

187. Dr. Richard Sackler was also aware, via a January 2001 email, about a community in the Southeastern U.S. where a number of children died from overdosing on OxyContin. The sales representative for the area attended a meeting at the local high school where two mothers of deceased children who overdosed on OxyContin were presenting on the dangers of OxyContin. "Statements were made that OxyContin sales were at the expense of dead children and the only difference between heroin and OxyContin is that you can get OxyContin from a doctor."

188. In February 2002, Dr. Richard Sackler received an email from Dr. Mortimer Sackler forwarding a news story regarding a "growing wave of drug abuse" involving OxyContin. The story mentions that law enforcement officials have seen a troubling number of cases in seven different states. Dr. Richard Sackler stated in response: "This is not too bad. It could have been far worse." That same month, Dr. Richard Sackler laid out his solution to the overwhelming evidence of abuse and diversion: blame it on the people. "[W]e have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals." This blame-the-victim mindset unsurprisingly permeated into Purdue's promotional materials.

189. Tellingly, the news stories were so depressing that Dr. Richard Sackler asked, in a November 2013 email, "[w]hy are all the alerts about negatives and not one about the positives of OxyContin tablets?" [redacted]

190. Notwithstanding the overwhelming evidence of abuse and diversion of OxyContin, which Purdue and the Sacklers were well aware, Purdue, with the Sacklers' participation and approval, nevertheless continued to supply OxyContin and other opioids to patients in California and the rest of the country through deceptive and misleading promotion.

H. THE SACKLERS DIRECTED AND ACTIVELY PARTICIPATED IN PURDUE'S DECEPTIVE PRACTICES

191. Purdue is a family-owned business. The Sacklers have always controlled Purdue, and occupied a majority of Purdue Pharma Inc.'s Board since its inception in 1990 until 2018. The last of the Sackler Board Members resigned earlier this year. [redacted]. The Sacklers had control

and oversight over Purdue's deceptive conduct. Since 1994, at the instruction of Jonathan Sackler, the Sacklers received all quarterly board reports and any other report directed to the Board. [redacted] Each of the Sacklers made decisions that misled California consumers and healthcare providers, and that resulted in and helped maintain the public health crisis California faces today. The Sacklers also took efforts to install leadership who would be loyal to the family, and did in fact appoint leadership who did their bidding.

192. The Sacklers were actively involved in directing Purdue's marketing strategies in a way that downplayed opioids' many risks and overstated their benefits. The Sacklers made decisions that caused Purdue to downplay the addictive nature of their opioids even though they were well aware of the highly addictive nature of opioids, which some of the Sacklers knew as early as the 1990s. Purdue employees provided the Sackler Board Members with reports regarding the devastation caused by Purdue's prescription opioids, including reports of overdose deaths and criminal activity. For example, in 2010, Purdue employees provided the Sackler Board Members with a map showing the close relationship between Region Zero prescribers and criminal activity, including pharmacy theft, burglaries, and robberies. In 2013, Purdue employees reported to the Sackler Board Members that drug overdose deaths had more than tripled since 1990, around the time OxyContin debuted. The Sackler Board Members were further told that the tens of thousands of deaths so far were only the "tip of the iceberg," and that for every overdose death there were more than a hundred others suffering from dependence or abuse.

The Sacklers Pushed the Company to Promote Higher Dosages for Longer Periods of Time

193. Notwithstanding the greater chance of abuse with higher doses, the Sacklers pushed the company to sell higher doses for longer periods of time. For example, in 2008, Dr. Richard Sackler directed that Purdue should "measure [its] performance by Rx's by strength, giving higher measures to higher strengths," copying Mortimer D.A. Sackler and Jonathan Sackler on his email instructions. In October 2013, Mortimer D.A. Sackler pressed for more information on "the breakdown of OxyContin market share by strength." The Sackler Board Members were told

that "the high dose prescriptions are declining" and "there are fewer patients titrating to the higher strengths from the lower ones." Purdue employees explained that sales of the highest doses were not keeping up with the Sacklers' expectations because some pharmacies had implemented "good faith dispensing" policies to double-check prescriptions that looked illegal and others were under pressure from the DEA. The employees promised to provide a new initiative to the Sacklers the following week to get sales representatives to generate prescriptions, which would be helped in part by increasing the budget for OxyContin promotion by $50 million.

