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Case No. C20190272
HON. JANET C. BOSTWICK

RUSING LOPEZ & LIZARDI, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800
Facsimile: (520)529-4262
Michael J. Rusing; mrusing@rllaz.com
State Bar No. 006617; PAN 50020
Andrew Sterling; asterling@rllaz.com
State Bar No. 030471; PAN 66585

LAW OFFICE OF JOSEPH C. TANN, P.L.L.C.
7735 North 78th Street
Scottsdale, AZ 85258
Telephone: (602) 432-4241
Joseph C. Tann; josephtann@josephtann.com
State Bar No. 029254

GRANT WOODS, P.C.
The Atticus Building
650 North 3rd Avenue
Phoenix, AZ 85003
Telephone: (602) 258-2599
Facsimile: (602) 258-5070
Grant Woods; gw@grantwoodspc.net
State Bar No. 006106

MIKE MOORE LAW FIRM, LLC
P.O. Box 321048
Flowood, MS 39232
Telephone: (601) 933-0070
Facsimile: (601) 933-0071
Mike Moore; mm@mikemoorelawfirm.com
Mississippi Bar No. 3452
*To be admitted Pro Hac Vice

Attorneys for Plaintiff City of Tucson

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF PIMA

The City of Tucson, a municipal corporation,

Plaintiff,

vs.

Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company; Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. N/K/A Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. N/K/A

NO.

COMPLAINT

(Assigned to _____)

Janssen Pharmaceuticals, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC F/K/A Actavis PLC; Allergan Finance LLC (F/K/A Actavis, Inc.); Watson Pharmaceuticals, Inc. N/K/A Actavis, Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. F/K/A Watson Pharma, Inc.; Insys Therapeutics, Inc.; Mallinckrodt, LLC; McKesson Corporation; Cardinal Health, Inc.; Amerisourcebergen Corporation; H.D. Smith, LLC; and Anda Pharmaceuticals, Inc.

Defendants.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

INTRODUCTION

1. Defendants manufacture and/or distribute opioid drugs across the nation including in Tucson, Arizona.

2. Defendants have engaged in a concerted effort over many years to expand the market for opioids and to increase their profits by misleading consumers and medical providers through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids, and by failing to take adequate steps to monitor the distribution and sale of opioids and failing to report suspicious orders to the proper authorities and governing bodies.

3. In part due to Defendants' actions and omissions, opioid addiction has reached epidemic levels over the past decade. On March 22, 2016, the FDA recognized opioid abuse as a public health crisis and on June 5, 2017, Arizona Governor Doug Ducey signed an emergency declaration to address the growing number of opioid overdoses and deaths in Arizona.

4. The rising numbers of persons addicted to opioids have led to significantly increased health care costs as well as a dramatic increase in social problems, including drug abuse and diversion and the commission of criminal acts to obtain opioids throughout the

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6363 North Swan Road, Suite 151
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United States, including Arizona and the City of Tucson. Consequently, public health and safety throughout the United States, including Arizona and the City of Tucson, has been significantly and negatively impacted due to the misrepresentations and omissions by Defendants regarding the appropriate uses and risks of opioids, ultimately leading to widespread inappropriate use of the drug.

5. As a direct and foreseeable consequence of Defendants' wrongful conduct, the City of Tucson has been required to spend millions of dollars each year to combat opioid addiction and abuse including, but not limited to, health care costs, criminal justice and victim-services costs, social costs, and lost productivity costs. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use and other actions described in this Complaint proximately caused injury to the City of Tucson and its residents.

JURISDICTION AND VENUE

6. Jurisdiction and venue are proper in this Court because this action arises out of events occurring in the City of Tucson and Pima County and each Defendant regularly transacted substantial business in the City of Tucson and Pima County.

PARTIES

A. Plaintiff

7. The City of Tucson is a municipal corporation duly constituted under the laws of the State of Arizona with legal authority to file this lawsuit.

B. Manufacturer Defendants

8. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware.

9. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

10. THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut. Defendants Purdue Pharma L.P., Purdue Pharma Inc. and The Purdue Frederick Company are collectively referred to in this Complaint as "Purdue.")

11. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania.

12. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc.

13. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly-owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania.

14. JOHNSON & JOHNSON ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersy.

15. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J.

16. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

17. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

18. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
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19. ENDO PHARMACEUTICALS INC. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Defendants Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are collectively referred to in this Complaint as "Endo.")

20. ALLERGAN PLC (f/k/a Actavis plc) is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland, and an administrative headquarters in Parsippany, New Jersey.

21. ALLERGAN FINANCE LLC, a wholly-owned subsidiary of Allergan plc, is a Nevada limited liability company headquartered in Parsippany, New Jersey.

22. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California.

23. ACTAVIS PHARMA, INC. (f/k/a WATSON PHARMA, INC) is a Delaware corporation with its principal place of business in New Jersey.

24. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

25. Upon information and belief, Defendants Actavis plc, Actavis, Inc., Allergan Finance, LLC, Actavis Group, Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. (collectively referred to in this Complaint as "Actavis") each is or was owned by Allergan plc, which uses or has used them to manufacture, distribute, market, and sell its drugs in the United States.

26. MALLINCKRODT, LLC is a limited liability company organized and existing under the laws of the State of Delaware and licensed to do business in Arizona. Mallinckrodt manufactures, markets, and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers.

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6363 North Swan Road, Suite 151
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27. INSYS THERAPEUTICS, INC. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona.

28. Purdue, Cephalon, Teva, Johnson & Johnson, Janssen, Endo, Actavis, Mallinckrodt, and Insys, collectively referred to in this Complaint as "Manufacturer Defendants," are companies whose primary business is the manufacture, marketing, and distribution of prescription drugs, including opioids. These Manufacturer Defendants manufacture, market, and sell prescription opioid pain medications, including the brand-name drugs OxyContin, Butrans, Hysingla ER, Actiq, Fentora, Opana/Opana ER, Percodan, Percocet, Zydone, Nucynta/Nucynta ER, Duragesic, Norco, Kadian, Subsys, and related generics.

C. Distributor Defendants

29. MCKESSON CORPORATION is a Delaware Corporation with its principal place of business in San Francisco, California. McKesson has regional offices in Scottsdale, Arizona that facilitate the distribution of medications, including opioids. McKesson is sixth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of $198 billion in 2017. McKesson distributes pharmaceuticals to retail pharmacies and institutions in all 50 states, including the State of Arizona and the City of Tucson. Upon information and belief, McKesson is a pharmaceutical distributor licensed to do business in Arizona and does substantial business in the State of Arizona and the City of Tucson.

30. CARDINAL HEALTH, INC. is an Ohio Corporation with its principal place of business in Dublin, Ohio. Cardinal describes itself as a "global, integrated health care services and products company," and is the fourteenth largest company by revenue in the United States, with annual revenue of $129.98 billion in 2017. Cardinal distributes pharmaceuticals, including prescription opioids, to retail pharmacies and institutions in all 50

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6363 North Swan Road, Suite 151
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states, including the State of Arizona and City of Tucson. Based on Cardinal's own estimates, one of every six pharmaceutical products dispensed to U.S. patients travels through the Cardinal Health network. Upon information and belief, Cardinal is a pharmaceutical distributor licensed to do business in Arizona and does substantial business in the State of Arizona and City of Tucson.

31. AMERISOURCEBERGEN DRUG CORPORATION is a Delaware Corporation with its principal place of business in Chesterbrook, Pennsylvania. Amerisource is the twelfth largest company by revenue in the United States, with annual revenue of more than $153 billion in 2017. Upon information and belief, Amerisource is a pharmaceutical distributor licensed to do business in the State of Arizona and does substantial business in the State of Arizona and City of Tucson.

32. H.D. SMITH, LLC ("H.D. Smith") is a Delaware Corporation with its principal place of business in Springfield, Illinois.

33. ANDA PHARMACEUTICALS, INC. ("Anda") is a Florida Corporation with its principal place of business located in Weston, Florida. Anda is licensed to do business in the State of Arizona and does substantial business in the State of Arizona and City of Tucson.

34. McKesson, Cardinal, AmerisourceBergen, H.D. Smith, and Anda collectively referred to in this Complaint as "Distributor Defendants," are in the chain of distribution of prescription opioids. Upon information and belief, the Distributor Defendants have distributed prescription opioids in the State of Arizona and the City of Tucson.

FACTUAL ALLEGATIONS

A. The Pain-Relieving and Addictive Properties of Opioids

35. Opioids are a class of drugs naturally found in the opium poppy plant. Some prescription opioids are made from the plant directly, and others are made by scientists in labs using the same chemical structure.

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6363 North Swan Road, Suite 151
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36. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, and they are regulated as controlled substances. While opioids can work to dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience often prolonged withdrawal symptoms—including severe anxiety, nausea, headaches, tremors, delirium, and pain—if opioid use is delayed or discontinued. When using opioids continuously, patients grow tolerant to their analgesic effects—requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

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

B. Manufacturer Defendants Used Every Available Avenue to Disseminate Their False and Deceptive Statements About Opioids

38. Tens of millions of Americans suffer from and seek treatment for chronic pain. To take advantage of the lucrative market for chronic pain patients, each Manufacturer Defendant developed a well-funded marketing scheme based on deception. Each Manufacturer Defendant used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use—statements that benefited not only themselves and the third-parties who gained legitimacy, but all opioid manufacturers. Yet these

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

statements were not only unsupported by and contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations.

39. Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in Arizona. Manufacturer Defendants also bankrolled and controlled professional societies and other ostensibly neutral third parties in order to lend these deceptive statements a veneer of independence and scientific legitimacy.

C. Manufacturer Defendants Spread and Continue to Spread Their False and Deceptive Statements Through Direct Marketing of Their Branded Opioids

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

41. Several Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs such as construction worker and chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement. Purdue also ran a series of ads called "Pain vignettes" for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Janssen used branded advertising and published reprints of journal articles

promoting the use of opioids to treat osteoarthritis, even though the FDA found, in reviewing the New Drug Application for Janssen's drug Nucynta ER, that Nucynta ER was no more effective than placebos in reducing osteoarthritis pain. Actavis distributed a product advertisement that falsely claimed that use of Kadian to treat chronic non-cancer pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives. The FDA later warned Actavis such claims were misleading.[1]

42. Second, each Manufacturer Defendant promoted the use of opioids for chronic pain through "detailers"—sales representatives who visited individual doctors and medical staff in their offices—and small-group speaker programs. Manufacturer Defendants have not corrected this misinformation. In 2014 alone, Manufacturer Defendants spent $168 million on detailing branded opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis.

