IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

1. PIONEER TELEPHONE COOPERATIVE, INC. EMPLOYEE BENEFITS PLAN;
2. BIOS COMPANIES, INC.WELFARE PLAN;
3. PIONEER TELEPHONE COOPERATIVE, INC. AS PLAN SPONSOR AND FIDUCIARY OF PIONEER TELEPHONE COOPERATIVE, INC. EMPLOYEE BENEFITS PLAN; and
4. BIOS COMPANIES, INC. AS PLAN SPONSOR AND FIDUCIARY OF BIOS COMPANIES, INC. WELFARE PLAN, all individually, and on behalf of all others similarly situated,

Plaintiffs,

vs.

1. PURDUE PHARMA, L.P.;
2 PURDUE PHARMA, INC.;
3. THE PURDUE FREDERICK COMPANY, INC.;
4. ENDO HEALTH SOLUTIONS INC.;
5. ENDO PHARMACEUTICALS, INC.;
6. PAR PHARMACEUTICAL, INC.;
7. PAR PHARMACEUTICAL COMPANIES, INC. f/k/a PAR PHARMACEUTICAL HOLDINGS, INC.;
8. JANSSEN PHARMACEUTICALS, INC.;
9. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
10. JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
11. JOHNSON & JOHNSON;
12. NORAMCO, INC.;
13. TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
14. TEVA PHARMACEUTICALS USA, INC.;
15. CEPHALON, INC.;
16. ALLERGAN PLC f/k/a ACTAVIS PLC;
17. ALLERGAN FINANCE LLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.;
18. WATSON LABORATORIES, INC.;
19. ACTAVIS LLC;
20. ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.;

Case No. CIV-18-994-G

PLAINTIFFS' ORIGINAL COMPLAINT AND JURY DEMAND

21. INSYS THERAPEUTICS, INC.,
22. MALLINCKRODT PLC;
23. MALLINCKRODT LLC;
24. SPECGX LLC;
25. AMERISOURCEBERGEN DRUG CORPORATION;
26. ANDA, INC.;
27. CARDINAL HEALTH, INC.; and
28. MCKESSON CORPORATION,

Defendants.

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COMES NOW Plaintiff Pioneer Telephone Cooperative, Inc. Employee Benefits Plan (the "Pioneer Plan"), Plaintiff Bios Companies, Inc. Welfare Plan (the "Bios Plan") (collectively the "Plaintiff ERISA Plans"), Plaintiff Pioneer Telephone Cooperative, Inc. as Plan Sponsor and Fiduciary of Pioneer Telephone Cooperative, Inc. Employee Benefits Plan ("Plaintiff Pioneer"), Plaintiff Bios Companies, Inc. as Plan Sponsor and Fiduciary of Bios Companies, Inc. Welfare Plan ("Plaintiff Bios") (collectively "Fiduciary Plaintiffs"), all individually, and on behalf of all others similarly situated (hereafter referred to as the "Proposed Classes"), bring this action to prevent future harm and to redress past wrongs to all private employer sponsored self-insured health plans subject to the Employee Retirement Income Security Act of 1974 ("ERISA"), alleging civil violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.*, seeking equitable relief under 29 U.S.C. § 1132(a)(3)(B), and seeking class certification pursuant to Fed. R. Civ. P. 23, against Defendants: Purdue Pharma, L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Johnson & Johnson; Noramco, Inc.; Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Allergan plc f/k/a Actavis plc; Allergan Finance LLC, f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Insys Therapeutics, Inc., Mallinckrodt plc; Mallinckrodt LLC;

SpecGX LLC; AmerisourceBergen Drug Corporation; Anda, Inc.; Cardinal Health, Inc.; and McKesson Corporation. This suit brings claims against the pharmaceutical manufacturers of prescription opioid drugs that engaged in a massive false marketing campaign to drastically expand the market for such drugs and their own market share, and claims against entities in the supply chain that reaped enormous financial rewards by refusing to monitor and restrict the improper distribution of those drugs.

CLASS ALLEGATIONS

1. **Class Definitions:** The Plaintiff ERISA Plans and the Fiduciary Plaintiffs bring this action pursuant to Fed. R. Civ. P. 23 on behalf of themselves, individually, and on behalf of classes of similarly situated plaintiffs. The Proposed Classes are as follows:

A. **Class A:** The Plaintiff ERISA Plans (Pioneer Plan and Bios Plan) bring this action pursuant to Fed. R. Civ. P. 23(b) (3) on behalf of themselves, individually, and on behalf of class of similarly situated ERISA Plans. Class A is defined as follows:

> All self-funded "group health plans" (as defined by 29 U.S.C. § 1191b(a)(1)), in the United States of America and its territories, that are established or maintained by a private employer, that were required to file a Form 5500 for the plan year beginning on or after January 1, 2018, and which have paid health and welfare expenses under the plan for any "participant"[1] or "beneficiary"[2] in any such plan for any opioid that was manufactured and marketed by the Defendants on and after January 1, 1996.
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> Excluded from Class A are: (1) self-funded employee welfare benefit plans (as defined by 29 U.S.C. § 1191b(a)(1)) which are no longer viable as of the date the Class is certified;

[1] As defined in 29 U.S.C. § 1002(7).
[2] As defined in 29 U.S.C. § 1002(8).

(2) self-funded employee welfare benefit plans subject to a collectively bargained for agreement; (3) any Judge or Magistrate presiding over this action and members of their families; (4) 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; (5) all Defendants in their capacities as sponsors, administrators, or fiduciaries of any employee benefit plans, and said employee benefit plans; and (6) counsel for Plaintiffs and Defendants.

B. **Class B:** The Fiduciary Plaintiffs (Plaintiff Pioneer and Plaintiff Bios), in their capacities as plan sponsors, administrators, and fiduciaries, bring this action pursuant to Fed. R. Civ. P. 23(b) (2) on behalf of themselves, individually, and on behalf of class of similarly situated ERISA Plan sponsors and Plan administrators. Class B is defined as follows:

All plan sponsors and plan administrators of all self-funded "group health plans" (as defined by 29 U.S.C. § 1191b(a)(1)), in the United States of America and its territories, that are established or maintained by a private employer, whose group health plan was required to file a Form 5500 for the plan year beginning on or after January 1, 2018, and which have paid health and welfare expenses under the plan for any "participant"[3] or "beneficiary"[4] in any such plan for any opioid that was manufactured and marketed by the Defendants on and after January 1, 1996.

Excluded from Class B are (1) all sponsors and plan fiduciaries of self-funded employee welfare benefit plans (as defined by 29 U.S.C. § 1191b(a)(1)) which are no longer viable as of the date the Class is certified; (2) all sponsors and plan fiduciaries of self-funded employee welfare benefit plans subject to a collectively bargained for agreement; (3) any Judge or Magistrate presiding over this action and members of their families; (4) Defendants, Defendants' subsidiaries,

[3] As defined in 29 U.S.C. § 1002(7).
[4] As defined in 29 U.S.C. § 1002(8).

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; (5) all Defendants in their capacities as sponsors, administrators, or fiduciaries of any employee benefit plans, and said employee benefit plans; and (6) counsel for Plaintiffs and Defendants.

2. **Numerosity:** With respect to the ERISA Plan members in Class A, each class member is required by federal law to file an annual Form 5500 with the Department of Labor and as such the members in Class A are objectively determinable. As provided in an annual Report to Congress published in March 2018, currently the Proposed Class A ERISA Plan members would include approximately 26,800 private employer self-funded plans. Based on the same publicly-available information, with respect to the Fiduciary Plaintiff members in Class B, members in Class B are objectively determinable from the same information. Based on the annual Report to Congress published in March 2018, currently the Proposed Class B members would include approximately 26,800 sponsors and administrators of private employer self-funded plans. The class members in Class A and Class B are geographically dispersed across the nation. Accordingly, the requirement in Fed. R. Civ. P. 23(a)(1) that "the class is so numerous that joinder of all members is impracticable" is met.

3. **Commonality:** There are many questions of fact common to the claims of the Plaintiffs. See "Facts Common to All Claims" below. In addition, because the Plaintiff ERISA Plans, the Fiduciary Plaintiffs, and all the members of the Proposed Classes are subject to federal laws under ERISA (and all the state insurance laws are generally

preempted by ERISA) there are many questions of law and fact common to the claims of the Plaintiffs. In addition:

A. With regard to Class A, the common questions include, but are not limited to, whether Defendants misrepresented the safety and efficacy of opioids, to the financial detriment of the class; whether Defendants overstated the benefits and downplayed the risks of the use of their opioids and aggressively marketed (directly and through key opinion leaders) these drugs to physicians, pharmacy benefit managers and third party administrators; whether distributors failed to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates; defendants' knowledge of and conduct regarding the alleged diversion of these prescription opiates, as well as the manufacturers' alleged improper marketing of such drugs; Defendants' obligations under the Controlled Substances Act to prevent diversion of opiates and other controlled substances into illicit channels whether Defendants failed to adhere to those standards, which caused the diversion of opiates; whether the Defendants engaged in conduct that violates federal RICO statutes in promoting the sales of and suppressing adverse information about opioids; and whether Defendants' unlawful actions have injured and damaged the Plaintiff ERISA Plans. Accordingly, the requirement in Fed. R. Civ. P. 23(a)(2) that "there are questions of law or fact common to the class" is satisfied.

B. With regard to Class B, the common questions include, but are not limited to, whether Defendants' unlawful conduct and continuing violations continue to cause improper losses to the Plans requiring injunctive relief; whether the Plaintiff ERISA Plans have subrogation rights, interests and/or liens; whether, for ERISA Plans that have such rights, with respect to (a) any settlement proceeds that are paid by any of the Defendants named in this lawsuit or (b) damages are awarded, (c) to any plaintiff in any lawsuit in *In re: National Prescription Opiate Litigation*, Cause 1:17-md-2804 (N.D. Ohio) against any of the Defendants named in this lawsuit, in which the plaintiff is an individual ERISA Plan participant or beneficiary of a Plan within Class A, the Plan applicable to that individual plaintiff or plaintiffs has a contractual right of subrogation or lien against any such settlement proceeds or damages award as provided under the applicable Plan documents; and whether declaratory relief is appropriate. Accordingly, the requirement in Fed. R. Civ. P. 23(a)(2) that "there are questions of law or fact common to the class" is satisfied.

4. **Typicality (Class A):** The Plaintiff ERISA Plans' claims are typical of the claims of all the other members in Class A. The Plaintiff ERISA Plans have the same

duties, rights and obligations under ERISA. The Plaintiff ERISA Plans sustained substantially similar injuries and have the same causes of action as a result of Defendants' uniform wrongful conduct, based upon the same conduct and interactions by Defendants that were made uniformly to the Plaintiff ERISA Plans, the Class A members, and the public. The Plaintiff ERISA Plans' claims arise out of the same common course of conduct giving rise to the claims of the other members of Class A. Accordingly, the requirement in Fed. R. Civ. P. 23(a)(3) that "the claims or defenses of the representative parties are typical of the claims or defenses of the class" is satisfied.

5. **Typicality (Class B):** The Fiduciary Plaintiffs' claims are typical of the claims of all the other members in Class B. As Plan sponsors and administrators, the Fiduciary Plaintiffs have the same duties, rights, and obligations under ERISA. As fiduciaries under ERISA, the Fiduciary Plaintiffs have a legal duty and obligation (i) to protect their respective Plans from incurring improper losses and (ii) when a third party causes improper expenses/losses to the Plans, to seek recovery of such expenses/losses from the third party. Because Defendants' uniform conduct has caused the same injury to the ERISA Plans over which the Fiduciary Plaintiffs exercise their duties, and have caused the ERISA Plans to incur improper losses, the Fiduciary Plaintiffs' claims are typical of the claims of other ERISA Plan sponsors and administrators. The Fiduciary Plaintiffs' claims arise out of the same common course of conduct giving rise to the claims of the other members of Class B. Accordingly, the requirement in Fed. R. Civ. P. 23(a)(3) that "the claims or defenses of the representative parties are typical of the claims or defenses of the class" is satisfied.

6. **Adequate Representation:** The Plaintiff ERISA Plans are members of Class A. The Fiduciary Plaintiffs are members of Class B. The Plaintiffs will fairly and adequately represent and protect the interests of the members in the respective Proposed Classes. The Plaintiffs have retained counsel with substantial experience in ERISA and prosecuting complex litigation and class actions. The Plaintiffs and their counsel are committed to vigorously prosecuting this action on behalf of the Proposed Class members and have the financial resources to do so. Neither the Plaintiffs nor their counsel has any interest adverse to those of the other class members. Accordingly, the requirement in Fed. R. Civ. P. 23(a)(4) that "the representative parties will fairly and adequately protect the interests of the class" is satisfied.

7. **Predominance**: The predominance requirement of Fed. R. Civ. P. 23(b)(3) is met because the common questions of law or fact predominate over any questions affecting only individual class members and the Proposed Classes are sufficiently cohesive to warrant adjudication by representation.

8. **Superiority:** Under Fed. R. Civ. P. 23(b)(3), class proceedings are superior to all other available methods for the fair and efficient adjudication of this controversy as requiring each of the over 26,800 members in each of the Proposed Classes to bring a separate cause of action would unnecessarily flood the courts around the country with lawsuits that are brought alleging the same federal causes of action that are based on the Defendants' uniform unlawful actions. In addition, all the class members in Class A are "ERISA Plans" and all the class members in Class B are ERISA Plan sponsors or administrators, they are all governed by the same federal laws under ERISA. Individual

litigation by the Proposed Class members would increase the delay and expense to all parties. 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. In addition, the adjudication of this controversy through a class action will avoid the possibility of inconsistent and possibly conflicting adjudications of the claims asserted herein.

9. **Injunctive and Declaratory Relief under Fed. R. Civ. P. 23(b)(2):** Defendants have acted and failed to act on grounds that apply generally to the Fiduciary Plaintiffs and the members in Class B. With respect to the Fiduciary Plaintiffs' request for injunctive, equitable, declaratory and/or other relief for the members in Class B, class certification under Fed. R. Civ. P. 23(b)(2) is appropriate. As plan sponsors and administrators, the Fiduciary Plaintiffs have a duty under ERISA, 29 USC §§ 1104(a) and 1109, to minimize plan losses and expenses, which require them to act before the Plans incur additional unnecessary and inappropriate costs and expenses caused by Defendants' fraudulent and inappropriate actions. As detailed in this Complaint, Defendants' unlawful conduct and violations are ongoing. Accordingly, under Fed. R. Civ. P. 23(b)(2), final injunctive relief and/or declaratory relief, which is provided by 29 U.S.C. § 1132(a)(3)(A) and (B), is appropriate with respect to the ERISA claim brought by the Fiduciary Plaintiffs.

10. Plaintiffs reserve the right to revise the class definitions and class allegations based on further investigation, including facts learned in discovery.

INTRODUCTION

11. In August 2016, the United States Surgeon General, Vivek Murthy, issued a letter to his colleagues asking for "help to solve an urgent healthcare crises facing America: The Opioid Epidemic." In his letter, the Surgeon General stated that "nearly two decades ago, we were encouraged to be more aggressive about treating pain, often without enough training and support to do so safely. This coincided with heavy marketing of opioids to doctors. Many of us were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain." The Surgeon General correctly noted that "the results have been devastating. Since 1999, opioid overdose has quadrupled and opioid prescriptions have increased markedly - almost enough for every adult in America to have a bottle of pills. Yet the amount of pain reported by Americans has not changed. Now, nearly two million people in America have a prescription opioid use disorder, contributing to increase of heroin use and the spread of HIV and Hepatitis C."

12. On October 27, 2017, the President of the United States declared the opioid epidemic a public health emergency.

13. Given that private employer sponsored health plans cover over 60% of all people in the United States and these employers cover more than 178 million people nationwide, these private health plans are bearing a large percentage of the costs associated with this opioid epidemic. In fact, it is estimated that private employers will spend over $378 billion on health benefits in 2018. As a result, private employers and their sponsored health plans are on the front line of a battle against this opioid epidemic that threatens hundreds of lives daily.

14. Sponsors of self-insured ERISA Plans pay their plans' covered health expenses directly, as the plans incur claims. In contrast, sponsors of fully-insured plans generally pay premiums to insurers and transfer all the responsibility of paying claims to them.[5]

15. The Plaintiff ERISA Plans are private, self-insured employee welfare benefit plans ("ERISA Plans" or "Plans") that provide prescription drug benefits utilized by millions of Americans. Where the patient/plan participant or plan beneficiary is covered by a drug benefit provided through an ERISA Plan, the patient is not primarily responsible for the cost of the drug he or she is prescribed. Although the physician prescribes, the pharmacist dispenses, and the patient takes the medication, it is the ERISA Plan that bears most of the cost of opioid prescriptions. The Plaintiff ERISA Plans pay approximately 80-90% of the cost of an opioid prescription, while the patient/plan participant pays a co-payment for the remainder.

16. The Patient Protection and Affordable Care Act (the "ACA") (P. L. 111-148) requires the Secretary of Labor to provide Congress with an annual report (the "*Report*") containing general information on self-insured employee health benefit plans and financial information regarding employers that sponsor such plans. The *Report* must use data from the Annual Return/Report of Employee Benefit Plan (the "Form 5500") which many self-insured health plans are required to file annually with the Department of Labor (the "Department"). For the year 2015, of health plans filing a 2015 Form 5500, about 26,800 were self-insured. Self-insured plans that filed a Form 5500 covered

[5] *Id.*

approximately 60 million participants in 2015. *See* Report to Congress: Annual Report on Self-Insured Group Health Plans (March 2018).[6]

17. The opioid epidemic and resulting crisis was no accident. The opioid crisis was created by the Defendants.

18. Defendants manufacture, market, sell, and/or distribute prescription opioids, which are powerful, highly addictive narcotic painkillers. The Defendants have engaged in an intentional decades-long, deceptive and misrepresentative marketing scheme to encourage doctors, patients, pharmacy benefit managers and employer sponsored health plans to use opioids to treat long-term and chronic pain and other similar medical conditions. The Defendants falsely minimized the risks of opioids, overstated their benefits, and generated far more opioid prescriptions than there should have been, creating the opioid epidemic.

19. The effectiveness of the Defendants' scheme cannot be denied:

(a) In 2016, 289 million prescriptions for opioids were filled in the United States, a month's supply for every adult. In 2015, there were 101.7 prescriptions per 100 persons. (About four in ten people addicted to opioids are covered by private health insurance.)[7]

(b) Since 1999, there have been more than 351,000 reported opioid-related deaths nationwide. In 2016 alone, opioids were involved in 42,249 overdose

[6] https://www.dol.gov/sites/default/files/ebsa/researchers/statistics/retirement-bulletins/annual-report-on-self-insured-group-health-plans-2018.pdf

[7] Cynthia Cox, et al., A look at how the opioid crisis has affected people with employer coverage. Peterson-Kaiser Health System Tracker (Sept. 4, 2018, 5:25 PM), https://www.healthsystemtracker.org/brief/a-look-at-how-the-opioid-crisis-has-affected-people-with-employer-coverage/#item-start.

deaths (66.4% of all drug overdose deaths) in the United States with 444 of those occurring in Oklahoma.

20. Defendants' conduct has generated huge sales of opioids fueled by the addictive nature of the Defendants' products resulting in enormous profits for the Defendants at the cost of opioid addiction and opioid-related deaths and emergency treatments for patients.

21. Defendants knew that the structure of the United States health care system meant that a substantial portion of the additional opioid prescriptions and resulting opioid addiction expenses would be paid by the private employer-sponsored health plans.

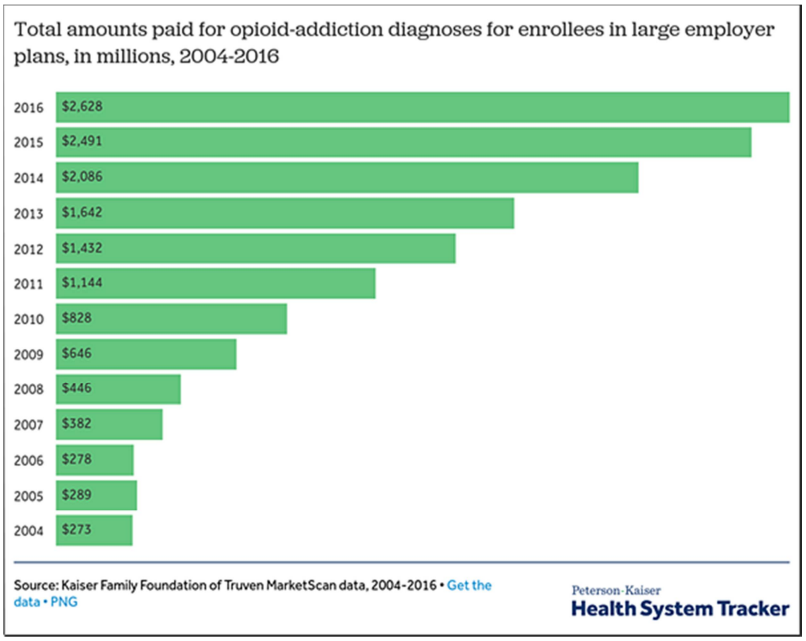
22. In 2010 when the ACA was signed into law, private employers with more than 50 full-time equivalent employees were essentially forced to offer health insurance to their full-time employees or face substantial penalties. The ACA also prohibited pre-existing condition exclusions. Couple these ACA provisions with the requirements of the Mental Health Parity Act ("MHPA") and Mental Health Parity and Addiction Equity Act ("MHPAEA"), the cost of substance abuse and addiction treatments has been placed squarely and disproportionately on the shoulders of private employer sponsored health plans.

23. Given the mechanics of prescription drug payment and reimbursement and the mandates of the ACA, the Plaintiff ERISA Plans are "customers" of the Defendants as co-payors with their patient/plan participant members, and as such, are the entities that have been most harmed financially by Defendants' fraudulent marketing schemes. As described below, the Plaintiff ERISA Plans were a primary and intended targets of

Defendants' unlawful marketing strategies, which successfully resulted in excessive and unnecessary prescriptions for opioid drugs and treatment for opioid addiction – the cost of which was primarily paid for by the ERISA Plans – which resulted in the direct injuries sustained by the ERISA Plans which gives rise to the claims raised herein.

24. In 2016, people covered by large private employer coverage received $2.6 billion in services for treatment of opioid addiction and overdose, up from $ 0.3 billion in 2004.[8] Of the $2.6 billion spent on treatment for opioid addiction and overdose in 2016 for people covered by large private employer coverage, $1.3 billion was for outpatient treatment, $911 million was for inpatient care, and $435 million was for prescription drugs.[9] In 2016, $2.3 billion in addiction and overdose services was covered by insurance and $335 million was paid out-of-pocket by patients.[10] (These totals include only payments for services covered by insurance; services paid fully out-of-pocket are not included, so these numbers are likely lower than the actual totals.)[11]

[8] Cynthia Cox, et al., A look at how the opioid crisis has affected people with employer coverage. Peterson-Kaiser Health System Tracker (Sept. 4, 2018, 5:25 P M), https://www.healthsystemtracker.org/brief/a-look-at-how-the-opioid-crisis-has-affected-people-with-employer-coverage/#item-start.
[9] *Id.*
[10] *Id.*
[11] *Id.*



25. As the entities directly reimbursing most, if not all, of the cost of opioid drug prescriptions, the Plaintiff ERISA Plans were a direct, primary, and intended victims of Defendants' fraudulent schemes. Defendants' unlawful schemes targeted and defrauded the Plaintiff ERISA Plans on a massive scale. The Marketing Defendants focused their marketing teams to give information and presentations to the Plaintiff ERISA Plans and their representatives and agents concerning the safety, efficacy, and formulary placement of their opioid drugs. As detailed herein, the information provided by Defendants to the ERISA Plans and their agents and representatives was false.

26. At all times material hereto, each Defendant knew that, because opioid drugs are FDA approved and effective for limited purposes, the products would be placed on ERISA Plans' drug formularies nationally. The Defendants knew that the Plaintiff ERISA Plans would reimburse for on-formulary prescriptions of opioid drugs, even if the drugs were being prescribed as a result of Defendants' respective covert, systematic, and illegal schemes to promote their opioid drugs. Consequently, the Plaintiff ERISA Plans

included many of the opioid drugs on their formularies, and unknowingly paid for opioid drug prescriptions for ineffective, unsafe, and/or unapproved purposes as a result of Defendants' false and misleading marketing practices.

27. This suit takes aim at the two primary causes of the opioid crisis: (a) a marketing scheme involving the false and deceptive marketing of prescription opioids, which was designed to dramatically increase the demand for and sale of opioids and opioid prescriptions; and (b) a supply chain scheme, pursuant to which the various entities in the supply chain failed to design and operate systems to identify suspicious orders of prescription opioids, maintain effective controls against diversion, and halt suspicious orders when they were identified, thereby contributing to the oversupply of such drugs and fueling an illegal secondary market.

28. On the demand side, the crisis was precipitated by the defendants who manufacture, sell, and market prescription opioid painkillers ("Marketing Defendants"). Through a massive marketing campaign premised on false and incomplete information, the Marketing Defendants engineered a dramatic shift in how and when opioids are prescribed by the medical community and used by patients. The Marketing Defendants relentlessly and methodically, but untruthfully, asserted that the risk of addiction was low when opioids were used to treat chronic pain, and overstated the benefits and trivialized the risk of the long-term use of opioids.

29. The Marketing Defendants' goal was simple: to dramatically increase sales by a two pronged approach – (1) convincing doctors to prescribe opioids not only for the kind of severe pain associated with cancer or short-term post-operative pain, but also for

common chronic pains, such as back pain and arthritis and (2) convincing pharmacy benefit companies/managers ("PBMs) to dramatically modify their formularies to allow opioids to be approved drugs for common chronic pain and arthritis. They did this even though they knew that opioids were addictive and subject to abuse, and that their other claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded.

30. The Marketing Defendants' push to increase opioid sales worked. Through their publications and websites, endless stream of sales representatives, "education" programs, and other means, Marketing Defendants dramatically increased their sales of prescription opioids and reaped billions of dollars of profit as a result. Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled. In 2012 alone, opioids generated $8 billion in revenue for drug companies. By 2015, annual sales of opioids grew to approximately $9.6 billion.

31. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers and distributors, (together, "Defendants"), who failed to maintain effective controls over the distribution of prescription opioids, and who instead have actively sought to evade such controls. Defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know could be necessary for legitimate medical uses, while failing to report, and to take steps to halt suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market. By providing misleading information to doctors, PBMs,

third-party administrators ("TPAs") and health plans about addiction being rare and opioids being safe even in high doses, then pressuring them into prescribing their products by arguing, among other things, that no one should be in pain, the Marketing Defendants created a population of addicted patients who sought opioids at never-before-seen rates. The scheme worked, and through it the Marketing Defendants caused their profits to soar as more and more people became dependent on opioids.

32. The Defendants' false and misleading statements deceived doctors, patients, and private employer-sponsored health plans and their agents and representatives (including their PBMs about the risks and benefits of opioids and convinced them that opioids were not only appropriate, but necessary to treat chronic pain. The Defendants targeted susceptible prescribers, like family doctors, and vulnerable patient populations, like participants in private employer-sponsored health plans, the elderly, and veterans. And they tainted the sources that doctors, patients, and private employer-sponsored health plans relied upon for guidance, including treatment guidelines, medical education programs, medical conferences and seminars, and scientific articles. As a result, Defendants successfully transformed the way doctors treat pain and the way private employer sponsored health plans and their PBMs define within their formularies how opioids can be used, 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 Defendants every year.

33. The explosion in opioid prescriptions and use has created a public health crisis not only in Oklahoma but throughout the United States. 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 throughout the United States.

34. The direct and proximate consequence of Defendants' misconduct is that every private employer sponsored group health plan as defined under 29 U.S.C. § 1191b(a)(1) paid more health care costs and expenses resulting from the oversupply of opioids and the direct impact (addiction, mental health and death) these addictive drugs have caused to participants and beneficiaries of ERISA Plans. The Plaintiff ERISA Plans were directly damaged due to increased costs which include, for example: (1) the cost of unnecessary opioid prescriptions paid by the Plans; (2) the cost of healthcare, medical care, therapeutic care, prescription drug purchases, and other medical costs and treatments for Plan participants and beneficiaries suffering from opioid-related addiction or disease, including overdoses and deaths, paid by the Plans; (3) the cost of mental-health services, treatment, counseling, rehabilitation services, and social services to Plan participants and beneficiaries who are victims of the opioid epidemic, paid by the Plans; and (4) the cost of providing treatment of infants who are Plan beneficiaries, who were born with opioid-

related medical conditions, or born dependent on opioids due to opioid drug use by the mother during pregnancy, paid by the Plans.

35. The unwarranted and exorbitant healthcare costs of opioid-related healthcare coverage caused by Defendants have cost the Plaintiff ERISA Plans and the Proposed Class members billions of dollars and have made an extremely negative impact on the overall cost of health insurance in the United States and in particular, on private employer sponsored health plans.

36. The Plaintiff ERISA Plans have suffered direct injuries from payments for prescription opioids that would not have been paid absent Defendants' fraud because: (1) the opioids would not have been approved on the Plaintiff ERISA Plans' formularies or would have been subject to additional controls and guidance; (2) the Plaintiffs ERISA Plans' would have had more control over preexisting controls, such as preauthorization requirements; (3) doctors would not have prescribed opioid medications at the same rate; and (4) the Plaintiffs ERISA Plans' would have been on notice that medications were being diverted to a secondary market. These costs and expenses to the Plaintiff ERISA Plans were clearly foreseeable and are the natural consequences of the Defendants' unlawful scheme to fraudulently inflate the use of opioids and to have ERISA Plans pay for opioids.

37. Defendants have not changed their ways or corrected their past misconduct but instead are continuing to fuel the opioid crisis.

