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13 UNITED STATES DISTRICT COURT
 14 NORTHERN DISTRICT OF CALIFORNIA
 15 SAN FRANCISCO DIVISION

17 THE YUOK TRIBE,
 18
 Plaintiff,

19 v.

20 PURDUE PHARMA L.P.; PURDUE PHARMA
 21 INC.; THE PURDUE FREDERICK COMPANY,
 INC.; CEPHALON, INC.; TEVA
 22 PHARMACEUTICAL INDUSTRIES, LTD.;
 TEVA PHARMACEUTICALS USA, INC.;
 23 JOHNSON & JOHNSON; JANSSEN
 PHARMACEUTICALS, INC.; ORTHO-
 24 MCNEIL-JANSSEN PHARMACEUTICALS,
 INC. n/k/a JANSSEN PHARMACEUTICALS,
 25 INC.; JANSSEN PHARMACEUTICA, INC. n/k/a
 JANSSEN PHARMACEUTICALS, INC.;
 26 NORAMCO, INC.; ENDO HEALTH
 SOLUTIONS, INC.; ENDO
 27 PHARMACEUTICALS, INC.;
 MALLINCKRODT PLC; MALLINCKRODT
 28 LLC; ALLERGAN PLC f/k/a ACTAVIS PLC;
 WATSON PHARMACEUTICALS, INC. n/k/a

Case No. 3:18-cv-1566

COMPLAINT

DEMAND FOR JURY TRIAL

1 ACTAVIS, INC.; WATSON LABORATORIES,
2 INC.; ACTAVIS, LLC; ACTAVIS PHARMA,
3 INC. f/k/a WATSON PHARMA, INC.; INSYS
4 THERAPEUTICS INC.;
5 AMERISOURCEBERGEN DRUG
6 CORPORATION; CARDINAL HEALTH, INC.;
7 and MCKESSON CORPORATION,

8 Defendants.

9 Plaintiff Yurok Tribe brings this Complaint against Defendants Purdue Pharma L.P.,
10 Purdue Pharma Inc., The Purdue Frederick Company, Inc., Cephalon, Inc., Teva Pharmaceutical
11 Industries, Ltd., Teva Pharmaceuticals USA, Inc., Johnson & Johnson, Janssen Pharmaceuticals,
12 Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals Inc., Janssen
13 Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., Noramco, Inc., Endo Health Solutions
14 Inc., Endo Pharmaceuticals Inc., Mallinckrodt Plc, Mallinckrodt LLC, Allergan PLC f/k/a Actavis
15 PLC, Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc., Watson Laboratories, Inc., Actavis, LLC,
16 Actavis Pharma, Inc. f/k/a/ Watson Pharma, Inc., Insys Therapeutics, Inc., (collectively, the
17 “Manufacturer Defendants”), AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and
18 McKesson Corporation (collectively, the “Distributor Defendants”) (the Manufacturer Defendants
19 and Distributor Defendants collectively, the “Defendants”). Based upon personal knowledge,
20 information, belief, and investigation of counsel, the Yurok Tribe specifically alleges:

21 **INTRODUCTION**

22 1. Opioid manufacturing and distributing companies systematically and repeatedly
23 disregarded the health and safety of the public, including the Yurok Tribe and the wider tribal
24 community. Defendants did so in order to maximize corporate profits and increase the market for
25 prescription opioids.

26 2. The Yurok Tribe has been forced to contend with the deadly aftermath of the
27 proliferation of opioids¹ in society. As a consequence of Defendants’ conduct as set forth below,
28

¹ “Opioids” as referred to in this Complaint are all or some of the drugs listed in the illustrative chart in ¶ 58 below.

1 Defendants should be required to make amends for the costs with which they have burdened
2 society, generally, and the Yurok Tribe, specifically.

3 3. For decades, pharmaceutical companies told the medical community that patients
4 would not become addicted to prescription opioid pain relievers, and healthcare providers began
5 to prescribe them at greater rates.

6 4. In “Understanding the Epidemic,” the Centers for Disease Control and Prevention
7 (the “CDC”) explained:

8 From 2000 to 2015 more than half a million people died from drug
9 overdoses. 91 Americans die every day from an opioid overdose.

10 We now know that overdoses from prescription opioids are a
11 driving factor in the 15-year increase in opioid overdose deaths.
12 The amount of prescription opioids sold to pharmacies, hospitals,
13 and doctors’ offices nearly quadrupled from 1999 to 2010, yet there
14 had not been an overall change in the amount of pain that
15 Americans reported. Deaths from prescription opioids—drugs like
16 oxycodone, hydrocodone, and methadone—have more than
17 quadrupled since 1999.

18 5. According to the National Institute on Drug Abuse, in 2015, more than 33,000
19 Americans died as a result of an opioid overdose, including prescription opioids, heroin, and
20 illicitly manufactured fentanyl.

21 6. That same year, an estimated 2 million people in the United States suffered from
22 substance use disorders related to prescription opioid pain relievers, and 591,000 suffered from a
23 heroin use disorder (though the two are not mutually exclusive).

24 7. In 2014, the Department of Health and Human Services (“HHS”) issued a report
25 on “Prescription Drug Abuse in Indian Country.” According to the HHS report, American Indian
26 and Alaskan Native populations have a high percentage of lifetime abuse of prescription drugs
27 (64.8%) and that 6.2% of the American Indian and Alaskan Native populations engaged in then-
28 current non-medical use of prescription drugs. That report also found that 12.7% of American
Indian and Alaskan Natives aged 12 and over were then-current users of illicit drugs.

8. In an open letter to the nation’s physicians in August 2016, the then-U.S. Surgeon
General expressly connected this “urgent health crisis” to “heavy marketing of opioids to

1 doctors . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive
2 when prescribed for legitimate pain.”

3 9. As Dr. Andrew Kolodny (a co-founder of Physicians for Responsible Opioid
4 Prescribing and former Chairman of Psychiatry at Maimonides Medical Center) has said: “This is
5 an out of control epidemic, not caused by a virus or a bacteria [sic]. This epidemic has been
6 caused by a brilliant marketing campaign that dramatically changed the way physicians treat
7 pain.”

8 10. Defendants’ marketing, and their use of seemingly independent medical and pain
9 management advocacy groups—and not any medical breakthrough—promoted prescribing
10 opioids for chronic pain and thus opened the floodgates for opioid use, abuse and addiction.²

11 11. Defendants falsely and misleadingly: (1) downplayed the serious risk of addiction;
12 (2) promoted the concept of “pseudo-addiction” and thus advocated that the signs of addiction
13 should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in
14 preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed and
15 do not constitute symptoms of addiction; (5) denied the risks of higher opioid dosages; and
16 (6) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent abuse and
17 addiction.

18 12. Defendants also falsely touted the benefits of long-term opioid use, including the
19 supposed ability of opioids to improve function and quality of life, even though there was no
20 good evidence to support Defendants’ claims.

21 13. Defendants disseminated these common messages to create a false understanding
22 of opioids. They disseminated these messages directly, through their sales representatives, and in
23 speaker groups led by physicians Defendants recruited for their support of Defendants’ marketing
24 messages.

25
26 ² Addiction is a spectrum of substance use disorders that range from misuse and abuse of drugs to
27 addiction. Throughout this Complaint, “addiction” refers to the entire range of substance abuse disorders
28 and defined in the Diagnostic and Statistical Manual of Mental Disorders (5th ed. 2013) (“DSM-V”).
Individuals suffer negative consequences wherever they fall on the substance use disorder continuum.

1 14. Defendants also worked through third parties they controlled by: (a) funding,
2 assisting, encouraging, and directing doctors, known as “key opinion leaders” (“KOLs”) and
3 (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional
4 societies and patient advocacy groups (“Front Groups”), including Health Distribution Alliance
5 (a/k/a Health Distribution Management Association) (“HDA” and “HDMA”), the Pain Care
6 Forum (“PCF”) and others. Defendants then worked together with those KOLs and Front Groups
7 to taint the sources that doctors and patients relied on for ostensibly “neutral” guidance, such as
8 treatment guidelines, medical conferences and seminars, and “scientific” articles. Defendants,
9 working individually and collectively, and through these Front Groups and KOLs, persuaded
10 doctors and patients that what Defendants had long known – that opioids are addictive drugs,
11 unsafe in most circumstances for long-term use – was untrue.

12 15. As Dr. Russell Portnoy, once President of the American Pain Society (one of the
13 Front Groups) has admitted: “I gave innumerable lectures in the late 1980s and 90s about
14 addiction that weren’t true.”

15 16. Each Defendant knew that its misrepresentations of the risks and benefits of
16 opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the
17 falsity of each Defendant’s misrepresentations has been confirmed by the U.S. Food and Drug
18 Administration (“FDA”) and CDC, including by the CDC in its Guideline for Prescribing Opioids
19 for Chronic Pain, issued in 2016 and approved by the FDA.

20 17. This epidemic, fueled by opioids lawfully prescribed by doctors, has resulted in a
21 flood of prescription opioids available for illicit use or sale, and a population of patients
22 physically and psychologically dependent on them. When those patients can no longer afford or
23 legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin.

24 **JURISDICTION**

25 18. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C.
26 § 1331 based on the federal claims asserted under the Racketeer Influenced and Corrupt
27 Organizations Act, 18 U.S.C. § 1961, *et seq.* (“RICO”) and this Court may exercise supplemental
28 jurisdiction pursuant to 28 U.S.C. § 1367 over the other claims.

1 19. The Court has personal jurisdiction over Defendants because at all relevant times
2 Defendants engaged in substantial business activities in the State of California, purposefully
3 directed their actions toward California, consensually submitted to the jurisdiction of California
4 when obtaining a manufacturer or distributor license, and have the requisite minimum contacts
5 with California necessary to constitutionally permit the Court to exercise jurisdiction.

6 **VENUE AND INTRADISTRICT ASSIGNMENT**

7 20. Venue is proper in this District under 28 U.S.C. § 1391 and 18 U.S.C. § 1965
8 because a substantial part of the events or omissions giving rise to the claim occurred in this
9 District and each Defendant transacted affairs and conducted activity that gives rise to the claim
10 of relief in this District. Civil L.R. 3-2(c).

11 **PARTIES**

12 **I. Plaintiff**

13 **A. The Yurok Tribe**

14 21. With more than 6,100 enrolled tribal members, the Yurok Tribe is the largest
15 federally recognized tribe in California, with a reservation located on the lower Klamath River in
16 Humboldt and Del Norte Counties in Northern California. The present-day Yurok Reservation
17 extends for one mile on either side of the Klamath River, from the Pacific Ocean at the mouth of
18 the river upstream approximately 44 miles to just above the Yurok village of Weitchpec and the
19 confluence with the Trinity River. The Yurok Reservation is delineated in this map by the red
20 boundary lines:



1 22. Tribal membership lives throughout Humboldt and Del Norte counties and
2 beyond, though the Yurok Reservation is largely represented by two zip codes: 95548 and
3 95546. The total population in zip code 95546 is 3,494; the population in zip code 95548 is
4 1,373.

5 23. The headquarters of the Yurok tribal government is located within the 95548
6 zone, which contains Klamath, Requa, and Klamath Glen.

7 24. The Tribe's ancestral territory extends well beyond the reservation with traditional
8 villages, sacred sites, throughout the surrounding area. Approximately 5,465 members of the
9 Yurok Tribe reside in locations outside of the Yurok Reservation largely in other areas of
10 Humboldt and Del Norte Counties. Representatives from these areas are elected to the Yurok
11 Tribal Council to represent their interests in the Yurok Tribal Government. The Yurok Tribal
12 Government provides its members in these locations with a variety of governmental services.
13 Regardless of location, many members rely on the Yurok Tribe for their health care, education,
14 social services, and judicial services. Tribal transit service even provides members rides to off-
15 reservation clinics and hospitals as needed for specialized services

16 25. The Yurok Reservation is located in the middle of one of America's first and
17 hardest hit regions by the opioid crisis—rural Northern California. In fact, Humboldt County
18 was one of the first counties in the entire nation to manifest significant signs of opioid diversion
19 and consequences of abuse. Humboldt County has had crisis-level overdose rates for over a
20 decade. Del Norte, while not experiencing the same rate of recorded opioid-related deaths, has a
21 population receiving opioid prescriptions at a rate that exceeds even neighboring Humboldt
22 County. The surrounding counties are also reportedly among the worst affected in the country,
23 with several demonstrating rates of abuse and overdose higher than West Virginia and Kentucky
24 (two regions notoriously devastated by opioids).

25 26. The Yurok Tribal Council has inherent sovereign governmental
26 authority/responsibility to safeguard and provide for the health, safety and welfare of Yurok
27 Tribal members as reflected in the Preamble to the Constitution of the Yurok Tribe.
28

1 27. Nothing herein shall be deemed a waiver of the Yurok Tribe’s sovereign
2 immunity.

