IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH DAKOTA
SOUTHERN DIVISION

DEBORAH GREEN-KUCHTA, individually and on behalf of all others similarly situated,

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; INSYS THERAPEUTICS, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ACTAVIS PLC; ACTAVIS, INC.; WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; MCKESSON CORPORATION; CARDINAL HEALTH, INC.; and AMERISOURCEBERGEN CORPORATION,

Defendants.

Case No. 18-cv-4132

CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

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Plaintiff Deborah Green-Kuchta ("Plaintiff") is a natural person and resident of South Dakota. Plaintiff brings this Class Action Complaint ("Complaint") against Defendants Purdue Pharma L.P., Purdue Pharma Inc., the Purdue Frederick Company, Inc., Insys Therapeutics, Inc., Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals, Inc., Actavis plc, Actavis, Inc., Watson Pharmaceuticals, Inc., and Watson Laboratories, Inc. (collectively, "Manufacturer Defendants"); McKesson Corporation, Cardinal Health, Inc., and AmerisourceBergen Corporation (collectively, "Distributor Defendants") (all together, "Defendants"), seeking redress for Defendants' alleged illegal acts that have caused Plaintiff's health insurance premiums to increase. Plaintiff, for her Complaint, alleges as follows upon personal knowledge as to herself and her own acts and experiences and, as to all other matters, upon information and belief, including investigation conducted by her attorneys.

INTRODUCTION

1. Prescription opioids have devastated communities across the country and in the State of South Dakota. Since 1999, there have been more than 183,000 reported opioid-related deaths nationwide—more than three times the number of U.S. soldiers who died in the Vietnam War. In addition to the tragic loss of life and the heartbreaking impact on children and loved ones, some estimates state that the opioid crisis is costing governmental entities and private companies as much as $500 billion per year.

2. Defendants manufacture, market, sell, and distribute prescription opioids, which are powerful, highly addictive narcotic painkillers. The Manufacturer Defendants have engaged in a cunning and deceptive marketing scheme to encourage doctors and patients to use opioids to treat chronic pain. In doing so, the Manufacturer Defendants falsely minimized the risks of

opioids, overstated their benefits, and generated far more opioid prescriptions than there should have been.

3. The opioid epidemic is the direct result of the Manufacturer Defendants' deliberately crafted, well-funded campaign of deception. For years, they misrepresented the risks posed by the opioids they manufacture and sell, misleading susceptible prescribers and vulnerable patient populations. As families and communities suffered from the scourge of opioid abuse, the Manufacturer Defendants earned billions in profits as a direct result of the harms they imposed.

4. The Manufacturer Defendants knew that their misrepresentations about the risks and benefits of opioids were not supported by, and sometimes were directly contrary to, the scientific evidence. Certain opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have entered agreements prohibiting them from making misrepresentations identified in this Complaint in other jurisdictions. Nonetheless, the Manufacturer Defendants continue to misrepresent the risks and benefits of long-term opioid use in South Dakota, and they have not corrected their past misrepresentations.

5. The Manufacturer Defendants' false and misleading statements deceived doctors and patients about the risks and benefits of opioids and convinced them that opioids were not only appropriate, but *necessary* to treat chronic pain. The Manufacturer Defendants targeted susceptible prescribers, like family doctors, and vulnerable patient populations, like the elderly and veterans. And they tainted the sources that doctors and patients relied upon for guidance, including treatment guidelines, medical education programs, medical conferences and seminars, and scientific articles. As a result, they successfully transformed the way doctors treat chronic pain, opening the floodgates of opioid prescriptions and dependence. Opioids are now the most

prescribed class of drugs, generating billions of dollars in revenue for the Manufacturer Defendants every year.

6. In addition, the Distributor Defendants could and should have prevented the brunt of the opioid epidemic, but instead allowed the country to be flooded with prescription opioids. Under federal law, distributors are required to secure and monitor drugs as they travel through commerce, to protect them from theft, and to reject and report suspicious or unusual orders by downstream pharmacies, doctors, or patients. But the Distributor Defendants neglected this duty, turning a blind eye to known or knowable problems in their own supply chains. By doing so, the Distributor Defendants created conditions in which vast amounts of opioids flowed freely from the Manufacturer Defendants to abusers and drug dealers—with the Distributor Defendants readily fulfilling suspicious orders from pharmacies and ignoring red flags that would require further investigation and resolution.

7. This behavior by the Distributor Defendants has allowed massive amounts of opioids to be diverted from legitimate channels of distribution into the illicit black market, fueling the opioid epidemic. The Distributor Defendants created an environment in which drug diversion can flourish. For years, the Distributor Defendants have had the ability to substantially reduce the death toll and adverse economic consequences of opioid diversion but opted to pursue corporate revenues instead. All of the Defendants in this action share responsibility for creating, sustaining, and prolonging the opioid epidemic.

8. The explosion in opioid prescriptions and use has created a public health crisis in South Dakota. An oversupply of prescription opioids has provided a source for illicit use or sale of opioids, while their widespread use has created a population of addicted and dependent patients. When those patients can no longer afford or legitimately obtain opioids, they often turn

to the street to buy prescription opioids or even heroin. In addition to the societal impact of deaths, overdoses, and rampant addiction, Defendants' conduct has created higher demand and thus higher prices for opioids, as well as the need for expensive medical treatment for a number of covered health conditions, resulting in increased insurance costs for South Dakota residents.

9. Defendants' conduct has fueled skyrocketing opioid addiction and opioid-related deaths and emergency treatments, and has generated huge sales of opioids at inflated prices.

10. The direct and proximate consequence of Defendants' misconduct is that every South Dakota purchaser of private health insurance paid higher premiums, co-payments, and deductibles. Insurance companies have considerable market power and pass onto their insureds the expected cost of future care—including opioid-related coverage. Accordingly, insurance companies factored in the unwarranted and exorbitant healthcare costs of opioid-related coverage caused by Defendants and charged that back to insureds in the form of higher premiums, deductibles, and co-payments.

11. This action seeks to hold Defendants accountable for the economic harm they have imposed on South Dakota purchasers of private health insurance.

PARTIES

12. Plaintiff Deborah Green-Kuchta is a natural person and resident and citizen of the State of South Dakota.

13. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of the State of Delaware with its principal place of business in Connecticut. Defendant Purdue Pharma Inc. is a New York corporation with its principal place of business in Connecticut. Defendant Purdue Frederick Company is a Delaware corporation with its principal place of business in Connecticut.

14. On information and belief, at all relevant times, Purdue Pharma L.P, Purdue Pharma Inc., and Purdue Frederick Company (together, "Purdue") acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

15. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States and New Jersey. OxyContin is Purdue's best-selling opioid, and it accounts for nearly one-third of the national painkiller market. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion.

16. Defendant Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys manufactures, markets, sells and distributes Subsys—a sublingual spray of fentanyl—in South Dakota and nationwide.

17. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Defendant 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. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a wholly owned subsidiary of Teva Ltd. and is incorporated in Delaware with its principal place of business in North Wales, Pennsylvania.

18. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the United States and South Dakota.

19. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011

acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

20. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012—the year immediately following the Cephalon acquisition—attributed a 22% increase in its specialty medicine sales to the inclusion of a full year of Cephalon's specialty sales, including *inter alia* sales of Fentora. Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon."

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

22. On information and belief, at all relevant times, Janssen Pharmaceuticals, Inc. and Johnson & Johnson (together, "Janssen") acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

23. Janssen manufactures, promotes, sells, and distributes drugs in the United States and South Dakota, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

24. Defendant Endo Pharmaceuticals Inc. is a Delaware corporation with its principal place of business in Pennsylvania, and is a wholly owned subsidiary of Endo Health Solutions Inc. Defendant Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Pennsylvania.

25. On information and belief, at all relevant times, Endo Pharmaceuticals Inc. and Endo Health Solutions Inc. (together, "Endo") acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described herein.

26. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States and South Dakota. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.25 billion in revenue from 2009 through 2013, and it accounted for 10% of Endo's total revenue during that period.

27. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States and South Dakota, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

28. On June 8, 2017, the FDA called for Endo to remove Opana ER from the market, concluding that the risks of the drug outweigh its benefits.

29. Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Defendant Actavis plc acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in June 2015. Before that, Defendant Watson Pharmaceuticals, Inc. acquired Defendant Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis plc in October 2013.

30. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in California, and is a wholly-owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as Watson Pharma, Inc. Actavis LLC is a Delaware limited liability company with its principal place of business in New Jersey. Each of these defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States.

31. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis.")

32. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic

and Opana, in the United States and South Dakota. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008 and began marketing Kadian in 2009.

33. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business in California. McKesson distributes substantial amounts of prescription opioids to providers and retailers in the United States and South Dakota.

34. Defendant Cardinal Health, Inc. ("Cardinal") is an Ohio corporation with its principal place of business in Ohio. Cardinal distributes substantial amounts of prescription opioids to providers and retailers in the United States and South Dakota.

35. Defendant AmerisourceBergen Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business in Pennsylvania. AmerisourceBergen distributes substantial amounts of prescription opioids to providers and retailers in the United States and South Dakota.

36. At all relevant times, Defendants promoted, marketed, advertised, distributed and sold opioid products in the State of South Dakota and to South Dakota residents, citizens, and businesses.

JURISDICTION AND VENUE

37. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2), because (i) at least one member of the putative Class is a citizen of a state different from Defendant Purdue Pharma, L.P., (ii) the amount in controversy exceeds $5,000,000, exclusive of interest and costs, and (iii) none of the exceptions under the subsection apply to this action.

38. This Court has personal jurisdiction over each Defendant because Plaintiff's claims arise out of, or relate to, each Defendants' contacts with South Dakota. For example:

- Defendants knowingly and intentionally sell, market, advertise, promote, and distribute their products in the State of South Dakota and to South Dakota residents, citizens, and businesses, as well as to the State of South Dakota;
- Defendants enter into contracts relating to the subject-matter of this action in the State of South Dakota;
- Defendants have directed advertising, marketing, and promotional efforts at the State of South Dakota and South Dakota residents, citizens, and businesses;
- Defendants have engaged in advertising, marketing, and promotional activities with the intent and expectation that these activities would reach and affect the State of South Dakota and/or South Dakota residents, citizens, and businesses;
- Defendants have delivered, distributed, dispensed, and sold opioids in South Dakota with the intent and the expectation that those products would be distributed to or purchased by South Dakota residents, citizens, and businesses; and
- As described herein, Plaintiff sues to vindicate injuries that have occurred within the State of South Dakota.

39. Venue is proper in this District because a substantial part of the events giving rise to Plaintiff's claims occurred in, were directed to, and/or emanated from this District. 28 U.S.C. § 1391(b).

FACTUAL ALLEGATIONS

A. Because Opioids Are Highly Addictive, Prevailing Medical Norms Dictated That They Should Not Be Prescribed for Chronic Pain.

40. Opioids are a class of chemical compounds that bind to opioid receptors in the human nervous system. Opioids elicit a euphoric response by stimulating pleasure centers in the brain. This euphoric response allows opioids to effectively mask pain, but it also causes the drugs to be highly addictive.

41. Common opioids include morphine, methadone, oxycodone, hydrocodone, codeine, and fentanyl. These drugs cannot be lawfully obtained without a valid prescription. Common brand names for these drugs include Vicodin, Percocet, and OxyContin. Heroin is also classified as an opioid.

42. Before the 1990s, generally accepted standards of medical practice dictated that opioids should be used only for cases of acute pain, surgery recovery, cancer treatment, or end-of-life palliative care. There was widespread medical consensus that opioids should not be used to treat chronic pain due to the lack of evidence that opioids improved patients' ability to overcome pain, 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.

43. In the limited cases where patients were prescribed opioids, the drugs ordinarily were administered in closely supervised environments, like inpatient-treatment or hospice facilities, and typically only for short periods of time. These closely supervised conditions mitigated the risk that patients might misuse opioids, and they allowed doctors to monitor patients for signs of potential addiction or dependence.

44. While these prevailing medical norms had strong scientific bases and reflected sound medical judgment, the Manufacturer Defendants viewed the medical community's hesitance to prescribe opioids as an impediment to substantial profits they could obtain from increased use of their opioid products. Thus, the Manufacturer Defendants devised a scheme to misrepresent the risks and benefits of opioids to increase prescriptions by tapping into the large and lucrative market for chronic-pain patients.

B. The Manufacturer Defendants Disseminate False and Misleading Statements About Opioids.

45. The Manufacturer Defendants employed a multi-pronged approach to misinform doctors and patients.

46. ***First***, the Manufacturer Defendants communicated directly to doctors and chronic-pain patients. For doctors, this took the form of in-person visits and communications from sales and promotional staff; continuing medical education programs;

advertisements, including in periodicals aimed at medical audiences; websites; and other means. For chronic-pain patients, this included websites; advertisements; publications aimed at the public; and other means.

