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SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF ORANGE

THE PEOPLE OF THE STATE OF CALIFORNIA, acting by and through Acting Santa Clara County Counsel James R. Williams and Orange County District Attorney Tony Rackauckas,

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ACTAVIS PLC; ACTAVIS, INC.; WATSON, PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; and ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; AND DOES 1 THROUGH 100, INCLUSIVE,

Defendants.

No. 30-2014-00725287-CU-BT-CXC

FOURTH AMENDED COMPLAINT FOR VIOLATIONS OF CALIFORNIA FALSE ADVERTISING LAW, CALIFORNIA UNFAIR COMPETITION LAW, AND PUBLIC NUISANCE, SEEKING RESTITUTION, CIVIL PENALTIES, ABATEMENT, AND INJUNCTIVE RELIEF

Judge: Honorable Kim G. Dunning
Department: CX104

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I. INTRODUCTION

1. Defendants manufacture, market, and sell prescription opioids (hereinafter opioids), including brand-name drugs like OxyContin and Percocet, and generics like oxycodone and hydrocodone, which are powerful narcotic painkillers. Historically, opioids were used only to treat short-term acute pain or for palliative (end-of-life) care because they were considered too addictive and debilitating for the treatment of chronic pain, like back pain, migraines, and arthritis.[1]

2. In the late 1990s, however, and continuing today, each Defendant began a sophisticated marketing scheme premised on deception to persuade doctors and patients that opioids can and should be used to treat chronic pain. Each Defendant spent, and some continue to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids and overstate the benefits of opioids. As to the risks, Defendants falsely and misleadingly: (1) downplayed the serious risk of addiction;[2] (2) promoted the concept of "pseudoaddiction," claiming that the 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 abuse and addiction. Defendants also falsely touted the benefits of long-term opioid use, including its supposed ability to improve function and quality of life, even though there was no "good evidence" to support those benefits.

3. Each Defendant knew that its longstanding and ongoing misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), including by the CDC in its *Guideline for Prescribing Opioids for Chronic Pain*, issued in

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

[2] Addiction is classified as a spectrum of "substance use disorders" that range from misuse and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on this spectrum. In this Complaint, "addiction" refers to the entire range of substance abuse disorders.

2016 and approved by the FDA (2016 CDC Guideline). Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have also entered into agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint in other jurisdictions. Yet even now, each Defendant continues to misrepresent the risks and benefits of long-term opioid use in California, and continues to fail to correct its past misrepresentations.

4. Defendants' false and misleading statements deceived doctors and patients about the risks and benefits of opioids and convinced them that opioids were not only appropriate but necessary for the treatment of chronic pain. Defendants targeted susceptible prescribers like family doctors as well as vulnerable patient populations like the elderly and veterans. And they tainted the sources that doctors and patients relied upon for guidance, including treatment guidelines, continuing medical education programs, medical conferences and seminars, and scientific articles. As a result, Defendants successfully transformed the way doctors treat chronic pain, opening the floodgates of opioid prescribing and use. Opioids are now the most prescribed class of drugs; they generated $11 billion in revenue for drug companies in 2014 alone. This explosion in opioid prescriptions and use has padded Defendants' profit margins at the expense of chronic pain patients. As the CDC recently concluded, "for the vast majority of [those] patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits."[3]

5. The explosion in opioid prescriptions and use caused by Defendants has led to a public health crisis in California. California faces skyrocketing opioid addiction and opioid-related overdoses and deaths as well as devastating social and economic consequences. This public health crisis is a public nuisance because it "is injurious to health" and interferes "with the comfortable enjoyment of life and property" (Civ. Code, § 3479) and because it affects "entire communit[ies]" and "neighborhood[s]" and "any considerable number of persons" (*id.*, § 3480). The effects of each Defendant's deceptive marketing scheme are catastrophic and are only getting worse. This is

[3] Thomas R. Frieden et al., *Reducing the Risks of Relief — The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501-1504 (2016).

especially so in Santa Clara and Orange Counties. In Orange County, for example, there were 286 overdose deaths in 2015, a 16% increase since 2013. As the FDA acknowledged in February 2016, "[t]hings are getting worse, not better, with the epidemic of opioid misuse, abuse and dependence."[4]

6. There is little doubt that each Defendant's deceptive marketing scheme has precipitated this public health crisis in California, including Santa Clara and Orange Counties, by dramatically increasing opioid prescriptions and use. An oversupply of prescription opioids has provided a source for illicit use or sale of opioids (the supply), while the widespread use of opioids has created a population of patients physically and psychologically dependent on them (the demand). 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.

7. The role of Defendants' deceptive marketing scheme in causing this public health crisis has become well-recognized in recent years. In her May 2014 testimony to the Senate Caucus on International Narcotics Control on behalf of the National Institutes of Health (NIH), Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."[5] And in August 2016, the former U.S. Surgeon General expressly connected the "urgent health crisis" to "heavy marketing of opioids to doctors . . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[6] California doctors, addiction treatment specialists, and law enforcement and public health officials confirm that prescription opioids lawfully prescribed by doctors have fueled this epidemic.

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[4] *Califf, FDA top officials call for sweeping review of agency opioids policies*, FDA News Release (Feb. 4, 2016), available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.

[5] America's Addiction to Opioids: Heroin and Prescription Drug Abuse, available at <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse> [as of July 7, 2017].

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

8. Absent each Defendant's deceptive marketing scheme, opioid prescribing, use, misuse, abuse, and addiction, would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.

9. By falsely downplaying the risks and grossly exaggerating the benefits of long-term opioid use through their deceptive marketing claims despite their knowledge of the falsity of those claims, Defendants have not only engaged in false advertising and unfair competition, they have also created or assisted in the creation of a public nuisance.[7] Although this Complaint focuses on Defendants' misconduct during the past six years and only references their earlier misconduct, every act of malfeasance committed by each Defendant since the late 1990s as part of its deceptive marketing scheme subjects that Defendant to liability for public nuisance because there is no statute of limitations for a public nuisance claim. (See Civ. Code, § 3490 ["No lapse of time can legalize a public nuisance, amounting to an actual obstruction of public right"]; *Wade v. Campbell* (1962) 200 Cal.App.2d 54, 61 ["the maintenance of a public nuisance may not be defended on the ground of laches or the statute of limitations"].)