3 **II. Defendants**

4 **A. Manufacturer Defendants**

5 **1. Purdue Entities**

6 28. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of
7 Delaware with its principal place of business in Stamford, Connecticut.

8 29. Defendant Purdue Pharma Inc. is a New York corporation with its principal place
9 of business in Stamford, Connecticut.

10 30. Defendant The Purdue Frederick Company, Inc. is a New York corporation with
11 its principal place of business in Stamford, Connecticut.

12 31. At all relevant times, Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue
13 Frederick Company, Inc. (collectively, “Purdue”) are or have been in the business of
14 manufacturing, selling, promoting, and/or distributing opioids throughout the United States.

15 **2. Cephalon Entities**

16 32. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of
17 business in Frazer, Pennsylvania.

18 33. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli corporation with its
19 principal place of business in Petah Tikva, Israel. Teva Pharmaceuticals Ltd. acquired Cephalon
20 in October 2011, and Cephalon Inc. became a wholly owned subsidiary of Teva Pharmaceuticals
21 Ltd.

22 34. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation with its
23 principal place of business in North Wales, Pennsylvania and is a wholly owned subsidiary of
24 Teva Pharmaceutical Industries, Ltd.

25 35. Cephalon, Inc., Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals
26 USA, Inc. (collectively, “Teva”) are in the business of manufacturing, selling, promoting, and/or
27 distributing both brand name and generic opioids throughout the United States.
28

1 **3. Janssen Entities**

2 36. Defendant Johnson & Johnson is a New Jersey corporation with its principal place
3 in New Brunswick, New Jersey.

4 37. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its
5 principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of
6 Johnson & Johnson.

7 38. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen
8 Pharmaceuticals, Inc., which was formerly known as Janssen Pharmaceutical, Inc.

9 39. Defendant Noramco, Inc. is a Delaware company headquartered in Wilmington,
10 Delaware and was a wholly owned subsidiary of Johnson & Johnson until July 2016. Noramco,
11 Inc. is or had been part of Johnson & Johnson's opium processing by making active
12 pharmaceutical ingredients ("APIs") for opioid painkillers.

13 40. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen
14 Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in
15 Titusville, New Jersey.

16 41. Johnson & Johnson, Janssen Pharmaceuticals, Inc., Noramco, Inc., Ortho-McNeil-
17 Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutical, Inc. (collectively, "Janssen") are or
18 have been in the business of manufacturing, selling, promoting, and/or distributing both brand
19 name and generic opioids throughout the United States.

20 **4. Endo Entities**

21 42. Defendant Endo Health Solutions Inc. is a Delaware corporation with its principal
22 place of business in Malvern, Pennsylvania.

23 43. Defendant Endo Pharmaceuticals Inc. is a wholly owned subsidiary of Endo.

24 44. Health Solutions Inc. and is a Delaware corporation with its principal place of
25 business in Malvern, Pennsylvania.

26 45. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. (collectively, "Endo")
27 are or have been in the business of manufacturing, selling, promoting, and/or distributing both
28 brand name and generic opioids throughout the United States.

1 46. Endo also is or has been in the business of manufacturing, selling, promoting,
2 and/or distributing generic opioids through its subsidiary, Qualitest Pharmaceuticals, Inc.,
3 including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

4 **5. Mallinckrodt Entities**

5 47. Defendant Mallinckrodt Plc is an Irish public limited company headquartered in
6 Staines-upon-Thames, United Kingdom and maintains a U.S. headquarters in St. Louis, Missouri.

7 48. Defendant Mallinckrodt, LLC is a limited liability company organized and
8 existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary
9 of Mallinckrodt, Plc. Mallinckrodt, Plc and Mallinckrodt, LLC (collectively, "Mallinckrodt") are
10 or have been in the business of manufacturing, selling, promoting, and/or distributing opioids
11 throughout the United States.

12 **6. Allergan Entities**

13 49. Defendant Allergan Plc is a public limited company incorporated in Ireland with
14 its principal place of business in Dublin, Ireland.

15 50. Defendant Actavis Plc acquired Defendant Allergan Plc in March 2015.

16 51. Defendant Watson Pharmaceuticals, Inc. had acquired Defendant Actavis, Inc. in
17 October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013
18 and then changed the name to Actavis Plc in October 2013.

19 52. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal
20 place of business in Corona, California, and is a wholly-owned subsidiary of Defendant Allergan
21 Plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.).

22 53. Defendant Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation
23 with its principal place of business in New Jersey and was formerly known as Watson Pharma,
24 Inc.

25 54. Defendant Actavis LLC is a Delaware limited liability company with its principal
26 place of business in Parsippany, New Jersey.

27 55. Each of these defendants is owned by Defendant Allergan Plc, which uses them to
28 market and sell its drugs in the United States.

1 56. Defendant Allergan Plc exercises control over these marketing and sales efforts
2 and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. Allergan Plc,
3 Actavis Plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc.,
4 Watson Pharma, Inc., and Watson Laboratories, Inc. (collectively, “Allergan”) are or have been in
5 the business of manufacturing, selling, promoting, and/or distributing both brand name and
6 generic opioids throughout the United States.

7 **7. Insys**

8 57. Insys Therapeutics, Inc. (“Insys”) is a Delaware company with its principal place
9 of business in Chandler, Arizona. Insys is or has been in the business of manufacturing, selling,
10 promoting, and/or distributing fentanyl-based cancer spray Subsys.

11 58. An illustrative list of opioids that the Manufacturer Defendants manufacture and
12 sell to the Distributor Defendants are listed in the following chart:

Company Names	Drugs		
	Drug Name	Chemical Name	Controlled Substance Act Schedule
Purdue Pharma, LP, Purdue Pharma, Inc., The Purdue Frederick Company	OxyContin	Oxycodone hydrochloride	Schedule II
	MS Contin	Morphine sulfate	Schedule II
	Dilaudid	Hydromorphone hydrochloride	Schedule II
	Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
	Butrans	Buprenorphine	Schedule III
	Hysingla ER	Hydrocodone bitartrate	Schedule II
	Targiniq ER	Oxycodone hydrochloride and naloxone hydrochloride	Schedule II
Cephalon, Inc., Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc.	Actiq	Fentanyl citrate	Schedule II
	Fentora	Fentanyl citrate	Schedule II
	Generic Oxycontin	Oxycodone hydrochloride	Schedule II

Company Names	Drugs		
	Drug Name	Chemical Name	Controlled Substance Act Schedule
Johnson & Johnson; Janssen Pharmaceuticals, Inc. (formerly Ortho-McNeil-Janssen Pharmaceuticals, Inc and Janssen Pharmaceutica, Inc.); Noramco, Inc.	Duragesic	Fentanyl	Schedule II
	Nucynta [In 2015, Janssen sold the rights to Nucynta and Nucynta ER]	Tapentadol	Schedule II
	Nucynta ER	Tapentadol	Schedule II
Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Qualitest Pharmaceuticals, Inc.	Opana ER	Oxymorphone hydrochloride	Schedule II
	Opana	Oxymorphone hydrochloride	Schedule II
	Percodan	Oxycodone hydrochloride and aspirin	Schedule II
	Percocet	Oxycodone hydrochloride and acetaminophen	Schedule II
	Generic oxycodone		Schedule II
	Generic oxymorphone		Schedule II
	Generic hydromorphone		Schedule II
Mallinckrodt PLC; Mallinckrodt, LLC (wholly-owned subsidiary of Mallinckrodt PLC)	Exalgo	Hydromorphone hydrochloride	Schedule II
	Roxicodone	Oxycodone hydrochloride	Schedule II
	ConZip and Ultram	Tramadol hydrochloride	Schedule IV
	Kadian	Morphine sulfate	Schedule II
Allergan Plc; Actavis LLC; Actavis Pharma, Inc.; Actavis Plc; Actavis, Inc.; Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; Watson Pharma, Inc.	Norco	Acetaminophen and hydrocodone	Schedule II
	Generic Duragesic	Fentanyl	Schedule II
	Generic Opana	Oxymorphone hydrochloride	Schedule II
	Subsys	Fentanyl	Schedule II

1 **B. Distributor Defendants**

2 **1. AmerisourceBergen**

3 59. Defendant AmerisourceBergen Drug Corporation (“AmerisourceBergen”) is a
4 Delaware corporation with its principal place of business located in Chesterbrook, Pennsylvania.
5 AmerisourceBergen is the second largest pharmaceutical distributor in North America.

6 60. According to its 2016 Annual Report, AmerisourceBergen is “one of the largest
7 global pharmaceutical sourcing and distribution services companies, helping both healthcare
8 providers and pharmaceutical and biotech manufacturers improve patient access to products and
9 enhance patient care.”

10 **2. Cardinal Health**

11 61. Defendant Cardinal Health, Inc. (“Cardinal Health”) is an Ohio Corporation with
12 its principal place of business in Dublin, Ohio. In 2016, Cardinal Health generated revenues of
13 \$121.5 billion.

14 62. Cardinal Health is a global distributor of pharmaceutical drugs and medical
15 products. It is one of the largest distributors of opioids in the United States. Additionally, in
16 December 2013, Cardinal Health formed a ten-year agreement with CVS Caremark to form the
17 largest generic drug sourcing operation in the United States. Cardinal Health has, at all relevant
18 times, distributed opioids nationwide.

19 **3. McKesson**

20 63. Defendant McKesson Corporation (“McKesson”) is a Delaware Corporation with
21 its principal place of business located in San Francisco, California.

22 64. McKesson is the largest pharmaceutical distributor in North America. McKesson
23 delivers approximately one-third of all pharmaceuticals used in North America.

24 65. In its 2017 Annual Report, McKesson states that it “partner[s] with pharmaceutical
25 manufacturers, providers, pharmacies, governments and other organizations in healthcare to help
26 provide the right medicines, medical products and healthcare services to the right patients at the
27 right time, safely and cost-effectively.”

28

1 66. According to the 2017 Annual Report, McKesson “pharmaceutical distribution
2 business operates and serves thousands of customer locations through a network of 27 distribution
3 centers, as well as a primary redistribution center, two strategic redistribution centers and two
4 repackaging facilities, serving all 50 states and Puerto Rico.”

5 67. All of the actions described in this Complaint are part of, and in furtherance of, the
6 unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants’
7 officers, agents, employees, or other representatives while actively engaged in the management of
8 Defendant’s affairs within the course and scope of their duties and employment, and/or with
9 Defendant’s actual, apparent, and/or ostensible authority.

10 **III. RELEVANT RELATED ENTITIES, *i.e.*, FRONT GROUPS**

11 68. The Front Groups and their councils, committees, task forces and working groups
12 provided the Manufacturer and Distributor Defendants with the opportunity to work closely
13 together in shaping their common goals and forming the enterprises’ organizations.

14 69. The PCF has been described as a coalition of drug makers, trade groups, and
15 dozens of non-profit organizations supported by industry funding. The PCF recently became a
16 national news story when it was discovered that lobbyists for members of the PCF quietly shaped
17 federal and state policies regarding the use of prescription opioids for more than a decade.

18 70. The Center for Public Integrity and the Associated Press obtained “internal
19 documents shed[ding] new light on how drug makers and their allies shaped the national response
20 to the ongoing wave of prescription opioid abuse.” Specifically, PCF participants spent over \$740
21 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including
22 opioid-related measures.

23 71. Not surprisingly, each of the Defendants who stood to profit from lobbying in
24 favor of prescription opioid use is a member of and/or participant in the PCF.

25 72. Each Manufacturer Defendant worked together through the PCF to advance the
26 interests of the enterprise. But, the Manufacturer Defendants were not alone.

27 73. In 2012, membership and participating organizations included the HDA (which
28 represents the Manufacturer and Distributor Defendants), Endo, Purdue, Johnson & Johnson,

1 Allergan, and Teva. The Distributor Defendants actively participated, and continue to participate
2 in the PCF, at a minimum, through their trade organization, the HDA.

3 74. The HDA led to the formation of interpersonal relationships and an organization
4 between the Defendants. Although the entire HDA membership directory is private, the HDA
5 website confirms that each of the Distributor Defendants and the Manufacturer Defendants are
6 members. And, the HDA and each of the Distributor Defendants sought the active membership
7 and participation of the Manufacturer Defendants by advocating that one of the benefits of
8 membership included the ability to develop direct relationships between Manufacturers and
9 Distributors at high executive levels.

10 75. In fact, the HDA touted the benefits of membership to the Manufacturer
11 Defendants, advocating that membership included the ability to, among other things, “network
12 one on one with manufacturer executives at HDA’s members-only Business and Leadership
13 Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and
14 sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and
15 working groups with peers and trading partners,” and “make connections.” The HDA and the
16 Distributor Defendants used membership in the HDA as an opportunity to create interpersonal
17 and ongoing organizational relationships between the Manufacturer and Distributor Defendants.