47. For example, the 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.

48. In addition, the Manufacturer Defendants 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. These detailers have spread and continue to spread misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors, including hundreds of South Dakota doctors. Not until February 2018 did Purdue announce that it will cease the practice of sending its salespeople to visit doctors to promote its opioid drugs.

49. The Manufacturer Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, they spent $168 million on detailing branded opioids to doctors—twice as much as they spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $10 million by Endo, and $2 million by Actavis.

50. The Manufacturer Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Moreover, more frequent prescribers of opioids in South Dakota are generally more likely to have received a detailing visit.

51. The Manufacturer Defendants' detailers have been reprimanded for their deceptive promotions. For example, 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."

52. ***Second***, the Manufacturer Defendants created, funded, controlled, and operated third-party organizations that communicated directly with doctors and chronic-pain patients to promote opioid use generally without naming specific brands.

53. The Manufacturer Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because such advertising is not submitted to and typically is not reviewed by the FDA. They also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source.

54. The Manufacturer Defendants' deceptive, unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA. For example, Endo's unbranded advertising stated that "People who take opioids as prescribed usually do not become addicted," which contradicted its concurrent, branded advertising for Opana ER, which warned that "use of opioid analgesic products carries the risk of addiction even under appropriate medical use."

55. Under the direction and control of the Manufacturer Defendants, these third-party organizations, known as "Front Groups," which include the American Pain Foundation ("APF")

and the American Academy of Pain Medicine ("AAPM"), generated treatment guidelines, unbranded materials, and programs that endorsed chronic opioid therapy. These guidelines, materials, and programs were not supported by the evidence at the time they were created, nor are they supported by the scientific evidence today. Indeed, they stand in marked contrast to the CDC's 2016 *Guideline for Prescribing Opioids for Chronic Pain* ("2016 CDC Guideline"). These Front Groups also assisted the Manufacturer Defendants by responding to negative articles, advocating against regulatory changes that would limit opioid prescriptions, and conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

56. These Front Groups depended on the Manufacturer Defendants for funding. As a result, the Manufacturer Defendants exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. Purdue's consulting agreement with APF, for example, gave it direct control over APF's work. The Manufacturer Defendants thus ensured that the Front Groups would disseminate only the messages that the Manufacturer Defendants wanted to promote. Nonetheless, the Front Groups held themselves out as independent and serving the needs of their members—whether patients suffering from pain, or the doctors treating those patients.

57. Through the Front Groups, the Manufacturer Defendants conspired to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which APF started in 2004. PCF is composed of representatives from opioid manufacturers (including Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not too negative and did not require mandatory participation by

prescribers, which the Manufacturer Defendants feared would reduce prescriptions. 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.

58. At all relevant times, the Manufacturer Defendants controlled, operated, funded, and acted in concert with APF, AAPM, and other Front Groups. The Manufacturer Defendants provided substantial funding for these organizations' activities. In 2010 alone, APF received more than $1 million from Defendant Endo, more than $100,000 from Defendant Purdue, as well as substantial contributions from Defendant Janssen.

59. At all relevant times, the Manufacturer Defendants were legally responsible for the acts, omissions, and representations of APF and AAPM; APF and AAPM acted as agents for Defendants; and Defendants conspired with APF, AAPM, and other third-party entities with respect to the conduct described herein.

60. ***Third***, the Manufacturer Defendants enlisted highly credentialed medical professionals to spread their false narratives about the risks and benefits of opioids and other pain-treatment options. These medical professionals engaged by the Manufacturer Defendants have been referred to as "key opinion leaders" or "KOLs," who include individuals such as Dr. Russell Portenoy and Dr. Lynn Webster.

61. Because these KOLs purported to act independently, the purpose and effect of their involvement was to lend legitimacy to the Manufacturer Defendants' false and misleading claims about opioids. The Manufacturer Defendants paid these KOLs to serve as consultants or on their advisory boards and to give talks or to present continuing medical education programs (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 the

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 the Manufacturer Defendants.

62. Pro-opioid doctors are one of the most important avenues that the Manufacturer Defendants have used to spread their false and misleading statements about the risks and benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the New York Attorney General ("NY AG") found in its 2015 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. The NY AG concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

63. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs, supportive of chronic opioid therapy. The Manufacturer Defendants created opportunities for KOLs to participate in research studies that the Manufacturer Defendants proposed or selected, and then cited and promoted favorable studies or articles by their KOLs.

64. Not surprisingly, the Manufacturer Defendants did not support or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

65. The 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. The Manufacturer Defendants exerted control over these activities through their KOLs. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices."

66. At all relevant times, the Manufacturer Defendants controlled, funded, and acted in concert with these KOLs; they were legally responsible for the acts, omissions, and representations of these KOLs, who acted as their agents; and the Manufacturer Defendants conspired with these KOLs regarding the conduct described herein.

67. Through all three of these avenues, the Manufacturer Defendants disseminated false and deceptive statements about opioids.

C. The Manufacturer Defendants Intentionally Misled Doctors and Consumers About the Risks and Benefits of Opioids to Generate Billions of Dollars in Improper Profits.

68. As explained above, for decades doctors had viewed opioids with suspicion, judging that the risk of addiction made such drugs inappropriate in all but a small number of situations.

69. To convince doctors and patients in South Dakota that opioids can and should be used to treat chronic pain, the Manufacturer Defendants had to convince them that long-term opioid use is both safe and helpful. They did so by deceiving those doctors and patients about the risks and benefits of long-term opioid use, making claims that were not supported by or were contrary to the scientific evidence. Even though guidance from the FDA and the CDC based on that evidence confirm that their claims were false and misleading, the Manufacturer Defendants have not corrected them and continue to spread them today.

1. <u>The Manufacturer Defendants Misrepresented the Known Risks of Long-Term Opioid Use.</u>

70. The 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 and rejected by the FDA and CDC. Specifically, they made false, misleading, and fraudulent representations to both physicians and consumers that: (1) starting patients on opioids was low-risk because most patients would not become addicted and 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 the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. The Manufacturer Defendants have not only failed to correct these misrepresentations, they continue to make them today.

a. The Manufacturer Defendants falsely represented that opioids pose a low risk of addiction.

71. First, the Manufacturer Defendants falsely minimized the risk of addiction and failed to disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of these false and misleading claims are described below:

- Actavis's predecessor caused a patient education brochure to be distributed 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 rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.

- Purdue and Cephalon 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.

- 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."

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

- In another publication, Endo represented that "[i]n general, people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted."

- 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." This guide is still available online.

- Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated" and that that opioid addiction is unlikely unless the patient is recovering from past drug or alcohol abuse.

- Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*—which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." This publication is still available online.

- In the APF publication *Getting the Help You Need*, the Manufacturer Defendants represented that "[s]tudies and clinical practice have shown that the risk of addiction is small when [opioids] are appropriately prescribed and taken as directed."

- In the same APF publication, the Manufacturer Defendants represented that "[u]nless you have a past or current history of substance abuse, the chance of addiction is low when these medications are prescribed properly and taken as directed."

- The same APF publication also stated: "Keep in mind, pain medicine in and of itself does not cause someone to become addicted."

- In a "Commonly Asked Questions and Answers" portion of the APF website, Defendants represented that "addiction is very rare when pain medicines are properly prescribed and taken as directed."

- Cephalon sponsored a guidebook called *Opioid Medications and REMS: A Patient's Guide*, which falsely represented that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids."

- Detailers for Purdue, Endo, and Janssen in South Dakota have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in South Dakota about 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.

- APF's Executive Director represented that "when taken as prescribed, under the direction of a physician for pain relief, opioids are safe and effective, and only in rare cases lead to addiction." He further represented that "less than 1% of patients become addicted" to opioids.

72. The representations identified above—and other similar representations by the Manufacturer Defendants—are false. Extensive medical research demonstrates that opioids pose a substantial risk of addiction, abuse, and overdose. In particular, opioids pose a substantial risk of addiction when they are used for extended periods of time—such as for treatment of chronic pain—and when they are administered outside the close supervision of medical professionals. Many studies have shown substantial risk of addiction where patients take opioids to treat chronic non-cancer pain.

73. Many patients become addicted to opioids even when they originally take opioids pursuant to a valid prescription. Indeed, one study found that 75% of those addicted to opioids first took them pursuant to a prescription. And research suggests that the overdose-death rate for those taking opioids pursuant to a prescription is higher than the rate for those using opioids non-medically.

74. One study examining opioid overdose deaths found that "92% of the decedents had been receiving [putatively] legitimate [opioid] prescriptions from health care providers for chronic pain."

75. Many patients become addicted to opioids even though they have no prior history of addiction or substance abuse. In fact, in 2016, the CDC "found insufficient evidence to determine how harms of opioids differ depending on past or current substance abuse disorder."

Indeed, the 2016 CDC Guideline found that 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."

76. The FDA's announcement of changes to the labels for extended release ("ER") and long acting ("LA") opioids in 2013 and for immediate release ("IR") opioids in 2016 further exposed the falsity of the Manufacturer Defendants' claims about the low risk of addiction. 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.

77. The Manufacturer Defendants' own FDA-approved drug label warnings 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.

78. In a 2016 settlement agreement with Endo, the New York Attorney General found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with

opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder."

79. Until at least April 2012, Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the NY AG found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements in South Dakota.

80. Doctors, consumers, and insurers reasonably relied on these misrepresentations. As a result, many doctors prescribed opioids when they otherwise would not have, and many patients requested and obtained opioids when they otherwise would not have. Insurers kept Manufacturer Defendants' opioids in their formularies and paid more than they were worth.

81. In particular, the Manufacturer Defendants' misrepresentations induced both doctors and consumers to use opioids to treat chronic pain, and induced insurers not to question this practice, which widespread medical norms had viewed as inappropriate before their misinformation campaign.

82. The Manufacturer Defendants knew that their representations described herein were false, and they made those representations with intent to defraud. The Manufacturer Defendants intentionally made the representations described herein to South Dakota citizens, residents, and businesses.

b. The Manufacturer Defendants falsely represented that many individuals who exhibit signs of addiction to opioids are experiencing "pseudoaddiction," which should be treated by increasing opioid use.

83. Second, the Manufacturer Defendants repeatedly misrepresented to insurers, doctors, and consumers that many individuals exhibiting signs of addiction were experiencing "pseudoaddiction"—a concept originally put forward by J. David Haddox, who later became a Vice President for Defendant Purdue, and popularized by Dr. Russell Portenoy, a KOL for Endo, Janssen, Cephalon, and Purdue. Defendants further falsely represented that the proper treatment for "pseudoaddiction" is more opioids.

84. Examples of these deceptive claims include the following:

- Purdue and Cephalon 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.

- 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." This website was accessible online until May 2012.

- 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.

- Endo also represented that "[s]ometimes people behave as if they are addicted, when they are really in need of more medicine. This can be treated with higher doses of medicine."

- 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."

- Purdue sponsored a CME program entitled Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse in 2011. In a role play, a chronic 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.

- Detailers for Purdue have directed doctors and their medical staffs in South Dakota to PartnersAgainstPain.com, which contained false and misleading materials describing pseudoaddiction.

- Purdue and Cephalon 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."

85. These representations are false. Significant medical literature casts doubt on the concept of "pseudoaddiction." For example, one medical study reviewed all academic medical publications discussing "pseudoaddiction" and concluded that, "[o]f the 224 articles, none exist that attempted to empirically validate the concept of pseudoaddiction."

86. The same study found that many of the articles that considered "pseudoaddiction as a genuine clinical phenomenon" were funded by opioid producers, including Defendants Janssen and Purdue.

87. In addition, the CDC's opioid-prescribing guidelines do not recognize "pseudoaddiction" as a legitimate medical concept. The 2016 CDC Guideline does not recognize the concept of pseudoaddiction and nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief.

88. As Dr. Lynn Webster later recognized, the concept of pseudoaddiction "obviously became too much of an excuse to give patients more medication . . . . It led us down a path that caused harm. It is already something we are debunking as a concept."

89. Even Defendant Endo 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 NY AG, in its 2016 settlement with Endo,

reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.'" Thus, Endo agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York.

90. Insurers, doctors and consumers reasonably relied on the Manufacturer Defendants' misrepresentations. As a result of that reasonable reliance, many doctors prescribed opioids when they otherwise would not have, and many patients requested and obtained opioids when they otherwise would not have. Insurers kept Manufacturer Defendants' opioids in their formularies and paid more than they were worth.

91. In particular, the false representations induced many doctors to increase opioid dosage based on the belief that patients' signs of addiction actually reflected "pseudoaddiction." In addition, the Manufacturer Defendants' false representations induced many doctors to continue prescribing opioids to patients exhibiting signs of addiction even though those doctors should have discontinued the prescriptions.

