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IN THE CIRCUIT COURT OF THE FIRST CIRCUIT

STATE OF HAWAI'I

STATE OF HAWAI'I, EX REL. CLARE E. CONNORS, ATTORNEY GENERAL, Plaintiff, vs. PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.;	CIVIL NO. 19-1-0862-06 JHA COMPLAINT; SUMMONS

RICHARD S. SACKLER, BEVERLY SACKLER, DAVID A. SACKLER, ILENE SACKLER LEFCOURT, JONATHAN D. SACKLER, KATHE SACKLER, MORTIMER D. A. SACKLER, AND THERESA SACKLER, and DOE DEFENDANTS 1 to 100,	)
Defendants.	)

COMPLAINT

Plaintiff, the State of Hawai'i, by Clare E. Connors, Attorney General (the "State"), brings this Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc. (collectively "Purdue"); Richard S. Sackler, Beverly Sackler, David A. Sackler, Ilene Sackler Lefcourt, Jonathan D. Sackler, Kathe Sackler, Mortimer D.A. Sackler, and Theresa Sackler (collectively, the "Sacklers") (collectively, "Defendants") and alleges, upon information and belief, as follows:

I. INTRODUCTION

1. The State of Hawai'i brings this civil enforcement action seeking civil penalties and other relief for Defendants' unfair and deceptive marketing of prescription opioids (hereinafter "opioids").[1]

2. Purdue Pharma Inc., Purdue Pharma L.P and the Purdue Frederick Company, Inc. (collectively "Purdue") is a Connecticut-based drug company that manufactures, markets, sells and distributes prescription opioid pain medications, including the brand-name drugs OxyContin, Butrans, and Hysingla ER. Through a deceptive and illegal scheme spanning more than two decades, Purdue created and has profited immensely from a tragic epidemic of opioid abuse and

[1] As used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

addiction across the nation, including Hawai'i. At the top of Purdue, eight members of a single family—the Sackler family—personally led the deception and personally pocketed billions of dollars.

3. Prescription opioids are dangerous narcotics. They are derived from and closely related to opium and heroin, and they are regulated as controlled substances. While opioids can work to dampen the perception of pain, they can also be deadly, with the potential to slow the user's breathing and cause fatal respiratory depression, especially at higher doses. Opioids are also highly addictive—most patients receiving more than a few weeks of opioid therapy will experience prolonged withdrawal symptoms, including severe anxiety, nausea, headaches, tremors, delirium and pain, if opioid use is delayed or discontinued. Moreover, when using opioids continuously, patients grow tolerant to their analgesic effects—requiring progressively higher doses and increasing the risks of withdrawal, addiction and overdose.

4. In recognition of these risks, the medical community historically used opioids cautiously and sparingly, typically only for short-term acute pain or for palliative (end-of-life) care. But when Purdue developed OxyContin in the late 1990s, the Sacklers knew that to expand the company's market (and their own profits), they needed to change perceptions to permit and encourage the use of opioids long-term for widespread chronic conditions, like back pain, migraines and arthritis. With that goal in mind, the Sacklers worked to cultivate a narrative that pain was undertreated and that pain treatment should be a higher priority for health care providers. Purdue's marketing efforts dovetailed with this narrative, as the company began to promote opioids generally, and its own opioids in particular, as safe, effective, and appropriate for long-term use for routine pain conditions. As part of the Sacklers' strategy, Purdue

misrepresented the risk of addiction as modest, manageable and outweighed by the benefits of opioid use.

5. In connection with this scheme, Purdue, at the Sacklers' behest and for its own and the Sacklers' benefit, spent millions of dollars on promotional activities and materials that falsely denied or trivialized the risks of opioids while overstating the benefits of using them for chronic pain. As to the risks, Defendants falsely and misleadingly, and contrary to the language of their drugs' labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudoaddiction" and thus advocated that signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent addiction. Defendants also made unfair and deceptive claims that Oxycontin provides twelve hours of pain relief. Conversely, Defendants falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientific evidence to support such claims.

6. Defendants disseminated these messages to reverse the popular and medical understanding of opioids. They disseminated the messages directly, through Purdue's sales representatives, and in speaker groups led by physicians Defendants recruited for their support of Purdue's marketing messages. Defendants also worked through third parties they controlled by having Purdue (1) fund, assist, encourage and direct doctors, known as "key opinion leaders" ("KOLs") and; (2) fund, assist, direct and encourage seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). Defendants worked together with these KOLs and Front Groups to taint the sources that doctors and patients

relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. In doing so, Defendants persuaded doctors and patients that what they had long believed—that opioids are addictive drugs, unsafe in most circumstances for long-term use—was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids.

7. Defendants' efforts were wildly successful. Opioids are now the most prescribed class of drugs. In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors … [m]any of [whom] were taught – incorrectly that opioids are not addictive when prescribed for legitimate pain."[2] The resulting epidemic, fueled by opioids lawfully prescribed by doctors, has resulted in a flood of prescription opioids available for illicit use or sale, and a population of patients physically and psychologically dependent on them. And when those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin. Nationwide, opioids were involved in 47,600 overdose deaths in 2017—a sixfold increase from 1999—according to the latest data from the U.S. Centers for Disease Control and Prevention ("CDC").[3]

8. Purdue executed this scheme at the direction of eight people in a single family that owned the company and controlled a majority of the seats on the company's board of directors: the Sacklers. The eight Sacklers named as defendants in this complaint are current and former directors and officers of Purdue and, at all times relevant to this lawsuit, exercised complete authority and control over Purdue's business decisions. The Sacklers knew that

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[2] Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at http://turnthetiderx.org/.