18 76. The HDA also offers a multitude of conferences, including annual business and
19 leadership conferences. The HDA and the Distributor Defendants advertise these conferences to
20 the Manufacturer Defendants as an opportunity to “bring together high-level executives, thought
21 leaders and influential managers . . . to hold strategic business discussions on the most pressing
22 industry issues.” The conferences also gave the Manufacturer and Distributor Defendants
23 “unmatched opportunities to network with [their] peers and trading partners at all levels of the
24 healthcare distribution industry.” The HDA and its conferences were significant opportunities for
25 the Manufacturer and Distributor Defendants to interact at a high-level of leadership.

26 77. As members, the Manufacturer and Distributor Defendants were eligible to
27 participate on councils, committees, task forces and working groups, including:
28

1 a. Industry Relations Council: “This council, composed of distributor and
2 manufacturer members, provides leadership on pharmaceutical distribution and supply chain
3 issues.”

4 b. Business Technology Committee: “This committee provides guidance to
5 HDA and its members through the development of collaborative e-commerce business solutions.
6 The committee’s major areas of focus within pharmaceutical distribution include information
7 systems, operational integration and the impact of e-commerce.” Participation in this committee
8 includes distributors and manufacturer members.

9 c. Health, Beauty and Wellness Committee: “This committee conducts
10 research, as well as creates and exchanges industry knowledge to help shape the future of the
11 distribution for health, beauty and wellness/consumer products in the healthcare supply chain.”
12 Participation in this committee includes distributors and manufacturer members.

13 d. Logistics Operation Committee: “This committee initiates projects
14 designed to help members enhance the productivity, efficiency and customer satisfaction within
15 the healthcare supply chain. Its major areas of focus include process automation, information
16 systems, operational integration, resource management and quality improvement.” Participation
17 in this committee includes distributors and manufacturer members.

18 e. Manufacturer Government Affairs Advisory Committee: “This committee
19 provides a forum for briefing HDA’s manufacturer members on federal and state legislative and
20 regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include
21 such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of
22 distribution, importation and Medicaid/Medicare reimbursement.” Participation in this committee
23 includes manufacturer members.

24 f. Bar Code Task Force: Participation includes Distributor, Manufacturer and
25 Service Provider Members.

26 g. eCommerce Task Force: Participation includes Distributor, Manufacturer
27 and Service Provider Members.
28

1 h. Contracts and Chargebacks Working Group: “This working group explores
2 how the contract administration process can be streamlined through process improvements or
3 technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and
4 chargeback professionals.” Participation includes Distributor and Manufacturer Members.

5 78. Other Front Groups include the American Academy of Pain Medicine, the
6 American Pain Society, the Federation of State Medical Boards, the Joint Commission and the
7 U.S. Pain Foundation.

8 79. The Front Groups – and their funding by the Defendants – have garnered scrutiny
9 by members of the United States Congress. In response to one Congressional inquiry in 2012, the
10 Federation of State Medical Boards disclosed its financial support from Purdue, Cephalon,
11 Mallinckrodt and Endo.

12 80. A recent report of a Senate subcommittee investigation disclosed that five opioid
13 manufacturers (including 3 of the Manufacturer Defendants – Purdue, Janssen and Insys)
14 provided nearly \$9 million in funding to Front Groups (not including money paid to individuals
15 affiliated with those groups). Purdue and Insys together contributed approximately \$7.3 million
16 of that total.

17 **IV. FACTUAL ALLEGATIONS**

18 **A. History of Opioids Sale, Marketing, Regulation and Addiction**

19 81. Since 1970, opioids have been regulated by the U.S. Drug Enforcement
20 Administration (“DEA”) as controlled substances.

21 82. Opioids include brand-name drugs (such as OxyContin) and generics (such as
22 Fentanyl, oxycodone and hydrocodone). They are derived from or possess properties similar to
23 opium and heroin, and, as such, they are highly addictive and dangerous and are also regulated by
24 the FDA as controlled substances.

25 83. Opioids provide effective treatment for short-term post-surgical and trauma-related
26 pain, and for palliative end-of-life care. They are approved by the FDA for use in the
27 management of moderate to severe pain where use of an opioid analgesic is appropriate for more
28 than a few days.

1 84. Defendants, however, have manufactured, promoted, and marketed opioids for the
2 management of pain by misleading consumers and medical providers through misrepresentations
3 or omissions regarding the appropriate uses, risks, and safety of opioids.

4 85. In 2014, there were 18,893 reported deaths involving prescription opioids in 2014,
5 up 16% from the previous year, according to the National Center for Health Statistics.

6 86. In 2016, traditional opioid painkillers, such as OxyContin and Percocet, were
7 involved in at least 14,400 overdose deaths and non-methadone synthetic opioids like fentanyl,
8 were linked to more than 20,100 overdose deaths based on the preliminary figures from the
9 National Center for Health Statistics.

10 87. In a November 2016 report, the DEA declared opioid prescription drugs, heroin,
11 and fentanyl as the most significant drug-related threats to the United States.

12 88. The CDC estimates that approximately three out of four new heroin addicts in the
13 United States started by abusing prescription opioids.

14 89. According to the CDC, opioids are responsible for the majority of drug overdoses
15 today.

16 **B. Defendants Statements and Silence About Opioid Dangers and Addiction**

17 90. Defendants have long known about the dangers of their opioid products.
18 Nevertheless, Defendants hid and misrepresented those dangers, all the while pouring alarming
19 quantities of opioids into communities all across the country. Notwithstanding having been
20 warned, sued, fined, and criminally convicted for failing to mitigate these problems, Defendants
21 have persisted in their harmful conduct.

22 **2. Manufacturer Defendants**

23 **a. Teva/Cephalon**

24 91. Cephalon used the mantra “pain is pain” when instructing its sales representatives
25 to market and sell its fentanyl product – Actiq lollipops – to all physicians, not just oncologists.

26 92. In 2008, Cephalon paid \$425 million to settle claims with the FDA for off-label
27 marketing of Actiq and other drugs. Cephalon executed a Corporate Integrity in connection with
28 its DOJ settlement.

1 93. As the DOJ press release stated:

2 From 2001 through at least 2006, Cephalon was allegedly
3 promoting the drug for non-cancer patients to use for such maladies
4 as migraines, sickle-cell pain crises, injuries, and in anticipation of
5 changing wound dressings or radiation therapy. Cephalon also
6 promoted Actiq for use in patients who were not yet opioid-tolerant,
7 and for whom it could have life-threatening results.

8 94. The DOJ press release further noted about the Actiq marketing:

9 “These are potentially harmful drugs that were being peddled as if
10 they were, in the case of Actiq, actual lollipops instead of a potent
11 pain medication intended for a specific class of patients” “This
12 company subverted the very process put in place to protect the
13 public from harm, and put patients’ health at risk for nothing more
14 than boosting its bottom line. People . . . need to know the
15 recommendations a doctor makes are not influenced by sales tactics
16 designed to convince the doctor that the drug being prescribed is
17 safe for uses beyond what the FDA has approved.”

18 Defendant Cephalon employed sales representatives and retained
19 medical professionals to speak to doctors about off-label uses of
20 Actiq. . . . The company funded continuing medical education
21 programs, through millions of dollars in grants, to promote off-label
22 uses of its drugs in violation of the FDA’s requirements.

23 95. One year later, in 2009, the FDA issued a warning letter to Cephalon for failing to
24 communicate in website search results, the risks associated with Fentanyl’s use.

25 96. In October 2017, Teva sponsored a Medscape continuing medical education
26 program, “Pharmacologic Management of Breakthrough or Incident Pain.” The published
27 materials made representations about opioid use that again suggested broader use than approved
28 by the FDA:

29 The use of opioid analgesics for the treatment of chronic pain
30 represents a key component of a comprehensive care program.
31 Indeed, long-acting opioids have been shown to improve the quality
32 of life in patients with chronic pain of both cancer and noncancer
33 etiology.

34 97. Those CME materials continued to downplay addiction and confuse physicians by
35 contradicting the definition of addiction established in the DSM-V:

36 The concern about patients with chronic pain becoming addicted to
37 opioids during long-term opioid therapy may stem from confusion
38 between physical dependence (tolerance) and psychological
39 dependence (addiction) that manifests as drug abuse. This
40 misunderstanding can lead to ineffective prescribing, administering,
41 or dispensing of opioids for chronic pain, resulting in

1 undertreatment.

2 98. In 2017, Teva entered into settlements with two California counties for its
3 marketing scheme relating to its opioid products. In addition to a financial payment, Teva must
4 “stop promoting opioid painkillers for off-label use, to refrain from false advertising and to
5 disclose any sponsorships of supplements discussing opioids that are placed in medical journals.
6 It must also disclose the risk of addiction any time it talks about the benefits of painkillers”

7 **b. Janssen**

8 99. Janssen has a long history of promoting opioids in a manner that encourages wider
9 use than approved.

10 100. In March 1998, the FDA issued a warning letter to Janssen regarding its
11 promotions of its fentanyl product, Duragesic. The FDA noted false and misleading statements
12 about risks associated with Duragesic use and demanded that Janssen immediately suspend those
13 promotions.

14 101. In March 2000, the FDA issued another warning letter to Janssen, addressing
15 promotional materials for Duragesic that again contained false and misleading statements:

16 a. You present the claim, “Low abuse potential!” This claim suggests that
17 Duragesic has less potential for abuse than other currently available opioids. ...[T]his claim is
18 contradictory to information in the approved product labeling (PI) that states, “Fentanyl is a
19 Schedule II controlled substance and can produce drug dependence similar to that produced by
20 morphine.” Therefore, this claim is false or misleading.

21 b. You present the claim, “It’s not just for end stage cancer anymore!” This
22 claim suggests that Duragesic can be used for any type of pain management. However, the PI for
23 Duragesic states, “Duragesic ... is indicated in the management of chronic pain patients who
24 require continuous opioid [sic] analgesia for pain that cannot be managed by lesser means....”
25 Therefore, the suggestion that Duragesic can be used for any type of pain management promotes
26 Duragesic’s [sic] for a much broader use than is recommended in the PI, and thus, is misleading.

27 102. That warning letter also admonished Janssen about unsubstantiated and misleading
28 claims that using Janssen’s Duragesic patch will improve a patient’s quality of life.

1 103. In September 2004, the FDA issued another warning letter addressed to fentanyl
2 marketing, including unsubstantiated claims of “improved social or physical functioning or
3 improved work productivity,” such as “Work, uninterrupted,” “Life, uninterrupted,” and “Game,
4 uninterrupted.”

5 104. In early 2010, Janssen introduced an online resource, PrescribeResponsibly.com,
6 that contained educational materials for doctors available both online and at medical conferences.

7 105. In August 2011, the FDA issued a warning letter to Janssen, for the promotion of
8 its opioid product, Nucynta, for uses beyond those approved.

9 106. In or about 2014, Janssen posted on PrescribeResponsibly.com an article, “Before
10 Prescribing Opioids – What to Know,” Janssen provides definitions of “addiction,” and its
11 symptoms, at odds with DSM-V. Janssen also uses a new, misleading term, “pseudo-addiction”
12 that it defines as: “a syndrome that causes patients to seek additional medications due to
13 inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately,
14 the inappropriate behavior ceases.”

15 107. That same article falsely claims that severe withdrawal symptoms, generally
16 recognized in the medical community as an indicator of addiction, arise instead from “abrupt
17 cessation” of opioids.

18 108. In another Prescribe Responsibly article, “Risks and Benefits of Opioid
19 Analgesics,” Janssen again minimizes the risk of addiction, stating: “Physical dependence with
20 long-term use of opioids should be expected. It is important to note that physical dependence is
21 not the same as addiction.”

22 109. In 2016, Janssen entered into a settlement agreement with the State of Kentucky
23 arising out of its promotion of an anti-psychotic drug for off-label use and the attendant risks to
24 off-label use. Janssen reportedly refused to update its label to reflect those risks because it feared
25 the financial impact of doing so.

26 **c. Purdue**

27 110. In 2000, the FDA sent a warning letter to Purdue relating to its promotion of
28 OxyContin as “Proven Effective in Arthritis Pain” that implied that OxyContin could serve as

1 first-line therapy for patients with arthritis. That promotion similarly misrepresented OxyContin's
2 safety for elderly, arthritic patients. The FDA ordered Purdue to cease using these promotional
3 materials.

4 111. In 2003, the FDA issued a warning letter addressing Purdue's "There Can be Life
5 in Relief" marketing campaign for OxyContin. The promotion misleadingly suggested that
6 OxyContin was effective and provided convenient dosing, while omitting or minimizing the risks
7 accompanying OxyContin's use. Additionally, the FDA admonished Purdue for promoting
8 OxyContin for a broader range of pain than approved.

