

1 **OFFICE OF THE COUNTY COUNSEL**
2 **COUNTY OF SANTA CLARA**

3 James R. Williams (SBN 271253)
4 Greta S. Hansen (SBN 251471)
5 Kavita Narayan (SBN 264191)
6 Laura S. Trice (SBN 284837)
7 Julia Spiegel (SBN 292469)
8 Lynnette K. Miner (SBN 304276)
9 70 West Hedding Street
10 East Wing, 9th Floor
11 San Jose, California 95110
12 Telephone: (408) 299-5900
13 Facsimile: (408) 292-7240

ORANGE COUNTY DISTRICT
ATTORNEY

Tony Rackauckas (SBN 51374)
Scott Zidbeck (SBN 150905)
Tracy Hughes (SBN 180494)
Joseph D'Agostino (SBN 115774)
401 Civic Center Drive
Santa Ana, CA 92701-4575
Telephone: (714) 834-3600
Facsimile: (714) 648-3636

8 **OFFICE OF THE COUNTY COUNSEL**
9 **COUNTY OF LOS ANGELES**

10 Mary C. Wickham (SBN 145664)
11 Robert E. Ragland (SBN 175357)
12 Scott Kuhn (SBN 190517)
13 Andrea Ross (SBN 179398)
14 Kenneth Hahn Hall of Administration
15 500 West Temple Street, 6th Fl.
16 Los Angeles, California 90012
17 Telephone: (213) 974-1811
18 Facsimile: (213) 626-7446

OFFICE OF THE CITY ATTORNEY
CITY OF OAKLAND

Barbara J. Parker (SBN 069722)
Maria Bee (SBN 167716)
Erin Bernstein (SBN 231539)
Malia McPherson (SBN 313918)
One Frank H. Ogawa Plaza, 6th Floor
Oakland, California 94612
Telephone: (510) 238-6392
Facsimile: (510) 238-6500

14 *[Additional Counsel Listed on Signature Page]*

15 **SUPERIOR COURT OF THE STATE OF CALIFORNIA**

16 **IN AND FOR THE COUNTY OF ORANGE**

17 THE PEOPLE OF THE STATE OF
18 CALIFORNIA, acting by and through Santa
19 Clara County Counsel James R. Williams,
20 Orange County District Attorney Tony
21 Rackauckas, Los Angeles County Counsel Mary
22 C. Wickham, and Oakland City Attorney Barbara
23 J. Parker,

Plaintiff,

v.

24 PURDUE PHARMA L.P.; PURDUE PHARMA
25 INC.; THE PURDUE FREDERICK
26 COMPANY, INC.; TEVA
27 PHARMACEUTICAL INDUSTRIES, LTD;
28 TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.; JANSSEN
PHARMACEUTICA, INC. n/k/a JANSSEN

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

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

Judge: Honorable Kim G. Dunning
Department: CX104

1 PHARMACEUTICALS, INC.; ENDO HEALTH
SOLUTIONS INC.; ENDO
2 PHARMACEUTICALS, INC.; ACTAVIS PLC;
ACTAVIS, INC.; WATSON,
3 PHARMACEUTICALS, INC. n/k/a ACTAVIS,
INC.; WATSON LABORATORIES, INC.;
4 ACTAVIS LLC; and ACTAVIS PHARMA,
INC. f/k/a WATSON PHARMA, INC.; AND
5 DOES 1 THROUGH 100, INCLUSIVE,
Defendants.

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1 **I. INTRODUCTION**

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

7 2. In the late 1990s, however, and continuing today, each Defendant began a
8 sophisticated marketing scheme premised on deception to persuade doctors and patients that
9 opioids can and should be used to treat chronic pain. Each Defendant spent, and some continue to
10 spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the
11 risks of opioids and overstate the benefits of opioids. As to the risks, Defendants falsely and
12 misleadingly: (1) downplayed the serious risk of addiction;² (2) promoted the concept of
13 “pseudoaddiction,” claiming that the signs of addiction should be treated with more opioids;
14 (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid
15 dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and
16 (6) exaggerated the effectiveness of abuse-deterrent opioid formulations to prevent abuse and
17 addiction. Defendants also falsely touted the benefits of long-term opioid use, including its
18 supposed ability to improve function and quality of life, even though there was no “good evidence”
19 to support those benefits.

20 3. Each Defendant knew that its longstanding and ongoing misrepresentations of the
21 risks and benefits of opioids were not supported by or were directly contrary to the scientific
22 evidence. Indeed, the falsity of each Defendant’s misrepresentations has been confirmed by the
23 U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention
24 (CDC), including by the CDC in its *Guideline for Prescribing Opioids for Chronic Pain*, issued in
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26 _____
¹ In this Complaint, “chronic pain” means non-cancer pain lasting three months or longer.

27 ² Addiction is classified as a spectrum of “substance use disorders” that range from misuse
28 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.

1 2016 and approved by the FDA (2016 CDC Guideline). Yet even now, each Defendant continues
2 to misrepresent the risks and benefits of long-term opioid use in California, and continues to fail to
3 correct its past misrepresentations.

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

16 5. The explosion in opioid prescriptions and use caused by Defendants has led to a
17 public health crisis in California. California faces skyrocketing opioid addiction and opioid-related
18 overdoses and deaths as well as devastating social and economic consequences. This public health
19 crisis is a public nuisance because it “is injurious to health” and interferes “with the comfortable
20 enjoyment of life and property” (Civ. Code, § 3479) and because it affects “entire communit[ies]”
21 and “neighborhood[s]” and “any considerable number of persons” (*id.*, § 3480). The effects of each
22 Defendant’s deceptive marketing scheme are catastrophic and are only getting worse. This is
23 especially so in Santa Clara, Orange and Los Angeles counties, and the City of Oakland. In Orange
24 County, for example, there were 286 overdose deaths in 2015, a 16% increase since 2013. In Los
25 Angeles County, there were nearly 400 overdose deaths involving prescription opioids each year
26

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

1 from 2006 to 2013. In 2016, Oakland’s age adjusted death rate from prescription opioid overdose
2 was approximately 4.3 per 100,000 residents, higher than the state average of 3.43 deaths per
3 100,000 residents; in some neighborhoods, deaths were as high as 10.21 per 100,000 residents. In
4 Oakland, the opioid epidemic has disproportionately affected communities of color, and the City’s
5 African American residents experience the adverse effects of addiction and overdose at
6 significantly higher rates.

7 6. As the FDA acknowledged in February 2016, “[t]hings are getting worse, not better,
8 with the epidemic of opioid misuse, abuse and dependence.”⁴

9 7. There is little doubt that each Defendant’s deceptive marketing scheme has
10 precipitated this public health crisis in California, including Santa Clara, Orange and Los Angeles
11 counties, and the City of Oakland, by dramatically increasing opioid prescriptions and use. An
12 oversupply of prescription opioids has provided a source for illicit use or sale of opioids (the
13 supply), while the widespread use of opioids has created a population of patients physically and
14 psychologically dependent on them (the demand). And when those patients can no longer afford or
15 legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin.

16 8. The role of Defendants’ deceptive marketing scheme in causing this public health
17 crisis has become well-recognized in recent years. In her May 2014 testimony to the Senate Caucus
18 on International Narcotics Control on behalf of the National Institutes of Health (NIH), Dr. Nora
19 Volkow explained that “aggressive marketing by pharmaceutical companies” is “likely to have
20 contributed to the severity of the current prescription drug abuse problem.”⁵ And in August 2016,
21 the former U.S. Surgeon General expressly connected the “urgent health crisis” to “heavy
22 marketing of opioids to doctors [m]any of [whom] were even taught – incorrectly – that
23

24
25 ⁴ *Califf, FDA top officials call for sweeping review of agency opioids policies*, FDA News
26 Release (Feb. 4, 2016), available at
27 <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm>.

28 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].

1 opioids are not addictive when prescribed for legitimate pain.”⁶ California doctors, addiction
2 treatment specialists, and law enforcement and public health officials confirm that prescription
3 opioids lawfully prescribed by doctors have fueled this epidemic.

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

7 10. By falsely downplaying the risks and grossly exaggerating the benefits of long-term
8 opioid use through their deceptive marketing claims despite their knowledge of the falsity of those
9 claims, Defendants have not only engaged in false advertising and unfair competition, they have
10 also created or assisted in the creation of a public nuisance.⁷ Although this Complaint focuses on
11 Defendants’ misconduct during the past six years and only references their earlier misconduct,
12 every act of malfeasance committed by each Defendant since the late 1990s as part of its deceptive
13 marketing scheme subjects that Defendant to liability for public nuisance because there is no
14 statute of limitations for a public nuisance claim. (See Civ. Code, § 3490 [“No lapse of time can
15 legalize a public nuisance, amounting to an actual obstruction of public right”]; *Wade v. Campbell*
16 (1962) 200 Cal.App.2d 54, 61 [“the maintenance of a public nuisance may not be defended on the
17 ground of laches or the statute of limitations”].)

18 11. Accordingly, Defendants’ conduct, both individually and collectively, has violated
19 and continues to violate the False Advertising Law, Bus. & Prof. Code, §§ 17500 et seq., the
20 Unfair Competition Law, Bus. & Prof. Code, §§ 17200 et seq.,⁸ and the Public Nuisance Law, Civ.
21 Code, §§ 3479 and 3480. The People of the State of California do not seek to limit the ability of
22

23 _____
24 ⁶ Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at
<http://turnthetidex.org/>.

25 ⁷ (See *County of Santa Clara v. Atlantic Richfield Co.* (2006) 137 Cal.App.4th 292, 306
26 [holding that plaintiffs “have adequately alleged that defendants are liable for the abatement of this
27 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”].)

28 ⁸ The claim under Bus. & Prof. Code §§ 17200 et seq. is asserted by the People only
through the Orange County District Attorney.

1 doctors in California to prescribe opioids. The People also do not ask this Court to weigh the risks
2 and benefits of long-term opioid use. Instead, the People seek an order requiring Defendants to
3 cease their unlawful promotion of opioids, to correct their misrepresentations, and to abate the
4 public nuisance they have created. To redress and punish Defendants' previous and current
5 violations of law, the People seek a judgment requiring Defendants to pay civil penalties, and any
6 fees or costs permitted under law.

7 **II. PARTIES**

8 **A. Plaintiff**

9 12. James R. Williams, County Counsel for the County of Santa Clara, Tony
10 Rackauckas, District Attorney for the County of Orange, Mary C. Wickham, County Counsel for
11 the County of Los Angeles, and Barbara J. Parker, City Attorney for the City of Oakland bring this
12 action on behalf of the People of the State of California (People) to protect the public from false
13 and misleading advertising, unlawful, unfair, and fraudulent business practices, and a public
14 nuisance.

15 **B. Defendants**

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

20 14. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin,
21 MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER,⁹ and Targiniq ER in the U.S. and
22 California. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of
23 OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006
24

25
26
27 ⁹ Long-acting or extended release (ER or ER/LA) opioids are designed to be taken once or
28 twice daily. Short-acting opioids, also known as immediate release (IR) opioids, last for
approximately 4-6 hours.

1 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs
2 (painkillers).

3 15. In May 2007, Purdue entered into a stipulated final judgment with the People of the
4 State of California, acting by and through the California Attorney General (Purdue Final
5 Judgment), based principally on Purdue's direct promotion of OxyContin up to May 8, 2007, the
6 effective date of the Final Judgment. The People do not seek, through this Complaint, to enforce
7 any provision of the Purdue Final Judgment, and are not seeking any relief against Purdue under
8 any state consumer protection law as defined by section (I)(1)(M) and footnote 1 of the Final
9 Judgment based on any conduct by Purdue that occurred at any time up to and including May 8,
10 2007 relating to Purdue's promotional and marketing practices regarding OxyContin. The People
11 do, however, assert claims arising under California law independent of the Purdue Final Judgment,
12 and seek penalties, in addition to injunctive relief, as afforded by those laws.