194. Also in 2013, staff proposed that one of Purdue's "Key Initiative[s]" should be to get patients to "stay on therapy longer," in order to make up for the loss in profits due to prescribers shifting away from higher dose opioids. The Sackler Board Members agreed. One way the company accomplished this was by pushing opioids savings card through direct mail and email, which Purdue employees reported to the Sackler Board Members was successful in getting patients to "remain on therapy longer."

195. This was not the first time Purdue pushed opioid savings cards. For example, in 2008, staff informed Dr. Kathe Sackler, Jonathan Sackler, and Mortimer D.A. Sackler that opioid savings cards would be used to maintain 2007 opioid prescribing levels in 2008 despite mounting pressures; Dr. Kathe Sackler then required staff to identify and quantify these pressures and their negative impact on projected sales.

196. In a 2014 memo, to Dr. Richard Sackler, Jonathan Sackler, and David Sackler, Raymond Sackler described how Purdue had defeated efforts to impose limitations on maximum dosage or duration.

The Sacklers Invested $1 Billion in Purdue's Development and Sale of Purported Abuse-Deterrent Formulations

197. With the expiration of Purdue's OxyContin patent looming near, the Sacklers invested nearly $1 billion in developing a purported abuse-deterrent formulation of OxyContin. Dr. Kathe Sackler, Dr. Richard Sackler, Mortimer D.A. Sackler, and Jonathan Sackler [redacted]

198. [redacted]

199. In 2017, when OxyContin's reformulation was determined by an independent non-profit to not effectively prevent opioid abuse, Theresa Sackler sought answers from Purdue staff on their counter-strategy to keep patients using the drug.

200. The Sacklers sanctioned the sale and marketing of purported abuse-deterrent formulations, even though there was no evidence that these new formulations decreased the chance of abuse or addiction.

Purdue Provided the Sacklers Regular Updates of the Company's Sales Figures and Projections

201. The Sackler Board Members were demanding in their oversight over sales projections. For example, in 2008 when Purdue staff gave projections indicating that sales of OxyContin could cease growing, Mortimer D.A. Sackler required responses to several questions about why sales would not increase, with Dr. Richard Sackler further instructing that answers needed to be provided "before tomorrow." In 2009, when Purdue staff predicted that sales of OxyContin may decline, Mortimer D.A. Sackler demanded an explanation why sales should not instead grow. In 2012, only two days passed between a request by Mortimer D.A. Sackler for more sales data and a follow-up request seeking an answer. In 2013, when Mortimer D.A. Sackler asked for more details on how sales would be increased, Purdue staff responded by highlighting efforts made to hire McKinsey & Company to explore techniques for keeping patients on opioids longer and targeting doctors with high numbers of continuing patients.

The Sacklers Directed the Heavy Promotion of its Opioids Through Aggressive Marketing Practices

202. The Sackler Board Members knew the important role sales representatives played in Purdue's opioid sales and accordingly made key decisions related to the company's sales representatives. The Sackler Board Members directed the sales representative messaging and

closely monitored sales representatives' compliance with their directives. They received regular updates regarding the number of sales representative visits, the number of prescriptions written, the revenue from the sale of opioids, and the cost of sales representative visits. They oversaw the strategies sales representatives employed to sell Purdue's opioids and oversaw the strategy to pay high prescribers to promote Purdue's opioids. They even meddled with the timing of a national sales meeting, with Mortimer D.A. Sackler expressing particular concern over not having too many consecutive days without doctors receiving sales visits.

