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**SUPERIOR COURT OF CALIFORNIA
CITY AND COUNTY OF SAN FRANCISCO**

17 **COUNTY OF SAN MATEO,**

18
19
20 Plaintiff,

21 v.

22 **McKESSON CORPORATION;**
23 **CARDINAL HEALTH, INC.;**
24 **AMERISOURCEBERGEN CORPORATION;**
25 **and,**
DOES 1-10.

26 Defendants.
27
28

**ENDORSED
FILED**
San Francisco County Superior Court

JUN 20 2018

CLERK OF THE COURT
KALENE APOLONIO
BY: Deputy Clerk

CASE NO: **CGC-18-567403**

COMPLAINT:

1. PUBLIC NUISANCE;
2. UNFAIR BUSINESS PRACTICES;
3. NEGLIGENCE; and,
4. VIOLATION OF THE CALIFORNIA FALSE ADVERTISING LAW

DEMAND FOR JURY TRIAL

COMPLAINT

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1 1. County of San Mateo (“Plaintiff” or “San Mateo”) hereby brings this action for
2 damages and relief against McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen
3 Corporation (collectively “Defendants” or “Defendant Distributors”) for violations of California
4 state law. Defendants are all distributors of opioid pharmaceuticals.

5 **I. INTRODUCTION**

6 2. San Mateo County has seen an incredible increase in deaths from opioids in the past
7 few years. Like other counties, across the United States, San Mateo County now spends millions of
8 dollars each year dealing with the fallout of the opioid epidemic. San Mateo’s on-going costs
9 include extra expenditures related to drug treatment, emergency room visits, law enforcement, and
10 social services (including for children born opioid-dependent and/or who have parents unable to
11 care for them because of their own respective addictions).



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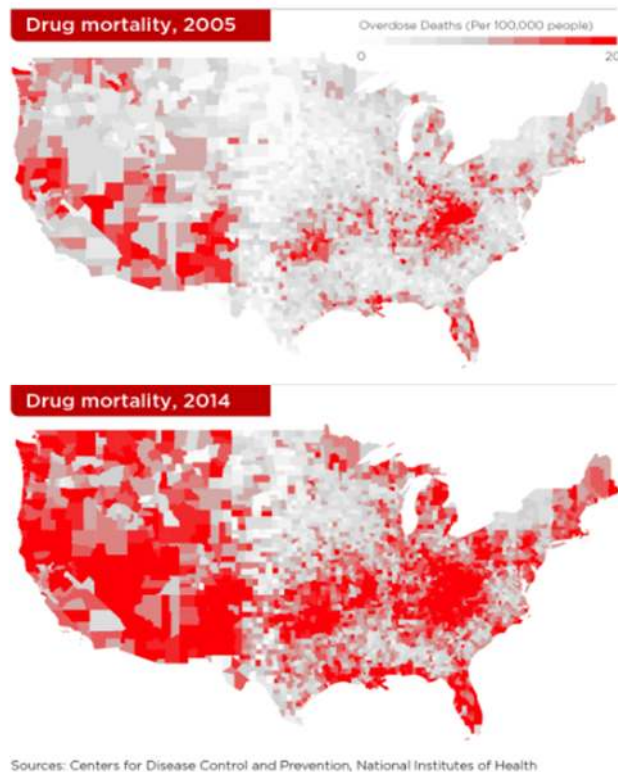
¹ Edith Cabuslay, *Opioids*, SMC HEALTH (2017), available at https://www.smchealth.org/sites/main/files/file-attachments/opioids101_presetnation_slides_2of2.pdf (Last Accessed June 13, 2018).

1 3. More than 200,000 people have died in the United States from overdoses involving
2 prescription opioids in the past twenty years. However, this figure tells only part of the story:
3 Prescription opioid abuse has fueled an ever-growing wildfire of illicit drug abuse in San Mateo
4 County. In particular, illegal opioid compounds directly related to the Opioid Crisis, such as heroin
5 and counterfeit forms of fentanyl, are widely abused, adding to the problem.

6 4. According to the most recent data available, **97 San Mateo County residents died**
7 **in 2017** from drug related causes, with **11 deaths directly tied to heroin use and another 26**
8 **deaths directly tied to other opioids**. In 2016, **San Mateo County saw 61 drug-related deaths**,
9 with 11 tied to heroin and 16 tied to other opioids. Between 2010 and 2014, opioids accounted for
10 **almost half of all filled scheduled drug prescriptions**. In 2015 there were an estimated **hundreds**
11 **of thousands of opioid prescriptions** filled in San Mateo County, a figure that has gone up each
12 year since then. County health officials estimate that thousands of residents are opioid dependent.

13 5. According to recent data from the Centers for Disease Control and Prevention
14 (“CDC”), “[a]n in-depth analysis of 2016 United States drug overdose data shows that America’s
15 overdose epidemic is spreading geographically and increasing across demographic groups.”² Drug
16 overdoses killed over 63,000 Americans in 2016. Approximately two-thirds of these deaths (66%)
17 involved a prescription opioid or an illicit opioid. Overdose deaths followed no clear demographic
18 pattern, and saw increased levels in both men and women, all races and ethnicities, and across all
19 levels of urbanization.

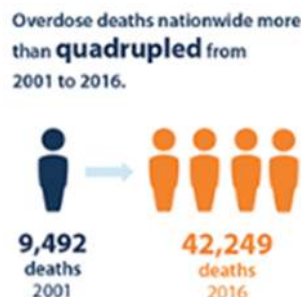
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27 ² *United States. Drug Overdose Deaths Continue to Rise; Increase Fueled by Synthetic Opioids*,
28 CENTER FOR DISEASE CONTROL AND PREVENTION (2018), available at
<https://www.cdc.gov/media/releases/2018/p0329-drug-overdose-deaths.html> (Last Accessed June 4, 2018).



6. According to the CDC's most recent analysis, released on March 29, 2018 and based on national 2015-2016 data:

- Overall drug *overdose death rates increased by 21.5 percent*;
- The overdose death rate from synthetic opioids (other than methadone) more than doubled, likely driven by illicitly manufactured fentanyl;
- The *prescription opioid-related overdose death rate increased by 10.6 percent*;
- The heroin-related overdose death rate increased by 19.5 percent.

7. The number of opioid prescriptions and the number of opioid deaths are directly and strongly correlated. Since 1999, opioid overdose deaths and the amount of prescription opioids sold has nearly quadrupled.³



³ CDC Wonder, CDC (2018), available at <https://wonder.cdc.gov/> (Last Accessed June 4, 2018).

1 8. Opioid manufacturers rely upon Defendants to distribute their drugs into the drug
2 economy. These distributors serve as middlemen, sending billions of doses of opioid pain pills to
3 pharmacists, hospitals, nursing homes and pain clinics, many in San Mateo County. Responsibility
4 for the crisis lies at the feet of the Defendant Distributors who are reaping billions of dollars in
5 profits while knowingly fueling the epidemic. In short, distributors and manufacturers are co-
6 conspirators who have engaged in a host of illegal, unfair and fraudulent practices prohibited under
7 California law and have caused a public nuisance under the law.

8 9. Defendants **McKesson, Cardinal** and **AmerisourceBergen** are the “Big Three”
9 distributors of pharmaceuticals, including legal opioids, in the United States, collectively
10 controlling approximately 89% of the market. The Big Three Defendant Distributors are some of
11 the largest companies in the United States, yet few outside of the healthcare industry know their
12 names. For example, **McKesson, headquartered in San Francisco, is the second largest**
13 **company in California by revenue** and the fifth largest in the United States. McKesson’s
14 revenue last year was close to \$200 billion.

15 10. The unnamed co-conspirators are the Pharmacy Services Administrative
16 Organizations (“PSAO”) **McKesson Access Health, Cardinal LeaderNET**, and
17 **AmerisourceBergen Elevate Provider Network**, the subsidiaries of the “Big Three” distributors.
18 PSAOs serve as middlemen between small and independent pharmacies and Pharmacy Benefit
19 Managers (“PMB”) and other entities. Like distributors, PSAOs have access to information that
20 would allow them to track and flag suspicious orders and report directly to their parent companies.

21 11. The manufacturers of opioids are likewise unnamed co-conspirators for their role in
22 the epidemic. This litigation is focused solely on the companies that distribute opioids. Distributors
23 are required by law to report suspicious orders and patterns of orders of opioids but have instead
24 turned a blind eye, choosing to benefit from the opioid epidemic to the tune of billions of dollars of
25 profits. Practically speaking, little difference exists between Defendant Distributors and street-
26 corner drug dealers.



12. The current opioid epidemic traces its roots back to 1996 when pharmaceutical company Purdue Pharma released OxyContin and started heavy marketing.⁴⁵ That same year, the American Pain Society dubbed pain as “the Fifth Vital Sign.”⁶ This phrase entered the lexicon through the keynote address at the American Pain Society’s 1996 annual conference in Los Angeles. The group went on to trademark the slogan: “Pain: The Fifth Vital Sign.” Purdue was a sponsor of the American Pain Society. Within two decades, overdose deaths would exceed the national peaks of gun deaths (occurred in 1993), AIDS deaths (1995), and car crash deaths (1972).⁷ Sadly, no peak for this epidemic is currently in sight.

13. Big Pharma was behind efforts to recognize pain as the “fifth vital sign” and Big Pharma, including the Big Three Distributors, has been behind efforts to curb the effectiveness of the United States Drug Enforcement Administration’s (DEA) efforts to stem illegal opioid prescriptions.












⁴ Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, AM. J. PUBLIC HEALTH, Feb. 2009, at 99(2): 221–227, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/> (Last Accessed June 4, 2018).

⁵ Barry Meier, *Pain Killer: An Empire of Deceit and the Origin of America’s Opioid Epidemic* (Random House, 2nd ed. 2018, p. xi).

⁶ *Pain: Current Understanding of Assessment, Management, and Treatments*, NATIONAL PHARMACEUTICAL COUNCIL (Dec. 2001) at 16-17, available at <http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf> (Last Accessed June 4, 2018).

⁷ Josh Katz, *Drug Deaths in America Are Rising Faster Than Ever*, N.Y. TIMES (Jun. 5, 2017), available at <https://www.nytimes.com/interactive/2017/06/05/upshot/opioid-epidemic-drug-overdose-deaths-are-rising-faster-than-ever.html?auth=login-smartlock> (Last Accessed June 4, 2018).

14. Soon after development of the “Fifth Vital Sign” campaign, pharmaceutical industry front groups began heavily promoting the now familiar 0-10 pain scale and began judging hospitals based on patient satisfaction with pain treatment.⁸

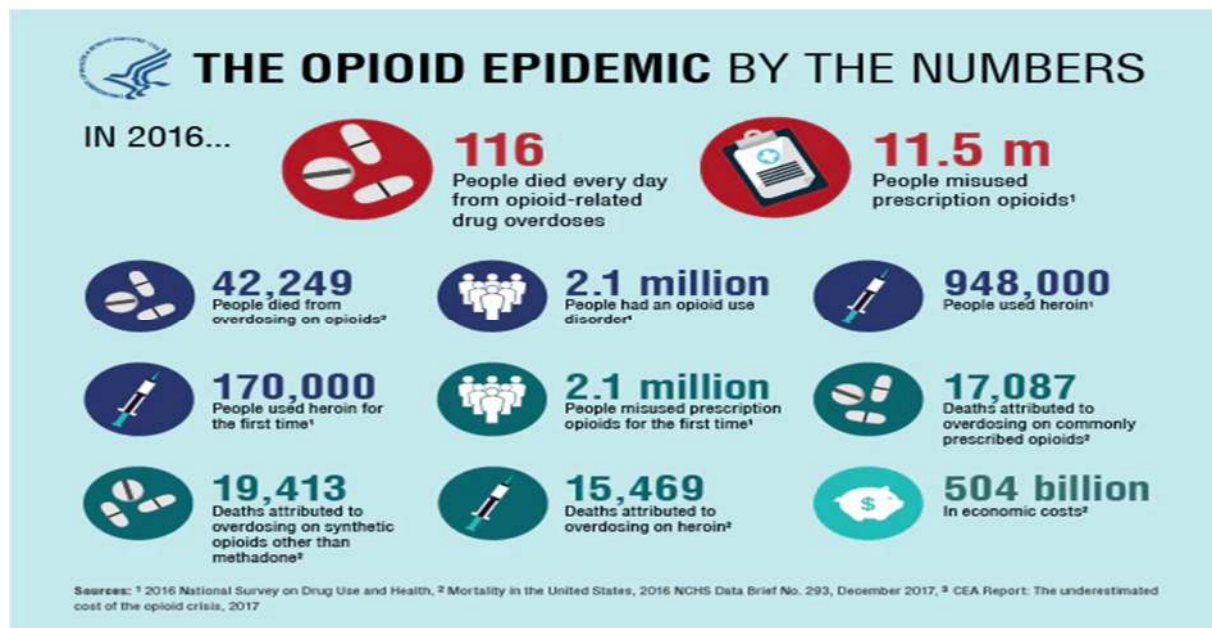
COMPARATIVE PAIN SCALE CHART (Pain Assessment Tool)										
										
0 Pain Free	1 Very Mild	2 Discomforting	3 Tolerable	4 Distressing	5 Very Distressing	6 Intense	7 Very Intense	8 Utterly Horrible	9 Excruciating Unbearable	10 Unimaginable Unspeaking
No Pain	Minor Pain			Moderate Pain			Severe Pain			
Feeling perfectly normal	Nagging, annoying, but doesn't interfere with most daily living activities. Patient able to adapt to pain psychologically and with medication or devices such as cushions.			Interferes significantly with daily living activities. Requires lifestyle changes but patient remains independent. Patient unable to adapt pain.			Disabling; unable to perform daily living activities. Unable to engage in normal activities. Patient is disabled and unable to function independently.			

15. Nationally, more than three out of five overdose deaths involve opioids⁹ — a dangerous, highly addictive and often lethal class of natural, synthetic and semi-synthetic painkillers. Prescription opioids include brand-name medications like OxyContin, Opana, Subsys, Fentora and Duragesic, as well as generic drugs like oxycodone, methadone and fentanyl. In all, more than 200,000 people died in the United States between 1999 and 2016 from overdoses directly related to prescription opioids.¹⁰ This number does not take into account the staggering number of additional illicit opioid deaths that can be related back to doctor-prescribed opioids; indeed, four out of five new heroin users began with prescription opioid misuse, which subsequently led to heroin use. The crisis has become so severe that “[o]n an average day in 2016, 175 people died of an overdose, a rate of seven fatalities an hour.”

⁸ Julia Lurie, *A Brief, Blood-Boiling History of the Opioid Epidemic*, MOTHER JONES (Feb. 2017), available at <https://www.motherjones.com/crime-justice/2017/12/a-brief-blood-boiling-history-of-the-opioid-epidemic/> (Last Accessed June 4, 2018).

⁹ *Opioid Overdose*, CDC (2017), available at <https://www.cdc.gov/drugoverdose/data/index.html> (last accessed June 8, 2018); Holly Hedegaard, Margaret Warner and Arialdi M. Miniño, *NCHS Data Brief No. 294: Drug Overdose Deaths in the United States, 1999-2016*, CDC (2017), available at <https://www.cdc.gov/nchs/data/databriefs/db294.pdf> (Last Accessed June 4, 2018).

¹⁰ Christopher M. Jones, *Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers — United States, 2002-2004 and 2008-2010*, 132 (1-2) DRUG AND ALCOHOL DEPENDENCE 95-100 (2013), available at [http://www.drugandalcoholdependence.com/article/S0376-8716\(13\)00019-7/fulltext](http://www.drugandalcoholdependence.com/article/S0376-8716(13)00019-7/fulltext) (Last Accessed June 4, 2018).



16. Further, according to Robert Anderson ("Anderson"), Chief of the Mortality Statistics Branch of the National Center for Health Statistics, deaths from synthetic opioids have undergone "more than an exponential increase," with an expected trend line for 2017 deaths that "will be at least as steep as 2016, if not steeper."¹² Between 2005 and 2016, fatal overdoses from synthetic opioids doubled. This surge in overdose deaths resulted in the first two-year drop in average United States life expectancy since the early 1960s.¹³

17. Defendant Distributors distribute prescription opioids, including brand-name drugs like OxyContin and Percocet, and generic equivalents like oxycodone and hydrocodone, all of which are narcotic painkillers, to doctors and hospitals in San Mateo County.