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

44. Manufacturer Defendants also identified doctors to serve, for payment, on their speaker bureaus and to attend programs with speakers and meals paid for by Manufacturer

[1] Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them in Arizona.

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Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. They were also one of the key ways Manufacturer Defendants' messages were disseminated as medical knowledge: these speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Manufacturer Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids.

45. Manufacturer Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. This, of course, is why Manufacturer Defendants engage in the practice. Manufacturer Defendants, moreover, know that detailing is effective because they purchase, manipulate, and analyze some of the most sophisticated data available in *any* industry to track, precisely, the rates of initial prescribing and renewal by individual doctors. This data allows Manufacturer Defendants to target, tailor, and monitor the impact of their core messages.

46. Manufacturer Defendants employed the same marketing strategies and deployed the same messages in Arizona as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Manufacturer Defendants' messages are consistently delivered across marketing channels—including detailing visits, speaker events, and advertising—and in each sales territory. Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

marketing their drugs.

47. Manufacturer Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons (the company employees who respond to physician inquiries); centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. Manufacturer Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

48. In February 2018, with legal challenges mounting, Purdue announced it would cease detailing physicians in respect to Purdue's branded opioids. Purdue did not, however, make any commitment to correct the misrepresentations its multi-decade detailing campaign has engendered in the medical community. Nor did Purdue commit to cease other deceptive marketing tactics, including the practice addressed below of laundering promotional messages through Front Groups and other ostensibly unbiased third parties. Far from reversing course, Purdue has indicated it will aggressively promote its drugs that treat opioid-induced constipation—drugs that can only be profitable if opioids are widely prescribed.

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

49. Manufacturer Defendants also deceptively marketed opioids in Arizona through unbranded advertising—*i.e.*, advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
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promote opioids for the treatment of chronic pain. Much in the same way Manufacturer Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, Manufacturer Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, CMEs, and medical conferences and seminars. To this end, Manufacturer Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

50. Manufacturer Defendants also marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

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

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

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
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E. Key Opinion Leaders ("KOLs")

52. Manufacturer Defendants also spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Manufacturer Defendants because their public positions supported the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs."

53. Manufacturer Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying Manufacturer Defendants by advancing their marketing goals. KOLs' professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by Manufacturer Defendants.

54. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. Manufacturer Defendants created opportunities for KOLs to participate in research studies Manufacturer Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, Manufacturer Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

55. Manufacturer Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain, and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. These guidelines and CMEs were not supported by the scientific evidence at the time they were created, and they are not supported by the scientific evidence today. Manufacturer Defendants were able to direct and exert control over each of these activities through their KOLs.

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6363 North Swan Road, Suite 151
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56. Pro-opioid doctors are one of the most important avenues Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. Manufacturer Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that through March 2015 the Purdue website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

57. Thus, even though some of Manufacturer Defendants' KOLs have recently moderated or conceded the lack of evidence for many of the claims they made, those admissions did not reverse the effect of the false and deceptive statements that continue to appear nationwide and in Arizona in Manufacturer Defendants' own marketing as well as treatment guidelines, CMEs and other seminars, scientific articles and research, and other publications available in paper or online.

58. Manufacturer Defendants utilized many KOLs, including many of the same ones.

59. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom Manufacturer Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

60. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy

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of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by Manufacturer Defendants.

61. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on *Good Morning America* in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast in Arizona and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[2]

62. To his credit, Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[3] Dr. Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[4]

63. Another KOL, Dr. Lynn Webster, was the founder of Lifetree Pain Clinic and

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[2] Good Morning America television broadcast, ABC News (Aug. 30, 2010).

[3] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J., Dec. 17, 2012.

[4] *Id.*

Lifetree Clinical Research in Salt Lake City. In 2013, Dr. Webster became the president of the American Academy of Pain Management (AAPM), a Front Group for the opioid industry (discussed further below), and he remained on AAPM's board of directors for a period thereafter. In these capacities, Dr. Webster authored numerous studies and CMEs supporting chronic opioid treatment, and the industry handsomely rewarded his efforts. Between 2009 and 2013, Dr. Webster received millions of dollars from drug companies, including at least eight payments from Defendant Cephalon—*the largest exceeding $1.6 million*.[5]

64. Among the misconceptions Dr. Webster peddled was the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indicators of undertreated pain. The only way to differentiate the two, Dr. Webster claimed, was to *increase* a patient's dose of opioids. As he wrote in his book *Avoiding Opioid Abuse While Managing Pain* (2007), which is still available, when facing signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response." Endo distributed this book to doctors and all Manufacturer Defendants latched onto the pseudoaddiction concept it articulated.

65. Another devastating contribution of Dr. Webster's is the so-called Opioid Risk Tool, a widely used five-question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to opioids. In reality, and as the CDC has advised, the Opioid Risk Tool is "extremely inconsistent."[6] But by giving doctors the false impression that opioids can be safely prescribed to a "screened" population, the Opioid Risk Tool became a catalyst for risky

[5] ProPublica Data, available at https://projects.propublica.org/d4d-archive/search?company%5Bid%5D=&period%5B%5D=&services%5B%5D=&state%5Bid%5D=45&term=Lynn+Webster&utf8=%E2%9C%93.

[6] CDC Guideline for Prescribing Opioids for Chronic Pain (March 18, 2016), available at https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

Rusing Lopez & Lizardi, P.L.L.C.
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prescribing and one that, conveniently, could be billed as a risk-mitigation tool for conscientious practitioners. It is thus little surprise that the tool has been aggressively promoted by Manufacturer Defendants, with versions of it appearing on websites run by Endo, Janssen, and Purdue.

66. Dr. Webster also maintained an active practice at his Lifetree Pain Clinic in Salt Lake City and, tragically, he practiced what he preached. As rumors of overdosed LifeTree patients spread, the DEA raided Dr. Webster's offices and discovered an entire file cabinet labeled "deceased patients."[7] Although Dr. Webster ultimately was not prosecuted, the investigation revealed that 20 patients overdosed and died under his care.

67. Today, Dr. Webster no longer treats patients. He does, however, still function as a mouthpiece for opioid manufacturers' agenda, who continue to pay him significant sums in consulting and other fees. Between 2013 and 2015, Dr. Webster received more than $150,000 from drug companies, most of it from manufacturers of opioids, including Defendant Cephalon.[8]

F. Front Groups

68. Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Manufacturer Defendants, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to

[7] https://www.deseretnews.com/article/900002328/the-untold-story-of-how-utah-doctors-and-big-pharma-helped-drive-the-national-opioid-epidemic.html.

[8] *See* ProPublica Data, available at https://projects.propublica.org/docdollars/doctors/pid/1136720.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

vulnerable patient populations targeted by Manufacturer Defendants.

69. These Front Groups depended on Manufacturer Defendants for funding and, in some cases, for survival. Manufacturer Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. For example, Purdue's consulting agreement with American Pain Foundation ("APF") gave it direct, contractual control over APF's work. These efforts assured that Front Groups would generate only the messages Manufacturer Defendants wanted to distribute. Despite this, the Front Groups concealed the extent to which they were bankrolled by Manufacturer Defendants, holding themselves out as independent professional societies faithfully serving the needs of their constituencies—whether patients suffering from pain or doctors treating those patients.

70. The U.S. Senate Homeland Security & Government Affairs Committee recently completed an investigation into the financial connections between opioid manufacturers and fourteen different Front Groups advocating opioid-related policies and practices. The investigation revealed that Defendants Purdue and Janssen, along with opioid manufacturers Mylan, Depomed, and Insys, contributed more than $10 million to opioid Front Groups and their affiliates between 2012 and 2017.[9] Of these manufacturers, Purdue contributed the most, with payments exceeding $4 million between 2012 and 2017. Janssen was the second largest contributor until 2015, when it sold the licensing rights to its opioid Nucynta.[10]

71. These disturbing contributions are only the tip of the iceberg. The Senate did not investigate contributions of other opioid manufacturers, including Defendants Endo and

[9] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member McCaskill's Office, *Fueling the Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* (Feb. 2018), at 1.

[10] *Id*. at 5-6.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

Cephalon, and thus, admittedly, did not "capture the full extent of the financial ties between opioid manufacturers and patient advocacy groups and professional societies."[11]

72. The results of the Senate's investigation are set forth in a February 2018 report authored by Missouri Senator McCaskill's office. The report identifies a "direct link between corporate donations" made by opioid manufactures and the Front Groups' "advancement of opioids-friendly messaging."[12] Elaborating, the report observes:

> Initiatives from the groups in this report often echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of opioid manufacturers. These groups have issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for over prescription and misbranding. Notably, a majority of these groups also strongly criticized 2016 guidelines from the Centers for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain—the first national standards for prescription opioids and a key federal response to the ongoing epidemic.[13]

73. Senator McCaskill's report concluded that "[t]hrough criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy organizations have often supported industry interests at the expense of their own constituencies."[14]

74. To reach a wide audience, and give the impression of professional consensus, Manufacturer Defendants have bankrolled a diverse array of Front Groups. All told, Purdue, Janssen, Endo and Cephalon contributed to more than a dozen Front Groups, including many of the same ones. Two of the most prominent are described below, but there are many others,

[11] *Id.* at 15.
[12] *Id*. at 1.
[13] *Id*.
[14] *Id*. at 3.

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6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

including the American Pain Society ("APS"), the Federation of State Medical Boards ("FSMB), the U.S. Pain Foundation ("USPF"), the American Geriatrics Society ("AGS"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF"), and Pain & Policy Studies Group ("PPSG").

75. The most prominent of Manufacturer Defendants' Front Groups was APF, which received more than $10 million in funding from opioid manufacturers from 2007 until it ceased operations in May 2012.[15] Endo alone provided more than half that funding; Purdue was next, at $1.7 million.

76. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for military veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among that target population. APF also engaged in a significant multimedia campaign – through radio, television and the Internet – to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach Arizona, including Tucson.

77. Dr. Perry Fine (a KOL from the University of Utah who received funding from Janssen, Cephalon, Endo, and Purdue), Dr. Portenoy, and Dr. Fishman (a KOL from the University of California - Davis who authored *Responsible Opioid Prescribing*, a publication sponsored by Cephalon and Purdue), all served on APF's Board and reviewed its publications. Another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

78. In 2009 and 2010, more than 80% of APF's operating budget came from

[15] Senator McCaskill's February 2018 report studied contributions between 2012 and 2017 and thus did not investigate industry contributions to APF.