13 16. CEPHALON, INC. is a Delaware corporation with its principal place of business in
14 Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. (Teva Ltd.) is an Israeli
15 corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired
16 Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. (Teva USA) is a wholly-owned
17 subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in
18 Pennsylvania. Teva USA acquired Cephalon in October 2011.

19 17. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq
20 and Fentora in the U.S. and California. Actiq and Fentora have been approved by the FDA only for
21 the "management of breakthrough cancer pain in patients 16 years of age and older who are already
22 receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."¹⁰ In
23 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for
24 its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million.

25 18. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell
26 Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for

27 _____
28 ¹⁰ Breakthrough pain is a short-term flare of moderate-to-severe pain in patients with
otherwise stable persistent pain.

1 Cephalon in the United States through Teva USA and has done so since its October 2011
2 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to
3 the public. Teva USA sells all former Cephalon branded products through its “specialty medicines”
4 division. The FDA-approved prescribing information and medication guide, which is distributed
5 with Cephalon opioids marketed and sold in California, discloses that the guide was submitted by
6 Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has
7 directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription
8 savings cards distributed in California, indicating Teva Ltd. would be responsible for covering
9 certain co-pay costs. All of Cephalon’s promotional websites, including those for Actiq and
10 Fentora, prominently display Teva Ltd.’s logo. Teva Ltd.’s financial reports list Cephalon’s and
11 Teva USA’s sales as its own, and its year-end report for 2012—the year immediately following the
12 Cephalon acquisition—attributed a 22% increase in its specialty medicine sales to “the inclusion of
13 a full year of Cephalon’s specialty sales.” Through interrelated operations like these, Teva Ltd.
14 operates in California and the rest of the United States through its subsidiaries Cephalon and Teva
15 USA. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its global
16 revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd.
17 would conduct those companies’ business in the United States itself. Upon information and belief,
18 Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the
19 benefit of Teva Ltd. as controlling shareholder. (Teva Pharmaceutical Industries, Ltd., Teva
20 Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as “Cephalon.”)

21 19. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its
22 principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of
23 JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in
24 New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now
25 known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of
26 business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as Janssen
27 Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in
28 Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen

1 Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon
2 information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs
3 and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen
4 Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as "Janssen.").

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

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

14 22. Endo develops, markets, and sells prescription drugs, including the opioids
15 Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and California. Opioids made up
16 roughly \$403 million of Endo's overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15
17 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012.
18 Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone,
19 hydromorphone, and hydrocodone products in the U.S. and California, by itself and through its
20 subsidiary, Qualitest Pharmaceuticals, Inc.

21 23. ALLERGAN PLC is a public limited company incorporated in Ireland with its
22 principal place of business in Dublin, Ireland. ACTAVIS PLC acquired Allergan plc in March
23 2015, and the combined company changed its name to Allergan plc in January 2013. Before that,
24 WATSON PHARMACEUTICALS, INC. acquired Actavis, Inc. in October 2012, and the
25 combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis plc in
26 October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place
27 of business in Corona, California, and is a wholly-owned subsidiary of Allergan plc (f/k/a Actavis,
28 Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a

1 Delaware corporation with its principal place of business in New Jersey, and was formerly known
2 as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its
3 principal place of business in Parsippany, New Jersey. Each of these defendants is owned by
4 Allergan plc, which uses them to market and sell its drugs in the United States. Upon information
5 and belief, Allergan plc exercises control over these marketing and sales efforts and profits from
6 the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan plc, Actavis plc,
7 Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma,
8 Inc., and Watson Laboratories, Inc. are referred to as “Actavis.”)

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

13 25. Plaintiff is ignorant of the true names or capacities, whether individual, corporate or
14 otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive,
15 and they are therefore sued herein pursuant to Code of Civil Procedure § 474. Plaintiff will amend
16 this Complaint to show their true names and capacities if and when they are ascertained. Plaintiff is
17 informed and believes, and on such information and belief alleges, that each of the Defendants
18 named as a DOE is responsible in some manner for the events and occurrences alleged in this
19 Complaint and is liable for the relief sought herein.

20 **III. JURISDICTION AND VENUE**

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

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

1 **IV. FACTUAL ALLEGATIONS**

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

9 29. To take advantage of the much larger and more lucrative market for chronic pain
10 patients, Defendants had to change this. Each Defendant developed a well-funded marketing
11 scheme based on deception. Each Defendant targeted susceptible prescribers and vulnerable patient
12 populations. Each Defendant used both direct marketing and unbranded advertising disseminated
13 by seemingly independent third parties to spread false and misleading statements about the risks
14 and benefits of long-term opioid use. These statements were not only unsupported by or contrary to
15 the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA
16 and CDC based on that same evidence. California doctors, including doctors in Santa Clara
17 County, confirm that Defendants began their marketing schemes decades ago and continue them
18 today. And the 2016 CDC Guideline makes it patently clear that their schemes were and continue
19 to be deceptive.

20 **A. Defendants Targeted Susceptible Prescribers And Vulnerable Patient Populations.**

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

23 31. For example, Defendants focused their deceptive marketing on primary care
24 doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were
25 less likely to be schooled in treating pain and the risks and benefits of opioids and therefore more
26 likely to accept Defendants’ misrepresentations. Interviews with California doctors, including
27

1 doctors in Santa Clara County, confirm that Defendants’ deceptive marketing scheme has long
2 targeted and continues to target primary care doctors in California.

3 32. Defendants also targeted vulnerable patient populations like the elderly and
4 veterans, who tend to suffer from chronic pain. Defendants targeted these vulnerable patients even
5 though the risks of long-term opioid use were significantly greater for them. For example, the 2016
6 CDC Guideline observed that existing evidence showed that elderly patients taking opioids suffer
7 from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to
8 adverse drug effects and interactions. The Guideline therefore concluded that there are “special
9 risks of long-term opioid use for elderly patients” and recommended that doctors use “additional
10 caution and increased monitoring” to minimize the risks of opioid use in elderly patients. The same
11 is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-
12 traumatic stress disorder, which interact dangerously with opioids.

13 **B. Defendants Used Multiple Avenues To Disseminate Their False And Misleading**
14 **Statements About Opioids.**

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

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

21 34. Defendants’ direct marketing of opioids generally proceeded on two tracks. First,
22 each Defendant conducted and continues to conduct advertising campaigns touting the purported
23 benefits of their branded drugs. For example, Defendants spent more than \$14 million on medical
24 journal advertising of opioids in 2011, nearly triple what they spent in 2001. This amount included
25 \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

26 35. A number of Defendants’ branded ads deceptively portrayed the benefits of opioids
27 for chronic pain. For example, since at least May 21, 2011, Endo has distributed and made
28 available on its website opana.com a pamphlet promoting Opana ER with photographs depicting

1 patients with physically demanding jobs like construction worker and chef, misleadingly implying
2 that the drug would provide long-term pain-relief and functional improvement. Purdue also ran a
3 series of ads, called “Pain vignettes,” for OxyContin in 2012 in medical journals. These ads
4 featured chronic pain patients and recommended OxyContin for each. One ad described a “54-year-
5 old writer with osteoarthritis of the hands” and implied that OxyContin would help the writer work
6 more effectively.

7 36. Second, each Defendant promoted the use of opioids for chronic pain through
8 “detailers” – sales representatives who visited individual doctors and medical staff in their offices –
9 and small group speaker programs. For example, from mid-2013 through 2015, Purdue, Janssen,
10 and Endo detailed at least 6,238, 584, and 195 prescribers in California respectively. Purdue itself
11 was responsible for more than 1 out of every 3 reported opioid-related detailing visits in California
12 by Defendants.

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

- 18 a. Describe the risk of addiction as low or fail to disclose the risk of addiction;
- 19 b. Describe their opioid products as “steady state” – falsely implying that these
20 products are less likely to produce the high and lows that fuel addiction – or
21 as less likely to be abused or result in addiction;
- 22 c. Tout the effectiveness of screening or monitoring patients as a strategy for
23 managing opioid abuse and addiction;
- 24 d. State that there is no maximum dose and that doctors can safely increase
25 doses without disclosing the significant risks to patients at higher doses;
- 26 e. Discuss “pseudoaddiction”;
- 27 f. State that patients would not experience withdrawal if they stopped using
28 their opioid products;

- 1 g. State that their opioid products are effective for chronic pain without
2 disclosing the lack of evidence for the effectiveness of long-term opioid use;
3 and
4 h. State that abuse-deterrent formulations are tamper- or crush-resistant and
5 harder to abuse or misuse.
6

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

11 39. Defendants¹¹ also identified doctors to serve, for payment, on their speakers'
12 bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker
13 programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be
14 selected to promote the drug); (2) recognition and compensation for the doctors selected as
15 speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These
16 speakers give the false impression that they are providing unbiased and medically accurate
17 presentations when they are, in fact, presenting a script prepared by Defendants. On information
18 and belief, these presentations conveyed misleading information, omitted material information, and
19 failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

20 40. Each Defendant devoted and continues to devote massive resources to direct sales
21 contacts with doctors. In 2014 alone, Defendants spent \$168 million on detailing branded opioids
22 to doctors. This amount is twice as much as Defendants spent on detailing in 2000. The amount
23 includes \$108 million spent by Purdue, \$34 million by Janssen, \$13 million by Cephalon, \$10
24 million by Endo, and \$2 million by Actavis.
25
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28 ¹¹ Upon information and belief, Actavis continued to carry out speaker programs after it
acquired Kadian.

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

7 42. Defendants’ detailers have been reprimanded for their deceptive promotions. A July
8 2010 “Dear Doctor” letter mandated by the FDA required Actavis to acknowledge to the doctors to
9 whom it marketed its drugs that “[b]etween June 2009 and February 2010, Actavis sales
10 representatives distributed . . . promotional materials that . . . omitted and minimized serious risks
11 associated with [Kadian],” including the risk of “[m]isuse, [a]buse, and [d]iversion of [o]pioids”
12 and, specifically, the risk that “[o]pioid[s] have the potential for being abused and are sought by
13 drug abusers and people with addiction disorders and are subject to criminal diversion.”

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

16 43. Defendants also deceptively marketed opioids in California through unbranded
17 advertising – i.e., advertising that promotes opioid use generally but does not name a specific
18 opioid. This advertising was ostensibly created and disseminated by independent third parties. But
19 by funding, directing, reviewing, editing, and distributing this unbranded advertising, Defendants
20 controlled the deceptive messages disseminated by these third parties and acted in concert with
21 them to falsely and misleadingly promote opioids for the treatment of chronic pain.¹²

22 44. Defendants marketed through third-party, unbranded advertising to avoid regulatory
23 scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA.
24 Defendants also used third-party, unbranded advertising to give the false appearance that the
25 deceptive messages came from an independent and objective source. Like tobacco companies,
26 Defendants used third parties that they funded, directed, and controlled to carry out and conceal

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28 ¹² 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.

1 their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use
2 for chronic pain.

