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 and THE PEOPLE OF THE STATE OF CALIFORNIA, acting by
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12 UNITED STATES DISTRICT COURT

13 NORTHERN DISTRICT OF CALIFORNIA

14 THE CITY AND COUNTY OF SAN
 FRANCISCO, CALIFORNIA and THE
 15 PEOPLE OF THE STATE OF CALIFORNIA,
 acting by and through San Francisco City
 16 Attorney DENNIS J. HERRERA,

17 Plaintiffs,

18 vs.

19 PURDUE PHARMA L.P., RICHARD S.
 20 SACKLER, JONATHAN D. SACKLER,
 MORTIMER D.A. SACKLER, KATHE A.
 21 SACKLER, ILENE SACKLER LEFCOURT,
 BEVERLY SACKLER, THERESA
 22 SACKLER, DAVID A. SACKLER, TRUST
 FOR THE BENEFIT OF MEMBERS OF THE
 23 RAYMOND SACKLER FAMILY, RHODES
 PHARMACEUTICALS L.P., CEPHALON,
 24 INC., TEVA PHARMACEUTICAL
 INDUSTRIES LTD., TEVA
 25 PHARMACEUTICALS USA, INC., ENDO
 INTERNATIONAL PLC, ENDO HEALTH
 26 SOLUTIONS INC., ENDO
 PHARMACEUTICALS INC., JANSSEN
 27 PHARMACEUTICALS, INC., INSYS
 THERAPEUTICS, INC., MALLINCKRODT,
 28 [Caption continued on following page]

Case No. 3:18-cv-7591

**COMPLAINT FOR: (1) PUBLIC NUISANCE
 (IN THE NAME OF THE PEOPLE OF THE
 STATE OF CALIFORNIA); (2) PUBLIC
 NUISANCE (ON BEHALF OF THE CITY AND
 COUNTY OF SAN FRANCISCO);
 (3) VIOLATION OF CALIFORNIA UNFAIR
 COMPETITION LAW; (4) VIOLATION OF
 FALSE ADVERTISING LAW; (5) VIOLATION
 OF RACKETEER INFLUENCED AND
 CORRUPT ORGANIZATIONS ACT;
 (6) NEGLIGENCE; (7) NEGLIGENT
 MISREPRESENTATION; AND
 (8) FRAUDULENT CONCEALMENT**

DEMAND FOR JURY TRIAL

1 PLC, MALLINCKRODT LLC, ALLERGAN
2 PLC f/k/a ACTAVIS PLC, WATSON
3 PHARMACEUTICALS, INC. n/k/a
4 ACTAVIS, INC., WATSON
5 LABORATORIES, INC., ACTAVIS LLC,
6 ACTAVIS PHARMA, INC. f/k/a/ WATSON
7 PHARMA, INC., AMERISOURCEBERGEN
8 CORPORATION, CARDINAL HEALTH,
9 INC. and McKESSON CORPORATION,
10 Defendants.

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Defendants.

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1 This civil action is a potential tag-along action and, in accordance with 28 U.S.C. §1407, should
 2 be transferred to the United States District Court for the Northern District of Ohio to be included in *In*
 3 *re National Prescription Opiate Litigation*, MDL No. 2804 (Hon. Dan A. Polster), for purposes of
 4 coordinated and consolidated pretrial proceedings.

5 I. INTRODUCTION

6 1. California, like many states across the country, is facing an unprecedented opioid
 7 addiction epidemic. In 2017, there were nearly 22 million opioid prescriptions in California.¹ The
 8 opioid addiction epidemic claimed the lives of more than 2,190 Californians in 2017.² That same year
 9 saw opioid overdoses straining California hospitals with 4,281 emergency room visits.³

10 2. In 2014, more than 47,000 people died in the United States from lethal drug overdoses.
 11 In 2015, that number exceeded 52,000.⁴ In 2016, it exceeded 63,000 – more than the number of
 12 Americans who died during the entirety of the Vietnam War, and more than the number of Americans
 13 who die from breast cancer every year.⁵ Sadly, this trend shows no sign of slowing. The number of
 14 overdose deaths in 2017 is estimated to have been more than 72,000.⁶

15 //

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17 ¹ *2017 California Opioid Overdose Surveillance Dashboard*, California Department of
 18 Public Health (hereinafter, “*2017 California Opioid Overdose Surveillance*”),
<https://discovery.cdph.ca.gov/CDIC/ODdash/> (last visited Dec. 14, 2018).

19 ² *Id.*

20 ³ *Id.*

21 ⁴ *Overdose Death Rates*, National Institute of Drug Abuse,
 22 <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates> (hereinafter,
 “*Overdose Death Rates*”) (last visited Dec. 14, 2018).

23 ⁵ *Vietnam War U.S. Military Fatal Casualty Statistics*, National Archives,
 24 <https://www.archives.gov/research/military/vietnam-war/casualty-statistics.html> (last visited Dec. 14,
 2018); Rose A. Rudd et al., *Increases in Drug and Opioid Involved Overdose Deaths – United States, 2010-2015*, 65 *Morbidity & Mortality Weekly Report* 1445-52 (2016),
 25 <https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm> (hereinafter, “*Rudd, Increases in Drug*
 26 *and Opioid Involved Overdose*”); Nadia Kounang, *Opioids now kill more people than breast cancer*,
 CNN (Dec. 21, 2017), [https://www.cnn.com/2017/12/21/health/drug-overdoses-2016-final-](https://www.cnn.com/2017/12/21/health/drug-overdoses-2016-final-numbers/index.html)
 numbers/index.html.

27 ⁶ Centers for Disease Control and Prevention National Center for Health Statistics, *Vital*
 28 *Statistics Rapid Release Provisional Drug overdose Death Counts*,
<https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm> (last visited Dec. 14, 2018).

1 3. More than three out of five of those deaths involve opioids – a dangerous, highly
2 addictive and often lethal class of natural, synthetic and semi-synthetic painkillers.⁷ Prescription opioids
3 include brand-name medications like OxyContin, Opana, Subsys, Fentora and Duragesic, as well as
4 generics like oxycodone, methadone and fentanyl. In all, more than 200,000 people died in the United
5 States between 1999 and 2016 from overdoses directly related to prescription opioids.

6 4. That number does not take into account the staggering number of additional illicit opioid
7 deaths that can be related back to prescribed opioids. Four out of five new heroin users began first with
8 prescription opioid misuse.⁸ It is thus unsurprising that heroin overdose deaths increased in lockstep
9 with those attributed to prescription opioids; the Centers for Disease Control found a fivefold increase
10 in the heroin death rate between 2002 and 2014.⁹ According to an article published in the *New England*
11 *Journal of Medicine*, two studies found that almost 80% of heroin users reported using prescription
12 opioids before initiating heroin use.¹⁰ Further, heroin use increased almost 140% among non-medical
13 users of prescription opioids from the period 2002-2004 to the period 2011-2013.¹¹ These changes
14 appear to be driven primarily by market forces – “increased accessibility, reduced price, and high purity
15 of heroin appear to be major drivers of the recent increases in rates of heroin use” and predate most
16 policies aimed at combatting the abuse and diversion of prescription opioids.¹²

17 5. Further, according to Robert Anderson (“Anderson”), Chief of the Mortality Statistics
18 Branch of the National Center for Health Statistics, deaths from synthetic opioids have undergone “more

19 _____
20 ⁷ And nearly half of those involve legal opioids prescribed by doctors to treat pain.

21 ⁸ Christopher M. Jones, *Heroin use and heroin use risk behaviors among nonmedical*
22 *users of prescription opioid pain relievers – United States, 2002-2004 and 2008-2010*, 132 (1-2) *Drug*
and Alcohol Dependence 95-100 (Sept. 1, 2013), [http://www.drugandalcoholdependence.com/article/S0376-8716\(13\)00019-7/fulltext](http://www.drugandalcoholdependence.com/article/S0376-8716(13)00019-7/fulltext).

23 ⁹ Centers for Disease Control and Prevention National Center for Health Statistics,
24 *Number and age-adjusted rates of drug-poisoning deaths involving opioid analgesics and heroin:*
United States, 1999-2014,
25 http://www.cdc.gov/nchs/data/health_policy/AADR_drug_poisoning_involving_OA_Heroin_US_2000-2014.pdf (last visited Dec. 14, 2018).

26 ¹⁰ Wilson M. Compton et al., *Relationship between Nonmedical Prescription-Opioid Use*
and Heroin Use, 374 N. Eng. J. Med 154-63 (2016), <https://www.nejm.org/doi/full/10.1056/NEJMra1508490>.

27 ¹¹ *Id.*

28 ¹² *Id.*

1 than an exponential increase”¹³ with an expected trend line for 2017 deaths that “will be at least as steep
 2 as 2016, if not steeper.”¹⁴ Between 2005 and 2016, fatal overdoses from synthetic opioids doubled.
 3 “This surge in overdose deaths resulted in the first two-year drop in average U.S. life expectancy since
 4 the early 1960s.” In all, more than 200,000 people died in the United States between 1999 and 2016
 5 from overdoses directly related to prescription opioids.¹⁵

6 6. Public health officials have called the current opioid epidemic the worst drug crisis in
 7 American history.¹⁶ According to Anderson, “I don’t think we’ve ever seen anything like this. Certainly
 8 not in modern times.”¹⁷ On October 26, 2017, President Donald Trump declared it a public health
 9 emergency. According to recent estimates, as many as 145 people in the United States die every day
 10 from opioid overdoses.¹⁸

11 7. The following charts¹⁹ illustrate the rise of opioid-related overdose deaths in the United
 12 States:²⁰

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15 //

16 ¹³ Internal quotation marks are omitted throughout this complaint except where the
 17 internal quotation marks set off a quote that resides within a longer quoted passage.

18 ¹⁴ Christopher Ingraham, *CDC releases grim new opioid overdose figures: ‘We’re talking*
 19 *about more than an exponential increase,*’ Wash. Post (Dec. 21, 2017),
https://www.washingtonpost.com/news/wonk/wp/2017/12/21/cdc-releases-grim-new-opioid-overdose-figures-were-talking-about-more-than-an-exponential-increase/?utm_term=.ad8576e16bea.

20 ¹⁵ *Prescription Opioid Overdose Data*, Centers for Disease Control and Prevention:
 Opioid Overdose, <https://www.cdc.gov/drugoverdose/data/overdose.html> (last visited Dec. 14, 2018).

21 ¹⁶ Julie Bosman, *Inside a Killer Drug Epidemic: A Look at America’s Opioid Crisis*, N.Y.
 22 Times (Jan. 6, 2017), <https://www.nytimes.com/2017/01/06/us/opioid-crisis-epidemic.html>.

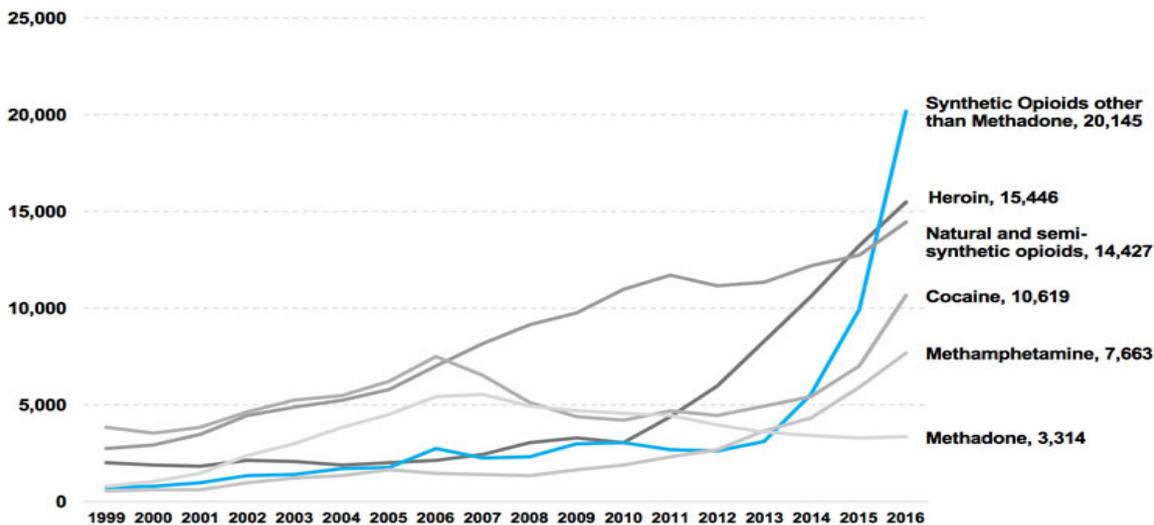
23 ¹⁷ *Drug overdoses now kill more Americans than guns*, CBS News (Dec. 9, 2016),
<https://www.cbsnews.com/news/drug-overdose-deaths-heroin-opioid-prescription-painkillers-more-than-guns/>.

24 ¹⁸ Patrick R. Keefe, *The Family that Built an Empire of Pain*, The New Yorker (Oct. 30,
 25 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>
 (hereinafter, “Keefe, *Empire of Pain*”).

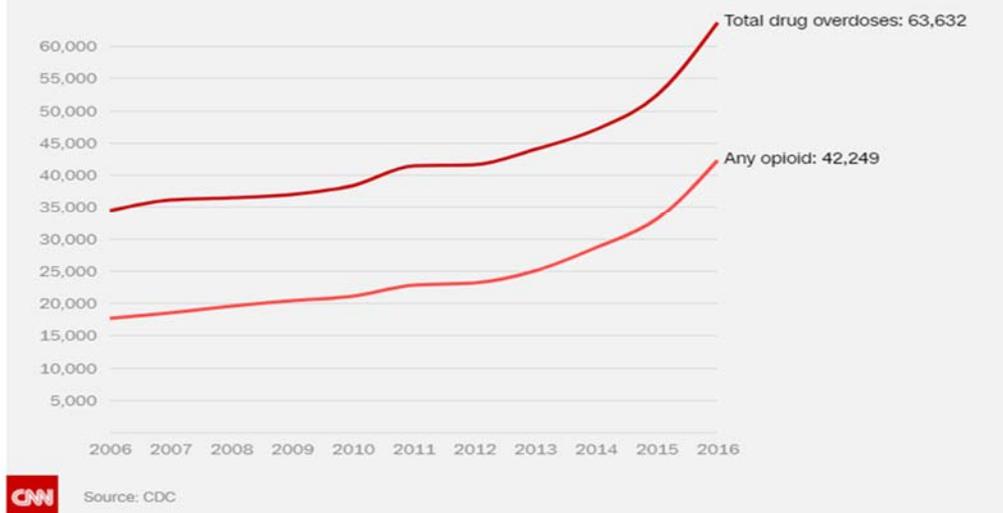
26 ¹⁹ German Lopez & Sarah Frostenson, *How the opioid epidemic became America’s worst*
 27 *drug crisis ever, in 15 maps and charts*, Vox (Mar. 29, 2017), <http://www.vox.com/science-and-health/2017/3/23/14987892/opioid-heroin-epidemic-charts> (hereinafter, “Lopez, *How the opioid epidemic*”).

28 ²⁰ *Overdose Death Rates*, *supra* n.4.

Drugs Involved in U.S. Overdose Deaths, 2000 to 2016



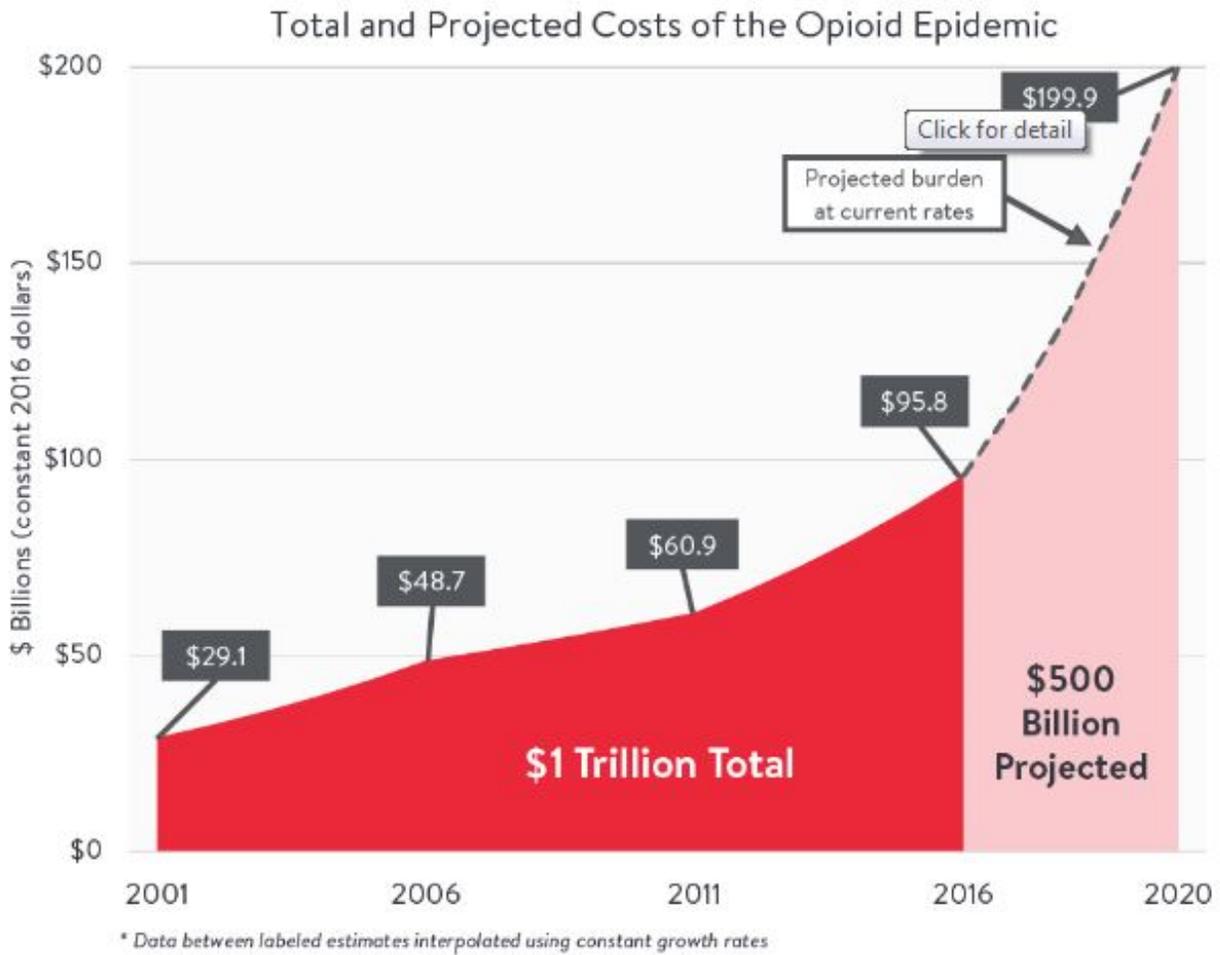
Total US drug overdoses from 2006-2016



Source: CDC

8. The opioid crisis and related expenses continue to grow. According to a report issued on February 13, 2018 by Altarum, a nonprofit health systems research and consulting organization, the cost of the country’s opioid crisis is estimated to have exceeded \$1 trillion from 2001 to 2017, and is projected to cost an additional \$500 billion by 2020:²¹

²¹ *Economic Toll Of Opioid Crisis In U.S. Exceeded \$1 Trillion Since 2001*, Altarum (Feb. 13, 2018), <https://altarum.org/about/news-and-events/economic-toll-of-opioid-crisis-in-u-s-exceeded-1-trillion-since-2001>.



Indeed, the Council of Economic Advisers, an agency within the Executive Office of the President of the United States, concluded in a November 2017 report that the economic cost of the opioid crisis was \$504 billion in 2015 alone. That figure is 2.8% of the 2015 gross domestic product.²²

9. According to a Centers for Disease Control and Prevention (“CDC”) report issued in March 2018, hospital emergency room visits for opioid overdoses rose 30% nationwide between July 2016 and September 2017, with overdoses increasing by 54% in large cities:

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²² The Council of Economic Advisors, *The Underestimated Cost of the Opioid Crisis 1* (Nov. 2017), <https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf>.

Opioid overdoses continued to increase
in cities and towns of all types.*



SOURCE: CDC's Enhanced State Opioid Overdose Surveillance (ESOOS) Program, 16 states reporting percent changes from July 2016 through September 2017.

* From left to right, the categories are:

1) non-core (non-metro), 2) micropolitan (non-metro), 3) small metro, 4) medium metro, 5) large fringe metro, 6) large central metro.

10. On February 27, 2018, then-Attorney General Jeff Sessions announced the creation of the U.S. Department of Justice (“DOJ”) Prescription Interdiction & Litigation (“PIL”) Task Force to fight the prescription opioid crisis.²³ “We have no time to waste,” then-Attorney General Sessions proclaimed. He continued:

“Every day, 180 Americans die from drug overdoses. This epidemic actually lowered American life expectancy in 2015 and 2016 for the first time in decades, with drug overdose now the leading cause of death for Americans under age 50. These are not acceptable trends and this new task force will make us more effective in reversing them and saving Americans from the scourge of opioid addiction.”

11. According to the press release accompanying its announcement, the PIL Task Force will, among other things, seek criminal and civil remedies to hold opioid manufacturers accountable for unlawful practices to ensure that distributors and pharmacies are obeying U.S. Drug Enforcement Administration (“DEA”) rules designed to prevent diversion and improper prescribing. In addition, then-Attorney General Sessions directed the PIL Task Force to examine state and local government lawsuits against opioid manufacturers to determine what assistance federal law, and presumably federal agencies such as the DEA, can provide.

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²³ Press Release, U.S. Department of Justice, Attorney General Sessions Announces New Prescription Interdiction & Litigation Task Force (Feb. 27, 2018), <https://www.justice.gov/opa/pr/attorney-general-sessions-announces-new-prescription-interdiction-litigation-task-force/>.

1 12. The City and County of San Francisco (“San Francisco”) has been hard-hit by the opioid
2 crisis and has expended substantial resources to combat its effects for more than a decade. San Francisco
3 responded to the crisis swiftly, but its efforts have been stymied and overwhelmed by the magnitude of
4 the epidemic. In 1999, for example, San Francisco began a program providing opioid users with
5 treatment on demand with methadone and, later, buprenorphine. Under this program, San Francisco
6 provided among the promptest access to these treatments by any locality. Indeed, heroin use indicators
7 consistently showed a peak in 1999 in the San Francisco Bay Area, followed by a significant decline.²⁴
8 And yet, in the early 2000s, San Francisco was consistently ranked among the worst metropolitan areas
9 for emergency room visits related to heroin.²⁵

10 13. Similarly, in 2003, San Francisco was the first city in the United States to make naloxone,
11 an emergency medication that rapidly reverses opioid overdoses, readily available to members of the
12 public through a partnership between the San Francisco Department of Public Health (“SFDPH”) and a
13 community-based program, the Drug Overdose Prevention and Education Project (“DOPE Project”).²⁶
14 The goal of the DOPE Project was to integrate overdose prevention education and naloxone distribution
15 into all settings serving people at risk for opioid overdose.²⁷ DOPE Project staff and SFDPH medical
16 providers have trained and distributed naloxone at syringe exchange programs, re-entry programs, pain
17 management clinics, methadone maintenance and buprenorphine treatment programs and single room
18 occupancy hotels.²⁸ These efforts also included training 65 librarians at the public library on naloxone
19 administration in 2017.²⁹ In 2017 alone, the program reported 1,247 overdose reversals, a number that
20 does not include naloxone administered by the San Francisco Police Department or paramedics or

21 ²⁴ John A. Newmeyer, *Patterns and Trends of Use in the San Francisco Bay Area*, 35 J.
22 of Psychoactive Drugs 127-32 (2003), <https://www.tandfonline.com/doi/pdf/10.1080/02791072.2003.10400507>.

23 ²⁵ Evelyn Nieves, *An Old Nemesis Scarring San Francisco*, N.Y. Times (Jan. 9, 2001),
24 <https://www.nytimes.com/2001/01/09/us/an-old-nemesis-keeps-scarring-san-francisco.html>.

25 ²⁶ Laura Enteen et al., *Overdose Prevention and Naloxone Prescription for Opioid Users*
26 *in San Francisco*, 87 J. Urb. Health 931-941 (2010), [http://harmreduction.org/wp-](http://harmreduction.org/wp-content/uploads/2012/02/AJPH-overdose.pdf)
27 [content/uploads/2012/02/AJPH-overdose.pdf](http://harmreduction.org/wp-content/uploads/2012/02/AJPH-overdose.pdf).

28 ²⁷ *Id.* at 933.

²⁸ *Id.*

²⁹ Ken Miguel, *San Francisco librarians trained to treat drug overdoses*, ABC 7 News
(Dec. 27, 2017), <https://abc7news.com/health/sf-librarians-trained-to-treat-drug-overdoses/2803729>.

1 naloxone prescribed by medical providers to lay people.³⁰ Treatment with naloxone and opioid agonists
2 are the two best-established interventions to reduce opioid overdose mortality.

3 14. And still, opioid overdose deaths in San Francisco have remained relatively constant
4 since 2006 at about 100 to 120 overdose deaths per year, with trends showing more deaths caused by
5 prescription opioids than by heroin.³¹ In 2009 and 2010, only 13 and 8, respectively, of those deaths
6 each year were from heroin.³² From 2010 through 2012, approximately 331 individuals died from
7 accidental overdose caused by opioids (310 involving prescription opioids and 31 involving heroin).³³

8 15. A June 2014 report by Alice A. Gleghorn, Ph.D. – the County Alcohol and Drug
9 Administrator for the San Francisco Department of Public Health – noted that indicators of heroin usage
10 in San Francisco had begun to climb: “Heroin indicators have reversed trends from low points reported
11 in 2011 and show growth in treatment admissions, treatment episode consensus, and drug reports among
12 items seized and analyzed by DEA NFLIS laboratories.”³⁴ Treatment admissions for heroin, estimated
13 at 1,781 in fiscal year 2010-2011, rose to 1,925 in fiscal year 2012-2013, and the number of treatment
14 episodes primarily related to heroin rose from 3,002 to 3,479 during that same period – more than the
15 treatment episodes caused by any other drug or alcohol in San Francisco.³⁵ Further, although
16 prescriptions of hydrocodone, the most frequently prescribed medication, had declined since 2011,
17
18

19 ³⁰ Nuala Sawyer, *A Radical Reversal*, SF Weekly (Apr. 4, 2018),
20 <http://www.sfweekly.com/topstories/a-radical-reversal> (hereinafter, “Sawyer, *Radical Reversal*”); San
21 Francisco Safe Injection Services Task Force, San Francisco Department of Public Health, 2017 Final
22 Report (Sept. 2017), <https://www.sfdph.org/dph/files/SISTaskforce/SIS-Task-Force-Final-Report-2017.pdf> (hereinafter, “SFDPH 2017 Final Report”).

22 ³¹ SFDPH 2017 Final Report, *supra* n.30, Appendix B at 5.

23 ³² U.S. Department of Health & Human Services, Substance Abuse and Mental Health
24 Services Administration, *DAWN ME 2010 County Profiles, San Francisco County, CA* (2010),
25 <https://www.samhsa.gov/data/sites/default/files/DAWNMEAnnualReport2010/DAWNMEAnnualReport2010/DAWN-ME-AnnualReport2010-009-CA.htm>.

26 ³³ AJ Visconti et al. *Opioid Overdose Deaths in the City and County of San Francisco: Prevalence Distribution and Disparities*, 92 (4) J. Urban Health 758-72 (Aug. 2015) (hereinafter, “Visconti, *Opioid Overdose Deaths*”), <https://www.ncbi.nlm.nih.gov/pubmed/26077643>.

27 ³⁴ Alice A. Gleghorn, Ph.D., *Drug Abuse Patterns and Trends in the San Francisco Bay Area—Update: June 2014*, Proceedings of the Community Epidemiology Work Group (June 2014),
28 <https://archives.drugabuse.gov/sites/default/files/sanfrancisco2014.pdf>.

³⁵ *Id.*

1 Dr. Gleghorn concluded that “various heroin and prescription opioid indicators, including treatment
2 admission and NFLIS data, showed sustained increases.”³⁶

3 16. Overall, as of 2015, heroin overdose deaths, previously common in San Francisco, had
4 become less common; whereas prescription opioid overdose had emerged as a significant concern,
5 particularly among individuals in high-poverty areas.³⁷ If not for the DOPE Project, San Francisco
6 would have seen several hundred more opioid deaths in 2016 alone.³⁸ By the end of 2016, there were
7 an estimated 25,000 people who inject drugs in San Francisco – approximately 14,000-17,000 of whom
8 inject heroin.³⁹ This represents over a 275% increase from the number of people who injected drugs in
9 San Francisco in 2005, which was estimated to be 9,000.⁴⁰

10 17. Further, since 2015, deaths due to fentanyl overdose have increased exponentially.
11 Twice as many people died of fentanyl overdoses in San Francisco in 2016 as in 2015.⁴¹ In early 2018,
12 the SFDPH unanimously endorsed a task force’s recommendation to open what could become the
13 nation’s first legal safe-injection site aimed at curbing the opioid epidemic, including the recent spike in
14 fentanyl-related overdoses.⁴²

15 //

17 ³⁶ *Id.*

18 ³⁷ Visconti, *Opioid Overdose Deaths*, *supra* n.33.

19 ³⁸ Sawyer, *Radical Reversal*, *supra* n.30.

20 ³⁹ Shelly N. Facente et al., *Correction: Estimated hepatitis C prevalence and key*
21 *population sizes in San Francisco: A foundation for elimination*, PloS One (Apr. 11, 2018),
22 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5895024/>; Coffin et al., *Trends in use of health care*
23 *and HIV prevention services for persons who inject drugs in San Francisco: results from National HIV*
24 *Behavioral Surveillance 2005-2012*, Drug and Alcohol Dependence Journal (Jan. 1, 2015),
25 <https://www.ncbi.nlm.nih.gov/pubmed/25468816>.

26 ⁴⁰ Yea-Hung Chen et al., *Estimated Number of People Who Inject Drugs in San*
27 *Francisco, 2005, 2009, and 2012*, AIDS Behav (Dec. 20, 2016),
28 <https://www.ncbi.nlm.nih.gov/pubmed/26721246>.

⁴¹ Sara Gaiser, *Fentanyl link confirmed in Haight-Ashbury deaths*, San Francisco
Examiner (Feb. 23, 2018), <http://www.sfexaminer.com/fentanyl-link-confirmed-haight-ashbury-deaths/>.

⁴² Mark Lieber, *Safe injection sites in San Francisco could be first in the US*, CNN (Feb.
7, 2018), <https://www.cnn.com/2018/02/07/health/safe-injection-sites-san-francisco-opioid-epidemic-bn/index.html>; Alex Barasch, *How Safe Injection Facilities Could Reduce Fentanyl Overdoses*, Slate
(Feb. 22, 2018), <https://slate.com/technology/2018/02/how-safe-injection-facilities-could-limit-fentanyl-overdoses.html>.

1 18. In 2017, more than 318,000 prescriptions were written for opioids in San Francisco, more
2 than 311 prescriptions for every 1,000 residents, and 194 emergency department visits resulting from
3 opioid overdoses, excluding heroin.⁴³

4 19. On May 17, 2018, then-Mayor Mark Farrell announced that he would invest \$6 million
5 to create a first-in-the-nation program with a dedicated drug addiction street team bringing opioid
6 treatment directly to people experiencing addiction on San Francisco streets.⁴⁴ In the press release, then-
7 Mayor Farrell was quoted as saying, “The opioid crisis plaguing our country is alive and visible on the
8 streets of San Francisco. The status quo is simply unacceptable. I am creating this program to directly
9 address drug addiction on our streets—to meet these individuals where they are and get them the help
10 they need, and to ensure that our streets remain safe for all our residents.”⁴⁵

11 20. Proactive programs described above have saved lives, but the toll of the opioid epidemic
12 cannot be measured by overdose deaths alone. Even though fewer lives have been lost, there are more
13 addicts in the general population, impacting crime, homelessness and other aspects of health and human
14 services.

15 21. Drug manufacturers’ deceptive marketing and sale of opioids to treat chronic pain is one
16 of the main drivers of the opioid epidemic. Historically, prescription opioids had been used for short-
17 term, post-surgical and trauma-related pain, and for palliative end-of-life care primarily in cancer
18 patients. Because opioids are highly addictive and dangerous, the U.S. Food and Drug Administration
19 (“FDA”) regulates them as Schedule II Controlled Substances, *i.e.*, drugs that have a high potential for
20 abuse and that may lead to severe psychological or physical dependence.

21 22. This demonstrated need for caution comports with the historical understanding of both
22 the medical community and the American culture at large regarding the serious consequences of opioid
23 use and misuse. Indeed, thousands of years of experience have taught that opioids’ ability to relieve
24

25 ⁴³ 2017 California Opioid Overdose Surveillance, *supra* n.1.

26 ⁴⁴ Press Release, Office of the Mayor, San Francisco, Mayor Mark Farrell Announces
27 Innovative Program to Fight Opioid Crisis on San Francisco Streets (May 17, 2018),
<https://sfmayor.org/article/mayor-mark-farrell-announces-innovative-program-fight-opioid-crisis-san-francisco-streets>.

28 ⁴⁵ *Id.*

1 pain comes at a steep price; opioids are dangerously addictive and often lethal substances. For
2 generations, physicians were taught that opioid painkillers were highly addictive and should be used
3 sparingly and primarily for patients near death.⁴⁶ The medical community also understood that opioids
4 were poorly suited for long-term use because tolerance would require escalating doses and dependence
5 would make it extremely difficult to discontinue their use.

6 23. The prevailing and accurate understanding of the enormous risks and limited benefits of
7 long-term opioid use constrained drug manufacturers' ability to drive sales. In order to decrease
8 reasonable concerns about opioids and to maximize profits, opioid manufacturers, including defendants
9 Purdue, the Sackler Defendants (defined below in §II *infra*), Janssen, Endo, Cephalon, Insys,
10 Mallinckrodt and Actavis (individually defined in §II *infra*) (collectively, the "Marketing Defendants")
11 engaged in a concerted, coordinated strategy to shift the way in which doctors and patients think about
12 pain and, specifically, to encourage the use of opioids to treat not just the relative few who suffer from
13 acute post-surgical pain and end-stage cancer pain, but the masses who suffer from common chronic
14 pain conditions.

15 24. Borrowing from the tobacco industry's playbook, the Marketing Defendants employed
16 ingenious marketing strategies, as detailed further herein, designed to "reeducate" the public and
17 prescribers. The Marketing Defendants deliberately conceived these strategies to create, and in fact did
18 create, an entirely new "health care" narrative – one in which opioids are considered safe and effective
19 for long-term use, and pain is aggressively treated at all costs. According to this newly fabricated
20 narrative, pain was seriously under-treated throughout the United States because opioids were under-
21 prescribed, and doctors came under enormous pressure to treat all kinds of pain with opioids.

22 25. The Marketing Defendants' intention was to normalize aggressive prescribing of opioids
23 for various kinds of pain by downplaying the very real risks of opioids, especially the risk of addiction,
24 and by exaggerating the benefits of use. To accomplish this goal, they intentionally misled doctors and
25 patients about the appropriate uses, risks, safety and efficacy of prescription opioids. They did so
26

27 ⁴⁶ Harriet Ryan et al., *OxyContin goes global – "We're only just getting started,"* L.A.
28 Times (Dec. 18, 2016), <http://www.latimes.com/projects/la-me-oxycotin-part3/> (hereinafter, "Ryan, *OxyContin goes global*").

1 directly through sales representatives and marketing materials and indirectly through financial
2 relationships with academic physicians, professional societies, hospitals, trade associations for state
3 medical boards and seemingly neutral third-party foundations.

4 26. False messages about the safety, addictiveness and efficacy were disseminated by
5 infiltrating professional medical societies and crafting and influencing industry guidelines in order to
6 disseminate false and deceptive pro-opioid communiques under the guise of science and truth.
7 According to a February 2018 report issued by U.S. Senator Claire McCaskill, opioid manufacturers,
8 including several of the Marketing Defendants here, paid nearly \$9 million between 2012 and 2017 to
9 advocacy groups and professional societies operating in the area of opioids policy.⁴⁷ The manufacturers
10 got their money's worth:

11 Initiatives *from the groups in this report often echoed and amplified messages*
12 *favorable to increased opioid use* – and ultimately, the financial interests of opioid
13 manufacturers. *These groups have issued guidelines and policies minimizing the risk*
14 *of opioid addiction and promoting opioids* for chronic pain, lobbied to change laws
15 directed at curbing opioid use, and argued against accountability for physicians and
16 industry executives responsible for overprescription and misbranding.⁴⁸

17 27. The purportedly neutral medical societies also “strongly criticized 2016 guidelines from
18 the . . . (CDC) that recommended limits on opioid prescriptions for chronic pain,” which the *February*
19 *2018 McCaskill Report* described as “a key federal response to the ongoing epidemic.” In conclusion,
20 the report found “a direct link between corporate donations and the advancement of opioids-friendly
21 messaging.”

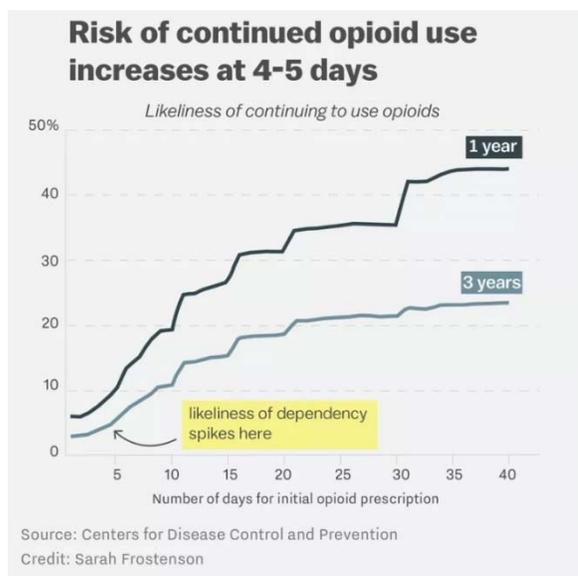
22 28. The Marketing Defendants assured the public and prescribers that the risk of becoming
23 addicted to prescription opioids among patients being treated for pain was less than 1%. In reality, many
24 people with no addiction history can become addicted after just weeks or even days of use.⁴⁹ According

25 ⁴⁷ *Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid*
26 *Manufacturers and Third-Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental
27 Affairs Committee, Ranking Member's Office at 1 (Feb. 13, 2018),
28 <https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf> (hereinafter, “*February 2018 McCaskill Report*”).

⁴⁸ Emphasis is added throughout unless otherwise noted.

⁴⁹ Anna Lembke, *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop* 22 (Johns Hopkins University Press 2016) (hereinafter, “Lembke (2016)”).

1 to estimates, as many as 56% of patients receiving long-term prescription opioid painkillers become
 2 addicted.⁵⁰ Indeed, almost one in five people who receive an opioid prescription with ten days' supply
 3 will still be taking opioids one year later.⁵¹ The following chart illustrates the degree to which the risk
 4 of dependency escalates based on the length of time for which the patient receives an initial opioid
 5 prescription:⁵²



16 29. By 2015, over 20 million prescriptions for federally controlled substances, such as
 17 opioids, were reported to the California Department of Justice. The Marketing Defendants' focus on
 18 driving opioid sales growth led to concomitant growth in the number of deaths resulting from opioid use
 19 and in hospital admissions for opioid-related addiction treatment.⁵³

20 //

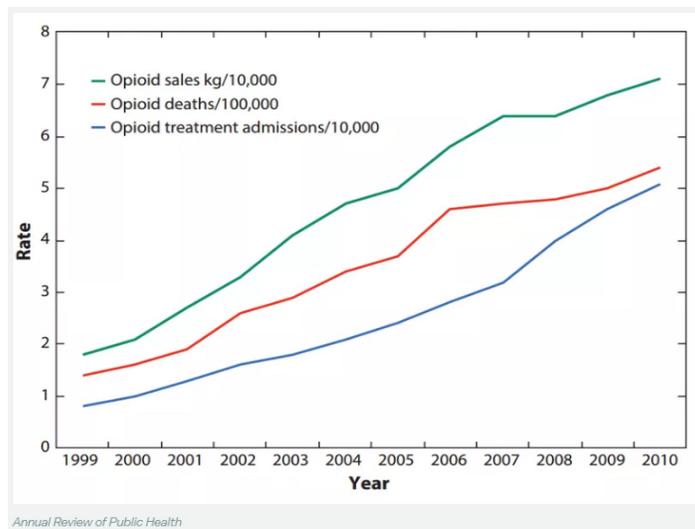
21 //

22 ⁵⁰ Bridget A. Martell et al., *Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction*, 146(2) *Ann. Intern. Med.* 116-27 (2007),
 23 <http://annals.org/aim/article/732048/systematic-review-opioid-treatment-chronic-back-pain-prevalence-efficacy-association> (hereinafter, "Martell, *Systematic Review*").

24 ⁵¹ Sarah Frostenson, *The risk of a single 5-day opioid prescription, in one chart*, *Vox* (Mar. 18, 20107, 7:30 AM), www.vox.com/2017/3/18/14954626/one-simple-way-to-curb-opioid-overuse-prescribe-them-for-3-days-or-less.

25 ⁵² Lopez, *How the opioid epidemic*, *supra* n.19.

26 ⁵³ Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 *Annu. Rev. Public Health* 559-74 (2015),
 27 <http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957>.
 28



30. Put simply, the Marketing Defendants manipulated and misrepresented medical science to serve their own agenda at great human cost. Indeed, in a study published on March 6, 2018 in the *Journal of the American Medical Association* (“JAMA”),⁵⁴ researchers who conducted the first randomized clinical trial designed to compare the efficacy of opioids and non-opioids (including acetaminophen, ibuprofen and lidocaine) for the treatment of moderate to severe back pain, hip pain or knee osteoarthritis pain concluded that patients who took opioids over the long term experienced improvements in pain-related function no better than patients who used safer alternatives.

31. Defendants McKesson, Cardinal Health and AmerisourceBergen (individually defined in §II *infra*) (collectively, the “Wholesaler Defendants”) are major distributors of controlled substances that act as middlemen between drug companies and pharmacies. Like the Marketing Defendants, the Wholesaler Defendants were also aware of a growing epidemic arising from the addiction to, and abuse of, prescription opioids they supplied. The Marketing Defendants and the Wholesaler Defendants were aware of the quantities and frequency with which those drugs were distributed to entities in San Francisco. However, both the Marketing Defendants and the Wholesaler Defendants persisted in failing to report suspicious sales as required by state and federal law. Their failure to follow the law significantly contributed to rising addiction and overdose rates in San Francisco.

⁵⁴ Erin E. Krebs et al., *Effect of Opioid vs. Nonopioid Medications on Pain-Related Function in Patients with Chronic Back Pain or Hip or Knee Osteoarthritis Pain, The SPACE Randomized Clinical Trial*, 319(9) JAMA 872-82 (2018) (hereinafter, “Krebs, *Effect of Opioid vs. Nonopioid Medications*”).

1 32. Defendants wholly failed to meet their obligation to timely report and put a halt to these
2 and other suspicious sales, fueling the flood of pills into San Francisco. As a result, for example, on
3 March 20, 2018, San Francisco surgeon Christopher Owens pleaded guilty to distributing oxycodone
4 without a medical need, in violation of 21 U.S.C. §841(a)(1) and (b)(1)(C).⁵⁵ Owens faces up to 20
5 years' imprisonment, a \$1 million fine and restitution.

6 33. The country's major opioid distributors have paid hefty fines for their failure to report
7 suspicious orders as required by law. McKesson, the largest prescription drug wholesale company in
8 the United States, agreed on January 17, 2017, to pay a \$150 million fine to the federal government. In
9 December 2016, Cardinal Health reached a \$44 million settlement with the federal government. One
10 month later, Cardinal Health reached a \$20 million settlement with the State of West Virginia.
11 AmerisourceBergen also agreed to pay West Virginia \$16 million in 2017.⁵⁶

12 34. Defendants' scheme was tremendously successful, if measured by profit. According to
13 *Fortune* magazine, McKesson, AmerisourceBergen and Cardinal Health are each among the top 15
14 companies in the Fortune 500. The Sackler family, which owns Purdue – a privately held company – is
15 listed on *Fortune's* list of America's wealthiest families; its "ruthless marketing of painkillers has
16 generated billions of dollars – and millions of addicts."⁵⁷

17 35. The impact of opioid addiction has devastated the nation, emerging as one of the
18 country's, and San Francisco's, major health threats. Former FDA Commissioner David A. Kessler has
19 called the failure to recognize the dangers of painkillers "one of the greatest mistakes of modern
20 medicine." As alleged herein, that "mistake" resulted in large part from defendants' false and misleading
21 messaging, which was carefully calculated to reach as many prescribers as possible, as well as
22 defendants' willingness to turn a blind eye to suspicious orders.

23
24
25 ⁵⁵ Press Release, U.S. Department of Justice, Medical Doctor Pleads Guilty To Unlawful
Distribution of Oxycodone (Mar. 20, 2018), <https://www.justice.gov/usao-ndca/pr/medical-doctor-pleads-guilty-unlawful-distribution-oxycodone>.