10. Accordingly, Defendants' conduct, both individually and collectively, has violated and continues to violate the False Advertising Law, Bus. & Prof. Code, §§ 17500 et seq., the Unfair Competition Law, Bus. & Prof. Code, §§ 17200 et seq., and the Public Nuisance Law, Civ. Code, §§ 3479 and 3480. The People of the State of California do not seek to limit the ability of doctors in California to prescribe opioids. The People also do not ask this Court to weigh the risks and benefits of long-term opioid use. Instead, the People seek an order requiring Defendants to cease their unlawful promotion of opioids, to correct their misrepresentations, and to abate the public nuisance they have created. To redress and punish Defendants' previous and current violations of law, the People seek a judgment requiring Defendants to pay civil penalties, restitution, and any fees or costs permitted under law.

[7] (See *County of Santa Clara v. Atlantic Richfield Co.* (2006) 137 Cal.App.4th 292, 306 [holding that plaintiffs "have adequately alleged that defendants are liable for the abatement of this public nuisance" by alleging that defendants "promot[ed] lead paint for interior use even though defendants knew for nearly a century that such a use of lead paint was hazardous to human beings"].)

II. PARTIES

A. Plaintiff

11. James R. Williams, County Counsel for the County of Santa Clara, and Tony Rackauckas, District Attorney for the County of Orange, bring this action on behalf of the People of the State of California (People) to protect the public from false and misleading advertising, unlawful, unfair, and fraudulent business practices, and a public nuisance.

B. Defendants

12. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA Inc. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, Purdue).

13. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER,[8] and Targiniq ER in the U.S. and California. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

14. In May 2007, Purdue entered into a stipulated final judgment with the People of the State of California, acting by and through the California Attorney General (Purdue Final Judgment), based principally on Purdue's direct promotion of OxyContin up to May 8, 2007, the effective date of the Final Judgment. The People do not seek, through this Complaint, to enforce any provision of the Purdue Final Judgment, and are not seeking any relief against Purdue under any state consumer protection law as defined by section (I)(1)(M) and footnote 1 of the Final Judgment based on any conduct by Purdue that occurred at any time up to and including May 8,

[8] Long-acting or extended release (ER or ER/LA) opioids are designed to be taken once or twice daily. Short-acting opioids, also known as immediate release (IR) opioids, last for approximately 4-6 hours.

2007 relating to Purdue's promotional and marketing practices regarding OxyContin. The People do, however, assert claims arising under California law independent of the Purdue Final Judgment, and seek restitution and civil penalties, in addition to injunctive relief, as afforded by those laws.

15. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as "Janssen.").

16. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and California, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

17. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo.")

18. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and California. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012.

Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and California, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

19. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis plc in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis.")

20. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the U.S. and California. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009.

21. Plaintiff is ignorant of the true names or capacities, whether individual, corporate or otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive, and they are therefore sued herein pursuant to Code of Civil Procedure § 474. Plaintiff will amend this Complaint to show their true names and capacities if and when they are ascertained. Plaintiff is informed and believes, and on such information and belief alleges, that each of the Defendants

named as a DOE is responsible in some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein.

III. JURISDICTION AND VENUE

22. This Court has jurisdiction over this action. Defendants are engaging in false and misleading advertising and unlawful, unfair, and deceptive business practices, and creating or assisting in the creation of a public nuisance in Santa Clara and Orange Counties, and the County Counsel and District Attorney have the right and authority to prosecute this case on behalf of the People.

23. Venue is proper in this Court because Defendants transact business in Orange County, and some of the acts complained of occurred in this venue.

IV. FACTUAL ALLEGATIONS

24. 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.

25. To take advantage of the much larger and more lucrative market for chronic pain patients, Defendants had to change this. Each Defendant developed a well-funded marketing scheme based on deception. Each Defendant targeted susceptible prescribers and vulnerable patient populations. Each Defendant used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and misleading statements about the risks and benefits of long-term opioid use. 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 same evidence. California doctors, including doctors in Santa Clara County, confirm that Defendants began their marketing schemes decades ago and continue them

today. And the 2016 CDC Guideline makes it patently clear that their schemes were and continue to be deceptive.

A. Defendants Targeted Susceptible Prescribers And Vulnerable Patient Populations.

26. As a part of their deceptive marketing scheme, Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including California.

27. For example, Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic paint patients and prescribe them drugs, but were less likely to be schooled in treating pain and the risks and benefits of opioids and therefore more likely to accept Defendants' misrepresentations. Interviews with California doctors, including doctors in Santa Clara County, confirm that Defendants' deceptive marketing scheme has long targeted and continues to target primary care doctors in California.

28. Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observed that existing evidence showed 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 concluded that there are "special risks of long-term opioid use for elderly patients" and recommended 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.

B. Defendants Used Multiple Avenues to Disseminate Their False and Misleading Statements About Opioids.

29. To spread their false and misleading statements, Defendants deceptively marketed their branded opioids directly to doctors and patients in California. Defendants also deployed seemingly unbiased and independent third parties to spread their false and misleading statements about the risks and benefits of opioids for the treatment of chronic pain throughout California.

1. Defendants Spread and Continue to Spread Their False and Misleading Statements Through Direct Marketing of Their Branded Opioids.

30. Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. This amount included $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

31. A number of Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, since at least May 21, 2011, Endo has distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Purdue also 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. Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them in California.

32. Second, each Defendant 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. For example, from mid-2013 through 2015, Purdue, Janssen, and Endo detailed at least 6,238,584, and 195 prescribers in California respectively. Purdue itself was responsible for more than 1 out of every 3 reported opioid-related detailing visits in California by Defendants.

33. As doctors in California, including doctors in Santa Clara and Orange County, interviewed by the People have confirmed, these detailers have spread and continue to spread misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors, including thousands of California doctors. For example, these doctors have confirmed that Defendants' detailers, over the past two years, continue to falsely and misleadingly:

a. Describe the risk of addiction as low or fail to disclose the risk of addiction;

b. Describe their opioid products as "steady state" – falsely implying that these products are less likely to produce the high and lows that fuel addiction – or as less likely to be abused or result in addiction;

c. Tout the effectiveness of screening or monitoring patients as a strategy for managing opioid abuse and addiction;

d. State that there is no maximum dose and that doctors can safely increase doses without disclosing the significant risks to patients at higher doses;

e. Discuss "pseudoaddiction";

f. State that patients would not experience withdrawal if they stopped using their opioid products;

g. State that their opioid products are effective for chronic pain without disclosing the lack of evidence for the effectiveness of long-term opioid use; and

h. State that abuse-deterrent formulations are tamper- or crush-resistant and harder to abuse or misuse.