3 45. Defendants’ deceptive unbranded marketing often contradicted what they said in
4 their branded materials reviewed by the FDA. For example, Endo’s unbranded advertising
5 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. ”

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

23 47. Pro-opioid doctors are one of the most important avenues that Defendants use to
24 spread their false and misleading statements about the risks and benefits of long-term opioid use.
25 Defendants know that doctors rely heavily and more uncritically on their peers for guidance, and
26 KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For
27 example, the New York Attorney General (NY AG) found in its settlement with Purdue that
28 through March 2015 the Purdue website *In the Face of Pain* failed to disclose that doctors who

1 provided testimonials on the site were paid by Purdue and concluded that Purdue’s failure to
2 disclose these financial connections potentially misled consumers regarding the objectivity of the
3 testimonials. KOLs have written, consulted on, edited, and lent their names to books and articles,
4 and given speeches and CMEs supportive of chronic opioid therapy. Defendants created
5 opportunities for KOLs to participate in research studies Defendants suggested or chose and then
6 cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did not
7 support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic
8 opioid therapy.

9 48. Defendants’ KOLs also served on committees that developed treatment guidelines
10 that strongly encourage the use of opioids to treat chronic pain and on the boards of pro-opioid
11 advocacy groups and professional societies that develop, select, and present CMEs. These
12 guidelines and CMEs were not supported by the scientific evidence at the time they were created,
13 and they are not supported by the scientific evidence today. Defendants were able to direct and
14 exert control over each of these activities through their KOLs. The 2016 CDC Guideline
15 recognizes that treatment guidelines can “change prescribing practices.”

16 49. Defendants also entered into arrangements with seemingly unbiased and
17 independent patient and professional organizations to promote opioids for the treatment of chronic
18 pain. Under the direction and control of Defendants, these “Front Groups” – which include, but are
19 not limited to, the American Pain Foundation (APF) and the American Academy of Pain Medicine
20 – generated treatment guidelines, unbranded materials, and programs that favored chronic opioid
21 therapy. These guidelines, materials, and programs were not supported by the evidence at the time
22 they were created, and they are not supported by the scientific evidence today. Indeed, they stand
23 in marked contrast to the 2016 CDC Guideline. These Front Groups also assisted Defendants by
24 responding to negative articles, by advocating against regulatory changes that would limit opioid
25 prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable
26 patient populations targeted by Defendants.

27 50. These Front Groups depended on Defendants for funding and, in some cases, for
28 survival. Defendants also exercised control over programs and materials created by these groups by

1 collaborating on, editing, and approving their content, and by funding their dissemination. For
2 example, Purdue’s consulting agreement with APF gave it direct, contractual control over APF’s
3 work. In doing so, Defendants made sure that the Groups would generate only the messages
4 Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent
5 and serving the needs of their members – whether patients suffering from pain or doctors treating
6 those patients.

7 51. Defendants worked together, through Front Groups, to spread their deceptive
8 messages about the risks and benefits of long-term opioid therapy. For example, Defendants
9 combined their efforts through the Pain Care Forum (PCF), which began in 2004 as an APF
10 project. PCF is comprised of representatives from opioid manufacturers (including Cephalon,
11 Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial
12 funding from Defendants. Among other projects, PCF worked to ensure that an FDA-mandated
13 education project on opioids was not unacceptably negative and did not require mandatory
14 participation by prescribers, which Defendants determined would reduce prescribing. PCF also
15 worked to address a perceived “lack of coordination” among its members and developed “key”
16 messages that were disseminated in programs and industry-run websites that were available and
17 accessible after May 21, 2011.

18 **C. Defendants’ Marketing Scheme Misrepresented The Risks And Benefits Of Opioids.**

19 52. To convince doctors and patients in California that opioids can and should be used
20 to treat chronic pain, Defendants had to convince them that long-term opioid use is both safe and
21 helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks
22 and benefits of long-term opioid use, Defendants made claims that were not supported by or were
23 contrary to the scientific evidence. Even though pronouncements by and guidance from the FDA
24 and the CDC based on that evidence confirm that their claims were false and misleading,
25 Defendants have not corrected them and continue to spread them today.

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

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

13 54. **First**, Defendants falsely claimed that the risk of addiction is low and that addiction
14 is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to
15 disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of
16 these false and misleading claims that were made by, are continuing to be made by, and/or have not
17 been corrected by Defendants after May 21, 2011 are described below:

- 18 a. Actavis’s predecessor caused a patient education brochure to be distributed in
19 2007 that claimed opioid addiction is possible, but “less likely if you have never
20 had an addiction problem.” Upon information and belief, based on Actavis’s
21 acquisition of its predecessor’s marketing materials along with the rights to
22 Kadian, Actavis continued to use this brochure in 2009 and beyond.
- 21 b. Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for People*
22 *Living with Pain* (2007), which instructed that addiction is rare and limited to
23 extreme cases of unauthorized dose escalations, obtaining duplicative opioid
24 prescriptions from multiple sources, or theft. This publication is still available
25 online.
- 24 c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that
25 “[p]eople who take opioids as prescribed usually do not become addicted.”
26 Another Endo website, PainAction.com, stated “Did you know? Most chronic
27 pain patients do not become addicted to the opioid medications that are
28 prescribed for them.” This website was still available online after May 21, 2011.
- 27 d. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone*
28 *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.”

1 A similar statement appeared on the Endo website www.opana.com – which was
2 accessible online after May 21, 2011.

- 3 e. Janssen reviewed, edited, approved, and distributed a patient education guide
4 entitled *Finding Relief: Pain Management for Older Adults* (2009), which
5 described as “myth” the claim that opioids are addictive, and asserted as fact that
6 “[m]any studies show that opioids are *rarely* addictive when used properly for
7 the management of chronic pain.” This guide is still available online.
- 8 f. Janssen currently runs a website, *Prescriberesponsibly.com* (last updated July 2,
9 2015), which claims that concerns about opioid addiction are “overestimated.”
- 10 g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its*
11 *Management* – which claims that less than 1% of children prescribed opioids
12 will become addicted and that pain is undertreated due to “misconceptions about
13 opioid addiction[.]” This publication is still available online.
- 14 h. Since at least May 21, 2011, detailers for Purdue, Endo, Janssen, and Cephalon
15 in California have minimized or omitted and continue to minimize or omit any
16 discussion with doctors or their medical staff in California, including Santa
17 Clara County, about the risk of addiction; misrepresented the potential for abuse
18 of opioids with purportedly abuse-deterrent formulations; and routinely did not
19 correct the misrepresentations noted above.

20 55. These claims are contrary to longstanding scientific evidence, as the FDA and CDC
21 have conclusively declared. As noted in the 2016 CDC Guideline approved by the FDA, there is
22 “extensive evidence” of the “possible harms of opioids (including opioid use disorder [an
23 alternative term for opioid addiction]).” The Guideline points out that “[o]pioid pain medication
24 use presents serious risks, including . . . opioid use disorder” and that “continuing opioid therapy
25 for 3 months substantially increases risk for opioid use disorder.” (Emphasis added.)

26 56. The FDA further exposed the falsity of Defendants’ claims about the low risk of
27 addiction when it announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in
28 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

1 the risk is not limited to patients who seek drugs illicitly; addiction “can occur in patients
2 appropriately prescribed [opioids].”

3 57. Thus, the warnings on Defendants’ own FDA-approved drug labels caution that
4 opioids “expose[] users to risks of addiction, abuse and misuse, which can lead to overdose and
5 death,” that the drugs contain “a substance with a high potential for abuse,” and that addiction “can
6 occur in patients appropriately prescribed” opioids. (Emphasis added.)

7 58. **Second**, Defendants falsely instructed doctors and patients that the signs of
8 addiction are actually signs of undertreated pain and should be treated by prescribing more opioids.
9 Defendants called this phenomenon “pseudoaddiction” – a term coined by Dr. David Haddox, who
10 went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Cephalon, Endo,
11 Janssen, and Purdue – and falsely claimed that pseudoaddiction is substantiated by scientific
12 evidence. Some illustrative examples of these deceptive claims that were made by, are continuing
13 to be made by, and/or have not been corrected by Defendants after May 21, 2011 – are described
14 below:

- 15 a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which
16 taught that behaviors such as “requesting drugs by name”, “demanding or
17 manipulative behavior,” seeing more than one doctor to obtain opioids, and
18 hoarding, are all signs of pseudoaddiction, rather than true addiction.
19 *Responsible Opioid Prescribing* remains for sale online. Endo also distributed
20 this document before and after May 21, 2011.
- 21 b. Janssen sponsored, funded, and edited the *Let’s Talk Pain* website, which in
22 2009 stated: “pseudoaddiction . . . refers to patient behaviors that may occur
23 when *pain is under-treated* Pseudoaddiction is different from true addiction
24 because such behaviors can be resolved with effective pain management.” This
25 website was accessible online until May 2012.
- 26 c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in
27 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing*
28 *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.

- 1 e. Purdue sponsored a CME program entitled *Path of the Patient, Managing*
2 *Chronic Pain in Younger Adults at Risk for Abuse* in 2011. In a role play, a
3 chronic pain patient with a history of drug abuse tells his doctor that he is taking
4 twice as many hydrocodone pills as directed. The narrator notes that because of
5 pseudoaddiction, the doctor should not assume the patient is addicted even if he
6 persistently asks for a specific drug, seems desperate, hoards medicine, or
7 “overindulges in unapproved escalating doses.” The doctor treats this patient by
8 prescribing a high-dose, long-acting opioid. This CME program was still
9 available after May 21, 2011.
- 6 f. Before and after May 21, 2011, detailers for Purdue have directed doctors and
7 their medical staffs in California, including Santa Clara County, to
8 PartnersAgainstPain.com, which contained false and misleading materials
9 describing pseudoaddiction.
- 10 g. Purdue sponsored APF’s *Treatment Options: A Guide for People Living with*
11 *Pain* (2007), which states: “Pseudo-addiction describes patient behaviors that
12 may occur when *pain is undertreated* . . . Pseudo-addiction can be distinguished
13 from true addiction in that this behavior ceases when pain is effectively treated.”
14 (emphasis added.) This publication is still available online.

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

18 60. **Third**, Defendants falsely instructed doctors and patients that addiction risk
19 screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably
20 identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations
21 were especially insidious because Defendants aimed them at general practitioners and family
22 doctors who lack the time and expertise to closely manage higher-risk patients on opioids.
23 Defendants’ misrepresentations made these doctors feel more comfortable prescribing opioids to
24 their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some
25 illustrative examples of these deceptive claims that were made by, are continuing to be made by,
26 and/or have not been corrected by Defendants after March 21, 2011 are described below:

- 27 a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a
28 doctor who became a member of Endo’s speakers bureau in 2010. The

1 supplement, entitled *Pain Management Dilemmas in Primary Care: Use of*
2 *Opioids*, emphasized the effectiveness of screening tools, claiming that patients
3 at high risk of addiction could safely receive chronic opioid therapy using a
4 “maximally structured approach” involving toxicology screens and pill counts.

- 5 b. Purdue sponsored a November 2011 webinar, *Managing Patient’s Opioid Use:*
6 *Balancing the Need and Risk*, which claimed that screening tools, urine tests,
7 and patient agreements prevent “overuse of prescriptions” and “overdose
8 deaths.”
- 9 c. As recently as 2015, Purdue has represented in scientific conferences that “bad
10 apple” patients – and not opioids – are the source of the addiction crisis and that
11 once those “bad apples” are identified, doctors can safely prescribe opioids
12 without causing addiction.
- 13 d. Since at least May 21, 2011, detailers for Purdue have touted and continue to
14 tout to doctors in California, including Santa Clara County, the reliability and
15 effectiveness of screening or monitoring patients as a tool for managing opioid
16 abuse and addiction.