26 ⁵⁶ Charles Ornstein, *Drug Distributors Penalized For Turning Blind Eye In Opioid*
27 *Epidemic*, National Public Radio (Jan. 27, 2017), [http://www.npr.org/sections/health-](http://www.npr.org/sections/health-shots/2017/01/27/511858862/drug-distributors-penalized-for-turning-blind-eye-in-opioid-epidemic)
shots/2017/01/27/511858862/drug-distributors-penalized-for-turning-blind-eye-in-opioid-epidemic.

28 ⁵⁷ Keefe, *Empire of Pain*, *supra* n.18.

1 36. Even where some defendants have previously been forced to admit the unlawful
2 marketing and sale of opioids and/or the failure to report suspicious orders, the conduct does not abate
3 because profits realized by the aggressive marketing and prescribing of opioids dwarf the penalties
4 imposed as a result of violations found. Thus, the incentive to push opioids remains. The scheme was
5 so financially successful, in fact, that despite the clear and obvious devastation it caused at home,
6 Purdue's owners, the Sackler Defendants, continue to pursue the same strategy abroad. As reported by
7 the *Los Angeles Times* in 2016, Purdue stated "[w]e're only just getting started," and intends to "[p]ut
8 the painkiller that set off the United States opioid crisis into medicine cabinets around the world. A
9 network of international companies owned by the family is moving rapidly into Latin America, Asia,
10 the Middle East, Africa and other regions, and pushing for broad use of painkillers in places ill-prepared
11 to deal with the ravages of opioid abuse and addiction."⁵⁸

12 **II. PARTIES**

13 37. Plaintiff the City and County of San Francisco is one of the 58 counties in the State of
14 California. It is self-insured for certain of the benefits it provides its employees and other beneficiaries.
15 San Francisco City Attorney Dennis J. Herrera is authorized to bring claims under California's Unfair
16 Competition Law ("UCL"), Cal. Bus. & Prof. Code §17200, *et seq.*, and California's False Advertising
17 Law ("FAL"), Cal. Bus. & Prof. Code §17500, *et seq.*, on behalf of Plaintiff The People of the State of
18 California ("the People").

19 38. Defendant Purdue Pharma L.P. is a Delaware limited partnership formed in 1991 with
20 headquarters located in Stamford, Connecticut. The company maintains four operational branches:
21 Purdue Pharma L.P., the Purdue Frederick Company, Purdue Pharmaceutical Products L.P. and Purdue
22 Products L.P. Defendant Rhodes Pharmaceuticals L.P. ("Rhodes") is a Delaware limited partnership
23 formed in or around 2007 with headquarters located in Coventry, Rhode Island. Purdue Pharma L.P.,
24 the Purdue Frederick Company, Purdue Pharmaceutical Products L.P., Purdue Products L.P. and Rhodes
25 are referred to collectively herein as "Purdue."

26 //

27
28 ⁵⁸ Ryan, *OxyContin goes global*, *supra* n.46.

1 39. Defendant Richard S. Sackler is a natural person residing in Travis County, Texas. He
2 has served as a member of the Board of Directors of Purdue and Purdue-related entities since the 1990s.

3 40. Defendant Jonathan D. Sackler is a natural person residing in Fairfield County,
4 Connecticut. He has served as a member of the Board of Directors of Purdue and Purdue-related entities
5 since the 1990s.

6 41. Defendant Mortimer D.A. Sackler is a natural person residing in New York County, New
7 York. He has served as a member of the Board of Directors of Purdue and Purdue-related entities since
8 the 1990s.

9 42. Defendant Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut.
10 She has served as a member of the Board of Directors of Purdue and Purdue-related entities since the
11 1990s.

12 43. Defendant Ilene Sackler Lefcourt is a natural person residing in New York County, New
13 York. She has served as a member of the Board of Directors of Purdue and Purdue-related entities since
14 the 1990s.

15 44. Defendant Beverly Sackler is a natural person residing in Fairfield County, Connecticut.
16 She has served as a member of the Board of Directors of Purdue and Purdue-related entities since the
17 1990s.

18 45. Defendant Theresa Sackler is a natural person residing in New York County, New York.
19 She has served as a member of the Board of Directors of Purdue and Purdue-related entities since the
20 1990s.

21 46. Defendant David A. Sackler is a natural person residing in New York County, New York.
22 He has served as a member of the Board of Directors of Purdue and Purdue-related entities since 2012.

23 47. Defendant Trust for the Benefit of Members of the Raymond Sackler Family (the
24 “Raymond Sackler Trust”) is a trust for which Defendants Beverly Sackler, Richard S. Sackler and/or
25 Jonathan D. Sackler are trustees. It is the 50% direct or indirect beneficial owner of Purdue and the
26 Purdue-related entities and the recipient of 50% of the profits from the sale of opioids by Purdue and
27 Purdue-related entities. Collectively, the defendants listed in ¶¶39-47 are referred to as the “Sackler
28 Defendants” or “Sackler Families.”

1 48. Defendant Cephalon, Inc. is a Delaware corporation with its headquarters and principal
2 place of business located in Frazer, Pennsylvania. Cephalon, Inc. was acquired by defendant Teva
3 Pharmaceutical Industries Ltd. (“Teva Ltd.”) in October 2011. Teva Ltd. is incorporated under the laws
4 of Israel with its principal place of business in Petah Tikva, Israel. Since Teva Ltd. acquired Cephalon,
5 Inc., its United States sales and marketing activities have been conducted by defendant Teva
6 Pharmaceuticals USA, Inc. (“Teva USA” and, together with Teva Ltd., “Teva”), a wholly owned
7 operating subsidiary of Teva Ltd. Teva USA’s headquarters and principal place of business are in North
8 Wales, Pennsylvania. Cephalon, Inc. and Teva are collectively referred to herein as “Cephalon.”

9 49. Defendant Endo International plc is an Irish public limited company with its headquarters
10 in Dublin, Ireland. Defendant Endo Health Solutions Inc. is a Delaware corporation with its
11 headquarters and principal place of business in Malvern, Pennsylvania. Defendant Endo
12 Pharmaceuticals Inc. (together with Endo International plc and Endo Health Solutions Inc., “Endo”) is
13 a Delaware corporation with its headquarters and principal place of business in Malvern, Pennsylvania.
14 Endo Pharmaceuticals Inc. is an indirectly, wholly owned subsidiary of Endo International plc.

15 50. Defendant Janssen Pharmaceuticals, Inc. (“Janssen”) (formerly known as Ortho-McNeil-
16 Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica) is headquartered in Titusville, New Jersey
17 and Raritan, New Jersey. Janssen is a wholly owned subsidiary of Johnson & Johnson, a New Jersey
18 corporation with its principal place of business in New Brunswick, New Jersey.

19 51. Defendant Insys Therapeutics, Inc. (“Insys”) is a Delaware corporation with its principal
20 place of business in Chandler, Arizona.

21 52. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in
22 Staines-Upon-Thames, Surrey, United Kingdom. Defendant Mallinckrodt LLC (together with
23 Mallinckrodt plc, “Mallinckrodt”) is a Delaware limited liability company with its headquarters in
24 Hazelwood, Missouri.

25 53. Defendant Allergan plc is a public limited company incorporated in Ireland with its
26 principal place of business in Dublin, Ireland. Actavis plc acquired Allergan plc in 2015, and the
27 combined company changed its name to Allergan plc. Defendant Actavis, Inc. was acquired by
28 Defendant Watson Pharmaceuticals, Inc. in October 2012, and the combined company changed its name

1 to Actavis, Inc. as of January 2013, then to Actavis plc in October 2013. Defendant Watson
2 Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and
3 is a wholly owned subsidiary of Allergan plc (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.).
4 Defendant Actavis Pharma, Inc. is a Delaware corporation with its principal place of business in New
5 Jersey and was formerly known as Watson Pharma, Inc. Defendant Actavis LLC is a Delaware limited
6 liability company with its principal place of business in Parsippany, New Jersey. Each of these
7 defendants and entities is owned by Defendant Allergan plc, which uses them to market and sell its drugs
8 in the United States. Collectively, the defendants and entities in this paragraph are referred to as
9 “Actavis.”

10 54. Defendant AmerisourceBergen Corporation (“AmerisourceBergen”) is a Delaware
11 corporation with its headquarters and principal place of business located in Chesterbrook, Pennsylvania.

12 55. Defendant Cardinal Health, Inc. (“Cardinal Health”) is an Ohio corporation with its
13 headquarters and principal place of business located in Dublin, Ohio.

14 56. Defendant McKesson Corporation (“McKesson”) is a Delaware corporation with its
15 headquarters and principal place of business located in San Francisco, California.

16 **III. JURISDICTION AND VENUE**

17 57. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1331. It has
18 supplemental jurisdiction over Plaintiffs’ state law claims pursuant to 28 U.S.C. §1367.

19 58. This is a judicial district where defendants are subject to personal jurisdiction in
20 accordance with 28 U.S.C. §1391 and Cal. Code Civ. Proc. §410.10, the California long-arm statute.
21 Defendants Purdue, the Sackler Defendants, Janssen, Endo, Cephalon, Insys, Mallinckrodt, Actavis,
22 McKesson, Cardinal Health and AmerisourceBergen purposefully availed themselves of the benefits,
23 profits and privileges deriving from their business activities in this state. Defendant McKesson has at
24 all relevant times maintained its corporate headquarters in San Francisco, California.

25 59. The non-resident defendants regularly engage in business within the State of California
26 and within this District. Defendants have committed tortious acts that have caused injury to San
27 Francisco. Defendants expect, or should reasonably have expected, those acts to have consequences in
28 the State of California and in San Francisco. Moreover, defendants solicited business within this

1 District, engaged in persistent courses of conduct here and derived substantial revenue from goods used
2 and services rendered in the State of California and this District through interstate commerce.

3 60. Defendants are regularly engaged in the business of manufacturing and distributing
4 prescription opioids, either directly or indirectly through third-party related entities, in the State of
5 California and, specifically, in San Francisco. Defendants' activities in San Francisco in connection
6 with the manufacture and distribution of prescription opioids were, and are, continuous and systematic,
7 and give rise to the causes of action alleged herein.

8 61. Venue is proper within this District and this Division pursuant to 28 U.S.C. §1391 and
9 Civ. L.R. 3-2(c) because Plaintiffs and Defendant McKesson are both located in this District and
10 Division, and a substantial part of the events or omissions giving rise to San Francisco's and the People's
11 claims occurred here.

12 **IV. FACTUAL ALLEGATIONS**

13 **A. Over the Course of More than Two Decades, the Marketing Defendants** 14 **Misled the Public Regarding the Dangers of Opioid Addiction and the** 15 **Efficacy of Opioids for Long-Term Use, Causing Sales and Overdose Rates** **to Soar**

16 62. From the mid-90s to the present, the Marketing Defendants aggressively marketed and
17 falsely promoted liberal opioid prescribing as presenting little to no risk of addiction, even when used
18 long term for chronic pain. They infiltrated academic medicine and regulatory agencies to convince
19 doctors that treating chronic pain with long-term opioids was evidence-based medicine when, in fact, it
20 was not. Huge profits resulted from these efforts, as did the present addiction and overdose crisis.

21 **1. Background on Opioid Overprescribing**

22 63. The Marketing Defendants' scheme to drive their rapid and dramatic expansion of
23 prescription opioids was rooted in two pieces of so-called evidence. First was the publication of a 100-
24 word letter to the editor published in 1980 in the *New England Journal of Medicine* ("1980 Letter to the
25 Editor").⁵⁹ A recent article about the 1980 Letter to the Editor, titled, "A 5-sentence letter helped trigger

26 ⁵⁹ The 1980 Letter to the Editor by Jane Porter ("Porter") and Dr. Herschel Jick ("Jick"),
27 reported that less than 1% of patients at Boston University Medical Center who received narcotics
28 while hospitalized became addicted. Jane Porter & Hershel Jick, *Addiction rate in patients treated*
with narcotics, 302(2) *New Eng. J. Med.* 123 (Jan. 10, 1980). However, the letter did not support the
conclusion for which it was often cited by the industry. Harrison Jacobs, *This one-paragraph letter*

1 America’s deadliest drug overdose crisis ever,” quoted a 2017 study in the *New England Journal of*
 2 *Medicine*, in which researchers concluded:

3 [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and
 4 uncritically cited as evidence that addiction was rare with long-term opioid therapy. We
 5 believe that this citation pattern contributed to the North American opioid crisis by
 helping to shape a narrative that allayed prescribers’ concerns about the risk of addiction
 associated with long-term opioid therapy.⁶⁰

6 64. Second was a single medical study published by Drs. Russell Portenoy (“Portenoy”) and
 7 Kathleen Foley (“Foley”) (“Portenoy Publication”).⁶¹ Portenoy emerged as one of the industry’s most
 8 vocal proponents of long-term opioid use, who essentially made it his life’s work to campaign for the
 9 movement to increase use of prescription opioids. He was one of Big Pharma’s⁶² “thought leaders” and
 10 was paid to travel the country to promote more liberal opioid prescribing for many types of pain. His
 11 talks were sponsored by the Marketing Defendants and organizations paid by them as continuing

12 _____
 13 *may have launched the opioid epidemic*, Bus. Insider (May 26, 2016),
 14 <http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5>
 15 (hereinafter, “Jacobs, *One-paragraph letter*”). As discussed in a 2009 article in the *American Journal*
 16 *of Public Health*, the 1980 Letter to the Editor “shed[] some light on the risk of addiction for acute
 17 pain, [but did] not help establish the risk of iatrogenic addiction when opioids are used daily for a
 prolonged time in treating chronic pain. [Indeed, t]here are a number of studies . . . that demonstrate
 that in the treatment of chronic non-cancer-related pain with opioids, there is a high incidence of
 prescription drug abuse.” Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial*
Triumph, Public Health Tragedy, 99(2) Am. J. Pub. Health 221-27 (Feb. 2009) (hereinafter, “Van Zee,
Promotion and Marketing”).

18 ⁶⁰ German Lopez, *A 5-sentence letter helped trigger America’s deadliest drug overdose*
 19 *crisis ever*, Vox (June 1, 2017), <https://www.vox.com/science-and-health/2017/6/1/15723034/opioid-epidemic-letter-1980-study>.

20 ⁶¹ In 1986, the medical journal *Pain*, which would eventually become the official journal
 21 of the American Pain Society (“APS”), published an article by Portenoy and Foley summarizing the
 22 results of a “study” of 38 chronic non-cancer pain patients who had been treated with opioid painkillers.
 23 Portenoy and Foley concluded that, for non-cancer pain, opioids “can be safely and effectively
 24 prescribed to selected patients with relatively little risk of producing the maladaptive behaviors which
 25 define opioid abuse.” However, their study was neither scientific nor did it meet the rigorous standards
 26 commonly used to evaluate the validity and strength of such studies in the medical community. For
 instance, there was no placebo control group, and the results were retroactive (asking patients to describe
 prior experiences with opioid treatment rather than less biased, in-the-moment reports). The authors
 themselves advised caution, stating that the drugs should be used as an “alternative therapy” and
 recognizing that longer-term studies of patients on opioids would have to be performed. None were.
 See Russell K. Portenoy & Kathleen M. Foley, *Chronic use of opioid analgesics in non-malignant pain:*
report of 38 cases, 25(2) *Pain* 171-86 (May 1986).

27 ⁶² “Big Pharma” is used herein to refer to large pharmaceutical companies, including, but
 28 not limited to, defendants, considered especially as a politically influential group.

1 medical education (“CME”) programs for doctors. He had financial relationships with at least a dozen
2 pharmaceutical companies, most of which produced prescription opioids.⁶³

3 65. On November 1, 2017, the President’s Commission on Combating Drug Addiction and
4 the Opioid Crisis noted the important and detrimental role played by the 1980 Letter to the Editor and
5 the Portenoy Publication. In a section of the Commission’s Report with the header “Contributors to the
6 Current Crisis,” the Commission wrote the following:

7 **Unsubstantiated claims:** One early catalyst can be traced to a single letter to the Editor
8 of the New England Journal of Medicine published in 1980, that was then cited by over
9 600 subsequent articles. With the headline “Addiction Rare in Patients Treated with
10 Narcotics,” the flawed conclusion of the five-sentence letter was based on scrutiny of
11 records of hospitalized patients administered an opioid. It offered no information on
12 opioid dose, number of doses, the duration of opioid treatment, whether opioids were
13 consumed after hospital discharge, or long-term follow-up, nor a description of criteria
14 used to designate opioid addiction. Six years later, another problematic study concluded
15 that “opioid maintenance therapy can be a safe, salutary and more humane alternative to
16 the options of surgery or no treatment in those patients with intractable non-malignant
17 pain and no history of drug abuse.” High quality evidence demonstrating that opioids
18 can be used safely for chronic non-terminal pain did not exist at that time. These reports
19 eroded the historical evidence (see Appendix 2) of iatrogenic addiction and aversion to
20 opioids, with the poor-quality evidence that was unfortunately accepted by federal
21 agencies and other oversight organizations.⁶⁴

22 66. Portenoy has now admitted that he minimized the risks of opioids.⁶⁵ In a 2011 interview
23 released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work
24 purposefully relied on evidence that was not “real” and left real evidence behind:

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

24 ⁶³ Lembke (2016), *supra* n.49, at 59 (citing Barry Meier, *Pain Killer: A “Wonder” Drug’s
Trail of Addiction and Death* (St. Martin’s Press, 1st ed. 2003)).

25 ⁶⁴ *The President’s Commission on Combating Drug Addiction and the Opioid Crisis* at 20
26 (Nov. 1, 2017), [https://www.whitehouse.gov/sites/whitehouse.gov/
files/images/Final_Report_Draft_11-1-2017.pdf](https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf).

27 ⁶⁵ Celine Gounder, *Who Is Responsible for the Pain-Pill Epidemic?*, *New Yorker* (Nov. 8,
28 2013), <http://www.newyorker.com/business/currency/who-is-responsible-for-the-pain-pill-epidemic>
(hereinafter, “Gounder, *Who Is Responsible*”).

1 *[opioids], and because the primary goal was to destigmatize, we often left evidence*
2 *behind.*⁶⁶

3 67. The damage, however, was already done. The Marketing Defendants used these two
4 publications, the 1980 Letter to the Editor and the Portenoy Publication, as the foundation for a massive,
5 far-reaching campaign to dramatically shift the thinking of healthcare providers, patients, policymakers
6 and the public on the risk of addiction presented by opioid therapy. By 1997, the APS and the American
7 Academy of Pain Medicine (“AAPM”) (both funded by the Marketing Defendants) issued a “landmark
8 consensus,” co-authored by Portenoy, stating there is little risk of addiction or overdose in pain
9 patients.⁶⁷

10 68. In the years following publication of the 1980 Letter to the Editor and the Portenoy
11 Publication, the Marketing Defendants introduced powerful prescription opioids into the market. Purdue
12 introduced MS Contin in 1987 and OxyContin in 1995, Janssen introduced Duragesic in 1990 and
13 Cephalon’s Actiq was first approved by the FDA in 1998. More recently, Endo’s Opana and Opana ER
14 were approved by the FDA in 2006, as was Janssen’s Nucynta in 2008 and Nucynta ER in 2011,
15 Cephalon’s Fentora in 2006 and Insys’ Subsys in 2012.

16 69. These branded prescription opioids and their generic counterparts are highly addictive.
17 Between doses, patients can suffer body aches, nausea, sweats, racing heart, hypertension, insomnia,
18 anxiety, agitation, opioid cravings, opioid-induced hyperalgesia (heightened sensitivity to pain) and
19 other symptoms of withdrawal. When the agony is relieved by the next dose, it creates a cycle of
20 dysphoria and euphoria that fosters addiction and dependence.

21 70. Despite the prescription opioids’ highly addictive qualities, the Marketing Defendants
22 launched aggressive pro-opioid marketing efforts that caused a dramatic shift in the public’s and
23 prescribers’ perception of the safety and efficacy of opioids for chronic long-term pain and everyday
24 use. Contrary to what doctors had previously understood about opioid risks and benefits, they were
25 encouraged for the last two decades by the Marketing Defendants to prescribe opioids aggressively and

26 ⁶⁶ Jacobs, *One-paragraph letter, supra* n.59; Andrew Kolodny, *Opioids for Chronic Pain:*
27 *Addiction is NOT Rare*, YouTube (Oct. 30, 2011), <https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be>.

28 ⁶⁷ Jacobs, *One-paragraph letter, supra* n.59.

1 were assured, based on false evidence provided directly by the Marketing Defendants and numerous
2 medical entities funded by the Marketing Defendants and others with financial interests in generating
3 more opioid prescriptions, that: (a) the risk of becoming addicted to prescription opioids among patients
4 being treated for pain was low, even as low as less than 1%; and (b) great harm was caused by “under-
5 treated pain.” These two foundational falsehoods led directly to the current opioid crisis.

6 71. The strategy was a brilliant marketing success. It was designed to redefine back pain,
7 neck pain, headaches, arthritis, fibromyalgia and other common conditions suffered by most of the
8 population at some point in their lives as a distinct malady – chronic pain – that doctors and patients
9 should take seriously and for which opioids were an appropriate, successful and low-risk treatment.
10 Indeed, studies now show more than 85% of patients taking OxyContin at common doses are doing so
11 for chronic non-cancer pain.⁶⁸

12 72. This false and misleading marketing strategy continued despite studies revealing that up
13 to 56% of patients receiving long-term prescription opioid painkillers for chronic back pain progress to
14 addictive opioid use, including patients with no prior history of addiction.⁶⁹

15 73. Despite the Marketing Defendants’ representations to the contrary, there was no evidence
16 of opioids’ efficacy for the treatment of chronic pain. In fact, the first randomized clinical trial designed
17 to make head-to-head comparisons between opioids and other kinds of pain medications was recently
18 published on March 6, 2018, in *JAMA*. The trial, sponsored by the U.S. Department of Veterans Affairs
19 (“Veterans Affairs”), was a randomized, 12-month study of 240 patients at Veterans Affairs primary
20 care clinics. Each of the eligible patients had moderate to severe chronic back pain or hip or knee
21 osteoarthritis despite the use of analgesic drugs.

22 74. The researchers reported that “[t]here was no significant difference in pain-related
23 function between the 2 groups” – those whose pain was treated with opioids and those whose pain was
24 treated with non-opioids, including acetaminophen and other non-steroidal anti-inflammatory drugs
25
26

27 ⁶⁸ Ryan, *OxyContin goes global*, *supra* n.46.

28 ⁶⁹ Lembke (2016), *supra* n.49, at 22 (citing Martell, *Systematic Review*, *supra* n.50).

1 (“NSAIDs”) like ibuprofen. As such, they concluded: “*Treatment with opioids was not superior to*
 2 *treatment with nonopioid medications for improving pain-related function over 12 months.*”⁷⁰

3 75. Thus, based on false and incomplete evidence, the Marketing Defendants expanded their
 4 market exponentially from patients with end-stage cancer and acute pain, an obviously limited customer
 5 base, to anyone suffering from chronic pain, which by some accounts includes approximately 100
 6 million Americans – nearly one-third of the country’s population.⁷¹ The treatment of chronic pain
 7 includes patients whose general health is good enough to refill prescriptions month after month, year
 8 after year, and the promotion, distribution (without reporting suspicious sales) and rampant sale of
 9 opioids for such treatment has made defendants billions of dollars. It has also led to the prevalence of
 10 opioid addiction and the overdose crisis in San Francisco.

11 2. The Fraudulent Sales Practices

12 76. As set forth below, the Marketing Defendants employed a variety of strategies to
 13 normalize the use of opioids for chronic long-term pain without informing the public and prescribers
 14 about the very significant risk of addiction, overdose and death.

15 a. The Marketing Defendants Funded Front Organizations that 16 Published and Disseminated False and Misleading Marketing Materials

17 77. The Marketing Defendants sponsored purportedly neutral medical boards and
 18 foundations that educated doctors and set guidelines for the use of opioids in medical treatment in order
 19 to promote the liberal prescribing of opioids for chronic pain. The following organizations, funded by
 20 the Marketing Defendants, advised doctors that liberal prescribing of opioids was both safe and
 21 effective. In truth, it was neither.

22 78. **Federation of State Medical Boards:** The Federation of State Medical Boards
 23 (“FSMB”) is a national organization that functions as a trade group representing the 70 medical and
 24 osteopathic boards in the United States. The FSMB often develops guidelines that serve as the basis for
 25 model policies with the stated goal of improving medical practice. Defendants Purdue, Cephalon and
 26

27 ⁷⁰ Krebs, *Effect of Opioid vs. Nonopioid Medications*, *supra* n.54.

28 ⁷¹ *AAPM Facts and Figures on Pain*, The American Academy of Pain Medicine,
http://www.painmed.org/patientcenter/facts_on_pain.aspx#refer (last visited Dec. 14, 2018).

1 Endo have provided substantial funding to the FSMB. Among its members are the Medical Board of
2 California and the Osteopathic Medical Board of California.

3 79. In 2007, the FSMB printed and distributed a physician’s guide on the use of opioids to
4 treat chronic pain titled, “Responsible Opioid Prescribing” by Dr. Scott M. Fishman (“Fishman”). After
5 the guide (in the form of a book, still available for sale on Amazon) was adopted as a model policy, the
6 FSMB reportedly asked Purdue for \$100,000 to help pay for printing and distribution. Ultimately, the
7 guide was disseminated by the FSMB to 700,000 practicing doctors.

8 80. The guide’s clear purpose is to focus prescribers on the purported under-treatment of pain
9 and falsely assure them that opioid therapy is an appropriate treatment for chronic, non-cancer pain:

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

* * *

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

- 15 1. Lack of knowledge of medical standards, current research, and clinical guidelines
16 for appropriate pain treatment;
- 17 2. The perception that prescribing adequate amounts of opioids will result in
18 unnecessary scrutiny by regulatory authorities;
- 19 3. ***Misunderstanding of addiction and dependence;*** and
- 20 4. Lack of understanding of regulatory policies and processes.⁷²

21 81. While it acknowledges the risk of “abuse and diversion” (with little attention to
22 addiction), the guide purports to offer “professional guidelines” that will “easily and efficiently” allow
23 physicians to manage that risk and “minimize the potential for [such] abuse.”⁷³ Indeed, it states that
24 even for those patients assessed to have risk of substance abuse, “it does not mean that opioid use will
25

26
27 ⁷² Scott M. Fishman, *Responsible Opioid Prescribing: A Physician’s Guide* 8-9
(Waterford Life Sciences 2007).

28 ⁷³ *Id.* at 9.

1 become problematic or that opioids are contraindicated,” just that physicians should use additional care
2 in prescribing.

3 82. The guide further warns physicians to “[b]e aware of the distinction between
4 pseudoaddiction and addiction” and teaches that behaviors such as “[r]equesting [drugs] by name,”
5 “[d]emanding or manipulative behavior,” “[o]btaining opioid drugs from more than one physician” and
6 “[h]oarding opioids,” which are, in fact, signs of genuine addiction, are all really just signs of
7 “pseudoaddiction.”⁷⁴ It defines “Physical Dependence” as an acceptable result of opioid therapy not to
8 be equated with addiction and states that while “[i]t may be tempting to assume that patients with chronic
9 pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing
10 medications,” there could be other acceptable reasons for non-adherence.⁷⁵ The guide, sponsored by the
11 Marketing Defendants and their pain foundations, became the seminal authority on opioid prescribing
12 for the medical profession and dramatically overstated the safety and efficacy of opioids and understated
13 the risk of opioid addiction.

14 83. In 2012, Fishman updated the guide and continued emphasizing the “catastrophic”
15 “under-treatment” of pain and the “crisis” such under-treatment created:

16 Given the magnitude of the problems related to opioid analgesics, it can be
17 tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids,
18 or legislation intended to improve pharmacovigilance may inadvertently curtail patient
19 access to care. As we work to reduce diversion and misuse of prescription opioids, *it’s*
20 ***critical to remember that the problem of unrelieved pain remains as urgent as ever.***⁷⁶

19 84. The updated guide still assures that “[o]pioid therapy to relieve pain and improve
20 *function is legitimate medical practice for acute and chronic pain of both cancer and noncancer*
21 *origins.*”⁷⁷

22 85. In another guide by Fishman, he continues to downplay the risk of addiction: “*I believe*
23 *clinicians must be very careful with the label ‘addict.’ I draw a distinction between a ‘chemical copper’*
24

25 ⁷⁴ *Id.* at 62.

26 ⁷⁵ *Id.*

27 ⁷⁶ Scott M. Fishman, *Responsible Opioid Prescribing: A Clinician’s Guide* 10-11
(Waterford Life Sciences 2012).

28 ⁷⁷ *Id.* at 11.

1 **and an addict.**⁷⁸ The guide also continues to present symptoms of addiction as symptoms of
2 “pseudoaddiction.”

3 86. The heightened focus on the under-treatment of pain was a concept designed by Big
4 Pharma to sell opioids. ***The FSMB actually issued a report calling on medical boards to punish***
5 ***doctors for inadequately treating pain.***⁷⁹ Among the drafters of this policy was Dr. J. David Haddox
6 (“Haddox”), who coined the term “pseudoaddiction,” which wholly lacked scientific evidence but
7 quickly became a common way for the Marketing Defendants and their allies to promote the use of
8 opioids even to patients displaying addiction symptoms. Haddox later became a Purdue vice president
9 who likened OxyContin to a vegetable, stating at a 2003 conference at Columbia University,⁸⁰ “If I gave
10 you a stalk of celery and you ate that, it would be healthy. But if you put it in a blender and tried to
11 shoot it into your veins, it would not be good.”⁸¹

12 87. As noted in §IV.A.2.c. *infra*, in 2012 and again in 2017, the guides and the sources of
13 their funding became the subject of a Senate investigation.

14 88. On June 8, 2012, the FSMB submitted a letter to the Senate Finance Committee
15 concerning its investigation into the abuse and misuse of opioids.⁸² While the letter acknowledged the
16 escalation of drug abuse and related deaths resulting from prescription painkillers, the FSMB continued
17 to focus on the “serious and related problem” that “[m]illions of Americans suffer from debilitating pain
18 – a condition that, for some, can be relieved through the use of opioids.” Among other things, the letter
19 stated that “[s]tudies have concluded that both acute pain and chronic pain are often under-treated in the
20 United States, creating serious repercussions that include the loss of productivity and quality of life.”
21 The letter cited no such studies. The letter also confirmed that the FSMB’s “Responsible Opioid
22

23
24 ⁷⁸ Scott M. Fishman, *Listening to Pain: A Physician’s Guide to Improving Pain Management Through Better Communication* 45 (Oxford University Press 2012).

25 ⁷⁹ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, at A1.

26 ⁸⁰ Gounder, *Who Is Responsible*, *supra* n.65.

27 ⁸¹ Keefe, *Empire of Pain*, *supra* n.18.

28 ⁸² June 8, 2012 Letter from Federation of State Medical Boards to U.S. Senators Max Baucus and Charles Grassley.

1 Prescribing: A Physician’s Guide” has been distributed in each of the 50 states and the District of
2 Columbia.

3 89. In addition, the FSMB letter disclosed payments the FSMB received from organizations
4 that develop, manufacture, produce, market or promote the use of opioid-based drugs from 1997 through
5 the present. Included in the payments received are the following payments from defendants:

<i>Company</i>	<i>Fiscal Year</i>	<i>Amount</i>
Purdue	2001	\$38,324.56
	2002	\$10,000.00
	2003	\$85,180.50
	2004	\$87,895.00
	2005	\$244,000.00
	2006	\$207,000.00
	2007	\$50,000.00
	2008	\$100,000.00
	Total Purdue Payments	\$822,400.06
Endo	2007	\$40,000.00
	2008	\$100,000.00
	2009	\$100,000.00
	2011	\$125,000.00
	2012	\$46,620.00
	Total Endo Payments	\$411,620.00
Cephalon	2007	\$30,000.00
	2008	\$100,000.00
	2011	\$50,000.00
	Total Cephalon Payments	\$180,000.00
Mallinckrodt	2011	\$100,000.00
		Total Mallinckrodt Payments

19 90. The letter also disclosed payments of \$40,000 by Endo and \$50,000 by Purdue to directly
20 fund the production of “Responsible Opioid Prescribing” and disclosed that sales of “Responsible
21 Opioid Prescribing” generated more than \$2.75 million in revenues from sales in California.⁸³

22 91. **The Joint Commission**: The Joint Commission is an organization that establishes
23 standards for treatment and accredits healthcare organizations in the United States. The Marketing
24 Defendants, including Purdue, contributed misleading and groundless teaching materials and videos to
25 the Joint Commission, which emphasized what Big Pharma coined the “under-treatment of pain,”
26 referenced pain as the “fifth vital sign” (the first and only unmeasurable/subjective vital sign) that must
27

28 ⁸³ *Id.* at 15.

1 be monitored and treated and encouraged the use of prescription opioids for chronic pain while
 2 minimizing the danger of addiction. It also called doctors' concerns about addiction "inaccurate and
 3 exaggerated."

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

8 93. In 2001, the Joint Commission and the National Pharmaceutical Council (founded in
 9 1953 and supported by the nation's major research-based biopharmaceutical companies⁸⁴) collaborated
 10 to issue a 101-page monograph titled, "Pain: Current understanding of assessment, management, and
 11 treatments." The monograph states falsely that beliefs about opioids being addictive are "erroneous":

12 *Societal issues that contribute to the undertreatment of pain include drug abuse*
 13 *programs and erroneous beliefs about tolerance, physical dependence, and addiction*
 14 *(see I.E.5). For example, some clinicians incorrectly assume that exposure to an*
 15 *addictive drug usually results in addiction.*

16 * * *

17 **b. Etiology, issues, and concerns**

18 Many medications produce tolerance and physical dependence, and some (e.g.,
 19 opioids, sedatives, stimulants, anxiolytics, some muscle relaxants) may cause addiction
 20 in vulnerable individuals. Most experts agree that *patients who undergo prolonged*
 21 *opioid therapy usually develop physical dependence but do not develop addictive*
 22 *disorders. In general, patients in pain do not become addicted to opioids. Although*
 23 *the actual risk of addiction is unknown, it is thought to be quite low.* A recent study of
 24 opioid analgesic use revealed "low and stable" abuse of opioids between 1990 and 1996
 25 despite significant increases in opioids prescribed. . . .

26 *Fear of causing addiction (i.e., iatrogenic addiction), particularly with opioid*
 27 *use, is a major barrier to appropriate pain management. This fear sometimes reflects*
 28 *a lack of understanding of the risk of addiction with therapeutic drug use. Although*
 29 *studies suggest that the risk of iatrogenic addiction is quite low (e.g., Perry and*
 30 *Heidrich, Zenz et al.), surveys indicate that clinicians often overestimate this risk.*⁸⁵

31 //

32 ⁸⁴ Currently funded by Johnson & Johnson, Purdue and Teva, among others.

33 ⁸⁵ National Pharmaceutical Council, Inc., *Pain: Current Understanding of Assessment,*
 34 *Management, and Treatments* at 16-17 (Dec. 2001), [http://www.npcnow.org/system/files/research/](http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf)
 35 [download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf](http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf) (footnotes
 36 and citations omitted).

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

4 ***Long-acting and sustained-release opioids are useful for patients with continuous***
 5 ***pain, as they lessen the severity of end-of-dose pain*** and often allow the patient to sleep
 through the night.

6 * * *

- 7 • Administer opioids primarily via oral or transdermal routes, using long-acting
 8 medications when possible.⁸⁶

9 In truth, there is no difference in abuse liability between short- and long-acting opioids prescribed to
 10 treat chronic pain.⁸⁷ Indeed, long-acting opioids often do not work for the full period stated and require
 11 additional doses for what is described as “breakthrough pain,” and “the higher the dose, the worse the
 12 side effects, including the risks of addiction and death due to accidental overdose.”⁸⁸

13 95. The Marketing Defendants’ infiltration and influence over the Joint Commission’s
 14 standards and literature exerted overwhelming pressure on doctors to treat and eliminate pain. As more
 15 and more doctors migrated from private practice to integrated healthcare systems in the 2000s, treatment
 16 options were dictated by, among other things, the Joint Commission’s guidelines.⁸⁹ Consistent with the
 17 guidelines, doctors who left pain untreated were viewed as demonstrating poor clinical skills and/or
 18 being morally compromised.⁹⁰

19 96. The U.S. General Accounting Office’s December 2003 Report to Congressional
 20 Requesters confirms that Purdue funded the “pain management educational courses” that taught the new

21 //

22 //

23 ⁸⁶ *Id.* at 38, 68 (Table 38).

24 ⁸⁷ Wilsey BL, Fishman S, Li CS, Storment J, Albanese A. Markers of abuse liability of
 25 short- vs long-acting opioids in chronic pain patients: a randomized cross-over trial. *Pharmacol*
 26 *Biochem Behav.* 2009;94(1):98-107 available at
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2757543/>.

27 ⁸⁸ Lembke, (2016), *supra* n.49, at 60.

28 ⁸⁹ *Id.* at 119.

⁹⁰ *Id.* at 42.

1 standard of care for treating pain. It further revealed that Purdue disseminated educational materials on
2 pain management, which ““facilitated [Purdue’s] access to hospitals to promote OxyContin.””⁹¹

3 97. **The American Pain Foundation**: The American Pain Foundation (“APF”), described
4 itself as the nation’s largest organization for pain patients.⁹² While APF held itself out as an independent
5 patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and
6 medical-device industry, including from defendants Purdue, Endo, Janssen and Cephalon. It received
7 more than \$10 million in funding from opioid manufacturers from 2007 to 2012, when it shut down days
8 after the U.S. Senate Committee on Finance (“Senate Finance Committee”) launched an investigation
9 of the APF’s promotion of prescription opioids.

10 98. The APF’s guides for patients, journalists and policymakers trivialized the risk of
11 addiction and greatly exaggerated the benefits associated with opioid painkillers.⁹³

12 99. For example, in 2001, the APF published “Treatment Options: A Guide for People Living
13 with Pain.”⁹⁴ The guide, which was produced due to support from companies including defendants
14 Cephalon and Purdue, misrepresented the risks associated with opioid use. Among other things, the
15 guide:

- 16 • lamented that opioids were sometimes called narcotics because “[c]alling opioid
17 *analgesics ‘narcotics’ reinforces myths and misunderstandings* as it places
emphasis on their potential abuse rather than on the importance of their use as
pain medicines”;⁹⁵
- 18 • stated that “[o]pioids are an essential option for treating *moderate* to severe pain
19 associated with surgery or trauma”;⁹⁶ and

20 ⁹¹ Gounder, *Who Is Responsible*, *supra* n.65; U.S. General Accounting Office,
21 GAO-04-110, *Prescription Drugs, OxyContin Abuse and Diversion and Efforts to Address the
Problem* (Dec. 2003), <http://www.gao.gov/new.items/d04110.pdf>.

22 ⁹² The APF was the focus of a December investigation by ProPublica in the *Washington
Post* that detailed its close ties to drugmakers.

23 ⁹³ Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down as Senators
24 Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012, 8:57 PM),
25 <https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups/>
(hereinafter, “Ornstein, *American Pain Foundation*”).

26 ⁹⁴ *Treatment Options: A Guide for People Living with Pain*, American Pain Foundation,
<https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last visited Dec. 14,
2018).

27 ⁹⁵ *Id.* at 11.

28 ⁹⁶ *d.*

- opined that “[r]estricting access to the most effective medications for treating pain [opioids] is not the solution to drug abuse or addiction.”⁹⁷

The guide included blurbs from Portenoy, who is quoted as saying “[t]his is a very good resource for the pain patient,” and Fishman, who is quoted as saying, “[w]hat a great job! Finally, a pill consumer resource created for patients with pain. A ‘must have’ for every physician’s waiting room.”⁹⁸

100. In 2003, the APF published a newsletter titled, “Best of . . . The Pain Community News” that purported to clarify any confusion over addiction and opioids and emphasized the “tragic consequence of leaving many people with severe pain under-treated because they – or their doctors – fear that opioids will cause addiction.”

101. In 2009, Endo sponsored the APF’s publication and distribution of “Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families” (“Exit Wounds”), a book described as “the inspirational story of how one courageous veteran, with the aid of his family, recovered and thrived despite near death, traumatic brain injury, and the loss of a limb.” It also purported to “offer[] veterans and their families comprehensive and authoritative information on . . . treatment options, and strategies for self-advocating for optimal pain care and medical resources inside and outside the VA system.”

102. Among other false statements, Exit Wounds reported: “Long experience with opioids shows that *people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications.*” Endo, through the APF, thus distributed false information with the purpose of providing veterans false information they could use to “self-advocat[e]” for opioids while omitting a discussion of the risks associated with opioid use.

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

⁹⁷ *Id.* at 15.

⁹⁸ *Id.* at 76.

1 [Teresa Shaffer (APF Action Network Leader):] As a person who has been
 2 living with pain for over 20 years, opioids are a big part of my pain treatment. And I
 3 have been hearing such negative things about opioids and the risk factors of opioids.
 4 Could you talk with me a little bit about that?

5 [Dr. Al Anderson (AAPM Board of Directors):] The general belief system in
 6 the public is that the opioids are a bad thing to be giving a patient. Unfortunately, it's
 7 also prevalent in the medical profession, so patients have difficulty finding a doctor *when*
 8 *they are suffering from pain for a long period of time*, especially *moderate* to severe
 9 pain. And *that's the patients that we really need to use the opioids* methods of treatment,
 10 because they are the ones who need to have some help with the function and they're the
 11 ones that need to be controlled enough so that they can increase their quality of life.⁹⁹

12 104. In reality, there is little scientific evidence to support the contention that opioids taken
 13 long-term improve function or quality of life for chronic pain patients.¹⁰⁰ To the contrary, there is ample
 14 evidence that opioids impose significant risks and adverse outcomes on long-term users and that they
 15 may actually reduce function.¹⁰¹ As a recent article in the *New England Journal of Medicine* concluded:
 16 “Although opioid analgesics rapidly relieve many types of acute pain and improve function, the benefits
 17 of opioids when prescribed for chronic pain are much more questionable.” The article continues, “opioid
 18 analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in
 19 a national epidemic of opioid overdose deaths and addictions.”¹⁰² More recent still, a study published

20 ⁹⁹ *Episode 1: Safe Use of Opioids (PainSAFE)*, Let's Talk Pain (Sept. 28, 2010),
 21 <https://www.youtube.com/watch?v=zeAlVAMRgsk>.

22 ¹⁰⁰ Lembke (2016), *supra* n.49, at 59 (citing *The Effectiveness and Risks of Long-Term*
 23 *Opioid Treatment of Chronic Pain*, Evidence Report/Technology Assessment., No. 218, Agency for
 24 Healthcare Research and Quality (Sept. 2014), https://effectivehealthcare.ahrq.gov/sites/default/files/related_files/chronic-pain-opioid-treatment_executive.pdf).

25 ¹⁰¹ Discussing the CDC's “March 2016 Guideline for Prescribing Opioids for Chronic
 26 Pain,” doctors wrote:

27 Most placebo-controlled, randomized trials of opioids have lasted 6 weeks or less, and
 28 we are aware of no study that has compared opioid therapy with other treatments in terms
 of long-term (more than 1 year) outcomes related to pain, function, or quality of life. The
 few randomized trials to evaluate opioid efficacy for longer than 6 weeks had consistently
 poor results. In fact, several studies have showed that use of opioids for chronic pain
 may actually worsen pain and functioning, possibly by potentiating pain perception.

29 Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-*
 30 *Prescribing Guideline*, 374 *New Eng. J. Med.* 1501-04 (Apr. 21, 2016),
 31 <http://www.nejm.org/doi/full/10.1056/NEJMp1515917?af=R&rss=currentIssue&#t=article> (footnote
 32 omitted).

33 ¹⁰² Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain –*
 34 *Misconceptions and Mitigation Strategies*, 374 *New Eng. J. Med.* 1253-63 (Mar. 31, 2016),
 35 <http://www.nejm.org/doi/full/10.1056/NEJMra1507771#t=article>.

1 in *JAMA* concluded that “[t]reatment with opioids was not superior to treatment with nonopioid
2 medications for improving pain-related function over 12 months.”¹⁰³

3 105. The APF also developed the National Initiative on Pain Control (“NIPC”), which ran a
4 facially unaffiliated website, www.painknowledge.org. NIPC promoted itself as an education initiative
5 and promoted its expert leadership team, including purported experts in the pain management field. The
6 website painknowledge.org promised that, on opioids, “your level of function should improve; you may
7 find you are now able to participate in activities of daily living, such as work and hobbies, that you were
8 not able to enjoy when your pain was worse.” Elsewhere, the website touted improved quality of life
9 (as well as “improved function”) as benefits of opioid therapy. In a brochure available on
10 painknowledge.org titled, “Pain: Opioid Facts,” the NIPC misleadingly stated that “people who have no
11 history of drug abuse, including tobacco, and use their opioid medication as directed will probably not
12 become addicted” and even refused to rule out the use of opioid pain relievers for patients who have a
13 history of addiction to opioids.¹⁰⁴

14 106. In or around 2011, the APF published the “Policymaker’s Guide,” sponsored by Purdue,
15 which dispelled the notion that “strong pain medication leads to addiction” by characterizing it as a
16 “*common misconception*[]”:

17 ***Many people living with pain, and even some health care practitioners, falsely believe***
18 ***that opioid pain medicines are universally addictive.*** As with any medication, there are
19 risks, but these risks can be managed when these medicines are properly prescribed and
20 taken as directed. For more information about safety issues related to opioids and other
21 pain therapies, visit <http://www.painsafe.org>.¹⁰⁵

22 107. The guide describes “pain in America” as “an evolving public health crisis” and
23 characterizes concerns about opioid addiction as misconceptions: “Unfortunately, too many Americans
24 are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining

24 ¹⁰³ Krebs, *Effect of Opioid vs. Nonopioid Medications*, *supra* n.54.