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6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As one of its board members, Dr. Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

79. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Manufacturer Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. APF functioned largely as an advocate for the interests of Manufacturer Defendants, not patients. Indeed, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

80. In practice, APF operated in close collaboration with Manufacturer Defendants. On several occasions, representatives of the Manufacturer Defendants, often at informal meetings at Front Group conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that Manufacturer Defendants would support projects conceived as a result of these communications.

81. APF assisted in other marketing projects for Manufacturer Defendants. One project– *APF Reporter's Guide: Covering Pain and Its Management* (2009) – recycled text that was originally created as part of the company's training document.

82. APF's clear lack of independence – in its finances, management, and mission

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6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

– and its willingness to allow Manufacturer Defendants to control its activities and messages support an inference that each Manufacturer Defendant that worked with it was able to exercise editorial control over its publications.

83. Indeed, the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and Manufacturer Defendants. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and Manufacturer Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization.

84. The American Academy of Pain Medicine ("AAPM"), with the assistance, prompting, involvement, and funding of Manufacturer Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

85. AAPM has received millions of dollars from opioid manufacturers since 2009, including nearly $1.2 million from Purdue and Janssen in 2012 through 2017 alone. AAPM also maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

86. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors

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6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Dr. Fine, Dr. Portenoy, and Dr. Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[16]

87. AAPM's staff understood they and their industry funders were engaged in a common task. Manufacturer Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

88. In 1997, AAPM and the American Pain Society jointly issued a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain,* which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was at the time a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011 and was taken down from AAPM's website only after a doctor complained, though it lingers on the Internet elsewhere.

89. Recognizing the importance of opioid treatment guidelines in securing the acceptance of chronic opioid therapy, AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including

[16] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), http://www.medscape.org/viewarticle/500829.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

KOLs Dr. Portenoy and Dr. Fine, received support from Janssen, Cephalon, Endo, and Purdue.

90. The 2009 AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 AAPM/APS Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members. The AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the AAPM/APS Guidelines have been cited 732 times in academic literature, were disseminated in Arizona during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

91. Manufacturer Defendants widely referenced and promoted the AAPM/APS 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

92. When the CDC issued guidelines in 2016 recommending the use of non-opioid therapies in the treatment of chronic pain, AAPM's immediate past president, Daniel Carr, was highly critical, stating "that the CDC guideline makes disproportionally strong recommendations based upon a narrowly selected portion of the available clinical evidence.[17]

93. In an effort to retain credibility, AAPM has obscured its financial ties to opioid manufacturers, including the Manufacturer Defendants. Nowhere on AAPM's website is it

[17] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member McCaskill's Office, *Fueling the Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* (Feb. 2017), at 1.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

disclosed that AAPM has received millions of dollars in funding from the industry it has supported. Far from it, AAPM has a page on its website purporting to list the "patrons" who have donated to the organization between January 1, 2017 and June 1, 2018—not a single opioid manufacturer (or other pharmaceutical company) is identified.[18]

94. AAPM recently became known as the Academy of Integrative Pain Management ("AIPM"). Despite the change in name, the academy has remained a vehicle funded by and operated on behalf of pharmaceutical companies generally and opioid manufacturers specifically. AIPM's executive director, Bob Twillman, recently reported that AIPM receives fifteen percent (15%) of its funding from pharmaceutical companies, not including revenue from advertisements in its publications. Its state advocacy project, the Academy's lobbying arm, is 100 percent funded by drug manufacturers and their allies.

95. Defendant Mallinckrodt also provided funding to organizations in order to disseminate false messages about opioids.

96. Until at least June 2007, Mallinckrodt gave education grants to pain-topics.org, a now defunct website that proclaimed to be an organization "dedicated to offering contents that are evidence-based, unbiased, non-commercial, and comply with the highest standards and principles of accrediting and other oversight organizations."

97. The FAQs section of the website contained misleading information about pseudoaddiction. Specifically, the website described pseudoaddiction as behavior that occurs in patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications and may be erroneously perceived as 'drug seeking.'"

98. Among its content, the website published a handout titled *Oxycodone Safety for Patients*, which advised doctors that "[p]atients' fears of opioid addiction should be

[18] *See* http://aapmfoundation.org/donors.

expelled."[19] The handout contained the following misleading information which downplayed the risk of addiction:

> **Will you become dependent on or addicted to oxycodone?**
>
> - ☐ After awhile, oxycodone causes *physical dependence*. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.
> - ☐ This is not the same as *addiction*, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.

This handout is still available to prescribers and patients today.

99. In 2010, according to a Mallinckrodt Policy Statement, Mallinckrodt launched the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." Mallinckrodt further states: "Through the C.A.R.E.S. Alliance website, prescribers and pharmacists can access tools and resources to assist them in managing the risks of opioid pain medications, and patients can find information designed to help them better manage their pain and understand the responsible use of the medications they take." By 2012, the C.A.R.E.S. Alliance and Mallinckrodt were promoting a book titled *Defeat Chronic Pain Now!*. The false claims and misrepresentations in this book include, but are not limited to, the following statements:

a. "Only rarely does opioid medication cause a true addiction."

b. The issue of tolerance is "overblown."

c. "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."

[19] Lee A. Kral, *Commonsense Oxycodone Prescribing & Safety*, http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

d. "It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

100. This book is still available online and elsewhere.

G. Efforts to Spread False and Deceptive Marketing Messages

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

H. This Marketing Scheme Misrepresented the Risks and Benefits of Opioids

102. To convince doctors and patients in Arizona and across the nation that opioids can and should be used to treat chronic pain, Manufacturer Defendants had to convince them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Manufacturer Defendants made claims that were not supported by or were contrary to the scientific evidence. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm their claims were false and deceptive, Manufacturer Defendants have not corrected them, or instructed their KOLs or Front Groups to correct

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

them, and they continue to spread them today.

I. Manufacturer Defendants Falsely Trivialized or Failed to Disclose the Known Risks of Long-term Opioid Use

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

104. ***First***, Manufacturer Defendants falsely claimed that the risk of opioid addiction is low, and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly, and they failed to disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of these false and deceptive claims are described below:

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

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

rights to Kadian, Actavis continued to use this brochure in 2007 and beyond.

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.

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

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

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

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

g. Purdue sponsored APF's– which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to

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6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

"misconceptions about opioid addiction." This publication is still available online.

h. Detailers for Purdue, Endo, Janssen, and Cephalon minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

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

106. The FDA further exposed the falsity of Manufacturer Defendants' claims about the low risk of addiction when it announced changes to the labels for Extended-Release/Long-Acting opioids in 2013 and for Immediate-Release opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

107. Manufacturer Defendants' claims are further proven false by the warnings on their FDA-approved drug labels that caution that opioids "expose users to risks of addiction, abuse and misuse, which can lead to overdose and death," that the drugs contain "a substance with a high potential for abuse," and that addiction "can occur in patients appropriately prescribed" opioids.

108. In 2016, the New York Attorney General found that Endo improperly marketed its opioid drug, Opana ER, as designed to be crush resistant, when Endo's own studies actually showed that the pill could be crushed and ground up. These misrepresentations bolstered Opana ER sales but provided a false sense of security to healthcare providers and their patients. The Attorney General also found Endo improperly instructed its sales representatives to diminish and distort risks associated with Opana ER, including serious dangers involving addiction.

109. In a subsequent settlement agreement, Endo agreed to stop improperly marketing Opana ER as crush resistant, to stop making statements that opioids generally are non-addictive or that most patients who take opioids do not become addicted and to create an abuse and diversion detection program that requires Endo's sales representatives to report to the company any healthcare providers they suspect of engaging in abuse and illegal diversion of opioids. Endo remains free, however, to continue its marketing misrepresentations in Arizona, including Tucson, and has not engaged in a campaign to reverse the impact of these false statements.

110. ***Second***, Manufacturer Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Manufacturer Defendants called this phenomenon "pseudoaddiction" – a term coined by the now infamous Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Portenoy, a KOL for Cephalon, Endo, Janssen, and

Purdue – and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims are described below:

a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of pseudoaddiction, rather than true addiction. *Responsible Opioid Prescribing* remains for sale online. The 2012 edition, which also remains available online, continues to teach that pseudoaddiction is real.

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

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

d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

e. Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role play, a chronic

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

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

111. The 2016 CDC Guideline rejects the concept of pseudoaddiction. Nowhere in the Guideline does it recommend that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

112. One of the Manufacturer Defendants has effectively repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the State of New York, in its 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.'" Consistent with this, Endo agreed not to "use the term

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

'pseudoaddiction' in any training or marketing" in New York. Endo, however, remains free to do so in Arizona.

113. ***Third,*** Manufacturer Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims are described below:

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

b. Endo, Janssen, and Purdue all linked websites they ran or administered to Dr. Webster's Opioid Risk Tool, a brief questionnaire that gave doctors false confidence in prescribing opioids for chronic pain.

c. Purdue sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

d. As recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and

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6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

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

115. ***Fourth***, to underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and they failed to disclose the increased difficulty of stopping opioids after long-term use.

116. For example, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.

117. Manufacturer Defendants deceptively minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid

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6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use. Yet the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to "pause and restart" tapers depending on the patient's response. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

118. ***Fifth***, Manufacturer Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Manufacturer Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples are described below:

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

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6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.

b. Cephalon and Purdue sponsored *APF's Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online.

c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was available during 2018 on Endo's website. In Q&A format, it asked: "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."

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

f. Purdue's *In the Face of Pain* website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages.

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6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

This publication is still available online.

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

i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," challenging the correlation between opioid dosage and overdose.

119. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established," while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

120. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged in response to a citizen petition by a physician group "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." In fact, a recent study found that 92% of persons who died from an opioid-related overdose were initially prescribed opioids for chronic pain.

121. ***Finally***, Manufacturer Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids, described below, has created false impressions

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6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.[20]

122. These abuse deterrent formulations (AD opioids) are harder to crush, chew, or grind; become gelatinous when combined with a liquid, making them harder to inject; or contain a counteragent such as naloxone that is activated if the tablets are tampered. Despite this, AD opioids are not "impossible to abuse."[21] They can be defeated – often quickly and easily – by those determined to do so. Moreover, they do not stop oral intake, the most common avenue for opioid misuse and abuse, and do not reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term as prescribed or who escalate their use by taking more pills or higher doses.