[3] *See* https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates

Purdue's misrepresentations about the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of those misrepresentations has been repeatedly confirmed by both the U.S. Food and Drug Administration ("FDA") and the CDC as well as numerous other agencies. And, in 2007, when Purdue pleaded guilty to federal criminal charges for deceptively marketing opioids and reached civil settlements with 26 states and the District of Columbia, the Sacklers were intimately involved with and aware of the investigations. Moreover, the Sacklers were certainly aware of the resolutions of those investigations, including Purdue's many commitments and obligations under the 2007 Judgment—which they voted to enter into. As directors holding a controlling majority of the Board, the Sacklers had the power to dictate how Purdue sold its drugs. But, rather than conforming Purdue's marketing practices to comply with the law, the Sacklers deliberately caused the company to mislead and obfuscate, nationwide as in Hawai'i. To protect their multi-billion-dollar revenue stream and conceal their personal involvement in the misconduct, the Sacklers used Purdue to perpetuate their fraudulent scheme, in clear violation of the law and with blatant disregard for the toll it took on the State and its citizens.

9. Hawai'i has not escaped the ravages of the opioid crisis. Opioid-related deaths in Hawai'i more than doubled between 2000, when there were 29 such deaths, and 2016, when there were 77. The vast majority of these deaths resulted from the use of prescription opioids (6 out of the 29 deaths in 2016 were a result of heroin, methadone, or synthetic opioids). Drug poisoning is the leading cause of death in Hawai'i, and has been since 2006 – outpacing falls, suffocation, and motor vehicle accidents.

10. Opioid-related fatalities are only the tip of the epidemic iceberg in Hawai'i. Non-fatal opioid poisonings far exceed fatalities. From 2010 through 2017, there were 3,056 hospital-

treated nonfatal opioid poisonings among Hawai'i residents. Like opioid-related fatalities, heroin only accounts for a relatively small fraction, 292 of such cases.

11. In keeping with these trends, prescription rates in Hawai'i rose steadily from 2006, reaching 50.4 prescriptions for every 100 Hawai'i residents in 2012. Two counties (Hawai'i and Kauai) regularly exceeded the national average.

12. A lawsuit of this kind cannot ignore the precipitating cause of the opioid crisis: a marketing scheme involving the unfair and deceptive marketing of prescription opioids, which was designed to, and in fact did, dramatically increase the demand for the sale and use of opioids and prescription opioids and, as a result, devastated the State of Hawai'i and its communities. This action seeks to recover from the company—and the family who directed and led that company—that did exactly that.

II. PARTIES

A. Plaintiff

13. The State of Hawai'i is a body politic created by the Constitution and laws of the State; as such, it is not a citizen of any state. This action, brought by the State in its sovereign capacity by and through Clare E. Connors, the Attorney General of the State of Hawai'i, is authorized under UDAP, Haw. Rev. Stat. §§ 480-2(d), 480-3.1, 480-15, and under *parens patriae* authority, on behalf of the State to enforce Hawai'i law. The Attorney General has the power to bring these claims on behalf of the State under the provisions of Haw. Rev. Stat. §§ 480-3.1.

B. Defendants

1. Purdue Defendants

14. Defendants Purdue Pharma L.P. ("PPL"), Purdue Pharma Inc. ("PPI"), and The Purdue Frederick Company, Inc. ("PFC") are Connecticut corporations that engaged in the promotion and sale of opioids nationally and in Hawai'i. The opioids promoted and sold by Purdue include:

Product Name	**Chemical Name**
OxyContin	Oxycodone hydrochloride, extended release
MS Contin	Morphine sulfate, extended release
Dilaudid	Hydromorphone hydrochloride
Dilaudid-HP	Hydromorphone hydrochloride
Butrans	Buprenorphine
Hysingla ER	Hydrocodone bitrate
Targiniq ER	Oxycodone hydrochloride and naloxone hydrochloride

15. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $3.1 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers). Sales of OxyContin (launched in 1996) went from a mere $49 million in its first full year on the market to $1.6 billion in 2002.

16. Purdue made thousands of payments to physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services. In fact, these payments were made to deceptively promote and maximize the use of opioids.

17. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay a $635 million fine – at the time, one of the largest settlements with a drug company for marketing misconduct. None of this stopped Purdue. In fact, Purdue continued to create the false perception that opioids were safe and effective for long-term use, even after being caught, by using unbranded marketing methods to circumvent the system. In short, Purdue paid the fine when caught and then continued business as usual, deceptively marketing and selling billions of dollars of opioids each year.

2. Sackler Defendants

18. Defendant Dr. Richard S. Sackler became a member of the Purdue board in 1990 and became its Co-chair in 2003, a position in which he remained until he left the board in 2018. He was also Purdue's head of research and development from at least 1990 through 1999 and its President from 1999 through 2003. At all times material to this Complaint, acting alone or in concert with others, Richard Sackler was personally aware of, was responsible for, engaged in, or directed the unfair and deceptive acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, Richard Sackler approved and oversaw unfair and deceptive conduct that was purposely directed at Hawai'i and gave rise to the State's claims as alleged in this Complaint.

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

20. Defendant Ilene Sackler Lefcourt was a member of Purdue's board from 1990 to 2018. At all times material to this Complaint, acting alone or in concert with others, Ilene Sackler Lefcourt was personally aware of, was responsible for, engaged in, or directed the unfair and deceptive acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, Ilene Sackler Lefcourt approved and oversaw unfair and deceptive conduct that was purposely directed at Hawai'i and gave rise to the State's claims as alleged in this Complaint.

21. Defendant Dr. Kathe A. Sackler was a member of Purdue's board from 1990 through 2018. At all times material to this Complaint, acting alone or in concert with others, Kathe Sackler was personally aware of, was responsible for, engaged in, or directed the unfair and deceptive acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, Kathe Sackler approved and oversaw unfair and deceptive conduct that was purposely directed at Hawai'i and gave rise to the State's claims as alleged in this Complaint.

22. Defendant Mortimer D. A. Sackler was a member of Purdue's board from 1993 through 2018. At all times material to this Complaint, acting alone or in concert with others, Mortimer Sackler was personally aware of, was responsible for, engaged in, or directed the unfair and deceptive acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, Mortimer Sackler approved and oversaw unfair and deceptive conduct that was purposely directed at Hawai'i and gave rise to the State's claims as alleged in this Complaint.

23. Defendant Beverly Sackler was a member of Purdue's board from 1993 through 2017. At all times material to this Complaint, acting alone or in concert with others, Beverly Sackler was personally aware of, was responsible for, engaged in, or directed the unfair and deceptive acts or practices set forth in this Complaint. As a member of Purdue's Board of

Directors, Beverly Sackler approved and oversaw unfair and deceptive conduct that was purposely directed at Hawai'i and gave rise to the State's claims as alleged in this Complaint.