18. In the late 1990s, the many un-named co-conspirator opioid manufacturers began a sophisticated marketing scheme premised on deception to persuade doctors and patients that

¹¹ *Sessions unveils new task force targeting opioid manufacturers, distributors* DAILY NEWS (Feb. 28, 2018), available at <https://www.studentnewsdaily.com/daily-news-article/sessions-unveils-new-task-force-targeting-opioid-manufacturers-distributors/> (Last Accessed June 13, 2018).

¹² Christopher Ingraham, *CDC releases grim new opioid overdose figures: 'We're talking about more than an exponential increase'*, WASH POST (Dec. 21, 2017), available at 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/?noredirect=on&utm_term=.7bcf3b709d68 (Last Accessed June 4, 2018).

¹³ Rob Stein, *Life Expectancy Drops Again As Opioid Deaths Surge In United States*, NPR (December 21, 2017), available at <https://www.npr.org/sections/health-shots/2017/12/21/572080314/life-expectancy-drops-again-as-opioid-deaths-surge-in-u-s> (Last Accessed June 4, 2018).

1 opioids can and should be used to treat chronic pain. The manufacturers spent, and some continue
2 to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize
3 the risks of opioids and overstate the benefits of opioids. As to the risks, manufacturers falsely and
4 misleadingly: (1) downplayed the serious risk of addiction; (2) promoted the concept of
5 "pseudoaddiction," claiming that the signs of addiction should be treated with more opioids;
6 (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid
7 dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and
8 (6) exaggerated the effectiveness of abuse-deterrent opioid formulations to prevent abuse and
9 addiction. Manufacturers also falsely touted the benefits of long-term opioid use, including its
10 supposed ability to improve function and quality of life, even though there was no "good evidence"
11 to support those benefits.

12 19. Each of the Defendant Distributors was aware of the misinformation being
13 disseminated by the manufacturers and took active steps to assist the manufacturers. The Defendant
14 Distributors knowingly supplied dangerous quantities of opioids while advocating for limited
15 government oversight and enforcement. Defendants refused or failed to identify, investigate, or report
16 suspicious orders of opioids to the authorities. Even when the Defendant Distributors had actual
17 knowledge that they were distributing opioids to drug diversion rings, they refused or failed to report
18 these sales.

19 20. By not reporting suspicious opioid orders or known diversions of prescription opioids,
20 not only were the Defendants able to continue to sell opioids to questionable customers, Defendants
21 ensured that the DEA had no basis for decreasing or refusing to increase production quotas for
22 prescription opioids.

23 21. The Defendant Distributors collaborated with each other and with opioid manufacturers
24 to maintain distribution of excessive amounts of opioids.

25 22. The explosion in opioid prescriptions and use caused by Defendants has led to a
26 public health crisis, including in San Mateo County. The County and California face skyrocketing
27 opioid addiction and opioid-related overdoses and deaths as well as devastating social and
28 economic consequences stemming from these issues. This public health crisis is a public nuisance

1 because it "is injurious to health" and interferes "with the comfortable enjoyment of life and
2 property" (Civ. Code, § 3479) and because it affects "entire communit[ies]" and "neighborhood[s]"
3 and "any considerable number of persons" (Civ. Code, § 3480). The effects of each Defendant's
4 distribution scheme are catastrophic and only getting worse.¹⁴

5 23. There is little doubt that each Defendant's actions has precipitated this public health
6 crisis in California, including in San Mateo County, by dramatically increasing opioid
7 prescriptions and use. An unchecked supply of prescription opioids has provided a source for the
8 illicit use or sale of opioids, while the widespread use of opioids has created a population of
9 patients physically and psychologically dependent on them. When those patients can no longer
10 afford or legitimately obtain opioids, they often turn to street-level dealers to buy prescription
11 opioids or even heroin to satisfy their needs, resulting in detriments to both health (including
12 through the potential ingestion of impure stock) and law enforcement (through crime related to
13 street-level drug dealers and attempts to obtain illegal drugs).

14 24. Absent each Defendant's willingness to pump billions of opioid pills into the public,
15 opioid prescribing, use, misuse, abuse, and addiction, would not have become so widespread, and
16 the opioid epidemic that now exists would have been averted or, at the very least, much less
17 severe.

18 25. Defendants have created or assisted in the creation of a public nuisance.¹⁵ Every act
19 of malfeasance committed by each Defendant since the late 1990s subjects the Defendant to
20 liability for public nuisance because there is no statute of limitations for a public nuisance claim.
21 (See Civ. Code, § 3490 ["No lapse of time can legalize a public nuisance, amounting to an actual
22 obstruction of public right"]; *Wade v. Campbell* (1962) 200 Cal.App.2d 54, 61 ["the maintenance
23 of a public nuisance may not be defended on the ground of laches or the statute of limitations"].)

24 ¹⁴ *Califf, FDA top officials call for sweeping review of agency opioids policies*, FDA News
25 Release (Feb. 4, 2016), available at
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm>.

26 ¹⁵ See *County of Santa Clara v. Atlantic Richfield Co.* (2006) 137 Cal.App.4th 292, 306
27 [holding that plaintiffs "have adequately alleged that defendants are liable for the abatement of this
28 public nuisance" by alleging that defendants "promot[ed] lead paint for interior use even though
defendants knew for nearly a century that such a use of lead paint was hazardous to human
beings"].

26. Defendants' conduct, both individually and collectively, has violated and continues to violate the Public Nuisance Law, Civ. Code, §§ 3479 and 3480, the Unfair Competition Law, Bus. & Prof. Code, §§ 17200 *et seq.*, and the False Advertising Law, Bus. & Prof. Code, §§ 17500 *et seq.*

27. This Court has personal jurisdiction over all of the Defendants by virtue of their business activities in this jurisdiction. All of the Defendants conduct substantial business within the State of California and the County of San Mateo.

II. PARTIES

A. PLAINTIFF

28. Plaintiff County of San Mateo (“the County”) is a county and a political subdivision of the State of California. San Mateo is the 14th most populous county in California, with a population of more than 770,000 residents. San Mateo is home to a number of significant venues in Northern California, including the San Mateo County Expo Center, the South San Francisco Expo Center, the Cow Palace, and numerous Silicon Valley companies.

29. Plaintiff brings this action to recover damages and to protect the residents of San Mateo County from a public nuisance, and unlawful, unfair, and fraudulent business practices.

30. Plaintiff, acting by and through John C. Beiers, County Counsel for the County of San Mateo, is authorized to bring the causes of action brought herein. The County is a body corporate and politic of the State of California Cal. Gov't Code § 23003 and is authorized to bring this action. Cal. Gov't Code § 23004(a).

31. The County of San Mateo has responsibility for the public health, safety and welfare of its citizens.

32. Opioid abuse, addiction, morbidity and mortality have created a serious public health and safety crisis, which is a public nuisance, in San Mateo County. Further, the diversion of legally produced controlled substances into the illicit market contributes to this public nuisance.

33. The distribution and diversion of opioids into California, and into San Mateo County and surrounding areas, created the foreseeable opioid crisis and opioid public nuisance for which Plaintiff seeks relief.

1 34. Plaintiff directly and foreseeably sustained all economic damages alleged herein.
2 Categories of past and continuing sustained damages include, *inter alia*: (1) costs for providing
3 medical care, additional therapeutic, and prescription drug purchases, and other treatments for
4 patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2)
5 costs for providing treatment, counseling, and rehabilitation services; (3) costs for providing
6 treatment of infants born with opioid-related medical conditions; (4) costs associated with law
7 enforcement and public safety relating to the opioid epidemic; (5) costs associated with providing
8 care for children whose parents suffer from opioid-related disability or incapacitation and (6) costs
9 associated with the County having to repair and remake its infrastructure, property and systems
10 that have been damaged by Defendants' actions, including, *inter alia*, its property and systems to
11 treat addiction and abuse, to respond to and manage an elevated level of crime, to treat injuries,
12 and to investigate and process deaths in San Mateo County. These damages have been suffered,
13 and continue to be suffered, directly by the County.

14 35. Plaintiff also seeks the means to abate the epidemic created by Defendants'
15 wrongful and/or unlawful conduct.

16 36. Plaintiff has standing to bring an action for the opioid epidemic nuisance created by
17 Defendants. Cal. Civ. Proc. Code § 731 ("A civil action may be brought in the name of the people
18 of the State of California to abate a public nuisance, as defined in Section 3480 of the Civil Code,
19 by the . . . county counsel of any county in which the nuisance exists.").

20 37. The County has standing to bring an action for damages incurred to its property by
21 the public nuisance created by Defendants. Cal. Civ. Proc. Code § 731 ("An action may be brought
22 by any person whose property is injuriously affected, . . . and by the judgment in that action the
23 nuisance may be enjoined or abated as well as damages recovered therefor.").

24 38. The County has standing to bring this claim for civil penalties under the California
25 False Advertising Act Cal. Bus. & Prof. Code § 17536 based on Defendants' aiding and abetting
26 the actions of un-named co-conspirators including the opioid manufactures.

27 39. The County has standing to recover damages incurred as a result of Defendants'
28 actions and omissions. Cal. Gov't Code § 23004(a).

1 **B. DEFENDANTS**

2 40. Defendant **McKesson Corporation** is a Delaware corporation with its headquarters
3 and principal place of business located in San Francisco, California.

4 41. Defendant **Cardinal Health Inc.** is an Ohio corporation with its headquarters and
5 principal place of business located in Dublin, Ohio, and does business in California.

6 42. Defendant **AmerisourceBergen Corporation** is a Delaware corporation with its
7 headquarters and principal place of business located in Chesterbrook, Pennsylvania, and does
8 business in California.

9 **C. DOE DEFENDANTS**

10 43. Plaintiff does not know the true names or capacities, whether individual, corporate
11 or otherwise, of other potential Defendants sued herein under the fictitious names DOES 1 through
12 10 and are therefore sued pursuant to Code of Civil Procedure § 474. Plaintiff will amend this
13 Complaint to show their true names and capacities if and when they are ascertained. Plaintiff is
14 informed and believes, and on such information and belief alleges, that each of the Defendants
15 named as a DOE is responsible in some manner for the events and occurrences alleged in this
16 Complaint and is liable for the relief sought herein.

17 **D. AIDING, ABETTING and CO-CONSPIRATORS**

18 44. Known unnamed co-conspirators include the manufacturers of prescription opioids,
19 including Purdue Pharma L.P.; Purdue Pharma Inc.; Purdue Frederick Company; Purdue
20 Pharmaceuticals Products L.P.; Purdue Products L.P.; Cephalon, Inc.; Teva Pharmaceutical
21 Industries Ltd.; Teva Pharmaceutical USA, Inc.; Endo International Plc; Endo Health Solutions,
22 Inc.; Endo Pharmaceuticals Inc.; Janssen Pharmaceuticals, Inc.; Insys Therapeutics, Inc.;
23 Mallinckrodt Plc; Mallinckrodt LLC; and numerous others.

24 **III. JURISDICTION AND VENUE**

25 45. This Court has jurisdiction over this action. Defendants are engaging in false and
26 misleading advertising and unlawful, unfair, and deceptive business practices, and creating or
27 assisting in the creation of a public nuisance in San Mateo County.

1 46. Venue is proper in this Court because all Defendants transact business in San Mateo
2 County and Defendant McKesson is headquartered in San Francisco. This Court has personal
3 jurisdiction over each defendant as each purposefully availed itself of the privilege of exploiting
4 forum-based business opportunities and the exercise of personal jurisdiction is consistent with Cal.
5 Civ. Proc. § 410.10.

6 **IV. GLOSSARY OF RELEVANT TERMS**

7 47. Plaintiff includes the following glossary of relevant terms, as those terms are used
8 in this Complaint.¹⁶

9 48. **Acute Pain:** Pain that usually starts suddenly and has a known cause, like an injury
10 or surgery. It normally gets better as your body heals and lasts less than three months.

11 49. **Benzodiazepines:** Sometimes called “benzos,” these are sedatives often used to
12 treat anxiety, insomnia, and other conditions. Combining benzodiazepines with opioids increases a
13 person’s risk of overdose and death.

14 50. **Big Pharma:** large pharmaceutical companies, especially as a politically influential
15 group.¹⁷

16 51. **Chronic pain:** Pain that lasts three (3) months or more and can be caused by a
17 disease or condition, injury, medical treatment, inflammation, or even an unknown reason.

18 52. **Drug misuse:** The use of prescription drugs without a prescription or in a manner
19 other than as directed by a doctor, including use without a prescription of one’s own; use in greater
20 amounts, more often, or longer than told to take a drug; or use in any other way not directed by a
21 doctor.

22 53. **Drug abuse or addiction:** Dependence on a legal or illegal drug or medication. *See*
23 Opioid use disorder.

26 ¹⁶ Except as otherwise noted, the terms in this Section are defined in accordance with the
27 definitions adopted by the CDC. *See Opioid Overdose: Commonly Used Terms*, CDC (2017),
available at <https://www.cdc.gov/drugoverdose/opioids/terms.html> (Last Accessed June 4, 2018).

28 ¹⁷ *Definition of Big Pharma*, WEBSTER (2018), available at <https://www.merriam-webster.com/dictionary/Big%20Pharma> (Last Accessed June 4, 2018).

54. **Extended-release/long-acting (ER/LA) opioids:** Slower-acting medication with a longer duration of pain-relieving action.

55. **Fentanyl:** Pharmaceutical fentanyl is a synthetic opioid pain medication, approved for treating severe pain, typically advanced cancer pain. It is 50 to 100 times more potent than morphine. However, illegally made fentanyl is sold through illegal drug markets for its heroin-like effect, and it is often mixed with illegal drugs such as heroin and/or cocaine as a combination product.

56. **Heroin:** An illegal, highly addictive opioid drug processed from morphine.

57. **Illicit drugs:** The non-medical use of a variety of drugs that are prohibited by law. These drugs can include: amphetamine-type stimulants, cocaine, heroin and other opioids, synthetic drugs, and MDMA (ecstasy).

58. **Immediate-release opioids:** Faster-acting medication with a shorter duration of pain-relieving action.

59. **Key-Opinion Leader (“KOL”):** A phrase used by marketing departments of pharmaceutical companies for especially influential physicians they seek to influence.¹⁸

60. **Medication-assisted treatment (MAT):** Treatment for opioid use disorder, combining the use of medications (methadone, buprenorphine, or naltrexone) with counseling and behavioral therapies.

61. **Morphine milligram equivalents (MME):** The number of milligrams of morphine an opioid dose is equal to when prescribed. This is how to calculate the total amount of opioids in a particular dose, accounting for differences in opioid drug type and strength.

62. **Naloxone:** A prescription drug that can reverse the effects of opioid overdose and can be life-saving if administered in time. The drug is sold under the brand name Narcan or Evzio.

¹⁸ Sergio Sismondo, PhD, *How to make opinion leaders and influence people*, 187 (10) CMAJ 759-760 (2015), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4500705/> (Last Accessed June 4, 2018); *see also Fueling an Epidemic: Report Two*, HSGAC (2018), available at <https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20T hird%20Party%20Advocacy%20Groups.pdf> (Last Accessed June 4, 2018).

63. **Narcotic:** Also known as “opioids,” the term “narcotic” comes from the Greek word for “stupor” and originally referred to a variety of substances that dulled the senses and relieved pain. Though some people still refer to all drugs as “narcotics,” today “narcotic” refers to opium, opium derivatives, and their semi-synthetic substitutes.¹⁹ A more current term for these drugs, with less uncertainty regarding its meaning, is “opioid.” Examples include the illicit drug heroin and pharmaceutical drugs like OxyContin®, Vicodin®, codeine, morphine, methadone, and fentanyl.

64. **Nonmedical use:** Taking drugs, whether obtained by prescription or otherwise, not in the way, for the reasons, or during the time period prescribed, or the use of prescription drugs by a person for whom the drug was not prescribed.