17 61. Once again, the 2016 CDC Guideline confirms that these statements were false,
18 misleading, and unsupported at the time they were made by Defendants. The Guideline notes that
19 there are no studies assessing the effectiveness of risk mitigation strategies – such as screening
20 tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and
21 deter abuse – “for improving outcomes related to overdose, addiction, abuse, or misuse.” As a
22 result, the Guideline recognizes that available risk screening tools “show insufficient accuracy for
23 classification of patients as at low or high risk for [opioid] abuse or misuse” and counsels that
24 doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid
25 therapy.” (Emphasis added.)

26 62. **Fourth**, to underplay the risk and impact of addiction and make doctors feel more
27 comfortable starting patients on opioids, Defendants falsely claimed that opioid dependence can
28 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

1 might occur. This publication was available on APF’s website until the organization dissolved in
2 May 2012. And detailers for Janssen, since at least May 21, 2011, have told and continue to tell
3 doctors in California, including Santa Clara County, that their patients would not experience
4 withdrawal if they stopped using opioids. Defendants deceptively minimized the significant
5 symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug
6 craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia
7 (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the
8 unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of
9 tapering, particularly after long-term opioid use. Yet the 2016 CDC Guideline recognizes that the
10 duration of opioid use and the dosage of opioids prescribed should be “limit[ed]” to “minimize the
11 need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,” because
12 “physical dependence on opioids is an expected physiologic response in patients exposed to
13 opioids for more than a few days.” (Emphasis added.) The Guideline further states that “tapering
14 opioids can be especially challenging after years on high dosages because of physical and
15 psychological dependence” and highlights the difficulties, including the need to carefully identify
16 “a taper slow enough to minimize symptoms and signs of opioid withdrawal” and to “pause[] and
17 restart[]” tapers depending on the patient’s response. The CDC also acknowledges the lack of any
18 “high-quality studies comparing the effectiveness of different tapering protocols for use when
19 opioid dosage is reduced or opioids are discontinued.”

20 63. Numerous California patients struggling with opioid addiction, including patients in
21 Santa Clara County, have described how difficult it is to stop taking prescription opioids due to the
22 extreme withdrawal symptoms. For example, one lawyer who was prescribed opioids for chronic
23 pain was told that she could easily taper off the drugs. After she became addicted, she attempted to
24 stop taking opioids. But she became so sick from withdrawal that she began buying opioids
25 illicitly. Indeed, she even considered using heroin to get through her withdrawal symptoms despite
26 her fear and aversion to injecting an illegal drug. Ultimately, the costs of prescription opioids drove
27 her to seek treatment for her addiction.

1 64. **Fifth**, Defendants falsely claimed that doctors and patients could increase opioid
2 dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher
3 dosages. The ability to escalate dosages was critical to Defendants’ efforts to market opioids for
4 long-term use to treat chronic pain because, absent this misrepresentation, doctors would have
5 abandoned treatment when patients built up tolerance and lower dosages did not provide pain
6 relief. Some illustrative examples of these deceptive claims that were made by, are continuing to be
7 made by, and/or have not been corrected by Defendants after May 21, 2011 are described below:

- 8 a. Actavis’s predecessor created a patient brochure for Kadian in 2007 that stated,
9 “Over time, your body may become tolerant of your current dose. You may
10 require a dose adjustment to get the right amount of pain relief. This is not
11 addiction.” Upon information and belief, based on Actavis’s acquisition of its
12 predecessor’s marketing materials along with the rights to Kadian, Actavis
13 continued to use these materials in 2009 and beyond.
- 14 b. Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for People*
15 *Living with Pain* (2007), which claims that some patients “need” a larger dose of
16 an opioid, regardless of the dose currently prescribed. The guide stated that
17 opioids have “no ceiling dose” and are therefore the most appropriate treatment
18 for severe pain.¹³ This guide is still available for sale online.
- 19 c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that
20 opioid dosages may be increased until “you are on the right dose of medication
21 for your pain.” The website was still accessible online after May 21, 2011.
- 22 d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your*
23 *Pain: Taking Oral Opioid Analgesics*, which was still available after May 21,
24 2011 on Endo’s website. In Q&A format, it asked “If I take the opioid now, will
25 it work later when I really need it?” The response is, “The dose can be
26 increased. . . . You won’t ‘run out’ of pain relief.”
- 27 e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain*
28 *Management for Older Adults* (2009), which was distributed by its sales force.
This guide listed dosage limitations as “disadvantages” of other pain medicines
but omitted any discussion of risks of increased opioid dosages. This guide is
still available online.

24 ¹³ Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of
25 a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs).
26 Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from
27 opioids. (See e.g., *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo)
28 [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].)

- 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.

65. 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.

66. 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

67. **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.

1 68. These abuse deterrent formulations (AD opioids) are harder to crush, chew, or
2 grind; become gelatinous when combined with a liquid, making them harder to inject; or contain a
3 counteragent such as naloxone that is activated if the tablets are tampered. Despite this, AD opioids
4 are not “impossible to abuse.”¹⁴ They can be defeated – often quickly and easily – by those
5 determined to do so. Moreover, they do not stop oral intake, the most common avenue for opioid
6 misuse and abuse, and do not reduce the rate of misuse and abuse by patients who become addicted
7 after using opioids long-term as prescribed or who escalate their use by taking more pills or higher
8 doses.

9 69. Because of these significant limitations on AD opioids and because of the
10 heightened risk for misconceptions and for the false belief that AD opioids can be prescribed
11 safely, the FDA has cautioned that “[a]ny communications from the sponsor companies regarding
12 AD properties must be truthful and not misleading (based on a product’s labeling), and supported
13 by sound science taking into consideration the totality of the data for the particular drug. Claims for
14 AD opioid products that are false, misleading, and/or insufficiently proven do not serve the public
15 health.”¹⁵

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

19 71. For example, Endo has marketed Opana ER as tamper- or crush-resistant and less
20 prone to misuse and abuse since at least May 21, 2011 even though: (1) the FDA rejected Endo’s
21 petition to approve Opana ER as abuse-deterrent in 2012; (2) the FDA warned in a 2013 letter that
22 there was no evidence that Opana ER “would provide a reduction in oral, intranasal or intravenous
23 abuse”; and (3) Endo’s own studies, which it failed to disclose, showed that Opana ER could still
24 be ground and chewed. Endo’s advertisements for the 2012 reformulation of Opana ER falsely
25 claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to
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27 ¹⁴ FDA Facts: Abuse-Deterrent Opioid Medications, available at
28 <<https://www.fda.gov/newsevents/newsroom/factsheets/lucm514939.htm>> [as of July 7, 2017].

¹⁵ *Ibid.*

1 abuse. And since 2012, detailers for Endo have informed California doctors, including doctors in
2 Santa Clara County, that Opana ER is harder to abuse, and nurse practitioners have reported
3 receiving tamper- and crush-resistant messages regarding Opana ER and demonstrations of Opana
4 ER's purported abuse deterrent properties.

5 72. Because Opana ER could be "readily prepared for injection" and was linked to
6 outbreaks of HIV and a serious blood disease, in May 2017, an FDA advisory committee
7 recommended that Opana ER be withdrawn from the market. The FDA adopted this
8 recommendation on June 8, 2017 and requested that Endo withdraw Opana ER from the market.¹⁶

9 73. Likewise, Purdue has engaged and continues to engage in deceptive marketing of its
10 AD opioids – i.e., reformulated Oxycontin and Hysingla – since at least May 21, 2011. Before
11 April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However,
12 numerous California prescribers report that, beginning in 2013 and continuing today, detailers from
13 Purdue regularly use the so-called abuse deterrent properties of Purdue's opioid products as a
14 primary selling point to differentiate those products from their competitors. Specifically, these
15 detailers: (1) claim that Purdue's AD opioids prevent tampering and cannot be crushed or snorted;
16 (2) claim that Purdue's AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less
17 likely to yield a euphoric high, and are disfavored by opioid abusers; (3) Purdue's AD opioids are
18 "safer" than other opioids; and (4) fail to disclose that Purdue's AD opioids do not impact oral
19 abuse or misuse and that its abuse deterrent properties can be defeated.

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

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28 ¹⁶ 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>

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

10 76. A 2015 study also shows that many opioid addicts are abusing Purdue’s AD opioids
11 through oral intake or by defeating the abuse deterrent mechanism. Indeed, *one-third* of the patients
12 in the study defeated the abuse deterrent mechanism and were able to continue inhaling or injecting
13 the drug. And to the extent that the abuse of Purdue’s AD opioids was reduced, those addicts
14 simply shifted to other drugs such as heroin.¹⁷ Despite this, J. David Haddox, the Vice President of
15 Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue’s
16 AD opioids are being abused in large numbers.

17 77. Similarly, the 2016 CDC Guideline states that “[n]o studies” support the notion that
18 “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,”
19 noting that the technologies “do not prevent opioid abuse through oral intake, the most common
20 route of opioid abuse, and can still be abused by nonoral routes.” Tom Frieden, the Director of the
21 CDC, has further reported that his staff could not find “any evidence showing the updated opioids
22 [ADFs] actually reduce rates of addiction, overdoses, or death.”¹⁸

23 78. These false and misleading claims about the abuse deterrent properties of their
24 opioids are especially troubling. First, Defendants are using these claims in a spurious attempt to
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26 ¹⁷ Cicero, Theodore J., and Matthew S. Ellis, “Abuse-deterrent formulations and the
27 prescription opioid abuse epidemic in the United States: lessons learned from Oxycontin” (2015)
28 72.5 *JAMA Psychiatry* 424-430.

¹⁸ Perrone, *Drugmakers push profitable, but unproven, opioid solution*, 12/15/16.

1 rehabilitate their image as responsible opioid manufacturers. Indeed, several California prescribers
2 have reported that Purdue has conveyed that its sale of AD opioids is “atonement” for its earlier
3 sins even though its true motive was to preserve the profits it would have lost when its patent for
4 OxyContin expired. Indeed, Purdue introduced its first AD opioid days before that patent would
5 have expired and petitioned the FDA to withdraw its non-AD opioid as unsafe and; thereby,
6 prevent generic competition. Second, these claims are falsely assuaging doctors’ concerns about
7 the toll caused by the explosion in opioid prescriptions and use and encouraging doctors to
8 prescribe AD opioids under the mistaken belief that these opioids are safer, even though they are
9 not. Finally, these claims are causing doctors to prescribe more AD opioids -- which are far more
10 expensive than other opioid products even though they provide little or no additional benefit.

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

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

14 80. To convince doctors and patients that opioids should be used to treat chronic pain,
15 Defendants also had to persuade them that there was a significant upside to long-term opioid use.
16 But as the 2016 CDC Guideline makes clear, there is “insufficient evidence to determine the long-
17 term benefits of opioid therapy for chronic pain.” (Emphasis added.) In fact, the CDC found that
18 “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for
19 chronic pain with outcomes examined at least 1 year later (with most placebo-controlled
20 randomized trials \leq 6 weeks in duration)” and that other treatments were more or equally beneficial
21 and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to
22 support long-term opioid use. In 2013, the FDA stated that it was “not aware of adequate and well-
23 controlled studies of opioids use longer than 12 weeks.” Despite this, Defendants falsely and
24 misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested
25 that these benefits were supported by scientific evidence. Not only have Defendants failed to
26 correct these false and misleading claims, they continue to make them today.