24. Defendant Theresa Sackler was a member of Purdue's board from 1993 through 2018. At all times material to this Complaint, acting alone or in concert with others, Theresa Sackler was personally aware of, was responsible for, engaged in, or directed the unfair and deceptive acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, Theresa Sackler approved and oversaw unfair and deceptive conduct that was purposely directed at Hawai'i and gave rise to the State's claims as alleged in this Complaint.

25. Defendant David A. Sackler was a member of Purdue's board from 2012 through 2018. For the period 2012 through 2018, acting alone or in concert with others, David Sackler was personally aware of, was responsible for, engaged in, or directed the unfair and deceptive acts or practices set forth in this Complaint. As a member of Purdue's Board of Directors, David Sackler approved and oversaw unfair and deceptive conduct that was purposely directed at Hawai'i and gave rise to the State's claims as alleged in this Complaint.

26. DOE DEFENDANTS 1 to 100 are sued herein under fictitious names for the reason that after diligent and good faith efforts their names, identities, and capacities, whether individual, corporate, associate, or otherwise, are presently unknown to Plaintiff. Plaintiff will make the names or identities of said Defendants known to the Court by filing a motion for certification after the same have been ascertained. Plaintiff is informed and believes, and based thereupon alleges, that each of the Defendants designated herein as a DOE DEFENDANT has taken part in and participated with, and/or aided and abetted, some or all of the other Defendants in some or all of the matters referred to herein, and each has been in some manner responsible for some or all of the deceptive and unfair acts and practices alleged herein.

27. Plaintiff is informed and believes, and based thereupon alleges, that at all relevant times, each Defendant has occupied agency, employment, joint venture, or other relationships with each of the other named and DOE DEFENDANTS; that at all times herein mentioned each Defendant has acted within the course and scope of said agency, employment, joint venture, and/or other relationship; that each other Defendant has ratified, consented to, and approved the acts of its agents, employees, joint venturers, and representatives; and that each has actively participated in, aided and abetted, or assisted one another in the commission of the wrongdoing alleged in this Complaint.

28. At all relevant times, Defendants, and each of them, have engaged in the business of, or were successors in interest to, entities engaged in the business of manufacturing, distributing, marketing, promoting, advertising, distributing, and/or selling their prescription opioids to individuals and entities in the State of Hawai'i, including the City and County of Honolulu, State of Hawai'i.

29. At all relevant times, Defendants have sold and supplied their prescription opioids to individuals and entities located within the State of Hawai'i.

III. JURISDICTION AND VENUE

30. Subject matter jurisdiction for this case is conferred upon this Court pursuant to Haw. Rev. Stat. § 603-21.5(3).

31. The instant Complaint does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332, as the State is not a citizen of any state and this action is not subject to the jurisdiction of the Class Action Fairness Act of 2005. Likewise, federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the Complaint, as it sets forth herein exclusively viable state law claims against Defendants. Nowhere herein does Plaintiff

plead, expressly or implicitly, any cause of action or request any remedy that arises under federal law. The issues presented in the allegations of this Complaint do not implicate any substantial federal issues and do not turn on the necessary interpretation of federal law. Specifically, Plaintiff expressly avers that the only causes of action claimed, and the only remedies sought herein, are founded upon the positive statutory, common, and decisional laws of Hawai'i. Further, the assertion of federal jurisdiction over the claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities. Accordingly, any attempt to subject this action to the jurisdiction of the federal courts would be without basis in law or fact, and a violation of Rule 11, Hawai'i Rules of Civil Procedure and/or Rule 11, Federal Rules of Civil Procedure.

32. Venue is proper in this Court pursuant to Haw. Rev. Stat. §§ 661-10 and 480-21(b), because the Office of the Attorney General and the seat of the State Government are situated in the City and County of Honolulu, State of Hawai'i, and the claims for relief asserted herein arose in large part in the City and County of Honolulu, State of Hawai'i.

IV. FACTUAL BACKGROUND

33. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.[4]

[4] In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

34. To take advantage of the lucrative market for chronic pain patients, Purdue, at the behest of and under the control of the Sacklers, developed a well-funded marketing scheme based on deception. Defendants used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread unfair and deceptive statements about the risks and benefits of long-term opioid use—statements that benefited not only Purdue and the third-parties who gained legitimacy when Purdue repeated those statements, but the Sacklers themselves. Yet these statements were not only unsupported by or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. Purdue also targeted susceptible prescribers and vulnerable patient populations.

A. Purdue used multiple avenues to disseminate its unfair and deceptive statements about the use of opioids for chronic pain

35. Purdue spread its unfair and deceptive statements by marketing its branded opioids directly to doctors and patients in Hawai'i. It also deployed seemingly unbiased and independent third parties that it controlled to spread its unfair and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain.

1. Purdue spread its unfair and deceptive statements through direct marketing of its brand opioids

36. Purdue's direct marketing of opioids generally proceeded on two tracks. First, Purdue conducted advertising campaigns touting the purported benefits of its brand drugs. A number of Purdue's advertisements deceptively portrayed the benefits of opioids for chronic pain. For example, Purdue ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

37. Second, Purdue promoted the use of opioids for chronic pain through "detailers" —sales representatives who visited individual doctors and medical staff in their offices—and small-group speaker programs. Purdue devoted massive resources to direct sales contacts with doctors. In 2014 alone, the company spent $108 million on detailing branded opioids to doctors.

38. In February 2018, with legal challenges mounting, Purdue announced that it would cease detailing physicians in respect to Purdue's branded opioids. Purdue did not, however, make any commitment to correct the misrepresentations its multi-decade detailing campaign has engendered in the medical community. Nor did Purdue commit to cease other deceptive marketing tactics, including the practice addressed below of laundering promotional messages through front groups and other ostensibly unbiased third parties. Far from reversing course, Purdue has indicated it will aggressively promote its drugs that treat opioid-induced constipation—drugs that can be profitable only if opioids are widely prescribed.