38. This action seeks to hold Defendants accountable for the economic harm Defendants have caused to the Plaintiff ERISA Plans, and to allow the fiduciary Plaintiffs

to meet their ERISA fiduciary responsibilities by recovering the costs/expenses the Plans incurred as a result of Defendants' fraudulent actions. In addition, these costs and expenses to the Plans were clearly foreseeable and the natural consequences of the Defendants' scheme to fraudulently inflate the use of opioids and the Plaintiffs' are in the best position to enforce the law as the party directly suffering economic injury.

JURISDICTION AND VENUE

39. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 because Plaintiffs' claims under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.,* raise a federal question.

40. This is a civil action by fiduciaries (as defined in 29 U.S.C. § 1002(21)(A)) of ERISA-regulated employee benefit plans and by ERISA-regulated employee benefit plans to obtain appropriate equitable relief provided by 29 U.S.C. § 1132(a)(3). Federal jurisdiction therefore exists under 28 U.S.C. § 1331 and 29 U.S.C. § 1132(e)(1).

41. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2), because (i) at least one of the putative Proposed Class members is a citizen of a state different from any Defendant and (ii) the amount in controversy exceeds $5,000,000.00, exclusive of interest and costs.

42. This Court has personal jurisdiction over each Defendant because the Plaintiff ERISA Plans' claims arise out of, or relate to, each Defendant's contacts with Oklahoma. For example:

- Defendants knowingly and intentionally sell, market, advertise, promote, and distribute their products in the State of Oklahoma and to Oklahoma residents, citizens, and businesses, as well as to the State of Oklahoma;

- Defendants enter into contracts relating to the subject-matter of this action in the State of Oklahoma;
- Defendants have directed advertising, marketing, and promotional efforts at the State of Oklahoma and Oklahoma residents, citizens, businesses, and employer-sponsored health plans;
- Defendants have engaged in advertising, marketing, and promotional activities with the intent and expectation that these activities would reach and affect the State of Oklahoma and/or Oklahoma residents, citizens, businesses, and employer-sponsored health plans;
- Defendants have delivered, distributed, dispensed, and sold opioids in Oklahoma with the intent and the expectation that those products would be distributed to or purchased by Oklahoma residents, citizens, and businesses and that Oklahoma employer-sponsored health plans would include opioids on their formularies and pay for or reimburse plan participants and beneficiaries for the cost of such opioids;
- The Plaintiff ERISA Plans have paid medical benefits to participants and beneficiaries of the Plans for injuries suffered by the participants and beneficiaries which were directly caused by the Defendants' actions; and
- As described herein, the Plaintiff ERISA Plans sue to vindicate their direct injuries that they sustained which occurred within the State of Oklahoma.

43. Venue is proper in this District under 28 U.S.C. § 1391(b), because a substantial part of the events giving rise to the Plaintiff ERISA Plans' claims and the claims of certain of the Proposed Class members (the Oklahoma ERISA Plans) occurred in, were directed to, and/or emanated from this District.

44. Venue is proper in this District under 29 U.S.C. § 1132(e)(2), because the Plaintiff ERISA Plans claims and the claims of certain of the Proposed Class members (the Oklahoma ERISA Plans) are in part administered in this District and various breaches alleged herein took place in this District.

PARTIES

I. PLAINTIFFS

45. The Plaintiff ERISA Plans are private sector "employee welfare benefit plans"[12] because they are a "plan, fund, or program which was heretofore or is hereafter established or maintained by an employer … to the extent that such plan, fund, or program was established or is maintained for the purpose of providing for its participants[13] or their beneficiaries,[14] through the purchase of insurance or otherwise, (A) medical, surgical, or hospital care or benefits, or benefits in the event of sickness…."

46. The Plaintiff ERISA Plans are "employee benefit plans."[15]

47. The Plaintiff ERISA Plans are "self-insured" plans because employer and/or employee contributions are used to fund the payment of benefits under the Plans.[16]

48. Plaintiff Pioneer is the "sponsor"[17] of the Pioneer Plan because it is an "employer"[18] that established the Pioneer Plan, and because it maintains the Pioneer Plan.

49. Plaintiff Pioneer is a "fiduciary"[19] of the Pioneer Plan because it exercises discretionary authority and discretionary control respecting management of the Pioneer Plan and exercises authority and control respecting management or disposition of its

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[12] As defined in 29 U.S.C. § 1002(1).
[13] As defined in 29 U.S.C. § 1002(7) (here, the eligible employees of Plaintiff ERISA Plans).
[14] As defined in 29 U.S.C. § 1002(8) (here, the eligible dependents of the Plaintiff ERISA Plans' eligible employees).
[15] As defined in 29 U.S.C. § 1002(3).
[16] The difference between a self-funded plan and a fully-insured plan is explained in *FMC Corp. v. Holliday*, 498 U.S. 52, 54 (1990) ("The Plan is self-funded; it does not purchase an insurance policy from any insurance company in order to satisfy its obligations to its participants"); *Soc'y of Professional Eng'g Emp. in Aerospace, v. Spirit Aerosystems, Inc.*, 681 Fed. App'x 717, 719 n. 2 (10th Cir. Mar. 15, 2017) ("A 'self-funded' health insurance plan differs from fully insured health insurance plans in that the employer assumes responsibility for payment of claims rather than the insurance company").
[17] As defined in 29 U.S.C. § 1002(16)(B).
[18] As defined in 29 U.S.C. § 1002(5).
[19] As defined in 29 U.S.C. § 1002(21)(A)(i) & (iii).

assets, and because it has discretionary authority and discretionary responsibility in the administration of the Pioneer Plan.

50. Plaintiff Pioneer is an "employer"[20] that is engaged in "commerce,"[21] specifically describe Pioneer employer's business.

51. Plaintiff Bios is the "sponsor" of the Bios Plan because it is an "employer" that established the Bios Plan, and because it maintains the Bios Plan.

52. Plaintiff Bios is a "fiduciary" of the Bios Plan because it exercises discretionary authority and discretionary control respecting management of the Bios Plan and exercises authority and control respecting management or disposition of its assets, and because it has discretionary authority and discretionary responsibility in the administration of the Bios Plan.

53. Plaintiff Bios is an "employer" that is engaged in "commerce," specifically describe Bios employer's business.

54. Plaintiff Pioneer is the plan sponsor of the Pioneer Telephone Cooperative, Inc. Health and Benefit Plan and has offices and employee/participants in the State of Oklahoma.

55. Plaintiff Bios is the plan sponsor of the Bios Companies, Inc. Health and Benefit Plan and has offices and employee/participants in the State of Oklahoma.

56. Pursuant to 29 U.S.C. § 1003(a), the Plaintiff ERISA Plans and the Proposed Class members are governed by the Employee Retirement Income Security Act of 1974, 29 U.S.C. §§ 1001-1461, as amended ("ERISA").

[20] As defined in 29 U.S.C. §1002(5).
[21] As defined in 29 U.S.C. §1002(11).

57. ERISA was established, in part, so that federal law would govern private employer self-insured plans instead of state insurance departments. This allows employers to be governed by federal law and to provide uniform and consistent treatment when they have employees in multiple states.

58. Plaintiff Pioneer and Plaintiff Bios bring this action in their capacities as plan sponsors and fiduciaries of the Pioneer and Bios Plans, for the benefit of the Pioneer Plan and the Bios Plan respectively.

59. At all times from the filing of this action through and including the present, the following is and has been true. Plaintiff Pioneer is and has been a corporation duly organized and existing under the laws of the State of Oklahoma, with its principal place of business in the State of Oklahoma. Plaintiff Pioneer is therefore considered a citizen of the State of Oklahoma for purposes of diversity jurisdiction under 28 U.S.C. § 1332(d)(2).

60. At all times from the filing of this action through and including the present, the following is and has been true. Plaintiff Bios is and has been a corporation duly organized and existing under the laws of the State of Oklahoma, with its principal place of business in the State of Oklahoma. Plaintiff Bios' headquarters are in Sapulpa, Oklahoma. Plaintiff Bios is therefore considered a citizen of the State of Oklahoma, for purposes of diversity jurisdiction under 28 U.S.C. § 1332(d)(2).

61. As reflected in the Plan documents for the Plaintiff ERISA Plans, Plaintiff Pioneer and Plaintiff Bios, on behalf of the Pioneer Plan and the Bios Plan respectively, both have a contractual right of subrogation against third parties with respect to any monies paid by the Plans for and on behalf of the Plan's participants and beneficiaries.

62. At all times material hereto, the Plaintiff ERISA Plans paid for or reimbursed Plan participants or beneficiaries for one or more of Defendants' opioid drug products. During the Class Period the Plaintiff ERISA Plans and the Proposed Class members have paid for thousands if not millions of opioid drug prescriptions and have paid for medical treatment and other costs caused by Plan participants' opioid addiction or use. As a result of Defendants' unlawful conduct, the Plaintiff ERISA Plans and the Proposed Class sustained injury when they added and maintained Defendants' opioid drugs to their formularies, purchased, paid for and/or provided reimbursement for opioid drugs, and paid for opioid addiction or opioid-related treatment to Plan participants and beneficiaries during the relevant period.

II. DEFENDANTS

A. Marketing Defendants

63. At all relevant times, the Marketing Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Marketing Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

1. Purdue Entities

64. Defendant Purdue Pharma L.P. ("PPL") is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut. None of the PPL's partners have citizenship in the State of Oklahoma.

65. Defendant Purdue Pharma Inc. ("PPI") is a New York corporation with its principal place of business in Stamford, Connecticut.

66. Defendant The Purdue Frederick Company, Inc. ("PFC") is a New York corporation with its principal place of business in Stamford, Connecticut.

67. PPL, PPI, and PFC and their DEA registrant subsidiaries and affiliates (collectively, "Purdue") are engaged in the manufacture, promotion, distribution, and sale of opioids nationally, and in Oklahoma, including the following:

Product Name	**Chemical Name**	**Schedule**[22]
OxyContin	Oxycodone hydrochloride, extended release	Schedule II
MS Contin	Morphine sulfate, extended release	Schedule II
Dilaudid	Hydromorphone hydrochloride	Schedule II
Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
Butrans	Buprenorphine	Schedule III
Hysingla ER	Hydrocodone bitrate	Schedule II
Targiniq ER	Oxycodone hydrochloride and naloxone hydrochloride	Schedule II

68. Purdue made thousands of payments to physicians nationwide, including in Oklahoma, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

[22] Since passage of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 *et seq.* ("CSA" or "Controlled Substances Act"), opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs; hydrocodone and tapentadol were recently reclassified from Schedule III to Schedule II. Schedule II drugs have a high potential for abuse, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.

69. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $3.1 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs *(i.e.,* painkillers). Sales of OxyContin (launched in 1996) went from a mere $49 million in its first full year on the market to $1.6 billion in 2002.

70. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States $635 million—at the time, one of the largest settlements with a drug company for marketing misconduct. None of this stopped Purdue. In fact, Purdue continued to create the false perception that opioids were safe and effective for long term use, even after being caught, by using unbranded marketing methods to circumvent the system. In short, Purdue paid the fine when caught and then continued business as usual, deceptively marketing and selling billions of dollars of opioids each year.

2. Actavis Entities

71. Allergan PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in January 2013. Defendant Actavis, Inc. was acquired by Watson Pharmaceuticals, 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. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of Allergan PLC (Allergan Finance, LLC, f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals,

Inc.). Defendant Actavis Pharma, Inc. is registered to do business with the Oklahoma Secretary of State as a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants and entities is owned by Defendant Allergan PLC, which uses them to market and sell its drugs in the United States. Collectively, these defendants and entities, and their DEA registrant subsidiaries and affiliates that manufacture, promote, distribute, and sell prescription opioids, are referred to as "Actavis."

72. Actavis manufactures or has manufactured the following drugs as well as generic versions of Kadian, Duragesic, and Opana in the United States:

Product Name	**Chemical Name**	**Schedule**
Kadian	Morphine sulfate, extended release	Schedule II
Norco	Hydrocodone bitartate and acetaminophen	Schedule II

3. Cephalon Entities

73. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009. Teva USA is a wholly-owned subsidiary of Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation (collectively, "Teva").

74. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

75. Teva USA and Cephalon, Inc. and their DEA registrant subsidiaries and affiliates (collectively, "Cephalon") work together to manufacture, promote, distribute and sell both brand name and generic versions of opioids in the United States, including the following:

Product Name	**Chemical Name**	**Schedule**
Actiq	Fentanyl citrate	Schedule II
Fentora	Fentanyl buccal	Schedule II

76. From 2000 forward, Cephalon has made thousands of payments to physicians nationwide, including in Oklahoma, many of whom were not oncologists and did not treat cancer pain, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

4. Janssen Entities

77. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

78. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly-owned subsidiary of J&J. J&J corresponds with the FDA regarding Janssen's products. Janssen Pharmaceuticals, Inc. formerly was known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

79. Defendant Noramco, Inc. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital.

80. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMP"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

81. Defendant Janssen Pharmaceutica, Inc. ("Janssen Pharmaceutica"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

82. J&J, Janssen Pharmaceuticals, OMP, and Janssen Pharmaceutica and their DEA registrant subsidiaries and affiliates (collectively, "Janssen") are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally, and in Oklahoma. Among the drugs Janssen manufactures or manufactured are the following:

Product Name	**Chemical Name**	**Schedule**
Duragesic	Fentanyl	Schedule II
Nucynta[23]	Tapentadol hydrochloride, immediate release	Schedule II
Nucynta ER	Tapentadol hydrochloride, extended release	Schedule II

83. Janssen made thousands of payments to physicians nationwide, including, upon information and belief, in Oklahoma, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety

[23] Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

surveillance and other services, but in fact to deceptively promote and maximize the use of opioids. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

84. Information from the U.S. Department of Justice's Office of the Inspector General shows that J&J made payments to prescribers, but does not indicate which drug was being promoted when J&J made these payments.

85. Janssen, like many other companies, has a corporate code of conduct, which clarifies the organization's mission, values and principles. Janssen's employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. J&J imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website "Ethical Code for the Conduct of Research and Development," names only J&J and does not mention Janssen anywhere within the document. The "Ethical Code for the Conduct of Research and Development" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

86. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "Pharmaceutical Companies of J&J" and as one of the "J&J Pharmaceutical Affiliates." It governs how "[a]ll employees of J&J Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise J&J Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales

associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case.

87. J&J made payments to thousands of physicians nationwide, including in Oklahoma, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

5. Endo Entities

88. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

89. Defendant Endo Pharmaceuticals, Inc. ("EPI") is a wholly-owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

90. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. Defendant Par Pharmaceuticals Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York (Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. collectively, "Par Pharmaceutical"). Par Pharmaceutical was acquired by Endo International plc in September 2015 and is an operating company of Endo International plc. EHS, EPI, and Par Pharmaceutical, and their DEA registrant subsidiaries and affiliates (collectively,

"Endo") manufacture opioids sold nationally. Among the drugs Endo manufactures or manufactured are the following:

Product Name	Chemical Name	Schedule
Opana ER	Oxymorphone hydrochloride, extended release	Schedule II
Opana	Oxymorphone hydrochloride	Schedule II
Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
Generic	Oxycodone	Schedule II
Generic	Oxymorphone	Schedule II
Generic	Hydromorphone	Schedule II
Generic	Hydrocodone	Schedule II

91. Endo made thousands of payments to physicians nationwide, including in Oklahoma, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

92. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012, accounting for over 10% of Endo's total revenue; Opana ER yielded revenue of $1.15 billion from 2010 to 2013. Endo also manufactures and sells generic opioids, both directly and through its subsidiaries, Par Pharmaceutical and Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

93. The Food and Drug Administration requested that Endo remove Opana ER from the market in June 2017. The FDA relied on post-marketing data in reaching its conclusion based on risk of abuse.

6. Insys Therapeutics, Inc.

94. Insys Therapeutics, Inc. is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys's principal product and source of revenue is Subsys:

Product Name	Chemical Name	Schedule
Subsys	Fentanyl	Schedule II

95. Insys made thousands of payments to physicians nationwide, including in Oklahoma, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

96. Subsys is a transmucosal immediate-release formulation (TIRF) of fentanyl, contained in a single-dose spray device intended for oral, under-the-tongue administration. Subsys was approved by the FDA solely for the treatment of breakthrough cancer pain.

97. In 2016, Insys made approximately $330 million in net revenue from Subsys. Insys promotes, sells, and distributes Subsys throughout the United States.

98. Insys's founder and owner was recently arrested and charged, along with other Insys executives, with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies. Other Insys executives and managers were previously indicted.

7. Mallinckrodt Entities

99. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri. Defendant Mallinckrodt LLC is a Delaware corporation with its headquarters in Hazelwood, Missouri. Defendant SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt PLC. Mallinckrodt PLC, Mallinckrodt LLC, and SpecGx LLC and their DEA registrant subsidiaries and affiliates (together, "Mallinckrodt") manufacture, market, sell and distribute pharmaceutical drugs throughout the United States. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

100. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release

combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

101. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the U.S. Drug Enforcement Administration's ("DEA") entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

102. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers ("PBMs") that have mail-order pharmacies, and hospital buying groups.

103. Among the drugs Mallinckrodt manufactures or has manufactured are the following:

Product Name	**Chemical Name**	**Schedule**
Exalgo	Hydromorphone hydrochloride, extended release	Schedule II
Roxicodone	Oxycodone hydrochloride	Schedule II
Xartemis XR	Oxycodone hydrochloride and acetaminophen	Schedule II
Methadose	Methadone hydrochloride	Schedule II
Generic	Morphine sulfate, extended release	Schedule II
Generic	Morphine sulfate oral solution	Schedule II

Product Name	Chemical Name	Schedule
Generic	Fentanyl transdermal system	Schedule II
Generic	Oral transmucosal fentanyl citrate	Schedule II
Generic	Oxycodone and acetaminophen	Schedule II
Generic	Hydrocodone bitartrate and acetaminophen	Schedule II
Generic	Hydromorphone hydrochloride	Schedule II
Generic	Hydromorphone hydrochloride, extended release	Schedule II
Generic	Naltrexone hydrochloride	unscheduled
Generic	Oxymorphone hydrochloride	Schedule II
Generic	Methadone hydrochloride	Schedule II
Generic	Oxycodone hydrochloride	Schedule II
Generic	Buprenorphine and naloxone	Schedule III

104. Mallinckrodt made thousands of payments to physicians nationwide, including in Oklahoma, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

105. Collectively, Purdue, Actavis, Cephalon, Janssen, Endo, Insys, and Mallinckrodt are referred to as "Marketing Defendants."

B. Distributor Defendants

106. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in "wholesale distribution," as defined under state and federal law. Plaintiffs allege the

unlawful conduct by the Distributor Defendants is a substantial cause for the volume of prescription opioids plaguing the nation.

1. AmerisourceBergen Drug Corporation

107. AmerisourceBergen Drug Corporation ("AmerisourceBergen"), through its various DEA registrant subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of $147 billion in 2016. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware.

2. Anda, Inc.

108. Defendant Anda, Inc., ("Anda") through its various DEA registrant subsidiaries and affiliated entities, including but not limited to, Anda Pharmaceuticals, Inc., is the fourth largest distributor of generic pharmaceuticals in the United States. Anda is registered to do business with the Oklahoma Secretary of State as a Florida corporation with its principal office located in Weston, Florida. In October 2016, Defendant Teva acquired Anda from Allergan plc (i.e., Defendant Actavis), for $500 million in cash. At all times relevant to this Complaint, Anda distributed prescription opioids throughout the United States, including in Oklahoma.

3. Cardinal Health, Inc.

109. Cardinal Health, Inc. ("Cardinal") describes itself as a "global, integrated health care services and products company," and is the fifteenth largest company by revenue in the U.S., with annual revenue of $121 billion in 2016. Through its various DEA

registrant subsidiaries and affiliated entities, Cardinal distributes pharmaceutical drugs, including opioids, throughout the country. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio. Cardinal, including its subsidiaries and affiliated entities, has been licensed as a wholesale distributor of dangerous drugs since 1990. Based on Defendant Cardinal's own estimates, one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

4. McKesson Corporation

110. McKesson Corporation ("McKesson") is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of $191 billion in 2016. McKesson, through its various DEA registrant subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country. McKesson is incorporated in Delaware, with its principal place of business in San Francisco, California.

111. In January 2017, McKesson paid a record $150 million to resolve an investigation by the U.S. Department of Justice ("DOJ") for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio, Florida, Michigan and Colorado. The DOJ described these "staged suspensions" as "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."

112. Defendants AmerisourceBergen, Anda, Cardinal, and McKesson are collectively referred to as the "Distributor Defendants."[1]

113. Defendants include the above referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the manufacture, promotion, distribution, sale, and/or dispensing of opioids.

C. Agency and Authority

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

FACTUAL ALLEGATIONS

I. FACTS COMMON TO ALL CLAIMS

A. Opioids' Long History of Addiction

115. The term "opioid" refers to a class of drugs that bind with opioid receptors in the brain and includes natural, synthetic, and semi-synthetic opioids. Natural opioids are derived from the opium poppy. Generally used to treat pain, opioids produce multiple effects on the human body, the most significant of which are analgesia, euphoria, and respiratory depression.

116. The medicinal properties of opioids have been recognized for millennia—as well as their potential for abuse and addiction. The opium poppy contains various opium alkaloids, three of which are used in the pharmaceutical industry today: morphine, codeine, and thebaine. Early use of opium in Western medicine was with a tincture of

opium and alcohol called laudanum, which contains all of the opium alkaloids and is still available by prescription today. Chemists first isolated the morphine and codeine alkaloids in the early 1800s.

117. In 1827, the pharmaceutical company Merck began large-scale production and commercial marketing of morphine. During the American Civil War, field medics commonly used morphine, laudanum, and opium pills to treat the wounded, and many veterans were left with morphine addictions. By 1900, an estimated 300,000 people were addicted to opioids in the United States, and many doctors prescribed opioids solely to prevent their patients from suffering withdrawal symptoms. The nation's first Opium Commissioner, Hamilton Wright, remarked in 1911, "The habit has this nation in its grip to an astonishing extent. Our prisons and our hospitals are full of victims of it, it has robbed ten thousand businessmen of moral sense and made them beasts who prey upon their fellows . . . it has become one of the most fertile causes of unhappiness and sin in the United States."[24]

118. Pharmaceutical companies tried to develop substitutes for opium and morphine that would provide the same analgesic effects without the addictive properties. In 1898, Bayer Pharmaceutical Company began marketing diacetylmorphine (obtained from acetylation of morphine) under the trade name "Heroin." Bayer advertised heroin as a non-addictive cough and cold remedy suitable for children, but as its addictive nature

[24] Nick Miroff, *From Teddy Roosevelt to Trump: How Drug Companies Triggered an Opioid Crisis a Century Ago*, The Wash. Post (Oct. 17, 2017), https://www.washingtonpost.com/news/retropolis/wp/2017/09/29/the-greatest-drug-fiends-in-the-world-an-american-opioid-crisis-in-1908/?utm_term=.7832633fd7ca .

became clear, heroin distribution in the U.S. was limited to prescription only in 1914 and then banned altogether a decade later.

119. Although heroin and opium became classified as illicit drugs, there is little difference between them and prescription opioids. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain.

120. Due to concerns about their addictive properties, prescription opioids have usually been regulated at the federal level as Schedule II controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970.

121. Throughout the twentieth century, pharmaceutical companies continued to develop prescription opioids like Percodan, Percocet, and Vicodin, but these opioids were generally produced in combination with other drugs, with relatively low opioid content.

122. In contrast, OxyContin, the product whose launch in 1996 ushered in the current opioid epidemic, is pure oxycodone. Purdue sold it in the following strengths: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. The weakest OxyContin delivers as much narcotic as the strongest Percocet, and some OxyContin tablets delivered sixteen times that.

123. Medical professionals describe the strength of various opioids in terms of morphine milligram equivalents ("MME"). According to the CDC, doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and one study found that patients who died of opioid overdose were prescribed an average of 98 MME/day.

124. Different opioids provide varying levels of MMEs. For example, just 33 mg of oxycodone provides 50 MME. Thus, at OxyContin's twice-daily dosing, the 50 MME/day threshold is nearly reached by a prescription of 15 mg twice daily. One 160 mg tablet of OxyContin, which Purdue took off the market in 2001, delivered 240 MME.

125. The wide variation in the MME strength of prescription opioids renders misleading any effort to define "market share" by the number of pills or prescriptions attributed to Purdue or other manufacturers. Purdue, in particular, focuses its business on branded, highly potent pills, causing it to be responsible for a significant percent of the total amount of MME in circulation, even though it currently claims to have a small percent of the market share in terms of pills or prescriptions.

126. Fentanyl is a synthetic opioid that is 100 times stronger than morphine and 50 times stronger than heroin. First developed in 1959, fentanyl is showing up more and more often in the market for opioids created by Marketing Defendants' promotion, with particularly lethal consequences.

127. The effects of opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" (also referred to as "breakthrough pain") and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours. Still other short-term opioids, such as Insys's Subsys, are designed to be taken in addition to long-

acting opioids to specifically address breakthrough cancer pain, excruciating pain suffered by some patients with end-stage cancer. The Marketing Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic or "breakthrough" pain.

128. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the "high." However, opioids depress respiration, and at very high doses can and often do arrest respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

129. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

130. As one doctor put it, the widespread, long-term use of opioids "was an experiment on the population of the United States. It wasn't randomized, it wasn't controlled, and no data was collected until they started gathering death statistics."

B. The Resurgence of Opioid Use in the United States

1. Purdue Markets its Addictive OxyContin into a Really Big Drug

131. Given the history of opioid abuse in the U.S. and the medical profession's resulting wariness, the commercial success of the Marketing Defendants' prescription opioids would not have been possible without a fundamental shift in prescribers' perception of the risks and benefits of long-term opioid use.

132. In the 1980s, Purdue, through its UK affiliate, acquired a Scottish drug producer that had developed a sustained-release technology suitable for morphine. Purdue marketed this extended-release morphine as MS Contin, and it quickly became Purdue's bestseller. As the patent expiration for MS Contin loomed, Purdue searched for a drug to replace it. Around that time, Richard Sackler, the son of one of the three brothers, who owns and controls Purdue, and who was also a trained physician, became more involved in the management of the company. Richard had grand ambitions for the company; according to a long-time Purdue sales representative, "Richard really wanted Purdue to be big—I mean *really* big."[25] Richard believed Purdue should develop another use for its "Contin" timed-release system.

133. In 1990, Purdue's vice president of clinical research, Robert Kaiko, sent a memo to Richard and other executives recommending that the company work on a pill containing oxycodone. At the time, oxycodone was perceived as less potent than morphine, largely because it was most commonly prescribed as Percocet, a relatively weak oxycodone-acetaminophen combination pill. MS Contin was not only approaching patent

[25] Christopher Glazek, *The Secretive Family Making Billions from the Opioid Crisis*, Esquire (Oct. 16, 2017), http://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/ .

expiration but had always been limited by the stigma associated with morphine. Oxycodone did not have that problem, and what's more, it was sometimes mistakenly called "oxycodeine," which also contributed to the perception of relatively lower potency, because codeine is weaker than morphine. Purdue acknowledged using this to its advantage when it later pled guilty to criminal charges of "misbranding" in 2007, admitting that it was "well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine" and "did not want to do anything 'to make physicians think that oxycodone was stronger or equal to morphine' or to 'take any steps . . . that would affect the unique position that OxyContin' "held among physicians."[26]

134. For Purdue and OxyContin to be *"really* big,"[27] Purdue needed to both distance its new product from the traditional view of narcotic addiction risk, and broaden the drug's uses beyond cancer pain and hospice care. A marketing memo sent to Purdue's top sales executives in March 1995 recommended that if Purdue could show that the risk of abuse was lower with OxyContin than with traditional immediate-release narcotics, sales would increase. As discussed below, Purdue did not find or generate any such evidence, but this did not stop Purdue from making that claim regardless.

135. Armed with this and other misrepresentations about the risks and benefits of its new drug, Purdue was able to open an enormous untapped market: patients with non-end-of-life, non-acute, everyday aches and pains. As Dr. David Haddox, a Senior Medical Director at Purdue, declared on the Early Show, a CBS morning talk program, "There are 50 million patients in this country who have chronic pain that's not being managed

[26] *Id.*
[27] *Id.*

appropriately every single day. OxyContin is one of the choices that doctors have available to them to treat that."[28]

136. In pursuit of these 50 million potential customers, Purdue poured resources into OxyContin's sales force and advertising, particularly to a far broader audience of primary care physicians who treated patients with chronic pain complaints.

137. Prior to Purdue's launch of OxyContin, no drug company had ever promoted such a pure, high-strength Schedule II narcotic to so wide an audience of general practitioners.

138. In the two decades following OxyContin's launch, Purdue continued to devote substantial resources to its promotional efforts.

139. Purdue has generated estimated sales of more than $35 billion from opioids since 1996, raking in more than $3 billion in 2015 alone. Remarkably, its opioid sales continued to climb even after a period of media attention and government inquiries regarding OxyContin abuse in the early 2000s and a criminal investigation culminating in guilty pleas in 2007. Purdue proved itself skilled at evading full responsibility and continuing to sell through the controversy. The company's annual opioid sales of $3 billion in 2015 represent a four-fold increase from its 2006 sales of $800 million.

140. Purdue has its eyes on even greater profits. Under the name of Mundipharma, Purdue is looking to new markets for its opioids—employing the exact same playbook in South America, China, and India as they did in the United States.

[28] Meier, *supra* note 13, at 156.