203. In 2014, on multiple occasions, staff told the Sackler Board Members that the two greatest risks to Purdue's business were "[c]ontinued pressure against higher doses of opioids," and "[c]ontinued pressure against long term use of opioids." They were told that the best way to address these risks was to continue to send sales representatives to detail prescribers, in particular by targeting the most susceptible prescribers.

The Sacklers Supported Funding to Groups that Pushed Opioids

204. The Sacklers sanctioned the funding of patient advocacy groups and KOLs. In 2008, Dr. Richard Sackler, Mortimer D.A. Sackler, Dr. Kathe Sackler, Ilene Sackler LefCourt, Theresa Sackler, and Jonathan Sackler [redacted]

The Sacklers Supported the Development of Addiction Treatment Drugs

205. The Sacklers sought to take advantage of the addicted population by getting into the treatment market. Project Tango was a proposed plan for Purdue to sell opioid treatment drugs. Dr. Kathe Sackler was particularly involved in Project Tango; she and staff wrote in internal documents that opioids and opioid addiction are "naturally linked" and that Purdue should seek to become an "end-to-end pain provider." A visual for the proposed project included a picture of a dark hole that a patient could fall into, leading to "opioid addiction treatment." Dr. Kathe Sackler and staff noted that the opioid addiction market had doubled from 2009 to 2014, noting its impressive compound annual growth rate. Dr. Kathe Sackler, Mortimer D.A. Sackler, Jonathan

Sackler, and David Sackler discussed the continuation of the project at a business development committee meeting in 2015. A year later, Dr. Richard Sackler, Mortimer D.A. Sackler, and Jonathan Sackler considered a revised version of Project Tango in which a company that treated opioid addiction would be purchased.

The Sacklers Regularly Made Demands for Information from Purdue Employees

206. The Sackler Board Members directed activities of Purdue staff when considering business opportunities. For example, in 2010, [redacted] In 2011, Dr. Kathe Sackler suggested looking at recent patient converts to OxyContin to see whether additional patients could be added. Mortimer D.A. Sackler discussed targeting cost-sensitive patients with a generic version of OxyContin. And Jonathan Sackler suggested focusing on dose strength when looking at impact on market share. In 2015, Purdue staff responded to concerns of Dr. Kathe Sackler and Mortimer D.A. Sackler regarding productivity data for each drug based on prescriber specialty and indication. And Jonathan Sackler sought further information regarding how opioid addiction prevention efforts by public health entities may affect OxyContin sales.

I. DR. RICHARD SACKLER WAS A HANDS-ON EXECUTIVE AND BOARD MEMBER WHO DIRECTED AND ACTIVELY PARTICIPATED IN PURDUE'S DECEPTIVE MARKETING

207. While each of the Sacklers played a part in creating the opioid epidemic, Dr. Richard Sackler, in particular, was a driving force in Purdue's deceptive practices. He held various positions at Purdue over the years, including Vice President of Medical, Director of Sales and Marketing, and President. Dr. Richard Sackler was also a member of the Board of Directors of Purdue Pharma Inc. from 1990 through mid-2018, and served as Chairman of the Board for a number of years. Even after he stepped down as President of Purdue in 2003, Dr. Richard Sackler remained a very active board member.

208. Dr. Richard Sackler directed many of Purdue's marketing messages, initiatives, and strategies. He recognized the key role the sales force played in promoting Purdue's deceptive marketing agenda, and ensured the sales force grew to provide adequate coverage of potential prescribers. He kept apprised of marketing plans and sales figures, forecasts, and budgets, often

following up with staff seeking additional information. He attended sales representative trainings, and even went into the field with sales representatives. Dr. Richard Sackler was so involved that employees expressed frustration with his micromanagement. Dr. Richard Sackler was highly motivated to drive sales (and ultimately, profits), and his active participation in Purdue's marketing paid off.