123. Because of these significant limitations, and because of the heightened risk for misconceptions and for the false belief that AD opioids can be prescribed safely, the FDA has cautioned that "[a]ny communications from the sponsor companies regarding AD properties must be truthful and not misleading (based on a product's labeling) and supported by sound science taking into consideration the totality of the data for the particular drug. Claims for AD opioid products that are false, misleading, and/or insufficiently proven do not serve the public health."[22]

124. Despite this admonition, Manufacturer Defendants have made and continue to make misleading claims about the ability of their so-called abuse-deterrent opioid

[20] Catherine S. Hwang, *et al.*, *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, 175(2) JAMA INTERN. MED. 302-4 (Dec. 8, 2014).

[21] FDA Facts: Abuse-Deterrent Opioid, available at https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm [as of September 24, 2017].

[22] *Id.*

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6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

formulations to prevent or reduce abuse and addiction and the safety of these formulations. For example, until July 2017 when Endo withdrew Opana ER from the market in response to pressure from the FDA to do so, Endo marketed Opana ER as tamper, or crush, resistant and less prone to misuse and abuse even though: (1) the FDA rejected Endo's petition to approve Opana ER as abuse-deterrent in 2012; (2) the FDA warned in a 2013 letter that there was no evidence that Opana ER "would provide a reduction in oral, intranasal or intravenous abuse"; and (3) Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. Endo's advertisements for the 2012 reformulation of Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse.

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

126. Because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and a serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that Endo withdraw Opana ER from the market.[23] Approximately one month later, Endo did so.[24]

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

[24] Press Release, "Endo Provides Update On Opana ER," July 6, 2017, available at http://www.endo.com/news-events/press-releases.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

127. Likewise, Purdue has engaged in deceptive marketing of its AD opioids – *i.e.*, reformulated Oxycontin and Hysingla. Before April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However, beginning in 2013 and continuing until at least February 2018, detailers from Purdue regularly used the so-called abuse deterrent properties of Purdue's opioid products as a primary selling point to differentiate those products from their competitors. Specifically, these detailers: (1) claimed that Purdue's AD opioids prevent tampering and cannot be crushed or snorted; (2) claimed that Purdue's AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (3) claimed that Purdue's AD opioids are "safer" than other opioids; and (4) failed to disclose that Purdue's AD opioids do not impact oral abuse or misuse and that its abuse deterrent properties can be defeated.

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

129. To the contrary, testimony in litigation against Purdue and other evidence indicates Purdue knew and should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin" and is still regularly tampered with and abused. Websites and message boards used by drug abusers, such as bluelight.org and Reddit, also report a variety of ways to tamper with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which the tablet has been dissolved. Even Purdue's own website describes a study it conducted that found continued abuse of OxyContin with so-called abuse deterrent properties. Finally, there are

no studies indicating that Purdue's AD opioids are safer than any other opioid products.

130. A 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral intake or by defeating the abuse deterrent mechanism. Indeed, one-third of the patients in the study defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug. And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted to other drugs such as heroin.[25] Despite this, David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are being abused in large numbers.

131. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes." Tom Frieden, the former Director of the CDC, has further reported that his staff could not find "any evidence showing the updated [AD] opioids actually reduce rates of addiction, overdoses, or death."[26]

132. Manufacturer Defendants' false and misleading claims about the alleged abuse-deterrent properties of their opioid drugs are especially troubling. First, these claims falsely assuage doctors' concerns about the toll caused by the explosion in opioid prescriptions and use and encourage doctors to prescribe AD opioids under the mistaken belief that these opioids are safer, even though they are not. These false and misleading claims are therefore causing doctors to prescribe more AD opioids – which are far more expensive than other

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

[26] Perrone, *Drugmakers push profitable, but unproven, opioid solution*, dated Dec. 15, 2016, available at https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

opioid products – even though they provide little or no additional benefit.

133. Second, Manufacturer Defendants are using these false and misleading claims in a spurious attempt to rehabilitate their image as responsible opioid manufacturers. In response to the flood of litigation filed against the company, Purdue has been taking out full-page advertisements in the *Wall Street Journal* touting its efforts to stem the opioid epidemic. Chief among Purdue's claims is its development of opioids with "abuse-deterrent properties." Notably, the advertisement contains a footnote that Purdue's marketing materials never included, which states: "Opioids with abuse-deterrent properties are not abuse-proof and don't prevent addiction, but they are part of a multifaceted approach to addressing the prescription opioid abuse crisis."

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

J. Gross Overstatement of the Benefits of Chronic Opioid Therapy

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

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Manufacturer Defendants failed to correct these false and deceptive claims, they continue to make them today.

136. For example, Manufacturer Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples are described below:

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

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

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

d. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

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Tucson, Arizona 85718
Telephone: (520) 792-4800

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

f. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life [they] deserve." The guide was available online until APF shut its doors in 2012.

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

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

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

j. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The Policymaker's Guide was originally published in 2011 and is still available online today.

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

l. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

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

a. "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . ."

b. "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."

c. "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

138. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

139. The 2016 CDC Guideline was not the first time a federal agency repudiated Manufacturer Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis, that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[27] And in 2008, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

140. Manufacturer Defendants also falsely and misleadingly emphasized and exaggerated the risks of competing products like Nonsteroidal Anti-inflammatory Drugs (NSAIDs), so that doctors and patients would look to opioids first for the treatment of chronic pain. For example, Manufacturer Defendants overstated the number of deaths from NSAIDS and prominently featured the risks of NSAIDS, while minimizing or failing to mention the serious risks of opioids. Once again, these misrepresentations by Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific

[27] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

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

141. Manufacturer Defendants also falsely and misleadingly promoted opioids as providing far more effective pain relief than NSAIDs and other non-opioid alternatives. Researchers recently analyzed the comparative effectiveness of four pain relief regimens in treating 411 adult patients admitted to emergency rooms for acute extremity pain. Three of the regimens included an opioid combined with acetaminophen (*e.g.*, Tylenol). The fourth was composed of ibuprofen and acetaminophen. The researchers asked patients receiving these regimens to rank their pain on a scale of 0-10 both before receiving medication and two hours later. Researchers found that all four regimens reduced pain, but that there was no statistically significant difference in the reported reduction of pain between the regimens—in other words, ibuprofen can be just as effective as opioids in treating pain.[28]

142. In addition, Purdue falsely and misleadingly promoted OxyContin as being unique among opioids in providing twelve continuous hours of pain relief with one dose. In fact, OxyContin does not last for twelve hours – a fact Purdue has known at all times relevant to this action. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under ten hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response but provides little or no pain relief at the end

[28] *See* Andrew K. Chang, MD, MS, Polly E. Bijur, PhD, David Esses, MD, Douglas P. Barnaby, MD, MS, Jesse Baer, MD, *Effect of Single Dose Opioid and Nonopioid Analgesics on Acute Extremity Pain in the Emergency Department*, JAMA (Nov. 2017).

of the dosing period when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial number" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of twelve hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

143. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full twelve hours. And if a doctor suggested that OxyContin does not last twelve hours, these sales representatives, at Purdue's instruction, recommended increasing the dose, rather than the frequency of use. Purdue gave its sales representatives these instructions to prevent doctors from switching to a different drug and to address the unwillingness of insurers to pay for more frequent use of OxyContin.

K. Other Unlawful, Deceptive, and Unfair Misconduct

144. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based "immediate-release" opioids. Neither is approved for nor has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain and refused to approve Fentora for the treatment of chronic pain because of the potential harms, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

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

a. Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

b. Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

c. In December 2011, Cephalon widely disseminated a journal supplement entitled "*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

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

147. For over a decade, Purdue has been able to track the distribution and prescribing of its opioids down to the retail and prescriber levels. Using this information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities, as mandated by law, or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that Purdue had promoted as less addictive— in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to act – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring" until years after law enforcement shut it down. In doing so, Purdue broke the law to protect its own profits at the expense of public health and safety.

148. In December 2013, the State of New York launched an investigation into deceptive marketing by Purdue of its opioid drug, OxyContin. New York found that Purdue failed to take the necessary steps to ensure their sales representatives properly flagged prescribers who may abuse or divert the medication and improperly maintained an unbranded pain advocacy website that creates the impression that it is neutral and unbiased. The company also failed to disclose that a number of the healthcare providers providing testimonials had financial relationships with Purdue.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

149. In August 2015, Purdue entered a settlement to resolve these charges, and agreed to pay a fine and promised to strengthen its Abuse and Diversion Detection and to disclose any financial arrangements with health care providers that appear on websites endorsing pain treatments like OxyContin. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

150. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

L. Targeting of Susceptible Prescribers and Vulnerable Patient Populations

151. As a part of their deceptive marketing scheme, Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the United States, including in the State of Arizona and the City of Tucson. For example, Manufacturer Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids, because they would therefore be more likely to accept Manufacturer Defendants' misrepresentations. Those primary care doctors then became sources of information for other primary care doctors who would go on to prescribe dangerous opioids to their patients.

152. Manufacturer Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Manufacturer Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

greater for them. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concludes that there are "special risks of long-term opioid use for elderly patients" and recommends that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

M. Although Manufacturer Defendants Knew That Their Marketing of Opioids Was False and Deceptive, They Fraudulently Concealed Their Misconduct

153. At all times relevant to this Complaint, Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and deceptive conduct. For example, Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Manufacturer Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain. Manufacturer Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. Manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

154. Manufacturer Defendants have concealed the extent to which they funded KOLs and Front Groups. Many Front Groups selectively disclose donors or provide no information whatsoever concerning industry backers. After studying payments to opioid-advocacy Front Groups in the 2012-2017 period, the Senate concluded that neither pharmaceutical companies nor Front Groups "fully or routinely disclose the extent of their financial relationships" and both the companies and the groups "fail to adequately disclose manufacturer contributions" resulting in a "lack of transparency."[29]

155. Finally, Manufacturer Defendants manipulated their promotional materials to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. Manufacturer Defendants distorted the meaning or import of scientific studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for Manufacturer Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by the City of Tucson.

156. Thus, Manufacturer Defendants successfully concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the claims that the City of Tucson now asserts. The City of Tucson did not know of the existence or scope of Defendants' industry-wide deception and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

N. Insys Employed Fraudulent, Illegal, and Misleading Marketing Schemes To Promote Subsys

157. Arizona-based Manufacturer Defendant Insys' opioid, Subsys, was approved by the FDA in 2012 for "management of breakthrough pain in adult cancer patients who are

[29] Senate Homeland Security & Governmental Affairs Committee, Ranking Member McCaskill's Office, *Fueling the Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* (Feb. 2018), at 1, 2, 11.

already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." Under FDA rules, Insys could only market Subsys for this use. Subsys contains the highly addictive narcotic, fentanyl, administered via a sublingual (under the tongue) spray, which provides rapid-onset pain relief. It is in the class of drugs described as Transmucosal Immediate-Release Fentanyl ("TIRF").