141. In May 2017, a dozen members of Congress sent a letter to the World Health Organization, warning it of the public health crisis, Purdue is marketing to the rest of the world through Mundipharma:

> We write to warn the international community of the deceptive and dangerous practices of Mundipharma International—an arm of Purdue Pharmaceuticals. The greed and recklessness of one company and its partners helped spark a public health crisis in the United States that will take generations to fully repair. We urge the World Health Organization (WHO) to do everything in its power to avoid allowing the same people to begin a worldwide opioid epidemic. Please learn from our experience and do not allow Mundipharma to carry on Purdue's deadly legacy on a global stage.…
>
> Internal documents revealed in court proceedings now tell us that since the early development of OxyContin, Purdue was aware of the high risk of addiction it carried. Combined with the misleading and aggressive marketing of the drug by its partner, Abbott Laboratories, Purdue began the opioid crisis that has devastated American communities since the end of the 1990s. Today, Mundipharma is using many of the same deceptive and reckless practices to sell OxyContin abroad. . . .
>
> In response to the growing scrutiny and diminished U.S. sales, the Sacklers have simply moved on. On December 18, the Los Angeles Times published an extremely troubling report detailing how in spite of the scores of lawsuits against Purdue for its role in the U.S. opioid crisis, and tens of thousands of overdose deaths, Mundipharma now aggressively markets OxyContin internationally. In fact, Mundipharma uses many of the same tactics that caused the opioid epidemic to flourish in the U.S., though now in countries with far fewer resources to devote to the fallout.[29]

142. Purdue's recent pivot to untapped markets—after extracting substantial profits from American communities and leaving local governments to address the devastating and still growing damage the company caused—only serves to underscore that

[29] Letter from Members of Congress to Dr. Margaret Chan, Director-General, World Health Organization (May 3, 2017), http://katherineclark.house.gov/_cache/files/a577bd3c-29ec-4bb9-bdba-1ca71c784113/mundipharma-letter-signatures.pdf .

Purdue's actions have been knowing, intentional, and motivated by profits throughout this entire story.

2. The Other Marketing Defendants Joined the Opioid Market and Participated in Creating the Crisis

143. Purdue created a market for the use of opioids for a range of common aches and pains by misrepresenting the risks and benefits of its opioids, but it was not alone. The other Marketing Defendants—already manufacturers of prescription opioids—positioned themselves to take advantage of the opportunity Purdue created, developing both branded and generic opioids to compete with OxyContin, while, together with Purdue and each other, misrepresenting the safety and efficacy of their products.

144. Endo, which already sold Percocet and Percodan, was the first to submit an application for a generic extended-release oxycodone to compete with OxyContin. At the same time, Endo sought FDA approval for another potent opioid, immediate-release and extended-release oxymorphone, branded as Opana and Oparia ER. Oxymorphone, like OxyContin's active ingredient oxycodone, is not a new drug; it was first synthesized in Germany in 1914 and sold in the U.S. by Endo beginning in 1959 under the trade name Numorphan. But Numorphan tablets proved highly susceptible to abuse. Called "blues" after the light blue color of the 10 mg pills, Numorphan provoked, according to some users, a more euphoric high than heroin. As the National Institute on Drug Abuse observed in its 1974 report, "Drugs and Addict Lifestyle," Numorphan was extremely

popular among addicts for its quick and sustained effect.[30] Endo withdrew oral Numorphan from the market in 1979.

145. Two decades later, however, as communities around the U.S. were first sounding the alarm about prescription opioids and Purdue executives were being called to testify before Congress about the risks of OxyContin and knowing of its prior misuse, Endo in essence rereleased Numorphan with a new trade name, Opana.

146. The clinical trials submitted with Endo's first application for approval of Opana were insufficient to demonstrate efficacy, and some subjects in the trials overdosed and had to be revived with naloxone. Endo then submitted new "enriched enrollment" clinical trials, in which trial subjects who do not respond to the drug are excluded from the trial, and obtained approval. Endo began marketing Opana and Opana ER in 2006.

147. Like Numorphan, Opana ER was highly susceptible to abuse. On June 8, 2017, the FDA sought removal of Opana ER. In its press release, the FDA indicated that "[t]his is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse."[31] On July 6, 2017, Endo agreed to withdraw Opana ER from the market.

148. Janssen, which already marketed the Duragesic (fentanyl) patch for severe pain, also joined Purdue in pursuit of the broader chronic pain market. It sought to expand the use of Duragesic through, for example, advertisements proclaiming, "It's not just for

[30] John Fauber & Kristina Fiore, *Abandoned Painkiller Makes a Comeback*, MedPage Today (May 10, 2015), https://www.medpagetoday.com/psychiatry/addictions/51448 .
[31] Press Release, U.S. Food & Drug Admin., *FDA Requests Removal of Opana ER for Risks Related to Abuse* (June 8, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm

end stage cancer anymore!"[32] This claim earned Janssen a warning letter from the FDA, for representing that Duragesic was "more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence."[33]

149. Janssen also developed a new opioid compound called tapentadol in 2009, marketed as Nucynta for the treatment of moderate to severe pain. Janssen launched the extended-release version, Nucynta ER, for treatment of chronic pain in 2011.

150. By adding additional opioids or expanding the use of their existing opioid products, the other Marketing Defendants took advantage of the market created by Purdue's aggressive promotion of OxyContin and reaped enormous profits. Before being pulled from the market by the FDA, Opana ER generated more than $1 billion in revenue for Endo in 2010 and again in 2013. Janssen also passed the $1 billion mark in sales of Duragesic in 2009.

C. The Marketing Defendants' Multi-Pronged Scheme to Change Prescriber Habits and Public Perception and Increase Demand for Opioids

151. The Marketing Defendants promoted, and profited from, their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading and lacked legitimate scientific research to support their claims. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Marketing Defendants of these risks. The Marketing Defendants had access to

[32] Letter from U.S. Food & Drug Admin. to Janssen (Mar. 30, 2000) at 2.
[33] *Id.*

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 are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC issued pronouncements based on existing medical evidence that conclusively expose the known falsity of these Defendants' misrepresentations.

152. The marketing scheme to increase opioid prescriptions centered around misrepresentations to deceive doctors, patients and employer – sponsored health plans and their agents and representatives (including the Plan's PBMs and/or third party administrators), which are discussed in detail below. The Marketing Defendants disseminated these misrepresentations through various channels, including through advertising, sales representatives, purportedly independent organizations these defendants funded and controlled, "Front Groups," so-called industry "Key Opinion Leaders," and Continuing Medical Education ("CME") programs discussed subsequently below.

1. The Marketing Defendants Knowingly Misrepresented the Truth About Opioids

153. Collectively the Marketing Defendants misrepresented not only that risk of addiction from chronic opioid therapy is low but to the extent there is a risk of addiction, that it can be easily identified and managed. They also misrepresented that opioid doses can be increased without limit or greater risks.

154. The Marketing Defendants countered challenges to these misrepresentations with further misrepresentations such as signs of addictive behavior are "pseudoaddiction," requiring more opioids and Opioid withdrawal can be avoided by tapering. When they

encountered problems with those misrepresentations, the Marketing Defendants claimed that new formulations of certain opioids successfully deter abuse.

155. The Marketing Defendants also misrepresented that long-term opioid use improved a patient's ability to function and dispersed the alternative forms of pain relief by misrepresenting that those alternatives posed greater risks than opioids. and the .

156. The Marketing Defendants knew that scheme was false , but nonetheless set out to convince physicians, PBMs, patients, employer-sponsored health plans and their agents, and the public at large of the truth of each of these propositions in order to expand the market for their opioids.

157. While each Marketing Defendant deceptively promoted their opioids specifically, and, together with other Marketing Defendants, opioids generally, not every Marketing Defendant propagated (or needed to propagate) each misrepresentation. Each Marketing Defendant's conduct, and each misrepresentation, contributed to the overall scheme to mislead doctors, patients, PBMs and third party payors, including ERISA Plans, about the risk and benefits of opioids. Central to the Marketing Defendants' marketing scheme was the misrepresentation that opioids are rarely addictive and therefore are safe for chronic pain, arthritis or pain that can be treated by a non-addictive alternative. Through their marketing efforts, the Marketing Defendants advanced the idea that the risk of addiction is low when opioids are taken as prescribed by "legitimate" pain patients. That, in turn, directly led to the expected and intended result that doctors prescribed more opioids to more patients—thereby enriching the Marketing Defendants and substantially contributing to the opioid epidemic.

158. Each of the Marketing Defendants claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to support those claims. None of them have acknowledged, retracted, or corrected their false statements.

159. In fact, studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, "even at recommended dose,"[34] and the risk substantially increases with more than three months of use.[35] As the CDC Guideline states, "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction). [36]

a. Purdue misrepresented the risk of addiction when taking opioids and in particular OxyContin

160. When it launched OxyContin, Purdue knew it would have to overcome the generally accepted standards of medical practice that opioids were addictive and should be only used for causes of acute pain, surgery recovery, cancer treatment, or end of life palliative care and the Medical communities' concerns about opioids' ability to improve a patient's functioning and the evidence that patients developed a tolerance to opioids over time. Purdue did not conduct any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants)

[34] *FDA Announces Safety Labeling Changes and Postmarket Study Requirements for Extended-Release and Long-Acting Opioid Analgesics*, MagMutual (Aug. 18, 2016), https://www.magmutual.com/learning/article/fda-announces-safety-labeling-changes-and-postmarket-study-requirements-opioids ; *see also* Press Release, U.S. Food & Drug Admin., FDA Announces Enhanced Warnings for Immediate-Release Opioid Pain Medications Related to Risks of Misuse, Abuse, Addiction, Overdose and Death, (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm .

[35] Deborah Dowell, M.D., *et al*., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States 2016,* 65(1) Morbidity & Mortality Wkly. Rep. 1, 21 (Mar. 18, 2016) (hereinafter, "CDC Guideline").

[36] *Id*. at 2.

found this "research" in the form of a one-paragraph letter to the editor published in the *New England Journal of Medicine* (NEJM) in 1980.

161. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction "rare" for patients treated with opioids[37] based on a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in patients' records.

162. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study.[38]

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

[37] Jane Porter & Herschel Jick, M.D., *Addiction Rare in Patients Treated with Narcotics*, 302(2) New Engl. J. Med. 123 (Jan. 10, 1980), http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221 .
[38] Meier, *supra*, at 174.

163. Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its source was a letter to the editor, not a peer-reviewed paper.[39] Citation of the letter, which was largely ignored for more than a decade, significantly increased after the introduction of OxyContin. While first Purdue and then other Marketing Defendants used it to assert that their opioids were not addictive, "that's not in any shape or form what we suggested in our letter," according to Dr. Jick.

164. Purdue specifically used the Porter and Jick letter in its 1998 promotional video, "I got my life back," in which Dr. Alan Spanos says, "In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than* 1%."[40] Purdue trained its sales representatives to tell prescribers that fewer than 1% of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)[41]

165. Other Defendants relied on and disseminated the same distorted messaging. The enormous impact of Defendants' misleading amplification of this letter was well documented in another letter published in the NEJM on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and in some cases "grossly misrepresented." In particular, the authors of this letter explained:

> [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the

[39] Porter & Jick, *supra* note 28.
[40] Our Amazing World, *Purdue Pharma OxyContin Commercial*, YouTube (Sept. 22, 2016), https://www.youtube.com/watch?v=Er78Dj5hyeI .
[41] Patrick R. Keefe, *The Family That Built an Empire of Pain,* New Yorker (Oct. 30, 2017) (hereinafter, "Keefe, *Empire of Pain*").

> North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy . . .[42]

166. "It's difficult to overstate the role of this letter," said Dr. David Juurlink of the University of Toronto, who led the analysis. "It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern."[43]

167. Alongside its use of the Porter and Jick letter, Purdue also crafted its own materials and spread its deceptive message through numerous additional channels. In its 1996 press release announcing the release of OxyContin, for example, Purdue declared, "The fear of addiction is exaggerated."[44]

168. At a hearing before the House of Representatives' Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue emphasized "legitimate" treatment, dismissing cases of overdose and death as something that would not befall "legitimate" patients: "Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional."[45]

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[42] Pamela T.M. Leung, B.Sc. Pharm., *et al., A 1980 Letter on the Risk of Opioid Addiction*, 376 New Engl. J. Med. 2194, 2194-95 (June 1, 2017), http://www.nejm.org/doi/full/10.1056/NEJMc1700150 .

[43] 33Marilynn Marchione, Assoc. Press, *Painful Words: How a 1980 Letter Fueled the Opioid Epidemic*, STAT News (May 31, 2017), https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/ .

[44] Press Release, Purdue Pharma, L.P., New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain (May 31, 1996, 3:47pm), http://documents.latimes.com/oxycontin-press-release-1996/ .

[45] *OxyContin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Com.*, 107th Cong. 1 (Aug. 28, 2001) (Statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm .

169. In a patient brochure about OxyContin, called "A Guide to Your New Pain Medicine and How to Become a Partner Against Pain," Purdue misled patients about the risk of addition by changing the definition of addition. In response to the question "Aren't opioid pain medications like OxyContin Tablets 'addicting'?," Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, "medical" purposes:

> Drug addiction means using a drug to get "high" rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.

170. Sales representatives marketed OxyContin as a product "to start with and to stay with."[46] Sales representatives also received training in alleging doctors' legitimate concerns about addiction with talking points they knew to be untrue about the drug's abuse potential. One of Purdue's early training memos compared doctor visits to "firing at a target," declaring that [a]s you prepare to fire your 'message,' you need to know where to aim and what you want to hit!"[47] According to the memo, the target is physician resistance based on concern about addiction: "The physician wants pain relief for these patients without addicting them to an opioid." [48]

171. Purdue, through its unbranded website *Partners Against Pain,*[49] stated the following: "Current Myth: Opioid addiction (psychological dependence) is an important

[46] Keefe, *Empire of Pain*, *supra* note 32.
[47] Meier, *supra* note 14 at 102.
[48] *Id.*
[49] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for better pain care, and a set of medical education resources distributed to prescribers by sales representatives. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."

clinical problem in patients with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids." "Addiction risk also appears to be low when opioids are dosed properly for chronic, noncancer pain."

172. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors' objections to prescribing opioids. The most common objection he heard about prescribing OxyContin was that "it's just too addictive."[50] May and his coworkers were trained to "refocus" doctors on "legitimate" pain patients, and to represent that "legitimate" patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less "habit-forming" than painkillers that need to be taken every four hours.

173. According to interviews with prescribers and former Purdue sales representatives, Purdue has continued to distort or omit the risk of addiction while failing to correct its earlier misrepresentations, leaving many doctors with the false impression that pain patients will only rarely become addicted to opioids.

174. With regard to addiction, Purdue's label for OxyContin has not sufficiently disclosed the true risks to, and experiences of, its patients. Until 2014, the OxyContin label stated in a black-box warning that opioids have "abuse potential" and that the "risk of abuse is increased in patients with a personal or family history of substance abuse."

[50] Interview by Patrick Keefe with Steven Mays, former sales representative for Purdue Pharma, L.P., *How OxyContin Was Sold to the Masses*, The New Yorker (Oct. 27, 2017), https://www.newyorker.com/podcast/the-new-yorker-radio-hour/how-oxycontin-was-sold-to-the-masses .

175. However, the FDA made clear to Purdue as early as 2001 that the disclosures in its OxyContin label were insufficient.

176. In 2001, Purdue revised the indication and warnings for OxyContin . In the United States, Purdue ceased distributing the 160 mg tablet of OxyContin.

177. In the end, Purdue narrowed the recommended use of OxyContin to situations when "a continuous, around-the-clock analgesic is needed for an extended period of time" and added a warning that "[t]aking broken, chewed, or crushed OxyContin tablets" could lead to a "potentially fatal dose." However, Purdue did not, until 2014, change the label to indicate that OxyContin should not be the first therapy, or even the first opioid, used, and did not disclose the incidence or risk of overdose and death even when OxyContin was not abused.

b. Endo misrepresented the risk of addiction

178. Endo also falsely represented that addiction is rare in patients who are prescribed opioids.

179. Until April 2012, Endo's website for Opana, www.Opana.com, stated that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."

180. Upon information and belief, Endo improperly instructed its sales representatives to diminish and distort the risk of addiction associated with Opana ER. Endo's training materials for its sales representatives in 2011 also prompted sales representatives to answer "true" to the statement that addiction to opioids is not common.

181. One of the Front Groups with which Endo worked most closely was the American Pain Foundation ("APF"), described more fully below. Endo provided substantial assistance to, and exercised editorial control, over the deceptive and misleading messages that APF conveyed through its National Initiative on Pain Control ("NIPC")[51] and its website *www.PainKnowledge.com*, which claimed that "[p]eople who take opioids as prescribed usually do not become addicted."

182. Another Endo website, *www.PainAction.com*, stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

183. In a brochure available on *www.PainKnowledge.com* titled *"Pain: Opioid Facts,"* Endo-sponsored NIPC stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted." In numerous patient education pamphlets, Endo repeated this deceptive message.

184. In a patient education pamphlet titled *"Understanding Your Pain: Taking Oral Opioid Analgesics,"* Endo answers the hypothetical patient question—"What should I know about opioids and addiction?"—by focusing on explaining what addiction is ("a chronic brain disease") and is not ("Taking opioids for pain relief"). It goes on to explain that "[a]ddicts take opioids for other reasons, such as unbearable emotional problems.

[51] Endo was one of the APF's biggest financial supporters, providing more than half of the $10 million APF received from opioid manufacturers during its lifespan. Endo was the sole funder of NIPC and selected APF to manage NIPC. Internal Endo documents indicate that Endo was responsible for NIPC curriculum development, web posting, and workshops, developed and reviewed NIPC content, and took a substantial role in distributing NIPC and APF materials. Endo projected that it would be able to reach tens of thousands of prescribers nationwide through the distribution of NIPC materials.

Taking opioids as prescribed for pain relief is not addiction." This publication is still available online.

185. An Endo publication, *Living with Someone with Chronic Pain,* stated, "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website, *www.Opana.com*, until at least April 2012.

186. In addition, a 2009 patient education publication, *Pain: Opioid Therapy,* funded by Endo and posted on *www.PainKnowledge.com*, incredibly omitted addiction from the "common risks" of opioids, as shown below:

As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:

- Constipation
- Drowsiness
- Confusion
- Nausea
- Itching
- Dizziness
- Shortness of breath

Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

c. Janssen misrepresented the risk of addition

187. Janssen misrepresented the addiction risk of opioids on its websites and print materials. One website, *Let's Talk Pain,* states, among other things, that "the stigma of drug addiction and abuse" associated with the use of opioids stemmed from a "lack of understanding about addiction." (Although Janssen described the website internally as an

unbranded third-party program, it carried Janssen's trademark and copy approved by Janssen.)

188. The *Let's Talk Pain* website also perpetuated the concept of pseudoaddiction, associating patient behaviors such as "drug seeking," "clock watching," and "even illicit drug use or deception" with undertreated pain, which can be resolved with "effective pain management."

189. A Janssen unbranded website, *www.PrescribeResponsibly.com*, states that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients."[52]

190. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief Pain Management for Older Adults,* which, as seen below, 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." Until recently, this guide was still available online:

[52] Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Mgmt.*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/opioid-pain-management (last updated July 2, 2015).

191. Janssen's website for Duragesic included a section addressing "Your Right to Pain Relief" and a hypothetical patient's fear that "I'm afraid I'll become a drug addict." The website's response: "Addiction is relatively rare when patients take opioids appropriately."

d. Cephalon misrepresented the risk of addiction

192. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient's Guide,* which included claims that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids." Similarly, Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

193. For example, a 2003 Cephalon-sponsored CME presentation titled *Pharmacologic Management of Breakthrough or Incident Pain,* posted on Medscape in February 2003, teaches:

> [C]hronic pain is often undertreated, particularly in the noncancer patient population. ... The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.[53]

[53] Michael J. Brennan, *et al*., *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape, http://www.medscape.org/viewarticle/449803 (behind paywall).

e. Actavis misrepresented the risk of addition

194. Through its "Learn More about customized pain control with Kadian" material, Actavis claimed that it is possible to become addicted to morphine-based drugs like Kadian, but that it is "less likely" to happen in those who "have never had an addiction problem." The piece goes on to advise that a need for a "dose adjustment" is the result of tolerance, and "not addiction."

195. Training for Actavis sales representatives deceptively minimizes the risk of addiction by: (i) attributing addiction to "predisposing factors" like family history of addiction or psychiatric disorders; (ii) repeatedly emphasizing the difference between substance dependence and substance abuse; and (iii) using the term pseudoaddiction, which, as described below, dismisses evidence of addiction as the undertreatment of pain and, dangerously, counsels doctors to respond to its signs with more opioids.

196. Actavis conducted a market study on takeaways from prescribers' interactions with Kadian sales representatives. The doctors had a strong recollection of the sales representatives' discussion of the low-abuse potential. Actavis' sales representatives' misstatements on the low-abuse potential was considered an important factor to doctors, and was most likely repeated and reinforced to their patients. Additionally, doctors reviewed visual aids that the Kadian sales representatives use during the visits, and Actavis noted that doctors associate Kadian with less abuse and no highs, in comparison to other opioids. Numerous marketing surveys of doctors in 2010 and 2012, for example, confirmed Actavis's messaging about Kadian's purported low addiction potential, and that it had less abuse potential than other similar opioids.

197. A guide for prescribers under Actavis's copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide includes the following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) "KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." The guide is copyrighted by Actavis in 2007, before Actavis officially purchased Kadian from Alpharma. These statements convey both that (a) Kadian does not cause euphoria and therefore is less addictive and that (b) Kadian is less prone to tampering and abuse, even though Kadian was not approved by the FDA as abuse deterrent, and, upon information and belief, Actavis had no studies to suggest it was.

f. Mallinkrodt misrepresented the risk of addiction

198. As described below, Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through the "C.A.R.E.S. Alliance" it created and led.

199. Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing

opioid pain medication abuse and increasing responsible prescribing habits." The "C.A.R.E.S. Alliance" itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

200. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled *Defeat Chronic Pain Now!* This book is still available online. The false claims and misrepresentations in this book include the following statements:

- "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."
- "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."
- "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."
- "**The bottom line**: Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."
- "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

201. In a 2013 *Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse,* which is still available online,

Mallinckrodt stated that, "[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated" and cites to a report that concludes that "the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others."

g. The Marketing Defendants misrepresented the risks associated with opioid addiction

202. Marketing Defendants' suggestions that the opioid epidemic is the result of bad patients who manipulate doctors to obtain opioids illicitly helped further their marketing scheme, but is at odds with the facts. While there are certainly patients who unlawfully obtain opioids, they are a small minority. For example, patients who "doctor-shop"—i.e., visit multiple prescribers to obtain opioid prescriptions—are responsible for roughly 2% of opioid prescriptions. The epidemic of opioid addiction and abuse is overwhelmingly a problem of false marketing (and unconstrained distribution) of the drugs, not problem patients.

203. While continuing to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted, the Marketing Defendants assert that to the extent that *some* patients are at risk of opioid addiction, doctors can effectively identify and manage that risk by using screening tools or questionnaires. In materials they produced, sponsored, or controlled, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for chronic pain. These tools, they say, identify those with higher addiction risks

(stemming from personal or family histories of substance use, mental illness, trauma, or abuse) so that doctors can then more closely monitor those patients.

204. Purdue shared its *Partners Against Pain* "Pain Management Kit," which contains several screening tools and catalogues of Purdue materials, which included these tools, with prescribers. Janssen, on its website *www.PrescribeResponsibly.com*, states that the risk of opioid addiction "can usually be managed" through tools such as opioid agreements between patients and doctors.[54] The website, which directly provides screening tools to prescribers for risk assessments, includes a "[flour question screener" to purportedly help physicians identify and address possible opioid misuse.[55]

205. Purdue and Cephalon sponsored the APF's *Treatment Options: A Guide for People Living with Pain* (2007), which also falsely reassured patients that opioid agreements between doctors and patients can "ensure that you take the opioid as prescribed."

206. Purdue sponsored a 2011 webinar taught by Dr. Webster, entitled *Managing Patient's Opioid Use: Balancing the Need and Risk.* This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."

207. Purdue sponsored a 2011 CME program titled *Managing Patient's Opioid Use: Balancing the Need and Risk.* This presentation deceptively instructed prescribers

[54] Howard A. Heit, M.D., FACP, FASAM & Douglas L. Gourlay, M.D., M.Sc., FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/before-prescribing-opioids#pseudoaddiction (last modified July 2, 2015).

[55] *Risk Assessment Resources,* Prescribe Responsibly, http://www.prescriberesponsibly.com/risk-assessment-resources (last modified July 2, 2015).

that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths."

208. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes.* The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

209. Endo paid for a 2007 supplement available for continuing education credit in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers' bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids,* (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* ("ORT") created by Dr. Webster and linked to Janssen or (b) the *Screener and Opioid Assessment for Patients with Pain,* and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts. The ORT was linked to by Endo-supported websites, as well.

210. There are three fundamental flaws in the Marketing Defendants' representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients identified through screening can take opioids long-term without triggering addiction, even with enhanced monitoring. Third, there is no

reliable scientific evidence that patients who are not identified through such screening identified through such screening can take opioids long-term without significant danger of addiction.

211. The Marketing Defendants instructed patients and prescribers that signs of addiction are actually indications of untreated pain, such that the appropriate response is to prescribe even more opioids. Dr. David Haddox, who later became a Senior Medical Director for Purdue, published a study in 1989 coining the term "pseudoaddiction," which he characterized as "the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management."[56] In other words, people on prescription opioids who exhibited classic signs of addiction—for example, asking for more and higher doses of opioids, self-escalating their doses, or claiming to have lost prescriptions in order to get more opioids—were not addicted, but rather simply suffering from undertreatment of their pain.

212. In the materials and outreach they produced, sponsored, or controlled, Defendants made each of these misrepresentations and omissions, and have never acknowledged, retracted, or corrected them.

213. Cephalon, Endo, and Purdue sponsored the Federation of State Medical Boards' ("FSMB") *Responsible Opioid Prescribing* (2007) written by Dr. Fishman and discussed in more detail below, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain

[56] David E. Weissman & J. David Haddox, *Opioid Pseudoaddiction—An Iatrogenic Syndrome*, 36(3) Pain 363, 363-66 (Mar. 1989), https://www.ncbi.nlm.nih.gov/pubmed/2710565 ("Iatrogenic" describes a condition induced by medical treatment).

opioids, and hoarding, which are signs of genuine addiction, are all really signs of "pseudoaddiction."

214. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its unbranded website, *www.PartnersAgainstPain. com* , in 2005, and circulated this pamphlet through at least 2007 and on its website through at least 2013. The pamphlet listed conduct including "illicit drug use and deception" that it claimed was not evidence of true addiction but "pseudoaddiction" caused by untreated pain.

215. According to documents provided by a former Purdue detailer, sales representatives were trained and tested on the meaning of pseudoaddiction, from which it can be inferred that sales representatives were directed to, and did, describe pseudoaddiction to prescribers. Purdue's Pain Management Kit is another example of publication used by Purdue's sales force that endorses pseudoaddiction by claiming that "pain-relief seeking behavior can be mistaken for drug-seeking behavior." Upon information and belief, the kit was in use from roughly 2011 through at least June 2016.

216. Similarly, internal documents show that Endo trained its sales representatives to promote the concept of pseudoaddiction. A training module taught sales representatives that addiction and pseudoaddiction were commonly confused. The module went on to state that: "The physician can differentiate addiction from pseudoaddiction by speaking to the patient about his/her pain and increasing the patient's opioid dose to increase pain relief."

217. Endo also sponsored a NIPC CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia,* which promoted

pseudoaddiction and listed "[d]ifferentiation among states of physical dependence, tolerance, pseudoaddiction, and addiction" as an element to be considered in awarding grants to CME providers.

218. Upon information and belief, Endo itself has 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 New York Attorney General, in a 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."[57] Endo thereafter agreed not to "use the term tseudoaddiction in any training or marketing" in New York.

219. Janssen sponsored, funded, and edited a website called *Let's Talk Pain,* which in 2009 stated "pseudoaddiction . . . refers to patient behaviors that may occur when *pain is undertreated* . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until at least May 2012.

220. Janssen also currently runs a website, *www.PrescribeResponsibly.com*, which claims that concerns about opioid addiction are "overestimated," and describes pseudoaddiction as "a syndrome that causes patients to seek additional medications due to

[57] Attorney General of the State of New York, *In the Matter of Endo Health Solutions Inc. & Endo Pharmaceuticals Inc*., Assurance No.:15-228, Assurance of Discontinuance Under Executive Law Section 63. Subdivision 15 at 7.

inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately the inappropriate behavior ceases."

221. The CDC Guideline does not recommend attempting to provide more opioids to patients exhibiting symptoms of addiction. Dr. Lynn Webster, a "key opinion leader" ("KOL") discussed below, admitted that pseudoaddiction "is already something we are debunking as a concept" and became "too much of an excuse to give patients more medication. It led us down a path that caused harm."

222. In an effort to underplay the risk and impact of addiction, the Marketing Defendants falsely claimed that, while patients become physically dependent on opioids, physical dependence is not the same as addiction and can be easily addressed, if and when pain relief is no longer desired, by gradually tapering patients' dose to avoid the adverse effects of withdrawal. Defendants failed to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—adverse effects that also make it less likely that patients will be able to stop using the drugs. Defendants also failed to disclose how difficult it is for patients to stop using opioids after they have used them for prolonged periods.

223. A non-credit educational program sponsored by Endo, *Persistent Pain in the Older Adult,* claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient's opioid dose over ten days. However, this claim is at odds with the experience of patients addicted to opioids. Most patients who have been taking opioids regularly will, upon stopping treatment, experience withdrawal, characterized by intense physical and psychological effects, including anxiety,

nausea, headaches, and delirium, among others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

224. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management,* which taught that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

225. To this day, the Marketing Defendants have not corrected or retracted their misrepresentations regarding tapering as a solution to opioid withdrawal.