25 ¹⁰⁴ *Pain: Opioid Facts*, Pain Knowledge (2007)
26 [https://web.archive.org/web/20101007102042/
http://painknowledge.org/patiented/pdf/Patient%20Education%20b380_b385%20%20pf%20opioid.pdf](https://web.archive.org/web/20101007102042/http://painknowledge.org/patiented/pdf/Patient%20Education%20b380_b385%20%20pf%20opioid.pdf) (last visited Dec. 14, 2018).

27 ¹⁰⁵ *A Policymaker’s Guide to Understanding Pain & Its Management*, American Pain
28 Foundation at 5 (Oct. 2011), [http://s3.documentcloud.org/documents/277603/apf-policymakers-
guide.pdf](http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf).

adequate care include: . . . *Misconceptions about opioid addiction.*¹⁰⁶ It even characterizes as a “myth” that “[c]hildren can easily become addicted to pain medications.”¹⁰⁷ The guide further asserts that “multiple clinical studies” have shown that opioids are effective in improving daily function, psychological health and health-related quality of life for chronic pain patients, which was not the case.¹⁰⁸

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

[T]he pills continue to have an influential champion in the American Pain Foundation, which describes itself as the nation’s largest advocacy group for pain patients. Its message: The risk of addiction is overblown, and the drugs are underused.

What the nonprofit organization doesn’t highlight is the money behind that message.

*The foundation collected nearly 90 percent of its \$5 million in funding last year from the drug and medical-device industry – and closely mirrors its positions, an examination by ProPublica found.*¹⁰⁹

109. **American Academy of Pain Medicine and American Pain Society:** The Marketing Defendants, including at least Endo, Janssen and Purdue, have contributed funding to the AAPM and the APS for decades.

110. In 1997, the AAPM issued a “consensus” statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. At the time, the chairman of the committee that issued the statement, Haddox, was a paid speaker for Purdue. Haddox

¹⁰⁶ *Id.* at 6.

¹⁰⁷ *Id.* at 40.

¹⁰⁸ The “Policymaker’s Guide” cites for support “Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects,” a review published in 2006 in the *Canadian Medical Association Journal*. *Id.* at 34. However, the review concludes: “For functional outcomes, **the other analgesics were significantly more effective than were opioids.**” Andrea D. Furlan et al., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) *Canadian Med. Assoc. J.* 1589-94 (May 23, 2006), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1459894/>. The Purdue-sponsored guide failed to disclose both this conclusion and the fact that the review analyzed studies that lasted, on average, five weeks and therefore could not support the long-term use of opioids.

¹⁰⁹ Charles Ornstein & Tracy Weber, *Patient advocacy group funded by success of painkiller drugs, probe finds*, *Wash. Post* (Dec. 23, 2011), https://www.washingtonpost.com/national/health-science/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probe-finds/2011/12/20/gIQAgvczDP_story.html?utm_term=.22049984c606.

1 was later hired as Purdue's vice president for health policy. The consensus statement, which also formed
2 the foundation of the 1998 guidelines, was published on the AAPM's website. AAPM's corporate
3 council includes Purdue, Depomed, Inc. ("Depomed"), Teva and other pharmaceutical companies.
4 AAPM's past presidents include Haddox (1998), Fishman (2005), Dr. Perry G. Fine ("Fine") (2011) and
5 Lynn R. Webster ("Webster") (2013), all of whose connections to the opioid manufacturers are well-
6 documented as set forth below.

7 111. At or about the same time, the APS introduced the "pain as the 5th vital sign" campaign,
8 followed soon thereafter by Veterans Affairs adopting that campaign as part of its national pain
9 management strategy.

10 112. The AAPM and APS issued guidelines in 2009 ("2009 Guidelines") that continued to
11 recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the
12 2009 Guidelines received funding from Janssen, Cephalon, Endo or Purdue.

13 113. The 2009 Guidelines falsely promoted opioids as safe and effective for treating chronic
14 pain and concluded that the risk of addiction was manageable for patients regardless of past abuse
15 histories.¹¹⁰ The 2009 Guidelines have been a particularly effective channel of deception and have
16 influenced not only treating physicians but also the body of scientific evidence on opioids; they were
17 reprinted in the journal *Pain*, have been cited hundreds of times in academic literature and remain
18 available online. The Marketing Defendants widely cited and promoted the 2009 Guidelines without
19 disclosing the lack of evidence to support their conclusions.

20 114. **The Alliance for Patient Access**: Founded in 2006, the Alliance for Patient Access
21 ("APA") is a self-described patient advocacy and health professional organization that styles itself as "a
22 national network of physicians dedicated to ensuring patient access to approved therapies and
23 appropriate clinical care."¹¹¹ It is run by Woodberry Associates LLC, a lobbying firm that was also
24

25 ¹¹⁰ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in*
26 *Chronic Noncancer Pain*, 10(2) J. Pain 113-30 (Feb. 2009), [http://www.jpain.org/article/S1526-5900\(08\)00831-6/pdf](http://www.jpain.org/article/S1526-5900(08)00831-6/pdf) (hereinafter, "Chou, *Clinical Guidelines*")

27 ¹¹¹ *About AfPA*, The Alliance for Patient Access, <http://allianceforpatientaccess.org> (last
28 visited Dec. 14, 2018). References herein to APA include two affiliated groups: the Global Alliance
for Patient Access and the Institute for Patient Access.

1 established in 2006.¹¹² As of June 2017, the APA listed 30 “Associate Members and Financial
2 Supporters.” The list includes Johnson & Johnson, Endo, Mallinckrodt, Purdue, Cephalon and Allergan.

3 115. APA’s board members have also directly received substantial funding from
4 pharmaceutical companies.¹¹³ For instance, board vice president Dr. Srinivas Nalamachu
5 (“Nalamachu”), who practices in Kansas, received more than \$800,000 from 2013 through 2015 from
6 pharmaceutical companies – nearly all of it from manufacturers of opioids or drugs that treat opioids’
7 side-effects, including from Endo, Insys, Purdue and Cephalon. Nalamachu’s clinic was raided by
8 Federal Bureau of Investigation (“FBI”) agents in connection with an investigation of Insys and its
9 payment of kickbacks to physicians who prescribed Subsys.¹¹⁴ Other board members include Dr. Robert
10 A. Yapundich from North Carolina, who received \$215,000 from 2013 through 2015 from
11 pharmaceutical companies, including payments by Cephalon and Mallinckrodt; Dr. Jack D. Schim from
12 California, who received more than \$240,000 between 2013 and 2015 from pharmaceutical companies,
13 including Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received
14 \$153,000 between 2013 and 2015 from pharmaceutical companies, including Endo, Purdue, Insys,
15 Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received \$700,000 between
16 2013 and 2015 from pharmaceutical companies.

17 116. Among its activities, the APA issued a white paper titled, “Prescription Pain Medication:
18 Preserving Patient Access While Curbing Abuse.”¹¹⁵ Among other things, the white paper criticizes
19 prescription monitoring programs, purporting to express concern that they are burdensome, not user
20 friendly and of questionable efficacy:

21 ¹¹² Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and*
22 *politicians to push Big Pharma’s agenda*, Health News Review (Oct. 2, 2017),
23 [https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-
politicians-push-big-pharmas-agenda/](https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/) (hereinafter, “Jaklevic, *Non-profit Alliance for Patient Access*”).

24 ¹¹³ All information concerning pharmaceutical company payments to doctors in this
25 paragraph is from ProPublica’s Dollars for Docs database, available at
26 <https://projects.propublica.org/docdollars/>.

27 ¹¹⁴ Andy Marso, *FBI seizes records of Overland Park pain doctor tied to Insys*, Kansas
28 *City Star* (July 20, 2017), [http://www.kansascity.com/news/business/health-
care/article162569383.html](http://www.kansascity.com/news/business/health-care/article162569383.html).

¹¹⁵ *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*,
Institute for Patient Access (Oct. 2013), [http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-
cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf](http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf).

1 Prescription monitoring programs that are difficult to use and cumbersome can place
 2 substantial burdens on physicians and their staff, ultimately leading many to stop
 3 prescribing pain medications altogether. This forces patients to seek pain relief
 medications elsewhere, which may be much less convenient and familiar and may even
 be dangerous or illegal.

4 * * *

5 In some states, physicians who fail to consult prescription monitoring databases before
 6 prescribing pain medications for their patients are subject to fines; those who repeatedly
 fail to consult the databases face loss of their professional licensure. Such penalties seem
 7 excessive and may inadvertently target older physicians in rural areas who may not be
 facile with computers and may not have the requisite office staff. Moreover, threatening
 8 and fining physicians in an attempt to induce compliance with prescription monitoring
 programs represents a system based on punishment as opposed to incentives. . . .

9 We cannot merely assume that these programs will reduce prescription pain medication
 use and abuse.¹¹⁶

10
 11 117. The white paper also purports to express concern about policies that have been enacted
 12 in response to the prevalence of pill mills:

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

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

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

24 119. In conclusion, the white paper states that “[p]rescription pain medications, and
 25 specifically the opioids, can provide substantial relief for people who are recovering from surgery,

26 ¹¹⁶ *Id.* at 4-5 (footnote omitted).

27 ¹¹⁷ *Id.* at 5-6.

28 ¹¹⁸ *Id.* at 6.

1 afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not
2 adequately respond to over-the-counter drugs.”¹¹⁹

3 120. The APA also issues “Patient Access Champion” financial awards to members of
4 Congress, including 50 such awards in 2015. The awards were funded by a \$7.8 million donation from
5 unnamed donors. While the awards are ostensibly given for protecting patients’ access to Medicare,
6 and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior
7 citizens and the middle class, they appear to be given to provide cover to and reward members of
8 Congress who have supported the APA’s agenda.¹²⁰

9 121. The APA also worked to promote policies to limit low-enforcement oversight of opioid
10 distribution. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability
11 of the DEA to police pill mills by enforcing the “suspicious orders” provision of the Comprehensive
12 Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801, *et seq.* (“CSA” or “Controlled
13 Substances Act”).¹²¹ The AAPM is also a signatory to this letter. An internal DOJ memo stated that the
14 proposed bill “could actually result in increased diversion, abuse, and public health and safety
15 consequences”¹²² and, according to DEA chief administrative law judge John J. Mulrooney
16 (“Mulrooney”), the law would make it “all but logically impossible” to prosecute manufacturers and
17 distributors, like the defendants here, in the federal courts.¹²³ The law passed both houses of Congress
18 and was signed into law in 2016.¹²⁴

19
20 ¹¹⁹ *Id.* at 7.

21 ¹²⁰ Jaklevic, *Non-profit Alliance for Patient Access*, *supra* n.112.

22 ¹²¹ Letter from Alliance for Patient Access et al., to Congressmen Tom Marino, Marsha
23 Blackburn, Peter Welch, and Judy Chu (Jan. 26, 2015), http://www.hoparx.org/images/hopa/advocacy/advocacy-activities/FINAL_Patient_Access_Letter_of_Support_House_Bill.pdf.

24 ¹²² Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*,
25 CBS News (Oct. 17, 2017), <https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/> (hereinafter, “Whitaker, *Opioid Crisis Fueled by Drug Industry*”).

26 ¹²³ John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug
27 Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101(2) Marquette L. Rev.
28 333-451 (Winter 2017), <http://scholarship.law.marquette.edu/cgi/viewcontent.cgi?article=5348&context=mulr>.

¹²⁴ Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No.
114-145, 130 Stat. 353 (codified as amended at 21 U.S.C. §§823(j), 824(c), (d)).

1 122. *Exposing the Financial Ties Between Opioid Manufacturers and Third-Party Groups:*

2 A February 12, 2018 report titled, “Fueling an Epidemic Report Two: Exposing the Financial Ties
3 Between Opioid Manufacturers and Third Party Advocacy Groups” and issued by the U.S. Senate
4 Homeland Security & Government Affairs Committee, Ranking Member’s Office, sheds additional light
5 on the financial connections between opioid manufacturers and purportedly neutral patient advocacy
6 organizations and medical professional societies that, unsurprisingly, have “echoed and amplified
7 messages favorable to increased opioid use – and ultimately the financial interests of opioid
8 manufacturers.”¹²⁵

9 123. The report details findings resulting from subpoenas issued by Senator McCaskill to five
10 opioid manufacturers, including three of the Marketing Defendants – Purdue, Janssen, Insys, Depomed
11 and Mylan N.V. (“Mylan”) – and to 15 purportedly neutral patient advocacy organizations and medical
12 professional societies. “The information produced to the Committee demonstrates that many patient
13 advocacy organizations and professional societies focusing on opioids policy have promoted messages
14 and policies favorable to opioid use while receiving millions of dollars in payments from opioid
15 manufacturers,” the report found. It continued: “Through criticism of government prescribing
16 guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy
17 organizations have often supported industry interests at the expense of their own constituencies.”¹²⁶

18 124. According to the report, the five manufacturers whose information was subpoenaed by
19 Senator McCaskill alone contributed almost \$9 million combined to patient advocacy organizations and
20 professional societies operating in the opioids policy area:

21 //

22 //

23 //

24 //

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26 //

27 ¹²⁵ *February 2018 McCaskill Report, supra* n.47, at 1.

28 ¹²⁶ *Id.* at 3.

FIGURE 1: Manufacturer Payments to Selected Groups, 2012-2017

	Purdue ²²	Janssen ²³	Depomed	Insys	Mylan	Total
Academy of Integrative Pain Management	\$1,091,024.86	\$128,000.00	\$43,491.95	\$3,050.00 ²⁴	\$0.00	\$1,265,566.81
American Academy of Pain Medicine	\$725,584.95	\$83,975.00	\$332,100.00	\$57,750.00	\$0.00	\$1,199,409.95
AAPM Foundation	\$0.00	\$0.00	\$304,605.00	\$0.00	\$0.00	\$304,605.00
ACS Cancer Action Network	\$168,500.00 ²⁵	\$0.00	\$0.00	\$0.00	\$0.00	\$168,500.00
American Chronic Pain Association	\$312,470.00	\$50,000.00	\$54,670.00	\$0.00	\$0.00	\$417,140.00
American Geriatrics Society	\$11,785.00 ²⁶	\$0.00	\$0.00	\$0.00	\$0.00	\$11,785.00
American Pain Foundation	\$25,000.00	\$0.00	\$0.00	\$0.00	\$0.00	\$25,000.00
American Pain Society	\$542,259.52	\$88,500.00	\$288,750.00	\$22,965.00	\$20,250.00	\$962,724.52
American Society of Pain Educators	\$30,000.00	\$0.00	\$0.00	\$0.00	\$0.00	\$30,000.00
American Society of Pain Management Nursing	\$242,535.00	\$55,177.85 ²⁷	\$25,500.00 ²⁸	\$0.00	\$0.00	\$323,212.85
The Center for Practical Bioethics	\$145,095.00	\$18,000.00	\$0.00	\$0.00	\$0.00	\$163,095.00
The National Pain Foundation ²⁹	\$0.00	\$0.00	\$0.00	\$562,500.00	\$0.00	\$562,500.00
U.S. Pain Foundation	\$359,300.00	\$41,500.00	\$22,000.00	\$2,500,000.00 ³⁰	\$0.00	\$2,922,800.00
Washington Legal Foundation	\$500,000.00	\$0.00	\$0.00	\$0.00	\$0.00	\$500,000.00
	\$4,153,554.33	\$465,152.85	\$1,071,116.95	\$3,146,265.00	\$20,250.00	\$8,856,339.13

125. As shown below, payments from Purdue comprise roughly half this funding, with Insys providing the second-largest amount:

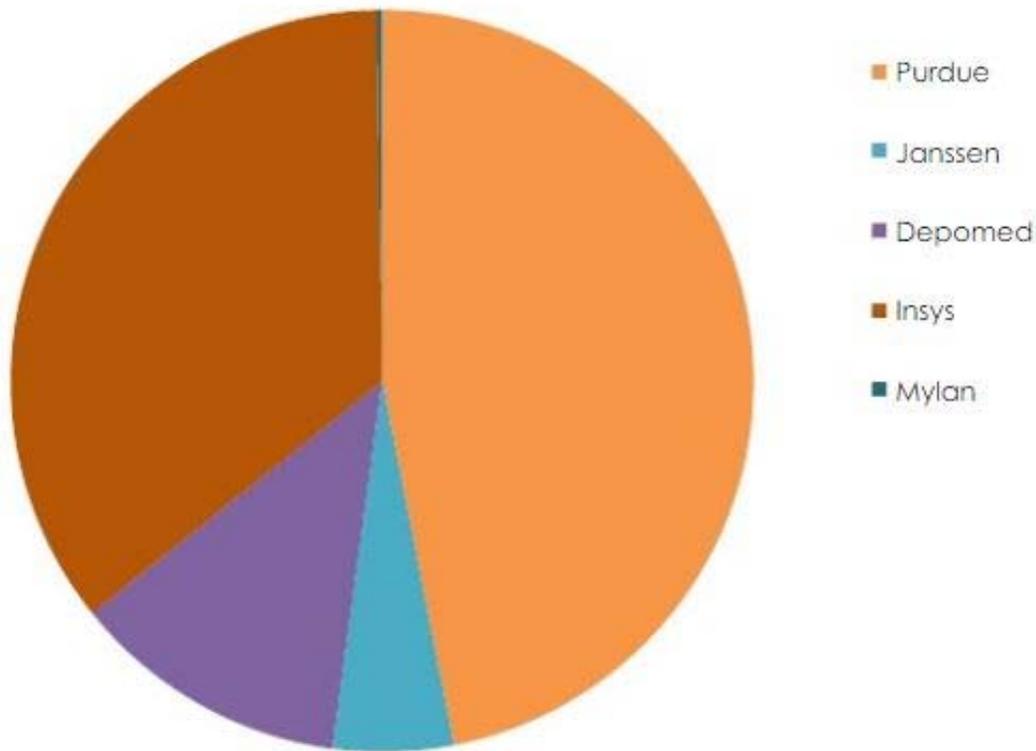
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FIGURE 2: Percentages of Total Payments by Manufacturer, 2012-2017



126. While Purdue's payments slowed starting in 2016, Insys' payments increased exponentially in 2017:

FIGURE 3: Manufacturer Yearly Payment Totals, 2012-2017

	2012	2013	2014	2015	2016	2017	Total
Purdue	\$824,227.86	\$973,328.00	\$812,451.95	\$935,344.00	\$558,067.52	\$50,135.00	\$4,153,554.33
Janssen	\$239,902.85 ³⁶	\$99,250.00	\$126,000.00				\$465,152.85
Depomed	\$73,080.00	\$135,300.00	\$113,600.00	\$350,000.00	\$318,257.47	\$80,879.48	\$1,071,116.95
Insys	\$14,040.00	\$68,000.00	\$34,200.00	\$530,025.00		\$2,500,000.00	\$3,146,265.00
Mylan				\$15,000.00	\$2,500.00	\$2,750.00	\$20,250.00
Total	\$1,151,250.71	\$1,275,878.00	\$1,086,251.95	\$1,830,369.00	\$878,824.99	\$2,633,764.48	\$8,856,339.13

127. In addition to the nearly \$9 million in payments to purportedly neutral patient advocacy organizations and medical professional societies, the five subpoenaed opioid manufacturers made an additional \$1.6 million in payments to the organizations' and societies' group executives, staff members, board members and advisory board members. When payments from all opioid manufacturers are

//

1 tabulated, more than \$10.6 million was paid to individuals affiliated with such organizations and
 2 societies from 2013 through the date of the report:

3 FIGURE 8: Payments from All Opioid Manufacturers to Group-Affiliated Individuals, 2013-
 4 Present⁵²

	Manufacturer Payments to Affiliated Individuals
The National Pain Foundation	\$8,307,243.47
AAPM Foundation	\$798,051.22
American Society of Pain Educators	\$749,564.78
American Academy of Pain Medicine	\$204,631.53
American Pain Society	\$187,699.34
ACS Cancer Action Network	\$154,578.09
American Chronic Pain Association	\$145,861.30
Academy of Integrative Pain Management	\$82,596.98
The Center for Practical Bioethics	\$16,945.88
American Geriatrics Society	\$7,548.35
U.S. Pain Foundation	\$138.91
American Pain Foundation	N/A
American Society of Pain Management Nursing	N/A
Washington Legal Foundation	N/A
Total	\$10,654,859.85

17 128. Included in the above-listed payments were payments of more than \$140,000 from opioid
 18 manufacturers, including Endo, Purdue and Mallinckrodt, to ten members of the American Chronic Pain
 19 Association Advisory Board; \$170,000 from Insys to National Pain Foundation (“NPF”) chairman and
 20 founder D. Daniel Bennett; and more than \$950,000 to members of the NPF board of directors from
 21 various opioid manufacturers, including more than \$250,000 from Insys alone.

22 129. Worse still, the organizations provided limited disclosures of these sources of funding –
 23 when they provided any information at all. The American Society of Pain Educators, the NPF, and the
 24 Academy of Integrative Pain Management provided no information concerning their policies for
 25 disclosing donors or donations, while several others stated explicitly that they did not disclose any
 26 information concerning donor relationships. When the groups investigated did disclose their sources of
 27 funding, they did so without providing specifics as donation amounts.

28 //

1 130. Most importantly, many of the groups investigated “amplified or issued messages that
2 reinforce industry efforts to promote opioid prescription and use, including guidelines and policies
3 minimizing the risk of addiction and promoting opioids for chronic pain.” Several of the groups “also
4 lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on
5 opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible
6 for overprescription and misbranding.”¹²⁷ The report provided details regarding four ways the groups
7 investigated set about these tasks.

8 131. First, the report states that “[m]any of the groups have issued guidelines to physicians
9 and other health practitioners that minimize the risk of opioid addiction or emphasize the long-term use
10 of opioids to treat chronic pain.”¹²⁸ The report provides examples, including: (a) the AAPM’s and APS’s
11 1997 consensus statement endorsing opioids for chronic pain and stating that the risk of addiction was
12 low; (b) the 2009 issuance of guidelines by the AAPM and the APS allegedly promoting opioids as safe
13 and effective for chronic pain and concluding the risk of addiction was manageable regardless of past
14 abuse history; (c) the 2009 issuance of guidelines by the American Geriatrics Society (“AGS”) for the
15 management of persistent pain recommending that opioids should be considered for all patients with
16 moderate to severe pain in older patients and stating that the risks of addiction are exceedingly low in
17 older patients; and (d) the creation of a 2009 patient education guide by the AGS, the AAPM and Janssen
18 stating that opioids are rarely addictive when used properly to manage chronic pain.

19 132. Second, the report notes that “[a]dvocacy groups have engaged in extensive lobbying
20 efforts to either defeat legislation restricting opioid prescribing or promote laws encouraging opioid
21 treatment with pain.”¹²⁹ For example, in 2014, the Academy of Integrative Pain Management and the
22 American Cancer Society Cancer Action Network led the effort to protect a law making it difficult to
23 discipline doctors for overprescribing opioids and prohibited doctors from refusing to prescribe opioids
24 unless they also referred the patient to an “opioid-friendly” doctor.

25 //

26 ¹²⁷ *Id.* at 12.

27 ¹²⁸ *Id.*

28 ¹²⁹ *Id.* at 13.

1 133. Third, the report admonished a majority of the groups for strongly criticizing CDC
2 guidelines issued in 2016 providing prescribing recommendations for primary care doctors who are
3 prescribing opioids for chronic pain outside of active treatment of cancer, palliative care and end-of life
4 care. These guidelines were “the first national standards for prescription painkillers” and were “perhaps
5 the first major step from the federal government [] toward limiting opioid prescriptions for chronic pain
6 in the face of an unprecedented public health crisis.”¹³⁰ However, most industry groups opposed the
7 guidelines. For example, David Carr, the immediate past president of the AAPM, criticized the
8 guidelines as reflecting “disproportionately strong recommendations based upon a narrowly selected
9 portion of the available clinical evidence.” Other groups complained that the draft guidelines “were not
10 transparent,” cited purported conflicts of interest among those who created them, criticized the “overly
11 secretive manner” in which they’d been developed and called them “inherently biased.”¹³¹

12 134. Fourth, several of the advocacy groups and professional societies organized legal efforts
13 to challenge government actions to punish executives responsible for fraudulent opioid marketing and
14 doctors who overprescribed opioids. For example, the NPF submitted an *amicus* brief to the U.S. Court
15 of Appeals for the Fourth Circuit in support of a doctor convicted of 16 counts of drug trafficking for
16 prescribing massive quantities of oxycodone and other narcotics – in one instance, more than 1,600 per
17 day – to patients in chronic pain. In its brief, the NPF opposed the conviction, criticizing the holding
18 that “a doctor acting in the good faith belief that he was serving the best medical interest of his patient
19 could be found to be a drug dealer.”¹³² The Washington Legal Foundation filed an *amicus* brief in the
20 U.S. Court of Appeals for the District of Columbia Circuit arguing that the exclusion of three former
21 Purdue executives from participation in federal healthcare programs for 12 years for their admitted
22 failure to prevent fraudulent marketing of OxyContin raised “serious constitutional due process
23 concerns.”

24 135. In conclusion, the report found that, while health advocacy organizations are “among the
25 most influential and trusted stakeholders in U.S. health policy,” the reality is that their “positions closely

26 ¹³⁰ *Id.* at 13-14.

27 ¹³¹ *Id.* at 14.

28 ¹³² *Id.* at 15.

1 correspond to the marketing aims of pharmaceutical and device companies,” including in the area of
 2 opioids policy. “The findings in this report indicate that this tension exists in the area of opioids policy
 3 – that organizations receiving substantial funding from manufacturers have, in fact, amplified and
 4 reinforced messages favoring increased opioid use.” This amplification “may have played a significant
 5 role in creating the necessary conditions for the U.S. opioids epidemic.”¹³³

6 **b. The Marketing Defendants Paid Key Opinion Leaders and**
 7 **Sponsored Speakers’ Bureaus to Disseminate False and**
 8 **Misleading Messaging**

9 136. The Marketing Defendants have paid millions of dollars to physicians to promote
 10 aggressive prescribing of opioids for chronic pain. Recently released federal data shows that the
 11 Marketing Defendants increased such payments to physicians who treat chronic pain even while the
 12 opioid crisis accelerated and overdose deaths from prescription opioids and related illicit drugs, such as
 13 heroin, soared to record rates.¹³⁴ These payments come in the form of consulting and speaking fees, free
 14 food and beverages, discount coupons for drugs and other freebies. The total payments from the
 15 Marketing Defendants to doctors related to opioids doubled from 2014 to 2015. Moreover, according
 16 to experts, research shows even small amounts of money can have large effects on doctors’ prescribing
 17 practices.¹³⁵ Physicians who are high prescribers are more likely to be invited to participate in
 18 defendants’ speakers’ bureaus. According to a study published by the U.S. National Institutes of Health,
 19 “[i]n the speakers’ bureau system, physicians are recruited and trained by pharmaceutical,
 20 biotechnology, and medical device companies to deliver information about products to other physicians,
 in exchange for a fee.”¹³⁶

21 137. According to a research letter published in *JAMA Internal Medicine* on May 14, 2018,
 22 doctors who had just one extra meal paid for by an opioid company were more likely to prescribe opioids
 23

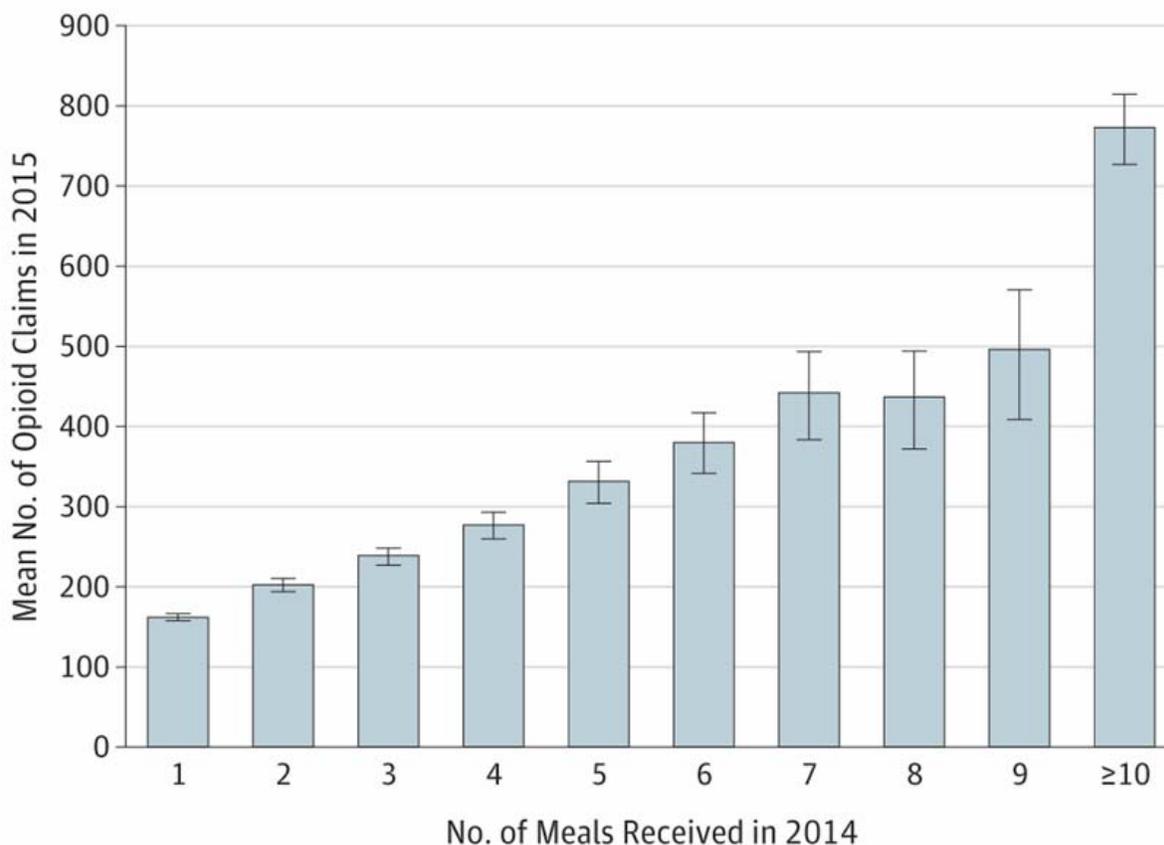
24 ¹³³ *Id.* at 17.

25 ¹³⁴ Joe Lawlor, *Even amid crisis, opioid makers plied doctors with perks*, Portland Press
 26 Herald (Dec. 25, 2016), <http://www.pressherald.com/2016/12/25/even-amid-crisis-opioid-makers-plied-doctors-with-perks/>.

27 ¹³⁵ *Id.*

28 ¹³⁶ Lynette Reid & Matthew Herder, *The speakers’ bureau system: a form of peer selling*,
 7(2) Open Med. e31-e39 (Apr. 2, 2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3863750/>.

1 than doctors who received fewer free meals:¹³⁷ The study found that Insys accounted for 50% of the
 2 non-research payments.¹³⁸



17 138. The use of speakers' bureaus has led to substantial ethical concerns within the medical
 18 field. As summarized in a 2013 publication by the Institute on Medicine as a Profession, which
 19 substantiated its findings by citing:

20 **The Problem:**

21 *Pharmaceutical companies often recruit physicians to perform speeches or*
 22 *presentations for the purpose of marketing a specific drug. In 2010, 8.6% of physicians*
 23 *reported having received payments for participating in speakers' bureaus. These*
speakers' bureaus leverage the credibility of physicians in order to promote the use of
pharmaceutical products. The physicians are generally trained to present a certain

24 ¹³⁷ Scott E. Hadland et al., *Association of Pharmaceutical Industry Marketing of Opioid*
 25 *Products to Physicians With Subsequent Opioid Prescribing*, JAMA Intern. Med. (May 14, 2018),
 26 <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2681059>. The study looked at the
 27 Open Payments database, which was used to pull out non-research payments to doctors in 2014. It
 then compared that data to claims in the Medicare Part D Opioid Prescriber Summary File from
 doctors who wrote opioid prescriptions in 2015, leaving in "all physicians with complete, nonduplicate
 information who had at least 10 opioid claims during 2015."

28 ¹³⁸ *Id.*

1 **message, or are provided with pre-produced slides. The audience may assume that**
 2 **these presentations are objective, when in fact they are heavily biased towards the**
 3 **interests of the industry sponsor.**

4 ***Speakers' bureaus may lead to the dissemination of false or biased information.***

5 Exposure to industry-sponsored speaking events is associated with decreased quality of
 6 prescribing. Additionally, the compensation provided for these engagements may
 7 influence the attitudes or judgment of the presenter.¹³⁹

8 139. For example, Fishman is a physician whose ties to the opioid drug industry are legion.
 9 He has served as an APF board member and as president of the AAPM, and has participated yearly in
 10 numerous CME activities for which he received "market rate honoraria." As discussed above, he has
 11 authored publications, including the seminal guides on opioid prescribing, which were funded by the
 12 Marketing Defendants. He has also worked to oppose legislation requiring doctors and others to consult
 13 pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself
 14 acknowledged his failure to disclose all potential conflicts of interest in a letter in *JAMA* titled,
 15 "Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion."¹⁴⁰

16 140. Similarly, Fine's ties to the Marketing Defendants have been well documented.¹⁴¹ He
 17 has authored articles and testified in court cases and before state and federal committees, and he, too,
 18 has served as president of the AAPM and argued against legislation restricting high-dose opioid
 19 prescription for non-cancer patients. Multiple videos feature Fine delivering educational talks about
 20 prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna
 21 Nicole Smith for pain did not make her an addict before her death.¹⁴² He has also acknowledged having
 22 failed to disclose numerous conflicts of interest.

23 //

24 ¹³⁹ *Speakers' Bureaus: Best Practices for Academic Medical Centers*, IMAP (Oct. 10,
 25 2013), [http://imapny.org/wp-content/themes/imapny/File%20Library/Best%20Practice%20](http://imapny.org/wp-content/themes/imapny/File%20Library/Best%20Practice%20toolkits/Best-Practices_Speakers--bureaus.pdf)
 26 [toolkits/Best-Practices_Speakers--bureaus.pdf](http://imapny.org/wp-content/themes/imapny/File%20Library/Best%20Practice%20toolkits/Best-Practices_Speakers--bureaus.pdf) (citing research in *JAMA*, *The Journal of Law,*
 27 *Medicine & Ethics* and *Academic Psychiatry*).

28 ¹⁴⁰ Scott M. Fishman, *Incomplete Financial Disclosures in a Letter on Reducing Opioid*
 Abuse and Diversion, 306(13) *JAMA* 1445 (2011); Tracy Weber & Charles Ornstein, *Two Leaders in*
Pain Treatment Have Long Ties to Drug Industry, ProPublica (Dec. 23, 2011, 2:14 PM),
<https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry>
 (hereinafter, "Weber, *Two Leaders in Pain*").

¹⁴¹ Weber, *Two Leaders in Pain*, *supra* n.140.

¹⁴² Linda Deutsch, *Doctor: 1,500 pills don't prove Smith was addicted*, *Seattle Times*
 (Sept. 22, 2010, 5:16 PM), [http://www.seattletimes.com/entertainment/doctor-1500-pills-dont-prove-](http://www.seattletimes.com/entertainment/doctor-1500-pills-dont-prove-smith-was-addicted/)
[smith-was-addicted/](http://www.seattletimes.com/entertainment/doctor-1500-pills-dont-prove-smith-was-addicted/).

1 141. Fishman and Fine are only two of the many physicians whom the Marketing Defendants
2 paid to present false or biased information on the use of opioids for chronic pain.

3 **c. Senate Investigations of the Marketing Defendants**

4 142. In May 2012, the Chair and Ranking Member of the Senate Finance Committee, Max
5 Baucus (D-MT) and Chuck E. Grassley (R-IA), launched an investigation into makers of narcotic
6 painkillers and groups that champion them. The investigation was triggered by “an epidemic of
7 accidental deaths and addiction resulting from the increased sale and use of powerful narcotic
8 painkillers,” including popular brand names like OxyContin, Vicodin and Opana.

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

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

16 *It is clear that the United States is suffering from an epidemic of accidental*
17 *deaths and addiction resulting from the increased sale and use of powerful narcotic*
18 *painkillers such as Oxycontin (oxycodone), Vicodin (hydrocodone), Opana*
19 *(oxymorphone). According to CDC data, “more than 40% (14,800)” of the “36,500 drug*
20 *poisoning deaths in 2008” were related to opioid-based prescription painkillers. Deaths*
21 *from these drugs rose more rapidly, “from about 4,000 to 14,800” between 1999 and*
22 *2008, than any other class of drugs, [killing] more people than heroin and cocaine*
23 *combined. More people in the United States now die from drugs than car accidents as*
24 *a result of this new epidemic. Additionally, the CDC reports that improper “use of*
25 *prescription painkillers costs health insurers up to \$72.5 billion annually in direct*
26 *health care costs.”*

27 * * *

28 Concurrent with the growing epidemic, the *New York Times* reports that, based
on federal data, *“over the last decade, the number of prescriptions for the strongest*
opioids has increased nearly fourfold, with only limited evidence of their long-term
effectiveness or risks” while “[d]ata suggest that hundreds of thousands of patients
nationwide may be on potentially dangerous doses.”

There is growing evidence pharmaceutical companies that manufacture and
market opioids may be responsible, at least in part, for this epidemic by promoting
misleading information about the drugs’ safety and effectiveness. Recent investigative
reporting from the *Milwaukee Journal Sentinel/MedPage Today* and *ProPublica*
revealed extensive ties between companies that manufacture and market opioids and non-
profit organizations such as the American Pain Foundation, the American Academy of

1 Pain Medicine, the Federation of State Medical Boards, and University of Wisconsin
2 Pain and Policy Study Group, and the Joint Commission.

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

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

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

20 145. The Senators demanded substantial discovery, including payment information from the
21 companies to various groups, including the front organizations identified above, and to physicians,
22 including Portenoy, Fishman and Fine, among others. They asked about any influence the companies
23 had on a 2004 pain guide for physicians that was distributed by the FSMB, on the APS’ guidelines and
24 on the APF’s Military/Veterans Pain Initiative. Almost immediately upon the launch of the Senate
25 investigation, the APF shut down “due to irreparable economic circumstances.” The opioid report
26 resulting from this investigation has not been released publicly.¹⁴⁵

27 //

28 //

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

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

28 ¹⁴⁵ Paul D. Thacker, *Senators Hatch and Wyden: Do your jobs and release the sealed*
opioids report, Stat News (June 27, 2016), [https://www.statnews.com/2016/06/27/opioid-addiction-](https://www.statnews.com/2016/06/27/opioid-addiction-orrin-hatch-ron-wyden/)
orrin-hatch-ron-wyden/; see also Ornstein, *American Pain Foundation*, *supra* n.93.

1 146. On March 29, 2017, it was widely reported¹⁴⁶ that yet another Senate investigation had
2 been launched:

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

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

9 147. On September 6, 2017, Senator McCaskill's first report, "Fueling an Epidemic: Insys
10 Therapeutics and the Systemic Manipulation of Prior Authorization," was published. The report found
11 that Insys manipulated the prior authorization process by misleading pharmacy benefit managers
12 ("PBMs") in order to increase sales of the Insys-manufactured opioid, Subsys.¹⁴⁷ The PBM prior
13 authorization process requires additional approval before dispensing and paying for certain powerful
14 and expensive drugs, which, in the case of Subsys, included "confirmation that the patient had an active
15 cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being
16 prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate."¹⁴⁸ The report
17 found Insys actively and systematically misled PBMs about the presence of breakthrough cancer pain
18 in potential Subsys patients to improperly circumvent the process, however.¹⁴⁹ On November 28, 2018,
19 the former Vice President of Sales of Insys pled guilty in federal court to his role in a nationwide
20 conspiracy to bribe medical practitioners to unnecessarily prescribe fentanyl-based pain medication and
21 defraud healthcare insurers.

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

24 ¹⁴⁷ *Fueling an Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior*
25 *Authorization*, U.S. Senate Homeland Security & Government Affairs Committee, Ranking Member's
26 Office at 2 (Sept. 6, 2017), [https://www.hsgac.senate.gov/imo/media/doc/REPORT%20-
%20Fueling%20an%20Epidemic%20-%20Insys%20Therapeutics%20and%20the%20Systemic%20
Manipulation%20of%20Prior%20Authorization.pdf](https://www.hsgac.senate.gov/imo/media/doc/REPORT%20-%20Fueling%20an%20Epidemic%20-%20Insys%20Therapeutics%20and%20the%20Systemic%20Manipulation%20of%20Prior%20Authorization.pdf).

27 ¹⁴⁸ *Id.* (quoting Complaint, *Blue Cross of California, Inc., et al. v. Insys Therapeutics, Inc.*,
(No. 2:17 CV 02286) (D. Ariz. July 12, 2017)).

28 ¹⁴⁹ *Id.*

1 148. On September 12, 2017, Senator McCaskill convened a Roundtable Discussion on
2 Opioid Marketing. During the hearing, Senator McCaskill stated:

3 The opioid epidemic is the direct result of a calculated marketing and sales
4 strategy developed in the 90's, which delivered three simple messages to physicians.
5 First, that chronic pain was severely undertreated in the United States. Second, that
6 opioids were the best tool to address that pain. And third, that opioids could treat pain
without risk of serious addiction. As it turns out, these messages were exaggerations at
best and outright lies at worst.

7 * * *

8 Our national opioid epidemic is complex, but one explanation for this crisis is
simple, pure greed.

9 149. Professor Adriane Fugh-Berman ("Fugh-Berman"), Associate Professor at Georgetown
10 University Medical Center and director of a program at Georgetown called Pharmed Out, which
11 conducts research on and educates the public about inappropriate pharmaceutical company marketing,
12 also testified during the hearing. She, too, placed the blame for the opioid crisis squarely at the feet of
13 pharmaceutical companies:

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

19 150. Fugh-Berman also answered why doctors were able to be convinced by pharmaceutical
20 companies' marketing efforts:

21 Why do physicians fall for this? Well, physicians are overworked, overwhelmed,
22 buried in paperwork and they feel unappreciated. Drug reps are cheerful. They're
23 charming. They provide both appreciation and information. Unfortunately, the
information they provide is innately unreliable.

24 Pharmaceutical companies influence healthcare providers' attitudes and their
25 therapeutic choices through financial incentives that include research grants, educational
grants, consulting fees, speaking fees, gifts and meals.

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

1 Pharmaceutical companies convinced healthcare providers that they were
 2 opiophobic and that they were causing suffering to their patients by denying opioids to
 3 patients with back pain or arthritis. They persuaded prescribers that patients with pain
 4 were somehow immune to addiction. Even when addiction was suspected, physicians
 5 were taught that it might not really be addiction, it might be pseudo-addiction, an
 6 invented condition that's treated by increasing opioid dosages.

7 Industry created the American Pain Foundation co-opted other groups including
 8 medical organizations, and they change state laws to eliminate curbs on opioid
 9 prescribing. Between 2006 and 2015, pharmaceutical companies and the advocacy
 10 groups they control employ 1,350 lobbyists a year in legislative hubs. Industry-
 11 influenced regulations and policies ensure that hospitalized patients were and are berated
 12 constantly about their level of pain and overmedicated with opioids for that pain. Even
 13 a week of opioids can lead a patient into addiction so many patients are discharged from
 14 hospitals already dependent on opioids.

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

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

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

25 **3. The Devastating Impact**

26 154. The impact of the Marketing Defendants' false messaging has been profound. The drug
 27 companies profited handsomely as more and more people became addicted to opioids and died of
 28 overdoses.¹⁵⁰

29 155. For Purdue, sales grew from \$48 million per year in 1996, to over \$1 billion per year in
 30 2000, to \$3.1 billion per year ten years later. In 2011, pharmaceutical companies generated revenues of
 31 \$11 billion from opioid sales alone.

32 //

33 //

34 ¹⁵⁰ German Lopez, *How big pharma got people hooked on dangerous opioids – and made*
 35 *tons of money off it*, Vox (Sept. 22, 2016, 3:00 PM), [http://www.vox.com/2016/2/5/10919360/opioid-](http://www.vox.com/2016/2/5/10919360/opioid-epidemic-chart)
 36 *epidemic-chart*.

1 156. The United States, including specifically San Francisco, is experiencing an
2 unprecedented opioid addiction and overdose epidemic, costing millions in health insurance and public
3 safety as well as lost productivity in the workforce.