Because these detailers must adhere to scripts and talking points drafted by Defendants, it can be reasonably inferred that most, if not all, of Defendants' detailers made and continue to make these misrepresentations to the thousands of California doctors they have visited and continue to visit. Defendants have not corrected this misinformation.

34. Defendants[9] also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker 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 give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these

[9] Upon information and belief, Actavis continued to carry out speaker programs after it acquired Kadian.

presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

35. Each Defendant devoted and continues to devote massive resources to direct sales contacts with doctors. In 2014 alone, Defendants spent $168 million on detailing branded opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $10 million by Endo, and $2 million by Actavis.

36. Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Moreover, more frequent prescribers of opioids in California are generally more likely to have received a detailing visit. And in some instances, more infrequent prescribers of opioids in California received a detailing visit from a Defendant's detailer and then prescribed only that Defendant's opioid products.

37. Defendants' detailers have been reprimanded for their deceptive promotions. A July 2010 "Dear Doctor" letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

2. Defendants Used a Diverse Group of Seemingly Independent Third Parties to Spread False and Misleading Statements About the Risks and Benefits of Opioids.

38. Defendants also deceptively marketed opioids in California 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, Defendants 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.[10]

39. Defendants 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. Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like tobacco companies, Defendants 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.

40. Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA. For example, Endo's unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy (Unbranded)	**Opana ER Advertisement (Branded)**
"People who take opioids **as prescribed usually do not become addicted**."	"All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use**."

[10] The phrase "acted in concert" includes conspiring to achieve some end and aiding and abetting in the commission of acts necessary to achieve some end.

41. Defendants also spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Defendants because their public positions supported the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs." Defendants paid these KOLs to serve as consultants or on their advisory boards and to give talks or present continuing medical education programs (CMEs), and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. KOLs' professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by Defendants.

42. Pro-opioid doctors are one of the most important avenues that Defendants use to spread their false and misleading statements about the risks and benefits of long-term opioid use. Defendants know that doctors rely heavily and more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the New York Attorney General (NY AG) found in its settlement with Purdue that through March 2015 the Purdue website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. Defendants created opportunities for KOLs to participate in research studies Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

43. Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage 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. These guidelines and CMEs were not supported by the scientific evidence at the time they were created, and they are not supported by the scientific evidence today. Defendants were able to direct and

exert control over each of these activities through their KOLs. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices."

44. Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Defendants, these "Front Groups" – which include, but are not limited to, the American Pain Foundation (APF) and the American Academy of Pain Medicine – generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. These guidelines, materials, and programs were not supported by the evidence at the time they were created, and they are not supported by the scientific evidence today. Indeed, they stand in marked contrast to the 2016 CDC Guideline. These Front Groups also assisted Defendants 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 Defendants.

45. These Front Groups depended on Defendants for funding and, in some cases, for survival. Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. For example, Purdue's consulting agreement with APF gave it direct, contractual control over APF's work. In doing so, Defendants made sure that the Groups would generate only the messages Defendants 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.

46. Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum (PCF), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from Defendants. 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 Defendants determined would reduce prescribing. PCF also worked to address a perceived "lack of coordination" among its members and developed "key" messages that were disseminated in programs and industry-run websites that were available and accessible after May 21, 2011.

C. Defendants' Marketing Scheme Misrepresented the Risks and Benefits of Opioids.

47. To convince doctors and patients in California that opioids can and should be used to treat chronic pain, Defendants 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, Defendants 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 their claims were false and misleading, Defendants have not corrected them and continue to spread them today.

1. Defendants Falsely Trivialized or Failed to Disclose the Known Risks of Long-Term Opioid Use.

48. To convince doctors and patients that opioids are safe, Defendants 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. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

49. **First**, Defendants 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 of opioids. Some illustrative examples of these false and misleading claims that were made by, are continuing to be made by, and/or have not been corrected by Defendants after May 21, 2011 are described below:

a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.

b. 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. This publication is still available online.

c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." This website was still available online after May 21, 2011.

d. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com – which was accessible online after May 21, 2011.

e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain." This guide is still available online.

f. Janssen currently runs a website, *Prescriberesponsibly.com* (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."

g. 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[]." This publication is still available online.

h. Since at least May 21, 2011, detailers for Purdue, Endo, and Janssen in California have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in California, including Santa Clara County, about 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.

50. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline approved 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." (Emphasis added.)

51. The FDA further exposed the falsity of Defendants' 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." (Emphasis added.) 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. (Emphasis added.) The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

52. Thus, the warnings on Defendants' 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. (Emphasis added.)

53. The NY AG, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed until at least April 2012 on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the NY AG found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do

not become addicted" in New York. Endo remains free, however, to make those statements in California.

54. **Second**, Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants 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 Endo, Janssen, and Purdue – and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by Defendants after May 21, 2011 – 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. *Responsible Opioid Prescribing* remains for sale online. Endo also distributed this document before and after May 21, 2011.

b. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when *pain is under-treated* . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until May 2012.

c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials. This CME program was still available after May 21, 2011.

d. 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." This pamphlet was still distributed after May 21, 2011.

e. Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse* in 2011. 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. This CME program was still available after May 21, 2011.

f. Before and after May 21, 2011, detailers for Purdue have directed doctors and their medical staffs in California, including Santa Clara County, to PartnersAgainstPain.com, which contained false and misleading materials describing pseudoaddiction.

g. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which states: "Pseudo-addiction describes patient behaviors that may occur when *pain is undertreated* . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated." (emphasis added.) This publication is still available online.

55. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline 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."

56. Even one of the Defendants has effectively repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the NY AG, in its 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.'" Consistent with this, Endo agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York. Endo, however, remains free to do so in California.

57. **Third**, Defendants 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 Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Defendants' 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 that were made by, are continuing to be made by, and/or have not been corrected by Defendants after March 21, 2011 are described below:

a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

b. Purdue sponsored a November 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."

c. 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.

d. Since at least May 21, 2011, detailers for Purdue have touted and continue to tout to doctors in California, including Santa Clara County, the reliability and effectiveness of screening or monitoring patients as a tool for managing opioid abuse and addiction.

58. Once again, the 2016 CDC Guideline confirms that these statements were false, misleading, and unsupported at the time they were made by Defendants. 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." (Emphasis added.)

59. **Fourth**, to underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Defendants 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. For example, a 2011 non-credit educational program sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days.

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. This publication was available on APF's website until the organization dissolved in May 2012. And detailers for Janssen, since at least May 21, 2011, have told and continue to tell doctors in California, including Santa Clara County, that their patients would not experience withdrawal if they stopped using opioids. Defendants deceptively minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug craving, 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." (Emphasis added.) 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."