226. In materials they produced, sponsored or controlled, Marketing Defendants instructed prescribers that they could safely increase a patient's dose to achieve pain relief. Each of the Marketing Defendants' claims was deceptive in that it omitted warnings of increased adverse effects that occur at higher doses, effects confirmed by scientific evidence.

227. These misrepresentations were integral to the Marketing Defendants' promotion of prescription opioids. As discussed above, patients develop a tolerance to opioids' analgesic effects, so that achieving long-term pain relief requires constantly increasing the dose.

228. In a 1996 sales memo regarding OxyContin, for example, a regional manager for Purdue instructed sales representatives to inform physicians that there is

"no[] upward limit" for dosing and ask "if there are any reservations in using a dose of 240mg-320mg of OxyContin."[58]

229. In addition, sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative wrote about how his regional manager would drill the sales team on their upselling tactics:

> It went something like this. "Doctor, what is the highest dose of OxyContin you have ever prescribed?" "20mg Q 1 2h." "Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?" "Okay." "Doctor, what if that patient them came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q 1 2h, would you do that?" "I don't know, maybe." "Doctor, but you do agree that you would at least Rx the 40mg dose, right?" "Yes." The next week the rep would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin.

230. These misrepresentations were particularly dangerous. As noted above, opioid doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and 50 MME is equal to just 33 mg of oxycodone. The recommendation of 320 mg every twelve hours is ten times that.

231. In its 2010 Risk Evaluation and Mitigation Strategy ("REMS") for OxyContin, however, Purdue does not address the increased risk of respiratory depression and death from increasing dose, and instead advises prescribers that "dose adjustments may be made every 1-2 days"; "it is most appropriate to increase the ql2h dose"; the "total daily dose can usually be increased by 25% to 50%"; and if "significant adverse reactions

[58] Letter from Windell Fisher, Purdue Regional Manager, to B. Gergely, Purdue Employee (Nov. 7, 1996), http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/ (last updated May 5, 2016) (hereinafter, "Letter from Fisher").

occur, treat them aggressively until they are under control, then resume upward titration."[59]

232. Endo sponsored a website, *www.PainKnowledge.com*, which claimed that opioids may be increased until "you are on the right dose of medication for your pain," at which point further dose increases would not be required.

233. Endo also published on its website a patient education pamphlet 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 ."

234. Purdue and Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids have "no ceiling dose" and therefore are safer than NSAIDs.

235. Marketing Defendants were aware of the greater dangers high-dose opioids posed. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events" and that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." A study of the Veterans Health Administration from 2004 to 2008 found the rate of overdose deaths is directly related to maximum daily dose.

[59] Purdue Pharma, L.P., *OxyContin Risk Evaluation and Mitigation Strategy*, https://web.archive.org/web/20170215190303/https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf (last modified Nov. 2010).

h. The Defendants misrepresented that opioids would improve a patient's ability to function and one's quality of life.

236. Despite the lack of evidence of improved function and the existence of evidence to the contrary, the Marketing Defendants consistently promoted opioids as capable of improving patients' function and quality of life because they viewed these claims as a critical part of their marketing strategies.

237. Janssen, for example, promoted Duragesic as improving patients' functioning and work productivity through an ad campaign that included the following statements: "[w]ork, uninterrupted," "[l]ife, uninterrupted," "[c]hronic pain relief that supports functionality," and "[i]mprove[s] . . . physical and social functioning."

238. Purdue noted the need to compete with this messaging, despite the lack of data supporting improvement in quality of life with OxyContin treatment:

> Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained release morphine ... We do not have such data to support OxyContin promotion. . . . In addition, Janssen has been using the "life uninterrupted" message in promotion of Duragesic for non-cancer pain, stressing that Duragesic "helps patients think less about their pain." This is a competitive advantage based on our inability to make any quality of life claims.[60]

239. Despite its acknowledgment that "[w]e do not have such data to support OxyContin promotion," Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association, proclaiming, "There Can Be Life With Relief," and showing a man happily fly-fishing alongside his grandson, implying that OxyContin would help users' function. This ad resulted in a warning letter, from the FDA, which

[60] Meier, *supra* at 281.

stated, "It is particularly disturbing that your November ad would tout 'Life With Relief' yet fail to warn that patients can die from taking OxyContin."[61]

240. Purdue sponsored 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. But the article cited as support for this in fact stated the contrary, noting the absence of long-term studies and concluding, "[f]or functional outcomes, the other analgesics were significantly more effective than were opioids."

241. A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

242. Similarly, since at least May of 2011, Endo has distributed and made available on its website, *www.Opana.com,* a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like those of a construction worker or chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement.

243. As noted above, 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." This guide features a man

[61] Chris Adams, *FDA Orders Purdue Pharma to Pull Its OxyContin Ads*, Wall St. J. (Jan. 23, 2003, 12:01am), https://www.wsj.com/articles/SB1043259665976915824 .

playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. It assures patients that, "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal." Similarly, *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva, Endo, and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

244. In addition, Janssen's *Let's Talk Pain,* website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," falsely implying that her experience would be representative.

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

246. Endo's NIPC website *www.PainKnowledge.com* claimed 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." In addition to "improved function," the website touted improved quality of life as a benefit of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC' s intent to make claims of functional improvement.

247. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient,* which claimed that chronic opioid therapy has been

"shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

248. Mallinckrodt's website, in a section on responsible use of opioids, claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[62]

249. The Marketing Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long term. The FDA, for years, has made clear through warning letters to manufacturers the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life.[63] Based upon a review of the existing scientific evidence, the CDC Guideline concluded that "there is no good evidence that opioids improve pain or function with long-term use."[64]

250. Consistent with the CDC's findings, substantial evidence exists demonstrating that opioid drugs are ineffective for the treatment of chronic pain and

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[62] Mallinckrodt Pharmaceuticals, *Responsible Use*, http://www.mallinckrodt.com/corporate-responsibility/responsible-use .

[63] The FDA has warned other drugmakers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] 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."). The FDA's warning letters were available to Defendants on the FDA website.

[64] CDC Guideline, *supra*, at 20.

worsen patients' health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. The few longer-term studies of opioid use had "consistently poor results," and "several studies have showed that [using] opioids for chronic pain may actually worsen pain and functioning,[65] along with general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.

251. The available evidence indicates opioids may worsen patients' health and pain. Increased duration of opioid use is strongly associated with increased prevalence of mental health disorders (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization. The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[66] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[67]

252. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to

[65] Thomas R. Frieden and Debra Houry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, New Eng. J. of Med., at 1503 (Apr. 21, 2016).
[66] CDC Guideline, *supra*, at 2, 18.
[67] Frieden & Houry, *Reducing the Risks of Relief*, *supra*, at 1503.

control pain, and these patients are unable to function normally."[68] In fact, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.[69] Another study demonstrated that injured workers who received a prescription opioid for more than seven days during the first six weeks after the injury were 2.2 times more likely to remain on work disability a year later than workers with similar injuries who received no opioids at al1.[70]

i. The Marketing Defendants discouraged the use of alternative forms of pain relief by exaggerating their risks

253. In materials they produced, sponsored or controlled, the Marketing Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs.

254. For example, in addition to failing to disclose in promotional materials the risks of addiction, overdose, and death, the Marketing Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;[71]

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[68] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747 .

[69] Jeffrey Dersh, *et al*., *Prescription Opioid Dependence is Associated With Poorer Outcomes in Disabling Spinal Disorders*, 33(20) Spine 2219-27 (Sept. 15, 2008).

[70] GM Franklin, BD Stover, JA Turner, D Fulton-Kehoe, TM Wickizer, *Early Opioid Prescription and Subsequent Disability Among Workers With Back Injuries: The Disability Risk Identification Study Cohort*, 33(2) Spine 199, 201-202 (Jan. 15, 2008).

[71] Letter from Janet Woodcock, M.D., Dir. of Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. of Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

hormonal dysfunction;[72] decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;[73] neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol or with benzodiazepines, which are used to treat anxiety and may be co-prescribed with opioids, particularly to veterans suffering from pain.[74]

255. The APF's *Treatment Options: A Guide for People Living with Pain,* sponsored by Purdue and Cephalon, warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdoses, when the figure is closer to 3,200.

256. Janssen sponsored *Finding Relief Pain Management for Older Adults* (2009), which listed dose limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased doses from opioids. *Finding Relief* described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "can increase the risk of heart attack and stroke." The only

[72] H.W. Daniell, *Hypogonadism in Men Consuming Sustained-Action Oral Opioids,* 3(5) J. Pain 377, 377-84 (2001).
[73] Bernhard M. Kuschel, *The Risk of Fall Injury in Relation to Commonly Prescribed Medications Among Older People—A Swedish Case-Control Study*, 25(3) Eur. J. Pub. H. 527, 527-32 (July 31, 2014).
[74] Karen H. Seal *et al.*, *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. of Am. Med. Assoc. 940, 940-47 (2012).

adverse effects of opioids listed are "upset stomach or sleepiness," which the brochure claims will go away, and constipation.

257. Endo's NIPC website, *Painknowledge.com*, which contained a flyer called *"Pain: Opioid Therapy."* This publication listed opioids' adverse effects but with significant omissions, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

258. As another example, the Endo-sponsored CME put on by NIPC, *Persistent Pain in the Older Adult,* discussed above, counseled that acetaminophen should be used only short-term and includes five slides on the FDA's restrictions on acetaminophen and its adverse effects, including severe liver injury and anaphylaxis (shock). In contrast, the CME downplays the risk of opioids, claiming opioids have "possibly less potential for abuse than in younger patients," and does not list overdose among the adverse effects. Some of those misrepresentations are described above; others are laid out below.

259. In April 2007, Endo sponsored an article aimed at prescribers, published in *Pain Medicine News,* titled "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain."[75] The article asserted:

> Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids—the gradual waning of relief at a given dose—and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.[76]

[75] Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, http://www.painmedicinenews.com/download/ BtoB_Opana_WM.pdf
[76] *Id*. at 1.

260. To help allay these concerns, Endo emphasized the risks of NSAIDs as an alternative to opioids. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids.

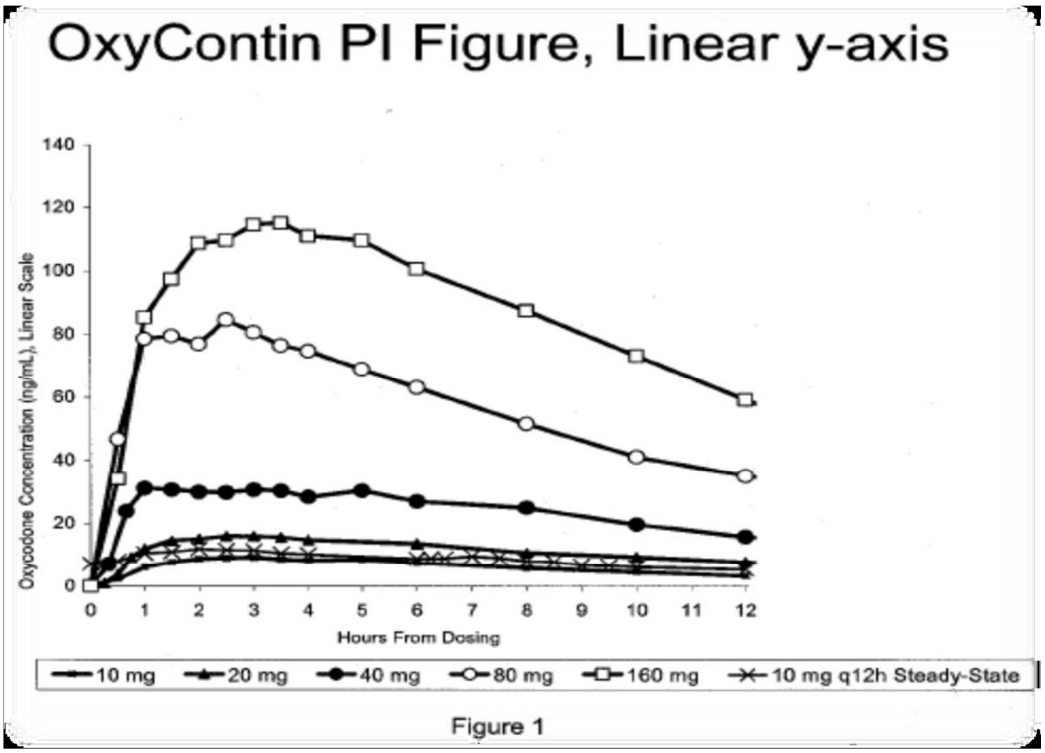
261. Additionally, Purdue acting with Endo sponsored *Overview of Management Options,* a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

262. As a result of the Marketing Defendants' deceptive promotion of opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.

263. Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action, making the knowingly false claim that OxyContin would provide 12 hours of pain relief for most patients. As laid out below, Purdue made this claim for two reasons. First, it provides the basis for both Purdue's patent and its market niche, allowing it to both protect and differentiate itself from competitors. Second, it allowed Purdue to imply or state outright that OxyContin had a more even, stable release

mechanism that avoided peaks and valleys and therefore the rush that fostered addiction and attracted abusers.

264. Purdue promotes OxyContin as an extended-release opioid, but the oxycodone does not enter the body at a linear rate. OxyContin works by releasing a greater proportion of oxycodone into the body upon administration, and the release gradually tapers, as illustrated in the following chart, which was apparently adapted from Purdue's own sales materials:



265. The reduced release of the drug over time means that the oxycodone no longer provides the same level of pain relief; as a result, in many patients, OxyContin does not last for the twelve hours for which Purdue promotes it—a fact that Purdue has known at all times relevant to this action.

266. OxyContin tablets provide an initial absorption of approximately 40% of the active medicine. This has a two-fold effect. First, the initial rush of nearly half of the powerful opioid triggers a powerful psychological response. OxyContin thus behaves more like an immediate-release opioid, which Purdue itself once claimed was more addicting in its original 1995 FDA- approved drug label. Second, the initial burst of oxycodone means that there is less of the drug at the end of the dosing period, which results in the drug not lasting for a full twelve hours and precipitates withdrawal symptoms in patients, a phenomenon known as "end of dose" failure. (The FDA found in 2008 that a "substantial number" of chronic pain patients will experience end-of-dose failure with OxyContin.)

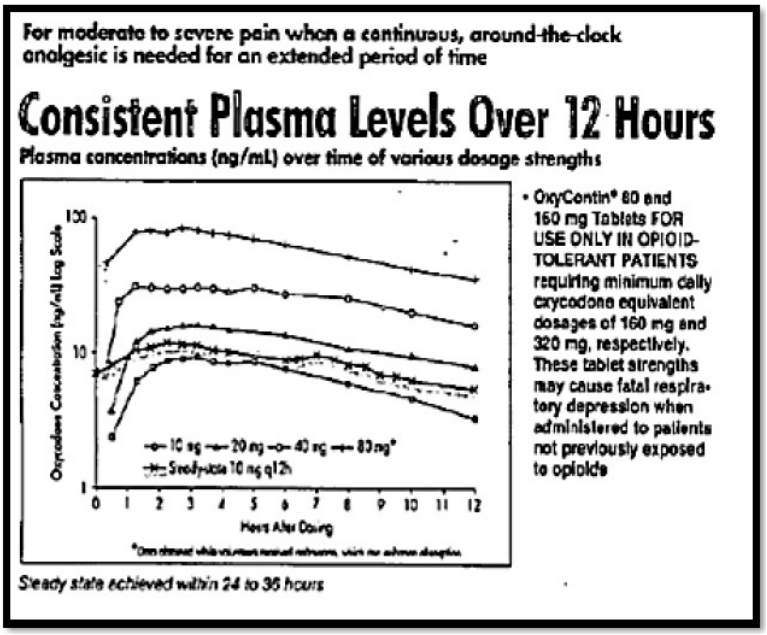
267. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[77] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

268. It was Purdue's decision to submit OxyContin for approval with 12-hour dosing. While the OxyContin label indicates that "[t]here are no well-controlled clinical

[77] Harriet Ryan, *et al*., "'*You Want a Description of Hell?' OxyContin's 12-Hour Problem*," L.A. Times, May 5, 2016, http://www.latimes.com/projects/oxycontin-part1/ (hereinafter, *"You Want a Description of Hell?"*).

studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," that is because Purdue has conducted no such studies.

269. Purdue nevertheless has falsely promoted OxyContin as if it were effective for a full twelve hours. Its advertising in 2000 included claims that OxyContin provides "Consistent Plasma Levels Over 12 Hours." That claim was accompanied by a chart, mirroring the chart on the previous page. However, this version of the chart deceptively minimized the rate of end-of-dose failure by depicting 10 mg in a way that it appeared to be half of 100 mg in the table's y-axis. That chart, shown below, depicts the same information as the chart above, but does so in a way that makes the absorption rate appear more consistent:



270. Purdue's 12-hour messaging was key to its competitive advantage over short-acting opioids that required patients to wake in the middle of the night to take their pills. Purdue advertisements also emphasized "Q12h" dosing. These include an advertisement in the February 2005 *Journal of Pain* and 2006 *Clinical Journal of Pain* featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message. A Purdue memo to the OxyContin launch team stated that "OxyContin's positioning statement is 'all of the analgesic efficacy of immediate-release oxycodone, with convenient ql2h dosing,'" and further that "[t]he convenience of ql2h dosing was emphasized as the most important benefit."[78]

271. In keeping with this positioning statement, a Purdue regional manager emphasized in a 1996 sales strategy memo that representatives should "convince[e] the physician that there is no need" for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and instead the solution is prescribing higher doses.[79] One sales manager instructed her team that anything shorter than 12-hour dosing "needs to be nipped in the bud, NOW!!"[80]

272. Purdue executives therefore maintained the messaging of twelve-hour dosing even when many reports surfaced that OxyContin did not last twelve hours. Instead of acknowledging a need for more frequent dosing, Purdue instructed its representatives to push higher-strength pills, even though higher dosing carries its own risks, as noted above. It also means that patients will experience higher highs and lower lows, increasing their

[78] Memorandum from Lydia Johnson, Marketing Executive at Purdue, to members of OxyContin Launch Team (Apr. 4, 1995), http://documents.latimes.com/oxycontin-launch-1995/ (last updated May 5, 2016).
[79] Letter from Fisher, *supra*.
[80] *You Want a Description of Hell?*, *supra*.

craving for their next pill. (Urging higher doses to avoid end-of-dose failure is like advising a pilot to avoid a crash by flying higher.) Nationwide, based on an analysis by the *Los Angeles Times,* more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 MED that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[81]

273. That OxyContin did not provide pain relief for a full twelve hours was known to Purdue, and Purdue's competitors, but was not disclosed to prescribers. Purdue's knowledge of some pain specialists' tendency to prescribe OxyContin three times per day instead of two was set out in Purdue's internal documents as early as 1999 and is apparent from MedWatch Adverse Event reports for OxyContin.

274. Even Purdue's competitor, Endo, was aware of the problem; Endo attempted to position its Opana ER drug as offering "durable" pain relief, which Endo understood to suggest a contrast to OxyContin. Opana ER advisory board meetings featured pain specialists citing lack of 12-hour dosing as a disadvantage of OxyContin. Endo even ran advertisements for Opana ER referring to "real" 12-hour dosing.

275. Purdue's failure to disclose the prevalence of end-of-dose failure meant that prescribers were misinformed about the advantages of OxyContin in a manner that preserved Purdue's competitive advantage and profits, at the expense of patients, who were placed at greater risk of overdose, addiction, and other adverse effects.

[81] CDC Guideline, *supra*, at 16.

j. The Marketing Defendants claimed that new formulations of certain opioids successfully deter abuse

276. Rather than take the widespread opioid-abuse of and addiction to opioids as reason to cease their untruthful marketing efforts, Marketing Defendants Purdue and Endo seized them as a competitive opportunity. These companies developed and oversold "abuse-deterrent formulation" ("ADF") opioids as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids, as well as an advantage of these expensive branded drugs over other opioids. These Defendants' false and misleading marketing of the benefits of their ADF opioids preserved and expanded their sales and falsely reassured prescribers thereby prolonging the opioid epidemic. Other Marketing Defendants, including Actavis and Mallinckrodt, also promoted their branded opioids as formulated to be less addictive or less subject to abuse than other opioids.

277. The CDC Guideline confirms 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 non-oral routes." Tom Frieden, the former Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or deaths."

k. Purdue's deceptive marketing of reformulated OxyContin and Hysingla ER

278. Purdue's reformulated ADF OxyContin was approved by the FDA in April 2010, shortly before generic versions of OxyContin were to become available, threatening to erode Purdue's profit. In response to a citizen petition filed by Purdue, the FDA allowed Purdue to claim abuse-deterrent properties in its label.

279. Purdue employed the same marketing scheme with respect to ADF. Purdue sales representatives regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue sales representatives:

a. claimed that Purdue's ADF opioids prevent tampering and that its ADFs could not be crushed or snorted;

b. claimed that Purdue's ADF opioids reduce opioid abuse and diversion; asserted or suggested that its ADF opioids are non-addictive or less addictive;

c. asserted or suggested that Purdue's ADF opioids are safer than other opioids, could not be abused or tampered with, and were not sought out for diversion; and

d. failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

280. If pressed, Purdue acknowledged that perhaps some "extreme" patients might still abuse the drug, but claimed the ADF features protect the majority of patients. These misrepresentations and omissions are misleading and contrary to Purdue's ADF labels, Purdue's own information, and publicly available data.

281. Purdue knew or should have known that reformulated OxyContin is not more tamper-resistant than the original OxyContin and is regularly tampered with and abused.

282. In the 2012 medical office review of Purdue's application to include an abuse-deterrence claim in its label for OxyContin, the FDA noted that the overwhelming majority of deaths linked to OxyContin were associated with oral consumption, and that only 2% of deaths were associated with recent injection and only 0.2% with snorting the drug.

283. The FDA's Director of the Division of Epidemiology stated in September 2015 that no data that she had seen suggested the reformulation of OxyContin "actually made a reduction in abuse," between continued oral abuse, shifts to injection of other drugs (including heroin), and defeat of the ADF mechanism. Even Purdue's own funded research shows that half of OxyContin abusers continued to abuse OxyContin orally after the reformulation rather than shift to other drugs.

284. A 2013 article presented by Purdue employees based on review of data from poison control centers, concluded that ADF OxyContin can reduce abuse, but it ignored important negative findings. The study revealed that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids after the reformulation of OxyContin. In short, the article deceptively emphasized the advantages and ignored the disadvantages of ADF OxyContin.

285. Websites and message boards used by drug abusers, such as bluelight.org and reddit.com, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in

which a tablet is dissolved. Purdue has been aware of these methods of abuse for more than a decade.

286. One-third of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, there was no meaningful reduction in opioid abuse overall, as many users simply shifted to other opioids such as heroin.

287. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff was to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated OxyContin product has had a meaningful impact on abuse."[82] Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

288. Despite its own evidence of abuse, and the lack of evidence regarding the benefit of Purdue's ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers. Purdue's recent advertisements in national newspapers also continues to claim its ADF opioids as evidence

[82] Jill Hartzler Warner, Assoc. Comm'r for Special Med. Programs, *Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee*; *Notice of Meeting*, 80(103) Fed. Reg. 30686, 30686 (May 29, 2015).

of its efforts to reduce opioid abuse, continuing to mislead prescribers, patients, payors, and the public about the efficacy of its actions.

l. Endo's deceptive marketing of reformulated Opana ER

289. As the expiration of its patent exclusivity for Opana ER neared, Endo also made abuse-deterrence a key to its marketing strategy.

290. Opana ER was particularly likely to be tampered with and abused. That is because Opana ER has lower "bioavailability" than other opioids, meaning that the active pharmaceutical ingredient (the "API" or opioid) does not absorb into the bloodstream as rapidly as other opioids when taken orally. Additionally, when swallowed whole, the extended-release mechanism remains intact, so that only 10% of Opana ER's API is released into the patient's bloodstream relative to injection; when it is taken intranasally, that rate increases to 43%. The larger gap between bioavailability when consumed orally versus snorting or injection, the greater the incentive for users to manipulate the drug's means of administration.

291. A January 4, 2011 FDA Discipline Review letter made clear to Endo that "[t]he totality of these claims and presentations suggest that, as a result of its new formulation, Opana ER offers a therapeutic advantage over the original formulation when this has not been demonstrated by substantial evidence or substantial clinical experience. In addition these claims misleadingly minimize the risks associated with Opana ER by suggesting that the new formulation's "INTAC" technology confers some form of abuse-deterrence properties when this has not been demonstrated by substantial evidence." The FDA acknowledged that while there is "evidence to support some limited improvement"

provided by the new coating, but would not let Endo promote any benefit because "there are several limitations to this data." Also, Endo was required to add language to its label specifically indicating that "Opana ER tablets may be abused by crushing, chewing, snorting, or injecting the product. These practices will result in less controlled delivery of the opioid and pose a significant risk to the abuser that could result in overdose and death."

292. Endo knew by July 2011 that "some newer statistics around abuse and diversion are not favorable to our product."

293. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant.

294. Even prior to its approval, the FDA had advised Endo that it could not market the new Opana ER as abuse-deterrent. The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse." In other words, Opana ER was still crushable. Indeed, Endo's own studies dating from 2009 and 2010 showed that Opana ER could be crushed and ground, and, in its correspondence with the FDA, Endo admitted this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction.

295. In a May 7, 2012 letter to Endo, the FDA showed that it was still concerned about Endo's promotion. . . for Opana ER.

296. Endo consciously chose not to do any post-approval studies that might satisfy the FDA. According to internal documents, the company decided, by the time its

studies would be done, generics would be on the market and "any advantages for commercials will have disappeared."

297. In August of 2012, Endo submitted a citizen petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted and that it was resistant to injection by syringe. Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse deterrence), which would prevent generic copies of original Opana ER.

298. Endo then sued the FDA, seeking to force expedited consideration of its citizen petition. The court filings confirmed Endo's true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to $135 million per year. Endo also claimed that if the FDA did not block generic competition, $125 million, which Endo spent on developing the reformulated drug to "promote the public welfare" would be lost.[83] The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."[84]

299. Despite Endo's purported concern with public safety, not only did Endo continue to distribute original, admittedly unsafe Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its

[83] Plf.'s Opp. To Defs.' and Intervenor's Motions to Dismiss and Plf.'s Reply in Supp. of Motion for Prelim. Inj. [ECF No. 23], *Endo Pharms. Inc. v. U.S. Food and Drug Admin., et al*., No. 1:12-cv-01936, at 20 (D.D.C. Dec. 14, 2012).

[84] Defs.' Resp. to the Court's Nov. 30, 2012 Order [ECF No. 9], *Endo Pharms. Inc. v. U.S. Food and Drug Administration, et al*.., No. 1:12-cv-01936, at 6 (D.D.C. Dec. 3, 2012).

dangers. In fact, Endo claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[85]

300. In its citizen petition, Endo asserted that redesigned Opana ER had "safety advantages." Endo even relied on its rejected assertion that Opana was less crushable to argue that it developed Opana ER for patient safety reasons and that the new formulation would help, for example, "where children unintentionally chew the tablets prior to an accidental ingestion."[86]

301. However, in rejecting the petition in a 2013 decision, the FDA found that "study data show that the reformulated version's extended-release features can be compromised when subjected to . . . cutting, grinding, or chewing." The FDA also determined that "reformulated Opana ER" could also be "readily prepared for injections and more easily injected[.]" In fact, the FDA warned that preliminary data—including in Endo's own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than *was* the case with the original formulation.

302. e, In a 2012, an internal memorandum to Endo account executives noted that abuse of Opana ER had "increased significantly" in the wake of the purportedly abuse-deterrent formulation. In February 2013, Endo received abuse data regarding Opana ER from Inflexxion, Inc., which gathers information from substance abusers entering treatment and reviews abuse-focused internet discussions, that confirmed continued abuse, particularly by injection.

[85] *Id.*; Endo News Release (Sept. 6, 2012) [ECF No. 18-4], *Endo Pharms. Inc. v. U.S. Food and Drug Admin., et al.*, No. 1:12-cv-01936 (D.D.C. Dec. 9, 2012) at 81.
[86] Citizen Petition, FDA Docket 2012-8-0895, at 5.

303. In 2009, only 3% of Opana ER abuse was by intravenous means. After the reformulation, injection of Opana ER increased by more than 500%. Endo's own data, presented in 2014, found between October 2012 and March 2014, 64% of abusers of Opana ER did so by injection, compared with 36% for the old formulation.[87] The transition into injection of Opana ER made the drug even less safe than the original formulation. Injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.

304. Publicly, Endo sought to marginalize the problem. On a 2013 call with investors, when asked about an outbreak of TTP in Tennessee from injecting Opana ER, Endo sought to limit its import by assigning it to "a very, very distinct area of the country."

Despite its knowledge that Opana ER was widely abused and injected, Endo marketed the drug as tamper-resistant and abuse-deterrent. A review of national surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper-resistant.

305. In its written materials, Endo marketed Opana ER as having been designed to be crush-resistant, knowing that this would (falsely) imply that Opana ER actually was crush-resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012 Endo press release announced "the completion of

[87] Theresa Cassidy *et al*., *The Changing Abuse Ecology: Implications for Evaluating the Abuse Pattern of Extended-Release Oxymorphone and Abuse-Deterrent Opioid Formulations*, Pain Week Abstract 2014, https://www.painweek.org/assets/documents/general/724-painweek2014acceptedabstracts.pdf .

the company's transition of its Opana ER franchise to the new formulation designed to be crush resistant."

306. The press release further stated that: "We firmly believe that the new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians **and payers**." (Emphasis added.) The press release described the old formulation of Opana as subject to abuse and misuse, but failed to disclose the absence of evidence that reformulated Opana was any better. In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."

307. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant." A January 2013 article in Pain Medicine News, based in part on an Endo press release, described Opana ER as "crush-resistant." This article was posted on the *Pain Medicine News* website, which was accessible to patients and prescribers.

308. Endo, upon information and belief, targeted particular geographies for the redesigned Opana ER where abuse was most rampant.

309. In March 2017, because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and TTP, an FDA advisory committee recommended that Opana be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017. Endo announced on July 6, 2017 that it would agree to stop marketing and selling Opana ER. However, by this point the damage had been done. Even then, Endo

continued to insist, falsely, that it "has taken significant steps over the years to combat misuse and abuse."

m. Other Marketing Defendants' misrepresentations regarding abuse deterrence

310. A guide for prescribers under Actavis's copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide declares that "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and "KADIAN may be less likely to be abused by health care providers and illicit users" because of its "[s]low onset of action." Kadian, however, was not approved by the FDA as abuse deterrent, and, upon information and belief, Actavis had no studies to suggest it was.

311. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt's promotional materials stated that "the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving."[88] One member of the FDA's Controlled Substance Staff, however, noted in 2010 that hydromorphone has "a high abuse potential comparable to oxycodone" and further stated that "we predict that Exalgo will have high levels of abuse and diversion."[89]

[88] Press Release, Covidien, FDA Approves Mallinckrodt's EXALGO® (hydromorphone HCl) Extended-Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-Severe Chronic Pain (Aug. 27, 2012), http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159

[89] 2010 Meeting Materials, Anesthetic and Analgesic Drug Products Advisory Committee, at 157-58, FDA, https://wayback.archive-it.org/7993/20170403223634/https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/ucm/193298.htm .

312. With respect to Xartemis XR, Mallinckrodt's promotional materials stated that "CARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."[90] In anticipation of Xartemis XR's approval, Mallinckrodt added 150-200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate "hundreds of millions in revenue."[91]

313. While Marketing Defendants promote patented technology as the solution to opioid abuse and addiction, none of their "technology" addresses the most common form of abuse—oral ingestion—and their statements regarding abuse-deterrent formulations give the misleading impression that these reformulated opioids can be prescribed safely.

2. The Marketing Defendants Disseminated Their Misleading Messages About Opioids Through Multiple Channels

314. The Marketing Defendants' false marketing campaign not only targeted the medical community who had to treat chronic pain, but also patients who experience chronic pain and in order to receive payment for their opioid product, Defendants targeted pharmacy benefit managers and employer sponsored health plans.

315. The Marketing Defendants used different methods to further their marketing scheme: (1) "Front Groups" with the appearance of independence from the Marketing Defendants; (2) Doctors paid by the Marketing Defendants to promote their pro-opioid message ("key opinion leaders" ("KOLs")); (3) Continuing Medical Education ("CME") programs controlled and/or funded by the Marketing Defendants; (4) branded advertising;

[90] Mallinckrodt, *Responsible Use of Opioid Pain Medications* (Mar. 7, 2014).
[91] Samantha Liss, *Mallinckrodt Banks on New Painkillers for Sales*, St. Louis Bus. J. (Dec. 30, 2013), http://argentcapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/ .

(5) unbranded advertising; (6) publications; direct, targeted communications with prescribers by sales representatives or "detailers"; and speakers bureaus and programs.

a. The Marketing Defendants Controlled Front Groups and Directed Those Groups to Deceptively Promote Opioid Use

316. Patient advocacy groups and professional associations funded by the Marketing Defendants with KOL's as president or board member were used to reach prescribers, patients, ERISA Plans and their agents (including their PBMs and TPAs), and policymakers. These "Front Groups" put out patient education materials, treatment guidelines and CMEs that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks.[92] Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of their own constituencies.

317. "Patient advocacy organizations and professional societies like the Front Groups `play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public.'"[93] "Even small organizations—with 'their large numbers and credibility with policymakers and the public'—have 'extensive influence in specific disease areas.' Larger organizations with extensive funding and outreach capabilities 'likely have a substantial effect on policies relevant to their industry sponsors.'"[94] Indeed, the U.S. Senate's report, *Fueling an*

[92] U.S. S. Homeland Sec. & Governmental Aff. Comm., Ranking Members' Office, *Fueling an Epidemic*, Feb. 12, 2018, https://www.hsdl.org/?abstract&did=808171 at 3 (hereinafter, "*Fueling an Epidemic*").
[93] *Id*. at 2.
[94] *Id.*

Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups,[95] which arose out of a 2017 Senate investigation and, drawing on disclosures from Purdue, Janssen, Insys, and other opioid manufacturers, "provides the first comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies operating in the area of opioids policy,"[96] found that the Marketing Defendants made millions of dollars of contributions to various Front Groups.

318. The Marketing Defendants also "made substantial payments to individual group executives, staff members, board members, and advisory board members" affiliated with the Front Groups subject to the Senate Committee's study.[97]

319. As the Senate *Fueling an Epidemic* Report found, the Front Groups "amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain."[98] They also "lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC Guideline on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescription and misbranding."[99]

320. The Marketing Defendants took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups, ensuring that Defendants were consistently in control of their content. By funding, directing,

[95] *Id.* at 3.
[96] *Id*. at 3.
[97] *Id*. at 10.
[98] *Id*. at 12-15.
[99] *Id*. at 12.

editing, approving, and distributing these materials, Defendants exercised control over and adopted their false and deceptive messages and acted in concert with the Front Groups and through the Front groups, with each other to deceptively promote the use of opioids for the treatment of chronic pain.

i. American Pain Foundation

321. The most prominent of the Front Groups was the American Pain Foundation ("APF"). While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from defendants Purdue, Endo, Janssen and Cephalon. APF received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. Endo was APF's largest donor and provided more than half of its $10 million in funding from 2007 to 2012.

322. For example, APF published a guide sponsored by Cephalon and Purdue titled *Treatment Options: A Guide for People Living with Pain,* and distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report. This guide contains multiple misrepresentations regarding opioid use which are discussed below.

323. APF also developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website, *www.PainKnowledge.com*. NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a third party and must meet certain requirements of

independence from pharmaceutical companies), including a series of "dinner dialogues." But it was Endo that substantially controlled NIPC, by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo's control of NIPC was such that Endo listed it as one of its "professional education initiative[s]" in a plan Endo submitted to the FDA. Yet, Endo's involvement in NIPC was nowhere disclosed on the website pages describing NIPC or *www.PainKnowledge.com*. Endo estimated it would reach 60,000 prescribers through NIPC.

324. APF was often called upon to provide "patient representatives" for the Marketing Defendants' promotional activities, including for Purdue's "Partners Against Pain" and Janssen's "Let's Talk Pain." Although APF presented itself as a patient advocacy organization, it functioned largely as an advocate for the interests of the Marketing Defendants, not patients. As Purdue told APF in 2001, the basis of a grant to the organization was Purdue's desire to strategically align its investments in nonprofit organizations that share [its] business interests.

325. In practice, APF operated in close collaboration with Defendants, submitting grant proposals seeking to fund activities and publications suggested by Defendants and assisting in marketing projects for Defendants.

326. Purdue and APF entered into a "Master Consulting Services" Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular Purdue "contacts" for each project and APF's periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations

APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF's funding) for any reason. APF's Board of Directors was largely comprised of doctors who received money from the Marketing Defendants, either as consultants or speakers at medical events. The close relationship between APF and the Marketing Defendants demonstrates APF's lack of independence, in its finances, management, and mission, and its willingness to allow Marketing Defendants to control its activities and messages supports an inference that each Defendant that worked with the APF was able to exercise editorial control over its publications—even when Defendants' messages contradicted APF's internal conclusions. For example, a roundtable convened by APF and funded by Endo acknowledged the lack of evidence to support chronic opioid therapy. APF's formal summary of the meeting notes concluded that: "[An] important barrier[] to appropriate opioid management [is] the lack of confirmatory data about the long-term safety and efficacy of opioids in non-cancer chronic pain, amid cumulative clinical evidence."

327. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately." Without support from Marketing Defendants, to whom APF could no longer be helpful, APF was no longer financially viable.

ii. American Academy of Pain Medicine and the American Pain Society

328. The American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[100] The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Russell Portenoy, who was also a spokesperson for Purdue. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

329. AAPM's corporate council includes Purdue, Depomed, Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Dr. Scott Fishman ("Fishman") (2005), Dr. Perry G. Fine ("Fine") (2011) and Dr. Lynn R. Webster ("Webster")(2013), all of whose connections to the opioid manufacturers are well-documented as set forth below.

330. Fishman, who also served as a KOL for Marketing Defendants, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[101]

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[100] *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997), http://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf (as viewed August 18, 2017).

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

331. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations.

332. AAPM describes the annual event as an "exclusive venue" for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids-37 out of roughly 40 at one conference alone.

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

334. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines"). AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOL Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and

Purdue. Of these individuals, six received support from Purdue, eight from Teva, nine from Janssen, and nine from Endo.

335. The 2009 Guidelines have been a particularly effective channel of deception. They have influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the *Journal of Pain,* have been cited hundreds of times in academic literature, were disseminated during the relevant period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Marketing Defendants promoted opioids, whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines. For that reason, the CDC has recognized that treatment guidelines can "change prescribing practices."[102]

336. The 2009 Guidelines are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. The Marketing Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the Guidelines or their financial backing of the authors of these Guidelines. For example, a speaker presentation prepared by Endo in 2009 titled *The Role of Opana ER in the Management of Moderate to Severe Chronic Pain* relies on the AAPM/APS Guidelines while omitting their disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.

[102] CDC Guideline, *supra*, at 2.

iii. Federation of State Medical Boards

337. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.

338. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

339. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies." The 1998 Guidelines that the pharmaceutical companies helped author taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option.

340. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing,* also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians and PBMS., including in Summit County.

341. FSMB's 2007 publication *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Purdue, Endo and Cephalon. The publication also received support from the American Pain Foundation and the American Academy of Pain Medicine. The publication was written by Dr. Fishman, and Dr. Fine served on the

Board of Advisors. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as "the leading continuing medical education (CME) activity for prescribers of opioid medications." This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.

342. The Marketing Defendants relied on the 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

iv. The Alliance for Patient Access

343. Founded in 2006, the Alliance for Patient Access ("APA") is a self-described patient advocacy and health professional organization that styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care."[103] It is run by Woodberry Associates LLC, a lobbying firm

[103] *About AfPA*, The All. for Patient Access, http://allianceforpatientaccess.org/about-afpa (last visited Apr. 25, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

that was also established in 2006.[104] As of June 2017, the APA listed 30 "Associate Members and Financial Supporters." The list includes J&J, Endo, Mallinckrodt, Purdue and Cephalon.

344. APA's board members have also directly received substantial funding from pharmaceutical companies.[105] For instance, board vice president Dr. Srinivas Nalamachu ("Nalamachu"), who practices in Kansas, received more than $800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids' side effects, including from defendants Endo, Insys, Purdue and Cephalon. Nalamachu's clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys. Other board members include Dr. Robert A. Yapundich from North Carolina, who received $215,000 from 2013 through 2015 from pharmaceutical companies, including payments by defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than $240,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received $153,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Purdue, Insys, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received $700,000 between 2013 and 2015 from pharmaceutical companies.

[104] Mary Chris Jaklevic, *Non-Profit Alliance for Patient Access Uses Journalists and Politicians to Push Big Pharma's Agenda*, Health News Rev. (Oct. 2, 2017), https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/ .

[105] All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica's Dollars for Docs database, https://projects.propublica.org/docdollars/ .

345. Among its' activities, APA issued a "white paper" titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse."[106] Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

> Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff; ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.
>
> * * *
>
> In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . . .
>
> We cannot merely assume that these programs will reduce prescription pain medication use and abuse.[107]

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

> Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.[108]

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[106] Pain Therapy Access Physicians Working Group, *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, (Dec. 2013), http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf .
[107] *Id*. at 4-5.
[108] *Id*. at 5-6.

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

> Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong—or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management—a situation fueled by the numerous regulations and fines that surround prescription pain medications.[109]

348. In conclusion, the white paper states that "[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs."[110]

v. The U.S. Pain Foundation

349. The U.S. Pain Foundation ("USPF") was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants. The USPF was one of the largest recipients of contributions from the Marketing Defendants, collecting nearly $3 million in payments between 2012 and 2015 alone. The USPF was also a critical component of the Marketing Defendants' lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertises its ties to the Marketing Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil *(i.e.,* Janssen), and Mallinckrodt as "Platinum," "Gold," and "Basic" corporate members.[105] Industry Front Groups like the American Academy of Pain Management, the

[109] *Id*. at 6.
[110] *Id.* at 7.

American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

b. The Marketing Defendants Paid the Key Opinion Leaders to Deceptively Promote Opioid Use

350. To falsely promote their opioids, the Marketing Defendants paid and cultivated a select circle of doctors who were chosen and sponsored by the Marketing Defendants for their supportive messages. As set forth below, pro-opioid doctors have been at the hub of the Marketing Defendants' well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception science and legitimate medical professionals favored the wider and broader use of opioids. These doctors include Dr. Russell Portenoy and Dr. Lynn Webster, as set forth in this section, as well as Dr. Perry Fine and Dr. Scott Fishman, as set forth below.

351. Although these KOLs were funded by the Marketing Defendants, the KOLs were used extensively to present the appearance that unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals. They served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and they were placed on boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs.

352. In return for their pro-opioid advocacy, the Marketing Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish. For example, Dr. Webster has received funding from Endo, Purdue, and Cephalon. Dr. Fine has received funding from Janssen, Cephalon, Endo, and Purdue.

353. Once the Marketing Defendants identified and funded KOLs and those KOLs began to publish "scientific" papers supporting the Marketing Defendants' false position that opioids were safe and effective for treatment of chronic pain, the Marketing Defendants poured significant funds and resources into a marketing machine that widely cited and promoted their KOLs and studies or articles by their KOLs to drive prescription of opioids for chronic pain. The Marketing Defendants cited to, distributed, and marketed these studies and articles by their KOLs as if they were independent medical literature so that it would be well-received by the medical community. By contrast, the Marketing Defendants did not support, acknowledge, or disseminate the truly independent publications of doctors critical of the use of chronic opioid therapy.

354. In their promotion of the use of opioids to treat chronic pain, the Marketing Defendants' KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and the Marketing Defendants.

i. Dr. Russell Portenoy

355. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."[111]

[111] R. Portenoy & K. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, 25(2) Pain 171 (1986).

356. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

> *The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs.* This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. *Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*[112]

According to Dr. Portenoy, the foregoing problems could constitute "compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain."[113]

357. Despite having taken this position on long-term opioid treatment, Dr. Portenoy ended up becoming a spokesperson for Purdue and other Marketing Defendants, promoting the use of prescription opioids and minimizing their risks. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described him "lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue,

[112] Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields & J.C. Liebeskind eds., 1994) (emphasis added).
[113] *Id*.

which flies in people to resorts to hear him speak. It was a compelling message: 'Does have been letting patients suffer; nobody really gets addicted; it's been studied.'"[114]

358. As one organizer of CME seminars who worked with Portenoy and Purdue pointed out, "had Portenoy not had Purdue's money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue's millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified."[115]

359. Dr. Portenoy was also a critical component of the Marketing Defendants' control over their Front Groups. Specifically, Dr. Portenoy sat as a Director on the board of the APF. He was also the President of the APS.

360. In recent years, some of the Marketing Defendants' KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature.[116] Dr. Portenoy has now admitted that he minimized the risks of opioids, and that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[117] He stated "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . ."[118]

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[114] Sam Quiñones, *Dreamland: The True Tale of America's Opiate Epidemic* 314 (Bloomsbury Press 2015).
[115] *Id*. at 136.
[116] *See*, *e.g.*, John Fauber, *Painkiller Boom Fueled by Networking*, J. Sentinel (Feb. 18, 2012), http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/ (reporting that a key Endo KOL acknowledged that opioid marketing went too far).
[117] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall St. J., https://www.wsj.com/articles/SB10001424127887324478304578173342657044604 (last updated Dec. 17, 2012, 11:36 AM).
[118] Id.

361. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not "real" and left real evidence behind:

> "I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, *none of which represented real evidence,* and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. *In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind."*[119]

362. Several years earlier, when interviewed by journalist Barry Meier for his 2003 book, *Pain Killer,* Dr. Portenoy was more direct: "It was pseudoscience. I guess I'm going to have always to live with that one."[120]

ii. Dr. Lynn Webster

363. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a Front Group that ardently supports chronic opioid therapy. He is a Senior Editor of *Pain Medicine,* the same journal that published Endo's special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At

[119] Harrison Jacobs, *This 1-Paragraph Letter May Have Launched the Opioid Epidemic,* AOL (May 26, 2016, 1:39 PM), https://www.aol.com/article/2016/05/26/letter-may-have-launched-opioid-epidemic/21384408/ ; https://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5 . Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be .
[120] Meier, *supra*, at 277.

the same time, Dr. Webster was receiving significant funding from Defendants (including nearly $2 million from Cephalon).

364. Dr. Webster created and promoted the Opioid Risk Tool ("ORT"), a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to presort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's ORT appear on, or are linked to, websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk.* Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors in Plaintiffs' communities.

365. Dr. Webster was himself tied to numerous overdose deaths. He and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the Marketing Defendants' promotional messages, Dr. Webster apparently believed the solution to patients' tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills.

366. At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled, "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim

safety results." The presentation's agenda description states: "Most patients with chronic pain experience episodes of breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment." The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the "[i]nterim results of this study suggest that FEBT is safe and well-tolerated in patients with chronic pain and BTP." This CME effectively amounted to off-label promotion of Cephalon's opioids—the only drugs in this category—for chronic pain, even though they were approved only for cancer pain.

367. Cephalon sponsored a CME written by Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain,* offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

iii. Dr. Perry Fine

368. Dr. Perry Fine authored articles and testified in court cases and before state and federal committees, and argued against legislation restricting high-dose opioid prescription for non-cancer patients. He has served on Purdue's advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS/AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was on the board of directors of APF.

369. Multiple videos feature Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith for pain did not make her an addict before her death.

370. He has also acknowledged having failed to disclose numerous conflicts of interest. For example, Dr. Fine failed to fully disclose payments received as required by his employer, the University of Utah—telling the university that he had received under $5,000 in 2010 from J&J for providing "educational" services, but J&J's website states that the company paid him $32,017 for consulting, promotional talks, meals and travel that year.

371. Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia,* in which they downplayed the risks of opioid treatment, such as respiratory depression and addiction:

> At clinically appropriate doses, . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.
> Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (i.e., for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.[121]

372. In November 2010, Dr. Fine and others published an article presenting the results of another Cephalon-sponsored study titled "Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients

[121] Perry G. Fine, MD & Russell K. Portenoy, MD, *A Clinical Guide to Opioid Analgesia*, McGraw-Hill Companies, 2004, at 20, 34, http://www.thblack.com/links/RSD/OpioidHandbook.pdf .

with Chronic Pain: An 18-Month Study."[122] In that article, Dr. Fine explained that the 18-month "open-label" study "assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for noncancer pain." The article acknowledged that: (a) "[t]here has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades"; (b) the "widespread acceptance" had led to the publishing of practice guidelines "to provide evidence-and consensus-based recommendations for the optimal use of opioids in the management of chronic pain"; and (c) those guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain."[123]

373. The article concluded: "[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable." They also conclude that the number of abuse-related events was "small."[124]

374. Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011 titled "Optimizing Opioid Therapy," he sets forth a "Guideline for Chronic Opioid Therapy" discussing "opioid rotation" (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it

[122] Perry G. Fine, *et al*., *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) J. Pain & Symptom Mgmt. 747-60 (Nov. 2010).
[123] *Id*. at 748.
[124] *Id*. at 759.

may take four or five switches over a person's "lifetime" to manage pain.[125] He states the "goal is to improve effectiveness which is different from efficacy and safety." Rather, for chronic pain patients, effectiveness "is a balance of therapeutic good and adverse events *over the course of years."* The entire program assumes that opioids are appropriate treatment over a "protracted period of time" and even over a patient's entire "lifetime." He even suggests that opioids can be used to treat *sleep apnea.* He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with "tools," but leaves that for "a whole other lecture."[126]

iv. Dr. Scott Fishman

375. Dr. Scott Fishman is a physician who has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received "market rate honoraria." As discussed below, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Marketing Defendants. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled "Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion."[127]

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

[126] *Id.*

[127] Scott M. Fishman, Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion, 306 (13) JAMA 1445 (Sept. 20, 2011), https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true ; Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 9:14 AM), https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry .

376. In 2007, Dr. Fishman authored a physician's guide on the use of opioids to treat chronic pain titled *Responsible Opioid Prescribing,* which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.

377. In 2012, Dr. Fishman updated the guide and continued emphasizing the "catastrophic" "under-treatment" of pain and the "crisis" such under-treatment created:

> Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it's critical to remember that the problem of unrelieved pain remains as urgent as ever.[128]

378. The updated guide still assures that "[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and noncancer origins."[129]

379. In another guide by Dr. Fishman, he continues to downplay the risk of addiction: "I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a 'chemical coper' and an addict."[130] The guide also continues to present symptoms of addiction as symptoms of "pseudoaddiction."

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[128] Scott M. Fishman, *Responsible Opioid Prescribing: A Guide for Michigan Clinicians*, 10-11 (Waterford Life Sciences, 2d ed. 2012).
[129] *Id*.
[130] Scott M. Fishman, *Listening to Pain: A Physician's Guide to Improving Pain Management Through Better Communication* 45 (Oxford University Press 2012).

c. The Marketing Defendants Disseminated Their Misrepresentation Through Continuing Medical Education Program

380. One way the Marketing Defendants aggressively distributed their false message was through thousands of Continuing Medical Education courses ("CMEs").

381. A CME is a professional education program provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations' conferences, and online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

382. The countless doctors and other health care professionals (including PBMs) who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to the Marketing Defendants' deceptions.

383. The Marketing Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically

titled to relate to the treatment of chronic pain, focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.

384. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC ("Medscape") and which disseminated false and misleading information to physicians across the country.

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

386. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo and Teva. The FSMB website described it as the "leading continuing medical education (CME) activity for prescribers of opioid medications." Endo sales representatives distributed copies of *Responsible Opioid Prescribing* with a special introductory letter from Dr. Scott Fishman.

387. In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally.

388. The American Medical Association ("AMA") recognized the impropriety that pharmaceutical company-funded CMEs creates, stating that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs

and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter."[131]

389. Physicians attended or reviewed CMEs sponsored by the Marketing Defendants during the relevant time period and were misled by them.

390. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, the Marketing Defendants could expect instructors to deliver messages favorable to them, as these organizations were dependent on the Marketing Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Marketing Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and the Marketing Defendants both measured the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

d. The Marketing Defendants Used "Branded" Advertising to Promote their Products to Doctors and Consumers

391. The Marketing Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. The Marketing Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the *Journal of Pain* and *Clinical Journal of Pain,* to journals with wider medical audiences, such as the *Journal of the American Medical Association.* The Marketing Defendants collectively spent more than $14 million on the medical journal

[131] Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011), at 1.

advertising of opioids in 2011, nearly triple what they spent in 2001. The 2011 total includes $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

392. The Marketing Defendants also targeted consumers in their advertising. They knew that physicians are more likely to prescribe a drug if a patient specifically requests it.[132] They also knew that this willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.[133] Endo's research, for example, also found that such communications resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations. The Marketing Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused "education and support" materials in the form of pamphlets, videos, or other publications that patients could view in their physician's office.

e. The Marketing Defendants Used "Unbranded" Advertising to Promote Opioid Use for Chronic Pain Without FDA Review.

393. The Marketing Defendants also aggressively promoted opioids through "unbranded advertising" to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as "disease awareness"—encouraging consumers to "talk to your doctor" about a certain health condition without promoting a specific product and, therefore, without providing balanced disclosures about the product's limits and risks. In contrast, a

[132] In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay *et al*., *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294-299 (Apr. 2014).
[133] *Id.*

pharmaceutical company's "branded" advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the FDA Guidance on pharmaceutical advertising refers to as "fair balance." Branded advertising is also subject to FDA review for consistency with the drug's FDA-approved label. Through unbranded materials, the Marketing Defendants expanded the overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising.

394. Many of the Marketing Defendants utilized unbranded websites to promote opioid use without promoting a specific branded drug, such as Purdue's pain-management website, *www.InTheFaceOfPain.com*. The website contained testimonials from several dozen "advocates," including health care providers, urging more pain treatment. The website presented the advocates as neutral and unbiased, but an investigation by the New York Attorney General later revealed that Purdue paid the advocates hundreds of thousands of dollars.

f. The Marketing Defendants Funded, Edited and Distributed Publications That Supported Their Misrepresentations.

395. The Marketing Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and third-party payors, including ERISA Plans. This literature served marketing goals, rather

than scientific standards, and was intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

396. The Marketing Defendants made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Marketing Defendants knew that the articles distorted the significance or meaning of the underlying study, as with the Porter & Jick letter. The Marketing Defendants also frequently relied on unpublished data or posters, neither of which are subject to peer review, but were presented as valid scientific evidence.

397. The Marketing Defendants published or commissioned deceptive review articles, letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or suppressing negative information that contradicted their claims or raised concerns about chronic opioid therapy.

398. For example, in 2007 Cephalon sponsored the publication of an article titled "Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate,"[134] published in the nationally circulated journal *Pain Medicine,* to support its effort to expand the use of its branded fentanyl products. The article's authors (including Dr. Lynn Webster, discussed above) stated that the "OTFC [fentanyl] has been shown to relieve BTP more rapidly than conventional oral, normal-release, or 'short acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the effect

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

of BTP on the [quality of life] of noncancer pain patients." The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

> In summary, BTP appears to be a clinically important condition in patients with chronic noncancer pain and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP and the potential benefits of BTP-specific therapy suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools. [135]

g. The Marketing Defendants Used Sales Representatives to Directly Disseminate Their Misrepresentations to Prescribers.

399. The Marketing Defendants' sales representatives executed carefully crafted marketing tactics, developed at the highest rungs of their corporate ladders, to reach targeted doctors with centrally orchestrated messages. The Marketing Defendants' sales representatives also distributed third-party marketing material to their target audience that was deceptive.

400. Each Marketing Defendant promoted opioids through sales representatives (also called "detailers") and, upon information and belief, small group speaker programs to reach out to individual prescribers. By establishing close relationships with doctors, the Marketing Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers' concerns about prescribing opioids for chronic pain.

[135] *Id.* at 287.

401. In accordance with common industry practice, the Marketing Defendants purchase and closely analyze prescription sales data from IMS Health (now IQVIA), a healthcare data collection, management and analytics corporation. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above.

402. Marketing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Marketing Defendants spent $166 million on detailing branded opioids to doctors. This amount is twice as much as Marketing Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Teva, and $10 million by Endo.

403. For its opioid, Actiq, Cephalon also engaged in direct marketing in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

h. Marketing Defendants Used Speakers' Bureaus and Programs to Spread Their Deceptive Messages

404. In addition to making sales calls, the Marketing Defendants' sales people also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by the Marketing Defendants. These speaker programs and associated speaker trainings serve three purposes: they provide an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; to qualify to be selected a forum in which to further market to the speaker himself or herself; and an

opportunity to market to the speaker's peers. The Marketing Defendants grade their speakers, and future opportunities are based on speaking performance, post-program sales, and product usage. Purdue, Janssen, Endo, Cephalon, and Mallinckrodt each made thousands of payments to physicians nationwide, for activities including participating on speakers' bureaus, providing consulting services, and other services.

405. As detailed below, Insys paid prescribers for *fake* speakers programs in exchange for prescribing its product, Subsys. Insys' schemes resulted in countless speakers programs at which the designated speaker did not speak, and, on many occasions, speaker programs at which the only attendees at the events were the speaker and an Insys sales representative. It was a pay- to-prescribe program.

406. Insys used speakers programs as a front to pay for prescriptions, and paid to push opioids onto patients who did not need them.

i. Insys Employed Fraudulent, Illegal, and Misleading Marketing Schemes to Promote Subsys

407. Insys's opioid, Subsys, was approved by the FDA in 2012 for "management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." Under FDA rules, Insys could only market Subsys for this use. Subsys consists of the highly addictive narcotic, fentanyl, administered via a sublingual (under the tongue) spray, which provides rapid-onset pain relief. It is in the class of drugs described as Transmucosal Immediate-Release Fentanyl ("TIRF").

408. To reduce the risk of abuse, misuse, and diversion, the FDA instituted a Risk Evaluation and Mitigation Strategy ("REMS") for Subsys and other TIRF products,

such as Cephalon's Actiq and Fentora. The purpose of REMS was to educate "prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose" for this type of drug and to "ensure safe use and access to these drugs for patients who need them."[136] Prescribers must enroll in the TIRF REMS before writing a prescription for Subsys.

409. Since its launch, Subsys has been an extremely expensive medication, and its price continues to rise each year. Depending on a patient's dosage and frequency of use, a month's supply of Subsys could cost in the thousands of dollars.

410. Due to its high cost, in most instances prescribers must submit Subsys prescriptions to insurance companies or health benefit payors for prior authorization to determine whether they will pay for the drug prior to the patient attempting to fill the prescription. According to the U.S. Senate Homeland Security and Governmental Affairs Committee Minority Staff Report ("Staff Report"), the prior authorization process includes "confirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate. If any one of these factors was not present, the prior authorization would be denied . . . ."[137]

411. These prior authorization requirements proved to be daunting. Subsys received reimbursement approval in only approximately 30% of submitted claims. In order to increase approvals, Insys created a prior authorization unit, called the Insys

[136] Press Release, U.S. Food & Drug Admin., *FDA Approves Shared System REMS for TIRF Products* (Dec. 29, 2011).
[137] *Fueling an Epidemic, supra*.