4 157. By 2002, “[l]ifetime *nonmedical* use of OxyContin increased from 1.9 million to 3.1
5 million people between 2002 and 2004, and in 2004 there were 615,000 new nonmedical users of
6 OxyContin.”¹⁵¹

7 158. By 2004, OxyContin had “become the most prevalent prescription opioid abused in the
8 United States.”¹⁵² The severity of the problem was first felt in states including Maine, West Virginia,
9 eastern Kentucky, southwestern Virginia and Alabama, where, from 1998 through 2000, hydrocodone
10 and oxycodone were being prescribed 2.5-5 times more often than the national average. By 2000, these
11 same areas had a prescription rate up to 5-6 times higher than the national average. These areas were
12 also the first to suffer increased abuse and diversion, which became apparent by 1999 and 2000.
13 Manufacturers then expanded the geographic market by investing hundreds of millions of dollars in
14 marketing, and the once-regional problem began to spread nationally. “[B]y 2004 OxyContin had
15 become a leading drug of abuse in the United States.”¹⁵³

16 159. As OxyContin sales grew between 1999 and 2002, so did sales of other opioids, including
17 fentanyl (226%), morphine (73%) and oxycodone (402%). And, as prescriptions surged between 1999
18 and 2010, so did deaths from opioid overdoses (from about 4,000 to almost 17,000).¹⁵⁴

19 160. In 2012 alone, an estimated 259 million opioid prescriptions were filled, enough to
20 medicate every adult in the United States for a month on a round-the-clock basis.¹⁵⁵ In 2014, there were
21 more than 47,000 drug overdose deaths nationwide, 61% involving a prescription or illicit opioid.¹⁵⁶

22
23
24 ¹⁵¹ Van Zee, *Promotion and Marketing*, *supra* n.59.

25 ¹⁵² *Id.*

26 ¹⁵³ *Id.*

27 ¹⁵⁴ Gounder, *Who Is Responsible*, *supra* n.65.

28 ¹⁵⁵ *Opioid Painkiller Prescribing*, Centers for Disease Control and Prevention: Vital Signs
(July 2014), <https://www.cdc.gov/vitalsigns/opioid-prescribing/>.

¹⁵⁶ Rudd, *Increases in Drug and Opioid Involved Overdose*, *supra* n.5.

1 The use of prescription painkillers cost health insurers up to \$72.5 billion annually in direct healthcare
2 costs.¹⁵⁷

3 161. The problem of opioid addiction has become so prevalent that California has responded
4 by mandating the use of a Controlled Substance Utilization Review and Evaluation System database to
5 evaluate excessive painkiller prescriptions and put a stop to them.¹⁵⁸

6 162. San Francisco has suffered, and continues to suffer, significant financial consequences
7 as a result of opioid over-prescription and addiction, including, but not limited to: (a) increased public
8 health expenditures; (b) law enforcement and judicial expenditures; (c) increased jail expenditures;
9 (d) increased subsidized housing and rehousing costs; (e) increased substance abuse treatment, diversion
10 and education plan expenditures, including payments to outside service providers; (f) increased
11 supportive housing costs; (g) increased emergency and medical care services; (h) increased social
12 services expenditures, including to adult and child protective services; (i) reduced worker productivity;
13 and (j) lost economic opportunity.

14 **B. The Marketing Defendants' Specific Unlawful Practices that Targeted San**
15 **Francisco Prescribers**

16 **1. Purdue**

17 163. Purdue manufactures, markets, sells and distributes opioids in San Francisco and
18 nationwide, including the following:

OxyContin (oxycodone hydrochloride extended release)	Opioid agonist ¹⁵⁹ indicated for pain severe enough to require daily, around-the-clock, long-term opioid treatment; not indicated as an as-needed (p.r.n.) analgesic. It was first approved by the FDA in December 1995.	Schedule II
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21 ¹⁵⁷ Katherine Eban, *OxyContin: Purdue Pharma's painful medicine*, Fortune Magazine
22 (Nov. 9, 2011), <http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/>
(hereinafter, "Eban, *Painful Medicine*").

23 ¹⁵⁸ Patrick McGreevy, *'Doctor shopping' targeted in new law signed by Gov. Brown to*
24 *curb epidemic of opioid overdose deaths*, L.A. Times (Sept. 27, 2016),
25 <http://www.latimes.com/politics/essential/la-pol-sac-essential-politics-updates-gov-brown-acts-to-curb-epidemic-of-1475015236-htmllstory.html>.

26 ¹⁵⁹ An "agonist" medication is one that binds to and fully activates targeted receptors in the
27 brain. They activate these neurotransmitter receptors to illicit a certain response. An "antagonist"
28 medication, on the other hand, works to prevent the binding of other chemicals to neurotransmitters in
order to block a certain response. Both may be used to offer pain relief. *Health Q&A*, Reference*,
<https://www.reference.com/health/difference-between-agonist-antagonist-drugs-838e9e0994a788eb>
(last visited Dec. 14, 2018).

MS Contin (morphine sulfate extended release)	Opioid agonist; controlled-release tablet form of morphine sulfate indicated for the management of severe pain; not intended for use as a p.r.n. analgesic; first approved in May 1987 as the first formulation of an opioid pain medicine that allowed dosing every 12 hours.	Schedule II
Dilaudid (hydromorphone hydrochloride)	Opioid analgesic; injectable and oral formulation; eight times more potent than morphine. ¹⁶⁰	Schedule II
Dilaudid-HP (hydromorphone hydrochloride)	Opioid analgesic; injectable and oral high-potency and highly concentrated formulation indicated for relief of moderate-to-severe pain in opioid-tolerant patients.	Schedule II
Hysingla ER (hydrocodone bitrate)	Brand-name extended-release form of hydrocodone bitrate indicated for the management of severe pain.	Schedule II
Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride)	Brand-name extended-release opioid analgesic made of a combination of oxycodone hydrochloride and naloxone hydrochloride. It was approved by the FDA on July 23, 2013.	Schedule II

a. Purdue Falsely Marketed Extended-Release Drugs as Safer and More Effective than Regular-Release Drugs

164. At all relevant times, the Sackler Families – Richard Sackler, Jonathan Sackler, Mortimer Sackler, Kathe Sackler, Beverly Sackler, Theresa Sackler, Ilene Sackler Lefcourt, David Sackler and the Raymond Sackler Trust – controlled Purdue and its related entities. This small group became extraordinarily wealthy because of their positions within Purdue and wielded immense amounts of power. Rather than use this power in a lawful and responsible manner, the Sackler Defendants directed and oversaw Purdue’s deceptive and unlawful sales and marketing practices.

165. The small and closely-held nature of Purdue and its associated entities makes the companies, in effect, the personal enterprises of the Sackler Defendants. The Sackler Defendants beneficially own and direct all the associate companies of Purdue in essentially the same manner as Purdue itself is controlled. All of Purdue’s profits from opioids go to Sackler Family trusts and entities.

166. The Sackler Defendants caused Purdue and associate companies that they owned and controlled to distribute hundreds of millions of dollars in profit from the sale of opioids.

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¹⁶⁰ *Dilaudid Addiction*, Suboxone California, <https://www.suboxonecalifornia.com/suboxone-treatment/dilaudid-addiction> (last visited Dec. 14, 2018).

1 167. Because the Sackler Families control Purdue's board, the officers of the company report
2 directly to them, ensuring the Sackler Families' control even if the company's officers were not
3 themselves members of the families.

4 168. Each of the Sackler Defendants named in this complaint has served on the board of
5 directors of Purdue, and some of them have also served as officers of Purdue and/or one or more Purdue-
6 related associate companies.

7 169. Purdue launched OxyContin 20 years ago with a bold marketing claim: "One dose
8 relieves pain for 12 hours, more than twice as long as generic medications."¹⁶¹ Prior to launching
9 OxyContin, Purdue conducted focus groups with doctors and "learned that the 'biggest negative' that
10 might prevent widespread use of the drug was ingrained concern regarding the 'abuse potential' of
11 opioids."¹⁶² In its initial press release launching the drug, Purdue told doctors that one OxyContin
12 would provide "smooth and sustained pain control all day and all night." Based in large part on that
13 promise, and on Purdue's repeated assurances that opioids were both effective and non-addictive,
14 OxyContin became America's bestselling painkiller.¹⁶³ Purdue had no evidentiary basis for those
15 claims.¹⁶⁴

16 170. In truth, Purdue's nationwide marketing claims were false and highly deceptive.
17 OxyContin was not superior to immediate-release opioids. And not only does OxyContin wear off early,
18 as Purdue's own early studies showed, it is highly addictive:

19 OxyContin's stunning success masked a fundamental problem: The drug wears off hours
20 early in many people, a Los Angeles Times investigation found. *OxyContin is a*

21 ¹⁶¹ Harriet Ryan et al., "You Want A Description of Hell?" *OxyContin's 12-Hour Problem*,
22 L.A. Times (May 5, 2016), <http://www.latimes.com/projects/oxycotin-part1/> (hereinafter, "Ryan,
Description of Hell").

23 ¹⁶² Keefe, *Empire of Pain*, *supra* n.18.

24 ¹⁶³ Press Release, Purdue Pharma L.P., New Hope for Millions of Americans Suffering
25 from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain (May 31, 1996),
<https://www.freelibrary.com/NEW+HOPE+FOR+MILLIONS+OF+AMERICANS+SUFFERING+FROM+PERSISTENT+PAIN%3A...-a018343260>.

26 ¹⁶⁴ Though the FDA's 1995 approval allowed Purdue to include a package insert for
27 OxyContin declaring the drug to be safer than its competitors due to its delayed release design, Purdue
28 had in fact "conducted no clinical studies on how addictive or prone to abuse the drug might be. . . .
The F.D.A. examiner who oversaw the process, Dr. Curtis Wright, left the agency shortly afterward.
Within two years, he had taken a job at Purdue." Keefe, *Empire of Pain*, *supra* n.18.

1 *chemical cousin of heroin, and when it doesn't last, patients can experience*
 2 *excruciating symptoms of withdrawal, including an intense craving for the drug.*¹⁶⁵

3 171. Furthermore, experts call the 12-hour dosing “an addiction producing machine.”¹⁶⁶
 4 Purdue had reportedly known for decades that it falsely promised 12-hour relief but nevertheless
 5 mobilized hundreds of sales representatives to “refocus” physicians on 12-hour dosing:

- 6 • Even before OxyContin went on the market, *clinical trials showed many patients*
 7 *weren't getting 12 hours of relief.* Since the drug's debut in 1996, the company
 8 has been confronted with additional evidence, including complaints from doctors,
 9 reports from its own sales reps and independent research.
- 10 • The company has held fast to the claim of 12-hour relief, in part to protect its
 11 revenue. OxyContin's market dominance and its high price – up to hundreds of
 12 dollars per bottle – hinge on its 12-hour duration. Without that, it offers little
 13 advantage over less expensive painkillers.
- 14 • When many doctors began prescribing OxyContin at shorter intervals in the late
 15 1990s, Purdue executives mobilized hundreds of sales reps to “refocus”
 16 physicians on 12-hour dosing. Anything shorter “needs to be nipped in the bud.
 17 NOW!!” one manager wrote to her staff.
- 18 • Purdue tells doctors to prescribe stronger doses, not more frequent ones, when
 19 patients complain that OxyContin doesn't last 12 hours. That approach creates
 20 risks of its own. Research shows that the more potent the dose of an opioid such
 21 as OxyContin, the greater the possibility of overdose and death.
- 22 • More than half of long-term OxyContin users are on doses that public health
 23 officials consider dangerously high, according to an analysis of nationwide
 24 prescription data conducted for the *Los Angeles Times*.¹⁶⁷

25 172. As reported by *The New York Times*, “internal Purdue Pharma documents show that
 26 company officials recognized even before the drug was marketed that they would face stiff resistance
 27 from doctors who were concerned about the potential of a high-powered narcotic like OxyContin to be
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23 ¹⁶⁵ The *Los Angeles Times* investigation, reported in three parts on May 5, July 10 and
 24 December 18, 2016, included the review of thousands of pages of confidential Purdue documents and
 25 court and other records. They span three decades, from the conception of OxyContin in the mid-1980s
 26 to 2011, and include e-mails, memoranda, meeting minutes and sales reports, as well as sworn
 27 testimony by executives, sales representatives and other employees. Ryan, *Description of Hell*, *supra*
 28 n.161. The *Los Angeles Times* reporters also examined FDA records, Patent Office files and medical
 journal articles, and interviewed experts in pain treatment, addiction medicine and pharmacology. *Id.*

¹⁶⁶ Kathleen Frydl, *Purdue Pharma: Corporate Fraud With a Body Count*, Altnet (May
 18, 2016), <http://www.altnet.org/drugs/purdue-pharma-corporate-fraud-body-count>.

¹⁶⁷ Ryan, *Description of Hell*, *supra* n.161.

1 abused by patients or cause addiction.” To combat this resistance, Purdue promised the long-acting,
2 extended-release formulation as safer and “less prone to such problems.”¹⁶⁸

3 173. Purdue’s sales culture in California, in particular, was one that required aggressive sales
4 of its opioids and embraced the sell-at-any-cost notion: “sell or be gone.” Aggressive quotas were put
5 into place for opioids including OxyContin, at all dosage levels, as well as Hysingla products. The
6 highest dosage for OxyContin was referred to by Purdue sales representatives as “hillbilly heroin.”
7 When sales representatives failed to meet their quotas, they were placed on performance employment
8 plans and/or terminated. When they were successful, they were richly rewarded with extravagant
9 bonuses and prizes. There was so much money to be made, and so much pressure to meet quotas, that
10 sales representatives became desensitized to what they were selling.

11 **b. Purdue Falsely Marketed Low Addiction Risk to Wide**
12 **Swaths of Physicians**

13 174. In addition to pushing OxyContin as safe and non-addictive by equating extended-release
14 with a lower risk, Purdue also promoted the use of prescription opioids for use in non-cancer patients,
15 who make up 86% of the total opioid market today.¹⁶⁹

16 175. Rather than targeting merely those physicians treating acute severe short-term, like post-
17 operative pain physicians or oncologists treating end-stage cancer pain, reports indicate that Purdue
18 heavily promoted OxyContin nationwide to doctors such as general practitioners, who often had little
19 training in the treatment of serious pain or in recognizing signs of drug abuse in patients.¹⁷⁰ According
20 to a report in *The New Yorker*, “[a] major thrust of the sales campaign was that OxyContin should be
21 prescribed not merely for the kind of severe short-term pain associated with surgery or cancer but also
22 for less acute, longer-lasting pain: arthritis, back pain, sports injuries, fibromyalgia” such that “[t]he
23 number of conditions that OxyContin could treat seemed almost unlimited.”¹⁷¹

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25 ¹⁶⁸ Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. Times (May
26 10, 2007), <http://www.nytimes.com/2007/05/10/business/11drug-web.html> (hereinafter, “Meier, *Guilty Plea*”).

27 ¹⁶⁹ Ornstein, *American Pain Foundation*, *supra* n.93.

28 ¹⁷⁰ Meier, *Guilty Plea*, *supra* n.168.

¹⁷¹ Keefe, *Empire of Pain*, *supra* n.18.

1 176. Sales representatives plied these and other physicians with coupons that were redeemable
 2 for a 7- to 30-day supply of free OxyContin, a Schedule II narcotic that by definition cannot be
 3 prescribed for more than one month at a time, with the promise that OxyContin was a safe opioid.
 4 Purdue “trained its sales representatives to carry the message that the risk of addiction was ‘less than
 5 one percent,’” and “[a] consistent feature in the promotion and marketing of OxyContin was a systematic
 6 effort to minimize the risk of addiction in the use of opioids for the treatment of chronic non-
 7 cancer-related pain.”¹⁷²

8 177. Sales representatives marketed OxyContin as a product “to start with and to stay with,”
 9 and Purdue deliberately exploited a misconception it knew many doctors held that oxycodone was less
 10 potent than morphine.¹⁷³ Sales representatives also received training in overcoming doctors’ concerns
 11 about addiction with talking points they knew to be untrue about the drug’s abuse potential. *The New*
 12 *Yorker* reported that “[i]n 2002, a sales manager from the company, William Gergely, told a state
 13 investigator in Florida that Purdue executives ‘told us to say things like it is “virtually” non-
 14 addicting.’”¹⁷⁴

15 178. Further, “[a]ccording to training materials, Purdue instructed sales representatives to
 16 assure doctors – repeatedly and without evidence – that ‘fewer than one per cent’ of patients who took
 17 OxyContin became addicted.” But “[i]n 1999, a Purdue-funded study of patients who used OxyContin
 18 for headaches found that the addiction rate was thirteen per cent.”¹⁷⁵

19 179. Even as late as 2015, if not later, Purdue sales representatives were telling physicians
 20 OxyContin was addiction resistant and had abuse-deterrent properties.

21 180. The marketing worked. Keith Humphreys, Professor of Psychiatry at Stanford and drug-
 22 policy adviser to the Obama Administration, said, “[t]hat’s the real Greek tragedy of this – that so many

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 26 ¹⁷² Van Zee, *Promotion and Marketing*, *supra* n.59.

27 ¹⁷³ Keefe, *Empire of Pain*, *supra* n.18.

28 ¹⁷⁴ *Id.*

¹⁷⁵ *Id.*

1 well-meaning doctors got co-opted. The level of influence is just mind-boggling. Purdue gave money
2 to continuing medical education, to state medical boards, to faux grassroots organizations.”¹⁷⁶

3 181. Purdue also tracked physicians’ prescribing practices by reviewing pharmacy
4 prescription data it obtained from I.M.S. Health, a company that buys bulk prescription data from
5 pharmacies and resells it to drug makers for marketing purposes. (Notably, Arthur Sackler co-founded
6 I.M.S. Health.) Rather than reporting highly suspicious prescribing practices, Purdue used the data to
7 track physicians who prescribed some opioids and might be persuaded to prescribe more. Purdue also
8 could identify physicians writing large numbers of prescriptions, and particularly for high-dose 80 mg
9 pills – potential signs of diversion and drug dealing.¹⁷⁷ It called the high-prescribing doctors “whales.”

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11 182. Purdue knew about many suspicious doctors and pharmacies from prescribing records,
12 pharmacy orders, field reports from sales representatives and, in some instances, its own surveillance
13 operations.¹⁷⁹ Since 2002, Purdue maintained a confidential roster of suspected reckless prescribers
14 known as “Region Zero.” By 2013, there were more than 1,800 doctors in Region Zero, but Purdue had
15 reported only 8% of them to authorities. The *Los Angeles Times* reported that “[a] former Purdue
16 executive, who monitored pharmacies for criminal activity, acknowledged that even when the company

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19 ¹⁷⁶ *Id.*

20 ¹⁷⁷ An 80 mg tablet is equivalent in strength to 16 Vicodin tablets, and was generally
21 reserved by doctors for patients with severe, chronic pain who had built up a tolerance over months or
22 years. In the illegal drug trade, however, “80s” were the most in demand. For those attempting to
23 detect how OxyContin was getting onto the black market, a physician writing a high volume of 80s
24 was a red flag. Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of*
25 *criminals and addicts. What the drugmaker knew*, L.A. Times (July 10, 2016),
26 <http://www.latimes.com/projects/la-me-oxycontin-part2/> (hereinafter, “Ryan, *More than 1 million*”).

27 ¹⁷⁸ Keefe, *Empire of Pain*, *supra* n.18.

28 ¹⁷⁹ Purdue’s “Abuse and Diversion Detection” program requires its sales representatives to
report to the company any facts that suggest a healthcare provider to whom it markets opioids may be
involved in the abuse or illegal diversion of opioid products. When a provider is reported under the
program, Purdue purportedly conducts an internal inquiry regarding the provider to determine whether
he or she should be placed on a “no-call” list. If a provider is placed on this list, Purdue sales
representatives may no longer contact the provider to promote the company’s opioid products. Bill
Fallon, *Purdue Pharma agrees to restrict marketing of opioids*, Stamford Advocate (Aug. 25, 2015,
3:32 PM), [http://www.stamfordadvocate.com/business/article/Purdue-Pharma-agrees-to-restrict-](http://www.stamfordadvocate.com/business/article/Purdue-Pharma-agrees-to-restrict-marketing-of-6464800.php)
[marketing-of-6464800.php](http://www.stamfordadvocate.com/business/article/Purdue-Pharma-agrees-to-restrict-marketing-of-6464800.php).

1 had evidence pharmacies were colluding with drug dealers, it did not stop supplying distributors selling
2 to those stores.”¹⁸⁰

3 **c. Purdue Funded Publications and Presentations with False**
4 **and Misleading Messaging**

5 183. As explained above, Purdue’s false marketing scheme did not end with its own sales
6 representatives and branded marketing materials. It extended far beyond, engaging third parties,
7 including doctors and front groups, to spread the false message of prescription opioids’ safety and
8 efficacy.

9 184. Purdue caused the publication and distribution of false and deceptive guidelines on opioid
10 prescribing. For example, as set forth above, Purdue paid \$100,000 to the FSMB to help print and
11 distribute its guidelines on the use of opioids to treat chronic pain to **700,000** practicing doctors. Among
12 the FSMB’s members are the Medical Board of California and the Osteopathic Medical Board of
13 California.

14 185. One of the advisors for Fishman’s 2007 publication, “Responsible Opioid Prescribing: A
15 Physician’s Guide,” and its 2012 update was Haddox, a longtime member of Purdue’s speakers’ bureau
16 who later became a Purdue vice president.

17 186. Similarly,¹⁸¹ multiple videos feature Fine delivering educational talks about the drugs.
18 In one video from 2011 titled, “Optimizing Opioid Therapy,” he sets forth a “Guideline for Chronic
19 Opioid Therapy” discussing “opioid rotation” (switching from one opioid to another) not only for cancer
20 patients, but for non-cancer patients, and suggests it may take four or five switches over a person’s
21 “lifetime” to manage pain.¹⁸² He states the “goal is to improve effectiveness which is different from
22 efficacy and safety.” Rather, for chronic pain patients, effectiveness “is a balance of therapeutic good
23 and adverse events **over the course of years.**” The entire program assumes that opioids are appropriate
24 treatment over a “protracted period of time” and even over a patient’s entire “lifetime.” He even
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26 ¹⁸⁰ Ryan, *More than 1 million*, *supra* n.177.

27 ¹⁸¹ Weber, *Two Leaders in Pain*, *supra* n.140.

28 ¹⁸² Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012),
https://www.youtube.com/watch?v=_G3II9yqgXI.

1 suggests that opioids can be used to treat *sleep apnea*. He further states that the associated risks of
 2 addiction and abuse can be managed by doctors and evaluated with “tools,” but leaves that for “a whole
 3 other lecture.”¹⁸³

4 187. Purdue provided many “teaching” materials free of charge to the Joint Commission.

5 188. Purdue also deceptively marketed the use of opioids for chronic pain through the APF,
 6 which was shut down after the Senate investigation launched in 2012. In 2010 alone, the APF received
 7 90% of its funding from drug and medical device companies. Purdue paid the APF unspecified amounts
 8 in 2008 and 2009 and between \$100,000 and \$499,999 in 2010.¹⁸⁴

9 d. The Guilty Pleas

10 189. In May 2007, Purdue and three of its executives pled guilty to federal charges of
 11 misbranding OxyContin for falsely marketing and promoting OxyContin as less addictive, less subject
 12 to abuse and diversion and less likely to cause tolerance and withdrawal symptoms than other pain
 13 medications in what the company acknowledged was an attempt to mislead doctors. Purdue was ordered
 14 to pay \$600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was
 15 misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science.
 16 Additionally, Michael Friedman (“Friedman”), the company’s president, pled guilty to a misbranding
 17 charge and agreed to pay \$19 million in fines; Howard R. Udell (“Udell”), Purdue’s top lawyer, pled
 18 guilty and agreed to pay \$8 million in fines; and Paul D. Goldenheim (“Goldenheim”), its former
 19 medical director, pled guilty and agreed to pay \$7.5 million in fines.

20 190. In a statement announcing the guilty plea, John Brownlee (“Brownlee”), the U.S.
 21 Attorney for the Western District of Virginia, stated:

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

25 ¹⁸³ *Id.*

26 ¹⁸⁴ American Pain Foundation, 2010 Annual Report at 16-19,
 27 <https://www.documentcloud.org/documents/277604-apf-2010-annual-report#document/> (last visited
 28 Dec. 15, 2018). Defendants Endo, Cephalon, and Janssen also made substantial payments to the APF
 in 2010: Endo more than \$1 million, Cephalon between \$50,000 and \$99,999, and Janssen between
 \$1,000 and \$49,999. *Id.* at 19.

1 ***But OxyContin offered no miracles to those suffering in pain. Purdue’s claims that***
 2 ***OxyContin was less addictive and less subject to abuse and diversion were false – and***
 3 ***Purdue knew its claims were false. The result of their misrepresentations and crimes***
 4 ***sparked one of our nation’s greatest prescription drug failures. . . . OxyContin was the***
 5 ***child of marketers and bottom line financial decision making.***¹⁸⁵

6 191. Brownlee characterized Purdue’s criminal activity as follows:

7 First, ***Purdue trained its sales representatives to falsely inform health care***
 8 ***providers that it was more difficult to extract the oxycodone from an OxyContin tablet***
 9 ***for the purpose of intravenous abuse.*** Purdue ordered this training even though its own
 10 study showed that a drug abuser could extract approximately 68% of the oxycodone from
 11 a single 10 mg OxyContin tablet by simply crushing the tablet, stirring it in water, and
 12 drawing the solution through cotton into a syringe.

13 Second, ***Purdue falsely instructed its sales representatives to inform health care***
 14 ***providers that OxyContin could create fewer chances for addiction*** than immediate-
 15 release opioids.

16 Third, ***Purdue sponsored training that falsely taught Purdue sales supervisors***
 17 ***that OxyContin had fewer “peak and trough” blood level effects than immediate-***
 18 ***release opioids resulting in less euphoria and less potential for abuse*** than short-acting
 19 opioids.

20 Fourth, ***Purdue falsely told certain health care providers that patients could stop***
 21 ***therapy abruptly without experiencing withdrawal symptoms and that patients who***
 22 ***took OxyContin would not develop tolerance*** to the drug.

23 And fifth, ***Purdue falsely told health care providers that OxyContin did not***
 24 ***cause a “buzz” or euphoria, caused less euphoria, had less addiction potential, had***
 25 ***less abuse potential, was less likely to be diverted than immediate-release opioids,*** and
 26 could be used to “weed out” addicts and drug seekers.¹⁸⁶

27 192. Specifically, Purdue pled guilty to illegally misbranding OxyContin in an effort to
 28 mislead and defraud physicians and consumers, while Friedman, Udell and Goldenheim pled guilty to
 the misdemeanor charge of misbranding OxyContin by introducing it into interstate commerce in
 violation of 21 U.S.C. §§331(a), 333(a)(1)-(2) and 352(a).

193. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers’
 bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund seemingly neutral
 organizations to disseminate the message that opioids were effective and non-addictive, and continued

¹⁸⁵ Press Release, U.S. Department of Justice, Statement of United States Attorney John
 Brownlee on the Guilty Plea of the Purdue Frederick Company and Its Executives for Illegally
 Misbranding OxyContin (May 10, 2007), [http://www.ctnewsjunkie.com/upload/2016/02/usdoj-
 purdue-guilty-plea-5-10-2007.pdf](http://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf).

¹⁸⁶ *Id.*

1 to aggressively market the liberal prescribing of opioids for chronic pain while diminishing the
2 associated dangers of addiction. After Purdue made its guilty plea in 2007,

3 it assembled an army of lobbyists to fight any legislative actions that might encroach on
4 its business. Between 2006 and 2015, Purdue and other painkiller producers, along with
5 their associated nonprofits, spent nearly nine hundred million dollars on lobbying and
6 political contributions – eight times what the gun lobby spent during that period.¹⁸⁷

6 194. Purdue has earned more than \$31 billion from OxyContin, the nation’s bestselling
7 painkiller, which constitutes approximately 30% of the United States market for painkillers. Since 2009,
8 Purdue’s national annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion,
9 up threefold from 2006 sales of \$800 million.¹⁸⁸

10 195. Purdue also made payments to physicians nationwide, including to San Francisco
11 physicians, for activities including participating on speakers’ bureaus, providing consulting services,
12 assisting in post-marketing safety surveillance and other services.

13 196. Based on an analysis of publicly disclosed reports from the years 2013 through 2016,
14 Purdue made nearly \$1.5 million in payments for expenses to San Francisco physicians that included
15 “food and beverage,” “charitable contribution,” “travel and lodging” and “consulting fee,” among other
16 types of expenses.

17 197. According to public records collected by ProPublica, in 2015 alone, Medicare Part D
18 paid \$85.6 million for claims arising from California physicians’ Oxycontin prescriptions.

19 **e. The Sacklers Establish Rhodes as a “Landing Pad” from**
20 **Purdue**

21 198. In or around November 2007, in the immediate aftermath of the guilty plea by Purdue
22 and its executives regarding the company’s false and misleading marketing of OxyContin, the Sackler
23 Defendants established Rhodes. According to a former senior manager at Purdue, “Rhodes was set up

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27 ¹⁸⁷ Keefe, *Empire of Pain*, *supra* n.18.

28 ¹⁸⁸ Eban, *Painful Medicine*, *supra* n.157.

1 as a ‘landing pad’ for the Sackler family in 2007, to prepare for the possibility that they would need to
2 start afresh following the crisis then engulfing OxyContin.’¹⁸⁹

3 199. The Sacklers’ involvement in Rhodes and its relationship to Purdue was not publicly
4 known until the September 9, 2018 publication of an article in the *Financial Times*. According to the
5 article, “Rhodes has not been publicly connected to the Sackler family before, and their ownership of
6 the company may weaken one of their longstanding defences: that they cannot be held responsible for
7 the opioid crisis because Purdue accounts for a small fraction of the overall prescriptions.”¹⁹⁰

8 200. Despite being registered as a separate company from Purdue, staff from Rhodes and
9 Purdue use the same employee handbook and “little distinction is made internally between the two
10 companies.”¹⁹¹

11 201. Rhodes manufactures, markets, sells and distributes the following opioids in
12 San Francisco and nationwide:

13 Hydromorphone hydrochloride	Generic opioid agonist.	Schedule II
14 Hydrocodone bitartrate and acetaminophen	Generic opioid agonist.	Schedule II
15 Oxycodone and acetaminophen	Generic opioid agonist.	Schedule II
16 Buprenorphine hydrochloride	Generic opioid agonist indicated for the treatment of opioid dependence.	Schedule III
17 Morphine sulfate	Generic opioid agonist.	Schedule II
18 Oxycodone hydrochloride	Generic opioid agonist.	Schedule II
19 Tapentadol hydrochloride	Generic opioid agonist.	Schedule II

20
21
22 202. According to the *Financial Times*, in 2016, Rhodes had a substantially larger share of
23 prescriptions in the U.S. prescription opioid market than Purdue.¹⁹²

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25 ¹⁸⁹ David Crow, *How Purdue’s ‘one-two’ punch fuelled the market for opioids*, *Financial Times* (Sept. 9, 2018), <https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c>.

26 ¹⁹⁰ *Id.*

27 ¹⁹¹ *Id.*

28 ¹⁹² *Id.*

1 203. According to public records collected by ProPublica, in 2015 alone, Medicare Part D
2 paid \$4.1 million for claims arising from California physicians' generic hydromorphone hydrochloride
3 prescriptions, \$102.7 million for claims arising from California physicians' generic hydrocodone
4 bitartrate/acetaminophen prescriptions, \$38.3 million for claims arising from California physicians'
5 generic oxycodone/acetaminophen prescriptions, \$34.4 million for claims arising from California
6 physicians' generic extended release morphine sulfate prescriptions and \$18.1 million for claims arising
7 from California physicians' generic oxycodone hydrochloride prescriptions.

8 **f. Purdue Failed to Monitor and Report Suspicious Sales as**
9 **Required**

10 204. The Controlled Substances Act and the regulations promulgated thereunder, 21 C.F.R.
11 §1300, *et seq.*, impose on all "registrants" the obligation to design and operate a system to monitor
12 suspicious orders of controlled substances and requires the registrant to notify the DEA field division
13 office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders
14 deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).
15 The CSA's requirements are also incorporated into California law. Cal. Bus. & Prof. Code §4301(o).

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

19 206. The California Code of Regulations requires all drug manufacturers and wholesalers to
20 report "all sales of dangerous drugs subject to abuse" to the Board of Pharmacy (the "Board") up to 12
21 times per year, pursuant to the Board's request. 16 C.C.R. §1782.

22 207. Purdue failed to design and operate a system to monitor suspicious orders of controlled
23 substances and/or failed to notify the appropriate DEA field division of suspicious orders. Purdue also
24 failed to report to the Board sales of dangerous drugs subject to abuse. Purdue's failure to timely report
25 these and other suspicious sales violated the CSA and California law.

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1 **2. The Sackler Family**

2 **a. The Individual Sackler Defendants Direct and Control**
3 **Purdue**

4 208. Richard Sackler is one of the six inventors listed on the original patent for OxyContin.
5 He began working for Purdue in the 1970s as an assistant to his father, Raymond Sackler, who served
6 as the president of the company at that time. Richard rose through leadership in the subsequent decades,
7 serving as President of Purdue from 1999 to 2003.

8 209. Richard Sackler resigned from his role in 2013 over apparent worry that executive
9 officers of Purdue would be held personally liable for any opioid-related liabilities. He continued to
10 serve as co-chair of Purdue's board with his uncle, Mortimer Sackler. This allowed the Sackler
11 Defendants to retain control of the company regardless of their involvement at the executive level.

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

17 211. At all relevant times, Richard Sackler served as trustee of one or more trusts that own
18 and control Purdue or Purdue-associated companies. He is the direct or indirect beneficiary of some
19 portion of 25% of the profits earned from the sale of opioids by Purdue and the Purdue-associated
20 companies listed herein.

21 212. Jonathan Sackler served as Senior Vice President of Purdue by 2000. Like Richard, his
22 brother, Jonathan resigned from his position in or after 2003, due to concerns that the executive officers
23 of Purdue would be personally liable for crimes and litigation stemming from Purdue's opioid products.
24 Jonathan continued to serve on Purdue's board after his resignation.

25 213. At all relevant times, Jonathan Sackler served as trustee of one or more trusts that own
26 and control Purdue or Purdue-associated companies. He is the direct or indirect beneficiary of some
27 portion of 25% of the profits earned from the sale of opioids by Purdue and the Purdue-associated
28 companies listed herein.

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1 214. Mortimer Sackler is the direct or indirect beneficiary of 7.14% of the profits earned from
2 the sale of opioids by Purdue and the Purdue-associated companies listed herein.

3 215. Kathe Sackler began serving as Senior Vice President of Purdue by 2000. She resigned
4 from her position in or about 2003 due to concerns that the executive officers of Purdue could be held
5 personally liable for crimes and litigation stemming from Purdue's opioid products. She continued to
6 serve on Purdue's board. She is the direct or indirect beneficiary of 7.14% of the profits earned from
7 the sale of opioids by Purdue and the Purdue-associated companies listed herein.

8 216. Ilene Sackler Lefcourt served as Vice President of Purdue during the initial development
9 and launch of OxyContin. She, too, resigned from her position around 2003 due to concerns of personal
10 liability for executive officers of Purdue for opioid-related crime and litigation, but continued to serve
11 on the board.

12 217. Beverly Sackler has served on the Board of Directors of Purdue and associated entities
13 since the 1990s. She serves as the trustee of one or more trusts that own or control Purdue and Purdue-
14 associated companies, and to which 50% of the profits of the companies' sale of opioids have been
15 conveyed. She is the direct or indirect beneficiary of some portion of the 50% of profits earned by the
16 Purdue through the sale of opioids.

17 218. Theresa Sackler has served on the Board of Directors of Purdue and associated entities
18 since the 1990s. She is the direct or indirect beneficiary of some portion of the 50% of profits earned
19 by Purdue through the sale of opioids.

20 219. David Sackler has served on the Board of Directors of Purdue and associated entities
21 since 2012. He is the direct or indirect beneficiary of some portion of 25% of the profits earned by
22 Purdue through the sale of opioids.

23 220. Richard Sackler, Jonathan Sackler, Mortimer Sackler, Kathe Sackler, Ilene Sackler
24 Lefcourt, Beverly Sackler, Theresa Sackler, David Sackler and the Raymond Sackler Trust (through its
25 trustees) each knowingly aided, participated in and benefited from the unlawful conduct of Purdue.

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b. The Sackler Defendants Oversee and Direct Purdue's Unlawful Conduct

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3 221. Prior to Purdue's entry into the opioid market, the general standard use of opioids was
4 for short-term periods, for example: acute pain, surgery recovery, cancer and palliative care. Chances
5 of opioid abuse are low when applied in this manner. Purdue went to great effort to influence public
6 perception of the perceived benefits and risks of long-term opioid use.

7 222. Arthur Sackler, the brother of Raymond and Mortimer Sackler, is largely responsible for
8 this change in public perception, effectively creating the pharmaceutical advertising industry. He
9 realized that direct advertising to doctors and prescribers would be the most effective means of turning
10 a profit. He paid prominent doctors to endorse his products, offered physicians perks and benefits,
11 published marketing material disguised as neutral medical journal articles and funded "education"
12 seminars that extolled the virtues of his drug products. His deceptive and unethical marketing techniques
13 led to Valium becoming the first hundred-million-dollar, then billion-dollar, prescription drug, and set
14 the precedent for the current problems with pharmaceutical marketing.

15 223. The Sackler Defendants have continued to direct Purdue's unlawful marketing
16 techniques, using many of the same unethical techniques developed by Arthur Sackler, in order to
17 maximize their sales of opioid products.

18 224. OxyContin was launched with one of the largest pharmaceutical marketing campaigns in
19 history, with roughly 1,000 sales representatives touting the drug's benefits. Representatives would
20 recommend OxyContin as the solution not just for acute, short-term pain, but also for less-acute, longer-
21 lasting pain. Sales training included lessons in overcoming doctors' concerns about health and addiction
22 by minimizing or downplaying OxyContin's true qualities. Purdue paid thousands of physicians to
23 present to medical conferences on the benefits of OxyContin.

24 225. Upon information and belief, members of the Sackler Families were deeply involved in
25 OxyContin's marketing campaign. Family members were on site at Purdue's headquarters daily,
26 controlling the management of the family business. According to a former sales representative, Richard
27 Sackler was "the dude that made it happen." In response to the concerns of benefit plans that OxyContin
28 //

1 was ripe for addictive use, Richard sent an email to sales representatives, asserting that “‘addiction’ may
2 be a convenient way to just say ‘NO.’”¹⁹³

3 226. In 1997, Richard and Kathe Sackler took part in a conspiracy to mislead doctors by
4 claiming oxycodone was half as strong as morphine when the opposite was the case. Purdue engaged
5 in this deception to alleviate the fears of medical professionals in prescribing the drug for non-acute
6 pain.

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

11 **c. Sackler Families Were Aware of the Abuse Potential of**
12 **OxyContin from at Least Summer 1999**

13 228. Purdue and members of the Sackler Families were aware that OxyContin and other
14 prescription medication could lead to addiction since at least summer 1999. An internal memo prepared
15 by Purdue employee, Maureen Sara, described the abuse and recreational use of OxyContin. The memo
16 was sent directly to Purdue’s board members, including Richard, Jonathan and Kathe Sackler.

17 229. In spite of the 1999 memo, Purdue President Michael Friedman testified before the U.S.
18 House of Representatives in 2001 that Purdue had not become aware of OxyContin’s potential for abuse
19 until 2000. No members of the Sackler Families attempted to correct this false narrative.

20 230. The Sackler Defendants were thus aware of potential liability for Purdue since at least
21 1999 due to OxyContin’s addictive nature. Instead of attempting to fix or solve the issue they had
22 created, the Sackler Defendants began to transfer profits from Purdue and associated companies to their
23 own private trusts and accounts in order to shield their funds from creditors. In 2015, for example, the
24 Sackler Families removed \$700 million from their privately held companies, two-thirds of which came
25 from Purdue. These transfers of ill-gotten gains were and are fraudulent, unjustly enriched the Sackler
26 Defendants and were done for the purpose of protecting the money from any civil or criminal judgment

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28 ¹⁹³ Patrick Radden Keefe, *The Family that Built an Empire of Pain*, *The New Yorker* (Oct. 30, 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>.

1 against Purdue for its participation in the opioid crisis. These transfers also left Purdue and its associated
2 entities undercapitalized and potentially unable to pay a judgment against it in this litigation.

3 231. Rather than protect the public's health once they became aware of OxyContin's potential
4 for abuse, the Sackler Families protected their own wealth.

5 **d. The Sackler Families Continued to Oversee Purdue's**
6 **Wrongdoing Even After Repeated Warnings and Fines**

7 232. The liability of the Sackler Defendants extends beyond their leadership of Purdue. They
8 were aware of, and obligated to address, Purdue's conduct due to previous investigations into the
9 company's deceptive practices.

10 233. Purdue Pharma Inc. and Purdue Pharma L.P. were under investigation by 26 states and
11 the DOJ from 2001 to 2017. In 2003, on the advice of legal counsel, every Sackler who held an executive
12 role at Purdue resigned to avoid personal liability for the conduct in which they had engaged and
13 continued to engage prior to and after their resignations.

14 234. In 2007, the directors of Purdue Pharma Inc. declared that it would pay roughly \$700
15 million and plead guilty to a felony for misleading doctors and patients about opioid medications. (The
16 company that paid the money, the Purdue Frederick Company, was a separate corporate entity that was
17 controlled by the same people and shared the same headquarters as Purdue Pharma L.P.). The company
18 acknowledged that its supervisors and employees had fraudulently promoted OxyContin as safer and
19 less addictive than other pain medications.

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

25 236. The 2007 convictions warned the directors against any further deception.

26 237. The directors also agreed to a Consent Judgment that ordered Purdue not to make any
27 false or misleading oral or written claims about OxyContin, including concerning the risk of addiction.
28 The Consent Judgment also required Purdue to establish a program that would identify high-prescribing

1 doctors, stop promoting OxyContin to them and report them. This program was to last from 2007 to
2 2017.

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

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

16 240. The years after the 2007 guilty plea and Corporate Integrity Agreement were filled with
17 alarming reports and stories about the opioid crisis. However, in spite of these widespread warnings,
18 Purdue’s directors, including members of the Sackler Families, did nothing to stop Purdue’s misconduct.

19 241. In 2008, opioid overdoses killed more Americans in that year than any year prior.

20 242. In 2009, the *American Journal of Public Health* published “The Promotion and
21 Marketing of OxyContin: Commercial Triumph, Public Health Tragedy.”¹⁹⁴ The article detailed the
22 misleading and deceptive nature of Purdue’s opioid marketing, including the misuse of sales
23 representatives, the targeting of high-prescribing practitioners and deception about the potential rates of
24 abuse. The CDC reported that deaths stemming from opioid use had tripled in the preceding year.

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28 ¹⁹⁴ Van Zee, *Promotion and Marketing*, *supra* n.59.

1 243. In 2010, *Time* magazine published “The New Drug Crisis: Addiction by Prescription.”¹⁹⁵
2 The article focused extensively on Purdue’s line of opioid products. Overdoses were the number one
3 cause of accidental death in 15 states that year, and Purdue’s directors were informed that Purdue would
4 not be able to get product liability insurance to cover OxyContin.

5 244. In 2011, the White House announced that prescription drug abuse was the nation’s
6 fastest-growing drug problem and called for educating healthcare providers about prescription drug
7 abuse to prevent overprescription. The CDC announced that prescription opioid overdoses had reached
8 never before seen levels and specifically called out Purdue’s line of opioid products. *Fortune* magazine
9 published an article that same year where Purdue executives were interviewed about the ongoing crisis
10 and the involvement of the company and the Sackler Families. The interviewees included Purdue Vice
11 President Alan Must, who admitted that Purdue was “well aware” of concerns about its conduct: “We
12 are well aware of detractors. For those individuals who think we’re evil . . . I don’t think there’s anything
13 we can do that is going to change their opinion.”¹⁹⁶

14 245. In 2012, the U.S. Senate announced an investigation into Purdue’s unlawful deception of
15 doctors and patients about the nature of its opioid products. The Senators warned of “an epidemic of
16 accidental deaths and addiction resulting from the increased sale and use of powerful narcotic
17 painkillers” in a letter to the CEO of Purdue Pharma, Inc. and Purdue Pharma L.P.¹⁹⁷ The Senate letter
18 specifically warned of the danger of higher levels of opioid dosage: “over the last decade, the number
19 of prescriptions for the strongest opioids has increased nearly fourfold, with only limited evidence of
20 their long-term effectiveness or risks while data suggest that hundreds of thousands of patients
21 nationwide may be on potentially dangerous doses.”¹⁹⁸ The Senate letter also warned about Purdue’s
22 deceptive tactics with doctors and patients: “There is growing evidence pharmaceutical companies that
23

24 ¹⁹⁵ Jeffrey Kluger, *The New Drug Crisis: Addiction by Prescription*, TIME (Sept. 17,
2010), <http://content.time.com/time/magazine/article/0,9171,2015763,00.html>.

25 ¹⁹⁶ Katherin Eban, *OxyContin: Purdue Pharma’s painful medicine*, FORTUNE (Nov. 9,
2011), <http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/>.

26 ¹⁹⁷ Letter from U.S. Senate Finance Committee to John H. Stewart, President and CEO of
27 Purdue Pharma L.P., dated May 8, 2012,
https://www.finance.senate.gov/imo/media/doc/Purdue_May_8.pdf (last visited Dec. 14, 2018).