158. To reduce the risk of abuse, misuse, and diversion, the FDA instituted a Risk Evaluation and Mitigation Strategy ("REMS") for Subsys and other TIRF products, such as Teva's Actiq and Fentora. The purpose of REMS was to educate "prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose" for this type of drug and to "ensure safe use and access to these drugs for patients who need them." Prescribers must enroll in TIRF-REMS before writing a prescription for Subsys.

159. Since its launch, Subsys has been an extremely expensive medication, and Insys has increased its prices every year. Depending on a patient's dosage and frequency of use, a month's supply of Subsys could cost in the thousands of dollars.

160. Due to its high cost, in most instances prescribers must submit Subsys prescriptions to insurance companies or health benefit payors for prior authorization to determine whether they will pay for the drug prior to the patient attempting to fill the prescription. According to the U.S. Senate Homeland Security and Governmental Affairs Committee Minority Staff Report, the prior authorization process includes "confirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate. If any one of these factors was not present, the prior authorization would be denied . . . meaning no reimbursement would be due."

161. These prior authorization requirements proved daunting. Initially, Subsys received reimbursement approval in only approximately 30% of submitted claims. In order

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

to increase approvals, Insys created a prior authorization unit, called the Insys Reimbursement Center (IRC) to obtain approval for Subsys reimbursements. This unit employed a number of fraudulent and misleading tactics to secure reimbursements, including falsifying medical histories of patients, falsely claiming that patients had cancer, and providing misleading information to insurers and payors regarding patients' diagnoses and medical conditions.

162. Subsys has proved to be extremely profitable for Insys. Insys made approximately $242.3 million in net revenue from Subsys in 2016. Between 2013 and 2016, the value of Insys stock rose 296%.

163. Since its launch in 2012, Insys has aggressively worked to grow its profits through fraudulent, illegal, and misleading tactics. Through its sales representatives and other marketing efforts, Insys deceptively promoted Subsys as safe and appropriate for uses such as neck and back pain, without disclosing the lack of approval or evidence supporting such uses and misrepresented the appropriateness of Subsys for treatment those conditions. It implemented a kickback scheme wherein it paid prescribers for fake speaker programs in exchange for prescribing Subsys. And it defrauded insurance providers and health benefit payors into paying for improper prescriptions of Subsys. These fraudulent and misleading schemes had the effect of pushing Insys' highly potent and dangerous opioid onto patients who did not need it, further exacerbating the opioid epidemic.

164. In addition, Insys incentivized its sales force to engage in illegal and fraudulent conduct. Many of the Insys sales representatives were new to the pharmaceutical industry and their base salaries were low compared to industry standard. The compensation structure was heavily weighed on commissions and rewarded reps for selling higher (and more expensive) doses of Subsys, a "highly unusual" practice because most companies consider dosing a patient-specific decision that should be made by a doctor.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

165. The Insys "speaker program" was perhaps its most widespread and damaging scheme. According to a report by the Southern Investigative Reporting Foundation ("SIRF"), a former Insys salesman, Ray Furchak, alleged in a qui tam action that the sole purpose of the speaker program was "in the words of his then supervisor Alec Burlakoff, 'to get money in the doctor's pocket.'" Furchak went on to explain that "[t]he catch . . . was that doctors who increased the level of Subsys prescriptions, and at higher dosages (such as 400 or 800 micrograms instead of 200 micrograms), would receive the invitations to the program—and the checks."

166. Insys' sham speaker program and other fraudulent and illegal tactics have been outlined in great detail in indictments and guilty pleas of Insys executives, employees, and prescribers across the country, as well as in a number of lawsuits against the company itself. Insys paid nearly $90,000 in "speaking fees" from 2013 through 2015 to just one pain doctor.

167. In May 2015, two Alabama pain specialists were arrested and charged with illegal prescription drug distribution, among other charges. The doctors were the top prescribers of Subsys, though neither were oncologists. According to prosecutors, the doctors received illegal kickbacks from Insys for prescribing Subsys. Both doctors had prescribed Subsys to treat neck, back, and joint pain. In May 2017, one of the doctors was sentenced to 20 years in prison.

168. In June 2015, a nurse practitioner in Connecticut described as the state's highest Medicare prescriber of narcotics, pled guilty to receiving $83,000 in kickbacks from Insys for prescribing Subsys. Most of her patients were prescribed the drug for chronic pain. Insys paid the nurse as a speaker for more than 70 dinner programs at a rate of approximately $1,000 per event; however, she did not give any presentations. In her guilty plea, the nurse admitted that she was receiving the speaker fees in exchange for writing prescriptions for Subsys.

169. In August 2015, Insys settled a complaint brought by the Oregon Attorney General, alleging that Insys paid doctors "speaking fees" to increase prescriptions of Subsys, among other allegations. In its complaint, the Oregon Department of Justice cited Insys for, among other things, misrepresenting to doctors that Subsys could be used to treat migraine, neck pain, back pain, and other ailments for which Subsys is neither safe nor effective, and employing an unconscionable scheme, including paying "speaking fees" that were actually kickbacks to doctors to incentivize the doctor to prescribe Subsys.

170. In February 2016, a former Insys sales manager pled guilty to conspiracy to commit health care fraud, including engaging in a kickback scheme in order to induce one of the Alabama prescribers discussed above to prescribe Subsys. The plea agreement states that nearly all of the Subsys prescriptions written by the doctor were off-label to non-cancer patients.

171. In August 2016 the State of Illinois sued Insys for its deceptive and illegal practices. The complaint alleged that Insys marketed Subsys to high-volume prescribers of opioid drugs instead of marketing to oncologists whose patients experienced the breakthrough cancer pain for which the drug is indicated. The complaint explains that Insys categorized prescribers into deciles (D1-D10) according to the number of rapid onset opioids (ROOs) prescribed. The sales reps were instructed to call on the highest volume ROO prescribers more frequently than the low volume ROO prescribers and were encouraged to obtain the majority of their sales from one or two high volume prescribers.

172. The Illinois complaint also details how Insys used its speaker program to pay high volume prescribers to prescribe Subsys. The speaker events took place at upscale restaurants in the Chicago area, and Illinois speakers received a speaker "honorarium" ranging from $700 to $5,100 in addition to their meal. The prescribers were allowed to order as much food and alcohol as they wanted. At most of the events, the "speaker" being paid

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

by Insys did not speak, and, on many occasions, the only attendees at the events were the "speaker" and an Insys sales rep.

173. In December 2016, six Insys executives and managers were indicted. The indictment alleged that the former Insys employees conspired to bribe prescribers, many of whom operated pain clinics, in order to induce them to prescribe Subsys. In exchange for bribes and kickbacks, the indictment states, the prescribers wrote large numbers of prescriptions for the patients, though most of them were not diagnosed with cancer. In announcing the indictments, the Special Agent in charge of the Boston Division of the FBI noted that this scheme "contributed to the growing opioid epidemic and placed profit before patient safety."

174. Insys' kickback scheme and misleading marketing of Subsys as appropriate for non-cancer pain contributed to the opioid epidemic in the State of Arizona and in the City of Tucson.

O. Manufacturer Defendants Have Created a Public Nuisance

175. Most opioid use begins with prescribed opioids, and that is why the Manufacturer Defendants' deceptive marketing campaign was a primary cause of the opioid epidemic that has unfolded in the City and across the country.[30] For opioids to be widely prescribed, Manufacturer Defendants had to convince doctors that they were a safe and effective means of treating chronic conditions such as back pain, headaches, arthritis, and fibromyalgia. And they were successful in doing so. Had doctors in the City and elsewhere been provided accurate and complete information, they would not have prescribed as many

[30] *See* U.S. Dep't of Health & Human Servs., *2011 National Survey on Drug Use and Health* (Sept. 2012), available at https://www.samhsa.gov/data/sites/default/files/2011MHFDT/2k11MHFR/Web/NSDUHmhfr2011.htm.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

opioids.

176. Manufacturer Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Without Manufacturer Defendants' deception, fewer patients in the City would be using opioids long-term to treat chronic pain, those patients using opioids would be using less of them, and there would not have been as many opioids available for misuse and abuse.

177. The efficacy of Manufacturer Defendants' marketing efforts can be seen by comparing opioid use in the United States against other countries, where restrictions on pharmaceutical advertising typically are more stringent. Although the United States contains only 4.6% of the world's population, Americans consume 80% of the global supply of prescription opioids.[31] Moreover, escalating opioid prescribing rates in the United States neatly track the elevated sums Manufacturer Defendants have expended on marketing their drugs, sums that rose from $91 million in 2000 to $288 million in 2011.

178. The role of Manufacturer Defendants' marketing scheme in contributing to the opioid epidemic has now been acknowledged by members of the medical community. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."[32]

179. In August 2016, then-U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health

[31] American Society of Interventional Pain Physicians, Fact Sheet, available at https://www.asipp.org/documents/ASIPPFactSheet101111.pdf.

[32] United States Cong., Senate Caucus on Int'l Drug Control, May 14, 2014, 113th Cong. 2nd sess. (Statement of Dr. Nora Volkow).

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[33]

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

181. The individual and combined effects of Manufacturer Defendants' conduct have caused an explosion in opioid prescribing, abuse, and overdose in the City of Tucson, in the State of Arizona, and across the country.

182. Manufacturer Defendants knew and should have known about the harms that their deceptive marketing would cause. Manufacturer Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. Manufacturer Defendants also had access to and carefully watched government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. In short, Manufacturer Defendants knew—and, indeed, intended—that their misrepresentations would persuade doctors to prescribe and patients to use their opioids for chronic pain, and they knew the lethal consequences of that endeavor.

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

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

183. Manufacturer Defendants also knew that patients were not the only ones harmed by their conduct. They knew that opioid dependency would place enormous burdens on government resources.

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

185. Manufacturer Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions.

P. Manufacturer Defendants' Conduct Has Led To Record Profits

186. While the opioid epidemic has taken an enormous toll on the City of Tucson and its residents, Manufacturer Defendants have realized blockbuster profits. In 2014 alone, opioids generated $11 billion in revenue for drug companies like Manufacturer Defendants. Indeed, financial information indicates that each Manufacturer Defendant experienced a material increase in sales, revenue, and profits from the false and deceptive advertising and other unlawful and unfair conduct described in this Complaint.