Dr. Richard Sackler Directed and Participated in Actions Related to the Sales Force

209. Dr. Richard Sackler was a hands-on executive and Board member who helped position a number of Purdue's key marketing messages and initiatives. He was keenly aware of the important role sales representatives played in communicating Purdue's deceptive marketing messages and driving sales, and accordingly voted over and over again to increase Purdue's sales force. The number of sales representatives grew from approximately 300 immediately following the 2007 guilty plea, to over 600 by May 2011, more than doubling in just four years. That figure remained close to 600 just a few months before Purdue announced, in February 2018, that its sales representatives would no longer promote opioids to prescribers.

210. Dr. Richard Sackler also met directly with sales representatives and their day-to-day supervisors, the district managers. He attended meetings with sales representatives and even went out into the field to promote Purdue's opioids alongside sales representatives.

211. For example, Dr. Richard Sackler met with sales representatives for several days at the Butrans Launch Meeting and discussed how they would promote Purdue's newest opioid. Dr. Richard Sackler followed-up with an email to CEO John Stewart (Stewart) and Vice President of Sales, Russell Gasdia (Gasdia), demanding to know how things were going out 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?" [redacted]

[redacted] Later that year, in response to Dr. Richard Sackler's repeated inquiries, Purdue staff sent a report regarding Butrans sales tactics to Dr. Richard Sackler, Dr. Kathe Sackler, Mortimer D.A. Sackler, Jonathan Sackler, and Theresa Sackler. When Jonathan Sackler expressed that these sales tactics were not sufficient, the sales team quickly developed a response and met with him.

212. Dr. Richard Sackler also commented on who sales representatives should be targeting. For example, in an email criticizing district managers for allowing sales representatives to target "non-high potential prescribers," Dr. Richard Sackler stated: "How can our managers have allowed this to happen?"

213. Dr. Richard Sackler also spent time in the field, shadowing sales representatives during their visits with healthcare providers. Many in executive management, including Stewart, Gasdia, and Vice President of Compliance, Bert Weinstein (Weinstein), shared concerns about Dr. Richard Sackler going into the field and meeting with healthcare providers. When the request first came through, Gasdia warned Weinstein that such action was "a potential compliance risk." After Weinstein had a chance to speak with Stewart, he reported back to Gasdia: "About 5 last night, John [Stewart] was walking by my office – I yelled out to stop him – and said that you had mentioned to me that Richard wanted to go into the field, and that you had raised concerns with me. John seemed angry, and asked if I had concerns. I told him could be issues and Richard could be out on a limb if he spoke about product at all or got into conversations with [healthcare providers], or identified himself, especially with FDA Bad Ad possibilities. John agreed Richard would have to be mum throughout, and not identify himself other than as a home office person."

214. Weinstein was concerned that Dr. Richard Sackler's visits with healthcare providers might trigger an FDA Bad Ad program report, which purpose is to raise awareness among healthcare providers about the importance of helping the FDA identify misleading promotional messages related to prescription drugs. Weinstein was worried that Dr. Richard Sackler would

deceptively promote Purdue's opioids to healthcare providers. He was right to be concerned.

215. When Dr. Richard Sackler returned from shadowing sales representatives, he questioned why a legally required warning about Butrans was in the contraindications section, which, according to Dr. Richard Sackler was the "worst place because it implies a danger of untoward reactions and hazards that simply aren't there," instead of a "less threatening section" like warnings.

Dr. Richard Sackler Directed and Participated in Purdue's Marketing Activities

216. Dr. Richard Sackler was also in the weeds when it came to Purdue's marketing efforts and sales performance. His interest in the minutiae and details of Purdue's sales and marketing activities continued even after he stepped down as President in 2003, where he remained a member of the Board. He often followed up with staff after Board meetings, seeking additional information, such as underlying data and updated reports.

217. Dr. Richard Sackler was a data-driven executive and Board member who demanded constant updates and often questioned the work he received. He regularly emailed and met with executive staff about sales performance and prescription figures. In one instance when Dr. Richard Sackler sought a meeting with Gasdia and Stewart to discuss OxyContin sales performance, Stewart commented that "Richard has asked me about this at least 5 times over the past few weeks, and I keep advising him that you and your group are working-up an analysis."