28 ¹⁹⁸ *Id.*

1 manufacture and market opioids may be responsible, at least in part, for this epidemic by promoting
 2 misleading information about the drugs' safety and effectiveness."¹⁹⁹ The Senate specifically warned
 3 the directors and CEO that they were under scrutiny, demanding that Purdue present a set of
 4 "presentations, reports, and communications to Purdue's management team or board of directors from
 5 2007 to the present."²⁰⁰

6 246. In 2013, the *Los Angeles Times* reported that Purdue had created a list of 1,800 doctors
 7 suspected of recklessly prescribing its opioids over the past decade, but had reported only 8% of them
 8 to authorities. Purdue attorney Robin Abrams gave multiple interviews to the newspaper. Abrams was
 9 a Vice President of Purdue, and she signed Purdue's 2007 settlement agreement. In 2013, she admitted
 10 that Purdue had the list, and said with regard to Purdue's unwillingness to disclose the list: "I don't
 11 really want to open up an opportunity for folks [to] come in here and start looking and second-
 12 guessing."²⁰¹

13 247. Abrams and Purdue's directors had good reason to be concerned: the state of Kentucky
 14 had brought a lawsuit against Purdue for deceiving doctors and patients about the nature of its opioid
 15 products. When Purdue's lawyers surveyed the local residents for potential jury service, one-third of
 16 respondents said they knew someone who had been hurt or had overdosed taking Purdue opioids, and
 17 29% knew someone who had died. Purdue itself filed these findings in court.

18 248. In 2014, Edward Mahony, the Executive Vice President, Chief Financial Officer and
 19 Treasurer of Purdue, announced that the Kentucky lawsuit was noteworthy enough to "jeopardize
 20 Purdue's long-term viability."²⁰² The Governor of Massachusetts declared the opioid crisis a public
 21 health emergency in the same year.

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 24 ¹⁹⁹ *Id.*

²⁰⁰ *Id.*

25 ²⁰¹ Scott Glover & Lisa Girion, *OxyContin maker closely guards its list of suspect doctors*,
 26 *Los Angeles Times* (Aug. 11, 2013), <https://www.latimes.com/local/la-me-rx-purdue-20130811-story.html>.

27 ²⁰² Tracy Staton, *Addiction-riddled Kentucky out for blood in \$1B suit against OxyContin-*
 28 *maker Purdue*, *FiercePharma.com* (Oct. 20, 2014), <https://www.fiercepharma.com/pharma/addiction-riddled-kentucky-out-for-blood-1b-suit-against-oxycontin-maker-purdue>.

1 249. In 2016, in an attempt to stop the threatening spread of opioid overprescribing, the CDC
2 published the *CDC Guideline for Prescribing Opioids for Chronic Pain*.

3 250. In 2017, the President of the United States announced that opioid use in the nation had
4 risen to the level of a national public health emergency.

5 251. Plaintiffs are informed and believe, and thereupon allege, that the directors and CEO
6 controlled the operation of Purdue's sales representatives. Director Richard Sackler testified that Purdue
7 primarily promoted its opioids through its sales representatives, and that regular visits from
8 representatives were the key to get doctors to continue to prescribe the drugs. The board knew which
9 drugs the sales representatives were to promote, the number of visits representatives made to doctors,
10 how much each visit cost the company and the quarterly plans for sales visits. The board approved
11 specific hiring plans for their sales representatives, hiring directors and regional managers and creating
12 sales territories for representatives to target doctors.

13 252. Plaintiffs are informed and believe, and thereupon allege, that the directors and CEO
14 oversaw the specific tactics used by sales representatives to sell opioids; for example, a board report
15 encouraged the use of iPads during sales visits, which increased the average length of meetings to 16.7
16 minutes.

17 253. Plaintiffs are informed and believe, and thereupon allege, that the directors and CEO
18 oversaw the promotional claims representatives used during sales visits. The directors and CEO
19 reviewed reports that Purdue sales representatives were deceptively promoting opioids as an appropriate
20 treatment for minor pain, among hundreds of other examples of unlawful marketing techniques in need
21 of correction.

22 254. Plaintiffs are informed and believe, and thereupon allege, that the directors and CEO
23 oversaw Purdue's research, which in some cases contradicted the company's marketing. Company
24 leadership received detailed and specific reports concerning Purdue opioids being used for "opioid-
25 naïve" patients and patients with osteoarthritis.

26 255. Plaintiffs are informed and believe, and thereupon allege, that company leadership was
27 directly informed of "Reports of Concern" filed by sales representatives regarding high-prescribing
28 doctors, as well as "field inquiries" in response to the reports.

1 256. Plaintiffs are informed and believe, and thereupon allege, that the directors and CEO
2 monitored sales representatives' emails. Purdue had a policy of prohibiting sales representatives from
3 communicating with doctors via email; when Purdue found that some representatives had in fact
4 e-mailed doctors, the company "investigated" the matter and told the board that the representatives had
5 been disciplined and the matter would be discussed at the next board meeting.

6 257. Plaintiffs are informed and believe, and thereupon allege, that the directors oversaw
7 Purdue's strategy to pay high-prescribing doctors to promote its opioids. The board was aware of the
8 amount paid to specific high prescribers and the return on investment it received from these payments.
9 The board knew that Purdue allowed a gift spending limit of \$750 per doctor per year and was told
10 specifically that paying doctors was a high-risk activity that could result in improper off-label use or
11 other promotional activity for opioids.

12 258. Plaintiffs are informed and believe, and thereupon allege, that the directors and CEO also
13 managed Purdue's focus on encouraging patients to use higher and higher doses of opioids, leading to
14 health issues, addiction and greater profits for the company. Upon learning that sales of 40mg and 80mg
15 strengths of OxyContin had fallen below sales targets, the board received multiple reports that public
16 health authority initiatives to have doctors consult with pain specialists before prescribing high opioid
17 doses were a "threat." The board oversaw measures to counteract against these initiatives and received
18 reports in 2013 that attempts to encourage increased total daily doses had had a positive impact on the
19 company's bottom line.

20 259. Plaintiffs are informed and believe, and thereupon allege, that the directors additionally
21 oversaw Purdue's plan to keep patients hooked on opioids for longer periods of time through higher
22 doses. The board received thorough reports of how many patients remained on Purdue opioids for
23 extended lengths of time, as well as internal documents that indicated patients on higher doses used the
24 product for longer amounts of time, creating greater chances of addiction and abuse. The board was
25 presented with a plan to create workshops and give specific direction to representatives about this link,
26 and that increasing opioid use was a focus point of the company. The board was told in writing that
27 encouraging higher doses "is a focal point of our promotion" and that sales representatives should push
28 doctors to increase patient doses as soon as three days after initial treatment. The board knew or should

1 have known that this sales tactic was both deceptive and placing patients at high risk of addiction and
2 overdose.

3 260. Plaintiffs are informed and believe, and thereupon allege, that the directors also oversaw
4 Purdue's use of "savings cards" to get patients on Purdue opioids for longer periods of time. The board
5 knew exactly how many thousands of cards were used each quarter, the Return on Investment, and the
6 goal of the program: for patients "to remain on therapy longer."

7 261. Plaintiffs are informed and believe, and thereupon allege, that the directors also oversaw
8 Purdue's targeting of prescribers without special knowledge of opioids, as they were the most likely to
9 respond to Purdue's sales techniques. Purdue proceeded with this strategy despite the DEA expressing
10 concern that Purdue was marketing its opioids to doctors who were not appropriately trained in pain
11 management. Purdue's leadership also oversaw a strategy of targeting elderly patients, using images of
12 older patients to target healthcare professionals who practiced in long-term care. The directors and CEO
13 knew or should have known both that this strategy was deceptive and that targeting doctors who lacked
14 special training in pain management and elderly patients increased the risk of addiction and overdose.

15 262. Plaintiffs are informed and believe, and thereupon allege, that Purdue's leadership was
16 also aware of a plan to steer patients away from safer pain-management medicines, which involved
17 efforts to emphasize the danger of acetaminophen-based pain medication to the liver. These efforts
18 included deceptive websites that the New York Attorney General specifically held to be misleading in
19 specific sections.

20 263. Plaintiffs are informed and believe, and thereupon allege, that Purdue's leadership also
21 oversaw the response to thousands of harm reports from patients, in one case receiving over 5,000
22 complaints in a single quarter.

23 264. Plaintiffs are informed and believe, and thereupon allege, that Purdue possesses
24 documents that show each of the reports mentioned above was sent to every individual defendant on the
25 board, including every Sackler Defendant with a board position.

26 265. These defendants' duplicitous and unlawful acts have damaged, and continue to damage,
27 the State of California in a substantial amount to be determined at trial. Damages incurred by San
28 Francisco include: (a) the costs of treating opioid addiction, including addiction treatment, emergency

1 room visits and inpatient and outpatient treatment; (b) the costs of maintaining harm reduction, overdose
 2 prevention and education on the dangers of opioid use; (c) special costs incurred by San Francisco for
 3 the public safety, health and welfare of its citizens; and (d) the economic harm to San Francisco resulting
 4 from the addiction epidemic.

5 3. Janssen

6 266. Janssen manufactures, markets, sells and distributes the following opioids in San
 7 Francisco and nationwide:

8 Duragesic (fentanyl)	Opioid analgesic delivered via skin patch; contains gel form of fentanyl, a synthetic opioid that is up to 100 times more potent than morphine; delivers fentanyl at regulated rate for up to 72 hours; first approved by the FDA in August 1990.	Schedule II
9 Nucynta ER (tapentadol hydrochloride)	Opioid agonist; extended-release formulation indicated for severe pain.	Schedule II
10 Nucynta (tapentadol hydrochloride)	Immediate-release version of tapentadol hydrochloride for the management of moderate to severe acute pain.	Schedule II

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 12
 13
 14 267. Janssen introduced Duragesic in 1990. It is indicated for the “management of pain in
 15 opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment
 16 and for which alternative treatment options are inadequate.” Janssen also marketed Nucynta, which was
 17 first approved by the FDA in 2008, formulated in tablet form and in an oral solution and indicated for
 18 the “relief of moderate to severe acute pain in patients 18 years of age or older.” Additionally, Janssen
 19 marketed Nucynta ER, which was first approved by the FDA in 2011 in tablet form. Initially, it was
 20 indicated for the “management of . . . pain severe enough to require daily, around-the-clock, long-term
 21 opioid treatment and for which alternative treatment options are inadequate.” This pain indication was
 22 later altered to “management of moderate to severe chronic pain in adults” and “neuropathic pain
 23 associated with diabetic peripheral neuropathy (DPN) in adults.” Janssen sold Nucynta and Nucynta
 24 ER to Depomed in 2015 for \$1.05 billion.

25 a. The FDA Warned Janssen Regarding Its False Messaging

26 268. On February 15, 2000, the FDA sent Janssen a letter concerning the alleged
 27 dissemination of “homemade” promotional pieces that promoted Duragesic in violation of the Federal
 28 Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §301, *et seq.* In a subsequent letter, dated

1 March 30, 2000, the FDA explained that the “homemade” promotional pieces were “false or misleading
2 because they contain misrepresentations of safety information, broaden Duragesic’s indication, contain
3 unsubstantiated claims, and lack fair balance.”

4 269. The March 30, 2000 letter identified specific violations, including misrepresentations
5 that Duragesic had a low potential for abuse:

- 6 • You present the claim, “Low abuse potential!” This claim suggests that
7 Duragesic has less potential for abuse than other currently available opioids.
8 However, this claim has not been demonstrated by substantial evidence.
9 Furthermore, this claim is contradictory to information in the approved product
10 labeling (PI) that states, “Fentanyl is a Schedule II controlled substance and can
11 produce drug dependence similar to that produced by morphine.” Therefore, this
12 claim is false or misleading.²⁰³

13 270. The March 30, 2000 letter also stated that the promotional materials represented that
14 Duragesic was “more useful in a broader range of conditions or patients than has been demonstrated by
15 substantial evidence.” Specifically, the FDA stated that Janssen was marketing Duragesic for
16 indications other than the treatment of chronic pain that cannot otherwise be managed, for which it was
17 approved:

- 18 • You present the claim, “It’s not just for end stage cancer anymore!” This claim
19 suggests that Duragesic can be used for any type of pain management. However,
20 the PI for Duragesic states, “Duragesic (fentanyl transdermal system) is indicated
21 in the management of chronic pain in patients who require continuous opioid
22 analgesia for pain that cannot be managed by lesser means” Therefore, the
23 suggestion that Duragesic can be used for any type of pain management promotes
24 Duragesic[] for a much broader use than is recommended in the PI, and thus, is
25 misleading. In addition, the suggestion that Duragesic can be used to treat any
26 kind of pain is contradictory to the boxed warning in the PI. Specifically, the PI
27 states,

28 BECAUSE SERIOUS OR LIFE-THREATENING HYPOVENTILATION COULD
OCCUR, DURAGESIC® (FENTANYL TRANSDERMAL SYSTEM) IS
CONTRAINDICATED:

- In the management of acute or post-operative pain, including use in out-patient
surgeries²⁰⁴

24 //

25 //

26 ²⁰³ NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia
27 Chianese, Janssen Pharmaceutica at 2 (Mar. 30, 2000).

28 ²⁰⁴ *Id.* at 2-3.

1 271. The March 30, 2000 letter also stated Janssen failed to adequately present
2 “contraindications, warnings, precautions, and side effects with a prominence and readability reasonably
3 comparable to the presentation of information relating to the effectiveness of the product”:

4 Although this piece contains numerous claims for the efficacy and safety of Duragesic,
5 ***you have not presented any risk information*** concerning the boxed warnings,
6 contraindications, warnings, precautions, or side effects associated with Duragesic’s use
7 Therefore, this promotional piece is lacking in fair balance, or otherwise
8 misleading, because it fails to address important risks and restrictions associated with
9 Duragesic therapy.²⁰⁵

10 272. On September 2, 2004, HHS sent Janssen a warning letter concerning Duragesic due to
11 “false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated
12 effectiveness claims for Duragesic,” including, specifically, “suggesting that Duragesic has a lower
13 potential for abuse compared to other opioid products.”

14 273. The September 2, 2004 letter warned Janssen regarding its claims that Duragesic had a
15 low reported rate of mentions in the Drug Abuse Warning Network (“DAWN”) as compared to other
16 opioids. The letter stated that the claim was false or misleading because the claim was not based on
17 substantial data and because the lower rate of mentions was likely attributable to Duragesic’s lower
18 frequency of use compared to other opioids listed in DAWN:

19 The file card presents the prominent claim, “Low reported rate of mentions in
20 DAWN data,” along with Drug Abuse Warning Network (DAWN) data comparing the
21 number of mentions for Fentanyl/combinations (710 mentions) to other listed opioid
22 products, including Hydrocodone/combinations (21,567 mentions),
23 Oxycodone/combinations (18,409 mentions), and Methadone (10,725 mentions). The
24 file card thus suggests that Duragesic is less abused than other opioid drugs.

25 This is false or misleading for two reasons. First, we are not aware of substantial
26 evidence or substantial clinical experience to support this comparative claim. The
27 DAWN data cannot provide the basis for a valid comparison among these products. As
28 you know, DAWN is not a clinical trial database. Instead, it is a national public health
surveillance system that monitors drug-related emergency department visits and deaths.
If you have other data demonstrating that Duragesic is less abused, please submit them.

 Second, Duragesic is not as widely prescribed as other opioid products. As a
result, the relatively lower number of mentions could be attributed to the lower frequency

²⁰⁵ *Id.* at 3 (emphasis in original).

1 of use, and not to a lower incidence of abuse. The file card fails to disclose this information.²⁰⁶

2 274. The September 2, 2004 letter also detailed a series of unsubstantiated, false or misleading
3 claims regarding Duragesic’s effectiveness. The letter concluded that various claims made by Janssen
4 were insufficiently supported, including that:

- 5 • “Demonstrated effectiveness in chronic back pain with additional patient
6 benefits, . . . 86% of patients experienced overall benefit in a clinical study based
7 on: pain control, disability in ADLs, quality of sleep.”
- 8 • “All patients who experienced overall benefit from DURAGESIC would
9 recommend it to others with chronic low back pain.”
- 10 • “Significantly reduced nighttime awakenings.”
- 11 • “Significant improvement in disability scores as measured by the Oswestry
12 Disability Questionnaire and Pain Disability Index.”
- 13 • “Significant improvement in physical functioning summary score.”
- 14 • “Significant improvement in social functioning.”²⁰⁷

15 275. In addition, the September 2, 2004 letter identified “outcome claims [that] are misleading
16 because they imply that patients will experience improved social or physical functioning or improved
17 work productivity when using Duragesic.” The claims include “‘1,360 [lives] . . . and counting,’
18 ‘[w]ork, uninterrupted,’ ‘[l]ife, uninterrupted,’ ‘[g]ame, uninterrupted,’ ‘[c]hronic pain relief that
19 supports functionality,’ ‘[h]elps patients think less about their pain,’ and ‘[i]mprove[s] . . . physical and
20 social functioning.’” The September 2, 2004 letter stated: “Janssen has not provided references to
21 support these outcome claims. We are not aware of substantial evidence or substantial clinical
22 experience to support these claims.”²⁰⁸

23 276. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths
24 resulting from the use of Duragesic and its generic competitor, manufactured by Mylan. The advisory
25 noted that the FDA had been “examining the circumstances of product use to determine if the reported
26 adverse events may be related to inappropriate use of the patch” and noted the possibility “that patients

26 ²⁰⁶ Warning Letter from Thomas W. Abrams, U.S. Department of Health and Human
27 Services, to Ajit Shetty, Janssen Pharmaceutica, Inc., at 2 (Sept. 2, 2004),
28 http://www.johnsonandtoxin.com/040920_duragesic_letter.pdf.

²⁰⁷ *Id.* at 2-3.

²⁰⁸ *Id.* at 3.

1 and physicians might be unaware of the risks” of using the fentanyl transdermal patch, which is a potent
2 opioid analgesic meant to treat chronic pain that does not respond to other painkillers.

3 277. Regardless, even after receiving these letters, Janssen instructed California sales
4 representatives to market Duragesic as having better efficacy, better tolerability and better patient
5 compliance because it was a patch instead of a pill. California sales representatives were instructed to
6 tell doctors that the patch provided better control in the event of patient opioid abuse because patients
7 could not increase the patch dosage. However, sales representatives were aware of patients who
8 increased the dosage by applying more than one patch at a time and were also aware that some patients
9 abused the patch by freezing, then chewing on it.

10 **b. Janssen Funded False Publications and Presentations**

11 278. Despite these repeated warnings, Janssen continued to falsely minimize the risks of
12 opioids. In 2009, PriCara, a “Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.,” sponsored a
13 2009 brochure, “Finding Relief: Pain Management for Older Adults,” aimed at potential patients. The
14 brochure included a free DVD featuring actress Kathy Baker, who played a doctor in the popular
15 television series “Picket Fences.”

16 279. The brochure represented that it was a source for older adults to gain accurate information
17 about treatment options for effective pain relief:

18 This program is aimed specifically at older adults and what they need to know to
19 get effective pain relief. You will learn that there are many pathways to this relief.

20 You will learn about your options for pain management and how to find the
21 treatment that’s right for you. By learning more about pain and the many ways it can be
22 treated, you are taking solid steps toward reducing the pain you or a loved one may be
23 feeling.²⁰⁹

24 280. Despite representing itself as a source of accurate information, the brochure included
25 false and misleading information about opioids, including a section seeking to dispel purported “myths”
26 about opioid usage:

27 **Opioid Myths**

28 **Myth:** Opioid medications are always addictive.

²⁰⁹ *Finding Relief, Pain Management for Older Adults* (2009).

1 **Fact:** Many studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.

2 **Myth:** Opioids make it harder to function normally.

3 **Fact:** When used correctly for appropriate conditions, opioids may make it *easier* for people to live normally.

4 **Myth:** Opioid doses have to get bigger over time because the body gets used to them.

5 **Fact:** Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.²¹⁰

6
7
8 281. Among the “Partners” listed in “Finding Relief: Pain Management for Older Adults” are
9 the AAPM, the AGS and the AGS Foundation for Health in Aging. Janssen (along with Purdue and
10 Endo) funded the AAPM. The AGS and the AGS Foundation for Health in Aging published a pain
11 guide titled, “Finding Relief: Pain Management for Older Adults,” which was funded by Janssen.²¹¹

12 282. In addition, Janssen disseminated false information about opioids on the website
13 Prescribe Responsibly, which remains publicly accessible at www.prescriberesponsibly.com.
14 According to the website’s legal notice, all content on the site “is owned or controlled by Janssen.”²¹²
15 The website includes numerous false or misleading representations concerning the relative safety of
16 opioids and omissions of the risks associated with taking them. For example, it states that while
17 practitioners are often concerned about prescribing opioids due to “questions of addiction,” such
18 concerns “are often overestimated. According to clinical opinion polls, true addiction occurs only in a
19 small percentage of patients with chronic pain who receive chronic opioid . . . analgesic therapy.”²¹³

20 283. Prescribe Responsibly also compared the risks of opioid use favorably to those associated
21 with NSAIDs, such as aspirin and ibuprofen, and stated that many patients develop tolerance for opioid
22 side effects:

23 //

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25 ²¹⁰ *Id.* (emphasis in original).

26 ²¹¹ *Id.*

27 ²¹² *Legal Notice*, Prescribe Responsibly, <http://www.prescriberesponsibly.com/legal-notice>
(last visited Dec. 14, 2018).

28 ²¹³ *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, <http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last visited Dec. 14, 2018).

1 Opioid analgesics are often the first line of treatment for many painful conditions
2 and may offer advantages over nonsteroidal anti-inflammatory drugs (NSAIDs). Opioid
3 analgesics, for example, have no true “ceiling dose” for analgesia and do not cause direct
4 organ damage; however, they do have several possible side effects, including
constipation, nausea, vomiting, a decrease in sexual interest, drowsiness, and respiratory
depression. With the exception of constipation, many patients often develop tolerance to
most of the opioid analgesic-related side effects.²¹⁴

5 284. Further, Prescribe Responsibly repeats the scientifically unsupported discussion of
6 “pseudoaddiction” as “a syndrome that causes patients to seek additional medications due to inadequate
7 pharmacotherapy being prescribed. Typically when the pain is treated appropriately, the inappropriate
8 behavior ceases.”²¹⁵ Thus, pseudoaddiction is defined as a condition requiring the prescription of more
9 or stronger opioids.

10 285. Janssen also made thousands of payments to physicians nationwide, including to San
11 Francisco physicians, for activities including participating on speakers’ bureaus, providing consulting
12 services, assisting in post-marketing safety surveillance and other services.

13 286. Based on an analysis of publicly disclosed reports from the years 2013 through 2016,
14 Janssen made nearly 5,000 individual payments to San Francisco physicians totaling more than
15 \$740,000 for expenses including education, food and beverage, travel and lodging charitable
16 contribution, consulting, compensation for services other than consulting, grants, space rental or facility
17 fees and travel and lodging fees.

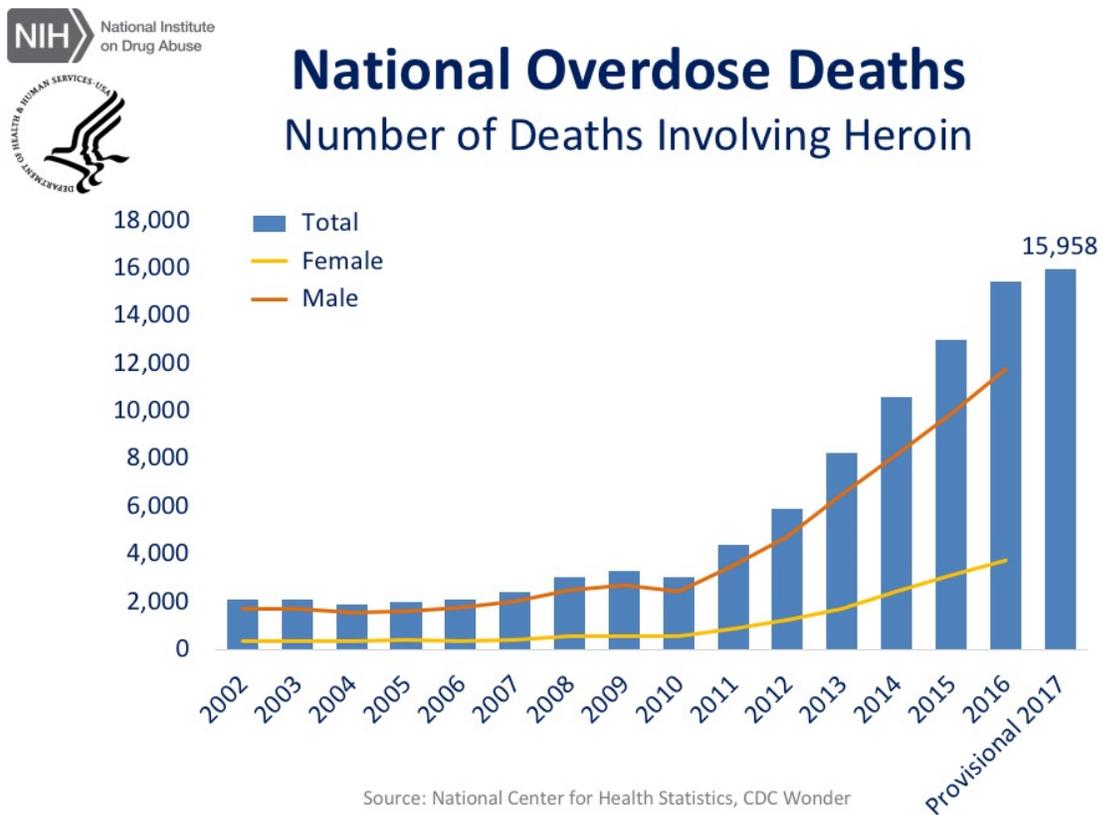
18 287. According to data collected by ProPublica, in 2014, California doctors prescribed nearly
19 \$1 million worth of Duragesic, more than \$500,000 worth of Nucynta and almost \$400,000 worth of
20 Nucynta ER to patients insured by Medicare Part D. In 2015, those amounts rose to more than \$2.4
21 million worth of Duragesic, almost \$3.4 million worth of Nucynta and more than \$2.8 million worth of
22 Nucynta ER.

23 288. As people became more and more hooked on prescription painkillers, they moved to
24 heroin, and increasingly to fentanyl, which is even more potent and cheaper than heroin, is increasingly
25

26 ²¹⁴ *Id.*

27 ²¹⁵ *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe
28 Responsibly, <http://www.prescriberesponsibly.com/articles/before-prescribing-opioids> (last visited
Dec. 14, 2018).

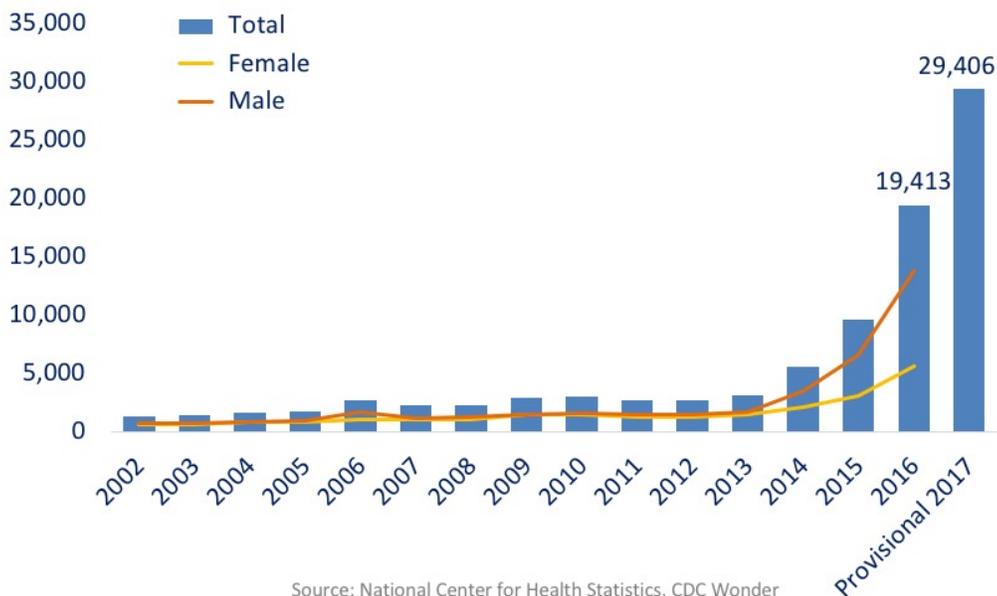
1 mixed with or sold as heroin and, as set forth above, was also being deceptively marketed by Janssen.
2 This transition to heroin and fentanyl caused a dramatic spike in overdose deaths in and around 2011:





National Overdose Deaths

Number of Deaths Involving Other Synthetic Opioids (Predominately Fentanyl)



c. Janssen Failed to Monitor and Report Suspicious Sales as Required

289. The federal CSA imposes on all “registrants” the obligation to design and operate a system to monitor suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. “Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. §1301.74(b). The CSA’s requirements are also incorporated into California law. Cal. Bus. & Prof. Code §4301(o).

290. Janssen is a “registrant” under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

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1 291. The California Code of Regulations requires all drug manufacturers and wholesalers to
2 report “all sales of dangerous drugs subject to abuse” to the Board up to 12 times per year, pursuant to
3 the Board’s request. 16 C.C.R. §1782.

4 292. Janssen failed to design and operate a system to monitor suspicious orders of controlled
5 substances and/or failed to notify the appropriate DEA field division of suspicious orders. Doctors
6 practicing in San Francisco and/or prescribing opioids to San Francisco residents have been arrested and
7 arraigned for writing an egregiously high number of opioid prescriptions. Janssen also failed to report
8 to the Board sales of dangerous drugs subject to abuse. Janssen’s failure to timely report these and other
9 suspicious sales violated the CSA.

10 4. **Endo**

11 293. Endo manufactures, markets, sells and distributes the following opioids in San Francisco
12 and nationwide:

13 Opana ER (oxymorphone hydrochloride)	Opioid agonist; extended-release tablet formulation; first drug in which oxymorphone was available in an oral, extended-release formulation; first approved in 2006.	Schedule II
14 Opana (oxymorphone hydrochloride)	Opioid agonist; first approved in 2006.	Schedule II
15 Percodan (oxymorphone hydrochloride and aspirin)	Branded tablet combining oxymorphone hydrochloride and aspirin; first approved in 1950; first marketed by Endo in 2004.	Schedule II
16 Percocet (oxymorphone hydrochloride and acetaminophen)	Branded tablet that combines oxymorphone hydrochloride and acetaminophen; first approved in 1999; first marketed by Endo in 2006.	Schedule II
17 Oxycodone	Generic product.	Schedule II
18 Oxymorphone	Generic product.	Schedule II
19 Hydromorphone	Generic product.	Schedule II
20 Hydrocodone	Generic product.	Schedule II

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22
23
24
25 294. The FDA first approved an injectable form of Opana in 1959. The injectable form of
26 Opana was indicated “for the relief of moderate to severe pain” and “for preoperative medication, for
27 support of anesthesia, for obstetrical analgesia, and for relief of anxiety in patients with dyspnea
28 //

1 associated with pulmonary edema secondary to acute left ventricular dysfunction.” However,
2 oxymorphone drugs were removed from the market in the 1970s due to widespread abuse.²¹⁶

3 295. In 2006, the FDA approved a tablet form of Opana in 5 mg and 10 mg strengths. The
4 tablet form was “indicated for the relief of moderate to severe acute pain where the use of an opioid is
5 appropriate.” Also in 2006, the FDA approved Opana ER, an extended-release tablet version of Opana
6 available in 5 mg, 10 mg, 20 mg and 40 mg tablet strengths. Opana ER was indicated “for the relief of
7 moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an
8 extended period of time.” Endo’s goal was to use Opana ER to take market share away from OxyContin;
9 thus it was marketed as being safer, with less abuse potential than OxyContin because it is supposed to
10 be crush-resistant.

11 296. According to Endo’s annual reports, sales of Opana and Opana ER regularly generate
12 several hundred million dollars in annual revenue for the company, growing from \$107 million in 2007
13 to as high as \$384 million in 2011. Over the last ten years, Percocet has generated an average of well
14 over \$100 million in annual revenue for the company.

15 **a. Endo Falsely Marketed Opana ER as Crush Resistant**

16 297. In December 2011, the FDA approved a reformulated version of Opana ER, which Endo
17 claimed offered “safety advantages” over the original formulation because the new version “is resistant
18 to crushing by common methods and tools employed by abusers of prescription opioids . . . [and] is less
19 likely to be chewed or crushed even in situations where there is no intent for abuse, such as where
20 patients inadvertently chew the tablets, or where caregivers attempt to crush the tablets for easier
21 administration with food or by gastric tubes, or where children accidentally gain access to the tablets.”

22 298. Endo publicized the reformulated version of Opana ER as “crush-resistant.” To combat
23 the fear of opioids, sales representatives touted it to doctors as a safer option due to its crush-resistance
24 and extended release. In a December 12, 2011 press release announcing FDA approval of the

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26 _____
27 ²¹⁶ John Fauber & Kristina Fiore, *Opana gets FDA approval despite history of abuse,*
28 *limited effectiveness in trials*, Milwaukee Journal Sentinel (May 9, 2015), <http://archive.jsonline.com/watchdog/watchdogreports/opana-gets-fda-approval-despite-history-of-abuse-limited-effectiveness-in-trials-b99494132z1-303198321.html/>.

1 reformulated Opana ER, Endo's executive vice president for research and development and chief
2 scientific officer highlighted the reformulated version's safety characteristics:

3 "FDA's approval of this new formulation of Opana ER is an important milestone
4 for both the Long Acting Opioid category as well as Endo's branded pharmaceutical
5 portfolio. . . . Patient safety is our top concern and addressing appropriate use of opioids
6 is a responsibility that we take very seriously. We firmly believe this new formulation
7 of Opana ER, coupled with our long-term commitment to awareness and education
8 around appropriate use of opioids will benefit patients, physicians and payers."

9 299. However, in October 2012, the CDC issued a health alert noting that 15 people in
10 Tennessee had contracted thrombotic thrombocytopenic purpura, a rare blood-clotting disorder, after
11 injecting reformulated Opana ER. In response, Endo's chief scientific officer stated that, while Endo
12 was looking into the data, he was not especially concerned: "Clearly, we are looking into this data, . . .
13 but it's in a very, very distinct area of the country."²¹⁷

14 300. Shortly thereafter, the FDA determined that Endo's conclusions about the purported
15 safety advantages of the reformulated Opana ER were unfounded. In a May 10, 2013 letter to Endo, the
16 FDA found that the tablet was still vulnerable to "cutting, grinding, or chewing," "can be prepared for
17 insufflation (snorting) using commonly available tools and methods" and "can [be readily] prepared for
18 injection." It also warned that preliminary data suggested "the troubling possibility that a higher
19 percentage of reformulated Opana ER abuse is via injection than was the case with the original
20 formulation."

21 301. A 2014 study co-authored by an Endo medical director corroborated the FDA's warning.
22 This 2014 study found that while overall abuse of Opana had fallen following Opana ER's
23 reformulation, it also found that injection had become the preferred way of abusing the drug.²¹⁸
24 However, the study reassured that it was not possible to draw a causal link between the reformulation
25 and injection abuse.

26 302. The study's failure to adequately warn healthcare providers and the public was
27 catastrophic. On April 24, 2015, the CDC issued a health advisory concerning its investigation of "a

28 ²¹⁷ Tom Dreisbach et al., *How A Painkiller Designed To Deter Abuse Helped Spark An
HIV Outbreak*, National Public Radio (Apr. 1, 2016), [http://www.npr.org/sections/health-
shots/2016/04/01/472538272/how-a-painkiller-designed-to-deter-abuse-helped-spark-an-hiv-outbreak](http://www.npr.org/sections/health-shots/2016/04/01/472538272/how-a-painkiller-designed-to-deter-abuse-helped-spark-an-hiv-outbreak).

²¹⁸ *Id.*

1 large outbreak of recent human immunodeficiency virus (HIV) infections among persons who inject
 2 drugs.”²¹⁹ The CDC specifically attributed the outbreak to the injection of Opana ER. As the advisory
 3 explained:

4 From November 2014 to January 2015, ISDH identified 11 new HIV infections
 5 in a rural southeastern county where fewer than 5 infections have been identified annually
 6 in the past. As of April 21, 2015, an on-going investigation by ISDH with assistance
 7 from CDC has identified 135 persons with newly diagnosed HIV infections in a
 8 community of 4,200 people; 84% were also HCV infected. Among 112 persons
 interviewed thus far, 108 (96%) injected drugs; all reported dissolving and injecting
 tablets of the prescription-type opioid oxymorphone (OPANA® ER) using shared drug
 preparation and injection equipment.²²⁰

9 **b. New York’s Investigation Found Endo Falsely Marketed
 Opana ER**

10 303. On February 18, 2017, the State of New York announced a settlement with Endo
 11 requiring it “to cease all misrepresentations regarding the properties of Opana ER [and] to describe
 12 accurately the risk of addiction to Opana ER.”²²¹ In the Assurance of Discontinuance that effectuated
 13 the settlement, the State of New York revealed evidence showing that Endo had known about the risks
 14 arising from the reformulated Opana ER even before it received FDA approval.

15 304. Among other things, the investigation concluded that:

- 16 • *Endo improperly marketed Opana ER as designed to be crush resistant even*
 17 *though Endo’s own studies dating from 2009 and 2010 showed that the pill*
could be crushed and ground;
- 18 • *Endo improperly instructed its sales representatives to diminish and distort the*
 19 *risks associated with Opana ER, including the serious danger of addiction; and*
- 20 • *Endo made unsupported claims comparing Opana ER to other opioids and*
 21 *failed to disclose accurate information regarding studies addressing the*
negative effects of Opana ER.

22 305. In October 2011, Endo’s director of project management e-mailed the company that
 23 developed the formulation technology for reformulated Opana ER to say there was little or no difference

24 ²¹⁹ *Outbreak of Recent HIV and HCV Infections Among Persons Who Inject Drugs,*
 25 Centers for Disease Control and Prevention, <https://emergency.cdc.gov/han/han00377.asp> (last visited
 Dec. 14, 2018).

26 ²²⁰ *Id.*

27 ²²¹ Press Release, Attorney General Eric T. Schneiderman, A.G. Schneiderman Announces
 Settlement With Endo Health Solutions Inc. & Endo Pharmaceuticals Inc. Over Marketing Of
 28 Prescription Opioid Drugs (Mar. 3, 2016), <https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals>.

1 between the new formulation and the earlier formulation, which Endo withdrew due to risks associated
2 with grinding and chewing:

3 ***“We already demonstrated that there was little difference between [the original and***
4 ***new formulations of Opana] in Study 108 when both products were ground. FDA***
5 ***deemed that there was no difference and this contributed to their statement that we had***
6 ***not shown an incremental benefit. The chewing study (109) showed the same thing no***
7 ***real difference which the FDA used to claim no incremental benefit.”***²²²

8 306. Endo conducted two additional studies to test the reformulated Opana ER’s crush
9 resistance. Study 901 tested whether it was more difficult to extract opioid from reformulated Opana ER
10 than from the original version, and whether it would take longer to extract opioid from reformulated
11 Opana ER than from the original version. The test revealed that both formulations behaved similarly
12 with respect to manipulation time and produced equivalent opioid yields.

13 307. The settlement also identified and discussed a February 2013 communication from a
14 consultant hired by Endo to the company in which the consultant concluded that “[t]he initial data
15 presented do not necessarily establish that the reformulated Opana ER is tamper resistant.” The same
16 consultant also reported that the distribution of the reformulated Opana ER had already led to higher
17 levels of abuse of the drug via injection.²²³

18 308. Despite the results of Endo’s own studies and the conclusions of Endo’s director of
19 project management and consultant, pamphlets produced by Endo and distributed to physicians
20 misleadingly marketed the reformulated Opana ER as “‘designed to be’ crush resistant,” and Endo’s
21 sales representative training identified Opana ER as “CR,” short for crush resistant.²²⁴

22 309. The Office of the Attorney General of New York also revealed that the “managed care
23 dossier” Endo provided to formulary committees of healthcare plans and PBMs misrepresented the
24 Opana ER studies. The dossier was distributed in order to assure the inclusion of reformulated
25 Opana ER in their formularies.

26 //

27 ²²² *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance
28 No. 15-228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 5 (Mar.
1, 2016), https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

²²³ *Id.* at 6.

²²⁴ *Id.*

1 310. According to Endo’s vice president for pharmacovigilance and risk management, the
2 dossier was presented as a complete compendium of all research on the drug. However, it omitted
3 certain studies: Study 108 (completed in 2009) and Study 109 (completed in 2010), which showed that
4 reformulated Opana ER could be ground and chewed.

5 311. The settlement also detailed Endo’s false and misleading representations about the non-
6 addictiveness of opioids and Opana. Until April 2012, Endo’s website for the drug, www.opana.com,
7 contained the following representation: “Most healthcare providers who treat patients with pain agree
8 that patients treated with prolonged opioid medicines usually do not become addicted.”²²⁵ However,
9 Endo neither conducted nor possessed a survey demonstrating that most healthcare providers who treat
10 patients with pain agree with that representation.

11 312. The Office of the Attorney General of New York also disclosed that training materials
12 provided by Endo to sales representatives stated: “Symptoms of withdrawal do not indicate
13 addiction.”²²⁶ This representation is inconsistent with the diagnosis of opioid-use disorder as provided
14 in the *Diagnostic and Statistical Manual of Mental Disorders by the American Psychiatric Association*
15 (*Fifth Edition*).

16 313. The Office of the Attorney General of New York also found that Endo trained its sales
17 representatives to falsely distinguish addiction from “pseudoaddiction,” which it defined as a condition
18 in which patients exhibit drug-seeking behavior that resembles, but is not the same as, addiction.
19 However, Endo’s vice president for pharmacovigilance and risk management testified that he was not
20 aware of any research validating the concept of pseudoaddiction.

21 **c. Endo Funded False Publications and Presentations**

22 314. Like several of the other Marketing Defendants, Endo provided substantial funding to
23 purportedly neutral medical organizations, including the APF.

24 //

25 //

26 //

27 ²²⁵ *Id.*

28 ²²⁶ *Id.* at 7.

1 315. For example, in April 2007, Endo sponsored an article aimed at prescribers, written by
2 Dr. Charles E. Argoff in *Pain Medicine News*, titled, “Case Challenges in Pain Management: Opioid
3 Therapy for Chronic Pain.”²²⁷

4 316. The article commenced with the observation that “[a]n estimated 50 to 60 million people
5 . . . suffer from chronic pain.” It continued:

6 Opioids represent a highly effective but controversial and often misunderstood
7 class of analgesic medications for controlling both chronic and acute pain. The
8 phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and
9 fears of abuse, diversion, and misuse of these medications by patients have led many
10 clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that
11 may be insufficient to provide meaningful relief.²²⁸

12 317. The article included a case study that focused on the danger of extended use of NSAIDs,
13 including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have
14 resulted from his protracted NSAID use. In contrast, the article did not provide the same detail
15 concerning the serious side effects associated with opioids. It concluded by saying that “use of opioids
16 may be effective in the management of chronic pain.”

17 318. Later, in 2014, Endo issued a patient brochure titled, “Understanding Your Pain: Taking
18 Oral Opioid Analgesics.” It was written by nurses Margo McCaffery and Chris Pasero and edited by
19 APF board member Portenoy.

20 319. The brochure included numerous false and misleading statements minimizing the
21 dangers associated with prescription opioid use. Among other things, the brochure falsely and
22 misleadingly represented that:

23 Addiction **IS NOT** when a person develops “withdrawal” (such as abdominal
24 cramping or sweating) after the medicine is stopped quickly or the dose is reduced by a
25 large amount. Your doctor will avoid stopping your medication suddenly by slowly
26 reducing the amount of opioid you take before the medicine is completely stopped.
27 Addiction also **IS NOT** what happens when some people taking opioids need to take a
28 higher dose after a period of time in order for it to continue to relieve their pain. This
normal “tolerance” to opioid medications doesn’t affect everyone who takes them and
does not, by itself, imply addiction. If tolerance does occur, it does not mean you will
“run out” of pain relief. Your dose can be adjusted or another medicine can be prescribed.

²²⁷ Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, *Pain Med. News*, http://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf.

²²⁸ *Id.*

* * *

How can I be sure I'm not addicted?

- Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problems.
- Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons – to relieve your pain and improve your function. You are not addicted.

* * *

Your doctor or nurse may instruct you to do some of the following:

- Take the next dose before the last dose wears off. If pain is present most of the day and night, the pain medicine may be taken at regularly scheduled times. If you are taking a short-acting opioid, this usually means taking it every 4 hours. You may need to set your alarm, especially at night, to be sure you take your dose before the pain returns and wakes you up.
- If your pain comes and goes, take your pain medicine when pain first begins, before it becomes severe.
- If you are taking a long-acting opioid, you may only need to take it every 8 to 12 hours, but you may also need to take a short-acting opioid in between for any increase in pain.²²⁹

320. In 2008, Endo also provided an “educational grant” to PainEDU.org, which produced a document titled, “Screener and Opioid Assessment for Patients with Pain (SOAPP) Version 1.0-14Q.” Endo and King Pharmaceuticals sponsor PainEDU.org.²³⁰ SOAPP describes itself “as a tool for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require.” It falsely highlights purportedly “recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems.”

321. Endo also sponsored the now-defunct website painknowledge.com, which was created by the APF and stated it was “a one-stop repository for print materials, educational resources, and physician tools across the broad spectrum of pain assessment, treatment, and management

²²⁹ Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharmaceuticals (2004), http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf (emphasis in original).

²³⁰ B. Eliot Cole, *Resources for Education on Pain and Its Management: A Practitioner's Compendium 2* (Am. Society of Pain Educators 2009), <https://www.paineducators.org/wp-content/uploads/2012/12/ASPE-ResForEducationOnPainAn.pdf>.