27 81. For example, Defendants falsely claimed that long-term opioid use improved
28 patients’ function and quality of life. Some illustrative examples of these deceptive claims that

1 were made by, are continuing to be made by, and/or have not been corrected by Defendants after
2 May 21, 2011 are described below:

- 3 a. Actavis distributed an advertisement that claimed that the use of Kadian to treat
4 chronic pain would allow patients to return to work, relieve “stress on your body
and your mental health,” and help patients enjoy their lives.
- 5 b. Endo distributed advertisements that claimed that the use of Opana ER for
6 chronic pain would allow patients to perform demanding tasks like construction
work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
7 These advertisements continued to be distributed after May 21, 2011.
- 8 c. Janssen sponsored and edited a patient education guide entitled *Finding Relief:
9 Pain Management for Older Adults* (2009) – which states as “a fact” that
10 “opioids may make it *easier* for people to live normally.” The guide lists
11 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.
- 12 d. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals
13 entitled “Pain vignettes,” which were case studies featuring patients with pain
conditions persisting over several months and recommending OxyContin for
14 them. The ads implied that OxyContin improves patients’ function.
- 15 e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon,
16 Endo and Purdue, taught that relief of pain by opioids, by itself, improved
patients’ function. The book remains for sale online.
- 17 f. Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for People
18 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.
- 19 g. Endo’s NIPC website *painknowledge.com* claimed in 2009 that with opioids,
20 “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
21 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
22 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
23 May 21, 2011.
- 24 h. Endo was the sole sponsor, through NIPC, of a series of non-credit educational
25 programs titled *Persistent Pain in the Older Patient*, which claimed that chronic
opioid therapy has been “shown to reduce pain and improve depressive
26 symptoms and cognitive functioning.” The CME was disseminated via webcast.
- 27 i. Janssen sponsored, funded, and edited a website, *Let’s Talk Pain*, in 2009,
28 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.

- 1 j. Purdue sponsored the development and distribution of APF's *A Policymaker's*
2 *Guide to Understanding Pain & Its Management*, which claimed that "multiple
3 clinical studies" have shown that opioids are effective in improving daily
4 function, psychological health, and health-related quality of life for chronic pain
5 patients." The *Policymaker's Guide* was originally published in 2011 and is still
6 available online today.
- 7 k. In a 2015 video on Forbes.com discussing the introduction of Hysingla ER,
8 Purdue's Vice President of Health Policy, J. David Haddox, talked about the
9 importance of opioids, including Purdue's opioids, to chronic pain patients'
10 "quality of life," and complained that CDC statistics do not take into account
11 that patients could be driven to suicide without pain relief.
- 12 l. Since at least May 21, 2011, Purdue's, Cephalon's, Endo's, and Janssen's sales
13 representatives have conveyed and continue to convey to prescribers in
14 California, including Santa Clara County, the message that opioids will improve
15 patient function.

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

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

83. 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),

1 drugs that can kill patients or commit them to a life of addiction or recovery do not improve their
2 function and quality of life.

3 84. The 2016 CDC Guideline was not the first time a federal agency repudiated
4 Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned
5 Actavis, in response to its advertising described in paragraph 67, that "[w]e are not aware of
6 substantial evidence or substantial clinical experience demonstrating that the magnitude of the
7 effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects
8 patients may experience ... results in any overall positive impact on a patient's work, physical and
9 mental functioning, daily activities, or enjoyment of life."¹⁹ And in 2008, the FDA sent a warning
10 letter to an opioid manufacturer, making it publicly made clear "that [the claim that] patients who
11 are treated with the drug experience an improvement in their overall function, social function, and
12 ability to perform daily activities . . . has not been demonstrated by substantial evidence or
13 substantial clinical experience."

14 85. Defendants also falsely and misleadingly emphasized or exaggerated the risks of
15 competing products like NSAIDs, so that doctors and patients would look to opioids first for the
16 treatment of chronic pain. For example, Defendants, before and after May 21, 2011, have
17 overstated the number of deaths from NSAIDS and have prominently featured the risks of
18 NSAIDS, while minimizing or failing to mention the serious risks of opioids. Once again, these
19 misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and
20 CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in
21 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for
22 which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC
23 Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain,
24 particularly arthritis and lower back pain.

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26 ¹⁹ Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns,
27 to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at
28 [http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyF
DA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259240.htm](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259240.htm).

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

5 87. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all
6 times relevant to this action. According to Purdue’s own research, OxyContin wears off in under
7 six hours in one quarter of patients and in under 10 hours in more than half. This is because
8 OxyContin tablets release approximately 40% of their active medicine immediately, after which
9 release tapers. This triggers a powerful initial response, but provides little or no pain relief at the
10 end of the dosing period, when less medicine is released. This phenomenon is known as “end of
11 dose” failure, and the FDA found in 2008 that a “substantial number” of chronic pain patients
12 taking OxyContin experience it. This not only renders Purdue’s promise of 12 hours of relief false
13 and misleading, it also makes OxyContin more dangerous because the declining pain relief patients
14 experience toward the end of each dosing period drives them to take more OxyContin before the
15 next dosing period begins, quickly increasing the amount of drug they are taking and spurring
16 growing dependence.

17 88. Purdue’s competitors were aware of this problem. For example, Endo ran
18 advertisements for Opana ER referring to “real” 12-hour dosing. Nevertheless, Purdue falsely
19 promoted OxyContin as if it were effective for a full 12 hours since at least May 21, 2011. Indeed,
20 at Purdue’s instruction, Purdue’s sales representatives continue to tell California doctors that
21 OxyContin lasts a full 12 hours. And if a doctor suggests that OxyContin does not last 12 hours,
22 these sales representatives, at Purdue’s instruction, recommend increasing the dose, rather than the
23 frequency of use. Purdue gave its sales representatives these instructions to prevent doctors from
24 switching to a different drug and to address the unwillingness of insurers to pay for more frequent
25 use of OxyContin.

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1 **D. Defendants Also Engaged In Other Unlawful and Unfair Misconduct.**

2 89. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even
3 though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant
4 individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is
5 approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly
6 prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve
7 Fentora for the treatment of chronic pain because of the potential harm, including the high risk of
8 “serious and life-threatening adverse events” and abuse – which are greatest in non-cancer patients.
9 The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be
10 used for cancer patients who are opioid-tolerant and should not be used for any other conditions,
11 such as migraines, post-operative pain, or pain due to injury.

12 90. Despite this, Cephalon conducted and continues to conduct a well-funded campaign
13 to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not
14 approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs,
15 KOLs, journal supplements, and detailing by its sales representatives to give doctors the false
16 impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

- 17 • Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent*
18 *and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009.
19 The CME instructed doctors that “clinically, broad classification of pain syndromes as
20 either cancer- or noncancer-related has limited utility” and recommended Actiq and
21 Fentora for patients with chronic pain. The CME is still available online.
- 22 • Cephalon’s sales representatives set up hundreds of speaker programs for doctors,
23 including many non-oncologists, which promoted Actiq and Fentora for the treatment of
24 non-cancer pain.
- 25 • In December 2011, Cephalon widely disseminated a journal supplement entitled
26 “Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl
27 Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)” to
28

1 Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three
2 publications that are sent to thousands of anesthesiologists and other medical
3 professionals. The Special Report openly promotes Fentora for “multiple causes of
4 pain” – and not just cancer pain.

5 91. Cephalon’s deceptive marketing gave doctors and patients the false impression that
6 Actiq and Fentora were not only safe and effective for treating chronic pain, but were also
7 approved by the FDA for such uses.

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

14 93. Although the U.S. Drug Enforcement Agency (DEA) has repeatedly informed
15 Purdue about its legal “obligation to design and operate a system to disclose . . . suspicious orders
16 of controlled substances” and to inform the DEA “of suspicious orders when discovered,” Purdue
17 also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs
18 after May 21, 2010, despite knowing about it for years. (See 21 C.F.R. § 1301.74(b); 21 U.S.C. §
19 823(e).)

20 94. For over a decade, Purdue has been able to track the distribution and prescribing of
21 its opioids down to the retail and prescriber levels. Through its extensive network of sales
22 representatives, Purdue had and continues to have knowledge of the prescribing practices of
23 thousands of doctors in California and could identify California doctors who displayed red flags for
24 diversion such as those whose waiting rooms were overcrowded, whose parking lots had numerous
25 out-of-state vehicles, and whose patients seemed young and healthy or homeless. Using this
26 information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately
27 prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement
28 authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to

1 demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had
2 promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of
3 generic copies of the drug because the drug was too likely to be abused. In an interview with the
4 *Los Angeles Times*, Purdue’s senior compliance officer acknowledged that in five years of
5 investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees
6 personally witnessed the diversion of its drugs. The same was true of prescribers; despite its
7 knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down
8 a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue’s
9 district manager described internally as “an organized drug ring.” In doing so, Purdue protected its
10 own profits at the expense of public health and safety.

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

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

21 **E. Although Defendants Knew That Their Marketing Of Opioids Was False And**
22 **Misleading, They Fraudulently Concealed Their Misconduct.**

23 97. Defendants, both individually and collectively, made, promoted, and profited from
24 their misrepresentations about the risks and benefits of opioids for chronic pain even though they
25 knew that their misrepresentations were false and misleading. The history of opioids, as well as
26 research and clinical experience over the last 20 years, established that opioids were highly
27 addictive and responsible for a long list of very serious adverse outcomes. The FDA and other
28 regulators warned Defendants of this, and Cephalon and Purdue entered into settlements in the

1 hundreds of millions of dollars to address similar misconduct that occurred before 2008.
2 Defendants had access to scientific studies, detailed prescription data, and reports of adverse
3 events, including reports of addiction, hospitalization, and deaths – all of which made clear the
4 harms from long-term opioid use and that patients are suffering from addiction, overdoses, and
5 death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based
6 on the medical evidence that conclusively expose the known falsity of Defendants’
7 misrepresentations.

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

15 99. Defendants also never disclosed their role in shaping, editing, and approving the
16 content of information and materials disseminated by these third parties. Defendants exerted
17 considerable influence on these promotional and “educational” materials in emails,
18 correspondence, and meetings with KOLs, Front Groups, and public relations companies that were
19 not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC,
20 did not disclose Endo’s involvement. Other Defendants, such as Purdue and Janssen, ran similar
21 websites that masked their own direct role.

22 100. Finally, Defendants manipulated their promotional materials and the scientific
23 literature to make it appear that these items were accurate, truthful, and supported by objective
24 evidence when they were not. Defendants distorted the meaning or import of studies they cited and
25 offered them as evidence for propositions the studies did not support. The lack of support for
26 Defendants’ deceptive messages was not apparent to medical professionals who relied upon them
27 in making treatment decisions, nor could it have been detected by the People.
28

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

5
6 **F. By Knowingly Causing an Explosion in Opioid Prescribing, Use, Misuse, Abuse, and**
7 **Addiction Through Their Deceptive Marketing Schemes and Unlawful and Unfair**
8 **Business Practices, Each Defendant Has Created or Assisted in the Creation of a**
9 **Public Nuisance.**

10
11 1. Defendants' Deceptive Marketing Scheme Has Caused and Continues to Cause a
12 Huge Increase in Opioid Prescriptions and Use in California, Including Santa Clara,
13 Orange and Los Angeles counties and the City of Oakland.