Q. Distributor Defendants Flooded the City and Surrounding Communities with Suspiciously Large Amounts of Opioids

187. Distributor Defendants are opioid distributors in the City of Tucson and the State of Arizona.

188. Distributor Defendants purchased opioids from Manufacturer Defendants and distributed them to pharmacies throughout the State of Arizona, including Tucson.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

189. Distributor Defendants played an integral role in the supply of opioids being distributed throughout the State of Arizona, including Tucson.

190. Distributor Defendants knew or had reason to know that the opioids they distributed were susceptible to diversion for illegal purposes, abused, overused, and otherwise sought for illegal and unhealthy purposes.

191. Distributor Defendants knew or had reason to know there was an alarming and suspicious rise in the distribution of opioids to retailers within the City.

192. As entities involved in the distribution of opioid drugs, Distributor Defendants were engaged in an abnormally and/or inherently dangerous activity and had a duty of care under Arizona law.

193. Distributor Defendants knew or should have known that they were supplying vast amounts of opioids into the City of Tucson, which was already facing abuse, diversion, misuse, and other problems associated with the opioid epidemic.

194. Distributor Defendants had a duty to notice suspicious or alarming orders of opioid pharmaceuticals and to report suspicious orders to the proper authorities and governing bodies including the DEA and the Arizona State Board of Pharmacy.

195. Distributor Defendants were in a unique position and had a duty to inspect, report, or otherwise limit the distribution and flow of opioids in Tucson.

196. Under Arizona law and federal law, Distributor Defendants were required to register with the Drug Enforcement Administration pursuant to the Controlled Substances Act ("CSA") and comply with a stringent series of federal statutes and regulations designed to prevent the diversion of narcotics. *See* A.R.S. § 32-1901.01 requiring that registrants "maintain effective controls against diversion of controlled substances or precursor chemicals to unauthorized persons or entities."

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

197. Through its incorporation of federal law, Arizona places a non-delegable duty on Distributor Defendants to monitor, detect, investigate, refuse to fill, and report suspicious orders of opioids.

198. Suspicious orders include orders of "unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b). Any of the red flags identified by law—size, deviation, or frequency—trigger a duty to report. However, this list is not exclusive. Other factors, such as whether the order is skewed toward high dose pills, which are more attractive to abusers and diverters, or orders that are composed largely of drugs valued for abuse (opioids, as well as drugs like benzodiazepines), instead of other high-volume drugs, such as cholesterol medicines, also should alert distributors to potential problems. The distributor's own observations—cash transactions or young and seemingly healthy patients filling prescriptions for opioids at a pharmacy they supply—can trigger reasonable suspicion. A single order can warrant scrutiny, or it may be a pattern of orders or an order that is unusual given the customer's individual history or its comparison to other customers in the area. Thus, the determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the customary activity of other customers of similar size or in the same area.

199. Distributor Defendants are also members of the Healthcare Distribution Management Association ("HDMA"). The HDMA created "Industry Compliance Guidelines" which stressed the critical role of each member of the supply chain in distributing controlled substances. The HDMA guidelines provided that "[a]t the center of a sophisticated supply chain, Distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

200. On September 27, 2006, the DEA sent a letter to each Distributor Defendant warning it would use its authority to revoke and suspend registrations when appropriate. The letter expressly warns that all distributors have a legal duty to design and operate a system to flag suspicious orders, to report all such suspicious orders, and to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.

201. On December 27, 2007, the DEA sent a second letter to each Distributor Defendant to highlight again the legal responsibilities of distributors to inform the DEA of suspicious orders of opioids and to maintain effective controls against diversion and to design and operate a system to disclose to the registrant suspicious orders of controlled substances. The letter further explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.
>
> The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the pattern throughout the segment of the regulated industry.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

> Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.
>
> When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."
>
> Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 U.S.C. §§ 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

202. Distributor Defendants, in the interest of financial gain, intentionally and repeatedly breached their statutory and common-law duties to monitor and report suspicious orders of opioids and to reduce the diversion of these drugs.

203. In 2008, McKesson paid a $13.25 million fine to the United States to settle claims it failed to report hundreds of suspicious orders from Internet pharmacies that sold drugs online to customers who didn't have legal prescriptions.

204. Despite this 2008 fine, McKesson failed to implement or adhere to a reasonable compliance program to comply with its duty to monitor and report suspicious orders of opioids.

205. In Colorado, for example, McKesson processed more than 1.6 million orders for controlled substances from June 2008 through May 2013, but reported just 16 orders as suspicious.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

206. In 2017, McKesson paid a $150 million fine to the United States and suspended the sale of controlled substances from distribution centers in several states (but not Arizona) to resolve further allegations that it failed to monitor or report suspicious opioid orders.

207. In 2008, Cardinal Health paid a $34 million fine to the United States to resolve allegations that it failed to monitor or report suspicious opioid orders.

208. In 2016, Cardinal Health agreed to pay a $44 million fine to the United States to resolve allegations that it failed to monitor or report suspicious opioid orders.

209. In 2017, Cardinal Health agreed to pay $20 million to the State of West Virginia to resolve allegations that it failed to monitor or report suspicious opioid orders.

210. In 2012, AmerisourceBergen was investiged by federal prosecutors regarding its procedures for monitoring the distribution of opiods and for reporting suspicious opioid orders.

211. In 2017, AmerisourceBergen agreed to pay $16 million to the State of West Virginia to resolve allegations that it failed to monitor or report suspicious opioid orders.

212. Despite the charges, fines, and penalties brought against the Distributor Defendants in the past, they continued to fail to adequately monitor and report suspicious orders or prevent the flow of prescription opioids, including into the City of Tucson.

213. Distributor Defendants have shipped millions of doses of highly addictive controlled opioid pain killers into Tucson.

214. Upon information and belief, Distributor Defendants did not refuse to ship or supply any opioid medications to any pharmacy in Tucson from 2007 to the present.

215. Many of the shipments to Tucson should have been stopped, or at the very least, reported or investigated as potential suspicious orders.

216. The sheer volume of the increase in opioid pain medications being distributed to retailers in Tucson should have put Distributor Defendants on notice to investigate and report such orders.

217. Distributor Defendants distributed an excessive and unreasonable amount of opioid pain medications to retailers in Tucson.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

218. Distributor Defendants knew or should have known that they were distributing levels of opioid medications that far exceeded the legitimate needs in Tucson.

219. Distributor Defendants paid their sales force bonuses and commissions on the sale of most or all of the highly addictive opioid pain medications sold to retailers in Tucson.

220. Distributor Defendants made substantial profits from the opioids sold to retailers in Tucson.

221. Distributor Defendants violated Arizona law and regulations by failing to properly monitor and report suspicious orders.

222. By the actions and inactions described in this Complaint, Distributor Defendants showed a reckless disregard for the safety of the residents of Tucson.

223. As a result of the long-standing refusal by Distributor Defendants to comply with their legal duties, the DEA has repeatedly taken administrative action to force compliance. The DOJ Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. The Office of Administrative Law Judges issued a recommended decision in a total of 177 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders. Drug Enforcement Administration Adjudication of Registrant Actions, United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, I-2014-003 (May 2014). The public record reveals many of these actions:

> On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center (Orlando Facility) alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement which resulted in the suspension of its DEA registration;
>
> On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center (Auburn Facility) for failure to maintain effective controls against diversion of hydrocodone;

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

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

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

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

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

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

On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland Facility; and

On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a record $150

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland, FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Santa Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA.

224. Rather than comply with their legal duties, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the DOJ to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the distributors the right to "cure" any violations of law before a suspension order can be issued.[34]

R. Defendants' Conduct Has Caused Plaintiff Substantial Economic Injury

225. The City of Tucson has been especially hard hit by the opioid crisis caused by Defendants' conduct.

226. In the *Arizona Opioid Emergency Response*, released in July of 2018, the Arizona Department of Health Services reported that, "in the past decade, 5,932 Arizonans

[34] *See* Lenny Bernstein and Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASH. POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.f643792a8e61; Lenny Bernstein and Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, WASH. POST (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.238e21724b50.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

died from opioid-induced causes."[35]

227. There were 526 opioid deaths in Arizona in 2013 and this number increased by at least 100 deaths each year from 2014-2017.[36] By 2016, more than two Arizonans died from opioid overdoses each day.[37]

228. In 2017, the number of reported deaths directly attributed to opioids in Arizona increased to 949.[38] This represents 2.6 deaths per day and is a 20.1% increase in opioid deaths since 2016, and a 109% increase since 2012.[39]

229. On June 5, 2017, Arizona Governor Doug Ducey declared a State of Emergency due to the opioid epidemic.

230. While the entire State of Arizona has been affected by the opioid epidemic, the City of Tucson has been, and continues to be, disproportionately impacted. The City has been acutely affected by Defendants' actions and is confronting a public health crisis of historic proportions.

231. The individual and combined effects of the Defendants' conduct described in this Complaint have caused an explosion in opioid prescribing, abuse, and overdose in the City of Tucson.

232. Approximately 536,000 people live in the City of Tucson, which is more than one half of Pima County's 1,022,800 residents.

233. In 2016, Pima County had a prescribing rate of 74.0 opioid prescriptions per

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

[35] *Arizona Opioid Emergency Response: June 2017-June 2018*, p. 2. Available at: https://www.azdhs.gov/documents/prevention/womens-childrens-health/injury-prevention/opioid-prevention/2017-opioid-emergency-response-report.pdf

[36] *Id.*

[37] *Id.*

[38] *Id.*

[39] *Id.*

100 people according to the CDC.[40]

234. In 2017, Pima County had the highest opioid death rate reported of any county in Arizona (17.1/100,000).[41]

235. Even though Pima County represents only approximately 15% of the State of Arizona's population, approximately 23% of all opioid-related deaths in Arizona in 2017 occurred in Pima County.[42]

236. In 2017 alone, Pima County had approximately 328 total drug overdose deaths, many of these overdose deaths occurred within Tucson city limits.[43]

237. Of these 328 drug overdose deaths, 218 deaths or 66% of total drug overdose deaths, included opiate drugs and fentanyl, either as a single drug or as a component of a poly-drug overdose.[44] By comparison, motor vehicle related fatalities accounted for 184 total deaths in Pima County during the same year.[45]

238. From June 15, 2017 to September 13, 2018, there were 1,699 opioid overdoses reported in Pima County.[46]

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

[40] CDC, U.S. State Prescribing Rates, 2016, available at https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html.