1 approaches.”²³¹ Among other featured content, painknowledge.com included a flyer titled, “Pain:
2 Opioid Therapy,” which failed to warn of significant adverse effects that could arise from opioid use,
3 including hyperalgesia, immune and hormone dysfunction, cognitive impairment, decreased tolerance,
4 dependence and addiction.

5 322. Endo, along with Janssen and Purdue, also provided grants to the APF to distribute Exit
6 Wounds, discussed above. *See supra* ¶¶101-102.²³²

7 323. Endo also made thousands of payments to physicians nationwide, including to San
8 Francisco physicians, for activities including participating on speakers’ bureaus, providing consulting
9 services, assisting in post-marketing safety surveillance and other services.

10 **d. FDA Requested Endo Withdraw Opana ER Due to the**
11 **Public Health Consequences of Abuse**

12 324. On June 8, 2017, the FDA requested that Endo remove reformulated Opana ER from the
13 market “based on its concern that the benefits of the drug may no longer outweigh its risks.”²³³
14 According to the FDA’s press release, it sought removal “due to the public health consequences of
15 abuse.” The decision to seek Opana ER’s removal from sale followed a March 2017 FDA advisory
16 committee meeting, during which a group of independent experts voted 18-8 that the drug’s benefits no
17 longer outweigh the risks associated with its use. According to Dr. Janet Woodcock, director of the
18 FDA’s Center for Drug Evaluation and Research, the risks include “several serious problems,” including
19 “outbreaks of HIV and Hepatitis C from sharing the drug after it was extracted by abusers” and “a[n]
20 outbreak of serious blood disorder.” Dr. Woodcock stated that if Endo did not comply with the request,
21 the FDA would issue notice of a hearing and commence proceedings to compel its removal.

22 ²³¹ *AboutPainKnowledge.org*, PainKnowledge,
23 <http://web.archive.org/web/20120119124921/http://www.painknowledge.org/aboutpaink.aspx> (last
visited Dec. 14, 2018).

24 ²³² *Iraq War Veteran Amputee, Pain Advocate and New Author Releases Exit Wounds: A*
25 *Survival Guide to Pain Management for Returning Veterans and Their Families*, Coalition for Iraq +
26 Afghanistan Veterans, <https://web.archive.org/web/20160804131030/http://coalitionforveterans.org/2009/10/iraq-war-veteran-amputee-pain-advocate-and-new-author-releases-exit-wounds-a-survival-guide-to-pain-management-for-returning-veterans-and-their-families/> (last visited Dec. 14, 2018).

27 ²³³ Press Release, U.S. Food & Drug Administration, FDA requests removal of Opana ER
28 for risks related to abuse (June 8, 2017), <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm562401.htm>.

1 325. On July 6, 2017, Endo pulled Opana ER from the U.S. market.

2 **e. Endo Failed to Monitor and Report Suspicious Sales as**
 3 **Required**

4 326. Opana ER has been widely prescribed in San Francisco. According to data collected by
 5 ProPublica, during 2014 and 2015, California doctors' prescriptions of Opana ER to patients insured by
 6 the Medicare Part D program totaled more than \$7.2 million and \$8.4 million, respectively. San
 7 Francisco is home of two of the top 20 Medicare Part D claimants during 2015 for prescriptions of
 8 Opana ER in all of California.²³⁴

9 327. The federal CSA imposes on all "registrants" the obligation to design and operate a
 10 system to monitor suspicious orders of controlled substances and requires the registrant to notify the
 11 DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of
 12 unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21
 13 C.F.R. §1301.74(b). The CSA's requirements are also incorporated into California law. Cal. Bus. &
 14 Prof. Code §4301(o).

15 328. Endo is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant
 16 as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires
 17 manufacturers of Schedule II controlled substances to register with the DEA.

18 329. The California Code of Regulations requires all drug manufacturers and wholesalers to
 19 report "all sales of dangerous drugs subject to abuse" to the Board up to 12 times per year, pursuant to
 20 the Board's request. 16 C.C.R. §1782.

21 330. Endo failed to design and operate a system to monitor suspicious orders of controlled
 22 substances and/or failed to notify the appropriate DEA field division of suspicious orders. Endo also
 23 failed to report to the Board sales of suspicious drugs subject to abuse. Endo's failure to timely report
 24 these and other suspicious sales violated the CSA and California law.

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 28 ²³⁴ *Prescribers of OPANA ER in California*, ProPublica,
<https://projects.propublica.org/checkup/drugs/1445/states/california> (last visited Dec. 14, 2018).

5. Cephalon

331. Cephalon manufactures, markets, sells and distributes the following opioids in San Francisco and nationwide:

Actiq (fentanyl citrate)	Opioid analgesic; oral transmucosal lozenge; indicated only for the management of breakthrough pain (“BTP”) in cancer patients – pain that for a short time “breaks through” medication that otherwise effectively controls a patient’s persistent pain – in patients 16 and older with malignancies; commonly referred to as a lollipop because designed to look and perform like one; approved in 1998 with restricted distribution program.	Schedule II
Fentora (fentanyl buccal)	Rapid-release tablet for BTP in cancer patients who are already receiving and tolerant of around-the-clock opioid therapy; approved 2006.	Schedule II
Generic of OxyContin (oxycodone hydrochloride)	Opiate agonist.	Schedule II

According to public records compiled by ProPublica, in 2015 alone, Medicare Part D paid \$3.77 million for claims arising from California physicians’ Fentora prescriptions.

332. Actiq is designed to resemble a lollipop and is meant to be sucked on at the onset of intense BTP in cancer patients. It delivers fentanyl citrate, a powerful opioid agonist that is 80 times stronger than morphine,²³⁵ rapidly into a patient’s bloodstream through the oral membranes.²³⁶ Because it is absorbed through those membranes, it passes directly into circulation without having to go through the liver or stomach, thereby providing faster relief.²³⁷

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²³⁵ See John Carreyrou, *Narcotic “Lollipop” Becomes Big Seller Despite FDA Curbs*, Wall St. J. (Nov. 3, 2006), <https://www.opiates.com/media/narcotic-lollipop-becomes-big-seller-despite-fda-curbs/> (hereinafter, “Carreyrou, *Narcotic Lollipop*”).

²³⁶ Actiq would later become part of a category of opioids now known as transmucosal immediate-release fentanyl (“TIRF”) products. “Transmucosal” refers to the means through which the opioid is delivered into a patient’s bloodstream, across mucous membranes, such as inside the cheek, under the tongue or in the nose.

²³⁷ *Cephalon, Inc.*, Company-Histories.com, <http://www.company-histories.com/Cephalon-Inc-Company-History.html> (last visited Dec. 14, 2018).

1 333. In November 1998, the FDA approved Actiq for only a very narrow group of people –
2 cancer patients “with malignancies who are already receiving and who are tolerant to opioid therapy for
3 their underlying persistent cancer pain.”²³⁸

4 334. Understanding the risks of introducing such an intense opioid analgesic to the market,
5 the FDA provided approval of Actiq “**ONLY** for the management of breakthrough cancer pain in patients
6 with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying
7 persistent cancer pain.”²³⁹ Further, the FDA explicitly stated that Actiq “**must not** be used in opioid
8 non-tolerant patients,” was contraindicated for the management of acute or postoperative pain, could be
9 deadly to children and was “intended to be used only in the care of opioid-tolerant cancer patients and
10 only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II
11 opioids to treat cancer pain.”

12 335. The FDA also required that Actiq be provided only in compliance with a strict risk-
13 management program that explicitly limited the drug’s direct marketing to the approved target
14 audiences, defined as oncologists, pain specialists, their nurses and office staff.²⁴⁰

15 336. In October 2000, Cephalon acquired the worldwide product rights to Actiq and began
16 marketing and selling Actiq in the United States.

17 337. Cephalon purchased the rights to Fentora, an even faster-acting tablet formulation of
18 fentanyl, from Cima Labs, and submitted a new drug application to the FDA in August 2005. In
19 September 2006, Cephalon received FDA approval to sell this faster-acting version of Actiq; but once
20 again concerned about the power and risks inherent to fentanyl, the FDA limited Fentora’s approval to
21 the treatment of BTP in cancer patients who were already tolerant to around-the-clock opioid therapy
22 for their underlying persistent cancer pain. Cephalon began marketing and selling Fentora in
23 October 2006.

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²³⁸ 1998 FDA Label.

26 ²³⁹ NDA 20-747 Letter from Cynthia McCormick, Center for Drug Evaluation and
27 Research, to Patricia J. Richards, Anesta Corporation, http://www.accessdata.fda.gov/drugsatfda_docs/applletter/1998/20747ltr.pdf.

28 ²⁴⁰ Carreyrou, *Narcotic Lollipop*, *supra* n.235.

1 **a. Cephalon Falsely and Aggressively Marketed Cancer Drug**
 2 **Actiq to Non-Cancer Treating Physicians**

3 338. Due to the FDA’s restrictions, Actiq’s consumer base was limited, as was its potential
 4 for growing revenue. In order to increase its revenue and market share, Cephalon needed to find a
 5 broader audience and thus began marketing its lollipop to treat headaches, back pain, sports injuries and
 6 other chronic non-cancer pain, targeting non-oncology practices, including, but not limited to, pain
 7 doctors, general practitioners, migraine clinics, anesthesiologists and sports clinics. It did so in violation
 8 of applicable regulations prohibiting the marketing of medications for off-label use and in direct
 9 contravention of the FDA’s strict instructions that Actiq be prescribed only to terminal cancer patients
 10 and by oncologists and pain management doctors experienced in treating cancer pain.

11 339. According to “[d]ata gathered from a network of doctors by research firm ImpactRx
 12 between June 2005 and October 2006” (“ImpactRx Survey”), Cephalon sales representatives’ visits to
 13 non-oncologists to market Actiq increased sixfold between 2002 and 2005. Cephalon representatives
 14 would reportedly visit non-oncologists monthly, providing up to 60 or 70 coupons (each coupon was
 15 good for six free Actiq lozenges) and encouraging prescribers to try Actiq on their non-cancer
 16 patients.²⁴¹

17 340. Cephalon’s efforts paid off. In 2000, Actiq generated \$15 million in sales.²⁴² By 2002,
 18 it attributed a 92% increase in Actiq sales to “a dedicated sales force for ACTIQ” and “ongoing changes
 19 to [its] marketing approach including hiring additional sales representatives and targeting our marketing
 20 efforts to pain specialists.”²⁴³ By 2005, Actiq’s sales total had jumped to \$412 million, making it (a
 21 drug approved for only a narrow customer base) Cephalon’s second-best-selling drug. By the end of
 22 2006, Actiq’s sales had exceeded \$500 million.²⁴⁴

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25 ²⁴¹ *Id.*

26 ²⁴² *Id.*

27 ²⁴³ Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003), <https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm>.

28 ²⁴⁴ Carreyrou, *Narcotic Lollipop*, *supra* n.235.

1 341. During the first six months of 2006, only 1% of the 187,076 prescriptions for Actiq filled
 2 at retail pharmacies were prescribed by oncologists. Results of the ImpactRx Survey suggested that
 3 “more than 80 percent of patients who use[d] the drug don’t have cancer.”²⁴⁵

4 **b. Government Investigations Found Cephalon Falsely**
 5 **Marketed Actiq for Off-Label Uses**

6 342. Beginning in or about 2003, former Cephalon employees filed four whistleblower
 7 lawsuits claiming the company had wrongfully marketed Actiq for unapproved, off-label uses. On
 8 September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office
 9 of the Inspector General of HHS and agreed to pay \$425 million in civil and criminal penalties for its
 10 off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press
 11 release, Cephalon trained sales representatives to disregard restrictions of the FDA-approved label,
 12 employed sales representatives and healthcare professionals to speak to physicians about off-label uses
 13 of the three drugs and funded CME to promote off-label uses. Specifically, the DOJ stated:

14 From 2001 through at least 2006, *Cephalon was allegedly promoting [Actiq] for non-*
 15 *cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries,*
 16 *and in anticipation of changing wound dressings or radiation therapy. Cephalon also*
 17 *promoted Actiq for use in patients who were not yet opioid-tolerant, and for whom it*
 18 *could have life-threatening results.*²⁴⁶

19 343. Then-acting U.S. Attorney Laurie Magid commented on the dangers of Cephalon’s
 20 unlawful practices:

21 *“This company subverted the very process put in place to protect the public from harm,*
 22 *and put patients’ health at risk for nothing more than boosting its bottom line. People*
 23 *have an absolute right to their doctors’ best medical judgment. They need to know the*
 24 *recommendations a doctor makes are not influenced by sales tactics designed to convince*
 25 *the doctor that the drug being prescribed is safe for uses beyond what the FDA has*
 26 *approved.”*²⁴⁷

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²⁴⁵ *Id.*

²⁴⁶ Press Release, U.S. Department of Justice, Pharmaceutical Company Cephalon To Pay \$425 Million For Off-Label Drug Marketing (Sept. 29, 2008), <https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonrelease.pdf>.

²⁴⁷ *Id.*

1 344. Upon information and belief, documents uncovered in the government’s investigations
 2 confirm that Cephalon directly targeted non-oncology practices and pushed its sales representatives to
 3 market Actiq for off-label use. For instance, the government’s investigations confirmed:

- 4 • Cephalon instructed its sales representatives to ask non-cancer doctors whether
 5 they have the potential to treat cancer pain. Even if the doctor answered “no,” a
 6 decision tree provided by Cephalon instructed the sales representatives to give
 7 these physicians free Actiq coupons.
- 8 • Cephalon targeted neurologists in order to encourage them to prescribe Actiq to
 9 patients with migraine headaches.
- 10 • Cephalon sales representatives utilized the assistance of outside pain management
 11 specialists when visiting non-cancer physicians to pitch Actiq. The pain
 12 management specialist would falsely inform the physician that Actiq does not
 13 cause patients to experience a “high” and carries a low risk of diversion toward
 14 recreational use.
- 15 • Cephalon set sales quotas for its sales and marketing representatives that could
 16 not possibly have been met solely by promoting Actiq for its FDA-approved
 17 indication.
- 18 • Cephalon promoted the use of higher doses of Actiq than patients required by
 19 encouraging prescriptions of the drug to include larger-than-necessary numbers
 20 of lozenges with unnecessarily high doses of fentanyl.
- 21 • Cephalon promoted Actiq for off-label use by funding and controlling CME
 22 seminars that promoted and misrepresented the efficacy of the drug for off-label
 23 uses such as treating migraine headaches and for patients not already opioid-
 24 tolerant.²⁴⁸

25 345. Still, the letters, the FDA’s safety alert, DOJ and state investigations and the massive
 26 settlement seemed to have had little impact on Cephalon as it continued its deceptive marketing strategy
 27 for both Actiq and Fentora.

28 **c. Cephalon Falsely and Aggressively Marketed Cancer Drug
 Fentora to Non-Cancer Treating Physicians**

346. From the time it first introduced Fentora to the market in October 2006, Cephalon
 targeted non-cancer doctors, falsely represented Fentora as a safe, effective off-label treatment for non-
 cancer pain and continued its disinformation campaign about the safety and non-addictiveness of

²⁴⁸ John Carreyrou, *Cephalon Used Improper Tactics to Sell Drug, Probe Finds*, Wall St. J. Nov. 21, 2006, at B1 (hereinafter, “Carreyrou, *Cephalon Used Improper Tactics*”).

1 Fentora specifically and opioids generally. In fact, Cephalon targeted the same pain specialists and non-
2 oncologists that it had targeted with its off-label marketing of Actiq, simply substituting Fentora.

3 347. During an investor earnings call shortly after Fentora's launch, Cephalon's CEO
4 described the "opportunity" presented by the use of Fentora for non-cancer pain:

5 *The other opportunity of course is the prospect for FENTORA outside of*
6 *cancer pain, in indications such as breakthrough lower back pain and breakthrough*
7 *neuropathic pain.*

8 * * *

9 Of all the patients taking chronic opioids, 32% of them take that medication to treat back
10 pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only
11 12% are taking them to treat cancer pain, 12%.

12 We know from our own studies that breakthrough pain episodes experienced by
13 these non-cancer sufferers respond very well to FENTORA. And for all these reasons,
14 we are tremendously excited about the significant impact FENTORA can have on patient
15 health and well being and the exciting growth potential that it has for Cephalon.

16 In summary, we have had a strong launch of FENTORA and continue to grow
17 the product aggressively. Today, that growth is coming from the physicians and patient
18 types that we have identified through our efforts in the field over the last seven years. In
19 the future, with new and broader indications and a much bigger field force presence, the
20 opportunity that FENTORA represents is enormous.²⁴⁹

21 **d. The FDA Warned Cephalon Regarding its False and Off-**
22 **Label Marketing of Fentora**

23 348. On September 27, 2007, the FDA issued a public health advisory to address numerous
24 reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora,
25 and warned of death or life-threatening side effects. The FDA warned: "Fentora should not be used to
26 treat any type of short-term pain."²⁵⁰

27 349. Nevertheless, in 2008, Cephalon pushed forward to expand the target base for Fentora
28 and filed a supplemental drug application requesting FDA approval of Fentora for the treatment of non-
cancer BTP. In the application and supporting presentations to the FDA, Cephalon admitted both that
it knew the drug was heavily prescribed for off-label use and that the drug's safety for such use had

26 ²⁴⁹ Seeking Alpha, Transcript of Q1 2007 Cephalon, Inc. Earnings Conference Call (May
27 1, 2007), <http://seekingalpha.com/article/34163-cephalon-q1-2007-earnings-call-transcript>.

28 ²⁵⁰ Press Release, U.S. Food & Drug Administration, Public Health Advisory: Important
Information for the Safe Use of Fentora (fentanyl buccal tablets) (Sept. 26, 2007).

1 never been clinically evaluated.²⁵¹ An FDA advisory committee lamented that Fentora’s existing risk
2 management program was ineffective and stated that Cephalon would have to institute a risk evaluation
3 and mitigation strategy for the drug before the FDA would consider broader label indications. In
4 response, Cephalon revised Fentora’s label and medication guide to add strengthened warnings.

5 350. But in 2009, the FDA once again informed Cephalon that the risk management program
6 was not sufficient to ensure the safe use of Fentora for already approved indications.

7 351. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of
8 Fentora (“Warning Letter”). The Warning Letter described a Fentora Internet advertisement as
9 misleading because it purported to broaden “the indication for Fentora by implying that any patient with
10 cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the
11 case.” Rather, Fentora was only indicated for those who were already opioid tolerant. It further
12 criticized Cephalon’s other direct Fentora advertisements because they did not disclose the risks
13 associated with the drug.

14 352. Flagrantly disregarding the FDA’s refusal to approve Fentora for non-cancer BTP and its
15 warning against marketing the drug for the same, Cephalon continued to use the same sales tactics to
16 push Fentora as it did with Actiq.

17 353. For example, on January 13, 2012, Cephalon published an insert in *Pharmacy Times*
18 titled, “An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal
19 Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate).” Despite the repeated warnings of the
20 dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first
21 sentence of the insert stated: “It is well recognized that the judicious use of opioids can facilitate effective
22 and safe management of chronic pain.”²⁵²

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25 ²⁵¹ *FENTORA (fentanyl buccal tablet) CII, Joint Meeting of Anesthetic and Life Support*
26 *Drugs and Drug Safety and Risk Management Advisory Committee, U.S. Food & Drug Administration*
(May 6, 2008).

27 ²⁵² *An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA*
28 *(Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate), Pharmacy Times* (Jan.
13, 2012), <http://www.pharmacytimes.com/publications/issue/2012/january2012/r514-jan-12-rem>s.

e. **Cephalon Funded False Publications and Presentations**

354. In addition to its direct marketing, Cephalon indirectly marketed through third parties to change the way doctors viewed and prescribed opioids – disseminating the unproven and deceptive messages that opioids were safe for the treatment of chronic, long-term pain, that they were non-addictive and that they were woefully under-prescribed to the detriment of patients who were needlessly suffering. It did so by sponsoring pro-opioid front groups, misleading prescription guidelines, articles and CME programs and paying physicians thousands of dollars every year to publicly opine that opioids were safe, effective and non-addictive for a wide variety of uses.

355. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC (“Medscape”) and which disseminated false and misleading information to physicians in San Francisco and across the country.

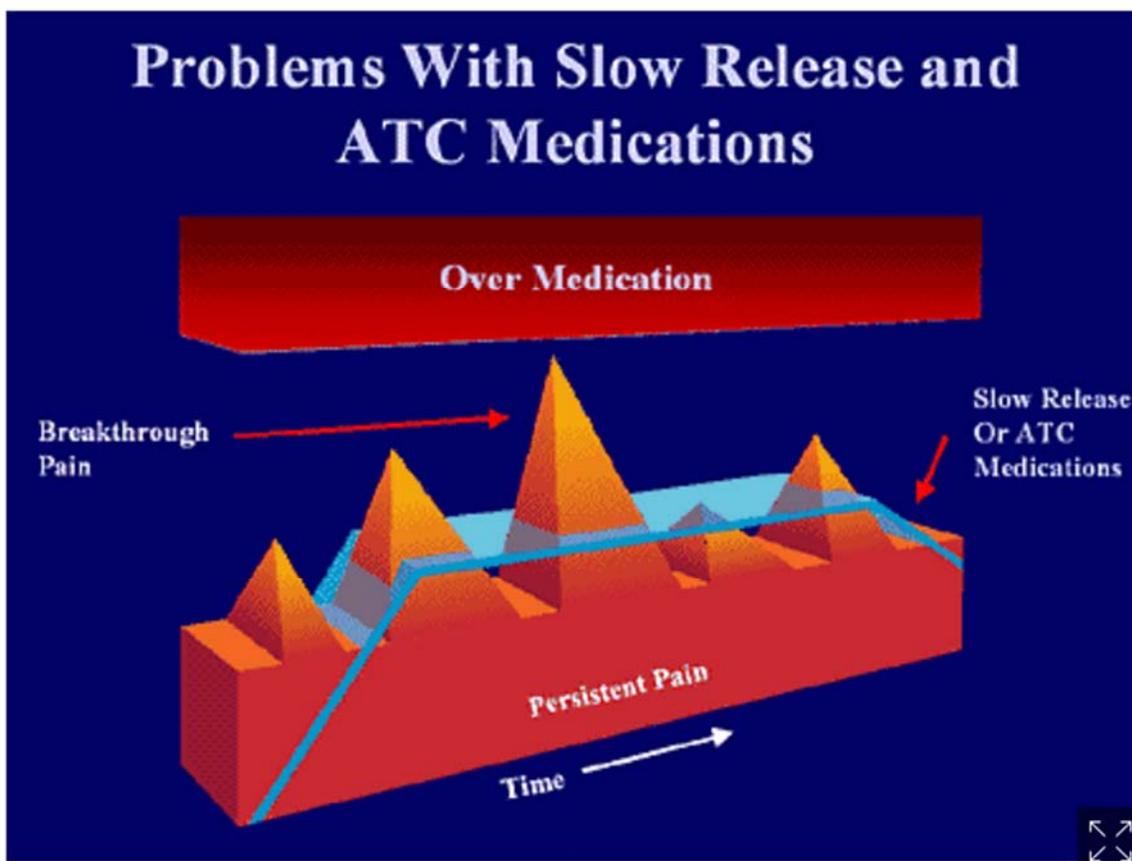
356. For example, a 2003 Cephalon-sponsored CME presentation titled, “Pharmacologic Management of Breakthrough or Incident Pain,” posted on Medscape in February 2003, stated:

*[C]hronic pain is often undertreated, particularly in the noncancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.*²⁵³

357. Another Cephalon-sponsored CME presentation titled, “Breakthrough Pain: Treatment Rationale with Opioids” was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who “previously operated back, complex regional pain syndromes, the neuropathies, and interstitial cystitis.” (One slide from that CME presentation is set forth below). The presentation describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using “targeted pharmacotherapeutics to affect multiple points

²⁵³ Michael J. Brennan et al., *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape, <https://www.medscape.org/viewarticle/449803> (last visited Dec. 14, 2018).

1 in the pain-signaling pathway.”²⁵⁴ The doctor lists fentanyl as one of the most effective opioids available
 2 for treating BTP, describing its use as an expected and normal part of the pain management process.
 3 Nowhere in the CME is cancer or cancer-related pain even mentioned.



18

19 358. Dr. Stephen H. Landy (“Landy”) authored a 2004 CME manuscript available on
 20 Medscape titled, “Oral Transmucosal Fentanyl Citrate for the Treatment of Migraine Headache Pain In
 21 Outpatients: A Case Series.” The manuscript preparation was supported by Cephalon. Landy describes
 22 the findings of a study of fentanyl citrate to treat migraine headache pain and concluded that “OTFC
 23 rapidly and significantly relieved acute, refractory migraine pain in outpatients . . . and was associated
 24 with high patient satisfaction ratings.”²⁵⁵ Based on an analysis of publicly available data, Cephalon paid

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26 ²⁵⁴ Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, <https://www.medscape.org/viewarticle/461612> (last visited Dec. 14, 2018).

27 ²⁵⁵ Stephen H. Landy, *Oral Transmucosal Fentanyl Citrate for the Treatment of Migraine*
 28 *Headache Pain In Outpatients: A Case Series*, 44(8) *Headache* (2004), https://www.medscape.com/viewarticle/488337_2 (last visited Dec. 14, 2018).

1 Landy approximately \$190,000 in 2009-2010 alone, and in 2015-2016, Cephalon paid Landy another
2 \$75,000.

3 359. In 2006, Cephalon sponsored a review of scientific literature to create additional
4 fentanyl-specific dosing guidelines titled, *Evidence-Based Oral Transmucosal Fentanyl Citrate*
5 *(OTFC®) Dosing Guidelines*.²⁵⁶ The article purports to review the evidence for dosing and efficacy of
6 oral transmucosal fentanyl citrate in the management of pain and produce dosing guidelines in both
7 cancer and non-cancer patients. In pertinent part, it states:

8 Oral transmucosal fentanyl citrate has a proven benefit in treating cancer-
9 associated breakthrough pain in opioid-tolerant patients with cancer, which is the Food
10 and Drug Administration (FDA)-approved indication for Actiq. ***Pain medicine***
11 ***physicians have also used OTFC successfully to provide rapid pain relief in moderate***
12 ***to severe noncancer pain in both opioid-tolerant and opioid-nontolerant patients.***²⁵⁷

13 360. Later in the article, the authors attempt to assuage doctors' concerns regarding possible
14 overdose and respiratory distress in non-cancer patients by arguing "[t]here is no evidence that opioid
15 ***safety and efficacy differs in opioid-tolerant patients with chronic noncancer pain.***" Regarding the
16 use of fentanyl to treat non-opioid-tolerant patients, the article's authors stated:

17 Alternatively, ***OTFC might also be used cautiously and safely for acute pain***
18 ***experienced by patients who are not opioid tolerant. Parenteral opioids are routinely***
19 ***used for acute pain in patients who are not opioid tolerant.*** Examples include episodic
20 pain (*i.e.*, refractory migraine pain, recurrent renal calculi, etc.) and acute pain that
21 follows surgery, trauma, or painful procedures (burn dressing change, bone marrow
22 aspiration, lumbar puncture). Assuming that clinical experience with IV morphine in
23 patients who are not opioid tolerant can be extrapolated, OTFC should be safe and
24 efficacious in such settings as well.²⁵⁸

25 361. Through its sponsorship of FSMB (*see supra* ¶¶78-90), Cephalon continued to encourage
26 the prescribing of opioid medication to "reverse . . . and improve" patient function, attributing patients'
27 displays of traditional drug-seeking behaviors as merely "pseudoaddiction."

28 362. Cephalon also disseminated its false messaging through speakers' bureaus and
publications. For example, at an AAPM annual meeting held February 22 through 25, 2006, Cephalon

26 ²⁵⁶ Gerald M. Aronoff et al., *Evidence-Based Oral Transmucosal Fentanyl Citrate (OTFC)*
27 *Dosing Guidelines*, 6(4) *Pain Med.* 305-14 (Aug. 2005).

27 ²⁵⁷ *Id.*

28 ²⁵⁸ *Id.*

1 sponsored a presentation by Webster and others titled, “Open-label study of fentanyl effervescent buccal
2 tablets in patients with chronic pain and breakthrough pain: Interim safety results.” The presentation’s
3 agenda description states: “Most patients with chronic pain experience episodes of breakthrough pain
4 (BTP), yet no currently available pharmacologic agent is ideal for its treatment.” The presentation
5 purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic
6 pain setting and promises to show the “[i]nterim results of this study suggest that FEFT is safe and well-
7 tolerated in patients with chronic pain and BTP.”²⁵⁹

8 363. Cephalon sponsored another CME presentation written by Webster and M. Beth Dove
9 titled, “Optimizing Opioid Treatment for Breakthrough Pain” and offered on Medscape from September
10 28, 2007 through December 15, 2008. The presentation stated that non-opioid analgesics and
11 combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at
12 treating BTP than pure opioid analgesics because of dose limitations on the non-opioid component.²⁶⁰

13 364. Fine authored a Cephalon-sponsored CME presentation titled, “Opioid-Based
14 Management of Persistent and Breakthrough Pain,” with Drs. Christine A. Miaskowski and Michael J.
15 Brennan. Cephalon paid to have this CME presentation published as a “Special Report” supplement of
16 the journal *Pain Medicine News* in 2009.²⁶¹ The CME presentation targeted a wide variety of non-
17 oncologist healthcare providers who treat patients with chronic pain with the objective of educating
18 “health care professionals about a semi-structured approach to the opioid-based management of
19 persistent and breakthrough pain,” including the use of fentanyl. The CME presentation purported to
20 analyze the “combination of evidence- and case-based discussions” and ultimately concluded:

21 Chronic pain is a debilitating biopsychosocial condition prevalent in both cancer
22 and noncancer pain populations. . . . Opioids have an established role in pain related to
23 cancer and other advanced medical illnesses, as well as an increasing contribution to the
24 long-term treatment of carefully selected and monitored patients with certain [chronic
noncancer pain] conditions. ***All individuals with chronic, moderate to severe pain***

25 ²⁵⁹ *Id.*

26 ²⁶⁰ Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, Medscape,
https://www.medscape.org/viewarticle/563417_6 (last visited Dec. 14, 2018).

27 ²⁶¹ Perry G. Fine et al., *Opioid-Based Management of Persistent and Breakthrough Pain*,
28 Special Report (2009), [https://www.yumpu.com/en/document/view/11409251/opioid-based-
management-of-persistent-and-breakthrough-pain/9](https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain/9).

1 *associated with functional impairment should be considered for a trial or opioid*
 2 *therapy, although not all of them will be selected.*²⁶²

3 365. Along with Purdue, Cephalon sponsored the APF's guide (*see supra* ¶¶97-108), which
 4 warned against the purported *under*-prescribing of opioids, taught that addiction is *rare* and suggested
 5 that opioids have "*no ceiling dose*" and are therefore the most appropriate treatment for severe pain.

6 366. A summary of the February 12-16, 2008 AAPM annual meeting reinforced the message,
 7 promoted both by the AAPM and the APS, that "the undertreatment of pain is unjustified." It continued:

8 *Pain management is a fundamental human right* in all patients not only with acute
 9 postoperative pain but also *in patients suffering from chronic pain*. Treating the
 10 underlying cause of pain does not usually treat all of the ongoing pain. Minimal
 11 pathology with maximum dysfunction remains the enigma of chronic pain. Chronic pain
 12 is only recently being explored as a complex condition that requires individual treatment
 13 and a multidisciplinary approach. It is considered to be a disease entity.²⁶³

14 367. Cephalon was one of several opioid manufacturers who collectively paid 14 of the 21
 15 panel members who drafted the 2009 APS-AAPM opioid treatment guidelines.²⁶⁴

16 368. In the March 2007 article titled, "Impact of Breakthrough Pain on Quality of Life in
 17 Patients with Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment with Oral
 18 Transmucosal Fentanyl Citrate,"²⁶⁵ published in the nationally circulated journal *Pain Medicine*,
 19 physicians paid by Cephalon (including Webster) described the results of a Cephalon-sponsored study
 20 seeking to expand the definition of BTP to the chronic, non-cancer setting. The authors stated that the
 21 "OTFC has been shown to relieve BTP more rapidly than conventional oral, normal-release, or 'short
 22 acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the
 23 effect of BTP on the [quality of life] of noncancer pain patients."²⁶⁶ The number-one-diagnosed cause
 24 of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%)
 25 and head pain (7%). The article cited Portenoy and recommended fentanyl for non-cancer BTP patients:

26 ²⁶² *Id.*

27 ²⁶³ Mohamed A. Elkersh & Zahid H. Bajwa, *Highlights From the American Academy of*
 28 *Pain Medicine 24th Annual Meeting*, 2(1) *Advances in Pain Management* 50-52 (2008).

²⁶⁴ *See* Chou, *Clinical Guidelines*, *supra* n.110.

²⁶⁵ Donald R. Taylor et al., *Impact of Breakthrough Pain on Quality of Life in Patients*
With Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal
Fentanyl Citrate (OTFC, ACTIQ), 8(3) *Pain Med.* 281-88 (Mar. 2007).

²⁶⁶ *Id.*

1 In summary, BTP appears to be a clinically important condition in patients with
 2 ***chronic noncancer pain*** and is associated with an adverse impact on QoL. This
 3 qualitative study on the negative impact of BTP ***and the potential benefits of BTP-***
 4 ***specific therapy*** suggests several domains that may be helpful in developing BTP-
 5 specific, QoL assessment tools.²⁶⁷

6 369. Cephalon also sponsored, through an educational grant, the regularly published journal
 7 *Advances in Pain Management*. A single 2008 issue of the journal contained numerous articles from
 8 Portenoy, Dr. Steven Passik (“Passik”), Dr. Kenneth L. Kirsh (“Kirsh”) and Webster, all advancing the
 9 safety and efficacy of opioids. In an article titled, “Screening and Stratification Methods to Minimize
 10 Opioid Abuse in Cancer Patients,” Webster expressed disdain for the prior 20 years of opioid phobia.

11 370. In another article from the same issue, “Appropriate Prescribing of Opioids and
 12 Associated Risk Minimization,” Passik and Kirsh stated: “[c]hronic pain, currently experienced by
 13 approximately 75 million Americans, is becoming one of the biggest public health problems in the US.”
 14 They assert that addiction is rare, that “[m]ost pain specialists have prescribed opioids for long periods
 15 of time with success demonstrated by an improvement in function” and that then-recent work had shown
 16 “that opioids do have efficacy for subsets of patients who can remain on them long term and have very
 17 little risk of addiction.”²⁶⁸

18 371. In November 2010, Fine and others published an article presenting the results of another
 19 Cephalon-sponsored study titled, “Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the
 20 Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study.”²⁶⁹
 21 In that article, Fine explained that the 18-month “open-label” study “assessed the safety and tolerability
 22 of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients
 23 receiving around-the-clock . . . opioids for noncancer pain.” The article acknowledged that: (a) “[t]here
 24 has been a steady increase in the use of opioids for the management of chronic noncancer pain over the
 25 past two decades”; (b) the “widespread acceptance” had led to the publishing of practice guidelines “to

25 ²⁶⁷ *Id.*

26 ²⁶⁸ Steven D. Passik & Kenneth L. Kirsh, *Appropriate Prescribing of Opioids and
 Associated Risk Minimization*, 2(1) *Advances in Pain Management* 9-16 (2008).

27 ²⁶⁹ Perry G. Fine et al., *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for
 28 the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month
 Study*, 40(5) *J. Pain & Symptom Management* 747-60 (Nov. 2010).

1 provide evidence- and consensus-based recommendations for the optimal use of opioids in the
 2 management of chronic pain”; and (c) those guidelines lacked “data assessing the long-term benefits
 3 and harms of opioid therapy for chronic pain.”²⁷⁰

4 372. The article concluded: “[T]he safety and tolerability profile of FBT in this study was
 5 generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable,
 6 manageable, and tolerable.” That article concluded that the number of abuse-related events was
 7 “small.”²⁷¹

8 373. From 2000 forward, Cephalon has paid doctors nationwide millions of dollars for
 9 programs relating to its opioids, many of whom were not oncologists and did not treat cancer pain.
 10 These doctors included Portenoy, Webster, Fine, Passik, Kirsh, Landy and others.

11 374. Cephalon’s payments to doctors have resulted in studies that support its sales but, on
 12 closer examination, are biased or irreparably flawed. For instance, and upon information and belief, the
 13 governmental whistleblower investigation into Actiq revealed that two studies touted by Cephalon had
 14 tested fewer than 28 patients and had no control group whatsoever.²⁷² A 2012 article evaluating the
 15 then-current status of transmucosal fentanyl tablet formulations for the treatment of BTP in cancer
 16 patients noted that clinical trials to date used varying criteria, that “the approaches taken . . . [did] not
 17 uniformly reflect clinical practice” and that “the studies ha[d] been sponsored by the manufacturer and
 18 so ha[d] potential for bias.”²⁷³

19 375. Teva, which acquired Cephalon, has repeatedly refused to produce information requested
 20 as part of a Senate investigation into opioid manufacturers and distributors. Senator McCaskill issued
 21 requests on July 26, 2017 and September 28, 2017. In a letter to Teva sent September 28, 2017, Senator
 22 McCaskill explained that “the company’s decision to obstruct basic oversight on the opioid epidemic
 23 should deeply concern shareholders.” On March 6, 2018, Senator McCaskill issued a press release
 24

25 ²⁷⁰ *Id.*

26 ²⁷¹ *Id.*

27 ²⁷² Carreyrou, *Cephalon Used Improper Tactics*, *supra* n.248.

28 ²⁷³ Eric Prommer & Brandy Fleck, *Fentanyl transmucosal tablets: current status in the management of cancer-related breakthrough pain*, 2012(6) Patient Preference and Adherence 465-75 (June 25, 2012).

1 castigating Teva for its continued refusal to comply with her requests: “Teva’s refusal to cooperate with
 2 Congressional requests strongly suggests they have something to hide.”²⁷⁴ As of July 12, 2018, the date
 3 Senator McCaskill’s third report titled, *Fueling an Epidemic: A Flood of 1.6 Billion Doses of Opioids*
 4 *into Missouri and the Need for Stronger DEA Enforcement*, was published, Teva remained
 5 uncooperative.²⁷⁵

6 **f. Cephalon Failed to Monitor and Report Suspicious Sales as**
 7 **Required**

8 376. The federal CSA imposes on all “registrants” the obligation to design and operate a
 9 system to monitor suspicious orders of controlled substances and requires the registrant to notify the
 10 DEA field division office in its area of any suspicious orders. “Suspicious orders include orders of
 11 unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21
 12 C.F.R. §1301.74(b). The CSA’s requirements are also incorporated into California law. Cal. Bus. &
 13 Prof. Code §4301(o).

14 377. Cephalon is a “registrant” under the federal CSA. 21 C.F.R. §1300.02(b) defines a
 15 registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn,
 16 requires manufacturers of Schedule II controlled substances to register with the DEA.

17 378. The California Code of Regulations requires all drug manufacturers and wholesalers to
 18 report “all sales of dangerous drugs subject to abuse” to the Board up to 12 times per year, pursuant to
 19 the Board’s request. 16 C.C.R. §1782.

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 23 ²⁷⁴ Press Release, U.S. Senate Committee on Homeland Security & Governmental Affairs,
 24 McCaskill: Teva Is Stonewalling a Senate Investigation (Mar. 6, 2018),
[https://www.hsgac.senate.gov/media/minority-media/mccaskill-teva-is-stonewalling-a-senate-](https://www.hsgac.senate.gov/media/minority-media/mccaskill-teva-is-stonewalling-a-senate-investigation)
[investigation.](https://www.hsgac.senate.gov/media/minority-media/mccaskill-teva-is-stonewalling-a-senate-investigation)

25 ²⁷⁵ *Fueling an Epidemic, Report Three: A Flood of 1.6 Billion Doses of Opioids into*
 26 *Missouri and the Need for Stronger DEA Enforcement*, U.S. Senate Homeland Security &
 27 Governmental Affairs Committee, Ranking Member’s Office at 1 (July 12, 2018),
[https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-](https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-A%20Flood%20of%201.6%20Billion%20Doses%20of%20Opioids%20into%20Missouri%20and%20the%20Need%20for%20Stronger%20DEA%20Enforcement.pdf)
 28 [A%20Flood%20of%201.6%20Billion%20Doses%20of%20Opioids%20into%20Missouri%20and%20the%20Need%20for%20Stronger%20DEA%20Enforcement.pdf](https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-A%20Flood%20of%201.6%20Billion%20Doses%20of%20Opioids%20into%20Missouri%20and%20the%20Need%20for%20Stronger%20DEA%20Enforcement.pdf) (hereinafter, “*July 2018 McCaskill Report*”)

1 379. Cephalon failed to design and operate a system to monitor suspicious orders of controlled
 2 substances and/or failed to notify the appropriate DEA field division of suspicious orders. Cephalon's
 3 failure to timely report these and other suspicious sales violated the CSA and California law.

4 **6. Insys**

5 380. Insys manufactures, markets, sells and distributes the following pharmaceutical drug in
 6 San Francisco and nationwide:

Subsys (fentanyl)	Fentanyl sublingual spray; semi-synthetic opioid agonist, approved in 2012.	Schedule II
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7
 8
 9 381. Subsys is indicated “for the management of breakthrough pain in cancer patients 18 years
 10 of age and older who are already receiving and are tolerant to opioid therapy for their underlying
 11 persistent cancer pain.”²⁷⁶ The indication also specifies that “SUBSYS is intended to be used only in
 12 the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and
 13 skilled in the use of Schedule II opioids to treat cancer pain.” In addition, the indication provides that
 14 “[p]atients must remain on around-the-clock opioids when taking SUBSYS.” Subsys is contraindicated
 15 for, among other ailments, the “[m]anagement of acute or postoperative pain including
 16 headache/migraine and dental pain.” It is available in 100 mcg, 200 mcg, 400 mcg, 600 mcg and
 17 800 mcg dosage strengths.

18 382. Insys' revenue is derived almost entirely from Subsys. According to its Form 10-K for
 19 2015, Insys reported revenues of \$331 million. Of that total, \$329.5 million was derived from sales of
 20 Subsys. According to data collected by ProPublica, during the single year of 2014, California doctors'
 21 prescriptions of Subsys to patients insured by the Medicare Part D program totaled more than \$14.4
 22 million, and in 2015, Subsys Medicare Part D prescriptions totaled more than \$22 million. The majority
 23 of Insys' sales of Subsys are through wholesalers including AmerisourceBergen, McKesson and
 24 Cardinal Health. In 2015, those wholesalers respectively comprised 20%, 17% and 14% of Insys' total
 25 gross sales of Subsys, respectively.

26
 27 ²⁷⁶ The indication provides that “[p]atients considered opioid tolerant are those who are
 28 taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg
 of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral
 hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer.”

1 383. According to Dr. Andrew Kolodny, executive director of Physicians for Responsible
 2 Opioid Prescribing and chief medical officer of the Phoenix House Foundation, fentanyl products are
 3 “the most potent and dangerous opioids on the market.”²⁷⁷

4 384. The dangers associated with Subsys are reflected by its extremely limited and specific
 5 indication, as it is approved solely for BTP in cancer patients already receiving opioids for persistent
 6 cancer-related pain.

7 385. Despite Subsys’ limited indication and the potent danger associated with fentanyl, Insys
 8 falsely and misleadingly marketed Subsys to doctors as an effective treatment for back pain, neck pain
 9 and other off-label pain conditions.²⁷⁸ Moreover, as of June 2012, Insys defined BTP in cancer patients
 10 to include mild pain: a “flare of *mild-to*-severe pain in patients with otherwise stable persistent pain,”
 11 based on a misleading citation to a paper written by Portenoy.²⁷⁹ Insys trained and instructed its sales
 12 representatives to use the false definition of breakthrough pain and specifically to use a core visual aid,
 13 including the improper definition, whenever they detailed Subsys to a healthcare provider or provider’s
 14 office.

15 386. According to a 2014 article in *The New York Times*, only 1% of prescriptions for Subsys
 16 were written by oncologists. Approximately half the prescriptions were written by pain specialists, with
 17 others written by other specialists including dentists and podiatrists.²⁸⁰

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21 ²⁷⁷ Dina Gusovsky, *The pain killer: A drug company putting profits above patients*, CNBC
 22 (Nov. 5, 2015, 10:13 AM), <http://www.cnbc.com/2015/11/04/the-deadly-drug-appeal-of-insys-pharmaceuticals.html>.

23 ²⁷⁸ *In the Matter of Insys Therapeutics, Inc.*, Notice of Unlawful Trade Practices and
 Proposed Resolution (July 10, 2015), [https://www.documentcloud.org/documents/2195731-](https://www.documentcloud.org/documents/2195731-insysdoj.html)
 24 [insysdoj.html](https://www.documentcloud.org/documents/2195731-insysdoj.html).

25 ²⁷⁹ Portenoy’s paper, “Breakthrough pain: definition, prevalence and characteristics,”
 which was featured in the 1990 issue of *Pain*, actually defined breakthrough pain as “a transitory
 26 . . . on a baseline pain of moderate intensity or less.” Russell K. Portenoy & Neil A. Hagen,
Breakthrough pain: Definition, prevalence and characteristics, 41(3) *Pain* 273-81 (July 1990).