9 112. In 2007, Purdue settled criminal and civil charges against it for "misbranding"
10 OxyContin. Purdue was forced to admit it illegally marketed and promoted OxyContin by
11 claiming it was less addictive and less subject to abuse than other pain medications. Purdue
12 agreed to pay nearly \$635 million in fines, and three of its executives pled guilty to federal
13 criminal charges for misleading regulators, doctors, and patients about OxyContin's risk of
14 addiction and its potential to be abused.

15 113. In 2009, Purdue e-mails show corporate knowledge of wholesale diversion of
16 opioids and the existence of pill mills in Los Angeles. Purdue apparently left the issue
17 unresolved.

18 114. In 2015, Purdue entered into an Assurance of Discontinuance with the State of
19 New York arising out of its sales practices related to OxyContin and its other opioid products. Of
20 note, the Assurance of Discontinuance addressed Purdue's use of an unbranded website, In the
21 Face of Pain, *available at* www.inthefaceofpain.com, to disseminate inaccurate information about
22 opioid use. The Assurance of Discontinuance imposed limitations on Purdue's use of such
23 websites and other social media, insisting that it prominently disclose its relationships with
24 unbranded websites maintained by Purdue. Instead, in the aftermath of this agreement, Purdue
25 deactivated the website.

26 115. In 2016, Purdue entered into a settlement agreement with the State of Kentucky
27 arising out of allegations that it misrepresented the addictive nature of OxyContin. In addition to a
28 monetary settlement, the State of Kentucky obtained injunctive relief set to expire in 2017.

1 **d. Endo**

2 116. In 2004, Endo published a brochure, "Understanding Your Pain: Taking Oral
3 Opioid Analgesics." Endo poses the question "What should I know about opioids and addiction?"
4 Endo's answers contradict medical knowledge regarding addiction, such as that which was later
5 codified in the DSM-V, as well as what was known at the time of publication:

6 It is important to understand what addiction is. Addiction **IS** a
7 chronic brain disease that can occur in some people exposed to
8 certain substances such as alcohol, cocaine, and opioids. Taking
9 opioids for pain relief is not addiction. People addicted to opioids
10 crave the opioid and use it regularly for reasons other than pain
11 relief.

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

25 117. In 2016, Endo entered into an Assurance of Discontinuance with the State of New
26 York, in part, arising out of Endo's marketing practices relating to Opana ER, including making
27 false statements such as promoting Opana ER as "crush resistant," and redefining symptoms of
28 addiction contrary to the DSM-V. The Assurance of Discontinuance also required Endo to
implement policies and procedures to identify and prevent diversion of Opana ER.

1 **e. Mallinckrodt**

2 118. In 2017, the Department of Justice fined Mallinckrodt \$35 million for failure to
3 report suspicious orders of controlled substances, including opioids, and for violating
4 recordkeeping requirements.

5 **f. Allergan**

6 119. In October 2000, the FDA sent a warning letter to Watson identifying misleading
7 promotional materials for its opioid product, Norco.
8

1 120. In February 2010, the FDA issued a warning letter to Allergan identifying
2 misleading marketing materials for its opioid product, Kadian, including misrepresenting a
3 broader use for Kadian than approved.

4 121. In August 2010, Allergan executed a Corporate Integrity Agreement in connection
5 with a settlement and agreement with the Justice Department arising out of Allergan's promotion
6 of another, non-opiate, drug for off-label uses.

7 **g. Insys**

8 122. Two former CEOs of Insys have been charged in an indictment along with other
9 former Insys executives and managers, who were initially charged in December 2016. The
10 indictment said that, beginning in 2012, John Kapoor, Michael Babich, and others devised a
11 scheme to pay speaker fees and other bribes to medical practitioners to prescribe Subsys and to
12 defraud insurers into approving payment for it.

13 123. Federal charges have also been filed in several other states against other ex-Insys
14 employees and medical practitioners who prescribed Subsys. Insys also faces lawsuits by
15 attorneys general in Arizona and New Jersey. It previously paid \$9.45 million to resolve
16 investigations by attorneys general in Oregon, New Hampshire, Illinois and Massachusetts.

17 **3. Distributor Defendants**

18 124. In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants
19 reminding them of their obligation to maintain effective controls against diversion of particular
20 controlled substances, to design and operate a system to disclose suspicious orders, and to inform
21 the DEA of any suspicious orders.

22 **a. McKesson**

23 125. In 2008, McKesson agreed to pay \$13.3 million to settle the allegations and to
24 strengthen its controls by implementing a three-tiered system that would flag buyers who
25 exceeded monthly thresholds for opioids.

26 126. Inspections of some of McKesson's distribution facilities in 2013 found the
27 company "did not fully implement or adhere to its own" compliance program. The findings
28 forced McKesson to admit that it failed to report suspicious opioid shipments to the DEA and

1 sign another settlement with DOJ that included tougher and verifiable compliance
2 responsibilities, as well as a \$150 million fine.

3 **b. Cardinal**

4 127. In 2013, Cardinal paid a \$34 million fine for failing to report suspicious orders of
5 controlled substances.

6 128. In February 2017, Cardinal Health agreed to pay the State of West Virginia \$20
7 million to settle claims regarding its distribution of opioids within the state.

8 **c. AmerisourceBergen**

9 129. In February 2017, AmerisourceBergen agreed to pay the State of West Virginia
10 \$16 million to settle claims regarding its distribution of opioids within the state.

11 **C. Impact of Opioid Abuse, Addiction and Diversion on Tribes**

12 130. American Indians suffer the highest per capita rate of opioid overdoses.

13 131. According to the Indian Health Service (“IHS”), there has been a “four-fold
14 increase in opioid overdoses from 1999 to 2013 among American Indians and Alaska Natives . . .
15 [T]wice the rate of the general U.S. population.”

16 132. The CDC reported that the “rates of death from prescription opioid overdose
17 among American Indian or Alaska Natives increased almost four-fold from 1.3 per 100,000 in
18 1999 to 5.1 per 100,000 in 2013. By 2014, the CDC reported “8.4 per 100,000 Native Americans
19 were dying of opioid overdoses, the highest number of any racial demographic.”

20 133. The impact on American Indian children is particularly devastating. In a study
21 conducted to examine substance-related disorders among adolescents across racial and ethnic
22 groups, “Racial/Ethnic Variations in Substance-Related Disorders Among Adolescents in the
23 United States,” the authors found, of 72,561 adolescents aged 12 to 17 years:

- 24 a. Analgesic opioids were the second most commonly used illegal drug after
25 marijuana;
- 26 b. Analgesic opioid use was comparatively prevalent among Native American
27 adolescents (9.7%);
- 28

- 1 c. Native Americans have the highest prevalence of use (47.5%) and disorders
2 (15.0%); and
3 d. 31.5% of Native Americans had substance-related disorders.

4 134. The study concluded:

5 Native Americans have the highest prevalence of substance use and
6 substance-related disorders, adding to evidence that young Native
7 Americans are a vulnerable group facing numerous stressors,
8 trauma, and health disparities (e.g., highest rate of suicide,
9 underfunded systems of care, and lack of access to appropriate
10 care). The results herein highlight a critical need for intervention to
11 reduce their burdens from substance use and for policies to address
12 presently underfunded systems of care and improve infrastructures
13 linking behavioral and primary health care services. [footnotes
14 omitted.]

15 135. The CDC reported that approximately 1 in 10 American Indian youths ages 12 or
16 older used prescription opioids for nonmedical purposes in 2012, double the rate for white youth.

17 136. The fact that adolescents are able to easily obtain prescription opioids through the
18 black market created by opioid diversion highlights the direct impact on the Yurok Tribe and
19 other tribal communities by Defendants' actions and inactions.

20 137. Even the youngest members of tribal communities bear the consequences of the
21 opioid abuse epidemic fueled by Defendants' conduct. Between 2009 and 2012, "American
22 Indian women [were] 8.7 times more likely to be diagnosed with maternal opiate dependence or
23 abuse during pregnancy," compared to non-Hispanic women. That translates into 1 in 10
24 pregnancies among American Indian women. As a result, many tribal infants suffer from opioid
25 withdrawal and Neonatal Abstinence Syndrome ("NAS").

26 138. Infants suffering from NAS are separated from their families and placed into the
27 custody of the tribal child welfare services or receive other governmental services so they can be
28 afforded medical treatment and be protected from drug-addicted parents.

139. The impact of NAS can be life-long. Most NAS infants are immediately
transferred to a neonatal intensive care unit for a period of days, weeks, or even months. NAS can
also require an emergency evacuation for care to save the infant's life. Such emergency
transportation costs tribes thousands of dollars for each occurrence.

1 140. Many NAS infants have short-term and long-term developmental issues that
2 prevent them from meeting basic cognitive and motor-skills milestones. Many will suffer from
3 vision and digestive issues; some are unable to attend full days of school. These disabilities
4 follow these children through elementary school and beyond.

5 141. Many of the parents of these children continue to relapse into prescription opioid
6 use and abuse, having an impact on their families and tribal communities for financial and other
7 support.

8 **D. The Impact of Defendants' Conduct on the Yurok Tribe**

9 142. The Yurok Tribe's own experience treating opioids illustrates these national trends
10 and those of the tribal community generally.

11 143. Indeed, the Yurok Tribe is currently facing a public health crisis that threatens to
12 undermine the safety and wellbeing of the entire community living on and adjacent to the Yurok
13 Reservation. Overarching health, public safety and law enforcement concerns relate to, among
14 others, prescription opioid drug abuse and major crimes involving opioid and drug use.

15 144. Prescribing rates for Humboldt and Del Norte have consistently been far higher
16 than those for the state of California as a whole, and remain unacceptably high despite recent
17 downward trends across the nation.

18 145. The Yurok Tribe and the surrounding community have among the highest
19 prescription drug use in the United States, despite being a small, rural, and under-served
20 population. The National Survey of Drug Use and Health for 2012–2014 identifies Humboldt and
21 Del Norte counties as having among the highest non-marijuana drug use in the country for
22 individuals 12 and over.

23 146. In 2013, the average number of 5 mg Vicodin per resident prescribed that year was
24 402 for Del Norte and 327 for Humboldt. This means that Del Norte residents were prescribed
25 enough opioid drugs (in morphine milligram equivalents) to give every man, woman, and child in
26 the county more than one dose a day for the entire year.

27 147. During each of the first eleven months of 2017, between 8,000 and 13,000 opioid
28 pills were prescribed to patients in zip code 95548 alone. In 95546, that number ranged from

1 43,000 to 53,000 pills per month. The total number of pills prescribed and filled by patients in
2 these two zip codes during the first eleven months of 2017 is a staggering 619,000 pills for this
3 population of less than 5,500 residents. Specifically as to Yurok Reservation zip code 95546:

4 a. Almost 30% of residents were prescribed opioids at least once in
5 2016 based on the number of *unique* patients receiving opioids.

6 b. A total of 314,730 opioid pills were dispensed by the sole DEA
7 registered pharmacy in the zip code area in 2016. With a population
8 just shy of 3,500 that amounts to 90 pills per person. Considering
9 solely the prescribed population, patients are receiving an opioid
10 pill a day.

11 c. In the first eleven months of 2017, that total number of dispensed
12 opioid pills had already exceeded 389,000 pills.

13 148. The opioid epidemic has escalated in the Yurok community with devastating
14 effects. Substantial opiate-related substance abuse, hospitalization, and death mirror Defendants'
15 increased distribution of opioids.

16 149. Because of the well-established relationship between the use of prescription
17 opioids and the use of non-prescription opioids, such as heroin, the increasing distribution of
18 opioids to members of the Yurok Tribe has caused the opioid epidemic to include heroin
19 addiction, abuse, and death. This is particularly concerning in light of the recent influx of
20 synthetic fentanyl products trafficked into the United States by Mexican cartels operating in the
21 California region.

22 150. In addition, there has been an increase in major crimes on the Yurok reservation
23 involving opioid use, including reports of human trafficking involving opioid abuse and
24 addiction, undermining the safety of the members of the Yurok Tribe.

25 151. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public
26 health and safety in the Yurok Tribe's community.