39. Purdue also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Purdue. These programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers gave the false impression that they were providing unbiased and medically accurate presentations when they were, in fact, presenting a script prepared by Purdue. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Purdue's prior misrepresentations about the risks and benefits of opioids.

40. Purdue's detailing to doctors was very effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence.

Even without such studies, Purdue purchases, manipulates and analyzes some of the most sophisticated data available in *any* industry, data available from a company called IQVIA, to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allows the company to target, tailor, and monitor the impact of their core messages. Thus, Purdue knew its detailing to doctors was effective.

41. Purdue employed the same marketing plans and strategies and deployed the same messages in Hawai'i as it did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that messages are accurately and consistently delivered across marketing channels—including detailing visits, speaker events, and advertising—and in each sales territory. Drug companies consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

42. Purdue then ensured marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. Purdue's sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to check on their performance and compliance.

2. Purdue used a diverse group of seemingly independent third parties to spread unfair and deceptive statements about the risks and benefits of using opioids for chronic pain

43. Purdue also deceptively marketed opioids in Hawai'i through unbranded advertising—*i.e.*, advertising that promotes opioid use generally but does not name a specific

opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Purdue controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. As much as Purdue controlled the distribution of its "core messages" via their own detailers and speaker programs, Purdue similarly controlled the distribution of these messages in scientific publications, treatment guidelines, CMEs, and medical conferences and seminars. To this end, Purdue used third-party public relations firms to help control those messages when they originated from third-parties.

44. Purdue also marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. Purdue also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, Purdue used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

a. Key Opinion Leaders ("KOLs")

45. Purdue also spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Purdue because their public positions supported the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs."

46. Purdue paid KOLs to serve as consultants or on its advisory board and to give talks or present CMEs, and Purdue's support helped these KOLs become respected industry experts. As

they rose to prominence, the KOLs touted the benefits of opioids to treat chronic pain, repaying Purdue by advancing its marketing goals. KOLs' professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by Purdue.

47. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. Purdue created opportunities for KOLs to participate in research studies Purdue suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, Purdue did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

48. Purdue's KOLs also served on committees that developed treatment guidelines strongly encouraging the use of opioids to treat chronic pain, and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Purdue was able to direct and exert control over each of these activities through its KOLs.

49. Pro-opioid doctors are one of the most important avenues that Purdue uses to spread its unfair and deceptive statements about the risks and benefits of long-term opioid use. Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy.

50. Thus, even though some of Purdue's KOLs have recently moderated or conceded the lack of evidence for many of the claims they made, those admissions did not reverse the effect of the unfair and deceptive statements that continue to appear nationwide and throughout Hawai'i in Purdue's own marketing as well as treatment guidelines, CMEs and other seminars, scientific articles and research, and other publications available in paper or online.

b. Front Groups

51. Purdue also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under Purdue's direction and control, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted Purdue by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Purdue. The Front Groups depended on Purdue for funding and, in some cases, for survival.

52. Purdue exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Purdue made sure that the Front Groups would generate only the messages Purdue wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members—whether patients suffering from pain or doctors treating those patients.

53. Purdue worked, through Front Groups, to spread its deceptive messages about the risks and benefits of long-term opioid therapy. For example, Purdue and other opioid manufacturers combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an American Pain Foundation ("APF") project. PCF is comprised of representatives from several opioid manufacturers and various Front Groups, almost all of which received substantial funding from Purdue. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which Purdue determined would reduce prescribing.

B. Purdue misrepresented the risks and benefits of using opioids for chronic pain

54. To convince doctors and patients in Hawai'i that opioids can and should be used to treat chronic pain, Purdue had to convince them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Purdue made claims that were not supported by or were contrary to the scientific evidence. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm that its claims were unfair and deceptive, Purdue has not corrected them, or instructed its KOLs or Front Groups to correct them, and continues to spread them today.

1. Purdue falsely trivialized or failed to disclose the known risks of long-term opioid use

55. To convince doctors and patients that opioids are safe, Purdue deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations—which are described below—reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive.

56. *First*, Purdue falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to

disclose the greater risk of addiction with prolonged use. Some illustrative examples of these unfair and deceptive claims are described below:

a. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft.

b. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*—which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]."

c. Sales representatives for Purdue minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

57. These claims are contrary to longstanding scientific evidence. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."

58. The FDA further exposed the falsity of Purdue's claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and

death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

59. The warnings on Purdue's own FDA-approved drug labels caution that opioids "expose[] users to risks of addiction, abuse and misuse, which can lead to overdose and death," that the drugs contain "a substance with a high potential for abuse," and that addiction "can occur in patients appropriately prescribed" opioids.

60. *Second*, Purdue falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Purdue called this phenomenon "pseudoaddiction"—a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Purdue—and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims are described below:

a. Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction.

b. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

c. Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

61. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline does not recommend that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, it explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

62. *Third*, Purdue falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Purdue aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Purdue's misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims are described below:

a. Purdue sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

b. As recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients—and not opioids—are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

63. Once again, the 2016 CDC Guideline confirms the falsity of these misrepresentations. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts

widely believed by doctors to detect and deter abuse—"for improving outcomes related to overdose, addiction, abuse, or misuse." As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

64. *Fourth*, to underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Purdue falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use.

65. For example, Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.

66. Purdue deceptively minimized the significant symptoms of opioid withdrawal—which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction—and grossly understated the difficulty of tapering, particularly after long-term opioid use. Yet the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." The Guideline further states that "tapering opioids can be especially challenging after years on high

dosages because of physical and psychological dependence" and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to "pause[] and restart[]" tapers depending on the patient's response. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

67. *Fifth*, Purdue falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Purdue's efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples are described below:

a. Purdue sponsored *APF's Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain.

b. Purdue's *In the Face of Pain* website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

c. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages.

d. Purdue sponsored a CME entitled *Overview of Management Options* that was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

e. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders,"[5] challenging the correlation between opioid dosage and overdose.

[5] www.cpdd.org.