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

412. Subsys has proved to be extremely profitable for Insys. Insys made approximately $330 million in net revenue from Subsys last year. Between 2013 and 2016, the value of Insys stock rose 296%.

413. Since its launch in 2012, Insys aggressively worked to grow its profits through fraudulent, illegal, and misleading tactics, including its reimbursement-related fraud. Through its sales representatives and other marketing efforts, Insys deceptively promoted Subsys as safe and appropriate for uses such as neck and back pain, without disclosing the lack of approval or evidence for such uses, and misrepresented the appropriateness of Subsys for treatment those conditions. It implemented a kickback scheme wherein it paid prescribers for fake speakers programs in exchange for prescribing Subsys. All of these fraudulent and misleading schemes had the effect of pushing Insys's dangerous opioid onto patients who did not need it.

414. Insys incentivized its sales force to engage in illegal and fraudulent conduct. Many of the Insys sales representatives were new to the pharmaceutical industry and their base salaries were low compared to industry standard. The compensation structure was heavily weighted toward commissions and rewarded reps more for selling higher (and

more expensive) doses of Subsys, a "highly unusual" practice because most companies consider dosing a patient-specific decision that should be made by a doctor."[138]

415. The Insys "speakers program" was perhaps its most widespread and damaging scheme. A former Insys salesman, Ray Furchak, alleged in a qui tam action that the sole purpose of the speakers program was "in the words of his then supervisor Alec Burlakoff, 'to get money in the doctor's pocket.' Furchak went on to explain that "[t]he catch . . . was that doctors who increased the level of Subsys prescriptions, and at higher dosages (such as 400 or 800 micrograms instead of 200 micrograms), would receive the invitations to the program—and the checks."[139] It was a pay-to-prescribe program.

416. Insys's sham speaker program and other fraudulent and illegal tactics have been outlined in great detail in indictments and guilty pleas of Insys executives, employees, and prescribers across the country, as well as in a number of lawsuits against the company itself.

417. In May of 2015, two Alabama pain specialists were arrested and charged with illegal prescription drug distribution, among other charges. The doctors were the top prescribers of Subsys, though neither were oncologists. According to prosecutors, the doctors received illegal kickbacks from Insys for prescribing Subsys. Both doctors had prescribed Subsys to treat neck, back, and joint pain. In February of 2016, a former Insys sales manager pled guilty to conspiracy to commit health care fraud, including engaging in a kickback scheme in order to induce one of these doctors to prescribe Subsys. The plea

[138] *Id*.
[139] Roddy Boyd, *Insys Therapeutics and the New 'Killing It'"*, S. Investigative Reporting Found., The Investigator, (Apr. 24, 2015), http://sirf-online.org/2015/04/24/the-new-killing-it/ .

agreement states that nearly all of the Subsys prescriptions written by the doctor were off-label to non-cancer patients. In May of 2017, one of the doctors was sentenced to 20 years in prison.

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

419. In August of 2015, Insys settled a complaint brought by the Oregon Attorney General. In its complaint, the Oregon Department of Justice cited Insys for, among other things, misrepresenting to doctors that Subsys could be used to treat migraine, neck pain, back pain, and other uses for which Subsys is neither safe nor effective, and using speaking fees as kickbacks to incentivize doctors to prescribe Subsys.

420. In August of 2016, the State of Illinois sued Insys for similar deceptive and illegal practices. The Complaint alleged that Insys marketed Subsys to high-volume prescribers of opioid drugs instead of to oncologists whose patients experienced the breakthrough cancer pain for which the drug is indicated. The Illinois Complaint also details how Insys used its speaker program to pay high volume prescribers to prescribe Subsys. The speaker events took place at upscale restaurants in the Chicago area, and Illinois speakers received an "honorarium" ranging from $700 to $5,100, and they were

allowed to order as much food and alcohol as they wanted. At most of the events, the "speaker" being paid by Insys did not speak, and, on many occasions, the only attendees at the events were the speaker and an Insys sales representative.

421. In December of 2016, six Insys executives and managers were indicted and then, in October 2017, Insys's founder and owner was arrested and charged with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies. A U.S. Department of Justice press release explained that, among other things: "Insys executives improperly influenced health care providers to prescribe a powerful opioid for patients who did not need it, and without complying with FDA requirements, thus putting patients at risk and contributing to the current opioid crisis."[140] A Drug Enforcement Administration ("DEA") Special Agent in Charge further explained that: "Pharmaceutical companies whose products include controlled medications that can lead to addiction and overdose have a special obligation to operate in a trustworthy, transparent manner, because their customers' health and safety and, indeed, very lives depend on it."[141]

j. The Marketing Defendants' Scheme Succeeded, Creating the Opioid Crisis.

i. Marketing Defendants Dramatically Expanded Opioid Prescribing and Use

422. Upon information and belief, each of the Marketing Defendants tracked the impact of their marketing efforts to measure their impact in changing doctors' perceptions

[140] Press Release, U.S. Dep't of Just., U.S. Attorney's Office, Dist. of Mass., Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering (Oct. 26, 2017), https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering .
[141] *Id*.

and prescribing of their drugs. They purchased prescribing and survey data that allowed them to closely monitor these trends, and they did actively monitor them. They monitored doctors' prescribing before and after sales visits, and before and after speaker programs, for instance. Defendants continued and, in many cases, expanded and refined their aggressive and deceptive marketing for one reason: it worked. As described in this Complaint, both in specific instances (e.g., the low abuse potential of various Defendants' opioids), and more generally, Defendants' marketing changed prescribers' willingness to prescribe opioids, led them to prescribe more of their opioids, and persuaded them not to stop prescribing opioids or to switch to "safer" opioids, such as ADF opioids.

423. Marketing Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain. These results are directly due to the Marketing Defendants' fraudulent marketing campaign focused on several misrepresentations.

ii. Marketing Defendants' Deception in Expanding Their Market Created and Fueled the Opioid Epidemic

424. Independent research demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their

abuse."[142] It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

425. There is a parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes. The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[143]

k. Defendants Throughout the Supply Chain Deliberately Disregarded Their Duties to Maintain Effective Controls and to Identify, Report, and Take Steps to Halt Suspicious Orders

426. The Marketing Defendants created a vastly and dangerously larger market for opioids. All of the Defendants compounded this harm by facilitating the supply of far more opioids that could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious breached both their statutory and common law duties.

427. For over a decade, as the Marketing Defendants increased the demand for opioids, all the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated

[142] Theodore J. Cicero *et al.*, *Relationship Between Therapeutic Use and Abuse of Opioid Analgesics in Rural, Suburban, and Urban* Locations in the United States, 16(8) Pharmacopidemiology and Drug Safety, 827-40 (2007).
[143] Robert M. Califf, M.D., *et al.*, *A Proactive Response to Prescription Opioid Abuse*, New Eng. J. Med., 1480-85 (2016), http://www.nejm.org/doi/full/10.1056/NEJMsr1601307 .

painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

428. Defendants are all required to register as either manufacturers or distributors pursuant to 21 U.S.C. § 823 and 21 C.F.R. §§ 1301.11, 1301.74.

429. Marketing Defendants' scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Marketing Defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. According to the CDC opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

430. 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 opioid prescriptions 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."[144]

l. All Defendants Have a Duty to Report Suspicious Orders and Not to Ship Those Orders Unless Due Diligence Disproves Their Suspicions

431. Multiple sources impose duties on the Defendants to report suspicious orders and further to not ship those orders unless due diligence disproves those suspicions.

432. First, under the common law, the Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By flooding Oklahoma with more opioids than could be used for legitimate medical purposes and by filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, Defendants breached that duty and both created and failed to prevent a foreseeable risk of harm.

433. Second, each of the Defendants assumed a duty, when speaking publicly about opioids and their efforts to combat diversion, to speak accurately and truthfully.

434. Third, each of the Defendants was required to register with the DEA to manufacture and/or distribute Schedule II controlled substances. *See* 21 U.S.C. § 823(a)-(b), (e); 28 C.F.R. § 0.100. As registrants, Defendants were required to "maint[ain] effective controls against diversion" and to "design and operate a system to disclose .. . suspicious orders of controlled substances." 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.74. Defendants were further required to take steps to halt suspicious orders. Defendants violated their obligations under federal law.

[144] *Id.*

435. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970. The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market. Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market." Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain. All registrants—which includes all manufacturers and distributors of controlled substances—must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion. When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

436. The CSA requires manufacturers and distributors of Schedule II substances like opioids to: (a) limit sales within a quota set by the DEA for the overall production of Schedule II substances like opioids; (b) register to manufacture or distribute opioids; (c) maintain effective controls against diversion of the controlled substances that they manufacture or distribute; and (d) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.

437. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs." When evaluating production quotas, the DEA was instructed to consider the following information:

> a. Information provided by the Department of Health and Human Services;
>
> b. Total net disposal of the basic class [of each drug] by all manufacturers;
>
> c. Trends in the national rate of disposal of the basic class [of drug];
>
> d. An applicant's production cycle and current inventory position;
>
> e. Total actual or estimated inventories of the class [of drug] and of all substances manufactured from the class and trends in inventory accumulation; and
>
> f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.

438. It is unlawful to manufacture a controlled substance in Schedule II, like prescription opioids, in excess of a quota assigned to that class of controlled substances by the DEA.

439. To ensure that even drugs produced within quota are not diverted, federal regulations issued under the CSA mandate that all registrants, manufacturers and distributors alike, "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Registrants are not entitled to be

passive (but profitable) observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." *Id.* Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id.* Other red flags may include, for example, "[o]rdering the same controlled substance from multiple distributors."

440. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a distributor or manufacturer need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

441. In sum, Defendants have several responsibilities under federal law with respect to control of the supply chain of opioids. First, they must set up a system to prevent diversion, including excessive volume and other suspicious orders. That would include reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. All suspicious orders must be reported to relevant enforcement authorities. Further, they must also stop shipment of any

order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.

442. Federal statutes and regulations reflect a standard of conduct and care below which reasonably prudent manufacturers and distributors would not fall. Together; these laws and industry guidelines make clear that Distributor and Marketing Defendants alike possess and are expected to possess specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the supply chain is not properly controlled.

443. Further, these laws and industry guidelines make clear that the Distributor Defendants and Marketing Defendants alike have a duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

444. The Federal Trade Commission ("FTC") has recognized the unique role of distributors. Since their inception, Distributor Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, Distributor Defendants also offer their pharmacy, or dispensing, customers a broad range of added services. For example, Distributor Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and

distribution facility that allows customers to reduce inventory carrying costs. Distributor Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support. *See Fed. Trade Comm'n v. Cardinal Health, Inc.,* 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal Health, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, Distributor Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

445. Marketing Defendants also have specialized and detailed knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors' offices and pharmacies, and from their purchase of data from commercial sources, such as IMS Health. Their extensive boots-on-the-ground activity through their sales force allows Marking Defendants to observe the signs of suspicious prescribing and dispensing discussed elsewhere in the Complaint—lines of seemingly healthy patients, out-of-state license plates, and cash transactions, to name only a few. In addition, Marketing Defendants regularly mined data, including, upon information and belief, chargeback data, which allowed them to monitor the volume and type of prescribing of doctors, including sudden increases in prescribing and unusually high dose prescribing, which would have alerted them, independent of their sales representatives, to suspicious prescribing. These

information points gave Marketing Defendants insight into prescribing and dispensing conduct that enabled them to play a valuable role in the preventing diversion and fulfilling their obligations under the CSA.

446. Defendants have a duty, and are expected, to be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.

447. Defendants breached these duties by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities they knew or should have known could not be justified and were indicative of serious problems of overuse of opioids.

3. Defendants Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders

448. The reason for the reporting rules is to create a "closed" system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.

449. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

450. Recently, Mallinckrodt, a prescription opioid manufacturer, admitted in a settlement with DEA that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA." Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product." Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."

451. Trade organizations to which Defendants belong have acknowledged that wholesale distributors have been responsible for reporting suspicious orders for more than 40 years. The Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")), a trade association of pharmaceutical distributors to which Distributor Defendants belong, has long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations do so, but "as responsible members of society." Guidelines established by the HDA also explain that distributors,

"[a]t the center of a sophisticated supply chain . . . are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."

452. The DEA also repeatedly reminded the Defendants of their obligations to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes. Each of the Distributor Defendants attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

453. The DEA also advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances that they are "one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people." The DEA's September 27, 2006 letter also expressly reminded them that registrants, in addition to reporting

suspicious orders, have a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." The same letter reminds distributors of the importance of their obligation to "be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes," and warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

454. The DEA sent another letter to Defendants on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The DEA' s December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.,* by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.,* 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."

4. Defendants Worked Together to Inflate the Quotas of Opioids They Could Distribute

455. Finding it impossible to legally achieve their ever-increasing sales ambitions, Defendants engaged in the common purpose of increasing the supply of opioids and

fraudulently increasing the quotas that governed the manufacture and distribution of their prescription opioids.

456. Wholesale distributors such as the Distributor Defendants had close financial relationships with both Marketing Defendants and customers, for whom they provide a broad range of value added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their dispensing customers and would be difficult and costly for the dispenser to reproduce. For example, "[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock." *Fed. Trade Comm'n v. Cardinal Health, Inc.,* 12 F. Supp. 2d 34, 41 (D.D.C. 1998). Through their generic source programs, wholesalers are also able "to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers." Wholesalers typically also offer marketing programs, patient services, and other software to assist their dispensing customers.

457. Distributor Defendants had financial incentives from the Marketing Defendants to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive

prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

458. The Marketing Defendants engaged in the practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts. The *Washington Post* has described the practice as industry-wide, and the HDA includes a "Contracts and Chargebacks Working Group," suggesting a standard practice. Further, in a recent settlement with the DEA, Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors)." The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants," meaning pharmacies or other dispensaries, such as hospitals. Marketing Defendants buy data from pharmacies as well. This exchange of information, upon information, and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well.

459. The contractual relationships among the Defendants also include vault security programs. Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opioids. The manufacturers negotiated agreements whereby the Marketing Defendants installed security vaults for the Distributor Defendants in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Defendants as a tool to

violate their reporting and diversion duties in order to reach the required sales requirements.

460. In addition, Defendants worked together to achieve their common purpose through trade or other organizations, such as the Pain Care Forum ("PCF") and the HDA.

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

462. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[145] Specifically, PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[146]

463. The Defendants who stood to profit from expanded prescription opioid use are members of and/or participants in the PCF.[147] In 2012, membership and participating organizations included Endo, Purdue, Actavis and Cephalon.[148] Each of the Marketing Defendants worked together through the PCF. But the Marketing Defendants were not

[145] Matthew Perrone & Ben Wieder, *Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic*, The Ctr. for Pub. Integrity, https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic (last updated Dec. 15, 2016, 9:09 AM) (emphasis added).
[146] Id.
[147] *PAIN CARE FORUM 2012 Meetings Schedule*, (last updated December 2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf
[148] Mallinckrodt became an active member of the PCF sometime after 2012.

alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.[149] The Distributor Defendants participated directly in the PCF as well.

464. Additionally, the HDA led to the formation of interpersonal relationships and an organization among the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and several of the Marketing Defendants, including Actavis, Endo, Purdue, Mallinckrodt, and Cephalon, were members of the HAD.[150] Additionally, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Marketing Defendants by advocating for the many benefits of members, including "strengthen[ing] . . . alliances."[151]

465. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[152] Clearly, the HDA and the

[149] *Id.*; The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. *Executive Committee*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/executive-committee (last accessed Apr. 25, 2018).
[150] *Manufacturer Membership*, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/membership/manufacturer .
[151] *Manufacturer Membership*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/membership/manufacturer (last accessed Apr. 25, 2018).
[152] Id.

Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships and "alliances" between the Marketing and Distributor Defendants.

466. The application for manufacturer membership in the HDA further indicates the level of connection among the Defendants and the level of insight that they had into each other's businesses.[153] For example, the manufacturer membership application must be signed by a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company.

467. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information. Manufacturer members were also asked to identify their "most recent year end net sales" through wholesale distributors, including the Distributor Defendants AmerisourceBergen, Anda, Inc., Cardinal Health, Henry Schein, McKesson, Miami-Luken, Prescription Supply, Inc. and their subsidiaries.

468. The closed meetings of the HDA's councils, committees, task forces and working groups provided the Marketing and Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

469. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these

[153] *Manufacturer Membership Application*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-application.ashx?la=en .

conferences to the Marketing Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers ... to hold strategic business discussions on the most pressing industry issues."[154] The conferences also gave the Marketing and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[155] The HDA and its conferences were significant opportunities for the Marketing and Distributor Defendants to interact at a high-level of leadership. It is clear that the Marketing Defendants embraced this opportunity by attending and sponsoring these events."[156]

470. After becoming members of HDA, Defendants were eligible to participate on councils, committees, task forces and working groups, including:

> a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."
>
> b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributor and manufacturer members.
>
> c. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement."

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[154] *Business and Leadership Conference—Information for Manufacturers*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers .

[155] *Id*.

[156] *2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance, https://web.archive.org/web/20160119143358/https://www.healthcaredistribution.org/events/2015-distribution-management-conference .

Participation in this committee includes distributor and manufacturer members.

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

e. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation in this group includes manufacturer and distributor members.

471. The Distributor Defendants and Marketing Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices. For example, on April 27, 2011, the HDA offered a Webinar to "accurately and effectively exchange business transactions between distributors and manufacturers . . . ." The Marketing Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell prescription opioids.

472. Taken together, the interaction and length of the relationships between and among the Marketing and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to

work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

473. The HDA and the PCF are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants were in communication and cooperation.

474. Publications and guidelines issued by the HDA nevertheless confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (the "Industry Compliance Guidelines") regarding diversion. As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of "[a] committee of HDMA members contribut[ing] to the development of this publication" beginning in late 2007.

475. This statement by the HDA and the Industry Compliance Guidelines support the allegation that Defendants utilized the HDA to form agreements about their approach to their duties under the CSA. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce Subcommittee on Health in April 2014, is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Here, it is apparent that all of the Defendants found the same balance—an overwhelming pattern and practice of failing to identify, report or halt suspicious orders, and failure to prevent diversion.

476. The Defendants' scheme had a decision-making structure driven by the Marketing Defendants and corroborated by the Distributor Defendants. The Marketing

Defendants worked together to control the state and federal government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and identify suspicious orders and report them to the DEA.

477. The Defendants worked together to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Marketing and Distributor Defendants did this through their participation in the PCF and HDA.

478. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

479. The Defendants also had reciprocal obligations under the CSA to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible for each other's compliance with their reporting obligations.

480. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be brought to the DEA' s attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

481. The desired consistency was achieved. As described below, none of the Defendants reported suspicious orders and the flow of opioids continued unimpeded.

5. Defendants Kept Careful Track of Prescribing Data and Knew About Suspicious Orders and Prescribers

482. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor and Marketing Defendants but has not been disclosed to the public.

483. Publicly available information confirms that Distributor and Marketing Defendants funneled far more opioids into communities across the United States than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to Distributor and Marketing Defendants, would have alerted them to potentially suspicious orders of opioids.

484. This information includes the following facts:

a. distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

b. manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;

c. manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion, as described in above;

d. Distributor Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and

e. Marketing Defendants purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

485. The conclusion that Defendants were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids-even the wider market for chronic pain.

486. At all relevant times, the Defendants were in possession of national, regional, state, and local prescriber- and patient-level data that allowed them to track prescribing patterns over time. They obtained this information from data companies, including but not limited to: IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the "Data Vendors").

487. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the Defendants identify suspicious orders or customers who

were likely to divert prescription opioids.[157] The "know your customer" questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

488. Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The Data Vendors' information purchased by the Defendants allowed them to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.[158]

489. IMS Health, for example, provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.

490. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the Defendants with charts analyzing the weekly prescribing patterns of multiple

[157] *Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances*, Drug Enf't Admin., Diversion Control Div., https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf ; Richard Widup, Jr., & Kathleen H. Dooley, Esq., *Pharmaceutical Production Diversion: Beyond the PDMA,* Purdue Pharma and McGuireWoods LLC (Oct. 2010), https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf .

[158] A Verispan representative testified that the Distributor Defendants use the prescribing information to "drive market share." *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 661712, *9-10 (Feb. 22, 2011).

physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.[159]

491. This information allowed the Defendants to track and identify instances of overprescribing. In fact, one of the Data Vendors' experts testified that the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.[160]

492. Defendants were, therefore, collectively aware of the suspicious orders that flowed daily from their manufacturing and distribution facilities.

493. Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. As described in detail below, Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against distributors in 178 registrant actions between 2008 and 2012 and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include seventy-six (76) actions involving orders to show cause and forty-one (41) actions involving immediate suspension orders, all for failure to report suspicious orders.

494. Sales representatives of the Defendants were also aware that the prescription opioids they were promoting were being diverted, often with lethal consequences.

495. Defendants' obligation to report suspicious prescribing ran head-on into their marketing strategy. Defendants did identify doctors who were their most prolific

[159] *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 705207, *467-471 (Feb. 22, 2011).
[160] In *Sorrell*, expert Eugene "Mick" Kolassa testified, on behalf of the Data Vendor, that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." Joint Appendix in *Sorrell v. IMS Health*, No. 10-779, 2011 WL 687134, at *204 (Feb. 22, 2011).

prescribers, not to report them, but to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement, nor to report those doctors who drove Defendants' sales.

496. Defendants purchased data from IMS Health (now IQVIA) or other proprietary sources to identify doctors to target for marketing and to monitor their own and competitors' sales. Marketing visits were focused on increasing, sustaining, or converting the prescriptions of the biggest prescribers, particularly through aggressive, high frequency detailing visits.

497. For example, at a national sales meeting presentation in 2011, Actavis pressed its sales representatives to focus on its high prescribers: "To meet and exceed our quota, we must continue to get Kadian scripts from our loyalists. MCOs will continue to manage the pain products more closely. We MUST have new patient starts or we will fall back into 'the big leak'. We need to fill the bucket faster than it leaks." "The selling message should reflect the opportunity and prescribing preferences of each account. High Kadian Writers / Protect and Grow/ Grow = New Patient Starts and Conversions." In an example of how new patients + a high volume physician can impact performance: "102% of quota was achieved by just one high volume physician initiating Kadian on 2-3 new patients per week."

498. This focus on marketing to the highest prescribers had two impacts. First, it demonstrates that manufacturers were keenly aware of the doctors who were writing large quantities of opioids. But instead of investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales.

6. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement

499. When a manufacturer or distributor does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action—or may not know to take action at all.

500. After being caught failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the future," including specific measures delineated in a "Compliance Addendum" to the Settlement. Yet, in 2017, McKesson paid $150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

501. More generally, the Distributor Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: "We

challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen and with a belief that doing 'the right thing' serves everyone." Defendant Cardinal likewise claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria." Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

502. Along the same lines, Defendant McKesson publicly claims that its "customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process," creating the impression that McKesson uses this tracking to help prevent diversion. Defendant McKesson has also publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."

503. Defendant AmerisourceBergen, too, has taken the public position that it is "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find

solutions that will support appropriate access while limiting misuse of controlled substances." A company spokeswoman also provided assurance that: "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients."

504. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Defendants, through their trade associations, HDMA and NACDS, filed an *amicus* brief in *Masters Pharmaceuticals,* which made the following statements:[1]"

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

b. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."

505. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

506. Defendant Mallinckrodt similarly claims to be "committed . . . to fighting opioid misuse and abuse," and further asserts that: "In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional

approach that includes educational efforts, monitoring for suspicious orders of controlled substances, ..."

507. Other Marketing Defendants also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."[161]

508. At the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue's recent pronouncements in response to the opioid abuse.

509. Touting the benefits of ADF opioids, Purdue's website asserts: "[W]e are acutely aware of the public health risks these powerful medications create . ... That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse ...."[162] Purdue's statement on "Opioids Corporate Responsibility" likewise states that "[f]or many years, Purdue has committed

[161] Purdue, *Setting The Record Straight On OxyContin's FDA-Approved Label* (May 5, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/ ; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, (July 11, 2016) https://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

[162] Purdue, *Opioids with Abuse-Deterrent Properties*, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/ .

substantial resources to combat opioid abuse by partnering with . .. communities, law enforcement, and government."[163] And, responding to criticism of Purdue's failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."[164]

510. These public pronouncements create the misimpression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

511. Public statements by the Defendants and their associates created the false and misleading impression to regulators, prescribers, ERISA Plans and their agents, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and further created the false impression that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

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[163] Purdue, *Opioids Corporate Responsibility*, https://www.purduepharma.com/about/company-values/opioids-corporate-responsibility/

[164] Purdue, *Setting The Record Straight On Our Anti-Diversion Programs* (July 11, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/ . Contrary to its public statements, Purdue seems to have worked behind the scenes to push back against law enforcement.

D. The Opioids Epidemic in Oklahoma

512. In 2012, more than two million Americans were abusing or dependent on opioids. Oklahoma is one of the leading states in prescription painkiller sales per capita, with 128 painkiller prescriptions dispensed per 100 people in 2012. From 1999 through 2016, approximately 351,630 Americans died from opioid-related overdoses, and thousands of those overdose deaths occurred in Oklahoma. In 2014, more than 60% of drug-overdose deaths nationally involved opioids. According to 2016 statistics, Oklahoma ranks number one in the nation in milligrams of opioids distributed per adult resident with approximately 877 milligrams of opioids distributed per adult resident.

513. A National Survey on Drug Use and Health revealed Oklahoma leads the nation in non-medical use of painkillers, with nearly 5% of the population aged 12 and older abusing or misusing painkillers, and Oklahoma's death rate from opioids is up a staggering 63% from 2016 to 2017. More than 62,000 Americans are believed to have fatally overdosed from opioids in 2017 alone.

514. The opioid epidemic has a significant human cost. In 2016, opioids were responsible for 1,901 overdose deaths in Oklahoma alone.

515. These deaths represent a tip of the iceberg small portion of the damage. 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 Oklahoma, the death rate from opioid abuse is up 63% year over year.

516. Opioid addiction is now the primary reason that Oklahoma residents seek substance abuse treatment, and admissions to drug treatment facilities in Oklahoma more than doubled from 2006-07 to 2010-11. Addiction treatment centers indicate that many of their patients started on legal opioid prescriptions.

517. Even when opioid users do not die from an overdose, they often require significant healthcare interventions. Emergency-room visits for opioid overdose increased nationwide and across all demographic groups between July 2016 and September 2017, according to ER records analyzed by the CDC. In most of these situations, these added costs are covered by the patient's employer-sponsored health plans. As a result, employer-sponsored health plans have paid billions of dollars for these health care costs.

E. The Plaintiff ERISA Plans Have Sustained Substantial Harm as a Result of Defendants' Unlawful Schemes.

1. The Plaintiff ERISA Plans were targeted by Defendants for Opioid Drug Coverage.

518. Over half the residents in the United States obtain health insurance benefits from their employer-sponsored health plan.

519. In 2014, Oklahoma residents alone paid more than $75 billion for healthcare, of which almost $30 billion was spent on private health insurance. As is true throughout the country, health care costs in Oklahoma are increasing at a rate far above core inflation. From 1991 to 2014, Oklahomans spent an average of 4.9% more per year on personal, health-care-related expenses.

520. As detailed herein, the Marketing Defendants have been engaged in fraudulent and illegal schemes to cause increased prescribing and reimbursement for their

opioid products. The Marketing Defendants were aware that the Plaintiff ERISA Plans and other third party payors wanted to restrict availability of certain highly addictive opioid medications to those suffering from cancer pain. The Marketing Defendants were further aware that healthcare and related costs associated with opioid use were of paramount importance to ERISA Plans and other third party payors. To circumvent these concerns, the Marketing Defendants planned and implemented false and misleading marketing campaigns to target Plaintiffs ERISA Plans through their PBMs and other agents to ensure formulary access for chronic non-cancer pain and other conditions, notwithstanding the lack of evidence of opioids' safety or efficacy for those conditions. All Defendants were aware that the growing evidence of prescription opioid diversion could lead ERISA Plans and other third party payors to make formulary decisions that would drastically reduce the access to opioids and to implement controls to prevent drug diversion. Defendants suppressed evidence of diversion so as to maintain formulary access and status for their opioids. As the entities directly reimbursing most, if not all, of the cost of opioid drug prescriptions in America, the Plaintiff ERISA Plans were the primary and intended victims of Defendants' fraudulent schemes.

521. A formulary is a list of medications that have been selected for the purpose of encouraging high quality and cost-effective prescribing of pharmaceuticals within a patient population. Formularies are segmented by the therapeutic uses of the drugs.

522. At all times material hereto, Defendants knew that because opioid drugs are FDA approved and effective for limited purposes, the products would be placed on ERISA Plans' formularies and that the Plaintiff ERISA Plans would reimburse for on-

formulary prescriptions of opioid drugs. Therefore, it was critical to Defendants' overall scheme of selling more opioids and increasing their profits that opioid drugs be included on ERISA Plan formularies.

523. Defendants' misrepresentations and omissions with regard to the effectiveness and safety of opioids was material to the Plaintiff ERISA Plans' decisions to include opioids on their formularies and to pay for them.

524. Based on Defendants' false and misleading marketing practices and covert, systematic, and illegal schemes to promote their opioid drugs, the Plaintiff ERISA Plans and/or their PBMs and other agents, relied on Defendants' misrepresentations and omissions by including many of Defendants' opioid drugs on their formularies and by unknowingly paying for opioid drug prescriptions for ineffective, unsafe, and/or unapproved purposes.