27 152. Costs for treatment related to the misuse, addiction, and/or overdose of opioids the
28 Tribe has borne include but are not limited to the following:

- 1 a. Emergency medical visits for opioid misuse, addiction, and/or overdose.
- 2 b. Emergency medical visits for infections, injuries, illnesses, and drug-
3 seeking related to opioid misuse, addiction, and/or overdose.
- 4 c. Hospitalizations related to the misuse, addiction, and/or overdose of
5 opioids.
- 6 d. Increased costs of administering and staffing the Yurok social services
7 department, including case workers and resources to aid (1) those members of the Tribe addicted
8 to and/or dependent on opioids; (2) the abused or neglected children and elders whose guardians
9 are slaves to opioid addiction; and (3) the many foster or adoptive guardians who take on the role
10 of caretaker in their absence.
- 11 e. Increased costs of administering and staffing the Yurok Department of
12 Public Safety, including police officers and resources to respond to increased opioid and related
13 drug trafficking and human trafficking, including coordination with County and federal law
14 enforcement.
- 15 f. Care, education and support of pregnant women addicted to opioids and of
16 their children born with NAS; including ongoing educational and developmental support to
17 address the long-term consequences of fetal opioid exposure; and
- 18 g. Treatment of victims and criminal offenders in the tribal court, including
19 holistic community-based treatment programming and regular drug screening.

20 **CLAIMS FOR RELIEF**

21 **FIRST CLAIM FOR RELIEF**

22 **RACKETEER INFLUENCED AND CORRUPT
23 ORGANIZATIONS (RICO) 18 U.S.C. § 1961 *et. seq.***

24 153. The Yurok Tribe incorporates by reference each of the paragraphs above as though
25 fully set forth herein.

26 154. Plaintiff brings this Count against all Defendants.

27 155. Defendants are persons within the meaning of 18 U.S.C. § 1961(3) who conducted
28 the affairs of the enterprises described below through a pattern of racketeering activity in
violation of 18 U.S.C. § 1962(c).

1 156. Section 1962(c) of RICO makes it unlawful “for any person employed by or
2 associated with any enterprise engaged in, or the activities of which affect, interstate or foreign
3 commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise’s
4 affairs through a pattern of racketeering activity or collection of unlawful debt.” 18 U.S.C.
5 § 1962(c).

6 **A. Relevant Enterprises**

7 157. The term “enterprise” includes “any individual, partnership, corporation,
8 association, or other legal entity, and any union or group of individuals associated in fact although
9 not a legal entity.” 18 U.S.C. § 1961(4). The definition of “enterprise” in § 1961(4) includes both
10 legitimate and illegitimate enterprises.

11 158. Defendants engaged in two relevant illegal enterprises in violation of these
12 statutes: the Opioid Promotion Enterprise and the Opioid Diversion Enterprise.

13 159. The Opioids Promotion Enterprise is an association-in-fact within the meaning of
14 18 U.S.C. § 1961(4), consisting of Defendants, including their employees and agents; Front
15 Groups, including their employees and agents; and KOLs; as well as external and other as yet
16 unknown marketing firms and distribution agents employed by Defendants in furtherance of the
17 Opioids Promotion Enterprise. All entities are persons within the meaning of 18 U.S.C. § 1961(3)
18 and acted to enable Defendants to fraudulently market opioids as scientifically proven as safe and
19 effective.

20 160. The Opioids Promotion Enterprise is an organization that functioned as an ongoing
21 organization and continuing unit. The Opioids Promotion Enterprise was created and organized to
22 effectuate a pattern of racketeering activity, and maintained systematic links for a common
23 purpose: to ensure the continued prescription of opioids for chronic pain. Each of these entities,
24 including the Defendants, is a “person” distinct from the Opioids Promotion Enterprise.

25 161. The Opioids Diversion Enterprise is an association-in-fact enterprise between the
26 Manufacturer Defendants and the Distributor Defendants, and executed by each of them. In
27 particular, each of the Defendants was associated with, and conducted or participated in, the
28 affairs of the enterprise, whose purpose was to engage in the unlawful sales of opioids, deceive

1 the public and federal and state regulators into believing that the Defendants were faithfully
2 fulfilling their statutory obligations.

3 162. The Defendants' scheme allowed them to make billions in unlawful sales of
4 opioids and, in turn, increase and maintain high production quotas with the purpose of ensuring
5 unlawfully increasing revenues, profits, and market share. As a direct result of the Defendants'
6 fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to
7 extract billions of dollars of revenue, while Plaintiff suffered injury caused by the reasonably
8 foreseeable consequences of the opioid epidemic. As explained in detail below, the Defendants'
9 misconduct violated § 1962(c) and Plaintiff is entitled to treble damages for its injuries under 18
10 U.S.C. § 1964(c).

11 163. Members of the Opioid Diversion Enterprise systematically and fraudulently
12 violated their statutory duty to maintain effective controls against diversion of their drugs, to
13 design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of
14 suspicious orders, and to notify the DEA of suspicious orders. As alleged herein, through the
15 Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful
16 sales of painkillers which, in turn, artificially and illegally increased the annual production quotas
17 for opioids allowed by the DEA. In doing so, the Defendants allowed hundreds of millions of
18 pills to enter the illicit market which allowed them to generate enormous profits.

19 164. Members of the Opioid Diversion Enterprise, finding it impossible to legally
20 achieve their ever-increasing sales ambitions, systematically and fraudulently violated their
21 statutory duty to maintain effective controls against diversion of their drugs, to design and operate
22 a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders,
23 and to notify the DEA of suspicious orders. As discussed in detail below, through the Defendants'
24 scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of
25 painkillers which, in turn, artificially and illegally increased the annual production quotas for
26 opioids allowed by the DEA. In doing so, the Defendants allowed hundreds of millions of pills to
27 enter the illicit market which allowed them to generate enormous profits.

28

1 165. Alternatively, the Defendants were members of a legal entity enterprise within the
2 meaning of 18 U.S.C. § 1961(4), through which the Defendants conducted their pattern of
3 racketeering activity in this jurisdiction and throughout the United States. Specifically, the HDA
4 is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit
5 corporation formed under the laws of the District of Columbia and doing business in Virginia. As
6 a non-profit corporation, HDA qualifies as an “enterprise” within the definition set out in 18
7 U.S.C. § 1961(4) because it is a corporation and a legal entity.

8 166. The Defendants are members, participants, and/or sponsors of the HDA and
9 utilized the HDA to conduct the Opioid Diversion RICO Enterprise and to engage in the pattern
10 of racketeering activity that gives rise to the Count.

11 167. Each of the Defendants is a legal entity separate and distinct from the HDA. And,
12 the HDA serves the interests of distributors and manufacturers beyond the Defendants.

13 168. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and
14 each of the Defendants exists separately from the HDA. Therefore, the HDA itself serves as a
15 RICO enterprise.

16 169. The association-in-fact enterprises (Opioid Promotion Enterprise and Opioid
17 Diversion Enterprise) and either or both of two legal enterprises (the HDA and PCF) were each
18 used by the Defendants to conduct the RICO Enterprise by engaging in a pattern of racketeering
19 activity. Therefore, the legal and association-in-fact enterprises are pleaded in the alternative and
20 are collectively referred to as the “RICO Enterprise.”

21 170. Alternatively, the Defendants were members of a legal entity enterprise within the
22 meaning of 18 U.S.C. § 1961(4), through which the Defendants conducted their pattern of
23 racketeering activity in this jurisdiction and throughout the United States. Specifically, the HDA
24 is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit
25 corporation formed under the laws of the District of Columbia and doing business in Virginia. As
26 a non-profit corporation, HDA qualifies as an “enterprise” within the definition set out in 18
27 U.S.C. § 1961(4) because it is a corporation and a legal entity.

28

1 171. The Defendants are members, participants, and/or sponsors of the HDA and
2 utilized the HDA to conduct the Opioid Diversion RICO Enterprise and to engage in the pattern
3 of racketeering activity that gives rise to the Count.

4 172. Each of the Defendants is a legal entity separate and distinct from the HDA. And,
5 the HDA serves the interests of distributors and manufacturers beyond the Defendants.

6 173. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and
7 each of the Defendants exists separately from the HDA. Therefore, the HDA itself serves as a
8 RICO enterprise.

9 174. The association-in-fact enterprises (Opioid Promotion Enterprise and Opioid
10 Diversion Enterprise) and the legal enterprise (HDA) were each used by the Defendants to
11 conduct the RICO Enterprise by engaging in a pattern of racketeering activity. Therefore, the
12 legal and association-in-fact enterprises are pleaded in the alternative and are collectively referred
13 to as the "RICO Enterprise."

14 175. It is unlawful for a registrant to manufacture a controlled substance in Schedule II,
15 like prescription opioids, that is (1) not expressly authorized by its registration and by a quota
16 assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.

17 176. At all relevant times, the Defendants operated as an enterprise formed for the
18 purpose of unlawfully increasing sales, revenues, and profits by disregarding their statutory duty
19 to identify, investigate, halt, and report suspicious orders of opioids and diversion of their drugs
20 into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them
21 to collectively benefit from the unlawful formation of a greater pool of prescription opioids from
22 which to profit. The Defendants conducted their pattern of racketeering activity in this
23 jurisdiction and throughout the United States through this enterprise.

24 177. At all relevant times, the RICO Enterprise: (a) had an existence separate and
25 distinct from each Defendant; (b) was separate and distinct from the pattern of racketeering in
26 which the Defendants engaged; (c) was an ongoing and continuing organization consisting of
27 legal entities, including each of the Defendants; (d) characterized by interpersonal relationships
28 among the Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f)

1 functioned as a continuing unit. Each member of the RICO Enterprise participated in the conduct
2 of the enterprise, including patterns of racketeering activity, and shared in the astounding growth
3 of profits supplied by fraudulently inflating opioid sales generated as a result of the RICO
4 Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and
5 then requesting the DEA increase production quotas, all so that the Defendants would have a
6 larger pool of prescription opioids from which to profit.

7 178. The RICO Enterprise also engaged in efforts to lobby against the DEA's authority
8 to hold the Defendants liable for disregarding their duty to prevent diversion.

9 179. Members of the PCF and the HDA lobbied for the passage of legislation to weaken
10 the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement
11 Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or
12 revoke registrations. The HDA and other members of the PCF contributed substantial amounts of
13 money to political campaigns for federal candidates, state candidates, political action committees,
14 and political parties. The PCF and its members spent significant funds on lobbying efforts while
15 the HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016.

16 180. The RICO Enterprise functioned by selling prescription opioids. While there are
17 some legitimate uses and/or needs for prescription opioids, the Defendants, through their illegal
18 enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to
19 increase revenue by violating State and Federal laws requiring the maintenance of effective
20 controls against diversion of prescription opioids, and the identification, investigation, and
21 reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal
22 of Defendants' scheme was to increase profits from opioid sales. But, Defendants' profits were
23 limited by the production quotas set by the DEA, so the Defendants refused to identify,
24 investigate, and/or report suspicious orders of their prescription opioids being diverted into the
25 illicit drug market. The end result of this strategy was to increase and maintain artificially high
26 production quotas of opioids so that there was a larger pool of opioids for Defendants to
27 manufacture and distribute for public consumption.
28

1 181. The RICO Enterprise engaged in, and its activities affected, interstate and foreign
2 commerce because the enterprise involved commercial activities across states lines, such as
3 manufacture, sale, distribution, and shipment of prescription opioids throughout the United States
4 and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the
5 same.

6 182. Within the RICO Enterprise, there were interpersonal relationships and common
7 communication by which the Defendants shared information on a regular basis.

8 183. These interpersonal relationships also formed the organization of the RICO
9 Enterprise. The RICO Enterprise used their interpersonal relationships and communication
10 network for the purpose of conducting the enterprise through a pattern of racketeering activity.

11 184. Each of the Defendants had a systematic link to each other through joint
12 participation in lobbying groups and trade industry organizations (such as PCF and
13 HDA/HDMA), contractual relationships (for example, between Insys and the Distributor
14 Defendants), and continuing coordination of activities. The Defendants participated in the
15 operation and management of the RICO Enterprise by directing its affairs, as described herein.

16 185. While the Defendants participated in, and are members of, the enterprise, they
17 each have a separate existence from the enterprise, including distinct legal statuses, different
18 offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting
19 requirements, and financial statements.

20 186. The Defendants exerted substantial control over the Opioid Diversion Enterprise
21 by their membership in the PCF, the HDA, and through their contractual relationships.

22 187. The 2012 PCF Meeting Schedule demonstrates that each of the Defendants
23 participated in meetings on a monthly basis, either directly or through their trade organization, in
24 a coalition of drug makers and their allies whose sole purpose was to shape the national response
25 to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the
26 PCF undertook on behalf of its members.

27 188. In fact, the HDA touted the benefits of membership to the Manufacturer
28 Defendants, advocating that membership included the ability to, among other things, “network

1 one on one with manufacturer executives at HDA’s members-only Business and Leadership
2 Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and
3 sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and
4 working groups with peers and trading partners,” and “make connections.” The HDA and the
5 Distributor Defendants used membership in the HDA as an opportunity to create interpersonal
6 and ongoing organizational relationships between the Manufacturer and Distributor Defendants.