68. Again, these claims conflict with the scientific evidence. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

69. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

70. *Finally*, Purdue's deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.[6]

71. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Purdue successfully convinced doctors and patients to discount those risks.

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[6] Catherine S. Hwang, *et al.*, *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, 175(2) JAMA INTERN. MED. 302-4 (Dec. 8, 2014).

2. Purdue grossly overstated the benefits of chronic opioid therapy

72. To convince doctors and patients that opioids should be used to treat chronic pain, Purdue also had to persuade them that there was a significant upside to long-term opioid use. But, as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials $\leq$ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." Despite this, Purdue misleadingly touted the benefits of long-term opioid use and falsely suggested that these benefits were supported by scientific evidence.

73. For example, Purdue falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples are described below:

a. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

b. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Purdue, taught that relief of pain by opioids, by itself, improved patients' function.

c. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in 2012.

d. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients."

e. Purdue's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

74. These claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline:

- "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . ."
- "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."
- "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

75. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction do not improve their function and quality of life.

76. Purdue also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the 2016 CDC Guideline specifically states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

77. In addition, Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours—a fact that Purdue has known at all times relevant to this action. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial number" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief unfair and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

3. Purdue also engaged in other unfair conduct

78. Purdue also unlawfully failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. But rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that Purdue had promoted as less addictive—in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue

failed to take action—even where Purdue employees personally witnessed the diversion of its drugs.

79. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets, and that Purdue's district manager described internally as "an organized drug ring," until years after law enforcement shut the clinic down. In doing so, Purdue protected its own profits at the expense of public health and safety.

C. Purdue targeted susceptible prescribers and vulnerable patient populations

80. As a part of its deceptive marketing scheme, Purdue identified and targeted susceptible prescribers and vulnerable patient populations in Hawai'i. For example, Purdue focused its deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Purdue's misrepresentations.

81. Purdue also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Purdue targeted these patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concludes that there are "special risks of long-term opioid use for elderly patients" and recommends that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

D. The Sacklers directed and led Purdue's misconduct

82. The Sacklers were the chief architects and beneficiaries of Purdue's deception. They knowingly and intentionally sent sales representatives to promote opioids to prescribers in Hawai'i thousands of times. The Sacklers knew and intended that the sales reps in Hawai'i would deceptively promote opioid sales that are risky for patients, including by:

- blaming the dangers of opioids on patients instead of the addictive drugs;
- pushing opioids for elderly patients, without disclosing the higher risks;
- pushing opioids for patients who had never taken them before, without disclosing the higher risks;
- pushing opioids as substitutes for safer medications, with improper comparative claims;
- falsely assuring doctors and patients that reformulated OxyContin was safe;
- pushing doctors and patients to use higher doses of opioids, without disclosing the higher risks;
- pushing doctors and patients to use opioids for longer periods of time, without disclosing the higher risks; and
- marketing opioids to doctors whom Purdue knew were writing dangerous prescriptions.

83. The Sacklers knew and intended that the sales reps would not tell Hawai'i doctors and patients the truth about Purdue's opioids. Indeed, they knew and intended these unfair and deceptive tactics to achieve their purpose by concealing the truth.

84. The Sacklers knew and intended that prescribers, pharmacists, and patients in Hawai'i would be misled by Purdue's deceptive sales campaign, and as a result would prescribe, dispense, and take Purdue opioids. Misleading these prescribers, pharmacists, and parties was the purpose of the sales campaign.

85. The Sacklers knew and intended that staff reporting to them would pay top prescribers tens of thousands of dollars to encourage other doctors to write dangerous prescriptions in Hawai'i.

86. The Sacklers knew and intended that staff reporting to them would reinforce these misleading acts through thousands of additional acts, including by sending deceptive publications to Hawai'i doctors.

87. The Sacklers knowingly and intentionally accepted profits from Purdue's deceptive business practices in Hawai'i.

88. The Sacklers knowingly and intentionally sought to conceal their personal involvement in the misconduct.

1. The Sacklers' misconduct leading to the 2007 judgment

89. The Sacklers' misconduct was particularly deceptive, unreasonable, and unlawful because they were already given a second chance. From the 1990s until 2007, they directed more than a decade of misconduct, which led to criminal convictions, civil judgments, and commitments that Purdue would not deceive doctors and patients again. That background confirms that the Sacklers' misconduct since 2007 was knowing and intentional.

90. The Sackler family's first drug company was the Purdue Frederick Company, which they bought in 1952. In 1990, they created Purdue Pharma Inc. and Purdue Pharma L.P. and, from day one, the Sackler family held a majority of seats on the Board. Richard, Ilene, Jonathan and Kathe Sackler took seats on the Board in 1990. Beverly, Mortimer, and Theresa Sackler became directors of Purdue Pharma in or around 1995. And David Sackler joined the Board in 2012.

91. Purdue launched OxyContin in 1996. It became one of the deadliest drugs of all time.[7] Upon information and belief, the FDA scientist who evaluated OxyContin wrote in his original review: "Care should be taken to limit competitive promotion." But, from the beginning, the Sacklers viewed limits on opioids as an obstacle to greater profits. To make more money, the Sacklers even considered whether they could sell OxyContin in some countries as an uncontrolled drug because of a potential "vast increase of the market potential." The inventor of OxyContin, Robert Kaiko, wrote to Richard Sackler to oppose this dangerous idea. At the OxyContin launch party, Richard Sackler spoke as the Senior Vice President responsible for sales. Upon information and belief, he told the audience: "the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense, and white..." Over the next twenty years, the Sacklers made Richard's boast come true across Hawai'i.

92. From the beginning, the Sacklers were behind Purdue's decision to deceive doctors and patients. In 1997, Richard Sackler, Kathe Sackler, and other Purdue executives determined—and recorded in secret internal correspondence—that doctors had the crucial misconception that OxyContin was weaker than morphine, which led them to prescribe OxyContin much more often, even as a substitute for Tylenol. In reality, OxyContin is more powerful than morphine. But, upon information and belief, Richard directed Purdue staff not to tell doctors the truth, because the truth

[7] *See e.g.*, 2016-03-15 telebriefing by CDC Director Tom Frieden ("We know of no other medication that's routinely used for a nonfatal condition that kills patients so frequently ... those who got the highest doses of opioids, more than 200 MMEs per day had a 1 in 32 chance of dying in just 2 ½ years ... almost all the opioids on the market are just as addictive as heroin"), available at https://www.cdc.gov/media/releases/2016/t0315-prescribing-opioids-guidelines.html.

could reduce OxyContin sales. The Sacklers were also the driving force behind Purdue's strategy to push opioids with the false promise that they create an enhanced "lifestyle."