218. On another occasion, Dr. Richard Sackler wrote to a sales employee on a Saturday morning in January 2010, ordering that his need to review historical sales data was "urgent" and should be completed "this weekend." When staff came through, Dr. Richard Sackler questioned the data, commenting "[t]his doesn't look complete . . . . Are you sure about your calculation [ ]?"

219. This "urgen[cy]" was not uncommon. Immediately after one sales meeting, Dr. Richard Sackler emailed staff asking for the raw data underlying their presentation. When staff had not responded within five minutes, he sent a reminder.

220. Shortly after the Butrans launch, Dr. Richard Sackler kept pushing for more sales notwithstanding the fact that sales had increased over 51% from the week prior. He wrote to Stewart and Gasdia: "This could be the beginning of a great story, but it may not be so great,

either . . . . I expected a stronger start than any other product." Dr. Richard Sackler requested further metrics on weekly prescriptions, including the number of prescriptions per sales representative visit by a prescriber's specialty, and a Board discussion of the barriers that sales representatives were encountering during promotion. Shortly thereafter, Dr. Richard Sackler wrote to Stewart, Gasdia, and Mike Innaurato, the head of Marketing: "What do I have to do to get a weekly report on Butrans sales without having to ask for it?" After Gasdia sent the first weekly report, Dr. Richard Sackler responded immediately: "What else more can we do to energize the sales and grow at a faster rate?"

221. At one budget presentation, Dr. Richard Sackler and Dr. Kathe Sackler asked staff to "identify specific programs that Sales and Marketing will implement to profitably grow the [extended-release oxycodone] market and OxyContin in light of competition; provide analytics around why/how the proposed increase in share-of-voice translates into sales and profitability growth; clarify the situation with respect to OxyContin being used by 35% of new patients, but only retaining 30% of ongoing patients."

222. Dr. Richard Sackler's hands-on management also extended to Internet marketing. After seeing online ads, both positive and negative, appearing indiscriminately on websites with content associated with the advertisement, Dr. Richard Sackler stressed to Stewart and Gasdia the importance of ensuring Purdue's Internet messaging is "linked to positive or at least neutral sources and not an article about how useless or damaging or dangerous [ ] our product that we are trying to promote" is.

Dr. Richard Sackler Was a Hands-On Micromanager

223. Dr. Richard Sackler's hands-on management was so intrusive and counterproductive at times, that staff often sought interference from colleagues and higher-ups. Staff advised each other: "avoid as much e mail with dr r as you can."

224. For example, after Dr. Richard Sackler wrote a series of questions to Gasdia on an early Saturday morning, copying Dr. Kathe Sackler, Mortimer D.A. Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, and Theresa Sackler, Gasdia wrote to then-CEO Stewart: "John, I know it is tricky, but Dr. Richard has to back off somewhat. He is pulling people in all directions,

creating a lot of extra work and increasing pressure and stress. I will draft a response but he is not realistic in his expectations and it is very difficult to get him to understand."

225. Dr. Richard Sackler kicked off one new year by asking staff for new customized reports. Staff complained to one another until Gasdia asked Stewart to intervene: "Can you help with this? It seems like every week we get one off requests from Dr. Richard," requests that "will take a lot of time and not add much value." Stewart commented: "You are not alone in receiving requests for extraordinary analyses and reports."

226. Dr. Richard Sackler interrupted sales staff many times a day with his numerous "urgent" requests. When staff had not provided updated charts by the next morning, Dr. Richard Sackler responded at 7:23 a.m.: "I had hoped you would have updated this with the relatively simple changes I proposed. Will I have it by noon?" When the staff person stated he was having computer issues and would have a colleague produce the chart, Dr. Richard Sackler stated "get to this ASAP."