65. **Non-opioid therapy:** Methods of managing chronic pain that do not involve opioids. These methods can include, but are not limited to, acetaminophen (Tylenol®) or ibuprofen (Advil®), cognitive behavioral therapy, physical therapy and exercise, medications for depression or for seizures, or interventional therapies (including injections).

66. **Non-pharmacologic therapy:** Treatments that do not involve medications, including physical treatments (e.g., exercise therapy, weight loss) and behavioral treatments (e.g., cognitive behavioral therapy).

67. **Opioid:** Natural or synthetic chemicals that interact with opioid receptors on nerve cells in the body and brain and reduce the intensity of pain signals and feelings of pain. This class of drugs includes the illegal drug heroin, synthetic opioids such as fentanyl, and pain medications available legally by prescription, such as oxycodone, hydrocodone, codeine, morphine, and many others. Opioid pain medications are generally safe when taken for a short time and as prescribed by a doctor, but because they produce euphoria in addition to pain relief, they can be, and too often are, misused. *See also*, “Narcotic.” Advocates of aggressive pain-treatment coined the term “opioid” to rebrand drugs that would otherwise be labelled “narcotics.”

¹⁹ *Drug Fact Sheet*, DEA, available at https://www.dea.gov/druginfo/drug_data_sheets/Narcotics.pdf (Last Accessed June 13, 2018).

68. **Opioid agonist/Opioid antagonist:** An "agonist" medication is one that binds to and fully activates targeted receptors in the brain. They activate these neurotransmitter receptors to illicit a certain response. An "antagonist" 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.²⁰

69. **Opioid analgesics:** Commonly referred to as prescription opioids, medications that have been used to treat moderate to severe pain in some patients. Categories of opioids for mortality data include:

- Natural opioid analgesics, including morphine and codeine;
- Semi-synthetic opioid analgesics, including drugs such as oxycodone, hydrocodone, hydromorphone, and oxymorphone;
- Methadone, a synthetic opioid; and
- Synthetic opioid analgesics other than methadone, including drugs such as tramadol and fentanyl.

70. **Opioid use disorder:** A problematic pattern of opioid use that causes significant impairment or distress. A diagnosis is based on specific criteria, such as unsuccessful efforts to cut down or control use, or use resulting in social problems and a failure to fulfill obligations at work, school, or home. Opioid use disorder has also been referred to as "opioid abuse or dependence" or "opioid addiction."

71. **Opiophobia:** A term coined by Big Pharma as a derogative term describing doctors who were too conservative in treating pain and prescribing opioids.²¹

72. **Overdose:** Injury to the body (poisoning) that happens when a drug is taken in excessive amounts. An overdose can be fatal or nonfatal.

²⁰ *What is the Difference Between Agonist and Antagonist Drugs*, REFERENCE (2018), available at <https://www.reference.com/health/difference-between-agonist-antagonist-drugs-838e9e0994a788eb#> (Last Accessed June 4, 2018).

²¹ Eric Levitz, *Purdue Pharma Knew Its Opioids Were Widely Abused by Late '90s*, NY MAG (May 29, 2018), available at <http://nymag.com/daily/intelligencer/2018/05/purdue-knew-its-opioids-were-widely-abused-by-late-90s.html> (Last Accessed June 4, 2018).

73. **Physical dependence:** Adaptation to a drug that produces symptoms of withdrawal within an individual when use of that drug is stopped.

74. **Prescription drug monitoring programs (PDMPs):** State-run electronic databases that track controlled substance prescriptions. PDMPs help providers identify patients at risk of opioid misuse, abuse and/or overdose due to overlapping prescriptions, high dosages, or the co-prescription of opioids with benzodiazepines. In California, CURES 2.0 (Controlled Substance Utilization Review and Evaluation System) is a database of Schedule II, III and IV controlled substance prescriptions dispensed in California, serving public health and regulatory oversight agencies, and law enforcement.

75. **Pseudoaddiction:** Pseudoaddiction, a concept coined in 1989, has frequently been cited to indicate that under-treatment of pain, rather than addiction, is the more pressing and authentic clinical problem in opioid-seeking patients. Industry sponsored publications argued that pseudoaddiction is an iatrogenic disease resulting from withholding opioids for pain that can be diagnosed, prevented, and treated with *more aggressive* opioid treatment.²²

76. **Tolerance:** Reduced response to a drug due to repeated use.

V. FACTUAL ALLEGATIONS

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

78. To take advantage of the much larger and more lucrative market for chronic pain patients, opioid manufacturers had to change this. Manufacturers developed a well-funded

²² Marion S. Greene and R. Andrew Chambers, *Pseudoaddiction: Fact or Fiction? An Investigation of the Medical Literature*, 2(4) CURRENT ADDICT REP. 310-317 (2015), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4628053/> (Last Accessed June 4, 2018).

1 marketing scheme to target susceptible prescribers and vulnerable patient populations.
2 Manufacturers funded seemingly independent third-parties (and used their own sales forces) to
3 spread false and misleading statements about the risks and benefits of long-term opioid use. These
4 statements were not only unsupported by or contrary to the scientific evidence, they were also
5 contrary to pronouncements by and guidance from the U.S. Food and Drug Administration
6 (“FDA”) and CDC based on that same evidence. California doctors, including doctors in San
7 Mateo County, confirm that Defendants began their marketing schemes decades ago and continue
8 them today.

9
10 **A. Manufacturers targeted susceptible prescribers and vulnerable patient populations**

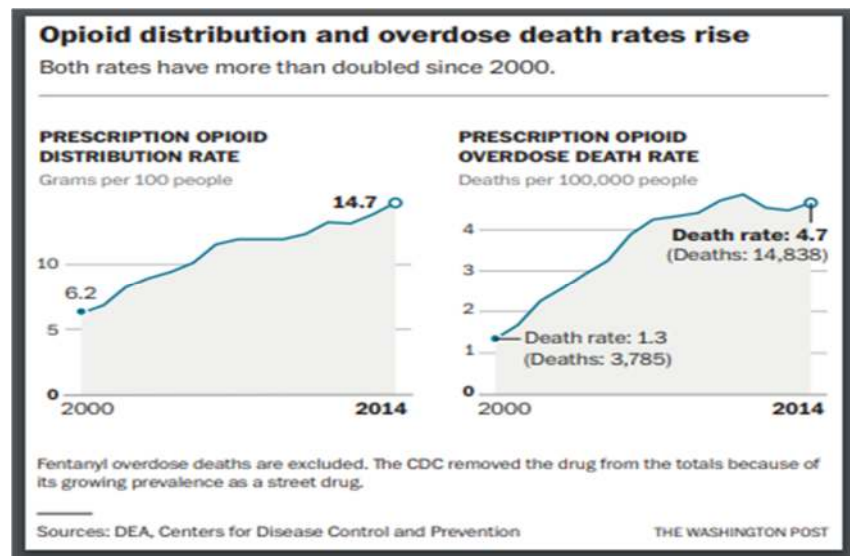
11 79. As a part of their deceptive marketing scheme, manufacturers identified and
12 targeted susceptible prescribers and vulnerable patient populations in the United States, including
13 in California.

14 80. For example, manufacturers focused their deceptive marketing on primary care
15 doctors, who were more likely to treat chronic pain patients and prescribe them drugs but were less
16 likely to be schooled in treating pain and the comparative risks and benefits of opioids, and
17 therefore more likely to accept manufacturers’ misrepresentations.

18 81. Manufacturers also targeted vulnerable patient populations like the elderly and
19 veterans, who are more likely than the average member of the population to suffer from chronic
20 pain. This targeting occurred even though the medical risks and injury potential of long-term
21 opioid use were significantly greater for them. For example, the 2016 CDC Guideline observed
22 that existing evidence showed that elderly patients taking opioids suffer from elevated fall and
23 fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects
24 and interactions. The Guideline therefore concluded that there are "special risks of long-term
25 opioid use for elderly patients" and recommended that doctors use "additional caution and
26 increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for
27 veterans, who are more likely to use anti-anxiety drugs (benzodiazepines), which interact
28 dangerously with opioids, for post-traumatic stress disorder.

B. Defendant Distributors knowingly supplied dangerous quantities of opioids while advocating for limited oversight and enforcement

82. Manufacturers rely upon distributors to circulate their drugs into the drug economy. The distributors serve as middlemen, sending billions of doses of opioid pain pills to pharmacists, hospitals, nursing homes and pain clinics in California and across the nation. According to the CDC, the increased distribution of opioids directly correlates to increased overdose death rates:



83. The Defendant Distributors track and keep a variety of information about the pharmacies and other entities to which they sell pharmaceuticals. For example, the Defendant Distributors use “know your customer” questionnaires that track the number and types of pills their customers sell, the absolute and relative amounts of controlled substances they sell, whether the customer purchases from other distributors, and the types of medical providers in the areas, among other information.

84. These questionnaires and other sources of information available to the Defendant Distributors provide ample data to put the Defendant Distributors on notice of suspicious orders, pharmacies, and doctors.

85. Nevertheless, the Defendant Distributors refused or failed to identify, investigate, or report suspicious orders of opioids to the DEA. Even when the Defendant Distributors had actual

²³ Lenny Bernstein & Scott Higham, *DEA Slowed Enforcement?*, WASHINGTON POST (Oct. 26, 2016), available at <http://msani.org/tag/opioids/> (Last Accessed June 8, 2018).

1 knowledge that they were distributing opioids to drug diversion rings, they refused or failed to
2 report these sales to the DEA.

3 86. By not reporting suspicious opioid orders or known diversions of prescription
4 opioids, not only were the Defendants able to continue to sell opioids to questionable customers,
5 but Defendants ensured that the DEA had no basis for decreasing or refusing to increase
6 production quotas for prescription opioids.

7 87. The Defendant Distributors collaborated with each other and with opioid
8 manufacturers to maintain the distribution of excessive amounts of opioids. One example of this
9 collaboration came to light through Defendants' work in support of legislation called the Ensuring
10 Patient Access and Effective Drug Enforcement (EPAEDE) Act, signed into law in 2016, which
11 limited the DEA's ability to stop the flow of opioids. Prior to this law, the DEA could use an
12 "immediate suspension order" to halt suspicious shipments of pills that posed an "imminent" threat
13 to the public. The EPAEDE Act changed the required showing to an "immediate" threat—an
14 impossible standard given the fact that the drugs may sit on a shelf for a few days after shipment.
15 The law effectively neutralized the DEA's ability to bring enforcement actions against distributors.

16 88. The legislation was drafted by a former DEA lawyer, D. Linden Barber, who is now
17 a senior vice president at Defendant Cardinal Health. Prior to leaving the DEA, Barber had worked
18 with Joseph Rannazzisi, then the chief of the DEA's Office of Diversion Control, to plan the
19 DEA's fight against the diversion of prescription drugs. As a result, when Barber began working
20 for Cardinal Health, he knew just how to neutralize the effectiveness of the DEA's enforcement
21 actions. Barber and other promoters of the EPAEDE Act portrayed the legislation as maintaining
22 patient access to medication critical for pain relief. In a 2014 hearing on the bill, Barber testified
23 about the "unintended consequences in the supply chain" of the DEA's enforcement actions. But
24 by that time, communities across the United States, including Plaintiff San Mateo County, were
25 grappling with the "unintended consequences" of Defendants' reckless promotion and distribution
26 of narcotics.

27 89. Despite egregious examples of drug diversion from around the country, the
28 promoters of the EPAEDE Act were successful in characterizing the bill as supporting patients'

1 rights. One of the groups supporting this legislation was the Alliance for Patient Access, a “front
2 group” as discussed further below, which purports to advocate for patients’ rights to have access to
3 medicines, and whose 2017 list of “associate members and financial supporters” included Purdue
4 Pharma (“Purdue”), Endo, Johnson & Johnson, Actavis, Mallinckrodt, and Cephalon. In a 2013
5 “white paper” titled “*Prescription Pain Medication: Preserving Patient Access While Curbing*
6 *Abuse*,” the Alliance for Patient Access asserted multiple “unintended consequences” of regulating
7 pain medication, including a decline in prescriptions as physicians felt both stigmatized and
8 burdened by regulations.²⁴

9 90. The Defendant Distributors are also part of the activities of the Alliance for Patient
10 Access, although their involvement has been hidden from the public. One example of their
11 involvement was revealed by the metadata of an electronic document uncovered by other
12 government entities in litigation against Big Pharma: a letter from the Alliance for Patient Access
13 in support of the EPAEDE Act.²⁵ That document was created by Kristen Freitas, a registered
14 lobbyist and the vice president for federal government affairs of the Healthcare Distributors
15 Alliance (HDA)—a trade group that represents Defendants McKesson, Cardinal Health, and
16 AmerisourceBergen.

17 91. Upon information and belief, the collaboration on the EPAEDE Act is just one
18 example of how the Defendant Distributors and opioid manufacturers, through third party “front
19 groups” like the Alliance for Patient Access and trade organizations like HDA, worked together
20 behind the scenes to ensure that the flow of dangerous narcotics into communities across the
21 country would not be restricted, and Defendants collaborated in other ways that remain hidden
22 from public view.

23 92. The Defendant Distributors have been the subject of numerous enforcement actions
24 by the DEA. In 2008, for example, McKesson was fined \$13.3 million and agreed to strengthen its

25 ²⁴ *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, INSTITUTE
26 FOR PATIENT ACCESS (Oct. 2013), available at
27 [http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-](http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf)
28 [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) (Last Accessed June 6, 2018).

²⁵ *Pierce County v. Purdue et al.* Amended Complaint filed May 25, 2018, U.S.D.C., WD WA,
Case Case: 1:18-op-45195-DAP (Doc. 14) at 32.

controls by implementing a three-tiered system that would flag buyers who exceeded monthly thresholds for opioids. Defendant Cardinal Health was fined \$34 million by the DEA in 2013 for failing to report suspicious orders. These penalties are discussed in greater detail below.

93. The Defendant Distributors were not simply passive transporters of opioids. They intentionally failed to report suspicious orders and actively pushed back against efforts to enforce the law and restrict the flow of opioids into communities like San Mateo County.

94. As the opioid crisis deepened, the DEA's Office of Diversion Control, led by Rannazzisi, stepped up enforcement, filing fifty-two immediate suspension orders against suppliers and pill mills in 2010 alone. However, the Defendant Distributors intentionally throttled back on reporting and immediate suspension orders plummeted:

DECLINING SUSPENSION ORDERS

The number of **immediate suspension orders** against doctors, pharmacies and drug companies has plummeted since fiscal year 2011.



Source: Drug Enforcement Administration

95. On October 23, 2017, CBS aired an episode of 60 Minutes featuring Rannazzisi, who held no punches in exposing the Defendant Distributor's role in deaths caused by the Defendant Distributors' failure to report suspicious orders as required by law:

JOE RANNAZZISI: This is an industry that's out of control. What they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die.

This is an industry that allowed millions and millions of drugs to go into bad pharmacies and doctors' offices, that distributed them out to people who had no legitimate need for those drugs.

[INTERVIEWER]: Who are these distributors?

1 **JOE RANNAZZISI:** The three largest distributors are Cardinal Health,
2 McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of
3 the drugs going downstream.

4 **[INTERVIEWER]:** You know the implication of what you're saying, that these
5 big companies knew that they were pumping drugs into American communities
6 that were killing people.

7 **JOE RANNAZZISI:** That's not an implication, that's a fact. That's exactly what
8 they did.²⁶



Ex-DEA agent Joe Rannazzisi and 60 Minutes correspondent Bill Whitaker CBS NEWS

17 96. Jim Geldhof, a 40-year veteran of the DEA who ran investigations in the Detroit
18 field office, corroborated Rannazzisi's account, saying that the wholesalers are "absolutely"
19 responsible for the opioids epidemic:
20

21 **[INTERVIEWER]:** These companies are a big reason for this epidemic?

22 **JIM GELDHOF:** Yeah, absolutely they are. And I can tell you with 100 percent
23 accuracy that we were in there on multiple occasions trying to get them to change
24 their behavior. And they just flat out ignored us.
25
26

27 ²⁶ Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS
28 NEWS (Oct. 17, 2017), available at <https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/> (Last Accessed June 6, 2018).