2. Defendants Made or Caused to Be Made Direct Misrepresentations to the Plaintiff ERISA Plans and their agents.

525. The Plaintiff ERISA Plans provide medical and pharmacy benefits to its employees through self-funded contracts with employers. Pharmacy benefit programs are a common component of the health care benefit offered by ERISA Plans to plan participants. Although the Plaintiff ERISA Plans remain financially responsible for the cost of pharmaceuticals, the Plaintiff ERISA Plans contract with third-party administrators ("TPAs"), PBMs, and/or other entities to provide pharmacy program administration and to process pharmacy claims. Some ERISA Plans choose to contract directly with a PBM for the management of their pharmacy benefit, rather than acquiring pharmacy benefits through a health plan. PBMs provide claim processing services. In addition, PBMs may

contract with retail pharmacies, provide mail order pharmacy services, negotiate rebates with drug manufacturers, develop formularies, and conduct drug utilization review activities. Through their contractual arrangement with ERISA Plans, a Plan's PBM performs its contractual services for the benefit of the Plaintiff ERISA Plans and the Plans' participants.

526. There are a number of programs or tools available to ERISA Plans (often working with or through their PBMs) to manage drug utilization within the Plans' insured population. The primary tools available for this purpose are formulary placement after review by pharmacy and therapeutics committees ("P&T committees"), cost sharing, claim edits and/or prior authorization.

527. Defendants knew that gaining insurance coverage, or favorable formulary status on private employer sponsored self-insured health plans, was essential to sales of their respective opioid drugs, as physicians base their prescribing on the Plaintiff ERISA Plans' and the Proposed Class member Plans' drug coverage. Each of the Defendants included in their strategic business plans a marketing plan targeting Plaintiffs and to whom they disseminated their false and misleading representations. Utilizing multiple channels, including a dedicated sales force that called on the Plaintiff ERISA Plans and the class members (or their PBMs, TPAs, representatives, or agents), third party organizations, medical societies, and conferences, Defendants directed their false and misleading efficacy and safety messages to the Plaintiff ERISA Plans and their agents, succeeding in gaining formulary status for their opioid drugs.

528. Each of the Defendant's strategic plans included multi-pronged targeting of the Plaintiff ERISA Plans. Defendants' common tactics included comprehensive business plans that carefully tracked the Plaintiff ERISA Plans' coverage decisions – *e.g.*, whether one or more opioid drugs was on formulary, what tier, and any restrictions.

529. Each of Defendants' managed markets account managers coordinated and reported the success of their multiple contacts with the Plaintiff ERISA Plans' and/or their agents via emails and telephone calls to their respective managed care supervisors, sales teams, and others, requiring extensive use of the wires and mails in interstate commerce.

530. Defendants made misrepresentations to the Plaintiff ERISA Plans and/or their agents and took deliberate actions to conceal from the Plaintiff ERISA Plans and their agents vital information about the safety and efficacy of the prescription opioids and the inordinate amount of opioids being diverted to a secondary market, which foreseeably resulted in the Plaintiff ERISA Plans paying for unnecessary opioids.

a. The Plaintiff ERISA Plans' agents, representative, TPAs and/or PBMs were Members and Attendees at Conferences as well as Recipients of AMCP Publications.

531. The Plaintiff ERISA Plans' agents, representatives, TPAs' and/or PBMs' pharmacy, clinical and/or medical management personnel regularly have participated in professional programs and organizations, such as the Academy of Managed Care Pharmacy ("AMCP"), as part of their job responsibilities and professional development. AMCP describes itself as "a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's

5,700-plus members develop and provide a diversified range of clinical, educational, and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit."

532. AMCP's stated goals include: (1) monitoring the safety and clinical effectiveness of new medications on the market; (2) alerting patients to potentially dangerous drug interactions when a patient is taking two or more medications prescribed by different providers; (3) designing and carrying out medication therapy management programs to ensure patients are taking medications that give them the best benefit to keep them healthy; and (4) creating incentives to control patients' out-of-pocket costs, including through lower copayments on generic drugs and certain preferred brands.

533. AMCP serves its members in many ways, including through live national conferences, online learning programs, continuing education ("CE") events, research in peer-reviewed literature and advocacy. Each is designed with the goal of advancing professional knowledge, improving the design and delivery of pharmacy benefits, and ultimately, patient satisfaction and health outcomes.

534. AMCP hosts two national meetings each year: the AMCP Managed Care & Specialty Pharmacy Annual Meeting and the AMCP Nexus conference. Both of these events draw thousands of managed care pharmacy leaders, including PBMs, TPAs and feature renowned keynote speakers, an array of educational sessions, extensive networking opportunities and an exhibit hall of companies and organizations sharing their latest innovations and services.

535. The Plaintiff ERISA Plans' TPAs and/or PBMs employ personnel who are members of AMCP and regularly attend AMCP meetings as well as regularly receive and read communications from AMCP. Many of Plaintiffs' ERISA Plans TPAs and/or PBMs employ personnel who are also actively involved AMCP members.

536. Drug manufacturers, including Defendants and their representatives, have at all times material hereto regularly attended AMCP events, exhibiting information about their opioid products as well as giving or sponsoring presentations to managed care and ERISA Plan representatives, including Plans' PBMs. Defendants' AMCP attendees regularly included sales representatives, national account directors, and managed markets / managed care personnel whose explicit aim was to influence Plaintiffs' and the Proposed Class members' drug formulary access.

537. At all times material hereto, Defendants' AMCP exhibits and presentations were calculated to be received and reviewed by the ERISA Plans' agents and representatives in attendance and thereby influencing their decisions to continue coverage of Defendants' opioid drugs on their formularies.

b. Plaintiff ERISA Plans' agents, representatives, TPAs and/or PBMs Regularly Received Managed Care Periodicals which Included Defendants' False and Misleading Representations Concerning the Safety and Efficacy of Opioid drugs.

538. The Plaintiff ERISA Plans' agents', representatives', TPAs' and/or PBMs' pharmacy and medical personnel are regular recipients of periodicals, sent through the mails and through electronic delivery through the wires, both in interstate commerce, which include information relevant to management of the pharmacy benefit for their

members. These periodicals include the AMCP Daily Dose, Journal of Clinical Pathways, First Report Managed Care, the Journal of Clinical Outcomes Management ("JCOM"), Managed Healthcare Executive, The American Journal of Managed Care, The American Journal of Pharmacy Benefits ("AJPB"), American Health & Drug Benefits, and Pharmacy Times. Plaintiffs' ERISA Plans agents', representatives', TPAs' and/or PBMs' employees regularly reviewed what they reasonably believed were reputable publications as part of gathering relevant information in their opioid coverage decision making.

539. Defendants utilized these and other periodicals to disseminate their false and misleading messages concerning opioid drugs to the representatives and agents of the Plaintiff ERISA Plans. Many of Defendants' marketing messages appeared in these publications.

c. Defendants' Representations to Pioneer Plan and Bios Plan

540. The Marketing Defendants frequently contacted Pioneer Plan and Bios Plan personnel and/or their PBM agents and representatives to discuss formulary coverage for their opioids.

541. The Marketing Defendants often discussed formulary management options with Bios Plan in order to obtain and maintain favorable formulary status for opioid medications, employing the misrepresentations and omissions alleged herein.

542. The Marketing Defendants also tried to manipulate and influence Pioneer Plan's PBM use of potential utilization management restrictions through direct misrepresentations or through misleading publications intended for managed care audiences.

3. The Plaintiff ERISA Plans have been directly injured by Defendants' Misconduct Which Proximately Caused the Plaintiff ERISA Plans Injuries.

543. Defendants jointly and individually targeted the Plaintiff ERISA Plans through their pharmacy directors and PBM representatives and agents, which resulted in direct harm to the Plans. For example:

- Each Manufacturer Defendant developed a dedicated managed care sales groups whose sole function it was to add or elevate Manufacturer Defendants' drugs on formularies. Each knowingly presented false and misleading information to achieve this goal.

- Marketing Defendants frequently contacted Plaintiffs ERISA Plans and/or their PBM representatives and agents to discuss formulary coverage for their opioids and made numerous misrepresentations to ensure coverage for those opioids, including, for instance, representing that purportedly abuse-deterrent and extended-release formulations would result in healthcare cost savings (for Plaintiffs).

- Marketing Defendants' account managers coordinated and reported the success for their multiple contacts with Plaintiffs and their agents, representatives, TPAs and/or PBMs to their supervisors, sales teams, and others.

- Marketing Defendants made numerous misrepresentations about the safety and efficacy of the drugs and their cost-effective benefits (benefits meant to entice Plaintiffs) at industry events, such as Academy of Managed Care Pharmacy ("AMCP") conferences that ERISA Plans, TPAs, and PBMs, including the Plaintiff ERISA Plans' agents, attended, and submitted misleading abstracts calculated to be received and reviewed by the attendees.

- Marketing Defendants placed false and misleading information about their prescription opioids and omitted information about those opioids required to make those statements not misleading in industry periodicals regularly reviewed by the Plaintiff ERISA Plans' agents.

- Marketing Defendants actively engaged their account management teams to find ways to deceptively circumvent Plaintiffs' controls on opioid prescribing and coverage.

544. Defendants worked together to conceal evidence of diversion and to circumvent their obligations to monitor, report, and prevent that diversion. Absent this concealment, the Plaintiff ERISA Plans and their agents would not have made the coverage and formulary placement decisions they did with respect to opioid drugs, and the Plaintiff ERISA Plans would have spent far less on the reimbursement of opioid drugs.

545. The Marketing Defendants directly targeted the Plaintiff ERISA Plans and their agents, who acted in reliance on these representations by giving prescription opioids preferred status on their formularies and agreeing to pay for them. Defendants' deception prevented the Plaintiff ERISA Plans and their agents from properly evaluating the appropriateness of those decisions. All Defendants breached their duty to monitor, assess, report, and halt suspicious orders which substantially contributed to the Plaintiff ERISA Plans' injuries in paying for opioid abuse, addiction, and overdose care – all of which were foreseeable to Defendants. Defendants knowingly created and supplied a secondary market, all to Defendants' benefit and at the Plaintiff ERISA Plans' unwitting expense. In other words, the Plaintiff ERISA Plans paid for prescription opioids that they otherwise would not have, but for Defendants' conduct. This is a direct injury to the Plaintiff ERISA Plans, not merely a derivative injury of another.

F. The Defendants Conspired To Engage In The Wrongful Conduct Complained Of Herein and Intended To Benefit Both Independently and Jointly From Their Conspiracy

1. Conspiracy Among Marketing Defendants

546. The Marketing Defendants agreed among themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids

for the management of pain in order to mislead physicians, patients, health care providers, and health care payors, including ERISA Plans and their agents, through misrepresentations and omissions regarding the appropriate uses, risks, and safety of opioids, to increase sales, revenue, and profit from their opioid products.

547. This interconnected and interrelated network relied on the Marketing Defendants' collective use of unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups developed and funded collectively by the Marketing Defendants intended to mislead consumers, medical providers, and third-party payors such as ERISA Plans of the appropriate uses, risks, and safety of opioids.

548. The Marketing Defendants' collective marketing scheme to increase opioid prescriptions, sales, revenues and profits centered around the development, the dissemination, and reinforcement of nine false propositions: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition dubbed "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

549. The Marketing Defendants knew that none of these propositions is true and that there was no evidence to support them.

550. Each Marketing Defendant worked individually and collectively to develop and actively promulgate these nine false propositions in order to mislead physicians, patients, health care providers, and healthcare payors, including ERISA Plans and their agents, regarding the appropriate uses, risks, and safety of opioids.

551. What is particularly remarkable about the Marketing Defendants' effort is the seamless method in which the Marketing Defendants joined forces to achieve their collective goal: to persuade consumers and medical providers of the safety of opioids, and to hide their actual risks and dangers. In doing so, the Marketing Defendants effectively built a new—and extremely lucrative—opioid marketplace for their select group of industry players.

552. The Marketing Defendants' unbranded promotion and marketing network was a wildly successful marketing tool that achieved marketing goals that would have been impossible to have been met by a single or even a handful of the network's distinct corporate members.

553. For example, the network members pooled their vast marketing funds and dedicated them to expansive and normally cost-prohibitive marketing ventures, such as the creation of Front Groups. These collaborative networking tactics allowed each Marketing Defendant to diversify its marketing efforts, all the while sharing any risk and exposure, financial and/or legal, with other Marketing Defendants.

554. The most unnerving tactic utilized by the Marketing Defendants' network, was their unabashed mimicry of the scientific method of citing "references" in their materials. In the scientific community, cited materials and references are rigorously

vetted by objective unbiased and disinterested experts in the field, scientific method, and an unfounded theory or proposition would, or should, never gain traction.

555. Marketing Defendants put their own twist on the scientific method: they worked together to manufacture wide support for their unfounded theories and propositions involving opioids. Due to their sheer numbers and resources, the Marketing Defendants were able to create a false consensus through their materials and references.

556. An illustrative example of the Marketing Defendants' utilization of this tactic is the wide promulgation of the Porter & Jick Letter, which declared the incidence of addiction "rare" for patients treated with opioids. The authors had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. These patients were *not* given long-term opioid prescriptions or provided opioids to administer to themselves at home, nor was it known how frequently or infrequently and in what doses the patients were given their narcotics. Rather, it appears the patients were treated with opioids for short periods of time under in-hospital doctor supervision.

557. Nonetheless, Marketing Defendants widely and repeatedly cited this letter as proof of the low addiction risk in connection with taking opioids in connection with taking opioids despite its obvious shortcomings. Marketing Defendants' egregious misrepresentations based on this letter included claims that less than one percent of opioid users became addicted.

558. Marketing Defendants' collective misuse of the Porter & Jick Letter helped the opioid manufacturers convince patients and healthcare providers that opioids were not a concern. The enormous impact of Marketing Defendants' misleading

amplification of this letter was well documented in another letter published in the NEJM on June, 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and in some cases "grossly misrepresented." In particularly, the authors of this letter explained:

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

559. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, the Marketing Defendants committed overt acts in furtherance of their conspiracy.

2. Conspiracy Among All Defendants

560. In addition, and on an even broader level, all Defendants took advantage of the industry structure, including end-running its internal checks and balances, to their collective advantage. Defendants agreed among themselves to increasing the supply of opioids and fraudulently increasing the quotas that governed the manufacture and supply of prescription opioids. Defendants did so to increase sales, revenue, and profit from their opioid products.

561. The interaction and length of the relationships between and among the Defendants reflects a deep level of interaction and cooperation between Defendants in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system.

The Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

562. Defendants collaborated to expand the opioid market in an interconnected and interrelated network in the following ways, as set forth more fully below, including, for example, membership in the Healthcare Distribution Alliance ("HDA").

563. Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their duties under the CSA to report suspicious orders. The Defendants overwhelmingly agreed on the same approach—to fail to identify, report or halt suspicious opioid orders, and fail to prevent diversion. Defendants' agreement to restrict reporting provided an added layer of insulation from DEA scrutiny for the entire industry as Defendants were thus collectively responsible for each other's compliance with their reporting obligations. Defendants were aware, both individually and collectively aware of the suspicious orders that flowed directly from Defendants' facilities.

564. Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting or suspicious orders to ensure consistency in their dealings with DEA.

565. The Defendants also worked together to ensure that the opioid quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not

reported to the DEA in order to ensure that the DEA had not basis for refusing to increase or decrease production quotas due to diversion.

566. The desired consistency, and collective end goal was achieved. Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

G. The Statutes Of Limitations Are Tolled and Defendants Are Estopped From Asserting Statutes Of Limitations As Defenses.

1. Continuing Conduct

567. The Plaintiff Plans and the Proposed Class members continue to suffer harm from the unlawful actions by the Defendants.

568. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The unlawful conduct is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The conduct causing the damages remains unabated.

2. Equitable Estoppel and Fraudulent Concealment

569. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive Plaintiffs and the Proposed Class members and to purposefully conceal their unlawful conduct and fraudulently assure the Plaintiff ERISA Plans and the Proposed Class members, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or

distributor status and to continue generating profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the Plaintiff ERISA Plans and the Proposed Class members, that they are working to curb the opioid epidemic.

570. The Defendants were deliberate in taking steps to conceal their conspiratorial behavior and active role in the deceptive marketing and the oversupply of opioids through overprescribing and suspicious sales, all of which fueled the opioid epidemic.

571. As set forth herein, the Marketing Defendants deliberately worked through Front Groups purporting to be patient advocacy and professional organizations, through public relations companies hired to work with the Front Groups and through paid KOLs to secretly control messaging, influence prescribing practices and drive sales. The Marketing Defendants concealed their role in shaping, editing, and approving the content of prescribing guidelines, informational brochures, KOL presentations and other false and misleading materials addressing pain management and opioids that were widely disseminated to regulators, prescribers, the Plaintiff ERISA Plans and the Proposed Class members, and the public at large. They concealed the addictive nature and dangers associated with opioid use and denied blame for the epidemic attributing it instead solely to abuse and inappropriate prescribing. They manipulated scientific literature and promotional materials to make it appear that misleading statements about the risks, safety and superiority of opioids were actually accurate, truthful, and supported by substantial scientific evidence. Through their public statements, omissions, marketing, and advertising, the Marketing Defendants' deceptions deprived the Plaintiff ERISA Plans and the Proposed Class

members of actual or implied knowledge of facts sufficient to put Plaintiffs on notice of potential claims.

572. Defendants also concealed from Plaintiffs and the Proposed Class members the existence of Plaintiffs' claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the public that their legal duties to report suspicious sales had been satisfied through public assurances that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways insisting they were good corporate citizens. These repeated misrepresentations misled regulators, prescribers, the Plaintiff ERISA Plans and the Proposed Class members, and the public, and deprived Plaintiffs of actual or implied knowledge of facts sufficient to put Plaintiffs on notice of potential claims.

573. The Plaintiff ERISA Plans and the Proposed Class members did not discover the nature, scope and magnitude of Defendants' misconduct, and its full impact on Plaintiffs, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

574. The Marketing Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing deceived the medical community, consumers, and the Plaintiff ERISA Plans and the Proposed Class members.

575. Further, Defendants have also concealed and prevented discovery of information, including data from the ARCOS database that will confirm their identities

and the extent of their wrongful and illegal activities. On April 11, 2018, the Northern District of Ohio Ordered the transactional ARCOS data be produced, over Defendants' strenuous objections. In so doing, the Court reviewed its previous decisions on this data and held that, because the transaction data had not yet been produced, the Plaintiffs *could not identify* the potential defendants in this litigation, and further held that such information was "critical":

> This means Plaintiff[s] still do[] not know: (a) which manufacturers (b) sold what types of pills (c) to which distributors; nor do they know (d) which distributors (e) sold what types of pills (1) to which retailers (g) in what locations. In any given case, therefore, the Plaintiffs] still cannot know for sure who are the correct defendants, or the scope of their potential liability. For example, the ARCOS spreadsheets produced by DEA show the top five distributors of oxycodone in Ohio in 2014 were Cardinal Health, AmerisourceBergen, McKesson, Walmart, and Miami-Luken; but there is no way to know whether (or how much) any of these five entities distributed oxycodone into Seneca County, Ohio (or any other particular venue). .. . [The] DEA and [the] defendants [have] conceded the data was relevant and necessary to litigation .. . . Discovery of precisely which manufacturers sent which drugs to which distributors, and which distributors sent which drugs to which pharmacies and doctors, is critical not only to all of plaintiff[s] claims, but also to the Court's understanding of the width and depth of this litigation.[165]

576. Defendants intended that their actions and omissions would be relied upon, including by the Plaintiff ERISA Plans and the Proposed Class members. Plaintiffs did not know and did not have the means to know the truth, due to Defendants' actions and omissions.

577. The Plaintiff ERISA Plans and the Proposed Class members reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

[165] Order of April 11, 2018 [Doc. 233] at pp. 6-7 (footnotes omitted).

578. Defendants' actions demonstrated both malice and also aggravated and egregious fraud. Defendants engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm. The Marketing Defendants' fraudulent wrongdoing was done with a particularly gross and conscious disregard.

H. The Marketing Defendants Persisted in Their Fraudulent Scheme Despite Repeated Admonitions, Warnings, and Even Prosecutions.

579. So determined were the Marketing Defendants to sell more opioids that they simply ignored multiple admonitions, warnings and prosecutions. These governmental and regulatory actions included:

1. FDA Warnings to Janssen Failed to Deter Janssen's Misleading Promotion of Duragesic.

580. On February 15, 2000, the FDA sent Janssen a letter concerning the dissemination of "homemade" promotional pieces that promoted the Janssen drug Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA explained that the "homemade" promotional pieces were "false or misleading because they contain misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance." The March 30, 2000 letter detailed numerous ways in which Janssen's marketing was misleading.

581. The letter did not stop Janssen. On September 2, 2004, the U.S. Department of Health and Human Services ("HHS") sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and ... unsubstantiated effectiveness claims for Duragesic," including,

specifically, "suggesting that Duragesic has a lower potential for abuse compared to other opioid products." The September 2, 2004 letter detailed a series of unsubstantiated, false, or misleading claims.

582. One year later, Janssen was still at it. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been "'examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch' and noted the possibility "that patients and physicians might be unaware of the risks" of using the fentanyl transdermal patch, which is a potent opioid analgesic approved only for chronic pain in opioid-tolerant patients that could not be treated by other drugs.

2. Governmental Action, Including Large Monetary Fines, Failed to Stop Cephalon from Falsely Marketing Actiq for Off-Label Use.

583. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay $425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Cephalon had trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs and funded CME to promote off-label uses.

584. Notwithstanding letters, an FDA safety alert, DOJ and state investigations, and the massive settlement, Cephalon has continued its deceptive marketing strategy.

3. FDA Warnings Did Not Prevent Cephalon from Continuing False and Off-Label Marketing of Fentora.

585. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: "Fentora should not be used to treat any type of short-term pain." Indeed, FDA specifically denied Cephalon's application, in 2008, to broaden the indication of Fentora to include treatment of non-cancer breakthrough pain and use in patients who were not already opioid-tolerant.

586. Flagrantly disregarding the FDA's refusal to broaden the indication for Fentora, Cephalon nonetheless marketed Fentora beyond its approved indications. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter, described a Fentora Internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case." It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

587. Despite this warning, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq. For example, on January 13, 2012, Cephalon published an insert in Pharmacy Times titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: "It

is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."

4. A Guilty Plea and a Large Fine Did Not Deter Purdue from Continuing Its Fraudulent Marketing of OxyContin.

588. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay $600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science. Additionally, Michael Friedman the company's president, pled guilty to a misbranding charge and agreed to pay $19 million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty and agreed to pay $8 million in fines; and Paul D. Goldenheim, its former medical director, pled guilty as well and agreed to pay $7.5 million in fines.

589. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund seemingly neutral organizations to disseminate the message that opioids were non-addictive as well as other misrepresentations. At least until early 2018, Purdue continued to deceptively market the benefits of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007, it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits,

spent nearly $900 million dollars on lobbying and political contributions—eight times what the gun lobby spent during that period.

I. Repeated Admonishments and Fines Did Not Stop Defendants from Ignoring Their Obligations to Control the Supply Chain and Prevent Diversion.

590. Defendants were repeatedly admonished and even fined by regulatory authorities, but continued to disregard their obligations to control the supply chain of dangerous opioids and to institute controls to prevent diversion.

591. In a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die." He further explained that:

> JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.
>
> [INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.

592. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing." He further explained that "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."

593. Government actions against the Defendants with respect to their obligations to control the supply chain and prevent diversion include:

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

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

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

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

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

f. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone; and

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

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

595. Despite its 2008 agreement with DEA, McKesson continued to fail to report suspicious orders between 2008 and 2012 and did not fully implement or follow the monitoring program it agreed to. It failed to conduct adequate due diligence of its customers, failed to keep complete and accurate• records in the CSMP files maintained for many of its customers and bypassed suspicious order reporting procedures set forth in the CSMP. It failed to take these actions despite its awareness of the great probability that its failure to do so would cause substantial harm.

596. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA. McKesson's 2017 agreement with DEA

documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."

597. As *The Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty than the $150 million ultimately agreed to for McKesson's continued and renewed breach of its duties, as much as a billion dollars, and delicensing of certain facilities. A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[flailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."

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

> DAVID SCHILLER: If they would stayed in compliance with their authority and held those that they're supplying the pills to, the epidemic would be nowhere near where it is right now. Nowhere near.
>
> * * *
>
> They had hundreds of thousands of suspicious orders they should have reported, and they didn't report any. There's not a day that goes by in the pharmaceutical world, in the McKesson world, in the distribution world, where there's not something suspicious. It happens every day.
>
> [INTERVIEWER:] And they had none.

> DAVID SCHILLER: They weren't reporting any. I mean, you have to understand that, nothing was suspicious?[166]

599. Following the 2017 settlement, McKesson shareholders made a books and records request of the company. According to a separate action pending on their behalf, the Company's records show that the Company's Audit Committee failed to monitor McKesson's information reporting system to assess the state of the Company's compliance with the CSA and McKesson's 2008 Settlements. More particularly, the shareholder action alleges that the records show that in October 2008, the Audit Committee had an initial discussion of the 2008 Settlements and results of internal auditing, which revealed glaring omissions; specifically:

a. some customers had "not yet been assigned thresholds in the system to flag large shipments of controlled substances for review";

b. "[d]ocumentation evidencing new customer due diligence was incomplete";

c. "documentation supporting the company's decision to change thresholds for existing customers was also incomplete"; and

d. Internal Audit "identified opportunities to enhance the Standard Operating Procedures."

600. Yet, instead of correcting these deficiencies, after that time, for a period of more than four years, the Audit Committee failed to address the CSMP or perform any more audits of McKesson's compliance with the CSA or the 2008 Settlements, the shareholder action's description of McKesson's internal documents reveals. During that period, McKesson's Audit Committee failed to inquire whether the Company was in compliance with obligations set forth in those agreements and with the controlled substances regulations more generally. It was only in January 2013 that the Audit Committee received an Internal Audit report touching on these issues.

[166] Bill Whitaker, *Whistleblowers: DEA Attorneys Went Easy on McKesson, the Country's Largest Drug Distributor*, CBS News (Dec. 17, 2017), https://www.cbsnews.com/news/whistleblowers-dea-attorneys-went-easy-on-mckesson-the-countrys-largest-drug-distributor/

601. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement]," as a DEA official working on the case noted. Quite the opposite, "their bad acts continued and escalated to a level of egregiousness not seen before." According to statements of "DEA investigators, agents and supervisors who worked on the McKesson case" reported in the *Washington Post,* "the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings." "Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."

602. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or "80s," as they were known on the street, were a prime target for diversion). Purdue claims that health care providers added to the database no longer were detailed, and that sales representatives received no compensation tied to these providers' prescriptions.

603. Yet, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. Purdue's former senior compliance officer acknowledged in an interview with the *Los Angeles Times* that in five years of investigating suspicious pharmacies, the company never

stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs.

604. The same was true of prescribers. For example, as discussed above, despite Purdue's knowledge of illicit prescribing from one Los Angeles clinic which its district manager called an "organized drug ring" in 2009, Purdue did not report its suspicions until long after law enforcement shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

605. The New York Attorney General found that Purdue placed 103 New York health care providers on its "No-Call" List between January 1, 2008 and March 7, 2015, and yet that Purdue's sales representatives had detailed approximately two-thirds of these providers, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period.

606. The New York Attorney General similarly found that Endo knew, as early as 2011, that Opana ER was being abused in New York, but certain sales representatives who detailed New York health care providers testified that they did not know about any policy or duty to report problematic conduct. The New York Attorney General further determined that Endo detailed health care providers who were subsequently arrested or convicted for illegal prescribing of opioids a total of 326 times, and these prescribers collectively wrote 1,370 prescriptions for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER).

607. As all of the governmental actions against the Marketing Defendants and against all the Defendants shows, Defendants knew that their actions were unlawful, and

yet deliberately refused to change their practices because compliance with their legal obligations would have decreased their sales and their profits.

II. FACTS PERTAINING TO CLAIMS UNDER RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ("RICO") ACT

A. The Opioid Marketing Enterprise

1. The Common Purpose and Scheme of the Opioid Marketing Enterprise

608. Knowing that their products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, the RICO Marketing Defendants[167] formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain.

609. In order to unlawfully increase the demand for opioids, the RICO Marketing Defendants formed an association-in-fact enterprise (the "Opioid Marketing Enterprise") with the "Front Groups" and KOLs described above. Through their personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise's common purpose. The RICO Marketing Defendants' substantial financial contribution to the Opioid Marketing Enterprise, and the advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.

[167] The RICO Marketing Defendants referred to in this section are those named in the First and Second Claims for Relief under 28 U.S.C. § 1964(c), including Purdue, Cephalon, Janssen, Endo, and Mallinckrodt.

610. The RICO Marketing Defendants, through the Opioid Marketing Enterprise, concealed the true risks and dangers of opioids from the medical community, the Plaintiff ERISA Plans, and the public, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the RICO Marketing Defendants named "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing present no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

611. The scheme devised, implemented and conducted by the RICO Marketing Defendants was a common course of conduct designed to ensure that the RICO Marketing Defendants unlawfully increased their sales and profits through concealment and misrepresentations about the addictive nature and effective use of the RICO Marketing Defendants' drugs. The RICO Marketing Defendants, the Front Groups, and the KOLs acted together for a common purpose and perpetuated the Opioid Marketing Enterprise's scheme, including through the unbranded promotion and marketing network as described above.