7 189. The Defendants maintained their interpersonal relationships by working together
8 and exchanging information and driving the unlawful sales of their opioids through their
9 contractual relationships, including chargebacks and vault security programs. The Manufacturer
10 Defendants engaged in an industry-wide practice of paying rebates and chargebacks to the
11 Distributor Defendants for sales of prescription opioids. As reported in *The Washington Post*,
12 identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide
13 practice whereby the Manufacturer Defendants paid the Distributor Defendants rebates and/or
14 chargebacks on their prescription opioid sales.

15 190. These contracts were negotiated at the highest levels, demonstrating ongoing
16 relationships between the Manufacturer and Distributor Defendants. In return for the rebates and
17 chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed
18 information regarding their prescription opioid sales, including purchase orders, ship notices,
19 acknowledgements, and invoices. The Manufacturer Defendants used this information to gather
20 high-level data regarding overall distribution and direct the Distributor Defendants on how to
21 most effectively sell the prescription opioids.

22 191. The contractual relationships among the Defendants also include vault security
23 programs. The Defendants are required to maintain certain security protocols and storage
24 facilities for the manufacture and distribution of their opioids. Manufacturers likely negotiated
25 agreements whereby the Manufacturers installed security vaults for Distributors in exchange for
26 agreements to maintain minimum sales performance thresholds. These agreements were used by
27 the Defendants as a tool to violate their reporting and anti-diversion duties.
28

1 192. Taken together, the interaction and length of the relationships between and among
2 the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation
3 between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were
4 not two separate groups operating in isolation or two groups forced to work together in a closed
5 system. The Defendants operated together as a united entity, working together on multiple fronts,
6 to engage in the unlawful sale of prescription opioids. The HDA and the PCF are but two
7 examples of the overlapping relationships and concerted joint efforts to accomplish common
8 goals and demonstrates that the leaders of each of the Defendants were in communication and
9 cooperation. Others include PhRMA and the use of “Hub Service” suppliers.

10 193. According to articles published by the Center for Public Integrity and The
11 Associated Press, the PCF has been lobbying on behalf of the Manufacturer and Distributor
12 Defendants for more than a decade. And, from 2006 to 2016 the Distributor and Manufacturer
13 Defendants worked together through the PCF to spend over \$740 million lobbying in the nation’s
14 capital and in all 50 statehouses on issues including opioid-related measures. Similarly, the HDA
15 has continued its work on behalf of Defendants, since at least 2000.

16 194. As alleged herein, Defendants began working together as early as 2006 through the
17 PCF and the HDA to promote the common purpose of their enterprise.

18 195. Defendants worked together as an ongoing and continuous organization
19 throughout the existence of their enterprise.

20 **B. Defendants’ Conduct**

21 196. During the time period alleged in this Complaint, the Defendants exerted control
22 over, conducted and/or participated in the RICO Enterprise by fraudulently failing to comply with
23 their Federal and State obligations to identify, investigate and report suspicious orders of opioids
24 in order to prevent diversion of those highly addictive substances into the illicit market, to halt
25 such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits,
26 as follows:

1 197. Defendants disseminated false and misleading statements to the public claiming
2 that they were complying with their obligations to maintain effective controls against diversion of
3 their prescription opioids.

4 198. Defendants disseminated false and misleading statements to the public claiming
5 that they were complying with their obligations to design and operate a system to disclose to the
6 registrant suspicious orders of their prescription opioids. Defendants disseminated false and
7 misleading statements to the public claiming that they were complying with their obligation to
8 notify the DEA of any suspicious orders or diversion of their prescription opioids.

9 199. Defendants paid nearly \$800 million dollars to influence local, state, and federal
10 governments through joint lobbying efforts as part of the PCF. The Defendants were all members
11 of the PCF either directly or indirectly through the HDA. The lobbying efforts of the PCF and its
12 members, included efforts to pass legislation making it more difficult for the DEA to suspend
13 and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious
14 orders of opioids.

15 200. The Defendants exercised control and influence over the distribution industry by
16 participating and maintaining membership in the HDA.

17 201. The Defendants applied political and other pressure on the DOJ and DEA to halt
18 prosecutions for failure to report suspicious orders of prescription opioids. Defendants lobbied
19 Congress to strip the DEA of its ability to immediately suspend registrations pending
20 investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."

21 202. The Defendants engaged in an industry-wide practice of paying rebates and
22 chargebacks to incentivize unlawful opioid prescription sales. The Manufacturer Defendants used
23 the chargeback program to acquire detailed, high-level data regarding sales of the opioids they
24 manufactured. And the Manufacturer Defendants used this high-level information to direct the
25 Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger
26 volumes.

27 203. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production
28 Quotas, year after year by submitting net disposal information that the Manufacturer Defendants

1 knew included sales that were suspicious and involved the diversion of opioids that had not been
2 properly investigated or reported by the Defendants.

3 204. The Distributor Defendants developed “know your customer” questionnaires and
4 files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was
5 intended to help the Defendants identify suspicious orders or customers who were likely to divert
6 prescription opioids. The “know your customer” questionnaires informed the Defendants of the
7 number of pills that the pharmacies sold, how many non-controlled substances are sold compared
8 to controlled substances, whether the pharmacy buys from other distributors, the types of medical
9 providers in the area, including pain clinics, general practitioners, hospice facilities, cancer
10 treatment facilities, and these questionnaires put the recipients on notice of suspicious orders.

11 205. The Defendants refused to identify, investigate and report suspicious orders to the
12 DEA when they became aware of them despite their actual knowledge of drug diversion rings.

13 206. The Defendants refused to identify suspicious orders and diverted drugs despite
14 the DEA issuing final decisions against the Distributor Defendants for failures to do so.

15 207. Defendants’ scheme had decision-making structure that was driven by the
16 Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer
17 Defendants worked together to influence the state and federal governments’ response to the
18 manufacture and distribution of prescription opioids by increasing production quotas through a
19 systematic refusal to maintain effective controls against diversion, and to identify and report
20 suspicious orders to the DEA.

21 208. The Defendants worked together to affect the flow of information and influence
22 state and federal governments and politicians to pass legislation that benefitted Defendants. The
23 Manufacturer and Distributor Defendants did this through their participation in the PCF and
24 HDA.

25 209. The Defendants also worked together to ensure that the Aggregate Production
26 Quotas, Individual Quotas, and Procurement Quotas allowed by the DEA stayed high and ensured
27 that suspicious orders were not reported to the DEA. By not reporting suspicious orders or
28 diversion of prescription opioids, the Defendants ensured that the DEA had no basis for

1 decreasing or refusing to increase the production quotas for prescription opioids due to diversion
2 of suspicious orders. The Defendants influenced the DEA production quotas in the following
3 ways:

4 a. The Distributor Defendants assisted the enterprise and the Manufacturer
5 Defendants in their lobbying efforts through the PCF;

6 b. The Distributor Defendants invited the participation, oversight and control
7 of the Manufacturer Defendants by including them in the HDA, including on the councils,
8 committees, task forces, and working groups;

9 c. The Distributor Defendants provided sales information to the Manufacturer
10 Defendants regarding their prescription opioids, including reports of all opioids prescriptions
11 filled by the Distributor Defendants;

12 d. The Manufacturer Defendants used a chargeback program to ensure
13 delivery of the Distributor Defendants' sales information;

14 e. The Manufacturer Defendants obtained sales information from
15 QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual
16 doctors across the nation were prescribing [opioids]."

17 f. The Distributor Defendants accepted rebates and chargebacks for orders of
18 prescription opioids;

19 g. The Manufacturer Defendants used the Distributor Defendants' sales
20 information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their
21 distribution efforts to specific areas where the purchase of prescription opioids was most frequent;

22 h. The Defendants identified suspicious orders of prescription opioids and
23 then continued filling those unlawful orders, without reporting them, knowing that they were
24 suspicious and/or being diverted into the illicit drug market;

25 i. The Defendants refused to report suspicious orders of prescription opioids
26 despite repeated investigation and punishment of the Distributor Defendants by the DEA for
27 failure to report suspicious orders; and
28

1 j. The Defendants withheld information regarding suspicious orders and
2 illicit diversion from the DEA because it would have revealed that the “medical need” for and the
3 net disposal of their drugs did not justify the production quotas set by the DEA

4 k. The scheme devised and implemented by the Defendants amounted to a
5 common course of conduct characterized by a refusal to maintain effective controls against
6 diversion, and all designed and operated to ensure the continued unlawful sale of controlled
7 substances.

8 **C. Pattern of Racketeering Activity**

9 210. The Defendants conducted and participated in the conduct of the RICO Enterprise
10 through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(B), including mail fraud
11 (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343); and 18 U.S.C. § 1961(D) by the felonious
12 manufacture, importation, receiving, concealment, buying selling, or otherwise dealing in a
13 controlled substance or listed chemical (as defined in section 102 of the Controlled Substance
14 Act), punishable under any law of the United States.

15 **1. Mail and Wire Fraud**

16 211. The Defendants carried out, or attempted to carry out, a scheme to defraud federal
17 and state regulators, and the public, including Plaintiff, by knowingly conducting or participating
18 in the conduct of the RICO Enterprise through a pattern of racketeering activity within the
19 meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of
20 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

21 212. The Defendants committed, conspired to commit, and aided and abetted in the
22 commission of at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C.
23 §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the
24 RICO Defendants committed, or aided and abetted in the commission of, were related to each
25 other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of
26 racketeering activity.” The racketeering activity was made possible by the Defendants’ regular
27 use of the facilities, services, distribution channels, and employees of the RICO Enterprise. The
28

1 Defendants participated in the scheme to defraud by using mail, telephone, and the Internet to
2 transmit mailings and wires in interstate or foreign commerce.

3 213. The Defendants used, directed the use of, and caused to be used, thousands of
4 interstate mail and wire communications in service of their scheme through virtually uniform
5 misrepresentations, concealments, and material omissions regarding their compliance with their
6 mandatory reporting requirements and the actions necessary to carry out their unlawful goal of
7 selling prescription opioids without reporting suspicious orders or the diversion of opioids into
8 the illicit market.

9 214. In devising and executing the illegal scheme, the Defendants devised and
10 knowingly carried out a material scheme and artifice to defraud by means of materially false or
11 fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of
12 executing the illegal scheme, the Defendants committed these racketeering acts, which number in
13 the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

14 215. The Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but
15 are not limited to:

16 a. Mail Fraud: The Defendants violated 18 U.S.C. § 1341 by sending or
17 receiving, or by causing to be sent and received, materials via U.S. mail or commercial interstate
18 carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell
19 the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

20 b. Wire Fraud: The Defendants violated 18 U.S.C. § 1343 by transmitting
21 and/or receiving, or by causing to be transmitted and/or received, materials by wire for the
22 purpose of executing the unlawful scheme to design, manufacture, market, and sell the
23 prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

24 216. The Defendants' use of the mail and wires includes, but is not limited to, the
25 transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third
26 parties that were foreseeably caused to be sent as a result of the Defendants' illegal scheme,
27 including but not limited to:

28 a. The prescription opioids themselves;

1 b. Documents and communications that facilitated the manufacture, purchase
2 and unlawful sale of prescription opioids;

3 c. Defendants' DEA registrations;

4 d. Documents and communications that supported and facilitated
5 Defendants' DEA registrations;

6 e. Documents and communications that supported and facilitated the
7 Defendants' request for higher aggregate production quotas, individual production quotas, and
8 procurement quotas;

9 f. Defendants' records and reports that were required to be submitted to the
10 DEA pursuant to 21 U.S.C. § 827;

11 g. Documents and communications related to the Defendants' mandatory
12 DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

13 h. Documents intended to facilitate the manufacture and distribution of
14 Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports, and
15 correspondence;

16 i. Documents for processing and receiving payment for prescription opioids;

17 j. Payments from the Distributors to the Manufacturers;

18 k. Rebates and chargebacks from the Manufacturers to the Distributors;

19 l. Payments to Defendants' lobbyists through the PCF;

20 m. Payments to Defendants' trade organizations, like the HDA, for
21 memberships and/or sponsorships;

22 n. Deposits of proceeds from Defendants' manufacture and distribution of
23 prescription opioids; and

24 o. Other documents and things, including electronic communications and
25 publication of articles, commentary and brochures on the websites of the Defendants, the Front
26 Groups and other associations publishing the statements of KOLs.

27 217. The Defendants, for the purpose of executing the illegal scheme, sent and/or
28 received (or caused to be sent and/or received) by mail or by private or interstate carrier,

1 shipments of prescription opioids and related documents by mail or by private carrier affecting
2 interstate commerce, including the following:

3 218. The Defendants also used the internet and other electronic facilities to carry out
4 their scheme and conceal the ongoing fraudulent activities. Specifically, the Defendants made
5 misrepresentations about their compliance with Federal and State laws requiring them to identify,
6 investigate, and report suspicious orders of prescription opioids and/or diversion of the same into
7 the illicit market.