97. Indeed, according to Rannazzisi, in pushing the EPAEDE Act the pharmaceutical industry succeeded in stripping the DEA of its most potent tool for fighting against diversion and abuse. What it really did, according to Jonathan Novak, who worked in the DEA's legal office, was strip the DEA of its ability to immediately freeze suspicious shipments of prescription narcotics to keep drugs off United States streets. A 2015 DOJ memo confirmed that the bill "could actually result in increased diversion, abuse, and public health and safety consequences."²⁷

98. 60 Minutes has reported that "According to federal filings, during the two years the legislation was considered and amended, [distributors and others in the industry] spent \$102 million lobbying Congress on the bill and other legislation, claiming the DEA was out of control, making it harder for patients to get needed medication." According to the same reporting, the chief administrative law judge of the DEA, Mulrooney, has written "that the new legislation 'would make it all but . . . impossible' to prosecute unscrupulous distributors."

99. The "Big Three" Distributors sued in this litigation are among our Nation's largest companies, yet the public knows relatively little about them. Each records over \$100 billion in revenue each year:

²⁷ Phil Williams, *Congressman Blackburn Faces Criticism Over Federal Drug Law*, NEWS CHANNEL 5 (Oct. 16, 2017), available at <https://www.newschannel5.com/news/newschannel-5-investigates/congressman-blackburn-faces-criticism-over-federal-drug-law> (Last Accessed June 13, 2018).



28

1. McKesson

100. McKesson is the fifth-largest company in the United States and the second-largest in California by revenue.²⁹ McKesson now brings in an annual revenue of nearly \$200 billion. It has grown exponentially in the past 20 years, fueled largely by opioid sales.



²⁸ McKesson Proxy Statement regarding executive compensation, dated July 26, 2017, available at <https://www.sec.gov/Archives/edgar/data/927653/000119312517205237/d341720ddef14a.htm> (Last accessed June 6, 2018).

²⁹ Joe Mathews, *McKesson: The business giant you've never heard of*, SF CHRON (Jan. 13, 2018), available at <https://www.sfchronicle.com/opinion/article/McKesson-The-business-giant-you-ve-never-heard-12492399.php> (Last accessed June 13, 2018).



101. McKesson is a wholesale pharmaceutical distributor of controlled and uncontrolled prescription medications, including opioids. It is the largest pharmaceutical drug distributor in the United States. It distributes pharmaceuticals through a network of distribution centers across the country, including one located in Santa Fe Springs, California and one in Sacramento, California. McKesson's corporate headquarters is in San Francisco.

102. McKesson supplies various United States pharmacies an increasing amount of the prescription opioids that are at the heart of the current opioid epidemic.



103. McKesson distribution centers are required to operate in accordance with the statutory provisions of the Controlled Substance Act ("CSA"). The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances, as that term is defined in the regulation. *See* 21 C.F.R.

§1301.74(b). The CSA authorizes the imposition of a civil 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) & (c)(1)(B). The CSA's requirements are also incorporated into California law. Cal. Bus. & Prof. Code §4301(o). Further, California law prohibits distributors from engaging in the following:

- Gross immorality;
- Incompetence;
- Gross negligence;
- Excessive furnishing of controlled substances;
- The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption;
- Knowingly selling, furnishing, giving away, or administering, or offering to sell, furnish, give away, or administer, any controlled substance to an addict;
- Violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs;

104. Plaintiff alleges that Defendants have violated each of these provisions of law and are also expressly liable for aiding and abetting similar violations of law by known and unknown co-conspirators, including opioid manufacturers. Cal. Bus. & Prof. Code §4301(o) provides:

Violating or attempting to violate, directly or indirectly, *or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy*, including regulations established by the board or by any other state or federal regulatory agency.

105. California also imposes independent requirements on distributors, including that all opioids that are distributed or furnished for sale in the State be distributed or furnished for legitimate purposes only (Cal. Health & Safety Code §11153.5) and that wholesalers report "all sales of dangerous drugs subject to abuse" to the California State Board of Pharmacy (the "Board") in excess of amounts it sets (16 C.C.R. §1782). Moreover, effective January 1, 2018, pharmaceutical wholesalers must notify the Board of suspicious orders placed by a California-licensed pharmacy or wholesaler. Cal. Bus. & Prof. Code §4169.1.

1 **a. McKesson Fined Millions by the DEA in 2008**

2 106. In a September 2005 meeting between the DEA and McKesson, the government
3 warned McKesson officials about excessive sales of their products ending up with pharmacies
4 filling illegal online prescriptions.³⁰

5 107. More specifically, McKesson was warned that three McKesson distribution centers
6 had received and filled hundreds of suspicious prescriptions for pharmacies participating in illicit
7 Internet sales, yet McKesson had failed to report the orders to the DEA. The online pharmacies
8 took orders from customers who had obtained fake prescriptions, resulting in criminal
9 prosecutions.

10 108. According to United States Attorneys, the orders McKesson received from these
11 pharmacies were unusually large, unusually frequent and substantially different from the normal
12 pattern. The government determined that millions of dosage units of controlled substances were
13 diverted from legitimate channels of distribution.

14 109. In or about 2007, the DEA again accused McKesson of failing to report suspicious
15 orders and launched an investigation.

16 110. In 2008, McKesson paid a \$13.25 million fine for failing to report hundreds of
17 suspicious hydrocodone orders from Internet pharmacies.

18 111. “By failing to report suspicious orders for controlled substances that it received
19 from rogue Internet pharmacies, the McKesson Corporation fueled the explosive prescription drug
20 abuse problem we have in this country,” then-DEA Administrator Michele M. Leonhart said in a
21 statement announcing the settlement.

22 112. As part of its agreement with the Justice Department, McKesson pledged to
23 temporarily suspend distribution of narcotics from two of its 30 distribution centers and to improve
24 its system for monitoring and reporting suspicious drug orders.

25
26
27 ³⁰ Shannon Henson, *McKesson Ponies Up \$13M To Settle Drug Claims*, LAW 360 (May 5, 2018),
28 available at <https://www.law360.com/articles/55133/mckesson-ponies-up-13m-to-settle-drug-claims> (Last accessed June 13, 2018).

1 113. As a result, McKesson developed a Controlled Substance Monitoring Program
2 ("CSMP") but nevertheless failed to design and implement an effective system to detect and report
3 "suspicious orders" for controlled substances distributed to its independent and small chain
4 pharmacy customers — i.e., orders that are unusual in their frequency, size or other patterns.
5 McKesson continued to fail to detect or disclose suspicious orders of controlled substances. It
6 failed to conduct adequate due diligence of its customers, failed to keep complete and accurate
7 records in the CSMP files maintained for many of its customers and bypassed suspicious order
8 reporting procedures set forth in the CSMP.

9 114. A mere four years after the \$13.25 million fine, McKesson again caught the eye of
10 the DEA. In 2012 state and local law enforcement began to investigate Platte Valley Pharmacy in
11 Brighton, Colorado, a small suburb of Denver with a population of 38,000. The pharmacist was
12 selling as many as 2,000 pain pills a day. Coordinating with state and local law enforcement, the
13 DEA's Denver field division began a criminal investigation, making undercover buys and
14 monitoring the size of drug purchases. Investigators found that most of the drugs came from
15 McKesson's warehouse in the city of Aurora, northeast of Denver. Despite being legally required
16 to notify the DEA about any orders of unusual size, frequency or pattern and to hold off on
17 shipping the drugs until those issues were resolved, McKesson filled 1.6 million orders from the
18 Aurora warehouse and reported only 16 as suspicious between June 2008 and May 2013. None of
19 the 16 involved Platte Valley, and the company reported them only after the DEA began its
20 investigation.³¹

21 115. Platte Valley Pharmacy ordered so much oxycodone that it repeatedly bumped up
22 against thresholds McKesson had set for the pharmacy. The company raised those limits and sent
23 more, DEA agents and investigators said. "The company would raise thresholds so pharmacies
24 could order more pills without setting off suspicious monitoring alarms inside the company," one
25

26 ³¹ Lenny Bernstein & Scott Higham, *'We feel like our system was hijacked': DEA agents say a*
27 *huge opioid case ended in a whimper*, WASH. POST (Dec. 17, 2017), available at
28 https://www.washingtonpost.com/investigations/mckesson-dea-opioids-fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8-62589434a581_story.html?utm_term=.86a1f511e7f2 (Last accessed June 13, 2018).

investigator said. “Did they think we wouldn’t look at them again? I don’t know. But they almost acted that way.” The pharmacist who received the drugs from McKesson is serving a fifteen-year prison sentence.

116. In 2013, the DEA again ramped up its investigation reports that McKesson was failing to maintain proper controls to prevent the diversion of opioids and failing to design and use an effective system to detect "suspicious orders" from pharmacies for powerful painkillers such as oxycodone, as required by the CSA. Nine DEA field divisions and 12 United States Attorneys built a case against McKesson for the company's role in the opioid crisis, which David Schiller ("Schiller"), Assistant Special Agent in Charge for the Denver Field Division and leader of the DEA team investigating McKesson, called "the best case we've ever had against a major distributor in the history of the Drug Enforcement Administration."³²

117. According to a December 17, 2017 exposé by the Washington Post, “[b]y 2014, investigators said they could show that the company had failed to report suspicious orders involving millions of highly addictive painkillers sent to drugstores from Sacramento, Calif., to Lakeland, Fla. Some of those went to corrupt pharmacies that supplied drug rings.”

118. A DEA memo outlined the investigative findings concerning McKesson:

- “Supplied controlled substances in support of criminal diversion activities.”
- “Ignored blatant diversion.”
- “Pattern of raising thresholds arbitrarily.”
- “Failed to review orders for suspicious activity.”
- “Ignored own procedures designed to prevent diversion.”

119. In addition to Aurora, investigators found that McKesson warehouses in Livonia, Mich., and Washington Court House, Ohio, were supplying pharmacies that sold to criminal drug rings, according to internal government documents obtained by Washington Post and 60 Minutes.

³² Bill Whitaker, *Whistleblowers: DEA Attorneys Went Easy on McKesson, the Country's Largest Drug Distributor*, CBS (Dec. 17, 2017), available at <https://www.cbsnews.com/news/whistleblowers-dea-attorneys-went-easy-on-mckesson-the-countrys-largest-drug-distributor/> (Last Accessed June 7, 2018).

1 120. “Notwithstanding, their bad acts continued and escalated to a level of egregiousness
2 not seen before,” Imelda L. Paredes, a DEA official working on the case, wrote in a memo on
3 March 30, 2015. “They were neither rehabilitated nor deterred by the 2008 [agreement].”

4 121. On December 17, 2017, CBS aired an episode of 60 Minutes featuring Assistant
5 Special Agent Schiller, who described McKesson as a company that killed people for its own
6 financial gain and blatantly ignored the CSA requirement to report suspicious orders:

7
8 **DAVID SCHILLER:** If they woulda stayed in compliance with their authority and
9 held those that they're supplying the pills to, the epidemic would be nowhere near
10 where it is right now. Nowhere near.

11 They had hundreds of thousands of suspicious orders they should have reported, and
12 they didn't report any. There's not a day that goes by in the pharmaceutical world, in
13 the McKesson world, in the distribution world, where there's not something
14 suspicious. It happens every day.

15 **[INTERVIEWER:]** And they had none.

16 **DAVID SCHILLER:** They weren't reporting any. I mean, you have to understand
17 that, nothing was suspicious?

18 **b. McKesson Fined \$150 Million by the DEA in 2017**

19 122. On January 17, 2017 McKesson agreed to pay a record \$150 million in fines and
20 suspend sales of controlled substances from distribution centers in four states (Colorado, Ohio,
21 Michigan and Florida) to settle allegations that the company violated federal law. According to the
22 DOJ, McKesson continued to fail to report suspicious orders between 2008 and 2012 and did not
23 fully implement or follow the monitoring program agreed to in 2008. As part of the agreement,
24 McKesson acknowledged that:

25 at various times during the Covered Time Period, it did not identify or report to DEA certain
26 orders placed by certain pharmacies, which should have been detected by McKesson as
27 suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA.³³

28 123. Behind the scenes, the DEA's field office investigators felt the system was rigged
and had wanted to completely revoke McKesson's licenses to distribute controlled substances.
“Within the ranks, we feel like our system was hijacked,” said Helen Kaupang, a DEA investigator

³³ *Settlement Agreement and Release*, DOJ (2017), available at <https://www.justice.gov/usao-nj/press-release/file/928631/download> (Last Accessed June 13, 2018).

1 and supervisor for 29 years who worked on the McKesson case in Denver before retiring in
2 September 2017.

3 124. While the \$150 million dollar fine set a record for a fine on drug distributors, it is a
4 fraction of the compensation received by McKesson board chairman and chief executive John H.
5 Hammergren, who, according to Bloomberg has received compensation worth \$781 million since
6 July 2017.³⁴

7 125. According to the Washington Post investigation:
8 DEA investigators, agents and supervisors who worked on the McKesson case said the company
9 paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of
10 them knowingly supplying drug rings.

11 Instead, the DEA officials said, the company raised its own self-imposed limits, known as
12 thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the
13 face of numerous red flags.

14 “They had multiple chances to correct their behavior going back to the Internet pharmacy days.
15 They promised everyone they were going to correct their behavior, and a year or two later, they
16 were doing it again,” said Jim Geldhof, a DEA program manager who worked on the McKesson
17 case in Detroit before retiring in 2015 after a 43-year career.



18 “Within the ranks, we feel like our system was hijacked,” said Helen Kaupang, who worked on the McKesson case. (Mark Abramson/For The Washington
19 Post)

20 **2. Cardinal Health**

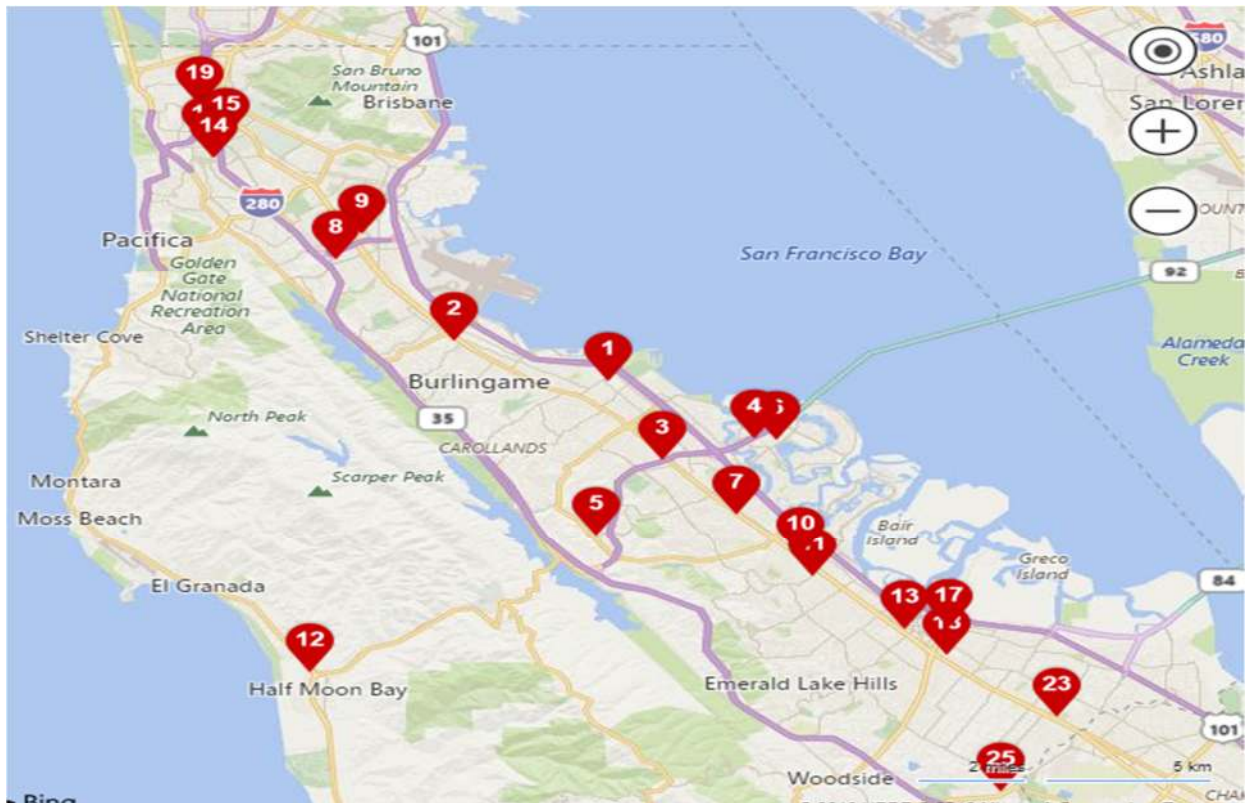
21 126. Cardinal Health describes itself as a global integrated healthcare services and
22 products company. It generated \$121.5 billion in total revenue during fiscal year 2016 (ending
23

24
25
26
27 ³⁴ Anders Melin, *Overdose Victim’s Dad Rallies Teamsters in Fight With McKesson*,
28 BLOOMBERG (July 21, 2017), available at <https://www.bloomberg.com/news/articles/2017-07-21/overdose-victim-s-dad-rallies-teamsters-in-fight-with-mckesson> (Last accessed June 13, 2018).