27 ²⁸⁰ Katie Thomas, *Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller*, N.Y.
 28 *Times* (May 13, 2014), [https://www.nytimes.com/2014/05/14/business/doubts-raised-about-off-label-](https://www.nytimes.com/2014/05/14/business/doubts-raised-about-off-label-use-of-subsys-a-strong-painkiller.html)
[use-of-subsys-a-strong-painkiller.html](https://www.nytimes.com/2014/05/14/business/doubts-raised-about-off-label-use-of-subsys-a-strong-painkiller.html).

1 **a. The Indictment of Insys Executives and the Arrest of Its**
 2 **Founder**

3 387. On December 8, 2016, several former Insys executives were arrested and indicted for
 4 conspiring to bribe practitioners in numerous states, many of whom operated pain clinics, in order to get
 5 them to prescribe Subsys. In exchange for bribes and kickbacks, the practitioners wrote large numbers
 6 of prescriptions for patients, most of whom were not diagnosed with cancer.²⁸¹

7 388. The indictment alleged that the former executives conspired to mislead and defraud
 8 health insurance providers, who were reluctant to approve payment for Subsys when it was prescribed
 9 for patients without cancer. In response, the former executives established a “reimbursement unit” at
 10 Insys, which was dedicated to assisting physicians by obtaining prior authorization for prescribing
 11 Subsys directly from insurers and PBMs. Insys’ reimbursement unit employees were told to inform
 12 agents of insurers and PBMs that they were calling “from” or that they were “with” the doctor’s office,
 13 or that they were calling “on behalf of” the doctor.

14 389. The executive defendants in the indictment include John Kapoor (“Kapoor”), Insys’
 15 former CEO and president, as well as the company’s former vice president of sales, former national
 16 director of sales, former vice president of managed markets and several former regional sales directors.
 17 On October 26, 2017, Kapoor – the billionaire founder, CEO and chairman of Insys, who owns a 60%
 18 stake in the company – was also charged with fraud and racketeering and was accused of offering bribes
 19 to doctors to write large numbers of prescriptions for Subsys. Most of the patients who received the
 20 medication did not have cancer.²⁸²

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24 ²⁸¹ Press Release, U.S. Attorney’s Office for the District of Massachusetts, Pharmaceutical
 25 Executives Charged in Racketeering Scheme (Dec. 8, 2016), [https://www.justice.gov/usao-
 26 ma/pr/pharmaceutical-executives-charged-racketeering-scheme](https://www.justice.gov/usao-ma/pr/pharmaceutical-executives-charged-racketeering-scheme) (hereinafter, “Insys Indictment Press
 Release”); *United States v. Babich, et al.*, No. 1:16-cr-10343-ADB, ECF. No. 1 (D. Mass. Dec. 6,
 2016), <https://www.justice.gov/usao-ma/press-release/file/916681/download> (hereinafter, “*Insys*
 Indictment”).

27 ²⁸² Michela Tindera, Opioid Billionaire Arrested On Racketeering Charges, *Forbes* (Oct.
 28 26, 2017), [https://www.forbes.com/sites/michelatindera/2017/10/26/opioid-billionaire-arrested-on-
 racketeering-charges/#1af3f9076a00](https://www.forbes.com/sites/michelatindera/2017/10/26/opioid-billionaire-arrested-on-racketeering-charges/#1af3f9076a00).

1 390. The charges against all seven executives include alleged violations of the federal Anti-
2 Kickback Law, the Racketeer Influenced and Corrupt Organizations (“RICO”) statute and conspiracy
3 to commit wire and mail fraud, as well as allegations of bribery and defrauding insurers.

4 391. If found guilty, the defendants face possible sentences of up to 20 years for conspiracy
5 to commit RICO and conspiracy to commit mail and wire fraud, as well as a fine of \$250,000 or twice
6 the amount of the pecuniary gain or loss. For the charge of conspiracy to violate the Anti-Kickback
7 Law, the defendants face a sentence of up to five years in prison and a \$25,000 fine.

8 392. The indictment details a coordinated, centralized scheme by Insys to illegally drive
9 profits. The company defrauded insurers from a call center at corporate headquarters where Insys
10 employees, acting at the direction of Insys’ former CEO and vice president of managed markets,
11 disguised their identity and the location of their employer and lied about patient diagnoses, the type of
12 pain being treated and the patient’s course of treatment with other medication.

13 393. Harold H. Shaw (“Shaw”), special agent in charge of the FBI Boston field division, said
14 in a statement, “[a]s alleged, these executives created a corporate culture at Insys that utilized deception
15 and bribery as an acceptable business practice, deceiving patients, and conspiring with doctors and
16 insurers.”²⁸³

17 **b. Insys Targeted Non-Cancer Treating Physicians and Funded**
18 **False Publications and Presentations**

19 394. As set forth in the above-referenced indictment, Insys targeted and bribed practitioners
20 in a number of ways. Insys bribed Subsys prescribers through strategic hires, employing sales
21 representatives and other employees at practitioners’ behest and with the expectation that such hires
22 would provide inroads with key practitioners. Further, the indictment alleges that Insys bribed
23 practitioners through a sham speakers’ bureau that was purportedly intended to increase brand awareness
24 using peer-to-peer educational lunches and dinners.

25 395. Specifically, in June 2012, former executives began using in-person meetings, telephone
26 calls and texts to inform Insys sales representatives that the key to sales was using the speakers’ bureau
27

28 ²⁸³ *Id.*

1 to pay practitioners to prescribe Subsys. As one of the company’s vice presidents for sales texted one
 2 of his sales representatives about potential physicians for the speakers’ bureau: “[t]hey do not need to
 3 be good speakers, they need to write a lot of [Subsys prescriptions].” The former Insys executives
 4 actively recruited physicians known to have questionable prescribing habits for these speakers’
 5 bureaus.²⁸⁴

6 396. Speakers’ bureaus were often just social gatherings at high-priced restaurants involving
 7 neither education nor presentations. Frequently, they involved repeat attendees, including physicians
 8 not licensed to prescribe Subsys. Many of the speakers’ bureaus had no attendees; sales representatives
 9 were instructed to falsely list names of attendees and their signatures on Insys’ sign-in sheets.

10 397. Insys made thousands of payments to physicians nationwide, including to San Francisco
 11 physicians, for participating on these speakers’ bureaus and for other services.

12 398. Moreover, the executives are charged with targeting practitioners who prescribed Subsys
 13 not only for cancer pain, but for all pain.

14 399. As set forth in the indictment, at one national speakers’ bureau in or about 2014, Insys’
 15 then-vice president of sales stated:

16 “These [doctors] will tell you all the time, well, I’ve only got like eight patients
 17 with cancer. Or, I only have, like, twelve patients that are on a rapid-onset opioids [sic].
 18 Doc, I’m not talking about any of those patients. I don’t want any of those patients.
 19 That’s, that’s small potatoes. That’s nothing. That’s not what I’m here doing. I’m here
 20 selling [unintelligible] for the breakthrough pain. If I can successfully sell you the
 [unintelligible] for the breakthrough pain, do you have a thousand people in your
 practice, a thousand patients, twelve of them are currently on a rapid-onset opioids [sic].
 That leaves me with at least five hundred patients that can go on this drug.”²⁸⁵

21 400. The indictment also alleges that, when agents of insurers or PBMs asked if a patient was
 22 being treated for BTP in cancer patients, Insys’ reimbursement unit employees were instructed to answer
 23 using a written script, sometimes called “the spiel”: “The physician is aware that the medication is
 24 intended for the management of breakthrough pain in cancer patients. The physician is treating the
 25 patient for their pain (or breakthrough pain, whichever is applicable).”²⁸⁶

26 ²⁸⁴ Insys Indictment Press Release, *supra* n.281.

27 ²⁸⁵ *Insys Indictment, supra* n.281, at 15.

28 ²⁸⁶ *Id.* at 44.

1 401. Insys' former executives also tracked and internally circulated the number of planned
 2 and completed speakers' bureau events for each speaker, as well as the number of Subsys prescriptions
 3 each speaker wrote, the percentage of such prescriptions compared to those written for Subsys'
 4 competitor drugs, the total amount of honoraria paid to each speaker and, for a period of time, an explicit
 5 calculation of the ratio of return on investment for each speaker. When a speaker did not write an
 6 appropriate number of Subsys prescriptions, as determined by Insys, the number of future events for
 7 which that speaker would be paid would be reduced unless and until he or she wrote more Subsys
 8 prescriptions.

9 402. In a press release issued when the indictment was announced, the Massachusetts U.S.
 10 Attorney, Carmen M. Ortiz, stated: "I hope that today's charges send a clear message that we will
 11 continue to attack the opioid epidemic from all angles, whether it is corporate greed or street level
 12 dealing."²⁸⁷

13 403. In the same press release, Shaw, the FBI Special Agent in charge of the Boston Field
 14 Division, linked the allegations to the national opioid epidemic:

15 *As alleged, top executives of Insys Therapeutics, Inc. paid kickbacks and*
 16 *committed fraud to sell a highly potent and addictive opioid that can lead to abuse and*
 17 *life threatening respiratory depression In doing so, they contributed to the*
 18 *growing opioid epidemic and placed profit before patient safety. These indictments*
 19 *reflect the steadfast commitment of the FBI and our law enforcement partners to*
 20 *confront the opioid epidemic impacting our communities, while bringing to justice*
 21 *those who seek to profit from fraud or other criminal acts.*²⁸⁸

22 404. The Special Agent in Charge at the Defense Criminal Investigative Service in the
 23 Northeast Field Office, Craig Rupert, commented specifically on the effect the criminal activities had
 24 on members of the military: "Causing the unnecessary use of opioids by current and retired U.S. military
 25 service members shows disregard for their health and disrespect for their service to our country"²⁸⁹

26 405. On August 31, 2017, Arizona Attorney General Mark Brnovich filed a lawsuit alleging
 27 violations of the Arizona Consumer Fraud Act of 1967 ("ACFA") by Insys, two of its former employees
 28 and three doctors. Attorney General Brnovich alleged that Insys and its two named employees – former

²⁸⁷ Insys Indictment Press Release, *supra* n.281.

²⁸⁸ *Id.*

²⁸⁹ *Id.*

1 Vice President of Sales Alec Burlakoff and former Manager of Reimbursement Services Elizabeth
2 Gurrieri – engaged in numerous deceptive or unfair acts and practices, including those related to:

- 3 • the use of the Insys Reimbursement Center (“IRC”), which was designed to obtain prior
4 authorization for Subsys from insurers and PBMs, misleading consumers about the prior
5 authorization process and the IRC’s practices;
- 6 • failing to warn consumers about IRC practices, even though Insys knew or had reason to
7 know that healthcare professionals using the IRC would not be in a position to reduce
8 foreseeable risks of harm due to the IRC’s practices;
- 9 • providing healthcare professionals with false and misleading information, and
10 concealing, suppressing or omitting material facts about the definition of “breakthrough
11 cancer pain” and the FDA-approved uses of Subsys, in order to deceive healthcare
12 professionals so that they would prescribe more Subsys;
- 13 • failing to warn consumers of the foreseeable risks of harm from Subsys and Insys’
14 practices while knowing or having reason to know that healthcare professionals to whom
15 Insys provided false and misleading information would not be in a position to reduce the
16 foreseeable risks of harm; and
- 17 • providing sham “speaker fees” to healthcare practitioners to induce, and in exchange for,
18 the healthcare practitioners writing Subsys prescriptions.

19 406. According to the complaint, between March 2012 and April 2017, the three defendant
20 doctors wrote more than \$33 million worth of Subsys prescriptions while being paid, on average,
21 approximately \$200,000 each in “speaker fees” by Insys.

22 407. According to the complaint, in order to be booked as speakers and receive speaker fees,
23 doctors were required to have at least 20 patients on Subsys. On the other hand, frequent prescribers of
24 Subsys were “rewarded” by being paid in speakers fees, which served to “notice[]” “their support of
25 Subsys” with “positive reinforcement.”

26 408. On April 13, 2018, the DOJ, joined by the states of California, Delaware, Florida,
27 Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Minnesota, Montana, Nevada, New Hampshire,
28 New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas,
Washington, Massachusetts and Virginia, and the District of Columbia, filed a False Claims Act
complaint against Insys, focusing on illegal kickbacks to doctors.

409. Similar to the claims in the ACFA litigation, the DOJ alleged:

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1 Since 2012, Insys has operated a “speaker program” through which it has paid
 2 Subsys prescribers to give speeches about Subsys to physicians and other healthcare
 3 professionals. Insys has pretended that these presentations were intended to provide
 4 potential Subsys prescribers with substantive medical information about the drug. In
 5 reality, many of these events have been mere pretexts for paying thousands of dollars in
 6 sham speaking fees to prescribers for the purpose of inducing them to prescribe Subsys.
 Many of these speeches have been attended only by the prescriber’s own office staff, by
 close friends who attended multiple presentations, or by people who were not medical
 professionals and had no legitimate reason for attending. Many of the “speeches” have
 not involved any actual substantive presentation by the purported “speaker.” The events
 have often been held in expensive restaurants.

7 **c. Insys Failed to Monitor and Report Suspicious Sales as**
 8 **Required**

9 410. The federal CSA imposes on all “registrants” the obligation to design and operate a
 10 system to monitor suspicious orders of controlled substances and requires the registrant to notify the
 11 DEA field division office in its area of any suspicious orders. “Suspicious orders include orders of
 12 unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21
 C.F.R. §1301.74(b).

13 411. Insys is a “registrant” under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant
 14 as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires
 15 manufacturers of Schedule II controlled substances to register with the DEA.

16 412. The California Code of Regulations requires all drug manufacturers and wholesalers to
 17 report “all sales of dangerous drugs subject to abuse” to the Board up to 12 times per year, pursuant to
 18 the Board’s request. 16 C.C.R. §1782.

19 413. Insys failed to design and operate a system to monitor suspicious orders of controlled
 20 substances and/or failed to notify the appropriate DEA field division of suspicious orders. Insys’ failure
 21 to timely report these and other suspicious sales violated the CSA and California law.

22 **7. Mallinckrodt**

23 414. Mallinckrodt manufactures, markets, sells and distributes pharmaceutical drugs in San
 24 Francisco and nationwide. Mallinckrodt is the largest U.S. supplier of opioid pain medications and
 25 among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

26 415. Among the drugs it distributes are the following:

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1 2 3	Exalgo (hydromorphone hydrochloride extended release)	Opioid agonist indicated for opioid-tolerant patients for management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options (<i>e.g.</i> , non-opioid analgesics) are inadequate. The FDA approved the 8, 12 and 16 mg tablets of Exalgo in March 2010 and 32 mg tablet in August 2012.	Schedule II
4 5 6	Roxicodone (oxycodone hydrochloride)	Brand-name instant-release form of oxycodone hydrochloride. Indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Acquired from Xanodyne Pharmaceuticals in 2012. Strengths range up to 30 mg per pill. Nicknames include Roxies, blues and stars.	Schedule II
7 8 9	Xartemis XR (oxycodone hydrochloride and acetaminophen)	The FDA approved Xartemis XR in March 2014 for the management of acute pain severe enough to require opioid treatment and in patients for whom alternative treatment options are ineffective, not tolerated or would otherwise be inadequate. It was the first extended-release oral combination of oxycodone and acetaminophen.	Schedule II
10	Methadose (methadone hydrochloride)	Branded generic product. Opioid agonist indicated for treatment of opioid addiction.	Schedule II
11	Morphine sulfate extended release	Generic product.	Schedule II
12	Fentanyl extended release	Generic product.	Schedule II
13	Fentanyl citrate	Generic product.	Schedule II
14	Oxycodone and acetaminophen	Generic product.	Schedule II
15	Hydrocodone bitartrate and acetaminophen	Generic product.	Schedule II
16	Hydromorphone hydrochloride	Generic product.	Schedule II
17	Hydromorphone hydrochloride extended release	Generic product.	Schedule II
18	Naltrexone hydrochloride	Generic product.	Schedule II
19	Oxymorphone hydrochloride	Generic product.	Schedule II
20	Methadone hydrochloride	Generic product.	Schedule II
21	Oxycodone hydrochloride	Generic product.	Schedule II
22			
23			

24
25 416. Mallinckrodt purchased Roxicodone from Xanodyne Pharmaceuticals in 2012.²⁹⁰

26
27 ²⁹⁰ *Mallinckrodt Announces Agreement with Xanodyne to Purchase Roxicodone*, Bus. Wire
28 (Aug. 23, 2012), <http://www.businesswire.com/news/home/20120823005209/en/Mallinckrodt-Announces-Agreement-Xanodyne-Purchase-Roxicodone%C2%AE>.

1 417. Mallinckrodt debuted Xartemis (MNK-795) at the September 4-7, 2013 PAINWeek in
2 Las Vegas.

3 **a. Mallinckrodt Funded False Publications and Presentations**

4 418. Like several of the other Marketing Defendants, Mallinckrodt provided substantial
5 funding to purportedly neutral organizations that disseminated false messaging about opioids.

6 419. For example, until at least February 2009, Mallinckrodt provided an educational grant to
7 Pain-Topics.org, a now-defunct website that touted itself as “a noncommercial resource for healthcare
8 professionals, providing open access to clinical news, information, research, and education for a better
9 understanding of evidence-based pain-management practices.”²⁹¹

10 420. Among other content, the website included a handout titled, “Oxycodone Safety Handout
11 for Patients,” which advised practitioners that “[p]atients’ fears of opioid addiction should be
12 dispelled.”²⁹² The handout included several false and misleading statements concerning the risk of
13 addiction associated with prescription opioids:

14 Will you become dependent on or addicted to oxycodone?

- 15 • After awhile, oxycodone causes physical dependence. That is, if you suddenly
16 stop the medication you may experience uncomfortable withdrawal symptoms,
17 such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite,
18 and other ill feelings. These may take several days to develop.
- 19 • This is not the same as addiction, a disease involving craving for the drug, loss of
20 control over taking it or compulsive use, and using it despite harm. Addiction to
21 oxycodone in persons without a recent history of alcohol or drug problems is
22 rare.²⁹³

23 421. Additionally, the FAQ section of Pain-Topics.org contained the following false and
24 misleading information downplaying the dangers of prescription opioid use:

25 **Pseudoaddiction** – has been used to describe aberrant patient behaviors that may
26 occur when pain is undertreated (AAPM 2001). Although this diagnosis is not supported
27 by rigorous investigation, it has been widely observed that patients with unrelieved pain
28 may become very focused on obtaining opioid medications, and may be erroneously

29 ²⁹¹ *Pain Treatment Topics*, Pain-Topics.org, <https://web.archive.org/web/20070104235709/http://www.pain-topics.org:80/> (last visited Dec. 14, 2018).

30 ²⁹² Lee A. Kral & Stewart B. Leavitt, *Oxycodone Safety Handout for Patients*, Pain-
31 Topics.Org (June 2007), <http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf>.

32 ²⁹³ *Id.*

1 perceived as “drug seeking.” Pseudoaddiction can be distinguished from true addiction
 2 in that the behaviors resolve when the pain is effectively treated. Along with this, two
 related phenomena have been described in the literature (Alford et al. 2006):

3 **Therapeutic dependence** – sometimes patients exhibit what is
 4 considered drug-seeking because they fear the reemergence of pain and/or
 5 withdrawal symptoms from lack of adequate medication; their ongoing quest for
 more analgesics is in the hopes of insuring a tolerable level of comfort.

6 **Pseudo-opioid-resistance** – other patients, with adequate pain control,
 7 may continue to report pain or exaggerate its presence, as if their opioid
 analgesics are not working, to prevent reductions in their currently effective doses
 of medication.

8 Patient anxieties about receiving inadequate pain control can be profound,
 9 resulting in demanding or aggressive behaviors that are misunderstood by healthcare
 practitioners and ultimately detract from the provision of adequate pain relief.²⁹⁴

10 422. Another document available on the website, “Commonsense Oxycodone Prescribing &
 11 Safety,” falsely suggests that generic oxycodone is less prone to abuse and diversion than branded
 12 oxycodone: “Anecdotally, it has been observed that generic versions of popularly abused opioids usually
 13 are less appealing; persons buying drugs for illicit purposes prefer brand names because they are more
 14 recognizable and the generics have a lower value ‘on the street,’ which also makes them less alluring
 15 for drug dealers.”²⁹⁵

16 423. In November 2016, Mallinckrodt paid Dr. Scott Gottlieb (“Gottlieb”), the new
 17 commissioner of the FDA, \$22,500 for a speech in London, shortly after the U.S. presidential election.²⁹⁶
 18 Gottlieb has also received money from the Healthcare Distribution Alliance (“HDA”), an industry-
 19 funded organization that pushes the agenda of large pharmaceutical wholesalers, and he has often
 20 criticized efforts aimed at regulating the pharmaceutical opioid market.²⁹⁷

21 424. Mallinckrodt also made thousands of payments to physicians nationwide, including to
 22 San Francisco physicians.

23 ²⁹⁴ *FAQs*, Pain-Topics.org,
 24 <https://web.archive.org/web/20070709031530/http://www.pain-topics.org:80/faqs/index1.php#tolerance> (last visited Dec. 14, 2018).

25 ²⁹⁵ Lee A. Kral, *Commonsense Oxycodone Prescribing & Safety*, Pain-Topics.org (June
 26 2007), <http://paincommunity.org/blog/wp-content/uploads/OxycodoneRxSafety.pdf>.

27 ²⁹⁶ Lee Fang, *Donald Trump’s Pick to Oversee Big Pharma Is Addicted to Opioid-Industry Cash*, *The Intercept* (Apr. 4, 2017, 2:15 PM), <https://theintercept.com/2017/04/04/scott-gottlieb-opioid/>.

28 ²⁹⁷ *Id.*

1 425. Exalgo, Roxicodone and Xartemis XR have been prescribed in San Francisco. According
 2 to data collected by ProPublica, during 2015, California doctors' prescriptions of Exalgo to patients
 3 insured by the Medicare Part D program totaled almost \$690,000, prescriptions of Roxicodone totaled
 4 over \$381,000 and prescriptions of Xartemis XR totaled a little over \$23,000.

5 **b. The DEA Investigates Suspicious Orders**

6 426. In 2008, the DEA and federal prosecutors launched an investigation into Mallinckrodt,
 7 charging that the company ignored red flags and supplied – and failed to report – suspicious orders for
 8 its generic oxycodone between 2008 and 2012.²⁹⁸ The U.S. Attorney's office in Detroit handled the case.
 9 The investigation uncovered that from 2008 to 2012, Mallinckrodt sent, for example, 500 million tablets
 10 of oxycodone into a single state, Florida – “66 percent of all oxycodone sold in the state.”²⁹⁹ According
 11 to the internal government documents obtained by the *Washington Post*, Mallinckrodt's failure to report
 12 could have resulted in “nearly 44,000 federal violations and exposed it to \$2.3 billion in fines.”³⁰⁰

13 427. Despite learning from the DEA that generic opioids seized in a Tennessee drug operation
 14 were traceable to one of its Florida distributors, Sunrise Wholesale (“Sunrise”) of Broward County,
 15 Mallinckrodt, in the following six weeks, sent 2.1 million tablets of oxycodone to Sunrise. In turn,
 16 Sunrise sent at least 92,400 oxycodone tablets to a single doctor over an 11-month period, who, in one
 17 day, prescribed 1,000 to a single patient.³⁰¹

18 428. According to documents obtained by the *Washington Post*, investigators also found
 19 “scores of alleged violations” at Mallinckrodt's plant in Hobart, New York. Those violations included
 20 the failure to keep accurate records, to document transfers of drugs and to secure narcotics.³⁰²

21 429. During the DEA's investigation, Mallinckrodt sponsored the HDA (known as the
 22 Healthcare Distribution Management Association until 2016), an industry-funded organization that
 23

24 ²⁹⁸ Lenny Bernstein & Scott Higham, *The government's struggle to hold opioid*
 25 *manufacturers accountable*, Wash. Post (Apr. 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.7ce8c975dd86.

26 ²⁹⁹ *Id.*

27 ³⁰⁰ *Id.*

28 ³⁰¹ *Id.*

³⁰² *Id.*

1 represents pharmaceutical distributors.³⁰³ The HDA initiated the Ensuring Patient Access and Effective
2 Drug Enforcement Act of 2016 (enacted April 19, 2016), which requires the DEA to give notice of
3 violations and an opportunity to comply, to pharmacies and distributors, before withdrawing licenses.
4 This Act substantially lessened the DEA's ability to regulate manufacturers and wholesalers.³⁰⁴

5 430. In May 2014, Mallinckrodt posted a video titled, "Red Flags: Pharmacists Anti-Abuse
6 Video." The video is a thinly veiled attempt to divert responsibility for the opioid epidemic away from
7 manufacturers and wholesalers, and toward individual pharmacists. The video was sponsored by the
8 Anti-Diversion Industry Working Group, which is composed of Cardinal Health, Actavis, McKesson,
9 Mallinckrodt, AmerisourceBergen and Qualitest – all of whom are conveniently missing from the list of
10 those responsible.³⁰⁵

11 431. In April 2017, Mallinckrodt reached an agreement with the DEA and the U.S. Attorneys
12 for the Eastern District of Michigan and Northern District of New York to pay \$35 million to resolve a
13 probe of its distribution of its opioid medications.³⁰⁶ Mallinckrodt finalized the settlement on July 11,
14 2017, agreeing to pay \$35 million while admitting no wrongdoing.³⁰⁷

15 **c. Mallinckrodt Failed to Monitor and Report Suspicious Sales**
16 **as Required**

17 432. The federal CSA imposes on all "registrants" the obligation to design and operate a
18 system to monitor suspicious orders of controlled substances and requires the registrant to notify the
19

20 ³⁰³ *Sponsors: HDA's Annual Circle Sponsors*, Healthcare Distribution Alliance,
<https://www.healthcaredistribution.org/hda-sponsors> (last visited Dec. 14, 2018).

21 ³⁰⁴ Chris McGreal, *Opioid epidemic: ex-DEA official says Congress is protecting drug*
22 *makers*, Guardian (Oct. 31, 2016, 9:26 EDT), [https://www.theguardian.com/us-](https://www.theguardian.com/us-news/2016/oct/31/opioid-epidemic-dea-official-congress-big-pharma)
[news/2016/oct/31/opioid-epidemic-dea-official-congress-big-pharma](https://www.theguardian.com/us-news/2016/oct/31/opioid-epidemic-dea-official-congress-big-pharma).

23 ³⁰⁵ National Association of Boards of Pharmacy, *Red Flags*, YouTube (May 20, 2014),
<https://www.youtube.com/watch?v=WY9BDgcdxaM>.

24 ³⁰⁶ Linda A. Johnson, *Mallinckrodt to Pay \$35M in Deal to End Feds' Opioid Probe*, U.S.
25 *News & World Report* (Apr. 3, 2017, 6:47 PM), [https://www.usnews.com/news/business/articles/2017-04-03/mallinckrodt-to-pay-35m-in-deal-to-end-](https://www.usnews.com/news/business/articles/2017-04-03/mallinckrodt-to-pay-35m-in-deal-to-end-feds-opioid-probe)
26 [feds-opioid-probe](https://www.usnews.com/news/business/articles/2017-04-03/mallinckrodt-to-pay-35m-in-deal-to-end-feds-opioid-probe).

27 ³⁰⁷ Press Release, U.S. Department of Justice, *Mallinckrodt Agrees to Pay Record \$35*
28 *Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for*
Recordkeeping Violations (July 11, 2017), [https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-](https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders)
[record-35-million-settlement-failure-report-suspicious-orders](https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders).

1 DEA field division office in its area of any suspicious orders. “Suspicious orders include orders of
 2 unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21
 3 C.F.R. §1301.74(b). The CSA’s requirements are also incorporated into California law. Cal. Bus. &
 4 Prof. Code §4301(o).

5 433. Mallinckrodt is a “registrant” under the federal CSA. 21 C.F.R. §1300.02(b) defines a
 6 registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn,
 7 requires manufacturers of Schedule II controlled substances to register with the DEA.

8 434. The California Code of Regulations requires all drug manufacturers and wholesalers to
 9 report “all sales of dangerous drugs subject to abuse” to the Board up to 12 times per year, pursuant to
 10 the Board’s request. 16 C.C.R. §1782.

11 435. Mallinckrodt failed to design and operate a system to monitor suspicious orders of
 12 controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders.
 13 Mallinckrodt’s failure to timely report these and other suspicious sales violated the CSA and California
 14 law.

15 8. Actavis

16 436. Actavis manufactures, markets, sells and distributes pharmaceutical drugs in San
 17 Francisco and nationwide. Until it sold its portfolio of generic opioids to Teva, Actavis was among the
 18 largest U.S. suppliers of opioid pain medications.

19 437. Among the drugs Actavis distributes or distributed during the times relevant to the
 20 allegations herein are the following:

21 Kadian (morphine sulfate, extended release)	22 Opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatments are inadequate. 20 mg, 50 mg and 100 mg strengths approved by the FDA in 1996. 30 mg and 60 mg strengths approved by the FDA in 2001. 80 mg strength approved by the FDA in 2006. 10 mg and 200 mg strengths approved by the FDA in 2007. 40 mg, 70 mg, 130 mg and 150 mg strengths approved by the FDA in 2012.	Schedule II
26 Norco (hydrocodone bitartrate and acetaminophen)	27 Opioid agonist initially indicated for the relief of moderate to moderately severe pain. Later, indication amended to treat acute pain severe enough to require opioid analgesic and for which alternative treatments are inadequate. Norco was initially approved by the FDA in 1997.	Schedule III (1997-2014) Schedule II (2014-present)

1 2 3 4 5 6	Oxymorphone hydrochloride extended-release tablets	Generic equivalent of Opana ER. Launched in 2013.	Schedule II
7 8 9 10 11 12 13 14 15 16	Morphine sulfate extended-release	Generic equivalent of Kadian. Launched in 2013.	Schedule II
17 18 19 20 21 22 23 24 25 26 27 28	Fentanyl citrate transdermal patch	Generic equivalent of Duragesic. Launched in 2007.	Schedule II

438. Actavis acquired Kadian from King Pharmaceuticals in 2008 for an amount up to \$127.5 million, depending on quarterly sales-related milestones.

439. Actavis marketed and sold generic opioids until it sold its generic opioid portfolio for \$40.5 billion to Teva in 2016.

440. According to public records collected by ProPublica, in 2015 alone, Medicare Part D paid \$1.6 million, \$1.3 million, \$2.6 million and \$34.4 million for claims arising from California physicians' Kadian, Norco, oxymorphone hydrochloride extended-release and morphine sulfate extended-release prescriptions, respectively. According to those same ProPublica records, one San Francisco physician filed the fifth most Medicare claims statewide for prescriptions of morphine sulfate extended-release in 2015.

a. The FDA Issued a Warning Letter to Actavis Concerning Extensive False and Misleading Claims in Kadian Marketing Materials

441. On February 18, 2010, the FDA's Division of Drug Marketing, Advertising, and Communications issued a warning letter ("2010 Warning Letter") to Actavis concerning the marketing of Kadian. The letter warned that certain marketing materials for Kadian "are false or misleading because they omit and minimize the serious risks associated with the drug, broaden and fail to present the limitations to the approved indication of the drug, and present unsubstantiated superiority and effectiveness claims" in violation of the FDCA and regulations promulgated thereunder. Specifically, the 2010 Warning Letter addressed two marketing materials: a Comparison Detailer and a Co-Pay Assistance Program brochure.

442. According to the 2010 Warning Letter, the marketing materials "present several effectiveness claims for Kadian but fail to present any contraindications, and also omit several warnings,

1 precautions, drug interactions and adverse events” including by failing to include “warnings regarding
2 potentially fatal abuse of opioids [and] use by individuals other than the patient for whom the drug was
3 prescribed.”

4 443. The 2010 Warning Letter also states that the Comparison Detailer “fails to present risk
5 information with a prominence and readability that is reasonably comparable to the presentation of
6 benefit information.” Whereas “the first five of the six pages of the Comparison Detailer prominently
7 present efficacy claims about Kadian using large, bolded headers and claims surrounded by a significant
8 amount of white space . . . using colorful charts and graphs,” “the only specific risk information
9 presented is relegated to the back cover . . . in a small font . . . beneath a large, bolded headline claim
10 that presents a benefit claim.”

11 444. The 2010 Warning Letter provides that the effect of these presentations “minimizes the
12 risks associated with Kadian and misleadingly suggests that Kadian is safer than has been
13 demonstrated.”

14 445. Further, the 2010 Warning Letter states that Kadian promotional materials were
15 misleading because they “present broad claims about the drug’s use in treating pain, therefore implying
16 that Kadian is appropriate for use in a broader range than it is approved to treat.” The 2010 Warning
17 Letter cites the following examples from the Comparison Detailer:

- 18 • “Allow for less breakthrough pain and more consistent pain relief for patients.”
- 19 • “Better pain control”
- 20 • “Improved pain control”
- 21 • “Allow patients to live with less pain”
- 22 • “Less Pain. More options.”

23
24 446. According to the 2010 Warning Letter, “[t]hese presentations in the Comparison Detailer
25 suggest that Kadian is appropriate for patients with broader types of pain than the drug is indicated for.”

26 447. The 2010 Warning Letter found similar problems in the Co-Pay Assistance Program
27 brochure, which included the following statements (emphases in original):

28 //

- 1 • **“Why is pain management important?** Pain management is a large part of your overall
2 health care plan. Many Americans suffer from chronic or ongoing pain . . . Managing
3 your pain the right way begins by talking to your healthcare provider. Discover the cause
4 of your pain by taking note of what makes your pain start and what makes it worse.”
- 5 • **“What is chronic pain?** Chronic pain is ongoing and can last longer than 6 months.
6 Chronic pain can be mild or severe. . . .”
- 7 • **“How can I treat my chronic pain?** To help manage your pain, your healthcare provider
8 will determine what level of pain control you need. Depending on what kind of pain you
9 have and how it affects your life, your healthcare provider will choose a drug that works
10 just for you.”

11 448. The 2010 Warning Letter states that these statements “suggest[] that patients with broader
12 types of chronic pain than the drug is indicated for are appropriate candidates for Kadian therapy, when
13 this is not the case. . . . Kadian is *only* appropriate for a very limited patient population who experience
14 pain.” (Emphasis in original.) It continues, “[i]n addition, the partial indication included on the back
15 cover of the Co-Pay Assistance Program brochure, unlike the chronic pain information, is written in
16 technical medical language that is not likely to be easily understood by consumers.”

17 449. Next, the 2010 Warning Letter identifies unsubstantiated superiority claims, including
18 that Kadian “[a]llow[s] for less breakthrough pain and more consistent pain relief for patients” and asks,
19 “Why settle for generic MS Contin tablets . . . When you can prescribe the benefits of KADIAN
20 capsules?” According to the Letter, these “claims and presentations misleadingly imply that Kadian has
21 been shown to be superior to MS Contin or generic controlled-release morphine” but the “FDA is not
22 aware of *any* substantial evidence or substantial clinical expertise that supports these claims and
23 presentations.” (Emphasis in original.)

24 450. The 2010 Warning Letter also identifies the following claims “supported by a historically
25 controlled study of inadequate design, completely lacking any concurrent control”; “[b]etter pain control
26 and improved sleep scores”; “[i]mproved pain control and sleep scores in patients treated with KADIAN
27 who were previously on CR morphine tablets”; and “[a]llow patients to live with less pain and get
28 adequate rest with less medication.” The 2010 Warning Letter states that the trial identified in support
of these claims “clearly do[es] not support any conclusion that Kadian is superior to alternative
treatments in pain or sleep measures.”

1 451. Further, the 2010 Warning Letter focuses on the Comparison Detailer’s inclusion of
2 dosing claims comparing Kadian with MS Contin and Avinza. The Detailer claims that Kadian presents
3 “[f]ewer barriers to prescribing” because “[t]he unique dosing flexibility of KADIAN gives you more
4 options with morphine” than does MS Contin or Avinza. However, “the FDA is unaware of any
5 substantial evidence or substantial clinical experience to support the claim that the above dosing
6 characteristics allow Kadian to have ‘fewer barriers to prescribing’ (the meaning of which is not clear)
7 as compared to other extended-release morphine products.”

8 452. In conclusion, the 2010 Warning Letter found that the Comparison Detailer and Co-Pay
9 Assistance Program brochure “misbrand Kadian in violation of the [FDCA].”

10 **b. Actavis Failed to Monitor and Report Suspicious Sales as**
11 **Required**

12 453. The federal CSA imposes on all “registrants” the obligation to design and operate a
13 system to monitor suspicious orders of controlled substances and requires the registrant to notify the
14 DEA field division office in its area of any suspicious orders. “Suspicious orders include orders of
15 unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21
16 C.F.R. §1301.74(b). The CSA’s requirements are also incorporated into California law. Cal. Bus. &
17 Prof. Code §4301(o).

18 454. Actavis is a “registrant” under the federal CSA. 21 C.F.R. §1300.02(b) defines a
19 registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn,
20 requires manufacturers of Schedule II controlled substances to register with the DEA.

21 455. The California Code of Regulations requires all drug manufacturers and wholesalers to
22 report “all sales of dangerous drugs subject to abuse” to the Board up to 12 times per year, pursuant to
23 the Board’s request. 16 C.C.R. §1782.

24 456. Actavis failed to design and operate a system to monitor suspicious orders of controlled
25 substances and/or failed to notify the appropriate DEA field division of suspicious orders. Actavis’s
26 failure to timely report these and other suspicious sales violated the CSA and California law.

27 //

28 //

1 **C. The Wholesaler Defendants Failed to Track and Report Suspicious Sales as**
 2 **Required by California and Federal Law**

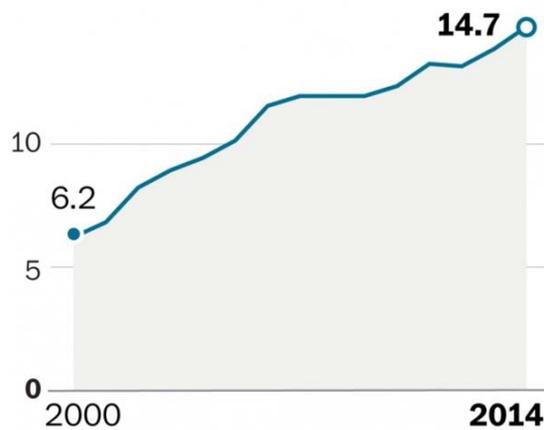
3 457. Manufacturers rely upon distributors to distribute their drugs. The distributors serve as
 4 middlemen, sending billions of doses of opioid pain pills to pharmacists, hospitals, nursing homes and
 5 pain clinics. According to the CDC, the increased distribution of opioids directly correlates to increased
 6 overdose death rates:

7 **Opioid distribution and overdose death rates rise**

8 Both rates have more than doubled since 2000.

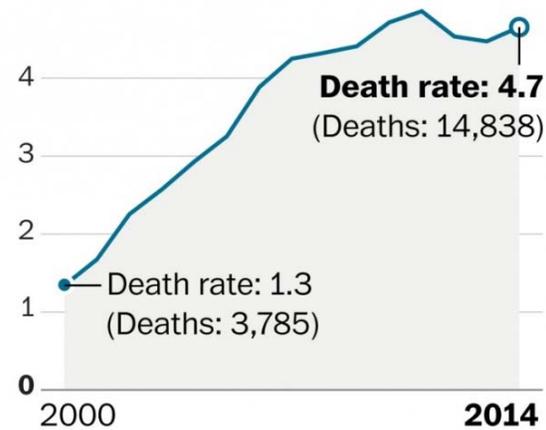
9
 10 **PRESCRIPTION OPIOID**
DISTRIBUTION RATE

11 Grams per 100 people



12 **PRESCRIPTION OPIOID**
OVERDOSE DEATH RATE

13 Deaths per 100,000 people



14
 15
 16
 17
 18
 19 Fentanyl overdose deaths are excluded. The CDC removed the drug from the totals because of
 20 its growing prevalence as a street drug.

21 Sources: DEA, Centers for Disease Control and Prevention

22 THE WASHINGTON POST

23 458. On October 23, 2017, CBS aired an episode of *60 Minutes* featuring former DEA agent
 24 Joe Rannazzisi (“Rannazzisi”), who blamed the Wholesaler Defendants for killing people by violating
 25 the CSA requirement to report suspicious orders:

26 **RANNAZZISI:** This is an industry that’s out of control. What they wanna do, is do what
 27 they wanna do, and not worry about what the law is. And if they don’t follow the law in
 28 drug supply, people die. That’s just it. People die.

* * *

1 This is an industry that allowed millions and millions of drugs to go into bad
2 pharmacies and doctors' offices, that distributed them out to people who had no
3 legitimate need for those drugs.

4 **[INTERVIEWER]:** Who are these distributors?

5 **RANNAZZISI:** The three largest distributors are Cardinal Health, McKesson, and
6 AmerisourceBergen. They control probably 85 or 90 percent of the drugs going
7 downstream.

8 **[INTERVIEWER]:** You know the implication of what you're saying, that these big
9 companies knew that they were pumping drugs into American communities that were
10 killing people.

11 **RANNAZZISI:** That's not an implication, that's a fact. That's exactly what they did.³⁰⁸

12 459. Jim Geldhof ("Geldhof"), a 40-year veteran of the DEA who ran investigations in the
13 Detroit field office, corroborated Rannazzisi's account, saying that the wholesalers are "absolutely"
14 responsible for the opioids epidemic:

15 **[INTERVIEWER]:** These companies are a big reason for this epidemic?

16 **GELDHOF:** Yeah, absolutely they are. And I can tell you with 100 percent accuracy
17 that we were in there on multiple occasions trying to get them to change their behavior.
18 And they just flat out ignored us.³⁰⁹

19 460. Indeed, according to Rannazzisi, the Wholesaler Defendants succeeded in lobbying
20 Congress to strip the DEA of its most potent tool for fighting against diversion and abuse. In 2013, a
21 bill was introduced in the House that "was promoted as a way to ensure that patients had access to the
22 pain medication they needed." What it "really did," however, "was strip the [DEA] of its ability to
23 immediately freeze suspicious shipments of prescription narcotics to keep drugs off U.S. streets." A
24 2015 DOJ memo confirmed that the bill "could actually result in increased diversion, abuse, and public
25 health and safety consequences."³¹⁰

26 461. During the two years the legislation was considered and amended, defendants and others
27 in the industry spent \$102 million lobbying Congress on the bill and other legislation, "claiming the
28 DEA was out of control [and] making it harder for patients to get needed medication." The APA co-

³⁰⁸ Whitaker, *Opioid Crisis Fueled by Drug Industry*, *supra* n.122.

³⁰⁹ *Id.*

³¹⁰ *Id.*

1 signed a letter in support of the legislation. As discussed *supra* ¶¶114-121, the APA receives funding
2 from numerous industry participants, including Johnson & Johnson, Endo, Mallinckrodt, Purdue and
3 Cephalon. Metadata associated with the letter co-signed by the APA shows that it was created by Kristen
4 L. Freitas (“Freitas”), vice president for federal government affairs at the HDA – the trade group that
5 represents McKesson, Cardinal Health and AmerisourceBergen. Freitas is also a registered lobbyist
6 who lobbied in support of the bill. According to the *July 2018 McCaskill Report*, patient advocacy
7 groups and professional societies – many of which were funded in part by opioid manufacturers – sent
8 a letter in November 2017 praising the 2016 law and warning that “unchecked DEA authority can result
9 in profound consequences for chronic pain sufferers.”³¹¹

10 462. According to *60 Minutes*, the chief administrative law judge of the DEA, Mulrooney, has
11 written “that the new legislation ‘would make it all but . . . impossible’ to prosecute unscrupulous
12 distributors.”³¹² The proposed bill was signed into law in 2016. The primary author of the bill is former
13 DEA associate chief counsel Linden Barber. He was recently hired by Cardinal Health as senior vice
14 president.

15 1. McKesson

16 463. McKesson, headquartered in San Francisco, is a wholesale pharmaceutical distributor of
17 controlled and uncontrolled prescription medications, including opioids. It is the largest pharmaceutical
18 drug distributor in the United States. It distributes pharmaceuticals through a network of distribution
19 centers across the country. McKesson ranked fifth on the 2017 Fortune 500 list, with over \$192 billion
20 in revenues.

21 464. McKesson supplies various United States pharmacies an increasing amount of
22 prescription opioids, products frequently misused that are at the heart of the current opioid epidemic.

23 465. McKesson distribution centers are required to operate in accordance with the statutory
24 provisions of the CSA. The regulations promulgated under the CSA include a requirement to design
25 and operate a system to detect and report “suspicious orders” for controlled substances, as that term is
26 defined in the regulation. *See* 21 C.F.R. §1301.74(b). The CSA authorizes the imposition of a civil

27 ³¹¹ *July 2018 McCaskill Report, supra* n.275, at 26.

28 ³¹² Whitaker, *Opioid Crisis Fueled by Drug Industry, supra* n.122.

1 penalty of up to \$10,000 for each violation of 21 C.F.R. §1301.74(b). *See* 21 U.S.C. §842(a)(5) &
2 (c)(1)(B). The CSA’s requirements are also incorporated into California law. Cal. Bus. & Prof. Code
3 §4301(o).

4 466. California also imposes independent requirements on distributors, including that all
5 opioids that are distributed or furnished for sale in the state be distributed or furnished for legitimate
6 purposes only (Cal. Health & Safety Code §11153.5) and that wholesalers report “all sales of dangerous
7 drugs subject to abuse” to the Board in excess of amounts it sets (16 C.C.R. §1782). Moreover, effective
8 January 1, 2018, pharmaceutical wholesalers must notify the Board of suspicious orders placed by a
9 California-licensed pharmacy or wholesaler. Cal. Bus. & Prof. Code §4169.1.