227. After yet another request from Dr. Richard Sackler, Gasdia pleaded: "Anything you can do to reduce the direct contact of Richard into the organization is appreciated." Just a week later, Dr. Richard Sackler wrote to Stewart, Gasdia, and others, criticizing them for U.S. sales being "among the worst" in the world.

228. Dr. Richard Sackler's actions were a substantial factor in causing the public health crisis we face today, and led to the dissemination of materially false and misleading information to healthcare providers, patients, and consumers.

CAUSES OF ACTION

FIRST CAUSE OF ACTION AGAINST ALL DEFENDANTS
VIOLATIONS OF BUSINESS AND PROFESSIONS CODE SECTION 17500
(Untrue or Misleading Representations)

229. The People reallege and incorporate by reference each of the paragraphs above as though fully set forth herein.

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230. Defendants have engaged in and continue to engage in, have aided and abetted and continue to aid and abet, and have conspired to and continue to conspire to engage in acts or practices that constitute violations of Business and Professions Code section 17500.

231. Defendants, with the intent to induce members of the public to purchase and utilize Purdue's opioid products, have made and caused to be made written and oral representations concerning OxyContin and other opioid products and matters of fact, which Defendants knew, or by the exercise of reasonable care should have known, were false, deceptive or misleading at the time they were made, by: promoting opioid products for uses that have not been shown to be safe or effective, by failing to adequately disclose or misrepresenting the risks and complications associated with the use of opioids products; and by representing that opioids products have sponsorship, approval, characteristics, uses, benefits, or qualities the products do not have.

232. Defendants' conduct is in continuing violation of the False Advertising Law, beginning at a time unknown to Plaintiff but no later than 1996, and continuing to within four years of the filing of this Complaint.

SECOND CAUSE OF ACTION AGAINST ALL DEFENDANTS
VIOLATIONS OF BUSINESS AND PROFESSIONS CODE SECTION 17200
(Acts of Unfair Competition)

233. The People reallege and incorporate by reference each of the paragraphs above as though fully set forth herein.

234. The Unfair Competition Law ("UCL"), Business and Professions Code section 17200, provides that "unfair competition shall mean and include unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising, and any act prohibited by" Business and Professions Code section 17500.

235. Defendants, in the course of engaging in the marketing, promoting, selling and distributing of OxyContin and other opioid products, have engaged in the following unlawful, unfair, or fraudulent acts and practices, among others, each of which constitute acts of unfair competition in violation of Business and Professions Code section 17200:

a. Defendants' actions constitute multiple violations of Business and Professions Code section 17500 as alleged in the First Cause of Action, which allegations are incorporated herein as if set forth in full.

b. Defendants' actions constitute multiple violations of Civil Code section 1770, subdivision (a)(5), by representing that OxyContin and Purdue's other opioid products have sponsorship, approval, characteristics, uses, benefits or qualities that they do not have.

c. Defendants' actions constitute multiple violations of Health and Safety Code section 11153.5 by furnishing controlled substances for other than legitimate medical purposes.

d. Defendants' actions created a continuing nuisance throughout pursuant to Civil Code sections 3479 and 3480 in violation of California Civil Code section 3494 as alleged in the Third Cause of Action, which allegations are incorporated herein as if set forth in full.

THIRD CAUSE OF ACTION AGAINST ALL DEFENDANTS
VIOLATION OF CIVIL CODE SECTION 3494
(Public Nuisance)

236. The People reallege and incorporate by reference each of the paragraphs above as though fully set forth herein.

237. A "nuisance" is defined in section 3479 of the Civil Code as "[a]nything which is injurious to health, including, but not limited to, the illegal sale of controlled substances, or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property . . . ."

238. A "public nuisance" is defined in section 3480 of the Civil Code as a nuisance "which affects at the same time an entire community or neighborhood, or any considerable number of persons, although the extent of the annoyance or damage inflicted upon individuals may be unequal."

239. Pursuant to Code of Civil Procedure section 3494, "a public nuisance may be abated by any public body or officer authorized thereto by law." Courts have recognized that the Attorney General has authority to maintain an action in the name of the People of the State of California to abate a public nuisance.