June 30, 2016). It is ranked 15th on the 2017 Fortune 500 list of top United States companies by revenue.

127. Cardinal Health has two operating segments: pharmaceutical and medical. Its pharmaceutical segment, at issue in this action, distributes branded and generic pharmaceutical, special pharmaceutical, over-the-counter and consumer products in the United States. Of Cardinal Health's \$121.5 billion in revenue during fiscal year 2016, \$109.1 billion was derived from the pharmaceutical operating segment.

128. Cardinal Health distributes pharmaceuticals through a network of distribution centers across the country. Cardinal Health's largest customer is CVS Health ("CVS"), which accounted for 25% of Cardinal Health's fiscal year 2016 revenue. According to its website, CVS operates pharmacies in San Mateo County.³⁵



129. Cardinal Health distribution centers are required to operate in accordance with the statutory provisions of the CSA and the regulations promulgated thereunder, 21 C.F.R. §1300 *et*

³⁵ *CVS Store Locator*, CVS (2018), available at <https://www.cvs.com/store-locator/landing> (Last accessed June 13, 2018).

1 *seq.* The regulations promulgated under the CSA include a requirement to design and operate a
2 system to detect and report "suspicious orders" for controlled substances as that term is defined in
3 the regulation. *See* 21 C.F.R. §1301.74(b). The CSA authorizes the imposition of a civil penalty of
4 up to \$10,000 for each violation of 21 C.F.R. §1301.74(b). *See* 21 U.S.C. §842(a)(5) & (c)(1)(B).
5 The CSA's requirements are also incorporated into California law. Cal. Bus. & Prof. Code
6 §4301(o).

7 130. California also imposes independent requirements on distributors, including that all
8 opioids be distributed or furnished for sale in the State be distributed or furnished for legitimate
9 purposes only (Cal. Health & Safety Code §11153.5) and that wholesalers report "all sales of
10 dangerous drugs subject to abuse" to the Board in excess of amounts it sets (16 C.C.R. §1782).
11 Moreover, since January 1, 2018, pharmaceutical wholesalers have been required to notify the
12 Board of suspicious orders placed by a California-licensed pharmacy or wholesaler. Cal. Bus. &
13 Prof. Code §4169.1.

14 **a. Cardinal Fined Millions by the DEA in 2008**

15 131. On October 2, 2008 Cardinal Health agreed to pay \$34,000,000 in civil penalties for
16 violations of the Controlled Substances Act.³⁶ According to the DOJ, Cardinal Health "failed to
17 report to DEA suspicious orders of hydrocodone that it then distributed to pharmacies that filled
18 illegitimate prescriptions originating from rogue Internet pharmacy Web sites. These prescriptions
19 violated applicable Federal and State law because they were not issued for a legitimate medical
20 purpose by physicians acting within the usual course of professional practice. Cardinal's conduct
21 allowed the "diversion" of millions of dosage units of hydrocodone from legitimate to non-
22 legitimate channels."

23 132. According to a DOJ press release regarding the 2008 penalty:
24 "Despite DEA's repeated attempts to educate Cardinal Health on diversion awareness and
25 prevention, Cardinal engaged in a pattern of failing to report blatantly suspicious orders for
controlled substances filled by its distribution facilities located throughout the United States," said

26 ³⁶ *Cardinal Health Inc., Agrees To Pay \$34 Million To Settle Claims That It Failed To Report*
27 *Suspicious Sales Of Widely-Abused Controlled Substances*, DOJ (Oct. 2, 2008), available at
28 https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html (Last Accessed June 13, 2018).

1 DEA Acting Administrator Michele M. Leonhart. “Cardinal’s negligent conduct contributed to our
2 nation’s serious pharmaceutical abuse problem. This substantial civil penalty underscores DEA’s
3 determination to prevent pharmaceutical diversion and protect the public health and safety by
4 continuing to hold companies responsible if they fail to fulfill their obligations under the Controlled
5 Substance Act.”

6 Seven Cardinal Health distribution centers received and filled thousands of suspicious orders placed
7 by pharmacies participating in illicit Internet schemes, but failed to report the orders to DEA. They
8 did so even after an Aug. 22, 2005, meeting at which DEA officials met with and warned Cardinal
9 officials about excessive sales of their products to pharmacies filling illegal online prescriptions.
10 The pharmacies filled purported online “prescriptions” for hydrocodone (contained in drugs such as
11 Vicodin), but the prescriptions were issued outside the normal course of professional practice and
12 not for a legitimate medical purpose. The United States. Attorneys allege that the orders that
13 Cardinal received from these pharmacies, and others, were unusually large, unusually frequent
14 and/or deviated substantially from the normal pattern.

15 133. Also in 2008, Cardinal Health subsidiary Cardinal Health 406 LLC was fined
16 \$150,000 for falsifying DEA records related to opioid sales.³⁷

17 134. According to a 60 Minutes investigation, in 2011 Cardinal Health went to
18 Rannazzisi’s bosses at the DEA to get Rannazzisi to back off his opioid investigation. By 2013
19 former DEA attorney Jonathan Novak said he noticed a “sea change” in the way distributors were
20 being prosecuted because the distributors had used their money and influence to get the
21 investigators to back off; unfortunately this was at the time that the opioid epidemic had already
22 begun worsening exponentially. As described *supra*, the next step in the Big Three’s playbook was
23 to lobby for passage of the EPAEDE Act, which made it “nearly impossible” for the DEA to go
24 after distributors.

25 **b. Cardinal Fined Millions (a second time) by the DEA in 2016**

26 135. On December 27, 2016, Cardinal was fined \$34 Million by the DEA. The fine was
27 due to Cardinal’s failure to report suspicious orders by pharmacies in Florida and Maryland.³⁸
28

25 ³⁷ *News Release*, DOJ (Jan. 4, 2008), available at
26 <https://www.justice.gov/archive/usao/pae/News/2008/jan/catalentrelease.pdf> (Last accessed June
27 13, 2018).

28 ³⁸ *United States Reaches \$34 Million Settlement with Cardinal Health for Civil Penalties under the
Controlled Substances Act*, DEA (Dec. 27, 2016), available at
<https://www.dea.gov/divisions/sea/2016/sea122716.shtml> (Last accessed June 13, 2018).

1 Among the suspicious orders that went unreported were oxycodone sales. Earlier in 2016, CVS
2 also agreed to pay the United States \$8 million to resolve violations of the CSA by its Maryland
3 pharmacies. According to the settlement agreement, CVS admitted that between 2008 and 2012
4 certain of its Maryland pharmacies dispensed oxycodone, fentanyl, hydrocodone and other
5 pharmaceuticals in violation of the CSA because the drugs were dispensed without ensuring that
6 the prescriptions were issued for legitimate medical purposes.

7 136. In the settlement agreement, Cardinal Health admitted, accepted and acknowledged
8 that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

- 9 • "timely identify suspicious orders of controlled substances and inform the
10 DEA of those orders, as required by 21 C.F.R. §1301.74(b)";
- 11 • "maintain effective controls against diversion of particular controlled
12 substances into other than legitimate medical, scientific, and industrial
13 channels, as required by 21 C.F.R. §1301.74, including the failure to make
14 records and reports required by the CSA or DEA's regulations for which a
15 penalty may be imposed under 21 U.S.C. §842(a)(5)"; and
- 16 • "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA
17 'Form 222' order forms and their electronic equivalent for Schedule II
18 controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305."

15 137. The settlement agreement was announced by the United States Attorney for the
16 District of Maryland, Rod J. Rosenstein ("Rosenstein"), and the DEA Special Agent in Charge —
17 Washington Field Division, Karl C. Colder ("Colder").³⁹

18 138. In the press release announcing the settlement agreement, Rosenstein stated:

19 Pharmaceutical suppliers violate the law when they fill unusually large or frequent orders
20 for controlled substances without notifying the DEA . . . Abuse of pharmaceutical drugs is
21 one of the top federal law enforcement priorities. Cases such as this one, as well as our \$8
22 million settlement with CVS in February 2016, reflect the federal commitment to prevent
the diversion of pharmaceutical drugs for illegal purposes.

23 139. In the press release, Colder clarified that the settlement primarily concerned the
24 opioid oxycodone:

25
26
27 ³⁹ *Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of Controlled*
28 *Substances Act*, DOJ (Dec. 23, 2016), available at <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act> (Last Accessed June 7, 2018).

1 DEA is responsible for ensuring that all controlled substance transactions take place within
2 DEA's regulatory closed system. All legitimate handlers of controlled substances must
3 maintain strict accounting for all distributions and Cardinal failed to adhere to this policy . .
4 . . Oxycodone is a very addictive drug and failure to report suspicious orders of oxycodone
5 is a serious matter. The civil penalty levied against Cardinal should send a strong message
6 that all handlers of controlled substances must perform due diligence to ensure the public
7 safety

8 140. Also in December 2016 Kinray LLC, a New York-based pharmaceutical subsidiary
9 of Cardinal Health agreed to pay \$10 million to the United States for failing to inform the DEA of
10 suspicious orders for certain controlled substances during the time period between January 1, 2011
11 and May 14, 2012.⁴⁰

12 141. In January 2017 Cardinal agreed to pay the State of West Virginia \$20 million
13 related to its opioid distributions in that state.⁴¹

14 142. In total, Cardinal has paid \$98,000,000 in fines due to violations of the Controlled
15 Substances Act. None of the \$98,000,000 in fines was directed to San Mateo County.

16 **c. Cardinal Continues to Draw Scrutiny in 2018**

17 143. In February 2018 the House Energy and Commerce Committee, as part of its pill
18 dumping investigation, demanded that Cardinal answer questions about its practices, that among
19 other things, led to Cardinal shipping 6,496,080 hydrocodone and oxycodone pills to a single
20 pharmacy in a small town with less than 200 people over a five year period:
21
22
23

24 ⁴⁰ *Manhattan U.S. Attorney Announces \$10 Million Civil Penalty Recovery Against New York*
25 *Pharmaceutical Distributor Kinray, Llc.*, DOJ (Dec. 23, 2016), available at
26 [https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-10-million-civil-penalty-](https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-10-million-civil-penalty-recovery-against-new-york)
27 [recovery-against-new-york](https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-10-million-civil-penalty-recovery-against-new-york) (Last accessed June 13, 2018).

28 ⁴¹ Charles Ornstein, *Drug Distributors Penalized for Turning Blind Eye in Opioid Epidemic*, NPR
(Jan. 27, 2017), available at [https://www.npr.org/sections/health-](https://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](https://www.npr.org/sections/health-shots/2017/01/27/511858862/drug-distributors-penalized-for-turning-blind-eye-in-opioid-epidemic)
(Last accessed June 13, 2018).

GREG WALDEN, OREGON
CHAIRMAN

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ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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Minority (202) 225-3641

February 15, 2018

Mr. George S. Barrett
Executive Chairman of the Board
Cardinal Health, Inc.
7000 Cardinal Place
Dublin, OH 43017

Mr. Michael C. Kaufmann
Chief Executive Officer
Cardinal Health, Inc.
7000 Cardinal Place
Dublin, OH 43017

Dear Messrs. Barrett and Kaufmann:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee is continuing to investigate the opioid epidemic in the U.S. that is taking 115 lives per day, according to the Centers for Disease Control and Prevention.⁴²

As part of our investigation, the Committee wrote to you on May 8, 2017, regarding your distribution practices generally, and in particular with respect to West Virginia. As we mentioned

42

144. On May 14, 2018 Cardinal Health Executive Chairman George Barrett testified before the House Energy and Commerce Committee, as part of the Committee's investigating into "pill dumping" by the distributors and apologized for Cardinal's role in the pill dumping.⁴³



⁴² *Combating the Opioid Epidemic: Examining Concerns About Distribution and Diversion*, E&C (May 8, 2018), available at <https://energycommerce.house.gov/hearings/combating-the-opioid-epidemic-examining-concerns-about-distribution-and-diversion/> (Last accessed June 13, 2018).

3. AmerisourceBergen

145. AmerisourceBergen is a wholesale distributor of pharmaceuticals, including controlled substances and non-controlled prescription medications. It handles the distribution of approximately 20% of all pharmaceuticals sold and distributed in the United States through a network of 26 pharmaceutical distribution centers, including one in Valencia, California, and one in Corona, California.⁴⁴ It ranked 11th on the Fortune 500 list in 2017, with over \$146 billion in annual revenue. Walgreens owns 26% percent of AmerisourceBergen's stock.

146. AmerisourceBergen distribution centers are required to operate in accordance with the statutory provisions of the CSA and the regulations promulgated thereunder, 21 C.F.R. §1300 *et seq.* The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances as that term is defined in the regulation. *See* 21 C.F.R. §1301.74(b). The CSA authorizes the imposition of a civil 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) & (c)(1)(B). The CSA's requirements are also incorporated into California law. Cal. Bus. & Prof. Code §4301(o).

147. California also imposes independent requirements on distributors, including that all opioids be distributed or furnished for sale in the State be distributed or furnished for legitimate purposes only (Cal. Health & Safety Code §11153.5) and that wholesalers report "all sales of dangerous drugs subject to abuse" to the Board in excess of amounts it sets (16 C.C.R. §1782). Moreover, since January 1, 2018, pharmaceutical wholesalers have been required to notify the Board of suspicious orders placed by a California-licensed pharmacy or wholesaler. Cal. Bus. & Prof. Code §4169.1.

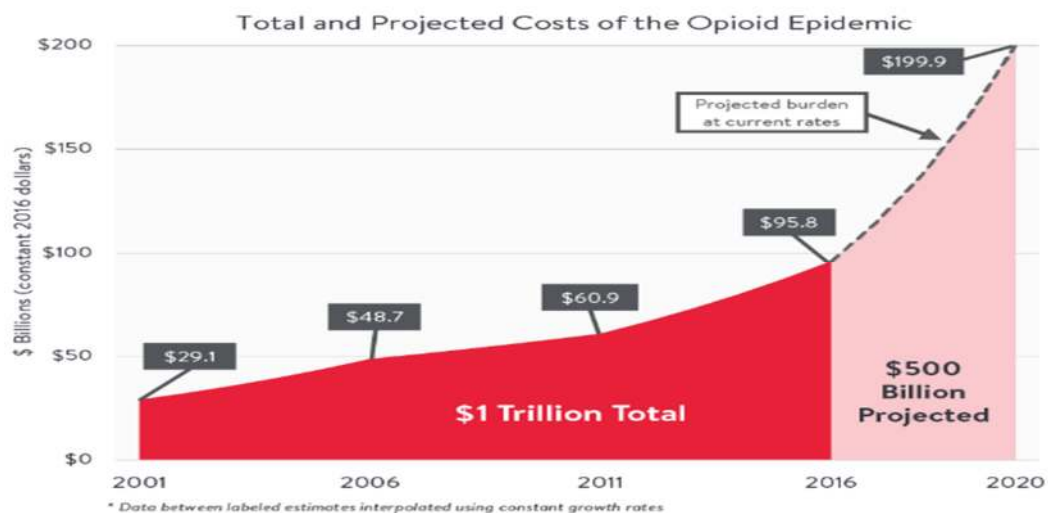
148. In 2012, West Virginia sued AmerisourceBergen and Cardinal Health, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance. Unsealed

⁴⁴ *AmerisourceBergen*, WIKIPEDIA (2018), available at <https://en.wikipedia.org/wiki/AmerisourceBergen> (Last Accessed June 7, 2018); *Drug Distribution Locations — Mainland US*, BATCHGEO (2018), available at <https://batchgeo.com/map/788de3747b01802c0171abfa8a4b5eca> (Last Accessed June 7, 2018).