60. Numerous California patients struggling with opioid addiction, including patients in Santa Clara County, have described how difficult it is to stop taking prescription opioids due to the extreme withdrawal symptoms. For example, one lawyer who was prescribed opioids for chronic pain was told that she could easily taper off the drugs. After she became addicted, she attempted to stop taking opioids. But she became so sick from withdrawal that she began buying opioids illicitly. Indeed, she even considered using heroin to get through her withdrawal symptoms despite

her fear and aversion to injecting an illegal drug. Ultimately, the costs of prescription opioids drove her to seek treatment for her addiction.

61. **Fifth**, Defendants 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 Defendants' 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 of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by Defendants after May 21, 2011 are described below:

a. Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.

b. 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.[11] This guide is still available for sale online.

c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain." The website was still accessible online after May 21, 2011.

d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was still available after May 21, 2011 on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."

e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines

[11] Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (See e.g., *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) [describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids]; *Finding Relief: Pain Management for Older Adults* (Janssen) [NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary "upset stomach or sleepiness" and constipation].)

but omitted any discussion of risks of increased opioid dosages. This guide is still available online.

f. Through March 2015, 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.

g. 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. This publication is still available online.

h. Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdose.

j. Since at least May 21, 2011, Purdue's detailers have told doctors in California, including Santa Clara County, that they should increase the dose of OxyContin, rather than the frequency of use, to address early failure.

62. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. 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.

63. 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." In fact, a recent study found that 92% of persons who died from an opioid-related overdose were initially prescribed opioids for chronic pain.

64. **Finally**, Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can prevent and 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.

65. These abuse deterrent formulations (AD opioids) are harder to crush, chew, or grind; become gelatinous when combined with a liquid, making them harder to inject; or contain a counteragent such as naloxone that is activated if the tablets are tampered. Despite this, AD opioids are not "impossible to abuse."[12] They can be defeated – often quickly and easily – by those determined to do so. Moreover, they do not stop oral intake, the most common avenue for opioid misuse and abuse, and do not reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term as prescribed or who escalate their use by taking more pills or higher doses.

66. Because of these significant limitations on AD opioids and because of the heightened risk for misconceptions and for the false belief that AD opioids can be prescribed safely, the FDA has cautioned that "[a]ny communications from the sponsor companies regarding AD properties must be truthful and not misleading (based on a product's labeling), and supported by sound science taking into consideration the totality of the data for the particular drug. Claims for AD opioid products that are false, misleading, and/or insufficiently proven do not serve the public health."[13]

67. Despite this admonition, Defendants have made and continue to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations to prevent or reduce abuse and addiction and the safety of these formulations.

68. For example, Endo has marketed Opana ER as tamper- or crush-resistant and less prone to misuse and abuse since at least May 21, 2011 even though: (1) the FDA rejected Endo's petition to approve Opana ER as abuse-deterrent in 2012; (2) the FDA warned in a 2013 letter that there was no evidence that Opana ER "would provide a reduction in oral, intranasal or intravenous abuse"; and (3) Endo's own studies, which it failed to disclose, showed that Opana ER could still

[12] FDA Facts: Abuse-Deterrent Opioid Medications, available at <https://www.fda.gov/newsevents/newsroom/factsheets/lucm514939.htm> [as of July 7, 2017].

[13] *Ibid.*

be ground and chewed. Endo's advertisements for the 2012 reformulation of Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. And since 2012, detailers for Endo have informed California doctors, including doctors in Santa Clara County, that Opana ER is harder to abuse, and nurse practitioners have reported receiving tamper- and crush-resistant messages regarding Opana ER and demonstrations of Opana ER's purposed abuse deterrent properties.

69. In a 2016 settlement with the NY AG, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The NY AG found those statements false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

70. Because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and a serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that Endo withdraw Opana ER from the market.[14]

71. Likewise, Purdue has engaged and continues to engage in deceptive marketing of its AD opioids – i.e., reformulated Oxycontin and Hysingla – since at least May 21, 2011. Before April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However, numerous California prescribers report that, beginning in 2013 and continuing today, detailers from Purdue regularly use the so-called abuse deterrent properties of Purdue's opioid products as a primary selling point to differentiate those products from their competitors. Specifically, these detailers: (1) claim that Purdue's AD opioids prevent tampering and cannot be crushed or snorted; (2) claim that Purdue's AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (3) Purdue's AD opioids are

[14] Press Release, "FDA requests removal of Opana ER for risks related to abuse," June 8, 2017, *available at*: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm

"safer" than other opioids; and (4) fail to disclose that Purdue's AD opioids do not impact oral abuse or misuse and that its abuse deterrent properties can be defeated.

72. These statements and omissions by Purdue are false and misleading and conflict with or are inconsistent with the FDA-approved label for Purdue's AD opioids – which indicates that abusers do seek them because of their high likability when snorted, that their abuse deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse deterrent properties and which does not indicate that AD opioids prevent or reduce abuse, misuse, or diversion.

73. To the contrary, testimony in litigation against Purdue and other evidence indicates that Purdue knew and should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin" and is still regularly tampered with and abused. Websites and message boards used by drug abusers, such as bluelight.org and reddit, also report a variety of ways to tamper with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which the tablet has been dissolved. Even Purdue's own website describes a study it conducted that found continued abuse of OxyContin with so-called abuse deterrent properties. Finally, there are no studies indicating that Purdue's AD opioids are safer than any other opioid products.

74. A 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral intake or by defeating the abuse deterrent mechanism. Indeed, *one-third* of the patients in the study defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug. And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted to other drugs such as heroin.[15] Despite this, J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are being abused in large numbers.

[15] Cicero, Theodore J., and Matthew S. Ellis, "Abuse-deterrent formulations and the prescription opioid abuse epidemic in the United States: lessons learned from Oxycontin" (2015) 72.5 *JAMA Psychiatry* 424-430.

75. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes." Tom Frieden, the Director of the CDC, has further reported that his staff could not find "any evidence showing the updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death."[16]

76. These false and misleading claims about the abuse deterrent properties of their opioids are especially troubling. First, Defendants are using these claims in a spurious attempt to rehabilitate their image as responsible opioid manufacturers. Indeed, several California prescribers have reported that Purdue has conveyed that its sale of AD opioids is "atonement" for its earlier sins even though its true motive was to preserve the profits it would have lost when its patent for OxyContin expired. Indeed, Purdue introduced its first AD opioid days before that patent would have expired and petitioned the FDA to withdraw its non-AD opioid as unsafe and; thereby, prevent generic competition. Second, these claims are falsely assuaging doctors' concerns about the toll caused by the explosion in opioid prescriptions and use and encouraging doctors to prescribe AD opioids under the mistaken belief that these opioids are safer, even though they are not. Finally, these claims are causing doctors to prescribe more AD opioids -- which are far more expensive than other opioid products even though they provide little or no additional benefit.