[41] *Id.*

[42] https://www.census.gov/quickfacts/fact/table/pimacountyarizona/PST045217

[43] *Annual Report* 2017. Pima County Office of the Medical Examiner. Appendix J. Available at: http://webcms.pima.gov/UserFiles/Servers/Server_6/File/Government/Medical%20Examiner/Resources/Annual-Report-2017.pdf

[44] *Id.*

[45] *Id.*

[46] Opioid Report, June 15, 2017 – September 13, 2018, available at https://www.azdhs.gov/documents/prevention/womens-childrens-health/injury-prevention/opioid-prevention/opioid-report.pdf

239. During the same period of time, Nalaxone, the opioid overdose antidote, was reportedly administered 1,253 times in Pima County.[47]

240. The City of Tucson has suffered and continues to suffer significant financial consequences as a result of Defendants' conduct described in this Complaint including, but not limited to, increased costs in providing law enforcement, judicial services, substance abuse treatment and diversion plans, emergency and medical care, and health insurance.

241. Defendants' conduct described in this Complaint has also created a larger public health crisis that imposes a substantial financial burden on the City of Tucson, and which is borne across an array of Tucson's Governmental Departments.

242. For example, in 2018 the Tucson Police Department designed and implemented an opioid deflection program involving self-referral by drug users (allowing opioid users to hand over their drugs at police substations and to ask for help, with no risk of arrest); deflection from being arrested (allowing police officers to divert persons detained with up to 2 grams of opiates to a treatment program); and outreach by officers and caseworkers to connect with people who recently overdosed or fell out of drug treatment.

243. As another example, in 2016 more than 400 officers from the Tucson Police Department were trained to administer and carry Nalaxone, a special nasal spray to help people overdosing on opioids.

244. These economic costs are direct, quantifiable, and would not have been incurred but for Defendants' conduct. They also do not express the full extent of the City of Tucson's injuries. Abating the opioid crisis in the City will require a sustained and expanded outlay of City resources, including police to address opioid-related crime and the means to process and rehabilitate opioid offenders through the criminal justice system.

[47] *Id.*

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

CAUSES OF ACTION

COUNT I
Public Nuisance
A.R.S. § 13-2917 / Common Law
(Against All Defendants)

245. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

246. Defendants, individually and acting through their employees and agents, and in concert with each other, through the conduct described in this complaint created a public nuisance as defined by A.R.S. § 13-2917 and under common law.

247. Defendants, individually and acting through their employees and agents, and in concert with each other, substantially interfered with and continue to interfere with the health, safety, and comfortable enjoyment of life of the community of Tucson. Defendants' conduct described in this Complaint is of a continuing nature, has occurred over the course of many years, is ongoing, and has produced permanent and long-lasting effects including causing death, serious health issues, and increased governmental expenditures.

248. Defendants intentionally caused, created, and contributed to this public nuisance.

249. Defendants' conduct described in this Complaint is unreasonable under the circumstances because it has negative utility and because it directly caused a public health epidemic and state of emergency of considerable proportions and has significantly and directly harmed the City of Tucson and its citizens.

250. Defendants' conduct directly and proximately caused substantial injury to the City of Tucson and its residents.

251. The City of Tucson suffered special injuries distinguishable from those suffered by the general public, including incurring substantial costs from investigating, monitoring,

treating, policing, and remediating the opioid epidemic. Tucson's damages are not merely derivative of harm to third parties.

COUNT II
Arizona Consumer Protection Act
A.R.S. § 44-1522(A)
(Against Manufacturer Defendants)

252. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

253. The Arizona Consumer Protection Act ("CPA"), provides: "The act, use or employment by any person of any deception, deceptive or unfair act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of any material fact with intent that others rely on such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice." A.R.S. § 44-1522(A).

254. Manufacturer Defendants have violated Arizona's Consumer Protection Act because they engaged in deception, deceptive or unfair acts and practices, concealment, and suppression or omission of material facts with intent that others rely on such concealment, suppression or omission in the conduct of commerce.

255. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addiction; in disseminating misleading information regarding the appropriateness of their opioids for certain conditions; in falsely promoting abuse-deterrent formulations as reducing abuse; in falsely claiming that OxyContin provides twelve hours of relief; and in falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids, Defendants have engaged in unfair or deceptive acts, misrepresentation, concealment, and suppression or omission of a material

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

fact with intent that others rely on such concealment, suppression or omission, in connection with the sale or advertisement of merchandise.

256. Specifically, the deceptive and unfair acts, include, but are not limited to:

a. Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

b. Defendants' claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with more opioids;

c. Defendants' claims that screening tools effectively prevent addiction;

d. Defendants' claims that opioid doses can be increased until pain relief is achieved;

e. Defendants' claims that opioids differ from NSAIDS in that they have no ceiling dose;

f. Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

g. Defendants' claims that chronic opioid therapy would improve patients' function and quality of life;

h. Purdue's and Endo's claims that abuse-deterrent opioids reduce tampering and abuse;

i. Purdue's claims that OxyContin provides a full twelve hours of pain relief;

j. Purdue's claims that they cooperate with and support efforts to prevent opioid abuse and diversion;

k. Insys' claims that Subsys was appropriate for treatment of non-cancer pain; and

l. Teva's claims that Actiq and Fentora were appropriate for treatment of non-cancer pain and its failure to disclose that Actiq and Fentora were not approved for such use.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

257. By engaging in the acts and practices alleged herein, Defendants further committed unfair methods of competition, unconscionable acts, and unfair and deceptive acts, including, but not limited to, the following:

a. Defendants' opioids are highly addictive and may result in overdose or death;

b. No credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

c. Defendants' high dose opioids subject the user to greater risks of addiction, other injury, or death;

d. Defendants' exaggerating the risks of competing products, such as NSAIDs, while ignoring the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines;

e. Defendants' claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

f. Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;

g. Purdue and Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the most common route of abuse (oral abuse), can be defeated with relative ease; and may increase overall abuse;

h. Manufacturer Defendants and Arizona Defendant Insys failed to report suspicious prescribers; and

i. Insys' use of kickback and insurance fraud schemes.

258. Defendants' statements about the use of opioids to treat chronic pain were not supported by or were contrary to the scientific evidence, as confirmed by the CDC and FDA.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

259. Defendant Insys' statements that Subsys was appropriate for treatment of non-cancer pain were false and unsupported by scientific evidence.

260. Plaintiff, a municipal corporation as a subdivision of the State of Arizona, is part of the class of persons that may avail themselves of a remedy.

261. Plaintiff has been injured and suffered actual damages as a direct and proximate result of Defendants' violations of the Arizona's Consumer Protection Act as alleged in this Complaint.

262. Plaintiff has suffered injury and loss as a result of Defendants' acts and practices alleged in this Complaint.

263. The misconduct alleged in this case is ongoing and persistent.

264. The misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur and is not part of the normal and expected costs of a local government's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

265. Plaintiff has incurred expenditures for special programs over and above its ordinary municipal services.

266. Defendants were consciously aware of the wrongfulness or harmfulness of their conduct and yet continued to act in the same manner in deliberate contravention to the rights of the City and other victims.

267. Defendants' conduct was outrageous, oppressive or intolerable in that it created a substantial risk of tremendous harm to others.

COUNT III
Fraudulent Misrepresentation
(Against Manufacturer Defendants)

268. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

269. Defendants, individually and acting through their employees and agents, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above.

270. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addiction; in falsely promoting abuse-deterrent formulations as reducing abuse; in falsely claiming that OxyContin provides twelve hours of relief; and in falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids, Defendants have engaged in misrepresentations and knowing omissions of material fact.

271. Specifically, misrepresentations or omissions include, but are not limited to:

a. Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

b. Defendants' claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with more opioids;

c. Defendants' claims that screening tools effectively prevent addiction;

d. Defendants' claims that opioid doses can be increased until pain relief is achieved;

e. Defendants' claims that opioids differ from NSAIDS in that they have no ceiling dose;

f. Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

g. Defendants' claims that chronic opioid therapy would improve patients' function and quality of life;

h. Purdue's and Endo's claims that abuse-deterrent opioids reduce tampering and abuse;

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

i. Purdue's claims OxyContin provides a full twelve hours of pain relief;

j. Purdue's claims that they cooperate with and support efforts to prevent opioid abuse and diversion;

k. Insys' claims that Subsys was appropriate for treatment of non-cancer pain; and

l. Teva's claims that Actiq and Fentora were appropriate for treatment of non-cancer pain and its failure to disclose that Actiq and Fentora were not approved for such use.

272. By engaging in the acts and practices alleged herein, Defendants omitted material facts that it had a duty to disclose by virtue of Defendants' other representations, including, but not limited to, the following:

a. Defendants' opioids are highly addictive and may result in overdose or death;

b. No credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

c. Defendants' high dose opioids subject the user to greater risks of addiction, other injury, or death;

d. Defendants' exaggerating the risks of competing products, such as NSAIDs, while ignoring the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines;

e. Defendants' claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

f. Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

g. Purdue and Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the most common route of abuse (oral abuse), can be defeated with relative ease; and may increase overall abuse;

h. Manufacturer Defendants failed to report suspicious prescribers; and

i. Insys' use of kickback and insurance fraud schemes.

273. Defendants' statements about the use of opioids to treat chronic pain and/or non-cancer pain conditions were false and not supported by or contrary to the scientific evidence.

274. Further, Defendants' omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading and likely to mislead City prescribers and consumers.

275. Defendants knew at the time they made their misrepresentations and omissions that they were false.

276. Defendants intended that Plaintiff and its residents would rely on their misrepresentations and omissions, knew that Plaintiff and its residents would rely on their misrepresentations, and that such reliance would cause Plaintiff to suffer loss.

277. Healthcare providers and residents in the City reasonably relied on Defendants' misrepresentations and omissions in writing, filling, and using prescriptions for Defendants' opioids, and Plaintiff and its agents reasonably relied on these misrepresentations and omissions in covering and paying for Defendants' opioids for chronic pain.

278. By reason of their reliance on Defendants' misrepresentations and omissions of material fact Plaintiff suffered actual pecuniary damage.

279. Defendants' conduct was accompanied by wanton and willful disregard of persons who foreseeably might be harmed by their acts and omissions.

280. The misconduct alleged in this case is ongoing and persistent.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

281. The misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur and is not part of the normal and expected costs of a local government's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

282. Plaintiff has incurred expenditures for special programs over and above its ordinary municipal services.

283. Defendants were consciously aware of the wrongfulness or harmfulness of their conduct and yet continued to act in the same manner in deliberate contravention to the rights of the City and other victims.

284. Defendants' conduct was outrageous, oppressive or intolerable in that it created a substantial risk of tremendous harm to others.