92. The Manufacturer Defendants knew that their representations described herein were false and made those representations with intent to defraud. The Manufacturer Defendants intentionally made their representations described herein to South Dakota citizens, residents, and businesses.

c. The Manufacturer Defendants misrepresented the signs of addiction and the ease of preventing addiction.

93. Third, the Manufacturer Defendants repeatedly misrepresented the signs of addiction, the appropriate medical response to evidence of patient addiction or dependence, and the ease of preventing addiction. Specifically, they falsely instructed insurers, doctors, and

patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them reliably to identify and safely to prescribe opioids to patients predisposed to addiction. The Manufacturer Defendants targeted these misrepresentations at general practitioners and family doctors who often lack the time and expertise to closely manage higher-risk patients on opioids. These misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, made patients more comfortable starting on opioid therapy for chronic pain, and induced insurers to not question this practice.

94. Examples of these deceptive claims include the following:

- Endo represented that "[t]aking opioids for pain relief is not addiction" and that "[a]ddiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problem."

- In the same publication, Endo suggested that patients use the following test to determine whether they are addicted to opioids: "Ask yourself: Would I want to take this medicine if my pain went away? If your answer no, you are taking opioids for the right reasons—to relieve pain and improve your function. You are not addicted."

- 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.

- Purdue sponsored a November 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."

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

- Detailers for Purdue have touted and continue to tout to doctors in South Dakota the reliability and effectiveness of screening or monitoring patients as a tool for managing opioid abuse and addiction.

95. These representations are false. In fact, a patient can be addicted to opioids while still experiencing pain. And a person addicted to opioids ordinarily is not in a position to judge objectively whether he or she would "want to take this medicine if [his or her] pain went away."

96. Moreover, the 2016 CDC Guideline confirms that these statements were false, misleading, and unsupported at the time they were made. 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."

97. The Manufacturer Defendants intentionally made the representations described herein to South Dakota citizens, residents, and businesses.

d. The Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem.

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

99. For example, a 2011 non-credit educational program sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that

"[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur. This publication was available on APF's website until the organization dissolved in May 2012.

100. And detailers for Janssen have minimized the risk of addiction by telling doctors in South Dakota that their patients would not experience withdrawal if they tried to stop using opioids. The Manufacturer Defendants deceptively minimized the significant symptoms of opioid withdrawal—which, as explained in the 2016 CDC Guideline, include drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid 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.

101. In fact, as the 2016 CDC Guideline recognizes, 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." Moreover, "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and there are difficulties associated with tapering, 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."

e. The Manufacturer Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk.

102. Fifth, the Manufacturer Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks at higher dosages. The ability to escalate dosages was critical to the Manufacturer Defendants' efforts to market and sell 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 ceased to provide pain relief.

103. Examples of these deceptive claims include the following:

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

- Purdue and Cephalon 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.

- 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."

- Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. 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."

- 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.

- Through March 2015, Purdue's *In the Face of Pain* website promoted 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.

- Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even

unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.

- 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 non-steroidal anti-inflammatory drugs ("NSAIDs") and other drugs, but not opioids, are unsafe at high dosages.

- Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdose.

104. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. The 2016 CDC Guideline states that 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.

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

f. The Manufacturer Defendants falsely claimed that the abuse-deterrent properties of some of their opioids can prevent and curb addiction and abuse.

106. Finally, the Manufacturer Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these

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

107. 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 with.

108. Despite this, AD opioids are not "impossible to abuse." They can be defeated, often quickly and easily. Moreover, they do not stop oral intake, the most common method of opioid misuse and abuse, and they 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.

109. As a result of these limitations on AD opioids and the heightened risk of misconceptions and 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."

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

111. For example, Endo has 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 misleadingly claimed that it was designed to be crush resistant, suggesting it was more difficult to abuse. And since 2012, detailers for Endo have informed South Dakota doctors that Opana ER is harder to abuse, and nurse practitioners have reported receiving tamper- and crush-resistant messages regarding Opana ER and demonstrations of Opana ER's purportedly abuse-deterrent properties.

112. In its 2016 settlement with the NY AG, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The NY AG found those statements false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG 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.

113. 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.

114. Likewise, Purdue has engaged and continues to engage 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, detailers from Purdue regularly touted to prescribers in South Dakota the so-called abuse-deterrent properties of Purdue's opioid products as a selling point to differentiate those products

from their competitors. Specifically, these detailers: (1) claim that Purdue's AD opioids prevent tampering and cannot be crushed or snorted; (2) claim 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) claim that Purdue's AD opioids are "safer" than other opioids; and (4) fail to disclose that Purdue's AD opioids do not impact oral misuse and that its abuse-deterrent properties can be defeated.

115. 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 they can be snorted, that their abuse-deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse-deterrent properties.

116. Testimony in litigation against Purdue and other evidence indicates that 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.

117. 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.

118. In spite of all this, J. 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.

119. 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 Director of the CDC, has further reported that his staff could not find "any evidence showing the updated opioids [abuse deterrents] actually reduce rates of addiction, overdoses, or death."

120. These false and misleading claims about the abuse-deterrent properties of the Manufacturer Defendants' opioids are especially troubling. First, the Manufacturer Defendants are using these claims in a spurious attempt to rehabilitate their image as responsible opioid manufacturers. Indeed, several prescribers have reported that Purdue has conveyed that its sale of AD opioids is "atonement" for its earlier sins even though its true motive was to preserve the profits it would have lost when its patent for OxyContin expired. Indeed, Purdue introduced its first AD opioid days before that patent would have expired and petitioned the FDA to withdraw its non-AD opioid as unsafe in an effort to prevent generic competition. Second, these claims have falsely assuaged doctors' concerns about the toll caused by the explosion in opioid prescriptions and use and encouraged doctors to prescribe AD opioids under the mistaken belief that these opioids are safer, even though they are not. Finally, these claims are causing doctors to

prescribe more AD opioids, which are far more expensive than other opioid products even though they provide little or no additional benefit.

121. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by the Manufacturer Defendants successfully convinced doctors and patients to discount those risks, and convinced insurers to continue paying, and overpaying, for AD formulations.

2. The Manufacturer Defendants Falsely Overstated the Positive Long-Term Outcomes of Opioids in Cases of Chronic Pain.

122. A doctor's decision to prescribe any treatment—including opioids—always depends on the balancing of the risks posed by the treatment against the likely benefits from the treatment. As described above, the Manufacturer Defendants repeatedly misrepresented the risks associated with opioids to persuade insurers, doctors, and consumers that opioids pose only minor risks that can be easily screened for, recognized, and avoided.

123. The Manufacturer Defendants also misrepresented the other side of the balance, falsely asserting that opioids produce positive long-term outcomes in cases of chronic pain.

124. As the 2016 CDC Guideline makes 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 also 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, the

Manufacturer Defendants falsely and misleadingly touted the benefits of long-term opioid use, which they suggested were supported by scientific evidence.

125. For example, the Manufacturer Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Examples of these deceptive claims include the following:

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

- Endo distributed advertisements that claimed that 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.

- 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.'"

- 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.

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

- Purdue and Cephalon 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 May 2012.

- 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.

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

- 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.

- Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The Policymaker's Guide was originally published in 2011 and is still available online today.

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

- Since at least May 21, 2011, Purdue's, Endo's, and Janssen's sales representatives have conveyed to prescribers in South Dakota the message that opioids will improve patient function.

126. The scientific literature does not support these claims. The FDA and other federal agencies have made this clear for years. For example, the 2016 CDC Guideline concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." In addition, the CDC stated 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 . . . ." "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy." "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

127. 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.

128. The 2016 CDC Guideline was not the first time a federal agency repudiated Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis, in response to its advertising, 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."

129. In 2008, the FDA sent a warning letter to an opioid manufacturer, making 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."

130. In addition, Purdue has misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours—a fact that 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 10 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 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 12 hours of relief false and misleading, 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 the drug they are taking and spurring growing dependence.

131. 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 12 hours. Indeed, Purdue's sales representatives were instructed to tell doctors that OxyContin lasts a full 12 hours. And if a doctor suggested that OxyContin does not last 12 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.

132. The Manufacturer Defendants' branded ads also deceptively portrayed the benefits of opioids for chronic pain. For example, Endo has distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like 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. 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 South Dakota.

133. The Manufacturer Defendants also repeatedly made these representations in writing. For example, in the APF publication *Exit Wounds*, Defendants described opioids as "the 'gold standard' of pain medications" and claimed that, if taken properly, opioids "increase a person's level of functioning."

134. These representations are false. Medical research does not support the conclusion that opioids increase positive long-term outcomes in cases of chronic pain.

135. The Manufacturer Defendants knew that the representations described above were false, and they made those representations with intent to defraud. The Manufacturer Defendants intentionally made the representations described herein to South Dakota citizens, residents, and businesses.

3. The Manufacturer Defendants Falsely Represented the Relative Risks Associated with Non-Opioid Pain-Relief and Pain-Treatment Strategies.

136. In addition to their misrepresentations regarding opioids, the Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would favor opioids for treatment of chronic pain.

137. For example, the 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 contravene pronouncements and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR 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.

138. The CDC has emphasized that non-opioid therapies are the "preferred" approach for treating chronic pain. Non-drug alternative treatments for chronic pain include a variety of treatments, including but not limited to cognitive behavioral therapy; exercise therapy; changes in diet or nutrition; and chiropractic and massage treatment. In addition, pharmaceutical alternatives to opioids include over-the-counter analgesics; NSAIDs; non-opioid prescription analgesics; and other drugs. The CDC has concluded that extensive research shows that these non-opioid treatment options offer greater benefits than long-term opioid treatment for chronic pain.

139. The Manufacturer Defendants recognized that the availability of these alternatives would reduce the demand for their opioid products. To reduce the comparative demand for these alternatives to opioids, the Manufacturer Defendants misrepresented both the risks and benefits associated with many alternative treatment options.

140. The Manufacturer Defendants repeatedly made these representations in writing. For example, in the APF publication *Exit Wounds*, the Manufacturer Defendants represented that if NSAIDs are taken in high doses, they can have "life threatening" effects. But the Manufacturer Defendants intentionally omitted the material fact that opioids pose severe risks—including significant risks of overdose and death—at high doses. In the same publication, the Manufacturer Defendants represented that acetaminophen poses significant health risks in large doses, but they intentionally omitted the material fact that opioids also pose severe risks at high doses.

141. In the APF publication *Treatment Options: A Guide for People Living with Pain*, the Manufacturer Defendants represented that "NSAIDs can cause life-threatening side effects in some persons" and that "[t]here are 10,000 to 20,000 deaths each year because of the side effects of this class of medicines." But the Manufacturer Defendants intentionally omitted the material

fact that opioids similarly pose severe and life-threatening effects and that comparable numbers of people die each year from opioid use. Indeed, one study found that since 1999, approximately 183,000 people died in the United States from opioid-related overdoses—that is, a little more than 10,000 per year.

142. In these and other similar representations, the Manufacturer Defendants repeatedly emphasized the risks associated with alternative pain treatments without disclosing similar—and often much more severe—risks associated with opioids. In reality, opioids pose more severe risks than do nearly all other pain-treatment options. One study found that the risk of death from out-of-hospital use of opioids was almost twice as likely to result in death than the use of alternatives like analgesic anticonvulsants.

143. These intentional omissions rendered the Manufacturer Defendants' representations false, misleading, deceptive, and fraudulent. Both doctors and consumers reasonably relied on these misrepresentations. And as a result of that reasonable reliance, many doctors prescribed opioids when they otherwise would not have, many patients requested and obtained opioids when they otherwise would not have, and insurers continued to pay for opioids when they would not have.

144. In particular, the Manufacturer Defendants' misrepresentations led many doctors to prescribe opioids when they otherwise would have prescribed or recommended non-opioid alternative treatments, and insurers covered opioids when they would have established policies that favored other pain treatment. And their misrepresentations led many consumers to request and/or take opioids when they otherwise would have requested and/or taken non-opioid alternatives.

145. The Manufacturer Defendants knew that the representations described herein were false, and they made those representations with intent to defraud. The Manufacturer Defendants intentionally made the representations described herein to South Dakota citizens, residents, and businesses.

D. The Manufacturer Defendants Engaged in Other Unlawful and Unfair Misconduct.

146. In addition to the misrepresentations described above, the Manufacturer Defendants engaged in other misconduct, including failing to recognize or to act on knowledge that their opioids were being diverted, and targeting susceptible prescribers and vulnerable patient populations.