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

2. Defendants Grossly Overstated the Benefits of Chronic Opioid Therapy.

78. To convince doctors and patients that opioids should be used to treat chronic pain, Defendants 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." (Emphasis added.) In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for

[16] Perrone, *Drugmakers push profitable, but unproven, opioid solution*, 12/15/16.

chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. 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, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and misleading claims, they continue to make them today.

79. For example, Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by Defendants after May 21, 2011 are described below:

a. Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects. These advertisements continued to be distributed after May 21, 2011.

c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it *easier* for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'" This guide was still available after May 21, 2011.

d. 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.

e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

f. 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 May 2012.

g. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site. This website was still accessible online after May 21, 2011.

h. Endo was the sole sponsor, through NIPC, of a series of non-credit educational programs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

i. Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function." This video is still available today on YouTube.

j. 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." The *Policymaker's Guide* was originally published in 2011 and is still available online today.

k. In a 2015 video on Forbes.com discussing the introduction of Hysingla ER, Purdue's Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue's opioids, to chronic pain patients' "quality of life," and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.

l. Since at least May 21, 2011, Purdue's, Endo's, and Janssen's sales representatives have conveyed and continue to convey to prescribers in California, including Santa Clara County, the message that opioids will improve patient function.

80. 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."

81. 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 or recovery do not improve their function and quality of life.

82. The 2016 CDC Guideline was not the first time a federal agency repudiated Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis, in response to its advertising described in paragraph 67, that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience … results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[17] And in 2008, the FDA sent a warning letter to an opioid manufacturer, making it publicly made clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

83. Defendants 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. For example, Defendants, before and after May 21, 2011, have overstated the number of deaths from NSAIDS and have prominently featured the risks of NSAIDS, while minimizing or failing to mention the serious risks of opioids. Once again, these misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and

[17] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/ucm259240.htm.

CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

84. In addition, since at least May 21, 2011, Purdue has misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. Indeed, Purdue's detailers have, within the last two years, told a doctor in Santa Clara County that OxyContin lasts 12 hours.

85. 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 false and misleading, 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.

86. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours since at least May 21, 2011. Indeed, at Purdue's instruction, Purdue's sales representatives continue to tell California doctors that OxyContin lasts a full 12 hours. And if a doctor suggests that OxyContin does not last 12 hours, these sales representatives, at Purdue's instruction, recommend increasing the dose, rather than the frequency of use. Purdue gave its sales representatives these instructions to prevent doctors from

switching to a different drug and to address the unwillingness of insurers to pay for more frequent use of OxyContin.

D. Defendants Also Engaged in Other Unlawful and Unfair Misconduct.

87. Since at least May 21, 2010, Purdue's sales representatives have pressed doctors to prescribe its opioids in order to be rewarded with talks paid by Purdue. One California doctor reported that a Purdue sales representative told her that she would no longer be asked to give paid talks unless she increased her prescribing of Purdue's drugs. Another doctor confirmed that, while on Purdue's speakers' bureau, he did not get asked to give many paid talks because he did not commonly prescribe Butrans, and doctors do not "get talks" if they do not prescribe the drug.

88. Although the U.S. Drug Enforcement Agency (DEA) has repeatedly informed Purdue about its legal "obligation to design and operate a system to disclose . . . suspicious orders of controlled substances" and to inform the DEA "of suspicious orders when discovered," Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs after May 21, 2010, despite knowing about it for years. (See 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(e).)

89. For over a decade, Purdue has been able to track the distribution and prescribing of its opioids down to the retail and prescriber levels. Through its extensive network of sales representatives, Purdue had and continues to have knowledge of the prescribing practices of thousands of doctors in California and could identify California doctors who displayed red flags for diversion such as those whose waiting rooms were overcrowded, whose parking lots had numerous out-of-state vehicles, and whose patients seemed young and healthy or homeless. Using this information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. 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. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down 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." In doing so, Purdue protected its own profits at the expense of public health and safety.

90. This misconduct by Purdue is ongoing. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015, Purdue's sales representatives, at various times, failed to timely report suspicious prescribing and continued to detail those prescribers even after they were placed on a "no-call" list.

91. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services, said in a *Los Angeles Times* article, "Any drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people's lives has a responsibility to report it." The NY AG's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

92. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY AG found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives detailed prescribers who were convicted of illegal prescribing of opioids after May 21, 2011, those representatives could have recognized potential signs of diversion and reported those prescribers but failed to do so.

E. Although Defendants Knew That Their Marketing of Opioids Was False and Misleading, They Fraudulently Concealed Their Misconduct.

93. Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Defendants of this, and Purdue entered into settlements in the hundreds of millions of dollars to address similar misconduct that occurred before 2008. Defendants 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 are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.

94. Moreover, at all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Defendants' false and misleading statements about the risks and benefits of long-term opioid use for chronic pain.

95. Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC,

did not disclose Endo's involvement. Other Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.

96. Finally, Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. Defendants 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 Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by the People.

97. Thus, Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the claims that the People now assert. The People did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

F. By Knowingly Causing an Explosion in Opioid Prescribing, Use, Misuse, Abuse, and Addiction Through Their Deceptive Marketing Schemes and Unlawful and Unfair Business Practices, Each Defendant Has Created or Assisted in the Creation of a Public Nuisance.

1. Defendants' Deceptive Marketing Scheme Has Caused and Continues to Cause a Huge Increase in Opioid Prescriptions and Use in California, Including Santa Clara and Orange Counties.

98. Defendants' misrepresentations deceived and continue to deceive doctors and patients in California, including Santa Clara and Orange Counties, about the risks and benefits of long-term opioid use. California doctors, including doctors in Santa Clara County, confirm this. Studies also reveal that many doctors and patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive. Indeed, California residents in treatment for opioid addiction, including residents of Santa Clara County, confirm that they were never told that they might become addicted to opioids when they started taking them,

were told that they could easily stop using opioids, or were told that the opioids they were prescribed were less addictive than other opioids.

99. Defendants knew and should have known that their misrepresentations about the risks and benefits of long-term opioid use were false and misleading when they made them.