93. Most of all, the Sacklers cared about money. Upon information and belief, in 1999, when an employee reported to Richard Sackler that Purdue was making more than $20,000,000 per week, Richard replied immediately that sales were "not so great." "After all, if we are to do 900M this year, we should be running at 75M/month. So it looks like this month could be 80 or 90M. Blah, humbug. Yawn. Where was I?"

94. In 1999, Richard Sackler became the CEO of Purdue. Jonathan, Kathe and Mortimer were Vice Presidents. Under the Sacklers' direction, the company hired hundreds of sales representatives and taught them to use false claims to sell drugs. For example, on the crucial issue of addiction, Purdue trained its sales reps to deceive doctors that the risk of addiction was "less than one percent."[8] Purdue mailed thousands of doctors promotional videos with that same false claim:

> There's no question that our best, strongest pain medicines are the opioids. But these are the same drugs that have a reputation for causing addiction and other terrible things. Now, in fact, the rate of addiction amongst pain patients who are treated by doctors is much less than one percent. They don't wear out, they go on working, they do not have serious medical side effects."[9]

A sales rep told a reporter: "We were directed to lie. Why mince words about it? Greed took hold and overruled everything. They saw that potential for billions of dollars and just went after it."[10]

95. In 2000, the Sacklers were warned that a reporter was "sniffing about the OxyContin abuse story." The Sacklers put the threat on the agenda for the next Board meeting and

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[8] Barry Meier, *Pain Killer* (1 ed. 2003) at 99.

[9] "I Got My Life Back" video transcript.

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

began covering their tracks. They planned a response that "deflects attention from the company's owners."

96. In January 2001, Richard Sackler received a plea for help from a Purdue sales rep. The representative described a community meeting at a local high school, organized by mothers whose children had overdosed on OxyContin and died. He reported to Richard Sackler that, "[s]tatements 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."

97. The next month, a federal prosecutor reported 59 deaths from OxyContin in a single state. But the Sacklers knew that the reports underestimated the problem. Upon information and belief, Richard Sackler wrote to Purdue executives: "This is not too bad. It could have been far worse."

98. That same month, Richard Sackler wrote down his solution to the overwhelming evidence of overdose and death: blame and stigmatize people who become addicted to opioids. Upon information and belief, Sackler wrote in a confidential email: "we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals." The Sacklers followed that strategy going forward by collecting millions from selling their addictive drugs, and blaming the terrible consequences on the people who became addicted.

99. In March 2001, the Sacklers finally achieved a long-sought goal: the front page of the *New York Times* reported that "OxyContin's sales have hit $1 billion, more than even Viagra's." The same article noted that "OxyContin has been a factor in the deaths of at least 120 people, and the medical examiners are still counting."

100. When *Time* magazine published an article shortly thereafter about OxyContin deaths in New England, Purdue employees told Richard Sackler they were concerned. Richard

responded with a message to his staff. Upon information and belief, he wrote that *Time*'s coverage of people who lost their lives to OxyContin was not "balanced," and the deaths were the fault of "the drug addicts," instead of Purdue.

101. That spring, Purdue executives met with the U.S. Drug Enforcement Administration ("DEA"). A senior DEA official sat across from Richard Sackler. Before the meeting ended, she leaned over the table and told Richard: "People are dying. Do you understand that?"[11]

102. As Purdue kept pushing opioids and people kept dying, the company became engulfed in a wave of investigations by state attorneys general, the DEA and the U.S. Department of Justice. In 2003, Richard Sackler left his position as President of Purdue. A few years later, Jonathan, Kathe and Mortimer Sackler resigned from their positions as Vice Presidents. But those moves were only for show. The Sacklers maintained control of the company. Their family owned Purdue. They controlled the Board. They paid themselves the profits. And, as alleged in detail below, they continued to direct Purdue's deceptive marketing campaign.

103. By 2006, prosecutors found damning evidence that Purdue intentionally deceived doctors and patients about its opioids. The Sacklers voted that their first drug company, the Purdue Frederick Company, should plead guilty to a felony for misbranding OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause side effects than other pain medications. The Sacklers also voted on the Board that three Purdue executives (Michael Friedman, Paul Goldenheim, and Howard Udell)—but not a single member of the Sackler family—should plead guilty as individuals.

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[11] 2001 meeting described in *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* by Barry Meier, pg. 158 (2003). The DEA official was Laura Nagel, head of the DEA Office of Diversion Control.

104. In May 2007, the Sacklers voted again to have their company plead guilty and enter a series of agreements that Purdue would never deceive doctors and patients about opioids again. The Purdue Frederick Company confessed to a felony and effectively went out of business. But the Sacklers continued their opioid business in their two other companies: Purdue Pharma Inc. and Purdue Pharma L.P.

105. The Sacklers voted to admit in an Agreed Statement of Facts that, for more than six years, supervisors and employees *intentionally* deceived doctors about OxyContin: "Beginning on or about December 12, 1995, and continuing until on or about June 30, 2001, certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications."[12]

106. To remove any doubt, the Sacklers voted to enter into a plea agreement that stated: "Purdue is pleading guilty as described above because Purdue is in fact guilty."[13] Those intentional violations of the law happened while Richard Sackler was CEO; Jonathan, Kathe and Mortimer were Vice Presidents; and Richard, Jonathan, Kathe, Mortimer, Ilene, Beverly and Theresa Sackler were all on the Board.

107. The Sacklers also voted for Purdue to enter a Corporate Integrity Agreement with the U.S. government. The agreement required the Sacklers to ensure that Purdue did not deceive doctors and patients again. The Sacklers promised to comply with rules that prohibit deception about Purdue opioids. They were required to complete hours of training to ensure that they understood the rules. They were required to report any deception. Indeed, Richard, Beverly, Ilene,

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[12] 2007-05-09 Agreed Statement of Facts, paragraph 20, available at https://www.documentcloud.org/documents/279028-purdue-guilty-plea.