1. The Manufacturer Defendants Failed to Act on Their Knowledge of the Diversion of Their Opioid Drugs.

147. The Manufacturer Defendants are able to track the distribution and prescription of their opioids, but failed to act on suspicious prescriptions. To the contrary, they continued to provide incentives for doctors to prescribe their opioids. For example, Purdue, through its sales representatives, pressed doctors to prescribe its opioids in order to be rewarded with talks paid by Purdue. One doctor reported that a Purdue sales representative told her that she would no longer be asked to give paid talks unless she increased her prescribing of Purdue's drugs. Another doctor confirmed that, while on Purdue's speakers' bureau, he was not asked to give many paid talks because he did not commonly prescribe Butrans, and doctors do not "get talks" if they do not prescribe the drug.

148. Although the DEA has repeatedly informed Purdue about its legal "obligation to design and operate a system to disclose . . . suspicious orders of controlled substances" and to inform the DEA "of suspicious orders when discovered," Purdue unlawfully and unfairly failed

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

149. For more than a decade, Purdue has been able to track the distribution and prescribing of its opioids down to the retail and prescriber levels. Through its extensive network of sales representatives, Purdue had knowledge of the prescribing practices of hundreds of doctors in South Dakota and could identify doctors who displayed red flags for diversion such as those whose waiting rooms were overcrowded, whose parking lots had numerous out-of-state vehicles, and whose patients seemed young and healthy or homeless. 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 Purdue is legally obligated to do) 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 based on its assertion that the drug was too likely to be abused.

150. 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 take action, 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 until years after law enforcement shut down 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." In doing so, Purdue protected its own profits at the expense of public health and safety.

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

152. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services, said in a *Los Angeles Times* article, "[a]ny drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people's lives has a responsibility to report it." The NY AG's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

153. 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 NY AG 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. The NY AG also found that, in certain cases where Endo's sales representatives detailed prescribers who were convicted of illegal prescribing of opioids, those representatives could have recognized signs of diversion and reported those prescribers but failed to do so.

2. The Manufacturer Defendants Specifically Targeted Susceptible Prescribers and Vulnerable Patient Populations.

154. As a part of their deceptive marketing scheme, the Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the United States, including South Dakota. For example, they 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 schooled in treating pain and the risks and benefits of opioids, and therefore more likely to trust the Manufacturer Defendants' misrepresentations.

155. The Manufacturer Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. They targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. The 2016 CDC Guideline observed that existing evidence showed 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 concluded that there are "special risks of long-term opioid use for elderly patients" and recommended that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients.

156. Similarly, the Manufacturer Defendants specifically targeted veterans, launching APF's "Military/Veterans Pain Initiative" focused entirely on pushing opioids to veterans and members of the military, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids. The Manufacturer Defendants also created publications containing misrepresentations regarding opioids that were specifically tailored to veterans, such as the APF publication *Exit Wounds*.

3. The Manufacturer Defendants Fraudulently Concealed Their Misconduct.

157. The Manufacturer Defendants made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and misleading. As described above, the medical community well-understood that opioids are highly addictive and dangerous. The Manufacturer Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the

harms from long-term opioid use and that patients have been suffering from addiction, overdose, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the falsity of the Manufacturer Defendants' misrepresentations, and Endo and Purdue have recently entered agreements with the NY AG.

158. The Manufacturer Defendants concealed their deceptive marketing including by disguising their role in the deceptive marketing of chronic opioid therapy by conspiring with Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the apparent objectivity of these third parties, who lent credibility to their false and misleading statements about the risks and benefits of long-term opioid use for chronic pain.

159. The Manufacturer Defendants also hid their active role in shaping and approving the content of information and materials disseminated by these third parties. The Manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in private emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies. 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 roles.

160. In addition, the Manufacturer Defendants distorted or omitted material facts in their promotional materials and influenced the scientific literature to create the false appearance that these materials were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer Defendants mischaracterized the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. Medical professionals and patients relied on this misinformation.

161. In short, the Manufacturer Defendants successfully conspired to conceal from the medical community, patients, and health care payers material facts that would have aroused suspicion of the claims set forth herein. Plaintiff did not know of the existence or scope of the Manufacturer Defendants' industry-wide fraud until recently, when allegations of their wrongdoing became widespread, nor could he have acquired such knowledge earlier through the exercise of reasonable diligence.

4. Defendant Insys Engaged in Conduct so Fraudulent That Its Former Executives Have Been Indicted.

162. In late 2016, several former Insys executives—including its former CEO and president, former vice president of sales, former national director of sales, and former vice president of managed markets—were arrested and indicted for conspiring to bribe practitioners in order to get them to prescribe Subsys. In exchange for bribes and kickbacks, the practitioners wrote illegitimate Subsys prescriptions for patients.

163. The indictment alleged that the former executives conspired to mislead and defraud health insurance providers. Specifically, the former executives established a "reimbursement unit" dedicated to obtaining prior authorization for Subsys prescriptions. Insys' reimbursement unit employees were told to inform agents of insurers and pharmacy benefit managers that they were calling "from" or that they were "with" the doctor's office, or that they were calling "on behalf of" the doctor.

164. The indictment details a coordinated, centralized scheme by Insys to illegally drive profits. The company defrauded insurers from a call center at corporate headquarters where Insys employees, acting at the direction of Insys' former CEO and vice president of managed markets, disguised their identity and the location of their employer, and lied about patient

diagnoses, the type of pain being treated and the patient's course of treatment with other medication.

E. The Manufacturer Defendants' Misinformation Campaign Resulted in Dramatic Increases in Opioid Use, Windfall Profits, and a Public-Health Crisis.

165. The Manufacturer Defendants' misrepresentations deceived and continue to deceive insurers, doctors, and patients in South Dakota about the risks and benefits of long-term opioid use. Studies show that many doctors and patients are not aware of or do not understand these risks and benefits. Patients often report that they were not warned they might become addicted to opioids prescribed to them. A 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told that opioids are potentially addictive. Many South Dakota residents in treatment for opioid addiction confirm that they were never told that they might become addicted to opioids when they started taking them, or that they could easily stop using opioids or that the opioids they were prescribed were less addictive than alternatives.

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

167. The Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices caused and continue to cause doctors in South Dakota to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent the Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices, these doctors would not have prescribed as many opioids to as many patients, and there would not have been as many opioids available for misuse and abuse or as much demand for those opioids.

168. The Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices also caused and continue to cause patients in South Dakota to purchase and use opioids for their chronic pain believing they are safe and effective. Absent their deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

169. The Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices have caused and continue to cause the prescribing and use of opioids to explode in South Dakota. Opioids are the most common means of treatment for chronic pain; 20% of office visits now include the prescription of an opioid; and 4 million Americans per year are prescribed a long-acting opioid. This surge in opioid use was not fueled by any scientific developments demonstrating that opioids were safe and effective for previously unaccepted uses. Instead, it was fueled by the Manufacturer Defendants' desire to sell more drugs to reap greater profits.

170. In South Dakota, the Manufacturer Defendants' deceptive marketing of the abuse-deterrent properties of their opioids has been particularly effective during the past few years. One survey reports that pain specialists were more likely to recognize that OxyContin had abuse-deterrent properties and to prescribe OxyContin specifically because of those properties. Further, prescribers who knew of OxyContin's abuse-deterrent properties were using more of it than those who did not know it was an AD opioid. Although sales of AD opioids still represent only a small fraction of opioids sold (less than 5% of all opioids sold in 2015), they represent a disproportionate share of opioid sales revenue ($2.4 billion or approximately 25% in opioid sales revenue in 2015).

171. The dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in the Manufacturer Defendants' spending on their deceptive marketing scheme. Their spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending had tripled to $288 million.

172. The Manufacturer Defendants' deceptive marketing scheme worked, causing doctors to write an escalating number of opioid prescriptions. That in turn caused a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the United States and South Dakota.

173. According to the CDC, between 1999 and 2014, sales of opioids nearly quadrupled. In 2012 alone, approximately 259 million opioid prescriptions were written in the United States. For context, the adult population of the United States is approximately 250 million. Thus, there may be nearly ten million more opioid prescriptions written each year than there are adults in the United States.

174. Countless individuals have become addicted to opioids as a result of the use of opioids for chronic-pain treatment, often with tragic results. In 2012, more than two million Americans were abusing or dependent on opioids. Since 1999, approximately 183,000 Americans died from opioid-related overdoses, and hundreds of those overdose deaths occurred in South Dakota. In 2014, more than 60% of drug-overdose deaths nationally involved opioids, and South Dakota's death rate from opioids is up nearly 150% from 2015 to 2016. More than 62,000 Americans are believed to have fatally overdosed from opioids in 2017 alone.

175. 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."

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

177. Not surprisingly, scientific evidence confirms 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."

178. Contrary to the Manufacturer Defendants' misrepresentations, most opioid addiction begins with legitimately prescribed opioids. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers, or the internet. Numerous doctors and substance abuse counselors note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic.

179. The opioid epidemic has a terrible human cost. In 2016, opioids were responsible for 42 overdose deaths in South Dakota.

180. These deaths represent the tip of the iceberg. According to 2009 data, for every overdose death that year, there were nine abuse treatment admissions, 30 emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and 795 non-medical users. And as recently reported, in South Dakota, the death rate from opioid abuse is up almost 150%.

181. The overprescribing of opioids for chronic pain caused by the Manufacturer Defendants' deceptive marketing scheme has also resulted in a dramatic rise in the number of infants in South Dakota who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome. These infants face painful withdrawal and may suffer long-term neurologic and cognitive impacts.

182. The Manufacturer Defendants' creation, through false and misleading advertising and other unlawful and unfair conduct, of a virtually limitless opioid market has significantly harmed communities in South Dakota. The Manufacturer Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and abuse. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.

183. The rise in opioid addiction caused by the Manufacturer Defendants' deceptive marketing scheme has also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year previously abused prescription opioids.

184. Many patients who become addicted to opioids will lose their jobs. Some will lose their homes and their families. Some will get treatment and fewer will successfully complete it; many of those patients will relapse, returning to opioids or some other drug. Of those who

continue to take opioids, some will overdose—some fatally, some not. Others will die prematurely from related causes—falling or getting into traffic accidents due to opioid-induced somnolence; dying in their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit drug transactions; or dying from opioid-induced heart or neurological disease.

185. Even when opioid users do not die from an overdose, they often require significant healthcare interventions. For example, in 2015, opioid use resulted in more than 30,000 hospitalizations and emergency-room visits. This represents a nearly 200% increase over the same figure from 2005.

186. Each year, opioid abuse imposes approximately $55 billion in health and social costs across the country, and it also imposes approximately $20 billion in costs for emergency and inpatient care.

187. Opioid abuse has also resulted in substantial additional social and economic costs that have destroyed countless South Dakota families and ravaged communities across the State.

188. The harms of opioid addiction and abuse have taken a particularly serious toll on older citizens. According to the AARP, the opioid-related hospitalization rate of Americans over the age of 65 has increased fivefold over the past two decades.

189. Absent the Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices, the public health crisis caused by opioid misuse, abuse, and addiction in South Dakota would have been averted or much less severe.

190. While the use of opioids has taken an enormous toll on the State of South Dakota and its residents, Defendants have realized blockbuster profits. In 2014 alone, opioids generated $11 billion in revenue for drug companies like the Manufacturer Defendants. As of 2016, Purdue

had earned as much as $31 billion from its promotion of OxyContin. Indeed, financial information indicates that each Defendant experienced a material increase in sales, revenue, and profits from the false and misleading advertising and other unlawful and unfair conduct described above.

F. The Distributor Defendants Engaged in Unlawful and Unfair Misconduct.

191. In addition to the misrepresentations by the Manufacturer Defendants described above, the Distributor Defendants engaged in misconduct, including their knowing and reckless failure to prevent the rampant diversion of opioids.

1. The Distributor Defendants Had a Duty to Exercise Reasonable Care in Distributing Opioid Drugs.

192. The Distributor Defendants have duties under South Dakota common law—as well as federal laws—to exercise reasonable care and not to create a foreseeable risk of harm to others.

193. The Distributor Defendants also are required to comply with the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq*. and its implementing regulations, which govern the distribution and dispensing of controlled substances. Among other reasons, Congress passed the CSA to protect against "the widespread diversion of [controlled substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566, 4572.

194. The CSA regulates the distribution of drugs from the manufacturing level through delivery to the patient. Opioid distributors are required to maintain effective controls against opioid diversion. They are also required to create and employ a system to identify and report suspicious orders of controlled substances to law enforcement authorities. Suspicious orders include orders of unusual size or frequency, or otherwise deviating substantially from normal patterns. To comply with these requirements, distributors must know their customers, report

suspicious orders, conduct due diligence, and terminate orders if there are indications of diversion.