100. Defendants' deceptive marketing scheme and their unlawful and unfair business practices caused and continue to cause doctors in California, including doctors in Santa Clara and Orange Counties, to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Defendants' deceptive marketing scheme and their unlawful and unfair business practices, these doctors would not have prescribed as many opioids to as many patients, and there would not have been as many opioids available for misuse and abuse or as much demand for those opioids.

101. Defendants' deceptive marketing scheme and their unlawful and unfair business practices also caused and continue to cause patients in California, including patients in Santa Clara and Orange Counties, to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them. Again, California doctors and patients confirm this.

102. Defendants' deceptive marketing and their unlawful and unfair business practices have caused and continue to cause the prescribing and use of opioids to explode in California, including Santa Clara and Orange Counties. Opioids are the most common means of treatment for chronic pain; 20% of office visits now include the prescription of an opioid, and 4 million Americans per year are prescribed a long-acting opioid. This surge in opioid use was not fueled by any scientific developments demonstrating that opioids were safe and effective for previously unaccepted uses; instead, it was fueled by Defendants' desire to sell more drugs.

103. In California, including Santa Clara and Orange Counties, Defendants' deceptive marketing of the abuse-deterrent properties of their opioids during the past few years has been particularly effective. For example, one survey reports that pain specialists were more likely to recognize that OxyContin had abuse deterrent properties and to prescribe OxyContin specifically

because of those properties. Further, prescribers who knew of OxyContin's abuse deterrent properties were using more of it than those who did not know it was an AD opioid. Although sales of AD opioids still represent only a small fraction of opioids sold (less than 5% of all opioids sold in 2015), they represent a disproportionate share of opioid sales revenue ($2.4 billion or approximately 25% in opioid sales revenue in 2015).

104. The dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their deceptive marketing scheme. Defendants' spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending had tripled to $288 million.

2. By Causing an Explosion in Opioid Prescriptions and Use, Defendants Have Created or Assisted in the Creation of a Public Nuisance in California, including Santa Clara and Orange Counties.

105. The escalating number of opioid prescriptions written by doctors who were deceived by Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and California.

106. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."

107. In August 2016, U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."

108. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving

prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

109. Contrary to Defendants' misrepresentations, most opioid addiction begins with legitimately prescribed opioids. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet. Numerous doctors and substance abuse counselors in California, including in Santa Clara County, note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic. Treatment centers in California, including centers in Santa Clara County, report that they treat a significant percentage – i.e., as high as 80% – of patients for opioid addiction. For example, one addiction treatment center in Santa Clara County reported that half of their opioid patients started with legitimate prescriptions, and that 75% of those patients later moved to illicit sources or drugs. Another counselor in Santa Clara County reported that almost all of the opioid addicts she treats began with legal prescriptions.

110. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. For example, in 2015, opioids were responsible for 286 overdose deaths in Orange County – a 16% increase since 2013 and a 63% increase over figures from a decade ago. In Santa Clara County, which has a little more than half the population of Orange County, prescription opioids were responsible for 134 overdose deaths in 2015 – nearly twice the figure from 2005.

111. These deaths represent the tip of the iceberg. According to 2009 data, for every overdose death that year, there were nine abuse treatment admissions, 30 emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and 795 non-medical users. And as reported in May 2016, in California, opioid overdoses resulting in hospital visits increased by 25% (accounting for population growth) from 2011 to 2014.

112. The overprescribing of opioids for chronic pain caused by Defendants' deceptive marketing scheme has also resulted in a dramatic rise in the number of infants in California who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence

syndrome. These infants face painful withdrawal and may suffer long-term neurologic and cognitive impacts.

113. Opioid addiction is now the primary reason that Californians seek substance abuse treatment, and admissions to drug treatment facilities in California more than doubled from 2006-07 to 2010-11. Addiction treatment centers indicate that many of their patients – for one facility in northern California, up to 90% – started on legal opioid prescriptions.

114. Defendants' creation, through false and misleading advertising and other unlawful and unfair conduct, of a virtually limitless opioid market has significantly harmed communities in California, including Santa Clara and Orange Counties. Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.

115. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year previously abused prescription opioids. And as reported in May 2016, heroin overdose deaths in California spiked by 34% from 2011 to 2013.

116. Many patients who become addicted to opioids will lose their jobs. Some will lose their homes and their families. Some will get treatment and fewer will successfully complete it; many of those patients will relapse, returning to opioids or some other drug. Of those who continue to take opioids, some will overdose – some fatally, some not. Others will die prematurely from related causes – falling or getting into traffic accidents due to opioid-induced somnolence; dying in their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit drug transactions; or dying from opioid-induced heart or neurological disease.

117. Absent each Defendants' deceptive marketing scheme and their unlawful and unfair business practices, the public health crisis caused by opioid misuse, abuse, and addiction in California, including Santa Clara and Orange Counties, would have been averted or much less severe.

118. The mother of one patient who became addicted to OxyContin and then heroin wrote to the People recounting such a story: "I want [my son] to have the chance at life he had before he became addicted to OxyContin. And really, not just [him]. But every single youth that the doctors and pharmaceutical companies have destroyed just so they could put another dollar in their pockets. Shame on them forever. My son wanted to be a [b]iologist when he grew up. He was a strong boy. He was a good boy. He is not the same boy."

119. These harms in California, including in Santa Clara and Orange Counties, caused by Defendants' deceptive marketing schemes and unlawful and unfair business practices are a public nuisance because they are "injurious to health" and interfere "with the comfortable enjoyment of life" and "property" (Civ. Code, § 3479) and because they "affect[] at the same time" "entire communit[ies]" and "neighborhoods" and "any considerable number of persons" (*id.*, § 3480).

3. Defendants Knew and Should Have Known That Their Deceptive Marketing Schemes Would Create or Assist in the Creation of this Public Nuisance in Santa Clara and Orange Counties.

120. Defendants knew and should have known about these harms that their deceptive marketing and unlawful and unfair business practices have caused and continue to cause in California, including in Santa Clara and Orange Counties. Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. Defendants also had access to and watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew – and, indeed, intended – that their misrepresentations would persuade doctors in California, including doctors in Santa Clara and Orange Counties, to prescribe and patients in California, including patients in Santa Clara and Orange Counties, to use their opioids for chronic pain.

4. Defendants' Conduct and Role in Creating or Assisting in the Creation of the Public Nuisance Is Not Excused by the Actions of any Third Parties and Justifies Greater Civil Penalties.