14 102. Defendants' misrepresentations deceived and continue to deceive doctors and
15 patients in California, including Santa Clara, Orange and Los Angeles counties and the City of
16 Oakland, about the risks and benefits of long-term opioid use. California doctors, including doctors
17 in Santa Clara County, confirm this. Studies also reveal that many doctors and patients are not
18 aware of or do not understand these risks and benefits. Indeed, patients often report that they were
19 not warned they might become addicted to opioids prescribed to them. As reported in January
20 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids
21 were potentially addictive. Indeed, California residents in treatment for opioid addiction, including
22 residents of Santa Clara County, confirm that they were never told that they might become addicted
23 to opioids when they started taking them, were told that they could easily stop using opioids, or
24 were told that the opioids they were prescribed were less addictive than other opioids.

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

27 104. Defendants' deceptive marketing scheme and their unlawful and unfair business
28 practices caused and continue to cause doctors in California, including doctors in Santa Clara,
Orange and Los Angeles counties and the City of Oakland, 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

1 prescribed as many opioids to as many patients, and there would not have been as many opioids
2 available for misuse and abuse or as much demand for those opioids.

3 105. Defendants' deceptive marketing scheme and their unlawful and unfair business
4 practices also caused and continue to cause patients in California, including patients in Santa Clara,
5 Orange and Los Angeles counties and the City of Oakland, to purchase and use opioids for their
6 chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing
7 scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients
8 using opioids would be using less of them. Again, California doctors and patients confirm this.

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

17 107. In California, including Santa Clara, Orange and Los Angeles counties, and the City
18 of Oakland, Defendants' deceptive marketing of the abuse-deterrent properties of their opioids
19 during the past few years has been particularly effective. For example, one survey reports that pain
20 specialists were more likely to recognize that OxyContin had abuse deterrent properties and to
21 prescribe OxyContin specifically because of those properties. Further, prescribers who knew of
22 OxyContin's abuse deterrent properties were using more of it than those who did not know it was
23 an AD opioid. Although sales of AD opioids still represent only a small fraction of opioids sold
24 (less than 5% of all opioids sold in 2015), they represent a disproportionate share of opioid sales
25 revenue (\$2.4 billion or approximately 25% in opioid sales revenue in 2015).

26 108. The dramatic increase in opioid prescriptions and use corresponds with the dramatic
27 increase in Defendants' spending on their deceptive marketing scheme. Defendants' spending on
28

1 opioid marketing totaled approximately \$91 million in 2000. By 2011, that spending had tripled to
2 \$288 million.

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

6
7 109. The escalating number of opioid prescriptions written by doctors who were
8 deceived by Defendants’ deceptive marketing scheme is the cause of a correspondingly dramatic
9 increase in opioid addiction, overdose, and death throughout the U.S. and California.

10 110. Representing the NIH’s National Institute of Drug Abuse in hearings before the
11 Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that
12 “aggressive marketing by pharmaceutical companies” is “likely to have contributed to the severity
13 of the current prescription drug abuse problem.”

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

20 112. Scientific evidence demonstrates a strong correlation between opioid prescriptions
21 and opioid abuse. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has
22 quadrupled since 1999 and has increased in parallel with [opioid] overdoses.” Patients receiving
23 prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the
24 CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to
25 reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”

26 113. Contrary to Defendants’ misrepresentations, most opioid addiction begins with
27 legitimately prescribed opioids. In 2011, 71% of people who abused prescription opioids got them
28 through friends or relatives, not from pill mills, drug dealers or the internet. Numerous doctors and

1 substance abuse counselors in California, including in Santa Clara County, note that many of their
2 patients who misuse or abuse opioids started with legitimate prescriptions, confirming the
3 important role that doctors' prescribing habits have played in the opioid epidemic. Treatment
4 centers in California, including centers in Santa Clara County, report that they treat a significant
5 percentage – i.e., as high as 80% – of patients for opioid addiction. For example, one addiction
6 treatment center in Santa Clara County reported that half of their opioid patients started with
7 legitimate prescriptions, and that 75% of those patients later moved to illicit sources or drugs.
8 Another counselor in Santa Clara County reported that almost all of the opioid addicts she treats
9 began with legal prescriptions.

10 114. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. For
11 example, in 2015, opioids were responsible for 286 overdose deaths in Orange County – a 16%
12 increase since 2013 and a 63% increase over figures from a decade ago. In Santa Clara County,
13 which has a little more than half the population of Orange County, prescription opioids were
14 responsible for 134 overdose deaths in 2015 – nearly twice the figure from 2005. In Los Angeles
15 County, opioids were responsible for 344 overdose deaths in 2016 – a 56% increase from 2001. In
16 2016, there were 51 opioid overdose deaths in Alameda County, with the highest burden of deaths
17 appearing to be in Oakland.

18 115. These deaths represent the tip of the iceberg. According to 2009 data, for every
19 overdose death that year, there were nine abuse treatment admissions, 30 emergency department
20 visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and 795 non-
21 medical users. And as reported in May 2016, in California, opioid overdoses resulting in hospital
22 visits increased by 25% (accounting for population growth) from 2011 to 2014. In Los Angeles
23 County, prescription opioid-related hospitalizations increased 30% from 2006 to 2013 (11,230 to
24 14,594); while prescription opioid-related emergency department visits increased 171% in the same
25 time period (3,354 to 9,075). The number of Los Angeles County medical examiner toxicology
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27
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1 cases testing positive for fentanyl doubled from 2015 to 2016.²⁰ Oakland’s Fire Department and
2 other paramedics administered Narcan more than 500 times per year from 2015-2017 to help
3 prevent opioid overdoses from resulting in fatalities.

4 116. The overprescribing of opioids for chronic pain caused by Defendants’ deceptive
5 marketing scheme has also resulted in a dramatic rise in the number of infants in California who
6 are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence
7 syndrome. These infants face painful withdrawal and may suffer long-term neurologic and
8 cognitive impacts.

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

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

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

24 120. Many patients who become addicted to opioids will lose their jobs. Some will lose
25 their homes and their families. Some will get treatment and fewer will successfully complete it;

27 ²⁰ Substance Abuse and Prevention Control, Medical Director’s Brief (Los Angeles
28 Department of Public Health).

1 many of those patients will relapse, returning to opioids or some other drug. Of those who continue
2 to take opioids, some will overdose – some fatally, some not. Others will die prematurely from
3 related causes – falling or getting into traffic accidents due to opioid-induced somnolence; dying in
4 their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit
5 drug transactions; or dying from opioid-induced heart or neurological disease.

6 121. Absent each Defendants’ deceptive marketing scheme and their unlawful and unfair
7 business practices, the public health crisis caused by opioid misuse, abuse, and addiction in
8 California, including Santa Clara, Orange and Los Angeles counties and the City of Oakland,
9 would have been averted or much less severe.

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

16 123. These harms in California, including in Santa Clara, Orange and Los Angeles
17 counties, and the City of Oakland, caused by Defendants’ deceptive marketing schemes and
18 unlawful and unfair business practices are a public nuisance because they are “injurious to health”
19 and interfere “with the comfortable enjoyment of life” and “property” (Civ. Code, § 3479) and
20 because they “affect[] at the same time” “entire communit[ies]” and “neighborhoods” and “any
21 considerable number of persons” (*id.*, § 3480).

22 3. Defendants Knew and Should Have Known That Their Deceptive Marketing
23 Schemes Would Create or Assist in the Creation of this Public Nuisance in Santa
24 Clara, Orange and Los Angeles Counties, and the City of Oakland.

25
26 124. Defendants knew and should have known about these harms that their deceptive
27 marketing and unlawful and unfair business practices have caused and continue to cause in
28 California, including in Santa Clara, Orange and Los Angeles counties, and the City of Oakland.

1 Defendants closely monitored their sales and the habits of prescribing doctors. Their sales
2 representatives, who visited doctors and attended CMEs, knew which doctors were receiving their
3 messages and how they were responding. Defendants also had access to and watched carefully
4 government and other data that tracked the explosive rise in opioid use, addiction, injury, and
5 death. They knew – and, indeed, intended – that their misrepresentations would persuade doctors in
6 California, including doctors in Santa Clara, Orange and Los Angeles counties, and the City of
7 Oakland, to prescribe and patients in California, including patients in Santa Clara, Orange and Los
8 Angeles counties and the City of Oakland, to use their opioids for chronic pain.

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

12 125. Defendants’ actions are not permitted nor excused by the fact that their drug labels
13 may have allowed or did not exclude the use of opioids for chronic pain. FDA approval of opioids
14 for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids.
15 Indeed, Defendants’ misrepresentations were directly contrary to pronouncements by and guidance
16 from the FDA based on the medical evidence and their own labels.

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

23 127. Finally, each Defendants’ conduct and role in creating or assisting in the creation of
24 the public health crisis now plaguing California is directly relevant to the amount of the civil
25 penalties to be awarded under Business & Professions Code §§ 17206 [“In assessing the amount of
26 the civil penalty, the court shall consider any one or more of the relevant circumstances presented
27 by any of the parties to the case, including, but not limited to, the following: the nature and
28 seriousness of the misconduct, the number of violations, the persistence of the misconduct, the

1 length of time over which the misconduct occurred, the willfulness of the defendant’s misconduct,
2 and the defendant’s assets, liabilities, and net worth,” emphasis added] and 17536 [same].

3 **G. Defendants’ Fraudulent Marketing Has Led To Record Profits.**

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

9 **V. CAUSES OF ACTION**

10 **FIRST CAUSE OF ACTION**

11 **FALSE ADVERTISING**

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

13 **(Against all Defendants)**

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

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

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

24 132. As alleged above, each Defendant, at all times relevant to this Complaint, violated
25 Section 17500 by making statements to promote the use of opioids to treat chronic pain that
26 omitted or concealed material facts, and by failing to correct prior misrepresentations and
27 omissions, about the risks and benefits of opioids. Each Defendant’s omissions, which are false and
28

1 misleading in their own right, render even their seemingly truthful statements about opioids false
2 and misleading.

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

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

8 135. At the time it made or disseminated its false and misleading statements or caused
9 these statements to be made or disseminated, each Defendant knew and should have known that the
10 statements were false or misleading and therefore likely to deceive the public. In addition,
11 Defendants knew and should have known that their false and misleading advertising created a false
12 or misleading impression of the risks and benefits of long-term opioid use and would result in
13 unnecessary and improper opioid prescriptions and use.

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

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

19 **SECOND CAUSE OF ACTION**

20 **UNFAIR COMPETITION**

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

22 **(Against all Defendants)**

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

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

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

4 141. Defendants’ business practices as described in this Complaint are deceptive and
5 violate Section 17200 because the practices are likely to deceive consumers in California.

6 142. Defendants knew and should have known at the time of making or disseminating
7 these statements, or causing these statements to be made or disseminated, that such statements were
8 false and misleading and therefore likely to deceive the public. Defendants’ omissions, which are
9 deceptive and misleading in their own right, render even Defendants’ seemingly truthful statements
10 about opioids false and misleading. All of this conduct, separately and collectively, was likely to
11 deceive California payors who purchased, or covered the purchase of, opioids for chronic pain.