240. Civil Code section 3490 states that "[n]o lapse of time can legalize a public nuisance, amounting to an actual obstruction of public right."

241. Defendants, individually and acting through their employees and agents, through false and misleading marketing, excessive promotion, excessive distribution of opioids, and/or the other unlawful, unfair or fraudulent business acts of practices described herein, engaged in conduct that was a substantial factor in creating and maintaining the opioid epidemic that threatens public health and safety and constitutes a continuing nuisance throughout the State pursuant to California Civil Code sections 3479 and 3480.

242. Defendants' conduct is injurious to the public health and has interfered with the comfortable enjoyment of life or property.

243. Defendants created a substantial and unreasonable threat to public health and safety. Defendants' conduct has caused significant harm and its social utility is outweighed by the gravity of the harm inflicted.

244. The public health hazard affects and/or interferes with an entire community's and/or a considerable number of persons' right to health, safety, peace, comfort, and convenience in the State of California—including, but not limited to, addiction, illness, and death—thereby constituting a public nuisance pursuant to California Civil Code section 3480.

245. Defendants are liable for public nuisance in that Defendants created and/or contributed to the creation of and/or assisted in the creation and/or were a substantial contributing factor in the creation of the public nuisance described herein through the conduct described herein, including, but not limited to the deceptive marketing that led to an epidemic of opioid addiction, resulting in substantial public injuries.

246. Defendants knew the public health hazard posed by their conduct and affirmatively directed and engaged in the widespread, deceptive promotion and over-promotion of the use of

extended-release opioids with knowledge of the public health hazard.

247. Defendants' conduct is a direct and proximate cause of the public nuisance. In the absence of Defendants' conduct, the public health hazard would have been avoided or much less severe.

248. The threat to the public health and safety posed by the public nuisance in the State of California will continue unless Defendants are ordered to abate, and do abate the nuisance. Defendants created or assisted in the creation of the nuisance, and therefore must abate the nuisance.

249. The People of the State of California are entitled to preliminary and permanent injunctions from this Court requiring Defendants to abate the nuisance present in the State of California.

PRAYER FOR RELIEF

WHEREFORE, the People pray for judgment as follows:

1. That pursuant to Code of Civil Procedure section 3494 Defendants be ordered and enjoined to abate the public nuisance that exists within the State of California.

2. That the Court assess a civil penalty of $2,500 against Defendants for each violation of Business and Professions Code section 17500 in an amount according to proof, under the authority of Business and Professions Code section 17536.

3. That the Court assess a civil penalty of $2,500 against Defendants for each violation of Business and Professions Code section 17200 in an amount according to proof, under the authority of Business and Professions Code section 17206.

4. In addition to any penalty assessed under Business and Professions Code section 17206, that the Court assess a civil penalty of $2,500 against Defendants for each violation of Business and Professions Code section 17200 perpetrated against a senior citizen or disabled person, in an amount according to proof, under the authority of Business and Professions Code section 17206.1.

5. That pursuant to Business and Professions Code section 17535, Defendants be permanently enjoined from making any false or misleading statements in violation of Business

and Professions Code sections 17500 and 17580.5 as alleged in this Complaint.

6. That the Court make such orders or judgments as may be necessary to prevent the use or employment by any Defendant and their agents, employees, and all other persons or entities, corporate or otherwise, in active convert or participation with any of them, of any practice that constitutes unfair competition under the authority of Business and Professions Code section 17203.

7. That Plaintiff recovers its costs of suit herein, including costs of investigation and attorneys' fees.

8. All such other and further relief as the Court deems just and proper to fully and successfully dissipate the effects of the alleged violations of Business and Professions Code section 17200 et seq., Business and Professions Code section 17500 et seq., and Code of Civil Procedure section 3494.

Dated: October 2, 2019

Respectfully Submitted,

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Docket No.: LA2017107339