8 219. At the same time, the Defendants misrepresented the superior safety features of
9 their order monitoring programs, ability to detect suspicious orders, commitment to preventing
10 diversion of prescription opioids, and that they complied with all state and federal regulations
11 regarding the identification and reporting of suspicious orders of prescription opioids.

12 220. Defendants also utilized the internet and other electronic resources to exchange
13 communications, to exchange information regarding prescription opioid sales, and to transmit
14 payments and rebates/chargebacks.

15 221. The Defendants also communicated by U.S. Mail, by interstate facsimile, and by
16 interstate electronic mail and with various other affiliates, regional offices, regulators,
17 distributors, and other third-party entities in furtherance of the scheme.

18 222. Several Defendants also entered into various Corporate Integrity Agreements with
19 various entities, including the Office of Inspector General and the United States Department of
20 Health and Human Services, that required the Defendants annually to certify in writing that the
21 Defendants had implemented effective compliance programs and were otherwise in compliance
22 with laws and regulations regarding, among other things, the manufacture and distribution of
23 opioids. Defendants submitted through the mail and wires certifications that were false and
24 misleading, in furtherance of the Opioid Diversion RICO Enterprise's operation and goals,
25 including false and misleading certifications required annually.

26 223. The mail and wire transmissions described herein were made in furtherance of
27 Defendants' scheme and common course of conduct to deceive regulators and the public that
28 Defendants were complying with their state and federal obligations to identify and report

1 suspicious orders of prescription opioids all while Defendants were knowingly allowing millions
2 of doses of prescription opioids to divert into the illicit drug market. The Defendants' scheme and
3 common course of conduct was intended to increase or maintain high production quotas for their
4 prescription opioids from which they could profit.

5 224. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate
6 wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants'
7 books and records. But, Plaintiff has described the types of, and in some instances, occasions on
8 which the predicate acts of mail and/or wire fraud occurred. They include thousands of
9 communications to perpetuate and maintain the scheme, including the things and documents
10 described in the preceding paragraphs.

11 225. The Defendants did not undertake the practices described herein in isolation, but as
12 part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons,
13 firms, and corporations, including third-party entities and individuals not named as defendants in
14 this Complaint, may have contributed to and/or participated in the scheme with the Defendants in
15 these offenses and have performed acts in furtherance of the scheme to increase revenues,
16 increase market share, and /or minimize the losses for the Defendants.

17 226. The Defendants aided and abetted others in the violations of the above laws,
18 thereby rendering them indictable as principals in the 18 U.S.C. §§1341 and 1343 offenses.

19 227. The Defendants hid from the general public, and suppressed and ignored warnings
20 from third parties, whistleblowers and governmental entities, about the reality of the suspicious
21 orders that the Defendants were filling on a daily basis—leading to the diversion of tens of
22 millions of doses of prescriptions opioids into the illicit market.

23 228. The Defendants, with knowledge and intent, agreed to the overall objective of their
24 fraudulent scheme and participated in the common illicit course of conduct to commit acts of fraud and
25 indecency in manufacturing and distributing prescription opioids.

26 229. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants
27 had to agree to implement similar tactics regarding marketing prescription opioids and refusing to
28 report suspicious orders.

1 230. The Defendants engaged in a pattern of related and continuous predicate acts for
2 years. The predicate acts constituted a variety of unlawful activities, each conducted with the
3 common purpose of obtaining significant monies and revenues from the sale of their highly
4 addictive and dangerous drugs. The predicate acts also had the same or similar results,
5 participants, victims, and methods of commission. The predicate acts were related and not
6 isolated events.

7 231. The predicate acts all had the purpose of generating significant revenue and profits
8 for the Defendants while Plaintiff was left with substantial injury to its business through the
9 damage that the prescription opioid epidemic caused. The predicate acts were committed or
10 caused to be committed by the Defendants through their participation in the RICO Enterprise and
11 in furtherance of its fraudulent scheme.

12 232. The pattern of racketeering activity and the RICO Enterprise are separate and
13 distinct from each other. Likewise, Defendants are distinct from the RICO Enterprise.

14 233. The pattern of racketeering activity is continuing as of the date of this Complaint
15 and will continue into the future unless enjoined by this Court.

16 234. Many of the precise dates of the Defendants' criminal actions have been hidden
17 and cannot be alleged without access to Defendants' books and records. Indeed, an essential part
18 of the successful operation of the RICO Enterprise alleged herein depended upon secrecy.

19 235. Each instance of racketeering activity was related, had similar purposes, involved
20 the same or similar participants and methods of commission, and had similar results affecting
21 similar victims, including consumers in this jurisdiction and the Plaintiff. Defendants calculated
22 and intentionally crafted the RICO Enterprise and their scheme to increase and maintain their
23 increased profits, without regard to the effect such behavior would have on Plaintiff. In designing
24 and implementing the scheme, at all times Defendants knew that those in the manufacturing and
25 distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral
26 third parties to provide objective and reliable information regarding Defendants' products and
27 their manufacture and distribution of those products. The Defendants were also aware that
28 Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system

1 and to protect against the non-medical diversion and use of their dangerously addictive opioid
2 drugs.

3 236. By intentionally refusing to report and halt suspicious orders of their prescription
4 opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting
5 a pattern of racketeering activity.

6 237. It was foreseeable to Defendants that refusing to report and halt suspicious orders,
7 as required by the CSA and Code of Federal Regulations, would harm Plaintiff by allowing the
8 flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

9 238. The last racketeering incident occurred within five years of the commission of a
10 prior incident of racketeering.

11 239. The Defendants conducted and participated in the conduct of the affairs of the
12 RICO Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by
13 the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise
14 dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled
15 Substance Act), punishable under any law of the United States.

16 240. The Defendants committed crimes that are punishable as felonies under the laws of
17 the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to
18 knowingly or intentionally furnish false or fraudulent information in, or omit any material
19 information from, any application, report, record, or other document required to be made, kept, or
20 filed under this subchapter. A violation of § 483(a)(4) is punishable by up to four years in jail,
21 making it a felony. 21 U.S.C. § 483(d)(1).

22 241. Each of the Defendants qualifies as a registrant under the CSA. Their status as
23 registrants under the CSA requires that they maintain effective controls against diversion of
24 controlled substances in schedule I or II, design and operate a system to disclose to the registrant
25 suspicious orders of controlled substances, and inform the DEA of suspicious orders when
26 discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

27
28

1 242. Pursuant to the CSA and the Code of Federal Regulations, the RICO Defendants
2 were required to make reports to the DEA of any suspicious orders identified through the design
3 and operation of their system to disclose suspicious orders.

4 243. The Defendants knowingly and intentionally furnished false or fraudulent
5 information in their reports to the DEA about suspicious orders, and omitted material information
6 from reports, records, and other documents required to be filed with the DEA, including the
7 Manufacturer Defendants' applications for production quotas. Specifically, the Defendants were
8 aware of suspicious orders of prescription opioids and the diversion of their prescription opioids
9 into the illicit market, and failed to report this information to the DEA in their mandatory reports
10 and their applications for production quotas.

11 244. For example, the DEA and DOJ began investigating McKesson in 2013 regarding
12 its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015,
13 McKesson filed a Form 8-K with the SEC announcing a settlement with the DEA and DOJ
14 wherein it admitted to violating the CSA and agreed to pay \$150 million and have some of its
15 DEA registrations suspended on a staggered basis. The settlement was finalized on January 17,
16 2017.

17 245. Purdue's experience in Los Angeles is another striking example of Defendants'
18 willful violation of the CSA and Code of Federal Regulations as it relates to reporting suspicious
19 orders of prescription opioids. In 2016, the *Los Angeles Times* reported that Purdue was aware of
20 a pill mill operating out of Los Angeles yet failed to alert the DEA. The *Los Angeles Times*
21 uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one
22 prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the
23 prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very
24 certain this is an organized drug ring." Despite knowledge of the staggering amount of pills being
25 issued in Los Angeles, and internal discussion of the problem, "Purdue did not shut off the supply
26 of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until
27 several years later when the clinic was out of business and its leaders indicted. By that time, 1.1
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1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other
2 criminals.”

3 246. Mallinckrodt also was recently the subject of a DEA and Senate investigation for
4 its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored
5 its responsibility to report suspicious orders as 500 million of its pills ended up in Florida
6 between 2008 and 2012. After six years of DEA investigation, Mallinckrodt agreed to a
7 settlement involving a \$35 million fine. Federal prosecutors summarized the case by saying that
8 Mallinckrodt’s response was that everyone knew what was going on in Florida but they had no
9 duty to report it.

10 247. These examples reflect the Defendants’ pattern and practice of willfully and
11 intentionally omitting information from their mandatory reports to the DEA as required by 21
12 C.F.R. § 1301.74. This conclusion is supported by the sheer volume of enforcement actions
13 available in the public record against the Distributor Defendants. For example:

14 a. On April 24, 2007, the DEA issued an Order to Show Cause and
15 Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center
16 alleging failure to maintain effective controls against diversion of controlled substances. On June
17 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA
18 registration;

19 b. On November 28, 2007, the DEA issued an Order to Show Cause and
20 Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution
21 Center for failure to maintain effective controls against diversion of hydrocodone;

22 c. On December 5, 2007, the DEA issued an Order to Show Cause and
23 Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center
24 for failure to maintain effective controls against diversion of hydrocodone;

25 d. On December 7, 2007, the DEA issued an Order to Show Cause and
26 Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution
27 Center for failure to maintain effective controls against diversion of hydrocodone;

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1 e. On January 30, 2008, the DEA issued an Order to Show Cause and
2 Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center for
3 failure to maintain effective controls against diversion of hydrocodone;

4 f. On May 2, 2008, McKesson Corporation entered into an Administrative
5 Memorandum of Agreement (“2008 MOA”) with the DEA which provided that McKesson would
6 “maintain a compliance program designed to detect and prevent the diversion of controlled
7 substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the
8 procedures established by its Controlled Substance Monitoring Program”;

9 g. On September 30, 2008, Cardinal Health entered into a Settlement and
10 Release Agreement and Administrative Memorandum of Agreement with the DEA related to its
11 Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations
12 by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled
13 substances at its distribution facilities located in McDonough, Georgia, Valencia, California and
14 Denver, Colorado;

15 h. On February 2, 2012, the DEA issued an Order to Show Cause and
16 Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center
17 for failure to maintain effective controls against diversion of oxycodone;

18 i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to
19 the DEA to resolve the civil penalty portion of the administrative action taken against its
20 Lakeland, Florida Distribution Center; and

21 j. On January 5, 2017, McKesson entered into an Administrative
22 Memorandum Agreement with the DEA wherein it agreed to pay a \$150,000,000 civil penalty for
23 violation of the 2008 MOA as well as failure to identify and report suspicious orders at its
24 facilities in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; La Crosse, Wisconsin;
25 Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Methuen,
26 Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West
27 Sacramento, California.

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1 k. In February 2017, Cardinal Health agreed to pay the State of West Virginia
2 \$20 million to settle claims regarding its distribution of opioids within the state.

3 l. In February 2017, AmerisourceBergen agreed to pay the State of West
4 Virginia \$16 million to settle claims regarding its distribution of opioids within the state.

5 248. These actions against the Distributor Defendants confirm that the Distributors
6 knew they had a duty to maintain effective controls against diversion, design and operate a
7 system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions
8 also demonstrate that the Manufacturer Defendants were aware of the enforcement against their
9 Distributors and the diversion of the prescription opioids and a corresponding duty to report
10 suspicious orders.

11 249. The pattern of racketeering activity is continuing as of the date of this Complaint
12 and will likely continue into the future unless enjoined by this Court. Many of the precise dates of
13 Defendants' unlawful actions were hidden and cannot be alleged without access to Defendants'
14 books and records. Indeed, an essential part of the successful operation of the RICO Enterprise
15 depended upon the secrecy of the participants in that enterprise.

16 250. Each instance of racketeering activity alleged herein was related, had similar
17 purposes, involved the same or similar participants and methods of commission, and had similar
18 results affecting similar victims, including Plaintiff and its community. Defendants calculated and
19 intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of
20 opioids, without regard to the effect such behavior would have on Plaintiff. The Defendants were
21 aware that Plaintiff relies on the Defendants to maintain a closed system of manufacturing and
22 distribution to protect against the non-medical diversion and use of their dangerously addictive
23 opioid drugs.

24 251. By intentionally refusing to report and halt suspicious orders of their prescription
25 opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting
26 a pattern of racketeering activity.

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1 268. The public nuisance is substantial and unreasonable. Defendants' actions caused
2 and continue to cause the public health epidemic described above and that harm outweighs any
3 offsetting benefit.