12 143. Defendants’ business practices as describe in this Complaint are unlawful and
13 violate Section 17200. These unlawful practices include, but are not limited to:

- 14 a. Defendants falsely advertised opioids in violation of the Sherman
15 Food, Drug, and Cosmetic Laws, HEALTH & SAFETY CODE
16 § 110390;
- 17 b. Defendants manufactured, sold, delivered, held, or offered for sale
18 opioids that had been falsely advertised in violation of the Sherman
19 Food, Drug, and Cosmetic Laws, HEALTH & SAFETY CODE
20 § 110395;
- 21 c. Defendants advertised misbranded opioids in violation of the
22 Sherman Food, Drug, and Cosmetic Laws, HEALTH & SAFETY
23 CODE §§ 110290, 110398, and 111330;
- 24 d. Defendants received in commerce opioids that were falsely
25 advertised or delivered or proffered for delivery opioids that were
26 falsely advertised in violation of the Sherman Food, Drug, and
27 Cosmetic Laws, HEALTH & SAFETY CODE § 110400;
- 28 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;

- 1 g. Defendants received in commerce opioids that were misbranded in
2 violation of the Sherman Food, Drug, and Cosmetic Laws, HEALTH
& SAFETY CODE §§ 110290, 111450, and 111330;
- 3 h. Defendants proffered for delivery opioids that were misbranded in
4 violation of the Sherman Food, Drug, and Cosmetic Laws, HEALTH
& SAFETY CODE §§ 110290, 111450, and 111330;
- 5 i. Defendants failed to adopt and comply with a Comprehensive
6 Compliance Program in violation of HEALTH & SAFETY CODE §
119402;
- 7 j. Defendants represented that opioids had sponsorship, approval,
8 characteristics, ingredients, uses, or benefits which they did not
9 have in violation of the Consumer Legal Remedies Act, CIV. CODE
§ 1770(a)(5);
- 10 k. Defendants represented that opioids were of a particular standard,
11 quality, or grade when they were of another in violation of
Consumer Legal Remedies Act, CIV. CODE § 1770(a)(7);
- 12 l. Defendants disparaged the goods of another by false or misleading
13 representation of fact in violation of Consumer Legal Remedies
Act, CIV. CODE § 1770(a)(8);
- 14 m. Defendants Purdue and Endo unlawfully failed to identify and
15 report suspicious prescribing to law enforcement and health
authorities; and
- 16 n. Defendants made or disseminated, directly or indirectly, untrue,
17 false, or misleading statements about the use of opioids to treat
chronic pain, or causing untrue, false, or misleading statements
18 about opioids to be made or disseminated to the general public in
violation of Section 17500.
- 19 o. Defendant Purdue directly or indirectly offered or paid
20 remuneration to doctors to prescribe its opioid products in violation
of WELFARE & INSTITUTIONS CODE § 14107.2,

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

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

26 146. Each time a Defendant marketed opioids in violation of Section 17200 constitutes a
27 separate violation. BUS. & PROF. CODE § 17206(b). The People therefore seek civil penalties up to
28

1 \$2,500 per violation pursuant to Section 17206 for each violation of Section 17200. The People
2 also seek civil penalties up to \$2,500 per violation under Section 17206.1.

3 **THIRD CAUSE OF ACTION**

4 **PUBLIC NUISANCE**
5 **Violations of California Civil Code Sections 3479 and 3480**

6 **(Against All Defendants)**

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

9 148. Civil Code Section 3479 provides that “[a]nything that is injurious to health ... or is
10 indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere
11 with the comfortable enjoyment of life or property ... is a nuisance.”

12 149. Civil Code Section 3480 defines a “public nuisance” as “one which affects at the
13 same time an entire community or neighborhood, or any considerable number of persons, although
14 the extent of the annoyance or damage inflicted upon individuals may be unequal.”

15 150. Civil Code section 3490 states that “[n]o lapse of time can legalize a public
16 nuisance, amounting to an actual obstruction of public right.”

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

19 152. Each Defendant, acting individually and in concert, has created or assisted in the
20 creation of a condition that is injurious to the health and interferes with the comfortable enjoyment
21 of life and property of entire communities or neighborhoods or of any considerable number of
22 persons in Santa Clara, Orange and Los Angeles counties, and the City of Oakland, in violation of
23 Civil Code Sections 3479 and 3480.

24 153. The public nuisance is substantial and unreasonable. Defendants’ actions caused and
25 continue to cause the public health epidemic described above in Santa Clara, Orange and Los
26 Angeles counties, and the City of Oakland, and that harm outweighs any offsetting benefit.

27 154. Defendants knew and should have known that their promotion of opioids was false
28 and misleading and that their deceptive marketing scheme and other unlawful, unfair, and

1 fraudulent actions would create or assist in the creation of the public nuisance – i.e., the opioid
2 epidemic.

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

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

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

15 **VI. PRAYER FOR RELIEF**

16 THE PEOPLE pray that the Court:

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

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

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

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

28

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

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

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

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

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

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

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

18 169. Order Defendants to pay the cost of the suit.

19 170. Provide such further and additional relief as the Court deems proper.
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1 DATED: June 8, 2018

2 **OFFICE OF THE COUNTY COUNSEL**
3 **COUNTY OF SANTA CLARA**

4 By Greta S. Hansen
5 James R. Williams, County Counsel
6 Greta S. Hansen, Chief Assistant County Counsel
7 Kavita Narayan, Lead Deputy County Counsel
8 Laura S. Trice, Lead Deputy County Counsel
9 Julia Spiegel, Deputy County Counsel
10 Lynnette K. Miner, Fellow
11 70 West Hedding Street
12 East Wing, 9th Floor
13 San Jose, CA 95110
14 Telephone: (408) 299-5900
15 Facsimile: (408) 292-7240
16 James.Williams@cco.sccgov.org
17 Greta.Hansen@cco.sccgov.org
18 Kavita.Narayan@cco.sccgov.org
19 Laura.Trice@cco.sccgov.org
20 Julia.spiegel@cco.sccgov.org
21 Lynnette.miner@cco.sccgov.org

22 **ORANGE COUNTY DISTRICT ATTORNEY**

23 By: Tony Rackauckas
24 Tony Rackauckas, District Attorney
25 Scott Zidbeck
26 Tracy Hughes
27 Joseph D'Agostino
28 Tony.rackauckas@da.ocgov.com
Scott.zidbeck@da.ocgov.com
Tracy.hughes@da.ocgov.com
Joe.d'agostino@da.ocgov.com
401 Civic Center Drive
Santa Ana, CA 92701-4575
Telephone: (714) 834-3600
Facsimile: (714) 648-3636

29 **OFFICE OF THE COUNTY COUNSEL**
30 **COUNTY OF LOS ANGELES**

31 By Mary C. Wickham
32 Mary C. Wickham, County Counsel
33 mwickham@counsel.lacounty.gov
34 Robert E. Ragland, Principal Deputy County Counsel
35 Scott Kuhn, Acting Assistant County Counsel
36 Andrea Ross, Principal Deputy County Counsel
37 Kenneth Hahn Hall of Administration
38 500 West Temple Street, Suite 648
Los Angeles, California 90012
Telephone: (213) 974-1811
Facsimile: (213) 626-7446

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HAGENS BERMAN SOBOL SHAPIRO LLP

Steve W. Berman, *Pro hac vice*
steve@hbsslaw.com
Thomas E. Loeser (SBN 202724)
tomloeser@hbsslaw.com
1918 Eighth Avenue, Suite 3300
Seattle, WA 98101
Telephone: (206) 623-7292
Facsimile: (206) 623-0594

HAGENS BERMAN SOBOL SHAPIRO LLP

Elaine Byszewski (SBN 222304)
elaine@hbsslaw.com
301 North Lake Avenue, Suite 203
Pasadena, CA 91101
Telephone: (213) 330-7150

HAGENS BERMAN SOBOL SHAPIRO LLP

Jennifer Fountain Connolly, *Pro hac vice*
jenniferc@hbsslaw.com
1701 Pennsylvania Ave., NW, Suite 300
Washington, DC 20006
Telephone: (202) 248-5403
Facsimile: (202) 580-6559

1 **PROOF OF SERVICE**

2 STATE OF CALIFORNIA, COUNTY OF ORANGE

3 I declare that I am over the age of eighteen (18) and not a party to this action. My business
4 address is: ROBINSON CALCAGNIE, INC., 19 Corporate Plaza Drive, Newport Beach, CA
5 92660. My email address is: dperkins@robinsonfirm.com

6 On June 8, 2018, served the foregoing document described as:
7 SIXTH AMENDED COMPLAINT FOR VIOLATIONS OF CALIFORNIA FALSE
8 ADVERTISING LAW, CALIFORNIA UNFAIR COMPETITION LAW, AND PUBLIC
9 NUISANCE, SEEKING CIVIL PENALTIES, ABATEMENT, AND INJUNCTIVE RELIEF
on the parties in this action by placing a true copy thereof in a sealed envelope addressed as stated
on the attached mailing list as follows:

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

13 _____ (By Electronic Service) I caused each document to be sent by electronic service by
14 transmitting a true and correct PDF version as indicated above of the foregoing
document(s) via each individual's email

15 _____ (By Federal Express) Said documents were delivered to an authorized courier or driver
16 authorized by the express service carrier to receive documents with delivery fees paid
or provided for.

17 _____ (By Mail) I am "readily familiar" with the firm's practice of collection and processing
18 correspondence for mailing. Under practice, it would be deposited with the U.S. Postal
19 Service on that same day with postage thereon fully prepaid at Newport Beach,
20 California in the ordinary course of business. I am aware that on motion of the party
served, service is presumed invalid if postal cancellation date or postage meter date is
more than one day after date of deposit for mailing in affidavit.

21 _____ (By Personal Service) I caused each document to be delivered by hand to the office of the
22 addressee.

23
24 X STATE: I declare under penalty of perjury under the laws of the State of California that the
25 foregoing is true and correct.

26 Executed on June 8, 2018, at Newport Beach, California.

27
28 /s/ Darleen Perkins

Darleen Perkins
SERVICE LIST

The People of the State of California, etc., vs. Purdue Pharma L.P., et al.
Orange County Superior Court Case No. 30-2014-00725287-CU-BT-CXC

<p>Collie F. James, IV MORGAN, LEWIS & BOCKIUS LLP 600 Anton Blvd., Suite 1800 Costa Mesa, California 92626 Tel: 714-830-0600 Fax: 714-830-0600 cjames@morganlewis.com</p>	<p><i>Attorneys for Defendants</i> <i>TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA PHARMACEUTICALS INC., CEPHALON, INC.; WATSON LABORATORIES, INC., ACTIVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.</i></p>
<p>Tinos Diamantatos, <i>pro hac vice</i> MORGAN, LEWIS & BOCKIUS LLP 77 West Wacker Drive, 5th Floor Chicago, IL 60601 Tel: 312-324-1145 Fax: 312-353-2067 tdiamantatos@morganlewis.com</p>	<p><i>Attorneys for Defendants</i> <i>TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA PHARMACEUTICALS INC., AND CEPHALON, INC.</i></p>
<p>Steven A. Reed, <i>pro hac vice</i> MORGAN, LEWIS & BOCKIUS LLP 1701 Market Street Philadelphia, PA 19103-2921 Tel: 215-963-5000 Fax: 215-963-5001 sreed@morganlewis.com</p>	<p><i>Attorneys for Defendants</i> <i>TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., WATSON LABORATORIES, INC., ACTAVIS LLC and ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.</i></p>
<p>Sean O. Morris, Esq. S. Albert Wang, Esq. Tiffany M. Ikeda, Esq. ARNOLD & PORTER LLP 777 S. Figueroa Street, 44th Floor Los Angeles, CA 90017-5844 Tel. 213-243-4000 Fax 213-243-4199 Sean.Morris@aporter.com S.Albert.Wang@aporter.com Tiffany.Ikeda@aporter.com</p>	<p><i>Defendant ENDO HEALTH SOLUTIONS INC. and ENDO PHARMACEUTICALS, INC.</i></p>