121. Defendants' actions are not permitted nor excused by the fact that their drug labels may have allowed or did not exclude the use of opioids for chronic pain. FDA approval of opioids

for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

122. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness and hijack what doctors wanted to believe – namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

123. Finally, each Defendants' conduct and role in creating or assisting in the creation of the public health crisis now plaguing California is directly relevant to the amount of the civil penalties to be awarded under Business & Professions Code §§ 17206 ["In assessing the amount of the civil penalty, the court shall consider any one or more of the relevant circumstances presented by any of the parties to the case, including, but not limited to, the following: the nature and seriousness of the misconduct, the number of violations, the persistence of the misconduct, the length of time over which the misconduct occurred, the willfulness of the defendant's misconduct, and the defendant's assets, liabilities, and net worth," emphasis added] and 17536 [same].

G. Defendants' Fraudulent Marketing Has Led To Record Profits.

124. While the use of opioids has taken an enormous toll on the State of California and its residents, Defendants have realized blockbuster profits. In 2014 alone, opioids generated $11 billion in revenue for drug companies like Defendants. Indeed, financial information indicates that each Defendant experienced a material increase in sales, revenue, and profits from the false and misleading advertising and other unlawful and unfair conduct described above.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION

FALSE ADVERTISING
Violations of Business and Professions Code Section 17500, *et seq*.

(Against all Defendants)

125. The People reallege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

126. Business and Professions Code Section 17500 (Section 17500) makes it unlawful for a business to make, disseminate, or cause to be made or disseminated to the public "any statement, concerning . . . real or personal property . . . which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading."

127. As alleged above, each Defendant, at all times relevant to this Complaint, violated Section 17500 by making and disseminating false or misleading statements about the use of opioids to treat chronic pain, or by causing false or misleading statements about opioids to be made or disseminated to the public.

128. As alleged above, each Defendant, at all times relevant to this Complaint, violated Section 17500 by making statements to promote the use of opioids to treat chronic pain that omitted or concealed material facts, and by failing to correct prior misrepresentations and omissions, about the risks and benefits of opioids. Each Defendant's omissions, which are false and misleading in their own right, render even their seemingly truthful statements about opioids false and misleading.

129. As alleged above, Defendants' statements about the use of opioids to treat chronic pain were not supported by or were contrary to the scientific evidence, as confirmed by recent pronouncements of the CDC and FDA based on that evidence.

130. As alleged above, each Defendant's conduct, separately and collectively, was likely to deceive California payors who purchased or covered the purchase of opioids for chronic pain.

131. At the time it made or disseminated its false and misleading statements or caused these statements to be made or disseminated, each Defendant knew and should have known that the

statements were false or misleading and therefore likely to deceive the public. In addition, Defendants knew and should have known that their false and misleading advertising created a false or misleading impression of the risks and benefits of long-term opioid use and would result in unnecessary and improper opioid prescriptions and use.

132. Pursuant to Business and Professions Code Section 17535, the People request an order enjoining Defendants from any further violations of Section 17500, *et seq*.

133. Pursuant to Business and Professions Code Section 17535, the People request restitution of any money acquired by virtue of Defendants' violations of Section 17500, *et seq*.

134. Pursuant to Business and Professions Code Section 17536, the People request an order assessing a civil penalty of two thousand five hundred dollars ($2,500) against Defendants for each violation of Section 17500, *et seq*.

SECOND CAUSE OF ACTION

UNFAIR COMPETITION
Violations of Business and Professions Code Section 17200, *et seq.*

(Against all Defendants)

135. The People reallege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

136. Each Defendant is named in this Cause of Action for its activities that occurred within four years of the filing of this action.

137. Business and Professions Code Section 17200 (Section 17200) prohibits any "unlawful, unfair or fraudulent business act or practice[]." Defendants have engaged in unlawful, unfair, and fraudulent business practices in violation of Section 17200 as set forth above.

138. Defendants' business practices as described in this Complaint are deceptive and violate Section 17200 because the practices are likely to deceive consumers in California.

139. Defendants knew and should have known at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were false and misleading and therefore likely to deceive the public. Defendants' omissions, which are deceptive and misleading in their own right, render even Defendants' seemingly truthful statements

about opioids false and misleading. All of this conduct, separately and collectively, was likely to deceive California payors who purchased, or covered the purchase of, opioids for chronic pain.

140. Defendants' business practices as describe in this Complaint are unlawful and violate Section 17200. These unlawful practices include, but are not limited to:

a. Defendants falsely advertised opioids in violation of the Sherman Food, Drug, and Cosmetic Laws, HEALTH & SAFETY CODE § 110390;

b. Defendants manufactured, sold, delivered, held, or offered for sale opioids that had been falsely advertised in violation of the Sherman Food, Drug, and Cosmetic Laws, HEALTH & SAFETY CODE § 110395;

c. Defendants advertised misbranded opioids in violation of the Sherman Food, Drug, and Cosmetic Laws, HEALTH & SAFETY CODE §§ 110290, 110398, and 111330;

d. Defendants received in commerce opioids that were falsely advertised or delivered or proffered for delivery opioids that were falsely advertised in violation of the Sherman Food, Drug, and Cosmetic Laws, HEALTH & SAFETY CODE § 110400;

e. Defendants manufactured, sold, delivered, held, or offered for sale opioids that had been misbranded in violation of the Sherman Food, Drug, and Cosmetic Laws, HEALTH & SAFETY CODE §§ 110290, 111440, and 111330;

f. Defendants misbranded opioids in violation of the Sherman Food, Drug, and Cosmetic Laws, HEALTH & SAFETY CODE §§ 110290, 111445, 111330;

g. Defendants received in commerce opioids that were misbranded in violation of the Sherman Food, Drug, and Cosmetic Laws, HEALTH & SAFETY CODE §§ 110290, 111450, and 111330;

h. Defendants proffered for delivery opioids that were misbranded in violation of the Sherman Food, Drug, and Cosmetic Laws, HEALTH & SAFETY CODE §§ 110290, 111450, and 111330;

i. Defendants failed to adopt and comply with a Comprehensive Compliance Program in violation of HEALTH & SAFETY CODE § 119402;

j. Defendants represented that opioids had sponsorship, approval, characteristics, ingredients, uses, or benefits which they did not have in violation of the Consumer Legal Remedies Act, CIV. CODE § 1770(a)(5);

k. Defendants represented that opioids were of a particular standard, quality, or grade when they were of another in violation of Consumer Legal Remedies Act, CIV. CODE § 1770(a)(7);

l. Defendants disparaged the goods of another by false or misleading representation of fact in violation of Consumer Legal Remedies Act, CIV. CODE § 1770(a)(8);

m. Defendants Purdue and Endo unlawfully failed to identify and report suspicious prescribing to law enforcement and health authorities; and

n. Defendants made or disseminated, directly or indirectly, untrue, false, or misleading statements about the use of opioids to treat chronic pain, or causing untrue, false, or misleading statements about opioids to be made or disseminated to the general public in violation of Section 17500.

o. Defendant Purdue directly or indirectly offered or paid remuneration to doctors to prescribe its opioid products in violation of WELFARE & INSTITUTIONS CODE § 14107.2,

141. Defendants' business practices as described in this Complaint are unfair and violate Section 17200 because they offend established public policy, and because the harm they cause to consumers in California greatly outweighs any benefits associated with those practices.