4 269. Defendants knew and should have known that their promotion of opioids was false
5 and misleading and that their deceptive marketing scheme and other unlawful, unfair, and
6 fraudulent actions would create or assist in the creation of the public nuisance—the opioid
7 epidemic.

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

14 271. Defendants have breached their duties to the Yurok Tribe by disseminating false
15 and misleading information on its own and through the Front Groups, regarding the dangers of
16 opioid use and by targeting physicians likely to prescribe opioids for pain management despite
17 the availability of other, less or non-addictive pain killers, and through their failures to know their
18 customers, report suspicious orders.

19 272. Each Defendant unlawfully provided false or misleading material information
20 about prescription opioids or unlawfully failed to use reasonable care or comply with statutory
21 requirements in the distribution of prescription opioids.

22 273. Defendants' acts and omissions created the opioid epidemic and thereby caused
23 injury to the health of Plaintiff and the members of the Yurok Tribe and interfered with the
24 comfortable enjoyment of life and property of others, specifically the Yurok Tribe and its
25 members.

26 274. Defendants' acts and omissions offend decency and include the illegal sales of
27 controlled substances.

28 275. Defendants' acts and omissions render members of the Yurok Tribe insecure.

1 276.

2 277. The Yurok Tribe did not consent, expressly or impliedly, to the wrongful conduct
3 of Defendants.

4 278. As a direct and legal result of the conduct of Defendants, Plaintiffs suffered harm
5 that is different from the type of harm suffered by the general public. Defendants' acts and
6 omissions proximately caused injury to the Yurok Tribe and its members including, *inter alia*,
7 recoupment of costs of providing or paying for the health care, pharmaceutical care, and other
8 necessary services of the Yurok Tribe, flowing from an ongoing and persistent public nuisance
9 which Plaintiff seeks to abate.

10 279. Defendants' acts and omissions affect the entire communities of the Yurok Tribe.

11 280. Defendants also have a duty to abate the nuisance caused the by prescription
12 opioid epidemic.

13 281. The public nuisance created, perpetuated, and maintained by Defendants can be
14 abated and further recurrence of such harm and inconvenience can be abated.

15 282. The hazardous condition which was created by and/or permitted to exist by
16 Defendants affected a substantial number of people at the same time within the general public,
17 including Plaintiff, and constituted a public nuisance under Civil Code §§ 3479 and 3480.

18 283. Defendants have failed to abate the nuisance they created.

19 284. The Yurok Tribe seeks economic damages from the Defendants as reimbursement
20 for the costs associated with past efforts to eliminate the hazards to public health and safety.

21 285. Pursuant to Code of Civil Procedure § 731, the Yurok Tribe seeks an order
22 providing for abatement of the public nuisance that Defendants created or assisted in the creation
23 of, and enjoining Defendants from future violations of Civil Code §§ 3479 and 3480.

24 286. The Yurok Tribe seeks economic damages from the Defendants to pay for the
25 costs to permanently eliminate the hazards to public health and safety and abate the public
26 nuisance.

27 287. As a direct result of Defendants' conduct, the Yurok Tribe and its community have
28 suffered actual injury and economic damages including, but not limited to, significant expenses

1 for police, emergency, health, education and training, prosecution, child protection, corrections,
2 judicial and other services.

3 288. Defendants are liable to the Yurok Tribe for the costs borne it as a result of the
4 opioid epidemic and for the costs of abating the nuisance created by Defendants.

5 **FOURTH CLAIM FOR RELIEF**
6 **UNJUST ENRICHMENT**

7 289. The Yurok Tribe incorporates by reference paragraphs 1 through 258 of this
8 Complaint as if fully set forth herein.

9 290. The Yurok Tribe has expended substantial amounts of money to fix or mitigate the
10 societal harms caused by Defendants' conduct.

11 291. The expenditures by The Yurok Tribe in providing healthcare services to people
12 who use opioids have added to Defendants' wealth. The expenditures by The Yurok Tribe have
13 helped sustain Defendants' businesses.

14 292. The Yurok Tribe has conferred a benefit upon Defendants, by paying for what may
15 be called Defendants' externalities-the costs of the harm caused by Defendants' negligent
16 distribution and sales practices.

17 293. Defendants are aware of this obvious benefit, and that retention of this
18 benefit is unjust.

19 294. Defendants made substantial profits while fueling the prescription drug epidemic
20 in the Yurok Tribe.

21 295. Defendants continue to receive considerable profits from the distribution of
22 controlled substances to the members of the Yurok Tribe.

23 296. Defendants have been unjustly enriched by their negligent, intentional, malicious,
24 oppressive, illegal and unethical acts, omissions, and wrongdoing.

25 297. It would be inequitable to allow Defendants to retain benefit or financial
26 advantage.

27 298. The Yurok Tribe demands judgment against each Defendant for restitution,
28 disgorgement, and any other relief allowed in law or equity

FIFTH CLAIM FOR RELIEF
NEGLIGENCE

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3 299. The Yurok Tribe incorporates by reference paragraphs 1 through 258 of this
4 Complaint as if fully set forth herein.

5 300. The opioid epidemic was a direct, legal, and proximate result of Defendants'
6 negligence. As a direct, proximate, and legal result of said negligence, Plaintiff suffered damages
7 as alleged herein.

8 301. Defendants' failure to comply with their duties of care proximately caused damage
9 to Plaintiff.

10 302. The negligence of Defendants was a substantial factor in causing Plaintiff's
11 damages.

12 303. As a further direct and proximate result of Defendants' negligence, Plaintiff and
13 the Yurok Tribe suffered damages including, but not limited to economic loss, business loss,
14 emotional distress, annoyance, disturbance, shame, inconvenience, drug addiction and/or
15 dependency, and neonatal abstinence syndrome.

16 304. There is moral blame attached to Defendants as a result of the terrible injuries and
17 suffering their misconduct caused, including the damage to Plaintiff.

18 305. Public policy supports finding a duty of care in this circumstance, and a finding of
19 a duty of care on Defendants will also deter Defendants from engaging in such behavior in the
20 future.

21 306. Further, the conduct alleged against Defendants in this complaint was despicable
22 and subjected the Yurok Tribe to cruel and unjust hardship in conscious disregard of their rights,
23 constituting oppression, for which Defendants must be punished by punitive and exemplary
24 damages in an amount according to proof. Defendants' conduct evidences a conscious disregard
25 for the safety and welfare of others, including Plaintiffs. Defendants' conduct was and is
26 despicable conduct and constitutes malice as defined by Civil Code § 3294. An officer, director,
27 or managing agent of Defendants personally committed, authorized, and/or ratified the despicable
28 and wrongful conduct alleged in this complaint.

1 307. Plaintiffs are entitled to an award of punitive damages sufficient to punish and
2 make an example of these Defendants.

3 **SIXTH CLAIM FOR RELIEF**
4 **UNFAIR COMPETITION (Ca. Bus. & Prof. Code § 17200)**

5 308. The Yurok Tribe incorporates by reference paragraphs 1 through 258 of this
6 Complaint as if fully set forth herein.

7 309. Business and Professions Code Section 17200 (the UCL) prohibits any “unlawful,
8 unfair or fraudulent business act or practice[.]”

9 310. At times, places, and involving participants known exclusively to Defendants and
10 third parties and concealed from Plaintiff, Defendants have engaged in unlawful, unfair, and
11 fraudulent business practices in violation of the UCL as set forth above. Defendants’ business
12 practices as described in this Complaint are deceptive and violate the UCL because the practices
13 are likely to deceive consumers in California.

14 311. Defendants knew and should have known at the time of making or disseminating
15 these statements, or causing these statements to be made or disseminated, that such statements
16 were false and misleading and therefore likely to deceive the public.

17 312. Defendants’ omissions, which are deceptive and misleading in their own right,
18 render even Defendants’ seemingly truthful statements about opioids false and misleading. All of
19 this conduct, separately and collectively, was likely to deceive California payors who purchased,
20 or covered the purchase of, opioids for chronic pain.

21 313. Defendants’ business practices as describe in this Complaint are unlawful an and
22 violate the UCL.

23 314. These unlawful practices include, but are not limited to:

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

1 b. Defendants represented that opioids were of a particular standard, quality,
2 or grade when they were of another in violation of Consumer Legal Remedies Act, Civ. Code
3 § 1770(a)(7);

4 c. Defendants disparaged the goods of another by false or misleading
5 representation of fact in violation of Consumer Legal Remedies Act, Civ. Code § 1770(a)(8);

6 d. Defendants unlawfully failed to identify and report suspicious prescribing
7 to law enforcement and health authorities; and

8 e. Defendants made or disseminated, directly or indirectly, untrue, false, or
9 misleading statements about the use of opioids to treat chronic pain, or causing untrue, false, or
10 misleading statements about opioids to be made or disseminated to the general public in violation
11 of the UCL.

12 f. Defendant Purdue directly or indirectly offered or paid remuneration to
13 doctors to prescribe its opioid products in violation of Welf. & Inst. Code § 14107.2,

14 315. Defendants’ business practices as described in this Complaint are unfair and
15 violate the UCL because they offend established public policy, and because the harm they cause
16 to consumers in California greatly outweighs any benefits associated with those practices.

17 316. As a direct and proximate result of the foregoing acts and practices, Defendants
18 have received, or will receive, income, profits, and other benefits, which they would not have
19 received if they had not engaged in the violations of the UCL described in this Complaint.

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

22 **SEVENTH CLAIM FOR RELIEF**

23 **FALSE ADVERTISING LAW (Ca. Bus. & Prof. Code § 17500)**

24 318. The Yurok Tribe incorporates by reference paragraphs 1 through 258 of this
25 Complaint as if fully set forth herein.

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

3 320. At times, places, and involving participants known exclusively to Defendants and
4 third parties and concealed from Plaintiff, Defendants violated the FAL by making and
5 disseminating false or misleading statements about the use of opioids to treat chronic pain, or by
6 causing false or misleading statements about opioids to be made or disseminated to the public.

7 321. Defendants violated the FAL by making statements to promote the use of opioids
8 to treat chronic pain that omitted or concealed material facts, and by failing to correct prior
9 misrepresentations and omissions, about the risks and benefits of opioids. Each Defendant’s
10 omissions, which are false and misleading in their own right, render even their seemingly truthful
11 statements about opioids false and misleading.

12 322. Defendants’ statements about the use of opioids to treat chronic pain were not
13 supported by or were contrary to the scientific evidence, as confirmed by later pronouncements of
14 the CDC, the FDA, and confirmed by recent investigations based on that evidence.

15 323. As alleged above, each Defendant’s conduct, separately and collectively, was
16 likely to deceive the Yurok Tribe who purchased or covered the purchase of opioids for chronic
17 pain.

18 324. Defendants knew and should have known, at the time they made or disseminated
19 the false and misleading statements or caused these statements to be made or disseminated, that
20 the statements were false or misleading and therefore likely to deceive the public.

21 325. In addition, Defendants knew and should have known that their false and
22 misleading advertising created a false or misleading impression of the risks and benefits of long-
23 term opioid use and would result in unnecessary and improper opioid prescriptions and use.

24 **PRAYER FOR RELIEF**

25 **WHEREFORE**, the Yurok Tribe prays that the Court:

- 26 A. Enter judgment against Defendants and in favor of the Yurok Tribe;
27 B. Award compensatory damages in an amount sufficient to fairly and completely
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1 compensate the Yurok Tribe for all damages; treble damages; pre-judgment and post-judgment
2 interest as provided by law, and that such interest be awarded at the highest legal rate;

3 C. Award damages caused by the opioid epidemic, including (1) costs for providing
4 medical care, additional therapeutic and prescription drug purchases including costs of
5 obtaining naloxone and suboxone, as well as other treatments for patients suffering from
6 opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing
7 culturally-informed treatment, counseling, detox and rehabilitation services; (3) costs for
8 providing treatment of infants born with opioid-related medical conditions, including NAS; (4)
9 costs for providing care for children whose parents suffer from opioid-related disability or
10 incapacitation; and (5) costs associated with law enforcement and public safety relating to the
11 opioid epidemic;
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13 D. Orders and procedures to abate the nuisance created by Defendants' wrongful
14 conduct;
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16 E. Enjoin the Defendants from continuing the wrongful conduct alleged herein and
17 further to enjoin the Defendants from the publication and/or dissemination of false and
18 misleading materials directly or indirectly through the Front Groups or the KOLs;

19 F. Award the Yurok Tribe its costs of suit, including reasonable attorneys' fees
20 as provided by law; and
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22 G. Award such further and additional relief as the Court may deem just and proper
23 under the circumstances.

24 **JURY DEMAND**

25 Pursuant to Federal Rule of Civil Procedure 38, the Yurok Tribe demands a trial by jury
26 on all issues so triable.
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Respectfully submitted,

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