[13] May 9, 2007 Plea Agreement.

Jonathan, Kathe, Mortimer, and Theresa Sackler each certified in writing to the government that he or she had read and understood the rules and would obey them.[14]

108. The 2007 Judgment and related agreements should have ended the misconduct for good. Instead, the Sacklers decided to break the law again and again, expanding and evolving their deceptive sales campaign to make more money at the expense of more patients and families.

2. The Sacklers' misconduct from 2007 until today

109. After 2007, the Sacklers continued to control Purdue's deceptive sales campaign. They directed the company to hire hundreds more sales reps. They insisted that sales reps repeatedly visit the most prolific prescribers. They directed reps to encourage doctors to prescribe more of the highest doses of opioids. They studied unlawful tactics to keep patients on opioids longer and then ordered staff to use those tactics in making sales. They asked for detailed reports about doctors suspected of misconduct, how much money Purdue made from them, and how few of them Purdue had reported to the authorities. Richard Sackler even went into the field himself to promote opioids to doctors and supervise reps face to face.

110. The Sacklers' directions were enforced throughout the company. When the Sacklers berated sales managers, the managers turned around and fired straight at reps in the field.

111. The Sacklers cared most of all about money. From 2007 to 2018, they voted to direct Purdue to pay their family billions of dollars, including millions from opioids sold in Hawai'i. These payments show the total control that the Sacklers exercised over Purdue. The payments were the motivation for the Sacklers' misconduct. And the payments were deliberate decisions to benefit from deception in Hawai'i and elsewhere, at great cost to patients and families.

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[14] *Id.*

E. Although they knew their conduct was deceptive and unfair, the Sacklers fraudulently concealed their conduct.

112. The Sacklers, both directly and indirectly, made, promoted, and profited from misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that the misrepresentations were unfair and deceptive. Research and clinical experience over the last several decades clearly establishes that opioids are highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned the Sacklers of this, and the Sacklers had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients were (and are) suffering from addiction, overdoses, and death in alarming numbers. Furthermore, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of the misrepresentations, and Purdue entered into agreements explicitly prohibiting it from making the misrepresentations.

113. Moreover, the Sacklers took steps to avoid detection of and to fraudulently conceal their personal involvement in the deceptive marketing and fraudulent conduct. For example, the Sacklers never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by Purdue to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. The Sacklers exerted considerable influence on these promotional and "educational" materials. The Sacklers distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for the Sacklers' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions. The Sacklers purposefully hid behind Purdue to conceal their own misconduct.

COUNT I
VIOLATION OF HAWAI'I LAW ON UNFAIR OR DECEPTIVE ACTS OR PRACTICES, HAW. REV. STAT. § 480-1 *ET SEQ.*

114. Plaintiff incorporates by reference and realleges all prior paragraphs of this Complaint as if set forth fully herein.

115. UDAP sets forth that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are unlawful." Haw. Rev. Stat. § 480-2(a).

116. Among other things, Haw. Rev. Stat. § 481A-3(a) defines actions that constitute a "deceptive trade practice" as including, but not limited to, the following:

> (5) Represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have . . . ; and
>
> (12) Engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.

Haw. Rev. Stat. § 481A-3(a)(5) and (12).

117. As set forth herein, Defendants' actions in marketing and promoting Purdue's prescription opioids fit within the definitions and scope of UDAP.

118. The Attorney General of the State of Hawai'i is authorized to bring an action to redress unfair or deceptive acts or practices under Haw. Rev. Stat. § 480(2)(d), as well as Haw. Rev. Stat. § 661-10. The Attorney General is specifically charged with the administration of UDAP, and may act *sua sponte* as the agent and legal representative of the State in civil proceedings to enforce the statute.

119. Defendants' unfair or deceptive acts or practices described above constitute multiple, separate violations of UDAP, but also collectively constitute an ongoing, continuing violation by Defendants. For example, Defendants engaged in unfair or deceptive acts or practices by:

a) Falsely claiming that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly;

b) Failing to disclose the greater risk of addiction with prolonged use;

c) Falsely instructing doctors and patients that the signs of addiction are actually "pseudoaddiction," signs of undertreated pain and should be treated by prescribing more opioids;

d) Falsely instructing doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction;

e) Underplaying the risk and impact of addiction and making doctors feel more comfortable starting patients on opioids, and falsely claiming that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, while not disclosing the increased difficulty of stopping opioids after long-term use;

f) Falsely claiming that doctors and patients could increase opioid dosages indefinitely without added risk and failing to disclose the greater risks to patients at higher dosages;

g) Creating false impressions that these so-called abuse-deterrent properties can curb addiction and abuse;

h) Misrepresenting that Oxycontin lasted a full 12 hours;

i) Grossly overstating the benefits of using opioids for chronic pain;

j) Failing to report illicit or unlawful prescribing of Purdue's prescription opioids;

k) Targeting susceptible prescribers and vulnerable patient populations; and

l) Concealing and misrepresenting the extent of the Sacklers' involvement in Purdue.

120. Those unfair and deceptive representations and omissions were made by Defendants in connection with their promotion and sale of Purdue's prescription opioids in the regular conduct of their trade or business within Hawai'i, directly or indirectly affecting the people of the State of Hawai'i.

121. Those unfair and deceptive representations and omissions were material because, among other things, they involved information that could affect the decisions of physicians and/or patients whether to prescribe or use Purdue's prescription opioids.

122. Those unfair and deceptive representations and omissions were unfair because, among other things, they offended public policy and/or were immoral, unethical, oppressive, unscrupulous and/or substantially injurious to consumers.

123. Plaintiff is informed and believes, and based thereupon alleges, that Defendants knew or should have known at the time of making those representations or omissions, or causing those representations or omissions to be made, that such representations or omissions were material and were likely to and/or would have a tendency to mislead physicians, patients and the public. In addition, Defendants knew or should have known that their marketing and promotional efforts were creating an untrue and misleading impression of the benefits and risks of using Purdue's prescription opioids for chronic pain.