10 467. In or about 2007, the DEA accused McKesson of failing to report suspicious orders and
11 launched an investigation. In 2008, McKesson entered into a settlement agreement with the DOJ and a
12 memorandum of agreement, agreeing to pay a \$13.25 million fine for failure to report suspicious orders
13 of pharmaceutical drugs and promising to set up a monitoring system.

14 468. As a result, McKesson developed a Controlled Substance Monitoring Program
15 (“CSMP”) but nevertheless failed to design and implement an effective system to detect and report
16 “suspicious orders” for controlled substances distributed to its independent and small chain pharmacy
17 customers – *i.e.*, orders that are unusual in their frequency, size or other patterns. McKesson continued
18 to fail to detect and disclose suspicious orders of controlled substances. It failed to conduct adequate
19 due diligence of its new or existing customers, failed to keep complete and accurate records in the CSMP
20 files maintained for many of its customers and bypassed suspicious order reporting procedures set forth
21 in the CSMP.

22 469. In 2013, the DEA again began investigating reports that McKesson was failing to
23 maintain proper controls to prevent the diversion of opioids and accused McKesson of failing to design
24 and use an effective system to detect “suspicious orders” from pharmacies for powerful painkillers such
25 as oxycodone, as required by the CSA. Nine DEA field divisions and 12 U.S. Attorneys General built a
26 case against McKesson for the company’s role in the opioid crisis, which David Schiller (“Schiller”),
27 then Assistant Special Agent in Charge for the Denver Field Division and leader of the DEA team
28

1 investigating McKesson, called “the best case we’ve ever had against a major distributor in the history
2 of the Drug Enforcement Administration.”³¹³

3 470. On December 17, 2017, CBS aired an episode of *60 Minutes* featuring Assistant Special
4 Agent Schiller, who described McKesson as a company that killed people for its own financial gain and
5 blatantly ignored the CSA requirement to report suspicious orders:

6 **SCHILLER:** If they woulda stayed in compliance with their authority and held those
7 that they’re supplying the pills to, the epidemic would be nowhere near where it is right
8 now. Nowhere near.

9 * * *

10 They had hundreds of thousands of suspicious orders they should have reported,
11 and they didn’t report any. There’s not a day that goes by in the pharmaceutical world,
12 in the McKesson world, in the distribution world, where there’s not something
13 suspicious. It happens every day.

14 **[INTERVIEWER]:** And they had none.

15 **SCHILLER:** They weren’t reporting any. I mean, you have to understand that, nothing
16 was suspicious?³¹⁴

17 471. Indeed, according to the DOJ, McKesson continued to fail to report suspicious orders
18 between 2008 and 2012, in violation of the company’s settlement with the DOJ, and never fully
19 implemented or followed the monitoring program required under the terms of the settlement to which it
20 agreed.

21 472. On January 17, 2017, in one of the most severe sanctions ever agreed to by a distributor,
22 McKesson agreed to pay a record \$150 million in fines and suspend sales of controlled substances from
23 distribution centers in four states (Colorado, Ohio, Michigan and Florida) to settle allegations that the
24 company violated federal law. As part of the 2017 agreement, McKesson acknowledged that:

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27 ³¹³ Bill Whitaker, *Whistleblowers: DEA Attorneys Went Easy on McKesson, the Country’s
28 Largest Drug Distributor*, CBS News (Dec. 17, 2017),
[https://www.cbsnews.com/news/whistleblowers-dea-attorneys-went-easy-on-mckesson-the-countrys-
largest-drug-distributor/](https://www.cbsnews.com/news/whistleblowers-dea-attorneys-went-easy-on-mckesson-the-countrys-largest-drug-distributor/).

³¹⁴ *Id.*

1 at various times during the Covered Time Period, it did not identify or report to DEA
2 certain orders placed by certain pharmacies, which should have been detected by
3 McKesson as suspicious, in a manner fully consistent with the requirements set forth in
4 the 2008 MOA.

5 2. Cardinal Health

6 473. Cardinal Health describes itself as a global integrated healthcare services and products
7 company. It generated \$121.5 billion in total revenue during fiscal year 2016 (ended June 30, 2016). It
8 is ranked 15th on the 2017 Fortune 500 list of top United States companies with revenues of over \$121
9 billion.

10 474. Cardinal Health has two operating segments: pharmaceutical and medical. Its
11 pharmaceutical segment, at issue in this action, distributes branded and generic pharmaceutical, special
12 pharmaceutical, over-the-counter and consumer products in the United States. Of Cardinal Health's
13 \$121.5 billion in revenue during fiscal year 2016, \$109.1 billion was derived from the pharmaceutical
14 operating segment.

15 475. Cardinal Health distributes pharmaceuticals through a network of distribution centers
16 across the country. Cardinal Health's largest customer is CVS Health ("CVS"), which accounted for
17 25% of Cardinal Health's fiscal year 2016 revenue. According to its website, CVS operates 23
18 pharmacies in San Francisco.³¹⁵

19 476. Cardinal Health distribution centers are required to operate in accordance with the
20 statutory provisions of the CSA and the regulations promulgated thereunder, 21 C.F.R. §1300, *et seq.*
21 The regulations promulgated under the CSA include a requirement to design and operate a system to
22 detect and report "suspicious orders" for controlled substances as that term is defined in the regulation.
23 *See* 21 C.F.R. §1301.74(b). The CSA authorizes the imposition of a civil penalty of up to \$10,000 for
24 each violation of 21 C.F.R. §1301.74(b). *See* 21 U.S.C. §842(a)(5) & (c)(1)(B). The CSA's
25 requirements are also incorporated into California law. Cal. Bus. & Prof. Code §4301(o).

26 477. California also imposes independent requirements on distributors, including that all
27 opioids that are distributed or furnished for sale in the state be distributed or furnished for legitimate

28 ³¹⁵ Store Locator, CVS Pharmacy, <https://www.cvs.com/store-locator/cvs-pharmacy-locations/California/San-Francisco> (last visited Dec. 14, 2018).

1 purposes only (Cal. Health & Safety Code §11153.5) and that wholesalers report “all sales of dangerous
2 drugs subject to abuse” to the Board in excess of amounts it sets (16 C.C.R. §1782). Moreover, effective
3 January 1, 2018, pharmaceutical wholesalers must notify the Board of suspicious orders placed by a
4 California-licensed pharmacy or wholesaler. Cal. Bus. & Prof. Code §4169.1.

5 478. On December 23, 2016, Cardinal Health agreed to pay the United States \$44 million to
6 resolve allegations that it violated the CSA in Maryland, Florida and New York by failing to report
7 suspicious orders of controlled substances, including oxycodone, to the DEA.³¹⁶

8 479. In the settlement agreement, Cardinal Health admitted, accepted and acknowledged that
9 it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

- 10 • “timely identify suspicious orders of controlled substances and inform the DEA
11 of those orders, as required by 21 C.F.R. §1301.74(b)”;
- 12 • “maintain effective controls against diversion of particular controlled substances
13 into other than legitimate medical, scientific, and industrial channels, as required
14 by 21 C.F.R. §1301.74, including the failure to make records and reports required
15 by the CSA or DEA’s regulations for which a penalty may be imposed under 21
16 U.S.C. §842(a)(5)”;
- 17 • “execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA
18 ‘Form 222’ order forms and their electronic equivalent for Schedule II controlled
19 substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305.”

20 480. The settlement agreement was announced by the U.S. Attorney for the District of
21 Maryland, Rod J. Rosenstein (“Rosenstein”), and the DEA Special Agent in Charge – Washington Field
22 Division, Karl C. Colder (“Colder”).³¹⁷

23 481. In the press release announcing the settlement agreement, Rosenstein stated:

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26 ³¹⁶ Earlier in 2016, CVS also agreed to pay the United States \$8 million to resolve
27 violations of the CSA by its Maryland pharmacies. According to the settlement agreement, CVS
28 admitted that between 2008 and 2012, certain of its Maryland pharmacies dispensed oxycodone,
fentanyl, hydrocodone and other pharmaceuticals in violation of the CSA because the drugs were
dispensed without ensuring that the prescriptions were issued for legitimate medical purposes.

³¹⁷ Press Release, U.S. Attorney’s Office for the District of Maryland, Cardinal Health
Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act (Dec. 23,
2016), <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act>.

1 “Pharmaceutical suppliers violate the law when they fill unusually large or
2 frequent orders for controlled substances without notifying the DEA Abuse of
3 pharmaceutical drugs is one of the top federal law enforcement priorities. Cases such as
4 this one, as well as our \$8 million settlement with CVS in February 2016, reflect the
federal commitment to prevent the diversion of pharmaceutical drugs for illegal
purposes.”³¹⁸

5 482. In the press release, Colder clarified that the settlement primarily concerned the opioid
6 oxycodone:

7 “DEA is responsible for ensuring that all controlled substance transactions take
8 place within DEA’s regulatory closed system. All legitimate handlers of controlled
9 substances must maintain strict accounting for all distributions and Cardinal failed to
10 adhere to this policy Oxycodone is a very addictive drug and failure to report
suspicious orders of oxycodone is a serious matter. The civil penalty levied against
Cardinal should send a strong message that all handlers of controlled substances must
perform due diligence to ensure the public safety”³¹⁹

11 3. AmerisourceBergen

12 483. AmerisourceBergen is a wholesale distributor of pharmaceuticals, including controlled
13 substances and non-controlled prescription medications. It handles the distribution of approximately
14 20% of all pharmaceuticals sold and distributed in the United States through a network of 26
15 pharmaceutical distribution centers, including one in Sacramento, California.³²⁰ It ranked 11th on the
16 Fortune 500 list in 2017, with over \$146 billion in annual revenue.

17 484. AmerisourceBergen distribution centers are required to operate in accordance with the
18 statutory provisions of the CSA and the regulations promulgated thereunder, 21 C.F.R. §1300, *et seq.*
19 The regulations promulgated under the CSA include a requirement to design and operate a system to
20 detect and report “suspicious orders” for controlled substances as that term is defined in the regulation.
21 *See* 21 C.F.R. §1301.74(b). The CSA authorizes the imposition of a civil penalty of up to \$10,000 for
22 each violation of 21 C.F.R. §1301.74(b). *See* 21 U.S.C. §842(a)(5) & (c)(1)(B). The CSA’s
23 requirements are also incorporated into California law. Cal. Bus. & Prof. Code §4301(o).

24
25 ³¹⁸ *Id.*

26 ³¹⁹ *Id.*

27 ³²⁰ *AmerisourceBergen*, Wikipedia, <https://en.wikipedia.org/wiki/AmerisourceBergen>
28 (hereinafter, “*AmerisourceBergen*”) (last visited Dec. 14, 2018); Drug Distribution Locations –
Mainland US, <https://batchgeo.com/map/788de3747b01802c0171abfa8a4b5eca> (last visited Dec. 14,
2018).

1 485. California also imposes independent requirements on distributors, including that all
 2 opioids that are distributed or furnished for sale in the state be distributed or furnished for legitimate
 3 purposes only (Cal. Health & Safety Code §11153.5) and that wholesalers report “all sales of dangerous
 4 drugs subject to abuse” to the Board in excess of amounts it sets (16 C.C.R. §1782). Moreover, effective
 5 January 1, 2018, pharmaceutical wholesalers must notify the Board of suspicious orders placed by a
 6 California-licensed pharmacy or wholesaler. Cal. Bus. & Prof. Code §4169.1.

7 486. In 2012, West Virginia sued AmerisourceBergen and Cardinal Health, as well as several
 8 smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit
 9 and protection, and antitrust laws and the creation of a public nuisance. Unsealed court records from
 10 that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal Health, together
 11 shipped 423 million pain pills to West Virginia between 2007 and 2012.³²¹ AmerisourceBergen itself
 12 shipped 80.3 million hydrocodone pills and 38.4 oxycodone pills during that time period.³²² Moreover,
 13 public documents also demonstrate that the average dose of each tablet distributed grew substantially
 14 during that time period. The Wholesaler Defendants, including AmerisourceBergen, shipped large
 15 quantities of oxycodone and hydrocodone tablets to the state. In 2016, AmerisourceBergen agreed to
 16 settle the West Virginia lawsuit by paying \$16 million to the state, with the funds set aside to fund drug
 17 treatment programs in order to respond to the opioid addiction crisis.

18 FIRST CAUSE OF ACTION

19 **Public Nuisance (in the Name of the People of the State of California)** 20 **Violations of California Civil Code §§3479-3480** 21 **(Against All Defendants)**

22 487. The People incorporate herein by reference all of the allegations in this complaint.

23 488. California Civ. Code §3479 provides that “[a]nything which is injurious to health . . . or
 24 is indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with
 25 the comfortable enjoyment of life or property . . . is a nuisance.”

26 //

27 ³²¹ Eric Eyre, *Drug firms poured 780M painkillers into WV amid rise of overdoses*,
 Charleston Gazette-Mail (Dec. 17, 2016), [http://www.wvgazettemail.com/news-
 health/20161217/drug-firms-poured-780m-painkillers-into-wv-amid-rise-of-overdoses](http://www.wvgazettemail.com/news-health/20161217/drug-firms-poured-780m-painkillers-into-wv-amid-rise-of-overdoses).

28 ³²² *AmerisourceBergen*, *supra* n.320.

1 489. California Civ. Code §3480 defines a “public nuisance” as “one which affects at the same
2 time an entire community or neighborhood, or any considerable number of persons, although the extent
3 of the annoyance or damage inflicted upon individuals may be unequal.”

4 490. California Civ. Proc. Code §731 authorizes the “city attorney of any . . . city in which the
5 nuisance exists” to bring a “civil action . . . in the name of the people of the State of California to abate
6 a public nuisance.”

7 491. A public nuisance cause of action is established where a defendant knowingly created or
8 assisted in the creation of a substantial and unreasonable interference with a public right.

9 492. California Civ. Code §3490 states that “[n]o lapse of time can legalize a public nuisance,
10 amounting to an actual obstruction of public right.”

11 493. Each of the Marketing Defendants acted in a way injurious to the public health and
12 interfered with the comfortable enjoyment of life and property of San Francisco’s residents by, among
13 other things, promoting and marketing the use of prescription opioids for indications not federally
14 approved, circulating false and misleading information concerning prescription opioids’ safety and
15 efficacy and/or downplaying or omitting the risk of addiction and overdose arising from the use of
16 prescription opioids. In so doing, each Marketing Defendant acted with oppression, fraud or malice.

17 494. Each of the defendants unreasonably interfered with the public health, safety, peace and
18 comfort of San Francisco’s residents by failing to design and operate a system that would disclose the
19 existence of suspicious orders of controlled substances or by failing to report suspicious orders of opioids
20 as required by the federal CSA, 21 C.F.R. §1301.74(b), and Cal. Bus. & Prof. Code §§4301 and 4164.
21 In so doing, each defendant acted with oppression, fraud or malice.

22 495. As detailed herein, defendants’ conduct has interfered, and continues to interfere, with
23 rights common to the general public of San Francisco and has caused its residents to sustain injury.

24 496. The People seek costs that will be associated with future efforts to abate the public
25 nuisance caused in whole or in part by defendants, as well as injunctive relief to lessen or prevent the
26 threat of future harm from defendants’ actions.

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1 **SECOND CAUSE OF ACTION**

2 **Public Nuisance (on Behalf of San Francisco)**
3 **Violations of California Civil Code §§3479-3480**
4 **(Against All Defendants)**

4 497. San Francisco incorporates herein by reference all of the allegations in this complaint.

5 498. California Civ. Code §3479 provides that “[a]nything which is injurious to health . . . or
6 is indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with
7 the comfortable enjoyment of life or property . . . is a nuisance.”

8 499. California Civ. Code §3480 defines a “public nuisance” as “one which affects at the same
9 time an entire community or neighborhood, or any considerable number of persons, although the extent
10 of the annoyance or damage inflicted upon individuals may be unequal.”

11 500. A public nuisance cause of action is established where a defendant knowingly created,
12 or assisted in the creation of, a substantial and unreasonable interference with a public right.

13 501. California Civ. Code §3490 states that “[n]o lapse of time can legalize a public nuisance,
14 amounting to an actual obstruction of public right.”

15 502. Under California law damages may be recovered in a public nuisance action brought by
16 a specially injured party.

17 503. Each of the Marketing Defendants acted in a way injurious to the public health and
18 interfered with the comfortable enjoyment of life and property of San Francisco’s residents by, among
19 other things, promoting and marketing the use of prescription opioids for indications not federally
20 approved, circulating false and misleading information concerning prescription opioids’ safety and
21 efficacy and/or downplaying or omitting the risk of addiction and overdose arising from the use of
22 prescription opioids. In so doing, each Marketing Defendant acted with oppression, fraud or malice.

23 504. Each of the defendants unreasonably interfered with the public health, safety, peace and
24 comfort of San Francisco’s residents by failing to design and operate a system that would disclose the
25 existence of suspicious orders of controlled substances or by failing to report suspicious orders of opioids
26 as required by the federal CSA, 21 C.F.R. §1301.74(b), and Cal. Bus. & Prof. Code §§4301 and 4164.
27 In so doing, each defendant acted with oppression, fraud or malice.

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1 by Cal. Bus. & Prof. Code §17500 and certain unfair methods of competition and unfair or deceptive
2 acts prohibited by the CLRA.

3 (a) Each Marketing Defendant circulated false and misleading information
4 concerning, among other things, the safety and efficacy of its prescription opioids and/or prescription
5 opioids generally, and falsely and misleadingly downplayed or omitted the risk of addiction arising from
6 their use. In addition, each Marketing Defendant represented that its prescription opioids and/or
7 prescription opioids in general had characteristics, uses and benefits that they did not have, and
8 disparaged other medications, including NSAIDs, by false and misleading representations of fact.

9 (b) Each defendant failed to design and operate a system to monitor suspicious orders
10 of controlled substances, and failed to disclose such suspicious orders, as required of “registrants” by
11 the federal CSA, 21 C.F.R. §1301.74(b), and Cal. Bus. & Prof. Code §§4301 and 4164. The CSA defines
12 “registrant” as any person who is registered pursuant to 21 U.S.C. §823. 21 C.F.R. §1300.02(b). Section
13 823(a)-(b) requires manufacturers and distributors of controlled substances on Schedule II, including
14 each of the defendants, to register. In addition, each defendant failed to report all sales of dangerous
15 drugs subject to abuse pursuant to 16 C.C.R. §1782.

16 (c) Each Wholesaler Defendant failed to notify the Board in writing of suspicious
17 orders of controlled substances, as required by Cal. Bus. & Prof. Code §4169.1.

18 511. Each defendant’s unlawful, unfair and deceptive acts or practices in violation of the UCL
19 offend California’s public policy, are immoral, unethical, oppressive or unscrupulous, are malicious,
20 wanton and manifest ill will and caused substantial injury to San Francisco and its residents.

21 512. As a direct and proximate result of the foregoing acts and practices, each defendant
22 received income, profits and other benefits that it would not have received if it had not engaged in UCL
23 violations. As a direct and proximate result of the foregoing acts and practices, each defendant has
24 obtained an unfair advantage over similar businesses that have not engaged in such practices. The
25 People seek injunctive relief, restitution and civil penalties as permitted by law for defendants’ UCL
26 violations.

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FOURTH CAUSE OF ACTION

**Violation of False Advertising Law
(By the People of the State of California)
(Cal. Bus. & Prof. Code §17500, *et seq.*)
(Against Marketing Defendants)**

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5 513. The People incorporate herein by reference all of the allegations in this complaint.

6 514. The False Advertising Law, Cal. Bus. & Prof. Code §17500, makes it unlawful for any
7 corporation or employee thereof to make or disseminate, or cause to be made or disseminated, any untrue
8 or misleading statement in connection with the sale of any good or service, when it was known or could
9 have been known by the exercise of reasonable care to be untrue or misleading.

10 515. During the relevant period and as detailed herein, each Marketing Defendant engaged in
11 unlawful, unfair and fraudulent business acts and practices in violation of the False Advertising Law by
12 making untrue and misleading statements in connection with the sale of goods. Each Marketing
13 Defendant circulated false and misleading information concerning, among other things, the safety and
14 efficacy of its prescription opioids and/or prescription opioids generally, and falsely and misleadingly
15 downplayed or omitted the risk of addiction arising from their use. In addition, each Manufacturing
16 Defendant represented that its prescription opioids and/or prescription opioids in general had
17 characteristics, uses and benefits that they did not have, and disparaged other medications, including
18 NSAIDs, by false and misleading representations of fact.

19 516. Each Marketing Defendant's misrepresentations and omissions in connection with the
20 sale of its prescription opioids offend California's public policy, are immoral, unethical, oppressive or
21 unscrupulous, are malicious, wanton and manifest ill will and caused substantial injury to San Francisco
22 and its residents.

23 517. As a direct and proximate result of the foregoing acts and practices, each defendant
24 received income, profits and other benefits that it would not have received if it had not engaged in
25 violations of the False Advertising Law. As a direct and proximate result of the foregoing acts and
26 practices, each defendant has obtained an unfair advantage over similar businesses that have not engaged
27 in such practices. The People seek injunctive relief, restitution and civil penalties as permitted by law
28 for the Marketing Defendants' violations of the False Advertising Law.

FIFTH CAUSE OF ACTION

**Violation of Racketeer Influenced and Corrupt Organizations Act
(on Behalf of San Francisco)
(18 U.S.C. §1962(c)-(d))
(Against All Defendants)**

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5 518. San Francisco incorporates herein by reference all of the allegations in this complaint.

6 519. At all relevant times, defendants have been “person[s]” under 18 U.S.C. §1961(3)
7 because they are capable of holding, and do hold, a “legal or beneficial interest in property.”

8 520. RICO makes it “unlawful for any person employed by or associated with any enterprise
9 engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate,
10 directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering
11 activity.” 18 U.S.C. §1962(c).

12 521. RICO makes it unlawful for “any person to conspire to violate” the provisions of 18
13 U.S.C. §1962(c). 18 U.S.C. §1962(d).

14 522. As alleged herein, at all relevant times, defendants moved aggressively to capture a large
15 portion of the opioid sales market. In so doing, the Marketing Defendants launched an aggressive
16 nationwide campaign over-emphasizing the under-treatment of pain and deceptively marketing opioids
17 as being: (a) rarely, if ever, addictive; (b) safe and effective for the treatment of chronic long-term pain
18 and everyday use; (c) abuse resistant or deterrent; and/or (d) safe and effective for other types of pain
19 for which the drugs were not approved. All defendants knowingly failed to report suspicious orders as
20 required by state and federal law, thereby inundating the market with opioids.

21 523. In particular, defendants, along with other entities and individuals, were employed by or
22 associated with, and conducted or participated in the affairs of, one or several RICO enterprises (the
23 “Opioid Fraud Enterprise”), whose purpose was to deceive opioid prescribers, the public and regulators
24 into believing that: (a) opioids were safe and effective for the treatment of long-term chronic pain;
25 (b) opioids presented minimal risk of addiction; and/or (c) defendants were in compliance with their
26 state and federal reporting obligations. In participating in these enterprises, defendants sought to
27 maximize revenues from the design, manufacture, sale and distribution of opioids which, in fact, were
28

1 highly addictive and often ineffective and dangerous when used for chronic long-term and other types
2 of pain.

3 524. As a direct and proximate result of their fraudulent scheme and common course of
4 conduct, defendants were able to extract billions of dollars of profit. As explained in detail below,
5 defendants' years-long misconduct violated 18 U.S.C. §1962(c)-(d).

6 **A. The Opioid Fraud Enterprise**

7 525. At all relevant times, defendants, along with other individuals and entities, including
8 unknown third parties involved in the marketing and sale of opioids, operated an "enterprise" within the
9 meaning of 18 U.S.C. §1961(4), because they are a group of individuals associated in fact, even though
10 they are not a collective legal entity. The Opioid Fraud Enterprise: (a) existed separately from each of
11 its component entities; (b) existed separately from the pattern of racketeering in which defendants
12 engaged; and (c) constituted an ongoing organization consisting of legal entities, including, but not
13 limited to, the Marketing Defendants, the Wholesaler Defendants, pharmacies, employees and agents of
14 the FSMB, APF, AAPM, APS and APA, as well as other entities and individuals, including physicians.

15 526. Within the Opioid Fraud Enterprise, there was a common communication network by
16 which members exchanged information on a regular basis through the use of wires and mail. The Opioid
17 Fraud Enterprise used this common communication network for the purpose of deceptively marketing,
18 selling and distributing opioids to the general public. When their products, sales, distributions and
19 failure to report suspicious sales were contested by other parties, the Opioid Fraud Enterprise members
20 took action to hide the scheme to continue its existence.

21 527. The participants in the Opioid Fraud Enterprise were systematically linked to each other
22 through corporate ties, contractual relationships, financial ties and the continuing coordination of
23 activities. Through the Opioid Fraud Enterprise, defendants functioned as a continuing unit with the
24 purpose of furthering the illegal scheme and their common purposes of increasing their revenues and
25 market share, and minimizing losses. Each member of the Opioid Fraud Enterprise reaped the bounty
26 generated by the enterprise by sharing the benefit derived from increased sales of opioids and other
27 revenue generated by the scheme to defraud prescribers and consumers and by failing to report
28 suspicious sales in San Francisco.

1 528. The Opioid Fraud Enterprise engaged in and continues to engage in deceptive marketing
2 of opioids as non-addictive, and as safe and effective for chronic long-term pain and for uses that are
3 not FDA-approved. Further, the Opioid Fraud Enterprise continues to not report suspicious sales. The
4 Opioid Fraud Enterprise has engaged in such activity for the purpose of maximizing the sale and profits
5 of opioids. To fulfill this purpose, the Opioid Fraud Enterprise has advocated for, and caused the over-
6 prescription and over-distribution of, opioids by marketing, promoting, advertising and selling opioids
7 throughout the country and across state boundaries and by failing to report suspicious sales. Their
8 receipt of monies from these activities has consequentially affected interstate and foreign commerce.
9 The Opioid Fraud Enterprise's past and ongoing practices thus constitute a pattern of racketeering
10 activity under 18 U.S.C. §1961(5).

11 529. The Opioid Fraud Enterprise functioned by marketing, selling and distributing opioids to
12 states, counties, other municipalities, doctors, healthcare organizations, pharmacies and the consuming
13 public, while failing to report suspicious sales. Through their illegal enterprise, defendants as co-
14 conspirators engaged in a pattern of racketeering activity that involves a fraudulent scheme to increase
15 revenue for defendants and the other entities and individuals associated in fact with the Opioid Fraud
16 Enterprise's activities through the deceptive marketing and sale of opioids and the failure to report
17 suspicious sales.

18 530. Defendants participated in operating and managing the Opioid Fraud Enterprise by
19 directing its affairs as described in this complaint. While defendants participated in, and are members
20 of, the Opioid Fraud Enterprise, they have a separate existence from the Opioid Fraud Enterprise,
21 including distinct legal statuses, different offices and roles, bank accounts, officers, directors,
22 employees, individual personhood, reporting requirements and financial statements.

23 531. Each member of the Opioid Fraud Enterprise furthered the ends of the Opioid Fraud
24 Enterprise through the acts and omissions pled in this complaint.

25 532. Each Marketing Defendant relentlessly promoted opioids to prescribers, regulators and
26 the public as having little to no risk of addiction, and as being safe and effective for the treatment of
27 chronic, long-term pain and other common, everyday uses. The Marketing Defendants' success in
28 maximizing sales was due to the tight collaboration among the Marketing Defendants through, and in

1 collaboration with, the pain foundations – a formidable partnership that marketed to hundreds of
2 thousands of prescribers across the country, including prescribers in San Francisco. The relationship
3 was strengthened, in part, by individuals, including physicians, that held different leadership roles at
4 different times across the various entities participating in the Opioid Fraud Enterprise over the years.

5 533. On numerous occasions, the Marketing Defendants funded the pain foundations’
6 marketing efforts. The Marketing Defendants specifically chose to partner with the pain foundations
7 and individual physicians to publish and otherwise disseminate misleading pro-opioid material, knowing
8 the public and prescribers would be more receptive to statements made by what they perceived to be
9 scholarly, neutral, third-party sources.

10 534. Furthermore, all defendants knowingly failed to design and operate a system to monitor
11 suspicious orders of controlled substances and failed to notify the appropriate DEA field division offices
12 in their areas of suspicious orders, including “orders of unusual size, orders deviating substantially from
13 a normal pattern, and orders of unusual frequency.” 21 C.F.R. §1301.74(b).

14 535. The members of the Opioid Fraud Enterprise worked together to further the enterprise by
15 the following manner and means:

16 (a) jointly planning to deceptively market and manufacture opioids that were
17 purportedly non-addictive, safe and effective for the treatment of chronic long-term pain;

18 (b) concealing the addictive qualities and risks of opioids from prescribers and the
19 public;

20 (c) misleading the public about the addictive nature, safety and efficacy of opioids;

21 (d) otherwise misrepresenting or concealing the highly dangerous nature of opioids
22 from prescribers and the public;

23 (e) illegally marketing, selling and/or distributing opioids;

24 (f) collecting revenues and profits from the sale of such products for uses for which
25 they are unapproved, unsafe or ineffective; and/or

26 (g) failing to report suspicious sales as required by the CSA.

27 536. To achieve their common goals, defendants hid from the general public the full extent of
28 the unsafe and ineffective nature of opioids for chronic and other types of pain as described herein.

1 Defendants suppressed and/or ignored warnings from third parties, whistleblowers and governmental
2 entities about the addictive, unsafe and often ineffective nature of opioids.

3 537. The foregoing allegations support that defendants were part of an association of entities
4 that shared a common purpose, had relationships across various members of the Opioid Fraud Enterprise
5 and collaborated to further the goals of the Opioid Fraud Enterprise for a continuous period of time. The
6 Marketing Defendants knowingly and intentionally engaged in deceptive marketing practices and
7 incentivized pain foundations, marketing firms and physicians to do so as well. Defendants knowingly
8 and intentionally failed to report suspicious orders as required by state and federal law and defendants
9 inundated the market with opioids.

10 **B. Mail and Wire Fraud**

11 538. To attempt to carry out and to carry out the scheme to defraud, defendants, each of whom
12 is a person associated in fact with the Opioid Fraud Enterprise, did knowingly conduct and participate,
13 directly and indirectly, in the conduct of the affairs of the Opioid Fraud Enterprise through a pattern of
14 racketeering activity within the meaning of 18 U.S.C. §§1961(1), 1961(5) and 1962(c). And defendants
15 employed the use of the mail and wire facilities, in violation of 18 U.S.C. §§1341 (mail fraud) and 1343
16 (wire fraud).

17 539. Specifically, defendants have committed, conspired to commit and/or aided and abetted
18 in the commission of at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C.
19 §§1341 and 1343) within the past four years. The multiple acts of racketeering activity which defendants
20 committed, or aided and abetted in the commission of, were related to each other and also posed a threat
21 of continued racketeering activity. They therefore constitute a “pattern of racketeering activity.” The
22 racketeering activity was made possible by defendants’ regular use of the facilities, services, distribution
23 channels and employees of the Opioid Fraud Enterprise. Defendants participated in the scheme to
24 defraud by using the mail, telephone and Internet to transmit mailings and wires in interstate or foreign
25 commerce.

26 540. In devising and executing the illegal scheme, defendants devised and knowingly carried
27 out a material scheme and/or artifice to defraud regulators, prescribers and the public to obtain money
28 from San Francisco by means of materially false or fraudulent pretenses, representations, promises or

1 omissions of material facts. For the purpose of executing the illegal scheme, defendants committed
2 these racketeering acts intentionally and knowingly with the specific intent to advance the illegal
3 scheme.

4 541. Defendants' predicate acts of racketeering, 18 U.S.C. §1961(1), include:

5 (a) Mail Fraud: Defendants violated 18 U.S.C. §1341 by sending and receiving, and
6 by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the
7 purpose of executing the unlawful scheme to deceptively market, sell and distribute the opioids by means
8 of false pretenses, misrepresentations, promises and omissions; and

9 (b) Wire Fraud: Defendants violated 18 U.S.C. §1343 by transmitting and/or
10 receiving, and by causing to be transmitted and/or received, materials by wire for the purpose of
11 executing the unlawful scheme to defraud and obtain money on misrepresentations and false pretenses,
12 promises and omissions.

13 542. Defendants' use of the mails and wires include, but are not limited to, the transmission,
14 delivery and shipment of deceptive marketing materials, the filling of suspicious orders, and the
15 misleading of regulators and the public as to defendants' compliance with state and federal reporting
16 obligations. These materials would not have been delivered, orders would not have been filled and
17 regulators would have not been misled but for defendants' illegal scheme, including:

18 (a) the FSMB's publication of opioid prescribing guidelines titled, "Responsible
19 Opioid Prescribing: A Physician's Guide," by Fishman;

20 (b) the FSMB's publication of "Responsible Opioid Prescribing: A Clinician's Guide
21 (Second Edition, Revised and Expanded)," by Fishman;

22 (c) the APF's publication of Exit Wounds;

23 (d) the AAPM's "consensus statement" and educational programs featuring Fine;

24 (e) the APA's publication and dissemination of "Prescription Pain Medication:
25 Preserving Patient Access While Curbing Abuse";

26 (f) false or misleading communications to the public and to regulators;

27 (g) failing to report suspicious orders as required by state and federal law;

28 //

1 (h) sales and marketing materials, including slide decks, presentation materials,
2 purported guidelines, advertising, web sites, product packaging, brochures, labeling and other writings
3 which misrepresented, falsely promoted and concealed the true nature of opioids;

4 (i) documents intended to facilitate the manufacture and sale of opioids, including
5 bills of lading, invoices, shipping records, reports and correspondence;

6 (j) documents to process and receive payment for opioids, including invoices and
7 receipts;

8 (k) payments to the foundations and physicians that deceptively marketed the
9 Marketing Defendants' opioids;

10 (l) deposits of proceeds; and

11 (m) other documents and things, including electronic communications.

12 543. Defendants also used the Internet and other electronic facilities to carry out the scheme
13 and conceal the ongoing fraudulent activities. For example, the Marketing Defendants made
14 misrepresentations about opioids on their websites, YouTube and through online ads, all of which were
15 intended to mislead prescribers and the public about the safety, efficacy and non-addictiveness of
16 opioids.

17 544. Defendants also communicated by U.S. mail, by interstate facsimile and by interstate
18 electronic mail with various affiliates, regional offices, divisions, distributors, regulators and other third-
19 party entities in furtherance of the scheme. The mail and wire transmissions described in this complaint
20 were made in furtherance of defendants' scheme and common course of conduct to deceive prescribers,
21 consumers and regulators, oversupply the market and fail to report suspicious sales.

22 545. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire
23 facilities have been concealed from San Francisco, and they cannot be alleged without access to
24 defendants' books and records. However, San Francisco has described the types of predicate acts of
25 mail and/or wire fraud that occurred. The secretive nature of the Opioid Fraud Enterprise's activities
26 made the unlawful tactics discussed in this complaint even more deceptive and harmful.

27 546. The foregoing allegations support that: (a) the Marketing Defendants engaged in a pattern
28 of racketeering activity by repeatedly engaging in wire and mail fraud to deceptively market their

1 products through the use of both print and electronic outlets; and (b) all defendants engaged in a pattern
2 of racketeering activity by repeatedly engaging in wire and mail fraud to deceive regulators and
3 oversupply the market while failing to report suspicious sales.

4 **C. Conspiracy Allegations**

5 547. Defendants have not undertaken the practices described herein in isolation, but as part of
6 a common scheme and conspiracy. In violation of 18 U.S.C. §1962(d) defendants conspired to violate
7 18 U.S.C. §1962(c), as described in this complaint.

8 548. Defendants conspired to incentivize and encourage various other persons, firms and
9 corporations, including third-party entities and individuals not named as defendants in this complaint,
10 to carry out offenses and other acts in furtherance of the conspiracy. Defendants conspired to increase
11 or maintain revenues, increase market share and/or minimize losses for defendants and their other
12 collaborators throughout the illegal scheme and common course of conduct. In order to achieve this
13 goal, defendants engaged in the aforementioned predicate acts on numerous occasions. Defendants,
14 with knowledge and intent, agreed to the overall objectives of the conspiracy and participated in the
15 common course of conduct to commit acts of fraud and indecency in defectively marketing and/or selling
16 opioids through the use of mail and wire fraud.

17 549. Indeed, for the conspiracy to succeed, each defendant had to agree to deceptively market,
18 sell and/or distribute opioids while failing to report suspicious sales. The unanimity of the Marketing
19 Defendants' marketing tactics and all defendants' failure to report suspicious sales gave credence to
20 their misleading statements and omissions to prescribers, consumers and regulators, and directly caused
21 opioids to inundate the market in San Francisco.

22 550. Defendants knew and intended that government regulators, prescribers, consumers and
23 governmental entities, including San Francisco, would rely on the collective material misrepresentations
24 and omissions made by them and the other Opioid Fraud Enterprise members about opioids and
25 suspicious sales. Defendants knew and recklessly disregarded the cost that would be suffered by the
26 public, including San Francisco.

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1 551. The Marketing Defendants knew that by partnering with the pain foundations and
2 individual physicians who carried a more neutral public image, they would be able to attribute more
3 scientific credibility to their products, thereby increasing their sales and profits.

4 552. Defendants also knew that by filling, and failing to report, suspicious sales, they would
5 significantly increase their sales and profits.

6 553. The foregoing illustrates defendants' liability under 18 U.S.C. §1962(d), by engaging in
7 their pattern of racketeering and conspiring to achieve their common goal of maximizing opioid sales.

8 554. As described herein, defendants engaged in a pattern of related and continuous predicate
9 acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the
10 common purpose of obtaining significant monies and revenues from consumers, based on defendants'
11 misrepresentations and omissions. The predicate acts also had the same or similar results, participants,
12 victims and methods of commission. The predicate acts were related and not isolated events. The
13 predicate acts all had the purpose of generating significant revenue and profits for defendants. The
14 predicate acts were committed or caused to be committed by defendants through their participation in
15 the Opioid Fraud Enterprise and in furtherance of their fraudulent scheme.

16 555. As alleged in this complaint, scores of counties and municipalities, including San
17 Francisco, relied on defendants' representations and omissions.

18 556. San Francisco's injuries were directly proximately caused by defendants' racketeering
19 activity. But for defendants' misstatements and omissions – and the scheme employed by the Opioid
20 Fraud Enterprise – San Francisco would not have been forced to bear the costs of the current opioid
21 epidemic.

22 557. As a direct and proximate result of each defendant's conduct and its pattern of
23 racketeering activity, San Francisco has been injured.

24 558. Defendants' violations of 18 U.S.C. §1962(c)-(d) have directly and proximately caused
25 injuries and damages to San Francisco, and San Francisco is entitled to bring this action for three times
26 its actual damages, as well as injunctive/equitable relief, costs and reasonable attorneys' fees in
27 accordance with 18 U.S.C. §1964(c).

28 //

SIXTH CAUSE OF ACTION

**Negligence
(on Behalf of San Francisco)
(Against All Defendants)**

559. San Francisco incorporates herein by reference all of the allegations in this complaint.

560. Negligence is established where the defendant owes the plaintiff a duty of care, breaches that duty and the plaintiff sustains harm proximately caused by the defendant's breach. A presumption of negligence (*negligence per se*) is established where a defendant's negligence involves the violation of a statute or regulation, where plaintiff is within the class of persons that the statute or regulation was designed to protect and the violation is a substantial factor in the plaintiff's harm.

561. Each of the Marketing Defendants owed San Francisco duties under statutory and common law, including: (a) the duty to comply with Cal. Bus. & Prof. Code §17200, *et seq.*'s prohibition on unlawful, unfair or fraudulent business acts or practices, Cal. Bus. & Prof. Code §17500, *et seq.*'s prohibition on the dissemination of untrue and misleading statements and the CLRA; (b) the duty to promote and market prescription opioids truthfully and without misleading statements and omissions; and (c) the duty to disclose the true risk of addiction associated with the use of prescription opioids.

562. Each of the Marketing Defendants breached these duties by, among other things, promoting and marketing the use of opioids in San Francisco for indications not federally approved, circulating false and misleading information to prescribers, regulators and the public in San Francisco concerning its products and downplaying or omitting the risk of addiction arising from their use.

563. Each of the defendants owed San Francisco duties under statutory and common law, including: (a) the duty not to fill suspicious or excessive orders; (b) the duty to abide by any government agreements entered into regarding the same; and (c) the duty to comply with the federal CSA, 21 C.F.R. §1301.74(b) and 16 C.C.R. §1782, as set forth above, and Cal. Bus. & Prof. Code §§4301 and 4164, which required the design and operation of a system to detect and disclose suspicious orders of controlled substances.

564. Each of the defendants breached these duties by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances in San Francisco and/or

1 by failing to report such suspicious orders to the appropriate regulators as required by state and federal
2 law.

3 565. Each of the Wholesaler Defendants owed San Francisco additional duties under statutory
4 law, including: (a) the duty under Cal. Health & Safety Code §11153.5 to ensure that all of the opioids
5 they distributed and furnished for sale in California and its counties were furnished only for legitimate
6 medical purposes; and (b) the duty under Cal. Bus. & Prof. Code §4169.1, which requires them to report
7 suspicious orders of opioids.

8 566. Each Wholesaler Defendant breached these duties by failing to take any reasonable
9 measures to ensure that the prescription opioids it distributed and furnished for sale in San Francisco
10 were furnished only for legitimate medical purposes and by failing to track and report suspicious sales.

11 567. San Francisco was within the protected class of persons that the UCL, the CLRA, Cal.
12 Bus. & Prof. Code §§4301, 4164 and 17500, 21 C.F.R. §1301.74(b), Cal. Health & Safety Code
13 §11153.5 and 16 C.C.R. §1782 were designed to protect.

14 568. San Francisco has suffered damages directly, proximately and foreseeably caused by
15 defendants' breaches of their statutory and common law duties.

16 569. Defendants' negligent acts as set forth herein were made with oppression, fraud or
17 malice.

18 SEVENTH CAUSE OF ACTION

19 Negligent Misrepresentation 20 (on Behalf of San Francisco) (Against the Marketing Defendants)

21 570. San Francisco incorporates herein by reference all of the allegations in this complaint.

22 571. A defendant is liable for negligent misrepresentation where, in the course of its business,
23 profession or employment, or in any other transaction in which it has a pecuniary interest, it supplies
24 false information for the guidance of others in their business transactions and where the defendant fails
25 to exercise reasonable care or competence in obtaining or communicating the false information at issue.

26 572. The Marketing Defendants are liable for the pecuniary loss caused to San Francisco by
27 its justifiable reliance upon the information. In the course of their businesses, each Marketing Defendant
28 made and caused to be made affirmatively false statements about prescription opioids, including, but

1 not limited to, statements and omissions concerning the safety and efficacy of prescription opioids and
2 the risk of addiction and overdose associated therewith. Each Marketing Defendant failed to exercise
3 reasonable care and competence in communicating the false information.

4 573. Each Marketing Defendant wrongfully concealed the falsity of its statements, the truth
5 about which San Francisco did not discover until recently despite exercising due diligence. San
6 Francisco, San Francisco's agents, persons on whom San Francisco and its agents justifiably relied and
7 the public justifiably relied on the false information the Marketing Defendants provided, both directly
8 and indirectly. As a result, San Francisco proceeded under the misapprehension that the opioid crisis
9 was a result of conduct by persons other than defendants. As a result, San Francisco was prevented from
10 taking more effective and earlier steps to respond to the opioid crisis.

11 574. Had San Francisco known the truth about the concealed facts, San Francisco would have
12 taken steps to correct the false and misleading information and also would not have authorized and paid
13 for certain prescription opioid treatments for its employees and inhabitants.

14 575. Each Marketing Defendant's dissemination of false statements demonstrated a conscious
15 disregard for the rights and safety of other persons that had a great probability of causing substantial
16 harm.

17 576. As a direct and proximate result of the Marketing Defendants' affirmatively false
18 statements, San Francisco suffered damages.

19 **EIGHTH CAUSE OF ACTION**
20 **Fraudulent Concealment**
21 **(on Behalf of San Francisco)**
22 **(Against the Marketing Defendants)**

23 577. San Francisco incorporates herein by reference all of the allegations in this complaint.

24 578. At all times relevant, each Marketing Defendant concealed and intentionally failed to
25 disclose material facts known to it including that: (a) there was no basis for making claims as to
26 prescription opioids' safety or efficacy for the treatment of certain indications for which each Marketing
27 Defendant promoted them; and (b) there was no basis for its representations concerning the risk of
28 addiction and overdose resulting from the use of prescription opioids, which each Marketing Defendant
substantially understated.

1 herein, including restitution, disgorgement of unjust enrichment, exemplary damages, punitive damages
2 and attorneys' fees;

3 E. Award civil penalties of up to \$2,500 per violation to The People of the State of California
4 as permitted by law under Cal. Bus. & Prof. Code §§17204 and 17536;

5 F. Award treble damages, as well as costs and reasonable attorneys' fees, in accordance
6 with 18 U.S.C. §1964(c); and

7 G. Award any such further relief as this Court deems appropriate.

8 **JURY DEMAND**

9 Plaintiffs hereby demand trial by jury on all claims so triable.

10 DATED: December 18, 2018

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