195. To prevent unauthorized users from obtaining opioids, the CSA created a distribution monitoring system for controlled substances based on the registration and tracking requirements imposed on distributors of controlled substances. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an automated drug reporting system that monitors the flow of Schedule II controlled substances from their point of manufacture through commercial distribution channels to point of sale. ARCOS accumulates data on distributors' acquisition/distribution transactions, which are then summarized into reports used by the DEA to identify any diversion of controlled substances into illicit channels of distribution. Everyone registered to distribute ARCOS reportable controlled substances is supposed to report acquisition and distribution transactions to the DEA.

196. Acquisition and distribution transaction reports provide data on each acquisition to inventory, identifying whether it is, for example, by purchase, transfer, or return from a customer, and each reduction from inventory, identifying whether it is, for example, by sale, transfer, theft, destruction, or seizure by government agencies. *See* 21 U.S.C. § 827(d)(l); 21 C.F.R. §§ 1304.33(e), (d). Inventory that has been lost or stolen is also reported separately to the DEA within one business day of discovery.

197. In addition to filing acquisition and distribution transaction reports, registrants are required to maintain complete and accurate records of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. *See* 21 U.S.C. §§ 827(a)(3), 1304.21 (a), 1304.22(b). It is unlawful to fail to abide by the recordkeeping and reporting requirements.

198. Distributors of controlled substances also are required to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific and industrial channels. When determining if a distributor has provided effective controls, the DEA Administrator refers to the security requirements set forth in the regulations, which provide standards for the physical security controls and operating procedures necessary to prevent diversion. *See* 21 C.F.R. § 1301.71.

199. Because the Distributor Defendants were already purporting to monitor and report on opioid transactions, their utter failure to take reasonable precautions to ensure the accuracy of their reports was an inexcusable breach of common law duty.

2. The Distributor Defendants Knowingly or Negligently Facilitated Widespread Diversion of Opioids.

200. Opioid diversion has been a widely publicized problem for years. Numerous publications, studies, agencies, and professional organizations have highlighted the dangerous rates of opioid abuse and overdose across the country and in South Dakota.

201. To address the problem of opioid diversion, the DEA has provided guidance to distributors in the form of publications, agency actions, and other documents on the requirements of suspicious order reporting.

202. For over a decade, the DEA has conducted one-on-one briefings with distributors regarding downstream customer sales and prudent due diligence steps. The DEA provided distributors with information on controlled substance distribution patterns and trends, including data on order volume, order frequency, and the ratio of controlled to non-controlled purchases. Distributors were also given case studies, legal findings against other registrants, and ARCOS profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA highlighted "red flags" that distributors should look for in order to identify

potential diversion. The DEA implemented this initiative to help distributors understand their duties with respect to diversion control.

203. In addition, the DEA has hosted numerous conferences to provide registrants with updated information about diversion trends and regulatory changes affecting the drug supply chain, the distributor initiative, and suspicious order reporting. The Distributor Defendants attended these conferences, which also provided opportunities to ask questions and raise concerns.

204. The DEA also participated in numerous meetings and events with the Healthcare Distribution Management Association (HDMA), which is now known as the Healthcare Distribution Alliance (HDA)—an industry trade association for drug wholesalers and distributors. DEA representatives have provided guidance concerning suspicious order monitoring to the HDA, which has published guidance documents for members on suspicious order monitoring, reporting requirements, and diversion of controlled substances.

205. In addition, the DEA Office of Diversion Control sent letters dated September 27, 2006 and December 27, 2007 to all registered distributors providing guidance on suspicious order monitoring of controlled substances and the responsibilities of registrants to conduct due diligence on customers of controlled substances.

206. The September 27, 2006 letter reminded registrants that they are required by law to exercise due diligence to avoid filling orders that may be diverted into the illicit market. It explained that as part of the legal obligation to maintain effective controls against diversion, distributors are required to exercise due care in confirming the legitimacy of all orders prior to filling. It also described indicia of diversion, including orders of excessive quantities of a limited variety of controlled substances, disproportionate ratios of controlled substances to non-

controlled prescription drugs, excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs, and orders of the same controlled substance from multiple distributors. The letter went on to describe what questions should be answered by a customer when attempting to determine whether an order is suspicious.

207. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to DEA registrants providing guidance and reiterating the legal requirements. The letter reminded registrants that suspicious orders must be reported promptly and simply on monthly transaction reports. It also advised that registrants must perform independent analyses of suspicious orders prior to the sales to determine if diversion appears likely, and that filing suspicious order reports and then completing the sales does not absolve registrants from legal responsibility. Finally, the letter directed registrants to review a recent DEA action that addressed criteria in determining suspicious orders and the obligation to maintain effective controls against diversion.

208. The Distributor Defendants also were notified by their own industry group, the HDMA, which published Industry Compliance Guidelines entitled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," which emphasized the responsibilities of each member of the supply chain in distributing controlled substances. These industry guidelines further stated that "At 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."

209. The Distributor Defendants have acknowledged the magnitude of the problem and their legal responsibilities to prevent diversion, and they have issued statements assuring the public they were supposedly undertaking a duty to curb the opioid epidemic.

210. For example, a Cardinal executive claimed that it uses "advanced analytics" to monitor its supply chain and that Cardinal was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

211. Similarly, McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and that it is "deeply passionate about curbing the opioid epidemic in our country."

212. Based on such assurances, in addition to the obligations imposed by law, the Distributor Defendants had a duty to protect the public against diversion from their supply chains. Despite these types of statements, however, the Distributor Defendants have knowingly or negligently allowed diversion. As a result of their misconduct, the Distributor Defendants have paid numerous civil fines and other penalties to state and federal regulators, including actions by the DEA for violations of the CSA.

213. For example, in 2008, Cardinal paid a $34 million penalty to settle allegations by the DEA about opioid diversion taking place at seven of its warehouses around the United States. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in Florida. And in December 2016, the U.S. Department of Justice announced another $34 million settlement with Cardinal for civil penalties under the CSA. In connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator had warned Cardinal against selling opioids to a particular pharmacy in Florida that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or to cease the supply of drugs to the suspect pharmacy. Instead, Cardinal's opioid shipments to the pharmacy *increased*—to almost 2 million doses of oxycodone in one year, while other comparable pharmacies received approximately 69,000 doses per year.

214. Similarly, in May 2008, McKesson entered into a settlement agreement with the DEA to settle claims that it had failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in the diversion of millions of doses of controlled substances. McKesson agreed to pay a $13.25 million civil fine. It was subsequently revealed that McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective that at one of its facilities in Colorado, between 2008 and 2013, it had filled more than 1.6 million orders, but reported just 16 orders from a single customer as suspicious. In 2015, McKesson was again alleged to have "suspicious order reporting practices for controlled substances." In 2017, McKesson agreed to pay a record $150 million civil penalty to the federal government to settle opioid diversion claims relating to diversion at 12 distribution centers in 11 states.

215. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. In 2012, AmerisourceBergen was again investigated for failing to protect against diversion of controlled substances into non-medically necessary channels. It has been reported that the U.S. Department of Justice subpoenaed AmerisourceBergen for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes."

216. Despite these and other penalties and settlements with law enforcement authorities over the past decade, the Distributor Defendants have continued to allow diversion of opioids to maximize their revenue.

3. The Distributor Defendants' Misconduct Facilitated the Opioid Epidemic.

217. Although the Distributor Defendants had the ability and duty to prevent opioid diversion, they continued to allow it, which enabled the opioid crisis to reach epidemic proportions.

218. The Distributor Defendants have supplied huge quantities of prescription opioids in South Dakota with actual or constructive knowledge that the opioids were ultimately being consumed for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but the Distributor Defendants negligently or intentionally failed to do so.

219. The Distributor Defendants knew or should have known that the amounts of opioids that they allowed to flow into South Dakota were far in excess of what could be consumed for medically-necessary purposes in the relevant communities.

220. The Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled substances would have protected against the danger of opioid diversion by: taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; more carefully scrutinizing the pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic factors concerning the increasing demand for narcotic painkillers in certain communities; proactively providing information to pharmacies and retailers about opioid diversion; and at a bare minimum, following applicable statutes, regulations, professional standards, and guidance from government agencies.

221. The Distributor Defendants made insufficient efforts to monitor or to perform due diligence to ensure that the controlled substances they had furnished were not being diverted to illegal uses.

222. On information and belief, the Distributor Defendants compensated certain of their employees, at least in part, based on the volume of their sales of opioids, thus improperly creating incentives that contributed to opioid diversion and the resulting epidemic of opioid abuse.

223. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the market with highly-addictive opioids would allow opioids to fall into the hands of addicts, criminals, vulnerable populations, and other unintended users. It was also reasonably foreseeable to the Distributor Defendants that, when unintended users gained access to opioids, tragic preventable injuries would result, including addiction, overdose, and death in South Dakota and throughout the United States.

224. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the opioid epidemic and would create access to opioids by unauthorized users, which, in tum, would perpetuate the cycle of addiction, demand, and illegal transactions.

225. The Distributor Defendants knew or should have known that a substantial amount of the opioids dispensed in and to South Dakota were being dispensed based on invalid or suspicious prescriptions. It is foreseeable that filling suspicious orders for opioids will cause harm to individual pharmacy customers, third parties, and the State of South Dakota.

226. The Distributor Defendants were aware of widespread prescription opioid abuse throughout the country and in South Dakota, but they nevertheless persisted in a pattern of

distributing commonly abused and diverted opioids in geographic areas and in such quantities, and with such frequency that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

227. The use of opioids by South Dakota citizens who were addicted or who did not have a medically-necessary purpose to use opioids could not occur without the knowing cooperation and assistance of the Distributor Defendants. If the Distributor Defendants had implemented and enforced effective controls to guard against diversion, South Dakota and its citizens would have avoided significant injury.

228. The Distributor Defendants made substantial profits from their distribution of opioids in South Dakota, including opioids that they knew or should have known were being diverted to improper channels.

G. South Dakota Purchasers of Health-Care Insurance Have Sustained Substantial Harm as a Result of All Defendants' Misconduct.

229. Health insurance is an individual or group policy that provides coverage for hospital, medical, surgical, and/or prescription drug benefits.

230. The Manufacturer and Distributor Defendants' misconduct has increased Plaintiff's cost of private health insurance in South Dakota.

231. In 2014, South Dakota residents paid more than $7.5 billion for healthcare, of which almost $2.5 billion was spent on private health insurance. As is true throughout the country, health care costs in South Dakota are increasing at a rate far above core inflation. From 1991 to 2014, South Dakotans spent an average of 5.8% more per year on personal, health-care-related expenses.

232. Insurance premiums—the fees paid to get and keep insurance—have risen at an even more alarming clip. From 2001 to 2014, South Dakota enrollees in private health insurance

have spent 5.9% more per year, increasing the total amount spent per person from $2,053 in 2001 to $4,335 in 2014. The average South Dakota family of four enrolled in private health insurance pays more than $17,000 per year to cover premiums, co-pays, and other health-care related expenses.

233. Many South Dakota employees obtain health insurance through an employer. South Dakota's providers of group health care insurance include: Avera Health Plans, Medica Insurance Company, Sanford Health Plans, South Dakota State Medical Holding Company (Dakotacare), and Wellmark of South Dakota Inc. (d/b/a Blue Cross and Blue Shield of South Dakota).

234. Other South Dakotans obtain individual health insurance. As elsewhere, South Dakotans typically buy individual health insurance when they do not have access to an employer plan and do not qualify for public health insurance like Medicaid or Medicare. South Dakota's providers of individual health insurance include: Avera Health Plans and Sanford Health Plans.

235. Group participants may pay all or part of the premium directly, or their employers may pay all or part of the premium directly. Individual purchasers (or members of their family) pay the entire premium directly. The "deductible" in a health-insurance plan is the amount the insured must pay each period (usually annually) before insurance starts to cover healthcare costs. A "co-pay" is a flat amount the insured pays per claim, such as a doctor visit or prescription. "Co-insurance" is the percentage of a bill that the insured pays under some plans after the deductible is met. Deductibles and co-payments often are higher under individual plans.

236. As a direct and proximate result of the conduct described herein, natural and corporate persons have sustained losses and injuries in the form of higher premiums, deductibles, and co-payments/co-insurance. Health care insurers in South Dakota have paid (and expect to

continue to pay) substantial amounts for opioid prescriptions that would never have been prescribed and/or filled absent all Defendants' misconduct, and have also paid (and expect to continue to pay) substantial amounts for treatment of individuals who became addicted to opioids and/or who became addicted to heroin or other drugs because of opioid use. Many of those individuals who became addicted to opioids—or who became addicted to heroin or other drugs because of opioid use—would never have become addicted or even received access to opioids absent Defendants' conduct described herein. These insurers have also paid for numerous other costs proximately caused by all Defendants' conduct, including care for babies born addicted to opioids, emergency-room treatments, and other claims.