<p>1 Joshua M. Davis, pro hac vice 2 ARNOLD & PORTER LLP 3 555 Twelfth Street, NW 4 Washington, DC 20004-1206 5 Tel: 202-942-5000 6 Fax: 202-942-5999 7 joshua.davis@aporter.com</p>	<p><i>Defendant ENDO HEALTH SOLUTIONS INC. and ENDO PHARMACEUTICALS, INC.</i></p>
<p>6 Marshall A. Camp 7 Moez M. Kaba 8 HUESTON HENNIGAN LLP 9 523 West 6th Street, Suite 400 10 Los Angeles, California 90014 11 Telephone: 213-788-4340 12 Facsimile: 888-775-0898 13 mcamp@hueston.com 14 mkaba@hueston.com</p>	<p><i>Defendant ENDO HEALTH SOLUTIONS INC. and ENDO PHARMACEUTICALS, INC.</i></p>
<p>11 John C. Hueston 12 HUESTON HENNIGAN LLP 13 620 Newport Center Drive, Suite 1300 14 Newport Beach, California 92660 15 Telephone: 949-229-8640 16 Facsimile: 888-775-0898 17 jhueston@hueston.com</p>	<p><i>Defendant ENDO HEALTH SOLUTIONS INC. and ENDO PHARMACEUTICALS, INC.</i></p>
<p>16 Charles C. Lifland 17 Estaban Rodriguez 18 Sabrina Strong 19 O'MELVENY & MYERS, LLP 20 400 S. Hope St. 21 Los Angeles, CA 90071 22 Tel: 213-430-6000 23 Fax: 213-430-6407 24 clifland@omm.com 25 esrodriguez@omm.com 26 sstrong@omm.com</p>	<p><i>Attorneys for Defendants JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. N/K/A JANSSEN PHARMACEUTICALS, INC., AND JANSSEN PHARMACEUTICA, INC. N/K/A JANSSEN PHARMACEUTICALS, INC.</i></p>
<p>23 Michael G. Yoder 24 O'MELVENY & MYERS, LLP 25 610 Newport Center Drive, 17th Floor 26 Newport Beach, California 92660 27 Tel: 949-823-6900 28 myoder@omm.com</p>	<p><i>Attorneys for Defendants JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. N/K/A JANSSEN PHARMACEUTICALS, INC., AND JANSSEN PHARMACEUTICA, INC. N/K/A JANSSEN PHARMACEUTICALS, INC.</i></p>

<p>1 Jason D. Russell 2 Kevin J. Minnick 3 Lisa M. Gilford 4 SKADDEN, ARPS, SLATE, MEAGHER & 5 FLOM LLP 6 300 South Grand Avenue 7 Los Angeles, CA 90071-3144 8 Tel: 213-687-5000 9 Fax: 213-687-5600 10 Jason.Russell@skadden.com 11 Kminnick@skadden.com 12 Lisa.gilford@skadden.com</p>	<p><i>Defendant PURDUE PHARMA L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC.</i></p>
<p>9 Mark S. Cheffo 10 QUINN EMANUEL URQUHART 11 SULLIVAN, LLP 12 51 Madison Avenue, 22nd Floor 13 New York, New York 10010 14 Tel: 212-849-7000 15 Fax: 212-849-7100 16 markcheffo@quinnemanuel.com</p>	<p><i>Attorneys for Defendant PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.</i></p>
<p>14 Jonathan S. Tam 15 QUINN EMANUEL URQUHART 16 SULLIVAN, LLP 17 50 California Street, 22nd Floor 18 San Francisco, California 94111 19 Tel: 415-875-6600 20 Fax: 415-875-6700 21 jonathantam@quinnemanuel.com</p>	<p><i>Attorneys for Defendant PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC</i></p>
<p>19 Ashley Neglis 20 KIRKLAND & ELLIS LLP 21 333 South Hope Street 22 Los Angeles, California 90071 23 Telephone: (213) 680-8114 24 Facsimile: (213) 680-8500 25 Ashley.neglia@kirkland.com</p>	<p><i>Attorneys for Specially Appearing Defendant ALLERGAN PLC F/K/A ACTAVIS PLC and Defendant ALLERGAN FINANCE, LLC F/K/A ACTAVIS, INC. F/K/A WATSON PHARMACEUTICALS, INC.</i></p>
<p>24 Jennifer G. Levy, P.C. 25 KIRKLAND & ELLIS LLP 26 655 Fifteenth Street, N.W. 27 Washington, D.C. 20005 28 Telephone: 202-879-5066 29 Facsimile: 202-879-5200 30 Jennifer.levy@kirkland.com</p>	<p><i>Attorneys for Specially Appearing Defendant ALLERGAN PLC F/K/A ACTAVIS PLC and Defendant ALLERGAN FINANCE, LLC F/K/A ACTAVIS, INC. F/K/A WATSON PHARMACEUTICALS, INC.</i></p>

<p>1 Donna Welch, P.C. 2 Martin L. Roth 3 Timothy W. Knapp 4 KIRKLAND & ELLIS LLP 5 300 North LaSalle 6 Chicago, Illinois 60654 7 Telephone: 312-862-2000 8 Facsimile: 312-862-2200 9 Donna.welch@kirkland.com 10 rothm@kirkland.com 11 tknapp@kirkland.com</p>	<p>Attorneys for Specially Appearing Defendant ALLERGAN Plc f/k/a ACTAVIA Plc and Defendant Allergan Finance LLC (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.</p>
<p>8 Mark P. Robinson, Jr. 9 Kevin F. Calcagnie 10 Daniel S. Robinson 11 Scot D. Wilson 12 ROBINSON CALCAGNIE, INC. 13 19 Corporate Plaza Drive 14 Newport Beach, California 92660 15 Telephone: (949) 720-1288 16 Facsimile: (949) 720-1292 17 mrobinson@robinsonfirm.com 18 kcalcagnie@robinsonfirm.com 19 drobinson@robinsonfirm.com 20 swilson@robinsonfirm.com 21 lilarazmara@robinsonfirm.com</p>	<p><i>Attorneys for Plaintiff</i> THE PEOPLE OF THE STATE OF CALIFORNIA</p>
<p>17 OFFICE OF THE COUNTY COUNSEL 18 COUNTY OF SANTA CLARA 19 James R. Williams, County Counsel 20 Greta S. Hansen, Chief Asst. County Counsel 21 Kavita Narayan 22 Laura S. Trice 23 Julia Spiegel 24 Lynnette K. Miner 25 70 West Hedding Street 26 East Wing, 9th Floor 27 San Jose, CA 95110 28 Tel.: 408-299-5900 Fax: 408-292-7240 James.williams@cco.sccgov.org Laura.trice@cco.sccgov.org Greta.hansen@cco.sccgov.org Kavita.narayan@cco.sccgov.org Lynnette.miner@cco.sccgov.org Julia.spiegel@cco.sccgov.org</p>	<p><i>Attorneys for Plaintiff</i> THE PEOPLE OF THE STATE OF CALIFORNIA</p>

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<p>Paul Kiesel, Esq. Helen Zukin, Esq. Nicole Ramirez KIESEL LAW LLP 8648 Wilshire Blvd. Beverly Hills, CA 90211-2910 Tel. 310-854-4444 Fax 310-854-0812 kiesel@kiesel-law.com zukin@kiesel-law.com nramirez@kiesel-law.com</p>	<p><i>Attorneys for Plaintiff</i> THE PEOPLE OF THE STATE OF CALIFORNIA</p>
<p>ORANGE COUNTY DISTRICT ATTORNEY Tony Rackauckas, District Attorney Joseph D'Agostino Scott Zidbeck Tracy Hughes, Deputy District Attorney Consumer and Environmental Protection Unit Deputy District Attorney 401 Civic Center Drive Santa Ana, CA 92701-4575 Tel: 714-834-3600 Fax: 714-648-3636 Tony.rackauckas@da.ocgov.com Joe.d'agostino@da.ocgov.com Tracy.hughes@da.ocgov.com Scott.zidbeck@dagov.com</p>	<p><i>Attorneys for Plaintiff</i> THE PEOPLE OF THE STATE OF CALIFORNIA</p>
<p>MOTLEY RICE LLC Linda Singer (<i>Pro hac vice</i>) David Ackerman (<i>Pro hac vice</i>) 401 9th St., N.W., Suite 1001 Washington, DC 20004 Tel: 202-386-9626 Fax: 202-386-9622 lsinger@motleyrice.com afu@motleyrice.com dbenner@motleyrice.com dackerman@motleyrice.com jforster@motleyrice.com</p>	<p><i>Attorneys for Plaintiff</i> THE PEOPLE OF THE STATE OF CALIFORNIA</p>

<p>1 HAGENS BERMAN SOBOL SHAPIRO LLP 2 Steve W. Berman (<i>Pro hac vice</i>) 3 Thomas E. Loeser 4 1918 Eighth Avenue, Suite 3300 5 Seattle, WA 98101 6 Tel: 206-623-7292 7 Fax: 206-623-0594 8 steve@hbsslaw.com 9 tomloeser@hbsslaw.com</p>	<p><i>Attorneys for Plaintiff</i> THE PEOPLE OF THE STATE OF CALIFORNIA</p>
<p>7 HAGENS BERMAN SOBOL SHAPIRO LLP 8 Elaine Byszewski 9 301 North Lake Avenue, Suite 203 10 Pasadena, CA 91101 11 Tel: 213-330-7150 12 Fax: 213-330-7152 13 Elaine@hbsslaw.com</p>	<p><i>Attorneys for Plaintiff</i> THE PEOPLE OF THE STATE OF CALIFORNIA</p>
<p>12 HAGENS BERMAN SOBOL SHAPIRO LLP 13 Jennifer Fountain Connolly (<i>Pro hac vice</i>) 14 1701 Pennsylvania Ave., NW, Suite 300 15 Washington, DC 20006 16 Tel: 202-248-5403 17 Fax: 202-580-6559 18 jenniferf@hbsslaw.com</p>	<p><i>Attorneys for Plaintiff</i> THE PEOPLE OF THE STATE OF CALIFORNIA</p>
<p>16 HAGENS BERMAN SOBOL SHAPIRO LLP 17 Ben Harrington 18 715 Hearst Ave, Suite 202 19 Berkeley, CA 94710 20 Telephone: (510) 725-3000 21 Facsimile: (510) 725-3001 22 benh@hbsslaw.com</p>	<p><i>Attorneys for Plaintiff</i> THE PEOPLE OF THE STATE OF CALIFORNIA</p>

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<p>OFFICE OF THE COUNTY COUNSEL COUNTY OF LOS ANGELES Mary C. Wickham Robert E. Ragland Scott Kuhn Andrea Ross Kenneth Hahn Hall of Administration 500 West Temple Street, 6th Floor Los Angeles, California 90012 Telephone: (213) 974-1811 Facsimile: (213) 974-7446 mwickham@counsel.lacounty.gov rragland@counsel.lacounty.gov skuhn@counsel.lacounty.gov aross@counsel.lacounty.gov</p>	<p><i>Attorneys for Plaintiff</i> THE PEOPLE OF THE STATE OF CALIFORNIA</p>
<p>OFFICE OF THE CITY ATTORNEY CITY OF OAKLAND Barbara J. Parker Maria Bee Erin Bernstein Malia McPherson One Frank H. Ogawa Plaza, 6th Floor Oakland, California 94612 Telephone: (510) 238-6392 Facsimile: (510) 238-6500 bparker@oaklandcityattorney.org mbee@oaklandcityattorney.org eberstein@oaklandcityattorney.org mmcpherson@oaklandcityattorney.org</p>	<p><i>Attorneys for Plaintiff</i> THE PEOPLE OF THE STATE OF CALIFORNIA</p>