124. Given the threat to the life, health and safety of patients created by Defendants' unfair or deceptive acts or practices, and the devastating impact that misconduct has had across the nation and in Hawai'i, penalties of $10,000 should be imposed upon each Defendant for each UDAP violation.

COUNT II
VIOLATION OF THE UDAP, CONSUMER FRAUDS AGAINST ELDERS
HAW. REV. STAT. § 480-13.5

125. Plaintiff incorporates by reference and realleges all prior paragraphs of this Complaint as if set forth fully herein.

126. UDAP sets forth that "[i]f a person commits a violation under section 480-2 which is directed toward, targets, or injures an elder, a court, in addition to any other civil penalty, may impose a civil penalty not to exceed $10,000 for each violation." Haw. Rev. Stat. § 480-13.5(a).

127. Defendants have knowingly marketed Purdue's prescription opioids specifically to elderly patients, many of whom are retired, through the above-described unfair and deceptive acts and practices.

128. As a result of Defendants' unfair or deceptive acts or practices directed specifically towards elders, Defendants' violation justify assessing additional penalties of up to $10,000, per Defendant, for each violation of UDAP that was directed toward or targeted elders.

COUNT III
UNJUST ENRICHMENT

129. Plaintiff incorporates by reference and realleges all prior paragraphs of this Complaint as if set forth fully herein.

130. Individuals and entities in Hawai'i conferred a benefit on Defendants in the form of the profits Defendants obtained because of sales of Purdue's prescription opioids in Hawai'i .

131. Defendants knowingly accepted such profits, to which they were not entitled.

132. Defendants' acceptance and retention of such profits under these circumstances was and is unjust and inequitable.

133. As a matter of equity, Defendants should be required to disgorge their unjustly obtained profits from purchases of Purdue's prescription opioids in Hawai'i.

COUNT IV
PUNITIVE DAMAGES

134. Plaintiff incorporates by reference and realleges all prior paragraphs of this Complaint as if set forth fully herein.

135. By engaging in the above-described unfair or deceptive acts or practices, Defendants acted wantonly or oppressively or with such malice as implies a spirit of mischief or criminal indifference to civil obligations.

136. By engaging in the above-described unfair or deceptive acts or practices, Defendants also engaged in willful misconduct and exhibited that entire want of care that would raise the presumption of a conscious indifference to consequences.

137. Accordingly, Plaintiff should be awarded punitive damages under Haw. Rev. Stat. § 661-10.

RELIEF

WHEREFORE, the State of Hawai'i, by and through its Attorney General, respectfully requests that this Court grant the following relief:

1. Entering Judgment in favor of the State in a final order against each of the Defendants;

2. Enjoining the Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries, and all other persons acting in concert or participation with them, from engaging in unfair or deceptive acts or practices in the marketing of Purdue's prescription opioids in Hawai'i and ordering temporary, preliminary, or permanent injunctive relief;

3. Declaring that each act and omission of each of the Defendants described in this Complaint constitute multiple, separate violations of UDAP;

4. Declaring that Defendants, and each of them, have engaged in a continuing violation of UDAP;

5. Imposing civil penalties of up to $10,000, per Defendant, for each violation of UDAP;

6. Imposing additional civil penalties of up to $10,000, per violation, per Defendant, for each violation of UDAP that was directed toward or targeted elders;

7. A determination that Defendants, and each of them, have been unjustly enriched by their unfair or deceptive acts or practices, and an order and judgment requiring

Defendants to disgorge to Plaintiff all of the ill-gotten gains obtained by Defendants, and each of them, as a result of their unfair or deceptive acts or practices;

8. Awarding judgment against Defendants, and each of them, requiring Defendants to pay punitive damages in amounts warranted by the evidence; and

9. Granting the State:

   a. Reasonable attorneys' fees and the costs of suit, as authorized by law;

   b. Pre-judgment and post-judgment interest, and

   c. All other relief as provided by law and/or as the Court deems appropriate and just.

Plaintiff asserts claims herein in excess of the minimum jurisdictional requirements of this Court.

DATED: Honolulu, Hawai'i, June 3, 2019.

L. RICHARD FRIED, JR.
PATRICK F. McTERNAN

Attorneys for Plaintiff

IN THE CIRCUIT COURT OF THE FIRST CIRCUIT

STATE OF HAWAI'I

STATE OF HAWAI'I, EX REL. CLARE E. CONNORS, ATTORNEY GENERAL, Plaintiff, vs. PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; RICHARD S. SACKLER, BEVERLY SACKLER, DAVID A. SACKLER, ILENE SACKLER LEFCOURT, JONATHAN D. SACKLER, KATHE SACKLER, MORTIMER D. A. SACKLER, AND THERESA SACKLER, and DOE DEFENDANTS 1 to 100, Defendants.	CIVIL NO. 19-1-0862-06 SUMMONS

SUMMONS

TO THE ABOVE-NAMED DEFENDANT(S):

You are hereby summoned and required to file with the court and serve upon L. Richard Fried, Jr. and/or Patrick F. McTernan, plaintiff's attorneys, whose address is 600 Davies Pacific Center, 841 Bishop Street, Honolulu, Hawai'i, 96813, an answer to the Complaint which is herewith served upon you, within twenty (20) days after service of this Summons upon you, exclusive of the date of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the Complaint.

This summons shall not be personally delivered between 10:00 p.m. and 6:00 a.m. on premises not open to the general public, unless a judge of the above-entitled court permits, in writing to this summons, personal delivery during those hours.

A failure to obey this summons may result in an entry of default and default judgment against the disobeying person or party.

DATE ISSUED: JUN 03 2019

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FIRST CIRCUIT COURT SEAL STATE OF HAWAII

CLERK

In accordance with the Americans with Disabilities Act and other applicable state and federal laws, if you require a reasonable accommodation for a disability, please contact the ADA Coordinator at the First Circuit Court Administration Office at PHONE NO. 539-4333, FAX 539-4322, or TTY 539-4853, at least ten (10) working days prior to your hearing or appointment date.