237. Plaintiff purchasers of private health insurance have been damaged as a result of paying prices that are higher as a direct result of all Defendants' misconduct. South Dakota health insurers are easily able to—and do—pass higher costs onto their insureds. Premiums in health-insurance markets do not reflect individual differences in costs, meaning that *all* insureds bear higher costs inflicted by the highest-risk insureds.

238. In South Dakota, as in most other states, insurers charge premiums based on assigned rate classes, a pool of insured individuals with similar health status. Because the premium charged is uniform for the entire risk class, excessive claims experienced by others raise premiums for everyone. This empirical reality makes economic sense. Insurers cannot know *ex ante* if an individual insured will take and become addicted to opioids, with the corresponding costs that ensue for that patient. So insurers charge every insured a higher premium—including the majority of insureds who never take opioids—to pay for the risk of future, opioid-related claims.

239. This is partially because insured patients with opioid abuse or dependence diagnoses cost health insurers more than average patients, in South Dakota and nationwide. In 2015, total annual per-patient charges (the costs of providing a health service) and allowed amounts (the maximum an insurer will pay for a covered health service) for services for patients with opioid abuse and dependence diagnoses were 550% higher than for the average insured patient.

240. Thus, as the opioid crisis has barreled forward across the country and in South Dakota, so has the pressure on insurance companies to raise premiums. Indeed, by one estimate, private insurance claims related to opioid dependence rose by an astonishing 3,200% nationwide from 2007 to 2014, and upon information and belief by a comparable percentage in South Dakota, with the brunt of this burden falling on those aged 19 to 35. This makes sense in light of the demonstrated increase in opioid-related emergency room visits and treatment center admissions, along with the growth in the percentage of privately insured Americans and South Dakotans over this period. Similarly, professional charges and allowed amounts grew by over 1,000% for patients diagnosed with opioid abuse or dependence from 2011 to 2015, further increasing insurance companies' incentive to increase their customers' rates.

241. The costs that all Defendants' conduct inflicted on the insurance market cannot be and have not been confined to opioid users because of such risk pooling. Empirical evidence evaluated by leading economists confirms this common-sense conclusion.

H. All Defendants Acted Wantonly, Willfully, Outrageously, and with Reckless Disregard for the Consequences of Their Actions.

242. When engaging in the conduct described herein, all Defendants acted wantonly, willfully, outrageously, and with reckless disregard for the consequences of their actions.

243. All Defendants knew and should have known about these harms that their unlawful and unfair business practices have caused and continue to cause in South Dakota. The 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. They knew—and, indeed, intended—that their misrepresentations would persuade doctors in South Dakota to prescribe and patients in South Dakota to use their opioids for chronic pain. Likewise, the Distributor Defendants knew of the risks and signs of diversion, and yet failed to take action that would have prevented or mitigated opioid diversion. All Defendants also had access to and watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death.

244. At all relevant times, all Defendants knew that the likely consequences of their actions would be that millions of individuals would become addicted to opioids and other drugs, which in turn would destroy countless families and communities across the nation and in South Dakota, while imposing tremendous medical and other costs that would be borne by all purchasers of health insurance.

245. Despite this knowledge, Defendants engaged in the conduct described herein for the purpose of obtaining billions of dollars in windfall profits, while destroying the lives of countless South Dakotans.

246. The Manufacturer Defendants' actions are not excused by the fact that their drug labels may have allowed or did not exclude the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give license to misrepresent the risks and benefits of opioids. Indeed, the Manufacturer Defendants' misrepresentations were directly contrary to

pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

247. Nor is Defendants' causal role broken by the involvement of doctors. The 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. The Manufacturer Defendants also were able to harness and hijack what doctors wanted to believe—namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

248. While insurance companies may refuse to cover ineffective or dangerous treatments, they too were misled by Defendants' pervasive campaign to convince the healthcare industry that opioids were effective and necessary for long-term pain management. Insurers paid Defendants for the care ordered by patients' doctors, as well as for the resulting costs of addiction: treatment, emergency-room care, and other claims. Those costs were ultimately passed along to Plaintiff and all Class Members.

FACTS SPECIFIC TO PLAINTIFF

249. Plaintiff is a natural person and resident and citizen of the State of South Dakota.

250. Since at least 2015, Plaintiff has purchased health insurance through the Federally Facilitated Marketplace from Blue Cross Blue Shield of Nebraska and Aetna, incurring monthly premiums in the minimum amount of $144.28.

CLASS ALLEGATIONS

251. **Class Definition**: Plaintiff brings this action pursuant to Fed. R. Civ. P. 23(b)(2) and (3) on behalf of himself and a Class of similarly situated individuals, defined as follows:

> All persons (including natural persons and entities) who purchased health insurance policies in South Dakota from 1996 through the present; and all persons who paid for any portion of employer-provided health insurance from 1996 through the present.

Excluded from the Class are: (1) any Judge or Magistrate presiding over this action and members of their families; (2) Defendants, Defendants' subsidiaries, parents, successors, predecessors, and any entity in which the Defendants or their parents have a controlling interest and their current, former, purported, and alleged employees, officers, and directors; (3) counsel for Plaintiff and Defendants; (4) persons who properly execute and file a timely request for exclusion from the Class; (5) the legal representatives, successors, or assigns of any such excluded persons; and (6) all persons who have previously had claims similar to those alleged herein finally adjudicated or who have released their claims against Defendants.

252. **Numerosity**: The exact number of Class Members is unknown to Plaintiff at this time, but it is clear that individual joinder is impracticable. As of 2014, the Centers for Medicare and Medicaid Services estimated that tens of thousands of people in South Dakota enrolled in private health insurance. Ultimately, the Class Members will be easily identified through third-party business records.

253. **Commonality and Predominance**: There are many questions of law and fact common to the claims of Plaintiff and the Class, and those questions predominate over any questions that may affect individual Class Members. Common questions for the Class include, but are not necessarily limited to the following:

- whether Defendants made material misrepresentations regarding the benefits and risks of their products;
- whether Defendants acted intentionally with respect to the foregoing;
- whether Defendants were negligent in the distribution of their products;
- whether Defendants acted in violation of state and federal law;

- whether the Class is entitled to restitution and/or disgorgement, in addition to, or as a substitute for, damages under South Dakota law; and
- whether Plaintiff is entitled to damages and/or injunctive relief.

254. **Typicality**: Plaintiff's claims are typical of the claims of all the other Class Members. Plaintiff and the Class Members sustained substantially similar damages as a result of Defendants' uniform wrongful conduct, based upon the same interactions that were made uniformly with Plaintiff and the public.

255. **Adequate Representation**: Plaintiff will fairly and adequately represent and protect the interests of the other Class Members. Plaintiff has retained counsel with substantial experience in prosecuting complex litigation and class actions. Plaintiff and her counsel are committed to vigorously prosecuting this action on behalf of the Class Members and have the financial resources to do so. Neither Plaintiff nor her counsel has any interest adverse to those of the other Class Members.

256. **Policies Generally Applicable to the Class**: Defendants have acted and failed to act on grounds generally applicable to Plaintiff and the other Class Members, requiring the Court's imposition of uniform relief to ensure compatible standards of conduct toward the Class.

257. **Superiority**: This case is also appropriate for class certification because class proceedings are superior to all other available methods for the fair and efficient adjudication of this controversy as joinder of all parties is impracticable. The damages suffered by individual Class Members will likely be relatively small compared to the burden and expense of individual prosecution of the complex litigation necessitated by Defendants' actions. Thus, it would be virtually impossible for individual Class Members to obtain effective relief from Defendants' misconduct. Even if Class Members could sustain such individual litigation, it would still not be preferable to a class action, because individual litigation would increase the delay and expense to

all parties due to the complex legal and factual controversies presented in this Complaint. By contrast, a class action presents far fewer management difficulties and provides the benefits of single adjudication, economies of scale, and comprehensive supervision by a single Court. Economies of time, effort, and expense will be fostered and uniformity of decisions ensured.

258. Plaintiff reserves the right to revise the Class Definition and Class Allegations based on further investigation, including facts learned in discovery.

CAUSES OF ACTION

COUNT I:
Violations of South Dakota's Deceptive Trade Practices and Consumer Protection Act, S.D. Codified Laws § 37-24-1, *et seq.*
(Against All Defendants)

259. Plaintiff repeats, reiterates, and realleges each and every allegation contained in the paragraphs above as if fully set forth herein.

260. Plaintiff brings this Count on behalf of all members of the Class who are or have been residents of South Dakota at any relevant time.

261. The South Dakota Deceptive Trade Practices and Consumer Protection Act ("Deceptive Trade Practices Act") prohibits a person, corporation or any other legal entity from knowingly using or employing any deceptive act or practice or any misrepresentation, or from concealing, suppressing or omitting any material fact, in connection "with the sale or advertisement of any merchandise."

262. Defendants violated the Deceptive Trade Practices Act because they knowingly engaged in false, misleading, fraudulent and deceptive business acts and practices in connection with the sale and advertisement of merchandise, as set forth above, and as a result of those unlawful acts and practices, Plaintiff and Class Members were adversely affected and suffered monetary loss.

263. Defendants' business acts and practices as described in this Complaint are fraudulent and deceptive, used misrepresentations and false promises, concealed and omitted material facts and violate South Dakota law because the acts and practices deceived doctors, insurers, and consumers in South Dakota, led to the advertisement and sale of opioids that should not have been marketed or sold, and thereby caused Plaintiff and Class Members to pay higher insurance premiums.

264. The Manufacturer Defendants knew and should have known at the time of making or disseminating the misleading statements described above, or causing these statements to be made or disseminated, that such statements were false, misleading, and deceptive. Their omissions, which are deceptive and misleading in their own right, render even seemingly truthful statements about opioids false and misleading. All of this conduct, separately and collectively, was likely to deceive South Dakota doctors, who prescribed opioids based on the Manufacturer Defendants' deception, and insurers who purchased, or covered the costs for the purchase of, opioids for chronic pain.

265. The Manufacturer Defendants' business acts and practices as described in this Complaint are knowing and willful violations of Deceptive Trade Practices Act.

266. In addition, the Distributor Defendants were in the position to implement effective business practices to guard against diversion of the highly-addictive opioid products they sell and distribute. They repeatedly purported to have done so. But those representations were untrue. Instead, they profited off the opioid epidemic by flouting anti-diversion laws, while burdening South Dakota consumers by their conduct and profiting from the sale of prescription opioids in quantities that far exceeded the number of prescriptions that could reasonably have been used for

legitimate medical purposes, despite having notice or actual knowledge of widespread opioid diversion from prescribing records, pharmacy orders, field reports, and sales representatives.

267. The Distributor Defendants' conduct constitutes an unlawful, false, fraudulent, and/or deceptive business practice, and includes the concealment, suppression and omission of material facts in carrying out their business practices, all in connection with the sale or advertisement of merchandise, including the Distributor Defendants' filling of suspicious or invalid orders for prescription opioids at both the wholesale and retail level; failing to maintain effective controls against opioid diversion; failing to operate an effective system to disclose suspicious orders of controlled substances; failing to report suspicious orders of controlled substances; failing to reasonably maintain necessary records of opioid transactions; and deliberately ignoring questionable and/or obviously invalid prescriptions and filling them anyway—all while purporting to have world-class and compliant systems, controls, and practices.

268. The Distributor Defendants' business acts and practices as described in this Complaint are knowing and willful violations of Deceptive Trade Practices Act.

269. All Defendants' fraudulent, unlawful, false, misleading, and/or deceptive activity alleged herein caused insurers to pay for ineffective and dangerous treatments, as well as the increased costs associated with opioid addiction. Those costs were passed on to Plaintiff and members of the Class in the form of increased insurance premiums.

270. As a direct and proximate result of the foregoing business acts and practices of Defendants in violation of the Deceptive Trade Practices Act, Plaintiff and Class Members have suffered or will suffer a monetary loss in the payment of increased insurance premiums, which

they would not have paid if Defendants had not engaged in the violations of Deceptive Trade Practices Act described in this Complaint.

271. As a direct and proximate result of the foregoing acts and practices, all Defendants have received, or will receive, income, profits, and other benefits, which they would not have received if they had not engaged in the violations of Deceptive Trade Practices Act described in this Complaint.

COUNT II:
Violations of the Racketeering Influenced And Corrupt Organizations Act, 18 U.S.C. §§ 1961, *et seq.*
(Against All Defendants)

272. Plaintiff repeats, reiterates, and realleges each and every allegation contained in the paragraphs above as if fully set forth herein.

273. At all relevant times, each Defendant is and has been a "person" within the meaning of 18 U.S.C. § 1961(3), because they are capable of holding, and do hold, "a legal or beneficial interest in property."

274. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity . . . " 18 U.S.C. § 1962(c). Each Defendant conducted and participated in the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c).

A. The Enterprise

275. Defendants formed an association-in-fact Enterprise and participated in the affairs of the Enterprise to increase the market for opioids through a pattern of racketeering activity. The Enterprise consists of (1) the Manufacturer Defendants, including their employees and agents,

(2) Front Groups, including their employees and agents, (3) the KOLs, and (4) the Distributor Defendants. The Enterprise's purpose was to fabricate a new market for opioids in chronic pain treatment and sell as many opioid products as possible through deception and willfully ignoring requirements to curtail the illegal drug market that the Enterprise's conduct created.

276. To accomplish this purpose, the Enterprise systematically misrepresented to the general public, doctors, and insurers the risks of using opioids for chronic pain, and flouted requirements to investigate and prevent the ensuing waive of suspicious orders. The Manufacturer Defendants, Front Groups, KOLs, and Distributor Defendants all conducted and participated in the affairs of the Enterprise by distributing false statements through the wires or mail or by violating the Controlled Substances Act. This campaign of illegality and misinformation translated into profits for all Defendants, and funding and payments to Front Groups and KOLs.

277. The participants in the Enterprise are systematically linked through contractual relationships, financial ties, and continued coordination of activities, spearheaded by the Manufacturer Defendants. There is regular communication between the Manufacturer Defendants, Distributor Defendants, Front Groups, and KOLs in which information is shared. This communication typically occurs, and continues to occur, through the use of the wires and mail in which the participants share information regarding overcoming objections to the use of opioids for chronic pain.

278. Distributor Defendants were willing participants in, and beneficiaries of, the Enterprise's campaign of deception. Distributor Defendants profited from the Enterprise's newly-expanded opioid market, and furthered the Enterprise's goal of profiting from that market by flouting legal requirements to report suspicious ordering. By the Distributor Defendants'

violating the CSA's requirements to prevent diversion, all Defendants were able to profit from both the legal and illegal drug markets created by the Enterprise's success in establishing the long-term opioid treatment market and the ensuing addiction crisis. Distributor Defendants were aware of the campaign of deception engineered by the Manufacturing Defendants, KOLs and Front Groups, but sought only to profit from the Enterprise's deception.

279. The Distributor Defendants are intimately connected with the Manufacturer Defendants through their industry organization, the HDA. According to the HDA's website, the HDA's executive committee includes an executive from each Distributor Defendant. Each Manufacturer Defendant is also a member of HDA.

280. HDA specifically advertises its benefits as a forum for meeting with distributors. The Distributor Defendants used membership in the HDA as an opportunity to create working relationships with Manufacturer Defendants. HDA, in turn, is a member of PCF. Each Manufacturer Defendant, or a related company, is a member of PCF.

281. Together, Defendants lobbied state governments and Congress to undermine enforcement and legal limitations that would otherwise have interfered with increased opioid sales. Between 2006 and 2015, the PCF spent more than $740 million lobbying to influence local, state and federal governments, including on opioid-related measures. The HDA and PCF lobbied for passage of the Ensuring Patient Access and Effective Drug Enforcement Act, which hobbled the DEA's ability to suspend or revoke registrations, permitting Distributor Defendants to further the Enterprise's goal of increasing opioid sales without regard to legal requirements or the effects on South Dakota residents. Defendants' coordination through the HDA, PCF, and lobbying activities—while not racketeering activity—evidence Defendants' knowledge of the structure of the Enterprise and purposeful participation in it.

282. At all relevant times, Front Groups were knowing and willing participants in the Enterprise's conduct, and reaped benefits from that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme. But for the Enterprise's unlawful scheme, Front Groups would have had the incentive to disclose the deceit by the Manufacturer Defendants to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Enterprise's scheme and reaped substantial benefits.

283. At all relevant times, KOLs were knowing and willing participants in the Enterprise's conduct, and reaped profits from that conduct. The Manufacturer Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. The Manufacturer Defendants' support helped these doctors become respected industry experts. And, as they rose to prominence, these doctors touted the benefits of opioids to treat chronic pain, repaying the Manufacturer Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front Groups were engaged in the same scheme, to the detriment of Plaintiff and Class Members. But for the Enterprise's unlawful scheme, KOLs would have been incentivized to disclose the deceit, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs perpetuated the Enterprise's scheme, and reaped substantial benefits.

284. Furthermore, as public scrutiny and media coverage have focused on how opioids have ravaged communities throughout the United States, the Front Groups and KOLs did not challenge the Manufacturer Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits.

285. The Front Groups and KOLs participated in the conduct of the Enterprise, sharing the common purpose of marketing opioids for chronic pain and, through a pattern of racketeering activity including multiple instances of wire and mail fraud, knowingly made material misstatements to physicians, consumers, and the general public in furtherance of the scheme, including that:

- it was rare, or there was a low risk, that the Manufacturer Defendants' opioids could lead to addiction;[1]
- the signs of addiction were actually signs of undertreated pain, known as "pseudoaddiction," that should be treated by more opioids;[2]
- doctors and patients could increase opioid dosages indefinitely without risk;[3] and
- long-term opioid use improved patients' function and quality of life.[4]

286. Without the misrepresentations of the Front Groups and KOLs, who were perceived as neutral and scientific, the Defendants alone could not have accomplished the purposes of the Enterprise.

287. During the time period described in this Complaint, the Manufacturer Defendants exerted control over the Enterprise and participated in the operation and management of the affairs of the Enterprise, directly or indirectly, in the following ways:

- The Manufacturer Defendants created a body of deceptive and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the

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1 APF, *Treatment Options: A Guide for People Living with Pain*, *supra* ¶ 72(b) APF, *Policymaker's Guide*, discussed *supra* ¶ 72(h).

2 Fishman, *Responsible Opioid Prescribing*, *supra* ¶ 85(a); APF, *Treatment Options*, *supra* ¶ 85(h).

3 APF, *Treatment Options*, *supra* ¶ 104(b); Endo, *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell Portenoy, ed.), *supra* ¶ 104(d); APF, *Policymakers' Guide*, *supra* ¶ 104(g).

4 Fishman, *Responsible Opioid Prescribing*, *supra* ¶ 126(e); APF, *Treatment Options*, *supra* ¶ 128(f), NIPC website & educational programs, *supra* ¶ 126(g),(h).

benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

- The Manufacturer Defendants selected, cultivated, promoted, and paid the KOLs based solely on their willingness to communicate and distribute the Manufacturer Defendants' messages about the use of opioids for chronic pain;
- The Manufacturer Defendants provided substantial opportunities for KOLs to participate in research studies on topics the Manufacturer Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;
- The Manufacturer Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, typically over meals or at conferences;
- The Manufacturer Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;
- The Manufacturer Defendants sponsored CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;
- The Manufacturer Defendants developed and disseminated pro-opioid treatment guidelines;
- The Manufacturer Defendants encouraged Front Groups to disseminate their pro-opioid messages to groups targeted by the Manufacturer Defendants, such as veterans and the elderly, and then funded that distribution;
- The Manufacturer Defendants concealed their relationship to and control of Front Groups and KOLs from the State and the public at large;
- The Manufacturer Defendants intended that Front Groups and KOLs would distribute, through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain; and
- The Manufacturer Defendants, Front Groups, and KOLs minimized the fact that opioids were being diverted due to the Distributor Defendants' misconduct.

288. During the time period described in this Complaint, the Distributor Defendants conducted and participated in the affairs of the Enterprise in the following ways:

- The Distributor Defendants violated the Controlled Substances Act and caused massive diversion of opioids by failing to investigate suspicious orders;

- The Distributor Defendants violated the Controlled Substances Act by failing to maintain adequate controls against diversion of prescription opioids;
- The Distributor Defendants refused to identify, investigate or report suspicious orders of prescription opioids being diverted into the illicit drug market; and
- The Distributor Defendants made false and misleading statements attempting to minimize their responsibility for preventing diversion and representing that they complied with the law.

289. The scheme had a hierarchical decision-making structure that was headed by the Manufacturer Defendants. The Manufacturer Defendants controlled representations made about their drugs, and doled out funds to Front Groups and payments to KOLs to ensure that their representations were consistent with the Manufacturer Defendants' messaging nationwide and throughout the State of South Dakota. Front Groups were dependent on the Manufacturer Defendants for their financial support, and KOLs were professionally dependent on the Manufacturer Defendants for the development and promotion of their careers. The Distributor Defendants worked hand-in-hand with the Manufacturer Defendants to limit government enforcement and increase sales of opioids through industry groups like the HDA and the PCF.

290. For the foregoing reasons, all Defendants, Front Groups, and KOLs were each willing participants in the Enterprise, had a common purpose and interest in furthering opioid prescribing and increasing sales of opioids without regard to diversion, and functioned within a structure designed to effectuate the common purpose.

291. The scheme devised and implemented by all Defendants, as well as other members of the Enterprise, amounted to a common course of conduct intended to encourage the prescribing and use of opioids for chronic pain and thereby secure payment from insurers for Defendants' opioids. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

292. The Enterprise was intended to and did affect interstate commerce, in that the statements made by the members of the Enterprise were passed through the wires or mail over state lines, and that the Enterprise increased sales of opioids through the channels of interstate commerce.

293. The impacts of the Enterprise continue to be felt, as opioids continue to be prescribed and used for chronic pain. Plaintiff continues to pay for the fallout from the Enterprise as insurers pass on the costs of opioid addiction and treatment.

B. Pattern of Racketeering Activity

294. Racketeering activity includes mail fraud, 18 U.S.C. § 1341, and wire fraud, 18 U.S.C. § 1343. 18 U.S.C. § 1961.

295. The Manufacturer Defendants, Front Groups, and KOLs all made misrepresentations detailed above in service of a scheme to deceive which was intended to, and did, deceive consumers, doctors and insurers about the safety and efficacy of opioid use. All were passed through the wires and/or mail, and constituted predicate acts within the meaning of RICO, including:

- The dissemination via wires and mail of APF's *Treatment Options* beginning in 2007 and continuing afterward, which misrepresented the risks of addiction, promulgated the false concept of pseudoaddiction, falsely represented that doctors and patients could increase opioid dosages without risk, and falsely represented that long-term opioid use could improve patients' quality of life;

- The dissemination via wires and mail of APF's *Policymaker's Guide* beginning in 2011 and continuing afterward, which misrepresented the risks of addiction and falsely represented that doctors and patients could increase opioid dosages indefinitely without risk;

- The dissemination via wire of Endo's pamphlet, edited by Russel Portenoy, *Understanding Your Pain*, available on Endo's website throughout the time period described in this Complaint, which falsely represented that doctors and patients could increase opioid dosages without risk;

- The dissemination via wires and mail of *Responsible Opioid Prescribing*, beginning in 2007 and afterward, which promulgated the false concept of pseudoaddiction and falsely represented that long-term opioid use could improve patients' quality of life; and

- The dissemination via wires and mail of the misrepresentations and false statements described above in paragraphs 72, 85, 95, 104, 111–119, 126, and 137–146.

296. The Distributor Defendants engaged in the violations of the law detailed above to enable the Enterprise to profit from its deceptive creation of the expanded market for opioids. Distributor Defendants' activities were coordinated and planned with the Manufacturer Defendants, as evidenced by coordinated lobbying efforts to weaken DEA enforcement. Distributor Defendants, through their relationships with the Manufacturer Defendants, were aware of the Enterprise's deceptive activity and sought only to enable the Enterprise to profit from it. To do so, Distributor Defendants engaged in the following predicate acts:

- Cardinal's violations of the CSA and federal law concerning the distribution of controlled substances—described above in paragraph 215—in 2008, 2012, and 2016, which resulted in fines, penalties or settlements with the DEA;

- McKesson's violations of the CSA and federal law concerning the distribution of controlled substances—described above in paragraph 216—in 2008 and 2017 which resulted in fines, penalties or settlements with the DEA; and

- AmerisourceBergen's violations of the CSA and federal law concerning the distribution of controlled substances—described above in paragraph 217—in 2007 and 2012 that resulted in penalties and an investigation by the Department of Justice.

297. Many of the precise dates of the Defendants' coordination have been hidden and cannot be alleged without access to the Defendants' records. Indeed, an essential part of the successful operation of the Enterprise alleged herein depended upon secrecy.

298. The Manufacturer Defendants', the Front Groups', and KOLs' deceptive activities were coordinated and planned in advance, as evidenced by the Front Groups' and KOLs' misleading statements described above that were supported, funded, or compensated by the Manufacturer Defendants. Many of the precise dates of the Manufacturer Defendants', Front

Groups', and KOLs' agreement to violate RICO, however, have been hidden and cannot be alleged without access to the Manufacturer Defendants', the Front Groups', and the KOLs' books and records. Indeed, for the deception to be successful, the coordination between the Manufacturer Defendants and the seemingly-independent Front Groups and KOLs had to remain secret.

299. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including doctors, insurers, and consumers in South Dakota. The Manufacturer Defendants, the Front Groups, and the KOLs calculated and intentionally crafted the opioids marketing scheme to increase and maintain their increased profits, without regard to the effect such behavior had on Plaintiff and Class Members. The Distributor Defendants knowingly and intentionally assisted the Enterprise in cashing in on the market that the Enterprise's deceptive conduct created.

300. By intentionally misrepresenting the risks and benefits of using opioids for chronic pain, subsequently failing to disclose such practices, and profiting off of the legal and illegal market that deception created, the Manufacturer Defendants, the Distributor Defendants, the Front Groups, and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

C. Damages

301. Defendants' violations of law and their pattern of racketeering activity have directly and proximately caused Plaintiff and Class Members to be injured in their business or property in the form of increases in insurance premiums.

302. But for Defendants', the Front Groups', and the KOLs' racketeering activities, Plaintiff and Class Members would not have paid the increases in insurance premiums associated with the opioid epidemic. It was foreseeable that Defendants' racketeering activities would result in insurers' losses in the form of (1) overpayment for ineffective drugs, and (2) massive healthcare costs associated with opioid addiction, and that those costs would be passed on to Plaintiff and Class Members.

303. Plaintiff and Class Members seek all legal and equitable relief permitted by RICO, including equitable relief, actual damages, treble damages, and attorneys' fees. 18 U.S.C. § 1964.

COUNT III:
Conspiracy to Violate the Racketeering Influenced and Corrupt Organizations Act, 18 U.S.C. §§ 1961, *et seq.*
(Against All Defendants)

304. Plaintiff repeats, reiterates, and realleges each and every allegation contained in the paragraphs above as if fully set forth herein.

305. At all relevant times, each Defendant is and has been a "person" within the meaning of 18 U.S.C. § 1961(3), because they are capable of holding, and do hold, "a legal or beneficial interest in property."

306. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. *See* 18 U.S.C. § 1962(d).

307. Defendants conspired to violate RICO, as alleged more fully above, by agreeing to conduct and participate in the affairs of the Enterprise detailed above.

A. The Enterprise

308. Plaintiff incorporates by reference Paragraphs 276 through 294 above concerning the Enterprise.

309. Each Defendant, KOL and Front Group was aware of the scope and nature of the Enterprise and intended to participate in it. The Manufacturer Defendants directed and supported the KOLs and Front Groups in disseminating false and misleading information about the necessity and risks of opioids, such as the publications supported and financed by the Manufacturer Defendants referenced in Count II above. The Distributor Defendants were aware of this deception through their relationships with the Manufacturer Defendants, including through the HDA and PCF's lobbying efforts, and agreed to serve the Enterprise's goals of profiting from this deception.

B. Pattern of Racketeering Activity

310. Plaintiff incorporates by reference Count II above concerning the Enterprise. Defendants agreed to conduct and participate in the affairs of the Enterprise detailed in those paragraphs.

C. Damages

311. Plaintiff incorporates by reference Paragraphs 302 through 304 above concerning the damages caused by the Enterprise.

COUNT IV:
Public Nuisance
(Against All Defendants)

312. Plaintiff repeats, reiterates, and realleges each and every allegation contained in the paragraphs above as if fully set forth herein.

313. South Dakota law prohibits acts or practices that injure or endanger the comfort, repose, health or safety of others, offend public morals, or that render other persons insecure in life or in the use of property, including unlawfully engaging in acts or failing to perform acts that injure or interfere with the right to life, safety, health and the use of property of the entire community, or any considerable numbers of persons in South Dakota.

314. Defendants' conduct as described herein constitutes a public nuisance under South Dakota law.

315. By the unlawful acts described in this Complaint, each Defendant, acting individually and in concert, has engaged in conduct or omissions that is injurious to the life, comfort, health and property of, and interferes with the rights of property of, entire communities or neighborhoods or of any considerable number of persons in South Dakota.

316. All Defendants' actions and omissions caused and continue to cause the public health epidemic described above, and that harm outweighs any offsetting benefit.

317. The Manufacturer Defendants knew and should have known that their promotion of opioids was false and misleading and that their deceptive marketing scheme and other unlawful, unfair, and fraudulent actions would create or assist in the creation of the public nuisance—*i.e.*, the opioid epidemic. The Manufacturer Defendants' actions and omissions were, at the very least, a substantial factor in opioids becoming widely available and widely used. Their actions and omissions were, at the very least, a substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain.

318. The Distributor Defendants knew and should have known that the rampant diversion of opioids that they enabled would create or assist in the creation of the public nuisance—*i.e.*, the opioid epidemic. The Distributor Defendants' actions and omissions were, at the very least, a substantial factor in opioids becoming widely available and widely used. Their actions and omissions were, at the very least, a substantial factor in the widespread diversion of opioids throughout South Dakota.

319. Without all Defendants' actions and omissions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.

320. All Defendants' actions and omissions have increased the cost of insuring individuals, and Plaintiff and Class Members—who pay insurance premiums—are injured in their property in the form of increases in insurance premiums.

321. Defendants' acts and omissions are unlawful, and they offend and substantially interfere with, or cause damage to the public in, the exercise of rights common to all, in a manner such as to offend the common good and public morals or endanger or injure the property, health, safety or comfort of a considerable number of persons.

322. Defendants' conduct caused injury to Plaintiff and Class Members by inflicting tremendous health care costs that were passed on to Plaintiff and Class Members, and Defendants' conduct will continue to cause such injury to the property of Plaintiff and Class Members if Defendants' conduct is not abated.

323. Plaintiff and Class Members suffered particular harm as purchasers of health insurance distinguishable from the harm suffered by the general public as a result of the public nuisance.

324. The public nuisance—*i.e.*, the opioid epidemic—created, perpetuated, and maintained by all Defendants can be abated and further recurrence of such harm and inconvenience, including the particular harm to Plaintiff and Class Members, can be abated.

325. Plaintiff requests an order directing Defendants to pay all particular damages caused to Plaintiff and Class Members by the public nuisance that they created, providing for

abatement of the public nuisance that Defendants created or assisted in the creation of, and enjoining Defendants from future violations of South Dakota law.

COUNT V:
Unjust Enrichment
(Against All Defendants)

326. Plaintiff repeats, reiterates, and realleges each and every allegation contained in the paragraphs above as if fully set forth herein.

327. To the detriment of Plaintiff and Class Members, all Defendants have been, and continue to be, unjustly enriched as a result of the unlawful and/or wrongful conduct alleged herein.

328. All Defendants have voluntarily and knowingly accepted and retained the inflated prices paid for their opioid products with full knowledge that the prices were inflated and that they were not lawfully entitled to such prices.

329. Plaintiff and Class Members bear the costs of the benefits conveyed to all Defendants in the form of increased insurance premiums.

330. Between Defendants and Plaintiff/Class Members, it would be unjust for Defendants to retain the benefits attained by their wrongful actions.

331. All Defendants have been unjustly enriched, in the form of inflated prices, at the expense of Plaintiff and Class Members who are entitled in equity to disgorgement and restitution of Defendants' wrongful profits, revenue, and benefits, to the extent, and in the amount deemed appropriate by the Court, and any other relief the Court deems just and proper to remedy Defendants' unjust enrichment.

COUNT VI:
Negligence
(Against All Defendants)

332. Plaintiff repeats, reiterates, and realleges each and every allegation contained in the paragraphs above as if fully set forth herein.

333. Each Defendant has a duty to exercise reasonable care in manufacturing, marketing, selling, and distributing highly dangerous medications in the State of South Dakota.

334. Defendants owe that duty to Plaintiff and Class Members. Defendants' profits as manufacturers and distributors are inextricably bound with the industry of health insurance, and any reasonably prudent manufacturer is aware of the basic mechanics of the insurance industry by which costs are passed on to others in a risk pool through premiums.

335. The Manufacturer Defendants knew and should have known that misleading doctors and insurers about the safety and efficacy of opioids for long-term pain treatment would cause significant costs, not just to those for whom opioids were an ineffective and dangerous treatment, but to insurers that absorb healthcare costs, and thus ultimately to insurance customers, including Plaintiff and Class Members. Similarly, the Distributor Defendants knew and should have known that allowing diversion of opioids would cause significant costs to consumers, insurers, and insurance customers like Plaintiff and Class Members.

336. The Manufacturer Defendants breached their duty to Plaintiff and Class Members through their false and misleading promotion of opioids and their deceptive marketing scheme, misrepresenting the nature of the drugs and aggressively promoting them for chronic pain.

337. The Distributor Defendants breached their duty to Plaintiff and Class Members to conform their behavior to the legal standard of reasonable conduct under the circumstances, in the light of the apparent risks, as well as through their failure to comply with South Dakota and federal laws protecting against diversion of controlled substances.

338. All Defendants' conduct caused opioids to become widely available and widely used, and Defendants' actions were, at the very least, a substantial factor in the widespread abuse of opioids. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.

339. As described above, Defendants' breach caused and proximately caused damages to Plaintiff and Class Members.

COUNT VII:
Civil Conspiracy
(Against All Defendants)

340. Plaintiff repeats, reiterates, and realleges each and every allegation contained in the paragraphs above as if fully set forth herein.

341. The Manufacturer Defendants have engaged, and continue to engage, in a massive marketing campaign to misstate and conceal the risks of treating chronic pain with opioids. Their aggressive marketing campaign enabled Manufacturer Defendants to overcome the longstanding medical consensus that opioids were unsafe for the treatment of chronic pain and resulted in a significant increase in the number of opioids prescribed nationwide.

342. In response to and in conjunction with this increased demand, the Distributor Defendants continuously supplied prescription opioids. These transactions occurred despite the Distributor Defendants having actual or constructive knowledge that they were habitually breaching their common law and statutory duties.

343. None of the Defendants would have succeeded in profiting so significantly from the opioid epidemic without the concerted conduct of the other parties as described in this Complaint.

344. As a result of the concerted action between the Manufacturer Defendants and the Distributor Defendants, South Dakota law was continually violated by the provision of opioids through the supply chain.

345. Defendants formed an agreement to commit the aforementioned overt and unlawful acts with the purpose or object to create a new market for opioids in chronic pain treatment and sell as many opioids as possible through deceptive, unlawful and fraudulent acts and practices.

346. Defendants commissioned the aforementioned overt and unlawful acts.

347. Plaintiff and Class Members incurred damages—in the form of increased health insurance premiums—as the actual and proximate result of Defendants' aforementioned conspiracy.

PRAYER FOR RELIEF

348. Plaintiff, on behalf of herself and the Class, respectfully requests that this Court enter an Order:

349. Declaring that the claims brought by Plaintiff may be maintained as a class action;

350. Declaring that Defendants have engaged in unlawful, fraudulent, deceptive, and unfair business acts and practices in violation of the South Dakota Deceptive Trade Practices and Consumer Protection Act;

351. Ordering Defendants to pay any damages suffered by their unlawful, fraudulent, deceptive, and unfair business practices;

352. Declaring that Defendants have violated RICO;

353. Ordering Defendants to divest themselves of any interest in the Enterprise and restraining Defendants from participating in further violations of RICO;

354. Declaring that Defendants have created a public nuisance and enjoining Defendants to abate the public nuisance that they created.

355. Ordering Defendants to pay all damages caused to Plaintiff and Class Members by the public nuisance that they created.

356. Declaring that Defendants have been unjustly enriched by their conduct at the expense of Plaintiff and Class Members;

357. Ordering Defendants to pay restitution of all benefits and disgorge all profits unjustly retained by Defendants;

358. Declaring that Defendants have acted negligently;

359. Ordering Defendants to pay all damages caused to Plaintiff and Class Members by their negligent actions;

360. Declaring that Defendants have engaged in an unlawful civil conspiracy;

361. Ordering Defendants to pay all damages caused to Plaintiff and Class Members by their civil conspiracy;

362. Awarding treble and punitive damages as appropriate;

363. Awarding injunctive relief as necessary to protect the interests of Plaintiff and the Class;

364. Awarding Plaintiff and the members of the Class their reasonable litigation expenses and attorneys' fees;

365. Awarding Plaintiff and the members of the Class pre- and post-judgment interest, to the extent allowable; and

366. Awarding such other and further relief as equity and justice may require.

JURY TRIAL DEMANDED

367. Plaintiff demands a jury trial for all claims so triable.

Respectfully submitted,

DEBORAH GREEN-KUCHTA, individually and on behalf of all others similarly situated,

Dated: 10/15/18

By: _____
One of Plaintiff's Attorneys

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**Pro Hac Vice* admission to be sought

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