1 court records from that case demonstrate that AmerisourceBergen, along with McKesson and
2 Cardinal Health, together shipped 423 million pain pills to West Virginia between 2007 and
3 2012.⁴⁵ AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million
4 oxycodone pills during that time period. Moreover, public documents also demonstrate that the
5 average dose of each tablet distributed grew substantially during that time period. The Defendant
6 Distributors, including AmerisourceBergen, shipped large quantities of oxycodone and
7 hydrocodone tablets to the state. In 2016, AmerisourceBergen agreed to settle the West Virginia
8 lawsuit by paying \$16 million to the state, with the funds set aside to fund drug treatment programs
9 in order to respond to the opioid addiction crisis.

10 C. The Opioid Epidemic is Costing San Mateo County and Other Counties 11 Around the Country Billions on an Annual Basis

12 149. According to a February 2018 study released by Altarum,⁴⁶ a nonprofit health
13 research and consulting institute, the cost of the country's opioid crisis is estimated to have
14 **exceeded \$1 trillion** from 2001 to 2017, and is projected to cost an additional \$500 billion by
15 2020:



25 ⁴⁵ Eric Eyre, *Drug firms poured 780M painkillers into WV amid rise of overdoses*, CHARLESTON
GAZETTE-MAIL (Dec. 17, 2016), available at

26 [https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-poured-m-painkillers-into-wv-](https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_99026dad-8ed5-5075-90fa-adb906a36214.html)
amid-rise-of/article_99026dad-8ed5-5075-90fa-adb906a36214.html (Last Accessed June 7, 2018).

27 ⁴⁶ *Economic Toll of Opioid Crisis in U.S. Exceeded \$1 Trillion Since 2001*, ALTARUM (Feb. 13,
2018), available at [https://altarum.org/about/news-and-events/economic-toll-of-opioid-crisis-in-u-](https://altarum.org/about/news-and-events/economic-toll-of-opioid-crisis-in-u-s-exceeded-1-trillion-since-2001)
s-exceeded-1-trillion-since-2001 (Last accessed June 13, 2018).

150. According to that same study:

The **annual cost** of the opioid crisis increased from \$29.1 billion in 2001 to an **estimated \$115 billion in 2017** (all cost estimates are shown in 2016 dollars). The **growth rate between 2011 and 2016 was double the rate observed between the previous 5 years**, and is projected to increase again in 2017. Based on these data, Altarum estimates the cost of opioid misuse, substance use disorders, and premature mortality to exceed \$500 billion over the next 3 years if concerted and sustained action to address the crisis is not taken and current use and mortality rates persist.

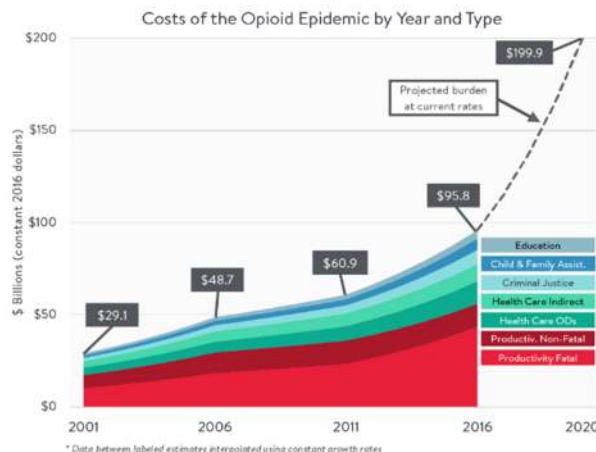
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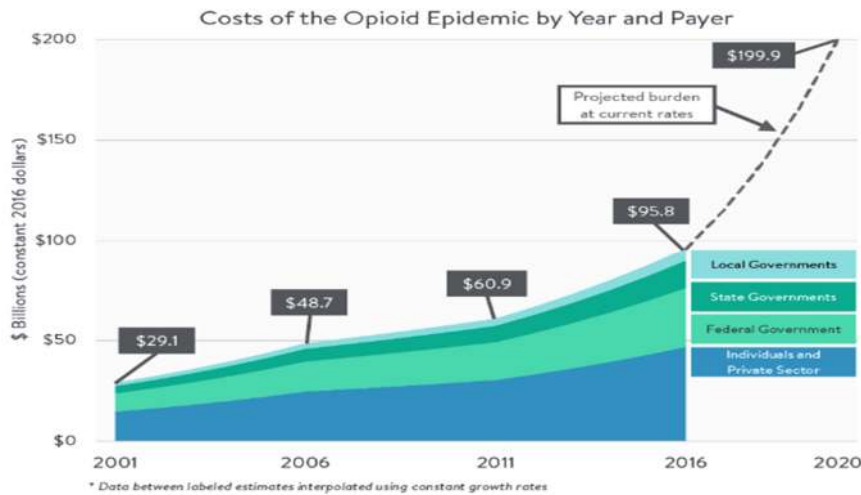
The costs of the opioid crisis are borne by individuals in the form of lost wages; the private sector in lost productivity and health care costs; and federal, state and local governments in lost tax revenue and additional spending on health care, social services, education and criminal justice.

151. San Mateo County is incurring millions of dollars in added costs due to the opioid epidemic, including costs related to:

- Lost tax revenues due to opioid-related fatalities and opioid use disorders;
- Increased healthcare costs resulting from overdoses and indirect health complications;
- Additional criminal justice costs;
 - Increased cost to the San Mateo County Sheriff's Office;
 - Increased cost to the San Mateo Superior Court;
 - Increased costs to the corrections system;
- Child and family services expenses; and
- Coroner costs.

152. According to the Altarum February 2018 study, costs are broken down as follows:





D. The Pharmaceutical Industry Grossly Overstated the Benefits of Opioid Therapy for Chronic Pain

153. To convince doctors and patients that opioids should be used to treat chronic pain, the industry also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." (Emphasis added.)⁴⁷ In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials < 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."⁴⁸ Despite this, manufacturers and distributors falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

154. For example, manufacturers falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples of these deceptive claims that

⁴⁷ *CDC Guidelines for Prescribing Opioids for Chronic Pain – United States, 2016*, CDC (Mar. 18, 2016), available at <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> (Last accessed June 13, 2018).

⁴⁸ Letter to Andrew Kolodny from Janet Woodcock, Sept. 10, 2013, available at <https://www.seattle.gov/documents/departments/cityAttorney/opioidLitigation/FDA-ResponsePROppetition.pdf> (Last accessed June 13, 2018).

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

- 3 a. Actavis distributed an advertisement that claimed that the use of Kadian to treat
4 chronic pain would allow patients to return to work, relieve "stress on your body and
5 your mental health," and help patients enjoy their lives.
- 6 b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain
7 would allow patients to perform demanding tasks like construction work or work as a
8 chef and portrayed seemingly healthy, unimpaired subjects.
- 9 c. Janssen sponsored and edited a patient education guide entitled *Finding Relief Pain*
10 *Management for Older Adults* (2009) — which states as "a fact" that "opioids may
11 make it *easier* for people to live normally." The guide lists expected functional
12 improvements from opioid use, including sleeping through the night, returning to
13 work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly,
14 opioid medications can make it possible for people with chronic pain to 'return to
15 normal'."
- 16 d. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled
17 "Pain vignettes," which were case studies featuring patients with pain conditions
18 persisting over several months and recommending OxyContin for them. The ads implied
19 that OxyContin improves patients' function.
- 20 e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon, Endo
21 and Purdue, taught that relief of pain by opioids, by itself, improved patients' function.
22 The book remains for sale online.
- 23 f. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living*
24 *with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality
25 of life we deserve." The guide was available online until APF shut its doors in May
26 2012.
- 27 g. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your
28 level of function should improve; you may find you are now able to participate in
activities of daily living, such as work and hobbies, that you were not able to enjoy
when your pain was worse." Elsewhere, the website touted improved quality of life (as
well as "improved function") as benefits of opioid therapy. The grant request that Endo
approved for this project specifically indicated NIPC's intent to make misleading
claims about function, and Endo closely tracked visits to the site.
- h. Endo was the sole sponsor, through NIPC, of a series of non-credit educational
programs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid
therapy has been "shown to reduce pain and improve depressive symptoms and
cognitive functioning." The CME was disseminated via webcast.

- i. Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function." This video is still available today on YouTube.
- j. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The *Policymaker's Guide* was originally published in 2011 and is still available online today.
- k. In a 2015 video on Forbes.com discussing the introduction of Hysingla ER, Purdue's Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue's opioids, to chronic pain patients' "quality of life," and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.
- l. Sales representatives have conveyed and continue to convey to prescribers in California, including San Mateo County, the message that opioids will improve patient function.

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

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

1 156. The CDC has also noted that the risks of addiction and death "can cause
2 distress and inability to fulfill major role obligations." As a matter of common sense (and
3 medical evidence), drugs can kill patients or commit them to a life of addiction.

4 157. The 2016 CDC Guideline was not the first time a federal agency repudiated
5 claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis, in
6 response to its advertising, that "[w]e are not aware of substantial evidence or substantial
7 clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in
8 alleviating pain, taken together with any drug-related side effects patients may experience ...
9 results in any overall positive impact on a patient's work, physical and mental functioning,
10 daily activities, or enjoyment of life."⁴⁹

11 158. The industry also falsely and misleadingly emphasized or exaggerated the risks
12 of competing products like NSAIDs, so that doctors and patients would look to opioids first
13 for the treatment of chronic pain. For example, the industry overstated the number of deaths
14 from NSAIDs and prominently featured the risks of NSAIDs, while minimizing or failing to
15 mention the serious risks of opioids. Once again, these misrepresentations contravened
16 pronouncements by and guidance from the FDA and CDC based on scientific evidence.
17 Indeed, the FDA changed the labels for extended-release and long-acting opioids in 2013 and
18 immediate-release opioids in 2016 to state that opioids should only be used as a last resort "in
19 patients for which alternative treatment options" like non-opioid drugs "are inadequate." And
20 the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for
21 chronic pain, particularly arthritis and lower back pain.

22 159. In addition, Purdue misleadingly promoted OxyContin as being unique among
23 opioids in providing 12 continuous hours of pain relief with one dose.

24 160. In fact, OxyContin does not last for 12 hours. According to Purdue's own
25 research, OxyContin wears off in under six hours in one quarter of patients and in under 10
26 hours in more than half. This is because OxyContin tablets release approximately 40% of their

27 _____
28 ⁴⁹ Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug
Boothe, CEO, Actavis Elizabeth LLC, Feb. 18, 2010.

1 active medicine immediately, after which release tapers. This triggers a powerful initial
2 response but provides little or no pain relief at the end of the dosing period, when less medicine
3 is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008
4 that a "substantial number" of chronic pain patients taking OxyContin experience it. This not
5 only renders Purdue's promise of 12 hours of relief false and misleading, it also makes
6 OxyContin more dangerous because the declining pain relief patients experience toward the
7 end of each dosing period drives them to take more OxyContin before the next dosing period
8 begins, quickly increasing the amount of drug they are taking and spurring growing
9 dependence.

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

19 162. According to a May 29, 2018 exposé by the New York Times, Purdue was well
20 aware that oxycodone was being abused from the early days of its marketing of the drug. The
21 Times cites a 120-page confidential Justice Department report that shows that Purdue knew
22 about "significant" abuse of OxyContin in the first years after the drug's introduction in 1996
23 and concealed that information.

newspaper stories and finding "we have in fact picked up references to abuse of our opioid products on the Internet." A copy of the memorandum was sent to FRIEDMAN. The article noted that "a prescription of 30 MS Contin 60-mg tablets worth approximately \$51 carried a mark-up of 2059%, fetching about \$1050 on the street (around \$35 per tablet)."⁵⁰

On August 2, 1996, PURDUE scientist Gary Ritchie emailed Mortimer Sackler, Raymond Sackler, Richard Sackler, Kathie Sackler, Jonathan Sackler, Mortimer D.A. Sackler, Chief Financial Officer Mahoney, FRIEDMAN, GOLDENHEIM, and UDELL the results of his research about the illicit extraction procedure for Oramorph versus MS Contin, stating "I found MS Contin mentioned a couple of times on the internet underground drug culture scene. Most of it is mentioned in the context of MS Contin morphine source."

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E. The Industry Engaged in Other Unlawful and Unfair Misconduct

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

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

- Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent*

⁵⁰ Barry Meier, *Origins of an Epidemic: Purdue Pharma Knew Its Opioids Were Widely Abused*, N.Y. TIMES (May 29, 2018), available at <https://www.nytimes.com/2018/05/29/health/purdue-opioids-oxycotin.html> (Last Accessed June 13, 2018).

1 *and Breakthrough Pain*, published in a supplement of Pain Medicine News in
2 2009. The CME instructed doctors that "clinically, broad classification of pain
3 syndromes as either cancer- or noncancer-related has limited utility" and
4 recommended Actiq and Fentora for patients with chronic pain. The CME is still
5 available online.

- 6 • Cephalon's sales representatives set up hundreds of speaker programs for
7 doctors, including many non-oncologists, which promoted Actiq and Fentora for
8 the treatment of non-cancer pain.
- 9 • In December 2011, Cephalon widely disseminated a journal supplement entitled
10 "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for
11 Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate
12 (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine
13 News — three publications that are sent to thousands of anesthesiologists and
14 other medical professionals. The Special Report openly promotes Fentora for
15 "multiple causes of pain" — and not just cancer pain.

16 165. Cephalon's deceptive marketing gave doctors and patients the false impression
17 that Actiq and Fentora were not only safe and effective for treating chronic pain but were also
18 approved by the FDA for such uses.

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

25 167. Although the DEA has repeatedly informed Purdue about its legal "obligation
26 to design and operate a system to disclose . . . suspicious orders of controlled substances" and
27 to inform the DEA "of suspicious orders when discovered," Purdue also unlawfully and
28

1 unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite
2 knowing about it for years. (*See* 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(e).)

3 168. For over a decade, Purdue has been able to track the distribution and prescribing
4 of its opioids down to the retail and prescriber levels. Through its extensive network of sales
5 representatives, Purdue had and continues to have knowledge of the prescribing practices of
6 thousands of doctors in California and could identify California doctors who displayed red flags
7 for diversion such as those whose waiting rooms were overcrowded, whose parking lots had
8 numerous out-of-state vehicles, and whose patients seemed young and healthy or homeless.
9 Using this information, Purdue has maintained a database since 2002 of doctors suspected of
10 inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or
11 law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them,
12 Purdue used the list to demonstrate the high rate of diversion of OxyContin — the same
13 OxyContin that Purdue had promoted as less addictive — in order to persuade the FDA to bar the
14 manufacture and sale of generic copies of the drug because the drug was too likely to be abused.
15 In an interview with the *Los Angeles Times*, Purdue's senior compliance officer acknowledged
16 that in five years of investigating suspicious pharmacies, Purdue failed to take action — even
17 where Purdue employees personally witnessed the diversion of its drugs. The same was true of
18 prescribers; despite its knowledge of illegal prescribing, Purdue did not report until years after
19 law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million
20 OxyContin tablets and that Purdue's district manager described internally as "an organized
21 drug ring."