142. As a direct and proximate result of the foregoing acts and practices, Defendants have received, or will receive, income, profits, and other benefits, which they would not have received if they had not engaged in the violations of Section 17200 described in this Complaint. The People therefore seek restitution from Defendants pursuant to Business & Professions Code Section 17535.

143. As a direct and proximate result of the foregoing acts and practices, Defendants have obtained an unfair advantage over similar businesses that have not engaged in such practices.

144. Each time a Defendant marketed opioids in violation of Section 17200 constitutes a separate violation. BUS. & PROF. CODE § 17206(b). The People therefore seek civil penalties up to $2,500 per violation pursuant to Section 17206 for each violation of Section 17200. The People also seek civil penalties up to $2,500 per violation under Section 17206.1.

THIRD CAUSE OF ACTION

PUBLIC NUISANCE
Violations of California Civil Code Sections 3479 and 3480

(Against All Defendants)

145. The People reallege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

146. Civil Code Section 3479 provides that "[a]nything that is injurious to health … 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 … is a nuisance."

147. Civil Code Section 3480 defines a "public nuisance" as "one 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."

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

149. Pursuant to Section 731 of the Civil Code, this action is brought by the People to abate the public nuisance created by the Defendants.

150. Each Defendant, acting individually and in concert, has created or assisted in the creation of a condition that is injurious to the health and interferes with the comfortable enjoyment of life and property of entire communities or neighborhoods or of any considerable number of persons in Santa Clara and Orange Counties in violation of Civil Code Sections 3479 and 3480.

151. The public nuisance is substantial and unreasonable. Defendants' actions caused and continue to cause the public health epidemic described above in Santa Clara and Orange Counties, and that harm outweighs any offsetting benefit.

152. Defendants knew and should have known that their promotion of opioids was false and misleading and that their deceptive marketing scheme and other unlawful, unfair, and fraudulent actions would create or assist in the creation of the public nuisance – i.e., the opioid epidemic.

153. Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used. Defendants' actions were, at the very least, a substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.

154. The public nuisance – i.e., the opioid epidemic – created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated.

155. Pursuant to Code of Civil Procedure § 731, the People request an order providing for abatement of the public nuisance that Defendants created or assisted in the creation of, and enjoining Defendants from future violations of Civil Code §§ 3479 and 3480.

VI. PRAYER FOR RELIEF

THE PEOPLE pray that the Court:

156. Declare that Defendants have made, disseminated as part of a plan or scheme, or aided and abetted the dissemination of false and misleading statements in violation of the False Advertising Law.

157. Enjoin Defendants from performing or proposing to perform any further false or misleading statements in violation of the False Advertising Law. Any injunctive relief the People may obtain against Purdue in this action shall not be duplicative of any injunctive terms that remain in place from the Final Judgment.

158. Order Defendants to pay restitution of any money acquired by Defendants' false and misleading advertising, pursuant to Business and Professions Code Sections 17500 and 17535.

159. Order Defendants to pay civil penalties for each act of false and misleading advertising, pursuant to Business and Professions Code Sections 17500 and 17536.

160. Declare that Defendants have engaged in unlawful, unfair, and deceptive business acts and practices in violation of the Unfair Competition Law.

161. Enjoin Defendants from performing or proposing to perform any acts in violation of the Unfair Competition Law. Any injunctive relief the People may obtain against Purdue in this action shall not be duplicative of any injunctive terms that remain in place from the Final Judgment.

162. Order Defendants to pay restitution of any money acquired by Defendants' unlawful, unfair, and deceptive business practices, pursuant to Business and Professions Code Section 17203.

163. Order Defendants to pay civil penalties for each act of unfair and unlawful competition, pursuant to Business and Professions Code Section 17206.

164. Order Defendants to pay civil penalties for each act of unfair and unlawful competition perpetrated against senior citizens or disabled persons, pursuant to Business and Professions Code Section 17206.1.

165. Order Defendants to pay treble the amount of all relief awarded by the Court, pursuant to Civil Code Section 3345.

166. Declare that Defendants have created a public nuisance in violation of Civil Code Sections 3479 and 3480.

167. Enjoin Defendants from performing any further acts in violation of Civil Code Sections 3479 and 3480.

168. Order Defendants to abate the public nuisance that they created in violation of Civil Code Sections 3479 and 3480.

169. Order Defendants to pay the cost of the suit, including attorneys' fees.

170. Provide such further and additional relief as the Court deems proper.

DATED: July 6, 2017.

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SUPERIOR COURT OF CALIFORNIA, COUNTY OF ORANGE

PROOF OF SERVICE

The People of the State of California v. Purdue Pharma, L.P., et al. 30-2014-00725287-CU-BT-CXC

I, Tam Lobach, say:

I am employed in the County of Santa Clara, State of California. I am over the age of 18, and not a party to the within action. My business address is 70 West Hedding Street, East Wing, 9th Floor, San Jose, California 95110-1770. On the date shown below, I served the foregoing document described as: **FOURTH AMENDED COMPLAINT FOR VIOLATIONS OF CALIFORNIA FALSE ADVERTISING LAW, CALIFORNIA UNFAIR COMPETITION LAW, AND PUBLIC NUISANCE, SEEKING RESTITUTION, CIVIL PENALTIES, ABATEMENT, AND INJUNCTIVE RELIEF** by placing a true copy thereof enclosed in a sealed envelope addressed as stated on the attached mailing list as follows:

_X_ (By Electronic Service www.onelegal.com) I caused each document to be sent by electronic transmission through One Legal, LLC, through the user interface at *www.onelegal.com* to all email addresses on the list maintained by One Legal.

_X_ STATE: I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on July 6, 2017, at San Jose, California.

Tam Lobach

I. SERVICE LIST

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Orange County Superior Court Case No. 30-2014-00725287-CU-BT-CXC

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