COUNT IV
Negligent Misrepresentation
(Against Manufacturer Defendants)

285. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

286. Defendants, individually and acting through their employees and agents, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above.

287. Defendants had a duty to exercise reasonable care in marketing and selling highly dangerous opioid drugs in the City.

288. Defendants negligently asserted false statements and omitted material facts regarding the benefits of and evidence for the use of opioids for chronic pain, while understating their very serious risks, including the risk of addiction.

289. These false statements included but are not limited to:

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

a. Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

b. Defendants' claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with more opioids;

c. Defendants' claims that screening tools effectively prevent addiction;

d. Defendants' claims that opioid doses can be increased until pain relief is achieved;

e. Defendants' claims that opioids differ from NSAIDS in that they have no ceiling dose;

f. Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

g. Defendants' claims that chronic opioid therapy would improve patients' function and quality of life;

h. Purdue's and Endo's claims that abuse-deterrent opioids reduce tampering and abuse;

i. Purdue's claims OxyContin provides a full twelve hours of pain relief;

j. Purdue's claims that they cooperate with and support efforts to prevent opioid abuse and diversion;

k. Insys' claims that Subsys was appropriate for treatment of non-cancer pain; and

l. Teva's claims that Actiq and Fentora were appropriate for treatment of non-cancer pain and its failure to disclose that Actiq and Fentora were not approved for such use.

290. Defendants intended that Plaintiff and its residents would rely on their misrepresentations and omissions, knew that Plaintiff and its residents would rely on their misrepresentations, and that such reliance would cause Plaintiff to suffer loss.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
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291. Healthcare providers and residents in the City reasonably relied on Defendants' misrepresentations and omissions in writing, filling, and using prescriptions for Defendants' opioids, and Plaintiff and its agents reasonably relied on these misrepresentations and omissions in covering and paying for Defendants' opioids for chronic pain.

292. By reason of their reliance on Defendants' misrepresentations and omissions of material fact Plaintiff suffered actual pecuniary damage.

293. Defendants' conduct was accompanied by wanton and willful disregard of persons who foreseeably might be harmed by their acts and omissions.

294. The misconduct alleged in this case is ongoing and persistent.

295. The misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur and is not part of the normal and expected costs of a local government's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

296. Plaintiff has incurred expenditures for special programs over and above its ordinary municipal services.

COUNT V
Negligence
(Against All Defendants)

297. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

298. Defendants at all relevant times had a duty to exercise reasonable care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs in the City.

299. Defendants have a duty to exercise reasonable care under the circumstances, in light of the risks. This includes a duty not to cause foreseeable harm to others. In addition, these Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had, and still have, a duty to exercise reasonable care to prevent the threatened harm.

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

300. In addition, Defendants each had a duty under Arizona law, which incorporates the federal Controlled Substances Act, to maintain effective controls against diversion of prescription opioids, to report suspicious orders of opioids, and not to fill suspicious orders unless and until due diligence had eliminated the suspicion.

301. Defendants also misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious prescribers. Defendants voluntarily undertook duties, through their statements to the media, regulators, and the public at large, to take all reasonable precautions to prevent drug diversion.

302. Upon information and belief, each of the Defendants repeatedly and intentionally breached its duties. These breaches included:

a. Selling prescription opioids in the supply chain when they knew, or should have known, that there was a substantial likelihood the sale was for non-medical purposes and that opioids are an inherently dangerous product when used for non-medical purposes;

b. Using unsafe distribution practices;

c. Inviting criminal activity into the City by disregarding precautionary measures built into Arizona's statutory and regulatory requirements related to controlled substances, to which they agreed to adhere in obtaining licenses or registrations from the Arizona State Board of Pharmacy and the DEA;

d. Failing to comply with the public safety laws described above;

e. Failing to acquire or utilize special knowledge or skills that relate to the dangerous activity of selling opioids in order to prevent or ameliorate such significant dangers;

f. Failing to review prescription orders for red flags;

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

g. Failing to report suspicious orders or failing to refuse to fill them; and

h. Failing to provide effective controls and procedures to guard against theft and diversion of controlled substances.

303. Each Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in selling dangerous controlled substances.

304. The foreseeable harm from a breach of these duties is the sale, use, abuse, and diversion of prescription opioids.

305. The foreseeable harm from a breach of these duties also includes abuse, addiction, morbidity and mortality in the City's communities.

306. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and the significant costs which would be imposed upon the governmental entities associated with those communities. Indeed, it is a violation of Arizona law for Defendants not to report suspicious orders and exercise due diligence not to ship such orders unless and until the suspicion has been removed. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse to prevent precisely these types of harms.

307. Reasonably prudent manufacturers and distributors of pharmaceutical products would know that aggressively marketing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids and to turn to the illegal drug market as a result of a drug addiction that was foreseeable to the Defendants. Reasonably prudent manufacturers and distributors would

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

know that failing to report suspicious prescribing, particularly while assuring the public of their commitment to fighting the opioid epidemic, would exacerbate problems of diversion and non-medical use of prescription opioids.

308. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from the negligence of Defendants. It does not seek damages which may have been suffered by individual citizens of the City for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of any of the Defendants.

309. These Defendants' breach of the duties described in this Count directly and proximately resulted in the injuries and damages alleged by Plaintiff.

310. The misconduct alleged in this case is ongoing and persistent.

311. The misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur and is not part of the normal and expected costs of a local government's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

312. Plaintiff has incurred expenditures for special programs over and above its ordinary municipal services.

COUNT VI
Strict Liability – Failure to Warn
(Against Manufacturer Defendants)

313. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

314. Manufacturer Defendants' opioids failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner because the drugs carried far greater risk and potential for abuse and addiction than Manufacturer

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

Defendants, through the false statements and other conduct alleged in this Complaint, led physicians, the City, and the public to believe.

315. Manufacturer Defendants knew or had reason to know of the defective nature of its products but, in conscious disgreagard for the foreseeable harm and in order to increase its sales and profits, Manufacturer Defendants continued to market and sell their products without proper warnings and with misprepresentations and omissions that contradicted and undermined the efficacy of its drug labels.

316. Due to the false statements and other conduct alleged in this Complaint, Manufacturer Defendants did not provide reasonable instructions or warnings regarding foreseeable risks of harm to prescribing and other health-care providers.

317. Due to the false statements and other conduct alleged in this Complaint, Manufacturer Defendants knew or had reason to know that prescribing and other health-care providers would not be in a position to reduce the risks of harm in accordance with any instructions or warnings it provided.

318. As a proximate cause of the failure of Manufacturer Defendants' products to perform as reasonably expected and Manufacturer Defendants' failure to appropriately warn of known and reasonably knowable dangers associated with the use of its products, the City has suffered and will continue to suffer damages as outlined in this Complaint.

COUNT VII
Unjust Enrichment
(Against All Defendants)

319. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

320. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, all Defendants have profited and benefited from opioid purchases made by

Rusing Lopez & Lizardi, P.L.L.C.
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Plaintiff, and all Defendants have profited and benefited from the increase in the distribution and purchase of opioids within the City.

321. In exchange for the opioid purchases, and at the time Plaintiff made these payments, Plaintiff expected that Defendants had not engaged in deceptive practices or practices contrary to Plaintiff's public policy and had not misrepresented any material facts regarding those risks.

322. In addition, Plaintiff has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

323. These expenditures include the provision of healthcare services and treatment services to people who use opioids.

324. These expenditures have helped sustain Defendants' businesses.

325. Plaintiff has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution practices.

326. Plaintiff has also conferred a benefit upon Defendants by paying for purchases by unauthorized users of prescription opioids from the Defendants' supply chain for non-medical purposes.

327. By distributing a large volume of opioids within the City and by acting in concert with third parties, Distributor Defendants have unjustly enriched themselves at Plaintiff's expense. By deceptively marketing opioids and engaging in the unlawful and unfair practices described in this Complaint, Defendants have unjustly enriched themselves at Plaintiff's expense.

328. Plaintiff has paid for the cost of each Defendants' externalities and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products. Because of their conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment they would

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

not otherwise have obtained. The enrichment was without justification and Plaintiff lacks a remedy provided by law.

329. In addition, by deceptively marketing opioids and engaging in the unlawful and unfair practices described in this Complaint, Defendants have unjustly enriched themselves at Plaintiff's expense. The Defendants have unjustly retained a benefit to Plaintiff's detriment, and these Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience. The enrichment was without justification and Plaintiff lacks a remedy provided by law.

330. Defendants have been unjustly enriched at the expense of Plaintiff. It would be inequitable for Defendants to retain the profits and benefits they have reaped from the deceptive practices, misrepresentations, and unlawful conduct alleged herein.

331. The misconduct alleged in this case is ongoing and persistent.

332. The misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur and is not part of the normal and expected costs of a local government's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

333. Plaintiff has incurred expenditures for special programs over and above its ordinary municipal services.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

a. A finding that by the acts alleged herein, Defendants have created a public nuisance;

b. For an injunction permanently enjoining Defendants from engaging in the acts and practices that caused the public nuisance;

c. For an order directing Defendants to abate and pay damages for the public

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
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nuisance;

d. For a finding that Defendants violated the Arizona Consumer Protection Act, A.R.S. § 44-1522(A), et seq.;

e. For a finding that Defendants made fraudulent misrepresentations;

f. Flor a finding that Defendants made negligent misrepresentations;

g. For a finding that Defendants were negligent;

h. For a finding that Defendants were unjustly enriched;

i. For compensatory damages in an amount sufficient to fairly and completely compensate for all damages alleged herein;

j. For restitution or disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law;

k. For an award of punitive and exemplary damages in an amount to punish Defendants and deter future culpable conduct;

l. For costs, filing fees, pre and post judgment interest, and attorney's fees; and

m. For all other and further relief to which this Court finds it is entitled.

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Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800

DATED this 17th day of January, 2019

RUSING LOPEZ & LIZARDI, P.L.L.C.

/s/ *Andrew Sterling*
Andrew Sterling, Esq.
Michael J. Rusing, Esq.

LAW OFFICE OF JOSEPH C. TANN, P.L.L.C
Joseph C. Tann, Esq.

GRANT WOODS, P.C.
Grant Woods, Esq.

MIKE MOORE LAW FIRM, LLC
Mike Moore, Esq**.**

Attorneys for Plaintiff

Rusing Lopez & Lizardi, P.L.L.C.
6363 North Swan Road, Suite 151
Tucson, Arizona 85718
Telephone: (520) 792-4800