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

26 170. As Dr. Mitchell Katz, director of the Los Angeles County Department of
27 Health Services, said in a *Los Angeles Times* article, "Any drug company that has information
28 about physicians potentially engaged in illegal prescribing or prescribing that is endangering

1 people's lives has a responsibility to report it." The NY AG's settlement with Purdue
2 specifically cited the company for failing to adequately address suspicious prescribing. Yet,
3 Purdue continues to profit from the prescriptions of such prolific prescribers. Defendant
4 Distributors aid and abet Purdue and other opioid manufactures.

5 **F. Although Defendants Knew that the Marketing of Opioids was False and**
6 **Misleading, They Fraudulently Concealed Their Misconduct, and the**
7 **Misconduct of Others**

8 171. Defendants, both individually and collectively, and in concert with
9 manufacturers and doctors, made, promoted, and profited from misrepresentations about the
10 risks and benefits of opioids for chronic pain even though they knew that the misrepresentations
11 were false and misleading. The history of opioids, as well as research and clinical experience
12 over the last 20 years, established that opioids were highly addictive and responsible for a long
13 list of very serious adverse outcomes. The DEA, FDA and other regulators warned Defendants
14 and their co-conspirators of this. Defendants had access to scientific studies, detailed
15 prescription data, and reports of adverse events, including reports of addiction, hospitalization,
16 and deaths — all of which made clear the harms from long-term opioid use and that patients are
17 suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA
18 and CDC have issued pronouncements based on the medical evidence that conclusively
19 expose the known falsity of Defendants' misrepresentations.

20 172. Moreover, at all times relevant to this Complaint, the Defendant Distributors
21 took steps to avoid detection of their co-conspirators and to fraudulently conceal deceptive
22 marketing and unlawful, unfair, and fraudulent conduct. For example, Defendants disguised
23 their own role in the deceptive marketing of chronic opioid therapy by funding and working
24 through third parties like front groups and KOLs. Defendants purposefully hid behind the
25 assumed credibility of these individuals and organizations and relied on them to vouch for the
26 accuracy and integrity of false and misleading statements about the risks and benefits of long-
27 term opioid use for chronic pain.

28 173. Defendants also never disclosed their role in shaping, editing, and approving the
content of information and materials disseminated by these third parties. Defendants exerted

1 considerable influence on these promotional and "educational" materials in emails,
2 correspondence, and meetings with front groups, and public relations companies that were not,
3 and have not yet become, public.

4 174. Thus, Defendants successfully concealed from the medical community,
5 patients, and health care payors facts sufficient to arouse suspicion of the claims that Plaintiff
6 now asserts. Plaintiff did not know of the existence or scope of Defendants' and their co-
7 conspirators' industry-wide fraud and could not have acquired such knowledge earlier through
8 the exercise of reasonable diligence.

9 **G. By Knowingly Allowing an Explosion in Opioid Prescribing, Use, Misuse,**
10 **Abuse, and Addiction Through Unlawful and Unfair Business Practices, Each**
11 **Defendant Has Created or Assisted the Creation of a Public Nuisance in San**
Mateo County

12 175. Defendants' misrepresentations deceived and continue to deceive doctors and
13 patients in San Mateo County, about the risks and benefits of long-term opioid use. California
14 doctors, including doctors in San Mateo County, confirm this. Studies also reveal that many
15 doctors and patients are not aware of or do not understand these risks and benefits. Indeed,
16 patients often report that they were not warned they might become addicted to opioids
17 prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid
18 patients found that 4 out of 10 were not told opioids were potentially addictive.⁵¹ Indeed,
19 California residents in treatment for opioid addiction, including residents of San Mateo
20 County, confirm that they were never told that they might become addicted to opioids when
21 they started taking them, were told that they could easily stop using opioids, or were told that
22 the opioids they were prescribed were less addictive than other opioids.

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27 ⁵¹ *Missed Questions, Missed Opportunities*, HAZELDEN BETTY FORD (Jan. 27, 2016), available
28 at <https://www.hazeldenbettyford.org/about-us/news-media/press-release/2016-doctors-missing-questions-that-could-prevent-opioid-addiction> (Last accessed June 13, 2018).



Dr. Scott Morrow, San Mateo County health officer, looks at a map of the county in his office while discussing efforts to combat the opioid epidemic by working with physicians who prescribe medication.

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

177. McKesson, Cardinal and AmerisourceBergen are behind efforts to recognize pain as the “fifth vital sign.” The Big Three Distributors are also behind efforts to curb the effectiveness of the DEA’s efforts to stem illegal opioid prescriptions.

178. Defendants' and their co-conspirators’ unlawful and unfair business practices caused and continue to cause doctors in California, including doctors in San Mateo County, to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent co-conspirators’ deceptive marketing scheme and Defendant’s and co-conspirators’ unlawful and unfair business practices, these doctors would not have prescribed as many opioids to as many patients, and there would not have been as many opioids available for misuse and abuse or as much demand for those opioids.

179. Defendants' unlawful and unfair business practices also caused and continue to cause patients in California, including patients in San Mateo County, to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' unlawful practices, fewer patients would be using opioids long-term to treat chronic pain, and those

⁵² Samantha Weigel, *County, doctors confront opioid abuse: Physicians urged to be cautious with how they prescribe medication*, DAILY JOURNAL (Apr. 24, 2017), available at https://www.smdailyjournal.com/news/local/county-doctors-confront-opioid-abuse-physicians-urged-to-be-cautious/article_77e8b7a0-c6ed-5ce4-99c9-eb12d57d0790.html (Last Accessed June 13, 2018).

1 patients using opioids would be using less of them. Ultimately Defendant Distributors are
2 tasked with monitoring and reporting regarding illegal or suspect purchases of opioids by
3 pharmacies; however, Defendants flagrantly violated the law.

4 180. The dramatic increase in opioid prescriptions and use corresponds with the
5 dramatic increase in Defendants' spending on lobbying. Between 2011 and 2017 McKesson
6 spent \$12,713,477 on lobbying, Cardinal spent \$13,030,000 and AmerisourceBergen spent
7 \$10,381,000.⁵³

8 **H. By Causing an Explosion in Opioid Prescriptions and Use Defendants Have**
9 **Created or Assisted in the Creation of a Public Nuisance in San Mateo County**

10 181. The escalating number of opioid prescriptions written by doctors who were
11 deceived by deceptive marketing schemes is the cause of a correspondingly dramatic increase in
12 opioid addiction, overdose, and death throughout the United States and California.

13 182. Representing the NIH's National Institute of Drug Abuse in hearings before the
14 Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained
15 that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the
16 severity of the current prescription drug abuse problem."⁵⁴

17 183. Scientific evidence demonstrates a strong correlation between opioid
18 prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever
19 prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses."
20 Patients receiving prescription opioids for chronic pain account for the majority of overdoses.
21 "[U]nintentional poisoning deaths" from prescription opioids similarly quadrupled between 1999
22 and 2010 outnumbering deaths from heroin and cocaine combined.⁵⁵ For these reasons, the CDC
23 has concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to

24 ⁵³ *Influence & Lobbying*, OPEN SECRETS (2018), available at
<https://www.opensecrets.org/lobby/search.php> (Last Accessed June 13, 2018).

25 ⁵⁴ *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, NIH (2014), available at
<https://www.drugcaucus.senate.gov/sites/default/files/Volkow%20Testimony.pdf> (Last Accessed
26 June 13, 2018).

27 ⁵⁵ Kathleen Frydl, *Purdue Pharma: Corporate Fraud With a Body Count*, HUFF POST (May 18,
2016), available at <http://www.alternet.org/drugs/purdue-pharma-corporate-fraud-body-count> (Last
28 Accessed June 4, 2018); Prescription Opioid Overdose Data, CDC (2017), available at
<https://www.cdc.gov/drugoverdose/data/overdose.html> (Last Accessed June 4, 2018).

reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity." Most misused prescription drugs are obtained directly or indirectly from a doctor's prescription; only 4% of persons misusing or addicted to prescription drugs report getting them from a drug dealer or stranger.⁵⁶

184. San Mateo County has seen an incredible increase in deaths from opioids in the past few years. Like other counties across the United States, San Mateo County now spends millions of dollars each year dealing with the fallout of an opioid epidemic. San Mateo's on-going costs include extra expenditures related to drug treatment, emergency room visits, law enforcement, and social services (including for children born opioid-dependent and/or who have parents unable to care for them because of their own respective addictions).

185. According to the most recent data available, **97 San Mateo County residents died in 2017** from drug related causes, with **11 deaths directly tied to heroin use and another 26 deaths directly tied to other opioids**. In 2016, San Mateo County saw **61 drug-related deaths**, with 11 tied to heroin and 16 tied to other opioids.

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

187. Between 2010 and 2014 an estimated **almost half of all filled scheduled drug prescriptions were for opioids**. By 2015 there were an estimated **hundreds of thousands of opioid prescriptions** filled in San Mateo County, a figure that has gone up since then. County health officials estimate that thousands of residents are opioid dependent.

188. In 2017, there were a total of 54 opioid-related overdose ambulance calls. This was an increase year-over-year from 2016 when there were 50 overdose calls.

⁵⁶ Anne Lembke, *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop* 18 (Johns Hopkins University Press 2016).

1 189. In Fiscal-Year 2016-2017 the San Mateo County Health System provided drug
2 treatment services to 456 individuals addicted to heroin and 123 individuals addicted to other
3 opiates for a total of 588 individuals.

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

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

13 192. Defendants' creation, through unlawful and unfair conduct, of a virtually limitless
14 opioid market has significantly harmed communities in California, including San Mateo County.
15 Defendants' success in extending the market for opioids to new patients and chronic pain
16 conditions has created an abundance of drugs available for non-medical and criminal use and
17 fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids that
18 are abused come, directly or indirectly, through doctors' prescriptions.

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

23 194. Many patients who become addicted to opioids will lose their jobs. Some will
24 lose their homes and their families. While some will get treatment, fewer will successfully
25 complete it and; many of those patients will relapse, returning to opioids or some other drug. Of
26 those who continue to take opioids, some will overdose — some fatally. Others will die
27 prematurely from related causes — falling or getting into traffic accidents due to opioid-induced
28

1 somnolence; dying in sleep from opioid-induced respiratory depression; suffering assaults while
2 engaging in illicit drug transactions; or dying from opioid-induced heart or neurological disease.

3 195. Absent each Defendants' unlawful and unfair business practices, the public
4 health crisis caused by opioid misuse, abuse, and addiction in California, including in San
5 Mateo County, would have been averted or would have been much less severe.

6 196. These harms in California, including in San Mateo County, caused by Defendants'
7 unlawful and unfair business practices are a public nuisance because they are "injurious to health"
8 and interfere "with the comfortable enjoyment of life" and "property" (Civ. Code, § 3479) and
9 because they "affect[] at the same time" "entire communit[ies]" and "neighborhoods" and "any
10 considerable number of persons" (*id.*, § 3480).

11
12 **I. Defendants Knew and Should Have Known That Their Practices Would
Create or Assist in the Creation of this Public Nuisance in San Mateo County**

13 197. Defendants knew and should have known about the harms that their unlawful
14 and unfair business practices have caused and continue to cause in California, including in San
15 Mateo County. Furthermore, Defendants knew and should have known about the harms that
16 their co-conspirators' false and misleading marketing have caused and continue to cause in
17 California, including in San Mateo County. Defendants closely monitored their sales and the
18 habits of the pharmacies that they were pumping opioid medications to. Defendants also had
19 access to and watched government and other data that tracked the explosive rise in opioid use,
20 addiction, injury, and death. They intended that the opioid epidemic would continue to increase
21 because it helped their profitability.

22 198. In Congressional testimony, Rannazzisi described the efforts by the DEA to
23 educate distributors:

24 DEA also established the Distributor Initiative Program in 2005 to educate registrants on
25 maintaining effective controls against diversion, and monitoring for and reporting
26 suspicious orders. This program was initially designed to educate wholesale distributors
27 who were supplying controlled substances to rogue Internet pharmacies and, more
28 recently, to diverting pain clinics and pharmacies. The goal of this educational program
is to increase distributor awareness and vigilance so that they cut off the source of
supply to these and other schemes. Wholesale distributors are required to design and
operate a system that will detect suspicious orders and report those suspicious orders to

1 DEA. Through the Distributor Initiative Program, DEA educates distributors about their
2 obligations under the CSA, as well as provides registrants with current trends and “red
3 flags” that might indicate that an order is suspicious, such as the type of drug(s) ordered,
4 orders of unusual size, orders that deviate from a normal pattern, frequency of orders,
5 breadth and type of products ordered, and the location of the customer.⁵⁷

6 199. Further, as previously chronicled, each of the Defendant Big Three Distributors
7 has been subject to substantial penalties for violations of the law: None can plead ignorance of
8 the epidemic or their role in it.

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

12 200. Defendants' actions are not permitted nor excused by the fact that drug labels
13 may have allowed or did not exclude the use of opioids for chronic pain. FDA approval of
14 opioids for certain uses did not give the Defendants' co-conspirators license to misrepresent the
15 risks and benefits of opioids. Indeed, the misrepresentations were directly contrary to
16 pronouncements by and guidance from the FDA based on the medical evidence and their own
17 labels. Defendant Distributors knew these facts and continued to supply billions of opioid pills
18 on an annual basis to fill legitimate and ill-legitimate prescriptions. In addition to supplying
19 opioids to pharmacies on demand, Distributors encouraged the stockpiling of excess opioids.
20 Further, Distributors knowingly broke the law by failing to report suspicious purchases.

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

28 ⁵⁷ *Statement of Joseph T. Rannazzisi*, DOJ (May 14, 2014), available at
<https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony.pdf> (Last
Accessed June 13, 2018).

202. Finally, each Defendants' conduct and role in creating or assisting in the creation of the public health crisis now plaguing San Mateo County is directly relevant to the amount of the civil penalties to be awarded under Business & Professions Code §§ 17206 ["In assessing the amount of the civil penalty, the court shall consider any one or more of the relevant circumstances presented by any of the parties to the case, including, but not limited to, the following: the nature and seriousness of the misconduct, the number of violations, the persistence of the misconduct, the length of time over which the misconduct occurred, the willfulness of the defendant's misconduct, and the defendant's assets, liabilities, and net worth," emphasis added] and 17536 [same]. While the use of opioids has taken an enormous toll on San Mateo County and its residents, Defendants have realized blockbuster profits. Financial information indicates that each Defendant experienced a material increase in sales, revenue, and profits from the false and misleading advertising and other unlawful and unfair conduct described above.

VI. CAUSES OF ACTION⁵⁸

FIRST CAUSE OF ACTION

PUBLIC NUISANCE

Violations of California Civil Code Sections 3479 and 3480

(Against Each Defendant)

203. Plaintiff re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

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

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

⁵⁸ Plaintiff is not asserting a claim under the Federal Pharmaceutical Prime Vendor Contract, known as the PPV Contract, nor any Federal statute, regulation or directive.

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

3 207. Pursuant to Section 731 of the Civil Code, this action is brought by
4 Plaintiff to abate the public nuisance created by the Defendants.

5 208. Each Defendant, acting individually and in concert with the other Defendants, and in
6 concert with unnamed co-conspirators, including opioid manufactures, has created or assisted in the
7 creation of a condition that is injurious to the health and interferes with the comfortable enjoyment of
8 life and property of entire communities or neighborhoods or of any considerable number of persons
9 in San Mateo County, in violation of Civil Code Sections 3479 and 3480.

10 209. The public nuisance is substantial and unreasonable. Defendants' actions caused
11 and continue to cause the public health epidemic described above in San Mateo County, and
12 that harm outweighs any offsetting benefit.

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

17 211. Defendants' actions were, at the very least, a substantial factor in opioids
18 becoming widely available and widely used. Defendants' actions were, at the very least, a
19 substantial factor in deceiving doctors and patients about the risks and benefits of opioids for
20 the treatment of chronic pain. Without Defendants' actions, opioid use, misuse, abuse, and
21 addiction would not have become so widespread, and the opioid epidemic that now exists
22 would have been averted or much less severe. As distributors of opioids, Defendants were in a
23 unique position to observe the flow of opioids and to take action when orders were placed for
24 suspicious quantities and at suspect intervals, among other things. The Defendants' role in
25 facilitating access to opioid drugs for long-term use—coupled with their failure to prevent,
26 monitor, identify, and report drug diversion—contributed to a vast increase in opioid overuse
27 and addiction, as well as an increase in costs to governmental entities including the County of
28 San Mateo. The Defendant Distributors' conduct thus directly caused a public health crisis,

1 including costs for excessive prescribing, addiction related treatment costs, law enforcement
2 costs, costs related to deaths, costs related to lost productivity of the work force, and costs
3 related to caring for children born addicted or with addicted parents.

4 212. The public nuisance — i.e., the opioid epidemic — created, perpetuated, and
5 maintained by Defendants can be abated and further recurrence of such harm and
6 inconvenience can be abated.

7 213. Pursuant to Code of Civil Procedure § 731, Plaintiff requests an order providing for
8 abatement of the public nuisance that Defendants created or assisted in creating. Plaintiff, acting
9 on its own behalf and on behalf of its residents, seeks costs associated with the county's efforts to
10 abate the public nuisance caused in whole or in part by Defendants.

11 **SECOND CAUSE OF ACTION**

12 **UNFAIR COMPETITION**

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

14 **(Against Each Defendant)**

15 214. Plaintiff re-alleges and incorporates by reference each of the allegations
16 contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of
17 Action.

18 215. At a minimum, each Defendant is named in this Cause of Action for its
19 activities that occurred within four years of the filing of this action. Plaintiff reserves the
20 right to prove at trial that the full extent of the Defendants' acts of Unfair Competition was
21 not known to Plaintiff until recently, and Plaintiff also reserves the right to demonstrate
22 that tolling extends the statute of limitations applicable to Plaintiff's claims against
23 Defendants.

24 216. Business and Professions Code Section 17200 (Section 17200) prohibits any
25 "unlawful, unfair or fraudulent business act or practice[]."

26 217. Defendants have engaged in unlawful, unfair, and fraudulent business
27 practices in violation of Section 17200 as set forth above.

1 218. Defendants' business practices, as described in this Complaint, are
2 deceptive and violate Section 17200 because the practices are likely to deceive consumers in
3 California.

4 219. Defendants aided and abetted the actions of the opioid manufacturers, and front
5 groups for the pharmaceutical industry and knew and should have known at the time that false
6 and misleading statements about opioids were being made that the statements were in fact false
7 and misleading and were therefore likely to mislead the public. Defendants made or disseminated
8 false and misleading statements or caused false and misleading statements to be made or
9 disseminated, that were likely to deceive the public. Defendants' omissions, which are deceptive
10 and misleading in their own right, render even Defendants' seemingly truthful statements about
11 opioids false and misleading. All of this conduct, separately and collectively, was likely to
12 deceive California doctors who prescribed opioid medications, patients, and payors, who
13 purchased, or covered the purchase of, opioids for chronic pain, and Counties, such as San Mateo
14 who were burdened with the aftermath of the opioid epidemic.

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

- 17
- 18 a. Defendants violated the CSA's requirements as incorporated into California law. Cal.
19 Bus. & Prof. Code §4301;
- 20 b. Defendants engaged in acts of gross immorality and aided and abetted the acts of
21 gross immorality by unnamed co-conspirators, including opioid manufacturers, in
22 violation of Cal. Bus. & Prof. Code §4301;
- 23 c. Defendants engaged in acts of incompetence and aided and abetted the acts of
24 incompetence by unnamed co-conspirators, including opioid manufacturers, in
25 violation of Cal. Bus. & Prof. Code §4301;
- 26 d. Defendants engaged in acts of gross negligence and aided and abetted the acts of
27 gross negligence by unnamed co-conspirators, including opioid manufacturers, in
28 violation of Cal. Bus. & Prof. Code §4301;
- e. Defendants excessively furnished controlled substances within the County of San
Mateo in violation of Cal. Bus. & Prof. Code §4301;

- 1 f. Defendants engaged in acts involving moral turpitude, dishonesty, fraud, deceit,
2 and/or corruption and aided and abetted such acts by unnamed co-conspirators,
3 including opioid manufacturers, in violation of Cal. Bus. & Prof. Code §4301;
4
5 g. Defendants knowingly sold and furnished controlled opioid substances to addicts in
6 violation of Cal. Bus. & Prof. Code §4301;
7
8 h. Defendants violated the statutes of this state, other states and of the United States
9 regulating controlled substances and dangerous drugs in violation of Cal. Bus. &
10 Prof. Code §4301;⁵⁹
11
12 i. Defendants violated Cal. Bus. & Prof. Code §4301 by aiding and abetting violations
13 of law by known and unknown co-conspirators, including opioid manufacturers
14 which is illegal pursuant to Cal. Bus. & Prof. Code §4301(o);
15
16 j. Defendants violated Cal. Health & Safety Code §11153.5 by furnishing for sale
17 and/or distributing opioids that were not solely for legitimate purposes;
18
19 k. Defendants failed to report to the California State Board of Pharmacy "all sales of
20 dangerous drugs subject to abuse" in excess of the amounts sets by the Board as
21 required by 16 C.C.R. §1782.
22
23 l. Defendants failed to report to the California State Board of Pharmacy suspicious
24 orders placed by one or more California-licensed pharmacy or wholesaler as
25 required by Cal. Bus. & Prof. Code §4169.1.
26
27 m. Defendants sold, delivered, held and/or offered for sale opioid drugs that were
28 falsely advertised in violation of the Sherman Food, Drug, and Cosmetic Laws, Health
and Safety Code § 110390;
n. Defendants, sold, delivered, held, or offered for sale opioids that had been falsely
advertised in violation of the Sherman Food, Drug, and Cosmetic Laws, Health &
Safety Code § 110395;
o. Defendants received in commerce opioids that were falsely advertised or delivered
or proffered for delivery opioids that were falsely advertised in violation of the
Sherman Food, Drug, and Cosmetic Laws, Health & Safety Code § 110400;
p. Defendants sold, delivered, held, or offered for sale opioids that had been
misbranded in violation of the Sherman Food, Drug, and Cosmetic Laws, Health &
Safety Code §§ 110290, 111440, and 111330;
q. Defendants misbranded opioids in violation of the Sherman Food, Drug, and
Cosmetic Laws, Health & Safety Code §§ 110290, 111445, 111330;

⁵⁹ Plaintiff does not assert a claim under the laws of the United States or of States other than California, rather Defendants' violations of such laws are actionable under the law of California.

- 1 r. Defendants received in commerce opioids that were misbranded in violation of the
2 Sherman Food, Drug, and Cosmetic Laws, Health & Safety Code §§ 110290,
3 111450, and 111330;
- 4 s. Defendants proffered for delivery opioids that were misbranded in violation of the
5 Sherman Food, Drug, and Cosmetic Laws, Health & Safety Code §§ 110290,
6 111450, and 111330;
- 7 t. Defendants failed to adopt and comply with a Comprehensive Compliance Program
8 in violation of Health & Safety Code § 119402;
- 9 u. Defendants represented that opioids had sponsorship, approval, characteristics,
10 ingredients, uses, or benefits which they did not have in violation of the Consumer
11 Legal Remedies Act, Civ. Code § 1770(a)(5);
- 12 v. Defendants represented that opioids were of a particular standard, quality, or grade
13 when they were of another in violation of Consumer Legal Remedies Act, Civ.
14 Code § 1770(a)(7);
- 15 1. Defendants disparaged the goods of another by false or misleading representation
16 of fact in violation of Consumer Legal Remedies Act, Civ. Code § 1770(a)(8);
- 17 m. Defendants unlawfully failed to identify and report suspicious prescribing to law
18 enforcement and health authorities; and,
- 19 n. Defendants made or disseminated, directly or indirectly, untrue, false, or
20 misleading statements about the use of opioids to treat chronic pain, or caused
21 untrue, false, or misleading statements about opioids to be made or disseminated to
22 the general public in violation of Section 17500.

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

27 222. As a direct and proximate result of the foregoing acts and practices, Defendants
28 have received, or will receive, income, profits, and other benefits associated with those practices,
which they would not have received if they had not engaged in violations of the UCL described
in this Complaint.

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

224. Each time a Defendant sold, delivered, held, or offered for sale opioids in violation of Section 17200, it constitutes a separate violation. Business and Professions Code § 17206(b). Plaintiff therefore seeks civil penalties up to \$2,500 per violation pursuant to Section 17206 for each violation of Section 17200. Plaintiff also seeks civil penalties up to \$2,500 per violation under Section 17206.1.

THIRD CAUSE OF ACTION

NEGLIGENCE

(Against Each Defendant)

225. Plaintiff incorporates herein by reference all of the allegations in this complaint.

226. 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.

227. Each of the Defendants owed Plaintiff duties under statutory and common law, including, but not limited to: (1) the duty not to fill suspicious or excessive orders; (2) the duty to enact policies that would prevent and protect against the diversion of Opioid drugs; (3) the duty to enact policies to identify and report suspicious orders; (4) the duty to abide by any government agreements entered into regarding the same; and, (5) the duty to comply with 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.

228. 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 and/or by failing to identify and report such suspicious orders to the appropriate regulators as required by law. Similarly, each of the Defendant failed to enact policies that would sufficiently prevent and protect against Opioid drug diversion.

1 229. Each of the Defendants owed Plaintiff additional duties under statutory law
2 including: (1) the duty under Cal. Health & Safety Code §11153.5 to ensure that all of the opioids
3 they distributed and furnished for sale in California and its counties were furnished only for
4 legitimate medical purposes; and (2) the duty under Cal. Bus. & Prof. Code §4169.1, which
5 requires them to report suspicious orders of opioids.

6 230. Each Defendant breached these duties by failing to take any reasonable measures to
7 ensure that the prescription opioids it distributed and furnished for sale in San Mateo County were
8 furnished only for legitimate medical purposes and by failing to track and report suspicious sales.

9 231. Plaintiff was within the protected class of persons that the UCL, Cal. Bus. & Prof.
10 Code §§4301, 4164 and 17500, Cal. Health & Safety Code §11153.5 and 16 C.C.R. §1782 were
11 designed to protect.

12 232. The Distributors' conduct fell below the reasonable standard of care in the
13 following ways:

- 14 • Using unsafe distribution practices;
- 15 • Failing to correctly review Opioid drug orders for suspicious orders;
- 16 • Failing to report suspicious orders;
- 17 • Failing to investigate orders before filling them;
- 18 • Failing to implement effective controls and procedures to address diversion of
- 19 controlled substances;
- 20 • Disregarding the CSA and DEA's suggestions for safe dispensing;
- 21 • Failing to determine whether the size of orders and/or collective volume of orders is
- 22 appropriate or very inappropriate given pertinent conditions.

23 233. Plaintiff has suffered damages directly, proximately and foreseeably caused by
24 defendants' breaches of their statutory and common law duties.

25 234. It was reasonably foreseeable that Defendants' breaches of the duties set forth in
26 this Cause of Action would cause harm to Plaintiff in the form of higher costs related to opioid use
27 in San Mateo County, as well as opioid abuse, addiction and opioid related deaths—costs that
28 would not have been paid but for Defendants' wrongful conduct. Thus Plaintiff has suffered

1 monetary losses proximately caused by Defendants' breaches of their duties set forth in this Cause
2 of Action.

3 235. Each Defendant's breaches of the common-law duties that they owed to Plaintiff
4 are the proximate cause of Plaintiff's injuries, and Plaintiff is entitled to all damages allowable by
5 law, costs and attorneys' fees, and any other relief the Court deems necessary and appropriate.

6 236. Defendants' negligent acts as set forth herein were made with oppression, fraud or
7 Malice entitling Plaintiff to exemplary damages.

8 **FOURTH CAUSE OF ACTION**

9 **FALSE ADVERTISING**

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

11 **(Against Each Defendant)**

12 237. Plaintiff re-alleges and incorporates by reference each of the allegations contained in
13 the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

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

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

22 240. As alleged above, each Defendant, at all times relevant to this Complaint, violated
23 Section 17500 by making statements to promote the use of opioids to treat chronic pain that
24 omitted or concealed material facts, and by failing to correct prior misrepresentations and
25 omissions, about the risks and benefits of opioids. Each Defendant's omissions, which are false
26 and misleading in their own right, render even their seemingly truthful statements about opioids
27 false and misleading.
28

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

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

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

12 244. Pursuant to Business and Professions Code Section 17536, Plaintiff requests an
13 order assessing a civil penalty of two thousand five hundred dollars (\$2,500) against Defendants
14 for each violation of Section 17500, *et seq.*

15 **VII. PRAYER FOR RELIEF**

16 WHEREFORE, Plaintiff respectfully prays that this Court grant the following relief:

17 245. Entering Judgment in favor of the County of San Mateo in a final order
18 against each of the Defendants;

19 246. A declaration that Defendants have created a public nuisance in violation of
20 Civil Code Sections 3479 and 3480;

21 247. An order that Defendants are required to abate the public nuisance that they
22 created in violation of Civil Code Sections 3479 and 3480;

23 248. An order that Defendants fund an "abatement fund" on behalf of San Mateo
24 County for the purposes of prospectively abating the ongoing opioid nuisance;

25 249. An order that Defendants compensate San Mateo County for damages to its
26 property due to the ongoing public nuisance caused by the opioid epidemic;

27 250. A declaration that Defendants have engaged in unlawful, unfair, and deceptive
28 business acts and practices in violation of the Unfair Competition Law;

1 251. An order that Defendants pay civil penalties for each act of unfair and
2 unlawful competition, pursuant to Business and Professions Code Section 17206;

3 252. An order that Defendants pay civil penalties for each act of unfair and unlawful
4 competition perpetrated against senior citizens or disabled persons, pursuant to Business and
5 Professions Code Section 17206.1;

6 253. An order that Defendants pay treble the amount of all relief awarded by the
7 Court, pursuant to Civil Code Section 3345;

8 254. A declaration that Defendants have made, disseminated as part of a plan or scheme,
9 or aided and abetted the dissemination of false and misleading statements in violation of the False
10 Advertising Law;

11 255. An order that Defendants pay civil penalties to San Mateo County of two thousand five
12 hundred dollars (\$2,500) for each act of false and misleading advertising, pursuant to Section 17536 of the
13 California Business and Professions Code;

14 256. An order that Defendants pay restitution to San Mateo County of any money acquired by
15 Defendants' false and misleading advertising, pursuant to the False Advertising Law;

16 257. An award of damages to San Mateo County for the damages caused by the opioid
17 epidemic, including (A) costs for providing medical care, additional therapeutic and prescription drug
18 purchases, and other treatments for patients suffering from opioid-related addiction, dependence or disease,
19 including overdoses and deaths; (B) costs for providing treatment, counseling, and rehabilitation services;
20 (C) costs for providing treatment of infants born with opioid-related medical conditions; (D) costs for
21 providing care for children whose parents suffer from opioid-related disability or incapacitation; and (E)
22 costs associated with law enforcement and public safety relating to the opioid epidemic;

23 258. An award of punitive damages;

24 259. An award of the costs of investigation, reasonable attorneys' fees, and all costs and
25 expenses of the litigation;

26
27
28

1 260. Such further and additional relief as the Court deems proper.

2
3 Dated: June 19, 2018

COUNTY OF SAN MATEO, COUNTY COUNSEL

4
5 By: 

JOHN C. BEIERS
JOHN D. NIBBELIN
DAVID A. SILBERMAN
KAREN ROSENTHAL

6
7
8 Dated: June 19, 2018

COTCHETT, PITRE & McCARTHY, LLP

9 By: 

JOSEPH W. COTCHETT
ANNE MARIE MURPHY
ADAM J. TROTT

Attorneys for Plaintiff

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14 **JURY DEMAND**

15 Plaintiff demands a jury trial on all issues so triable.

16 Dated: June 19, 2018

COUNTY OF SAN MATEO, COUNTY COUNSEL

17
18 By: 

JOHN C. BEIERS
JOHN D. NIBBELIN
DAVID A. SILBERMAN
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20
21 Dated: June 19, 2018

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