612. There was regular communication between the RICO Marketing Defendants, Front Groups and KOLs, in which information was shared, misrepresentations were

coordinated, and payments were exchanged. Typically, the coordination, communication and payment occurred, and continues to occur, through the repeated and continuing use of the wires and mail in which the RICO Marketing Defendants, Front Groups, and KOLs share information regarding overcoming objections and resistance to the use of opioids for chronic pain. The RICO Marketing Defendants, Front Groups and KOLs functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

613. At all relevant times, the Front Groups were aware of the RICO Marketing Defendants' conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Plaintiffs. But for the Opioid Marketing Enterprise's unlawful fraud, the Front Groups would have had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

614. At all relevant times, the KOLs were aware of the RICO Marketing Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. The RICO Marketing Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. The RICO Marketing Defendants' support helped the KOLs become respected industry experts. And,

as they rose to prominence, the KOLs falsely touted the benefits of using opioids to treat chronic pain, repaying the RICO Marketing 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 consumers, prescribers, and the Plaintiffs. But for the Opioid Marketing Enterprise's unlawful conduct, the KOLs would have had incentive to disclose the deceit by the RICO Marketing Defendants and the Opioid Marketing Enterprise, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs furthered the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

615. As public scrutiny and media coverage focused on how opioids ravaged communities in Oklahoma and throughout the United States, the Front Groups and KOLS did not challenge the RICO Marketing Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence.

616. The RICO Marketing Defendants, Front Groups and KOLs engaged in certain discrete categories of activities in furtherance of the common purpose of the Opioid Marketing Enterprise. As described herein, the Opioid Marketing Enterprise's conduct in furtherance of the common purpose of the Opioid Marketing Enterprise involved: (1) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain (described in detail above); (2) lobbying to

defeat measures to restrict over-prescription; (3) efforts to criticize or undermine CDC guidelines; and (4) efforts to limit prescriber accountability.

617. In addition to disseminating misrepresentations about the risks and benefits of opioids, the Opioid Marketing Enterprise also furthered its common purpose by criticizing or undermining CDC Guideline. Members of the Opioid Marketing Enterprise criticized or undermined the CDC Guideline, which represented "an important step—and perhaps the first major step from the federal government—toward limiting opioid prescriptions for chronic pain."

618. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized the draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines."

619. The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating "that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence."

620. The RICO Marketing Defendants alone could not have accomplished the purpose of the Opioid Marketing Enterprise without the assistance of the Front Groups and KOLs, who were perceived as "neutral" and more "scientific" than the RICO Marketing Defendants themselves. Without the work of the Front Groups and KOLs in

spreading misrepresentations about opioids, the Opioid Marketing Enterprise could not have achieved its common purpose.

621. The impact of the Opioid Marketing Enterprise's scheme is still in place—i.e., opioids continue to be prescribed and used for chronic pain throughout the nation, including Oklahoma, and the epidemic continues to injure the Plaintiff ERISA Plans.

622. As a result, it is clear that the RICO Marketing Defendants, the Front Groups, and the KOLs were each willing participants in the Opioid Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

2. The Conduct of the Opioid Marketing Enterprise violated Civil RICO

623. From approximately the late 1990's to the present, each of the RICO Marketing Defendants exerted control over the Opioid Marketing Enterprise and participated in the operation or management of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the 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 third party payors, including ERISA Plans;

b. Creating and providing a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the 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 third party payors, including ERISA Plans;

c. Creating and providing a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the 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 third party payors, including ERISA Plans;

d. Creating and providing a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that (i) understated the risks and overstated the 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 third party payors, including ERISA Plans;

e. Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;

f. Providing substantial opportunities for KOLs to participate in research studies on topics the RICO Marketing Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

g. Paying KOLs to serve as consultants or on the RICO Marketing Defendants' advisory boards, on the advisory boards and in leadership positions on Front Groups, and to give talks or present CMEs, typically over meals or at conferences;

h. Selecting, cultivating, promoting, creating and paying Front Groups based solely on their willingness to communicate and distribute the RICO Marketing Defendants' messages about the use of opioids for chronic pain;

i. Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the RICO Marketing Defendants suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

j. Paying significant amounts of money to the leaders and individuals associated with Front Groups;

k. Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;

l. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

m. Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

n. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;

o. Concealing their relationship to and control of Front Groups and KOLs from the Plaintiff ERISA Plans, and the public at large; and

p. Intending 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.

624. The Opioid Marketing Enterprise had a hierarchical decision-making structure that was headed by the RICO Marketing Defendants and corroborated by the KOLs and Front Groups. The RICO Marketing Defendants controlled representations made about their opioids and their drugs, doled out funds to PBMs and payments to KOLs, and ensured that representations made by KOLs, Front Groups, and the RICO Marketing Defendants' sales detailers were consistent with the Marketing Defendants' messaging throughout the United States and Oklahoma. The Front Groups and KOLS in the Opioid Marketing Enterprise were dependent on the RICO Marketing Defendants for their financial structure and for career development and promotion opportunities.

625. The Front Groups also conducted and participated in the conduct of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The Front Groups promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were consistent with the RICO Marketing Defendants' messages;

b. The Front Groups distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;

d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The Front Groups strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and

f. The Front Groups concealed their connections to the KOLs and the RICO Marketing Defendants.

626. The RICO Marketing Defendants' Front Groups, "with their large numbers and credibility with policymakers and the public—have 'extensive influence in specific disease areas.'" The larger Front Groups "likely have a substantial effect on policies relevant to their industry sponsors."[168] "By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic."[169]

627. The KOLs also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The KOLs promised to, and did, make representations regarding opioids and the RICO Marketing Defendants' drugs that were

[168] *Fueling an Epidemic*, *supra*, at 1.
[169] *Id.* at 2.

consistent with the RICO Marketing Defendants' messages themselves;

b. The KOLs distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

c. The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the RICO Marketing Defendants;

d. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The KOLs strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and

f. The KOLs concealed their connections to the Front Groups and the RICO Marketing Defendants, and their sponsorship by the RICO Marketing Defendants.

628. The scheme devised and implemented by the RICO Marketing Defendants and members of the Opioid Marketing Enterprise, amounted to a common course of conduct intended to increase the RICO Marketing Defendants' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

3. The RICO Marketing Defendants Controlled and Paid Front Groups and KOLs to Promote and Maximize Opioid Use.

629. As discussed in detail above, the RICO Marketing Defendants funded and controlled the various Front Groups, including APF, AAPM/APS, FSMB, Alliance for Patient Access, and USPF. The Front Groups, which appeared to be independent, but were

not, transmitted the RICO Marketing Defendants' misrepresentations. The RICO Marketing Defendants and the Front Groups thus worked together to promote the goals of the Opioid Marketing Enterprise.

630. The RICO Marketing Defendants worked together with each other through the Front Groups that they jointly funded and through which they collaborated on the joint promotional materials described above.

631. Similarly, as discussed in detail above, the RICO Marketing Defendants paid KOLs, including Drs. Portenoy, Fine, Fishman, and Webster, to spread their misrepresentations and promote their products. The RICO Marketing Defendants and the KOLs thus worked together to promote the goals of the Opioid Marketing Enterprise.

4. Pattern of Racketeering Activity

632. The RICO Marketing Defendants' scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of racketeering activity as described herein.

633. The pattern of racketeering activity used by the RICO Marketing Defendants and the Opioid Marketing Enterprise likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing Enterprise, including essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain, with the goal of profiting from increased sales of the RICO Marketing Defendants' drugs induced by consumers,

prescribers, regulators and Plaintiffs' reliance on the RICO Marketing Defendants' misrepresentations.

634. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity, through which the RICO Marketing Defendants, the Front Groups and the KOLs defrauded and intended to defraud the Plaintiff ERISA Plans, among others.

635. The RICO Marketing Defendants devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive and effective use of opioids for long-term chronic, non-acute and non-cancer pain. The RICO Marketing Defendants and members of the Opioid Marketing Enterprise knew that these representations violated the FDA approved use these drugs, and were not supported by actual evidence. The RICO Marketing Defendants intended that that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to advance, and for the purpose of executing, their illegal scheme.

636. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain to prescribers, regulators and the public, including Plaintiffs, the RICO Marketing Defendants, the Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

637. The RICO Marketing Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, *inter alia:*

a. Marketing materials about opioids, and their risks and benefits, which the RICO Marketing Defendants sent to health care providers, transmitted through the internet and television, published, and transmitted to Front Groups and

   KOLs located across the country and the State of Oklahoma;

b. Written representations and telephone calls between the RICO Marketing Defendants and Front Groups regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

c. Written representations and telephone calls between the RICO Marketing Defendants and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

d. E-mails, telephone and written communications between the RICO Marketing Defendants and the Front Groups agreeing to or implementing the opioids marketing scheme;

e. E-mails, telephone and written communications between the RICO Marketing Defendants and the KOLs agreeing to or implementing the opioids marketing scheme;

f. Communications between the RICO Marketing Defendants, Front Groups and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

g. Communications between the RICO Marketing Defendants, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

h. Written and oral communications directed to State agencies, federal and state courts, private insurers, and ERISA Plans and their agents throughout the nation that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and

i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme.

638. In addition to the above-referenced predicate acts, it was intended by and foreseeable to the RICO Marketing Defendants that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

639. To achieve the common goal and purpose of the Opioid Marketing Enterprise, the RICO Marketing Defendants and members of the Opioid Marketing Enterprise hid from the consumers, prescribers, regulators and the Plaintiffs: (a) the fraudulent nature of the RICO Marketing Defendants' marketing scheme; (b) the fraudulent nature of statements made by the RICO Marketing Defendants and by their KOLs, Front Groups and other third parties regarding the safety and efficacy of prescription opioids; and (c) the true nature of the relationship between the members of the Opioid Marketing Enterprise.

640. The RICO Marketing Defendants and each member of the Opioid Marketing Enterprise agreed, with knowledge and intent, to the overall objective of the RICO Marketing Defendants' fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

641. Indeed, for the RICO Marketing Defendants' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that the RICO Marketing Defendants each financed, supported, and worked through the same KOLs and Front

Groups, and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines.

642. The RICO Marketing Defendants' predicate acts all had the purpose of creating the opioid epidemic that substantially injured the Plaintiffs' ERISA Plans' business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Marketing Defendants. The predicate acts were committed or caused to be committed by the RICO Marketing Defendants through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

B. The Opioid Supply Chain Enterprise

643. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort to "a categorical denial of any criminal behavior or intent."[170] Defendants' actions went far beyond what could be considered ordinary business conduct. For more than a decade, certain Defendants, the "RICO Supply Chain Defendants" (Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen) worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

[170] McKesson Responds to Recent 60 Minutes Story About January 2017 Settlement With the Federal Government, McKesson, http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response (last visited Apr. 21, 2018).

644. Knowing that dangerous drugs have a limited place in our society, and that their dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse and addiction causes to individuals, society and governments, Congress enacted the Controlled Substances Act ("CSA"). Specifically, through the CSA, which created a closed system of distribution for controlled substances, Congress established an enterprise for good. CSA imposes a reporting duty that cuts across company lines. Regulations adopted under the CSA require that companies who are entrusted with permission to operate within this system cannot simply operate as competitive in an "anything goes" profit-maximizing market. Instead, the statute tasks them to watch over each other with a careful eye for suspicious activity. Driven by greed, Defendants betrayed that trust and subverted the constraints of the CSA's closed system.

645. As "registrants" under the CSA, the RICO Supply Chain Defendants are duty bound to identify and report "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." [171] Critically, these Defendants' responsibilities do not end with the products they manufacture or distribute—there is no such limitation in the law because their duties cut across company lines. Thus, when these Defendants obtain information about the sales and distribution of other companies' opioid products, as they did through data mining companies like IMS Health, they were legally obligated to report that activity to the DEA.

646. If morality and the law did not suffice, competition dictates that the RICO Supply Chain Defendants would turn in their rivals when they had reason to suspect

[171] 21 C.F.R. § 1301.74(b).

suspicious activity. Indeed, if a manufacturer or distributor could gain market share by reporting a competitor's illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so. Under the CSA this whistleblower or watchdog function is not only a protected choice, but a statutory mandate. Unfortunately, however, that is not what happened. Instead, knowing that investigations into potential diversion would only lead to shrinking markets, the Rico Supply Chain Defendants elected to operate in a conspiracy of silence, in violation of both the CSA and RICO.

647. The RICO Supply Chain Defendants' scheme required the participation of all. If any one member broke rank, its compliance activities would highlight deficiencies of the others, and the artificially high quotas they maintained through their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for the DEA to go after any one of them. Accordingly, through the connections they made as a result of their participation in the Healthcare Distribution Alliance ("HDA"), the RICO Supply Chain Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances." But, privately, the RICO Supply Chain Defendants refused to act and through their lobbying efforts, they collectively sought to undermine the impact of the CSA. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants' duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued

after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Yet, the RICO Supply Chain Defendants apparently all found the same profit-maximizing balance -- intentionally remaining silent to ensure the largest possible financial return.

648. As described above, at all relevant times, the RICO Supply Chain Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute. In support of this common purpose and fraudulent scheme, the RICO Supply Chain Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.

649. At all relevant times, as described above, the RICO Supply Chain Defendants exerted control over, conducted and/or participated in the Opioid Supply Chain Enterprise by fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate unlawful profits, as follows:

650. The RICO Supply Chain Defendants disseminated false and misleading statements to state and federal regulators claiming that:

a. the quotas for prescription opioids should be increased;

b. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;

c. they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;

d. they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and

e. they did not have the capability to identify suspicious orders of controlled substances.

651. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[172]

652. The CSA and the Code of Federal Regulations, require the RICO Supply Chain Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make

[172] *HDMA is Now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/ (last updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html ; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html ; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail (Feb. 18, 2017), http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills- .

reports as required by the CSA and Code of Federal Regulations amounts to a criminal violation of the statute.

653. The RICO Supply Chain Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Marketing Defendants' applications for production quotas. Specifically, the RICO Supply Chain Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

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

655. In devising and executing the illegal scheme, the RICO Supply Chain Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

656. For the purpose of executing the illegal scheme, the RICO Supply Chain Defendants committed racketeering acts, which number in the thousands, intentionally

and knowingly with the specific intent to advance the illegal scheme. These racketeering acts, which included repeated acts of mail fraud and wire fraud, constituted a pattern of racketeering.

657. The RICO Supply Chain Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Marketing Defendants, the Distributor Defendants, or third parties that were foreseeably caused to be sent as a result of the RICO Supply Chain Defendants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that supported and/or facilitated the RICO Supply Chain Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

c. Documents and communications that facilitated the manufacture, purchase and sale of prescription opioids;

d. RICO Supply Chain Defendants' DEA registrations;

e. Documents and communications that supported and/or facilitated RICO Supply Chain Defendants' DEA registrations;

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

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

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

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

j. Payments from the Distributors to the Marketing Defendants;

k. Rebates and chargebacks from the Marketing Defendants to the Distributors Defendants;

m. Payments to the RICO Supply Chain Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

n. Deposits of proceeds from the RICO Supply Chain Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

658. The RICO Supply Chain Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

Defendant Group Name	**Company Names**	**Drugs**		
		Drug Name	**Chemical Name**	**CSA Schedule**
Purdue	(1)Purdue Pharma, LP, (2)Purdue Pharma, Inc., (3)The Purdue Frederick Company	OxyContin	Oxycodone hydrochloride extended release	Schedule II
		MS Contin	Morphine sulfate extended release	Schedule II
		Dilaudid	Hydromorphone hydrochloride	Schedule II
		Dilaudid-HP	Hydromorphone hydrochloride	Schedule II

Defendant Group Name	Company Names	Drugs		
		Drug Name	**Chemical Name**	**CSA Schedule**
		Butrans	Buprenorphine	Schedule II
		Hysinga ER	Hydrocodone bitrate	Schedule II
		Targiniq ER	Oxycodone hydrochloride	Schedule II
Cephalon	(1)Cephalon, Inc., (2)Teva Pharmaceutical Industries, Ltd., (3)Teva Pharmaceuticals USA, Inc.	Actiq	Fentanyl citrate	Schedule II
		Fentora	Fentanyl citrate	Schedule II
		Generic oxycodone	Oxycodone hydrochloride	Schedule II
Endo	(1) Endo Health Solutions, Inc., (2) Endo Pharmaceuticals In c., (3) Qualitest Pharmaceuticals, Inc. *(wholly-owned subsidiary of Endo)*	Opana ER	Oxymorphone hydrochloride extended release	Schedule II
		Opana	Oxymorphone hydrochloride	Schedule II
		Percodan Oxymorphone	hydrochloride and aspirin	Schedule II
		Percocet	Oxymorphone hydrochloride and	Schedule II
		Generic oxycodone		Schedule II
		Generic oxymorphone		Schedule II
		Generic hydromorphone		Schedule II
		Generic hydrocodone		Schedule II
Mallinckrodt	(1) Mallinckrodt plc, (2) Mallinckrodt LLC *(wholly-owned subsidiary of Mallinckrodt plc)*	Exalgo	Hydromorphone hydrochloride	Schedule II
		Roxicodone	Oxycodone hydrochloride	Schedule II
Allergan	(1) Allergan Plc, (2) Actavis LLC, (3) Actavis Phanna, Inc., (4) Actavis Plc,	Kadian	Morphine Sulfate	Schedule II
		Norco (Generic of Kadian)	Hydrocodone and acetaminophen	Schedule II

Defendant Group Name	Company Names	Drugs		
		Drug Name	Chemical Name	CSA Schedule
	(5)Actavis, Inc., (6)Watson Pharmaceuticals, Inc., Watson Pharma, Inc. Duragesic	Generic	Fentanyl	Schedule II
		Generic Opana	Oxymorphone hydrochloride	Schedule II

659. Each of the RICO Supply Chain Defendants identified manufactured, shipped, paid for and received payment for the drugs identified above, throughout the United States.

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

661. At the same time, the RICO Supply Chain Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

662. The RICO Supply Chain Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

663. The RICO Supply Chain Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

664. The mail and wire transmissions described herein were made in furtherance of the RICO Supply Chain Defendants' scheme and common course of conduct to deceive regulators, the public and the Plaintiffs that these Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Supply Chain Defendants' scheme and common course of conduct was to increase or maintain high production quotas for their prescription opioids from which they could profit.

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

666. The RICO Supply Chain Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as

defendants in this Complaint, may have contributed to and/or participated in the scheme with these Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Supply Chain Defendants.

667. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

668. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs' business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

669. As described above, the RICO Supply Chain Defendants were repeatedly warned, fined, and found to be in violation of applicable law and regulations, and yet they persisted. The sheer volume of enforcement actions against the RICO Supply Chain Defendants supports this conclusion that the RICO Supply Chain Defendants operated through a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74.

670. 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 the Plaintiff ERISA Plans. The RICO Supply Chain Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on the Plaintiff ERISA Plans. The RICO Supply Chain Defendants were aware that the Plaintiff ERISA Plans rely on these Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

671. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the RICO Supply Chain Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF (BROUGHT BY PLAINTIFF ERISA PLANS)

Violation of RICO, 18 U.S.C. § 1961 et seq.—Opioid Marketing Enterprise (Against Purdue, Cephalon, Janssen, Endo, and Mallinckrodt (the "RICO Marketing Defendants"))

672. Plaintiffs repeat, re-allege, and incorporate by reference each and every allegation set forth above as if fully set forth herein.

673. The RICO Marketing Defendants—through the use of "Front Groups" that appeared to be independent of the RICO Marketing Defendants; through the dissemination of publications that supported the RICO Marketing Defendants' scheme; through continuing medical education ("CME") programs controlled and/or funded by the RICO

Marketing Defendants; by the hiring and deployment of so-called "key opinion leaders," ("KOLs") who were paid by the RICO Marketing Defendants to promote their message; and through the "detailing" activities of the RICO Marketing Defendants' sales forces—conducted an association-in-fact enterprise, and/or participated in the conduct of an enterprise through a pattern of illegal activities (the predicate racketeering acts of mail and wire fraud) to carry-out the common purpose of the Opioid Marketing Enterprise, *i.e.,* to unlawfully increase profits and revenues from the continued prescription and use of opioids for long-term chronic pain. Through the racketeering activities of the Opioid Marketing Enterprise sought to further the common purpose of the enterprise through a fraudulent scheme to change prescriber habits and public perception about the safety and efficacy of opioid use by convincing them that each of the nine false propositions alleged earlier were true. In so doing, each of the RICO Marketing Defendants knowingly conducted and participated in the conduct of the Opioid Marketing Activities by engaging in mail and wire fraud in violation of 18 U.S.C. §§ 1962(c) and (d).

674. The Opioid Marketing Enterprise alleged above, is an association-in-fact enterprise that consists of the RICO Marketing Defendants (Purdue, Cephalon, Janssen, Endo, and Mallinckrodt); the Front Groups (APF, AAPM, APS, FSMB, USPF, and AGS); and the KOLs (Dr. Portenoy, Dr. Webster, Dr. Fine, and Dr. Fishman).

675. Each of the RICO Marketing Defendants and the other members of the Opioid Marketing Enterprise conducted and participated in the conduct of the Opioid Marketing Enterprise by playing a distinct role in furthering the enterprise's common purpose of increasing profits and sales through the knowing and intentional dissemination

of false and misleading information about the safety and efficacy of long-term opioid use, and the risks and symptoms of addiction, in order increase the market for prescription opioids by changing prescriber habits and public perceptions and increase the market for opioids.

676. Specifically, the RICO Marketing Defendants each worked together to coordinate the enterprise's goals and conceal their role, and the enterprise's existence, from the public by, among other things, (i) funding, editing and distributing publications that supported and advanced their false messages; (ii) funding KOLs to further promote their false messages; (iii) funding, editing and distributing CME programs to advance their false messages; and (iv) tasking their own employees to direct deceptive marketing materials and pitches directly at physicians and, in particular, at physicians lacking the expertise of pain care specialists (a practice known as sales detailing).

677. Each of the Front Groups helped disguise the role of RICO Marketing Defendants by purporting to be unbiased, independent patient-advocacy and professional organizations in order to disseminate patient education materials, a body of biased and unsupported scientific "literature," and "treatment guidelines" that promoted the RICO Marketing Defendants false messages.

678. Each of the KOLs were physicians chosen and paid by each of the RICO Marketing Defendants to influence their peers' medical practice by promoting the Marketing Defendant's false message through, among other things, writing favorable journal articles and delivering supportive CMEs as if they were independent medical

professionals, thereby further obscuring the RICO Marketing Defendants' role in the enterprise and the enterprise's existence.

679. Further, each of the RICO Marketing Defendants, KOLs and Front Groups that made-up the Opioid Marketing Enterprise had systematic links to and personal relationships with each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The systematic links and personal relationships that were formed and developed allowed members of the Opioid Marketing Enterprise the opportunity to form the common purpose and agree to conduct and participate in the conduct of the Opioid Marketing Enterprise. Specifically, each of the RICO Marketing Defendants coordinated their efforts through the same KOLs and Front Groups, based on their agreement and understanding that the Front Groups and KOLs were industry friendly and would work together with the RICO Marketing Defendants to advance the common purpose of the Opioid Marketing Enterprise; each of the individuals and entities who formed the Opioid Marketing Enterprise acted to enable the common purpose and fraudulent scheme of the Opioid Marketing Enterprise.

680. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each RICO Marketing Defendant and its members; (b) was separate and distinct from the pattern of racketeering in which the RICO Marketing Defendants engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the RICO Marketing Defendants; (d) was characterized by interpersonal relationships between and among each member of

the Opioid Marketing Enterprise, including between the RICO Marketing Defendants and each of the Front Groups and KOLs; (e) had sufficient longevity for the enterprise to pursue its purpose and functioned as a continuing unit.

681. The persons and entities engaged in the Opioid Marketing Enterprise are systematically linked through contractual relationships, financial ties, personal relationships, and continuing coordination of activities, as spearheaded by the RICO Marketing Defendants.

682. The RICO Marketing Defendants conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase profits and revenue by changing prescriber habits and public perceptions in order to increase the prescription and use of prescription opioids, and expand the market for opioids.

683. The RICO Marketing Defendants each committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity *(i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Marketing Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Marketing Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Marketing Enterprise, the U.S. Mail and interstate wire facilities. The RICO

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

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

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

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

685. Indeed, as summarized herein, the RICO Marketing Defendants used the mail and wires to send or receive thousands of communications, publications, representations, statements, electronic transmissions and payments to carry-out the Opioid Marketing Enterprise's fraudulent scheme.

686. Because the RICO Marketing Defendants disguised their participation in the enterprise, and worked to keep even the enterprise's existence secret so as to give the false appearance that their false messages reflected the views of independent third parties, many of the precise dates of the Opioid Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records maintained by the RICO Marketing Defendants, Front Groups, and KOLs. Indeed, an essential part of the

successful operation of the Opioid Marketing Enterprise alleged herein depended upon secrecy. However, Plaintiffs have described the occasions on which the RICO Marketing Defendants, Front Groups, and KOLs disseminated misrepresentations and false statements to prescribers, regulators and the Plaintiff ERISA Plans and their agents, and how those acts were in furtherance of the scheme.

687. 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 Oklahoma consumers, prescribers, regulators and the Plaintiff ERISA Plans. The RICO Marketing Defendants, Front Groups and KOLs calculated and intentionally crafted the scheme and common purpose of the Opioid Marketing Enterprise to ensure their own profits remained high. In designing and implementing the scheme, the RICO Marketing Defendants understood and intended that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding the RICO Marketing Defendants' products.

688. The RICO Marketing Defendants' pattern of racketeering activity alleged herein and the Opioid Marketing Enterprise are separate and distinct from each other. Likewise, the RICO Marketing Defendants are distinct from the Opioid Marketing Enterprise.

689. The pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and, upon information and belief, will continue into the future unless enjoined by this Court.

690. The racketeering activities conducted by the RICO Marketing Defendants, Front Groups and KOLs amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Oklahoma consumers, prescribers, regulators and the Plaintiff ERISA Plans. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Oklahoma consumers, prescribers, regulators and the Plaintiff ERISA Plans. The RICO Marketing Defendants have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Opioid Marketing Enterprise.

691. Each of the RICO Marketing Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

692. As described herein, the RICO Marketing Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant money and revenue from the marketing and sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

693. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

694. The RICO Marketing Defendants' violations of law and their pattern of racketeering activity directly and proximately caused the Plaintiff ERISA Plans' injury in their business and property. The RICO Marketing Defendants' pattern of racketeering activity logically, substantially and foreseeably caused an opioid epidemic. Plaintiffs' injuries, as described herein, were not unexpected, unforeseen or independent.[173] Rather, as Plaintiffs allege, the RICO Marketing Defendants knew that the opioids were unsuited to treatment of long-term chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse.[174] Nevertheless, the RICO Marketing Defendants engaged in a scheme of deception that utilized the mail and wires in order to carry-out the Opioid Marketing Enterprises' fraudulent scheme, thereby increasing sales of their opioid products.

695. It was foreseeable and expected that the RICO Marketing Defendants' Opioid Marketing Enterprise would lead to a nationwide opioid epidemic, including increased opioid addiction and overdose.[175]

696. Specifically, the RICO Marketing Defendants' creating, and then participating in, the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme, has injured the Plaintiff ERISA Plans in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic. The Plaintiff ERISA Plans'

[173] *Travelers Prop. Cas. Co. of Am.* v. *Actavis, Inc.*, 16 Cal. App. 5th 1026, 1030 (2017).
[174] *Id*. at 1041.
[175] *Id.*

injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

a. the cost of unnecessary opioid prescriptions paid by the Plans;

b. the cost of healthcare, medical care, therapeutic care, prescription drug purchases, and other medical costs and treatments for Plan participants and beneficiaries suffering from opioid-related addiction or disease, including overdoses and deaths, paid by the Plans;

c. the cost of mental-health services, treatment, counseling, rehabilitation services, and social services to Plan participants and beneficiaries who are victims of the opioid epidemic, paid by the Plans; and

d. the cost of providing treatment of infants who are Plan beneficiaries, who were born with opioid-related medical conditions, or born dependent on opioids due to opioid drug use by the mother during pregnancy, paid by the Plans; and

697. The Plaintiff ERISA Plans' injuries were directly and thus proximately caused by these Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of Plaintiffs' injuries. But for the opioid-addiction epidemic the RICO Marketing Defendants created through their Opioid Marketing Enterprise, the Plaintiff ERISA Plans would not have lost money or property.

698. The Plaintiff ERISA Plans are the most directly harmed entities and there are no other plaintiffs better suited to seek a remedy for the economic harms at issue here.

699. The Plaintiff ERISA Plans seek all legal and equitable relief as allowed by law, including, *inter alia,* actual damages; treble damages; equitable and/or injunctive relief; forfeiture; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest.

SECOND CLAIM FOR RELIEF (BROUGHT BY PLAINTIFF ERISA PLANS)

Violation of RICO, 18 U.S.C. § 1961 *et seq*.—Opioid Supply Chain Enterprise (Against Defendants Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen—"RICO Supply Chain Defendants")

700. Plaintiffs repeat, re-allege, and incorporate by reference each and every allegation set forth above as if fully set forth herein.

701. At all relevant times, the RICO Supply Chain Defendants were and are "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

702. The RICO Supply Chain Defendants together formed an association-in-fact enterprise, the Opioid Supply Chain Enterprise, for the purpose of increasing the quota for and profiting from the increased volume of opioid sales in the United States. The Opioid Supply Chain Enterprise is an association-in-fact enterprise within the meaning of § 1961. The Opioid Supply Chain Enterprise consists of the RICO Supply Chain Defendants.

703. The RICO Supply Chain Defendants were members of the Healthcare Distribution Alliance (the "HDA").[176] Each of the RICO Supply Chain Defendants is a member, participant, and/or sponsor of the HDA, and has been since at least 2006, and utilized the HDA to form the interpersonal relationships of the Opioid Supply Chain Enterprise and to assist them in engaging in the pattern of racketeering activity that gives rise to the Count.

704. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an existence separate and distinct from each of the RICO Supply Chain Defendants; (b) was

[176] *History*, Health Distribution Alliance, https://www.healthcaredistribution.org/about/hda-history (last accessed Sept. 15, 2017).

separate and distinct from the pattern of racketeering in which the RICO Supply Chain Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Supply Chain Defendants; (d) was characterized by interpersonal relationships among the RICO Supply Chain Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit.. Each member of the Opioid Supply Chain Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid quotas and resulting sales.

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

706. The RICO Supply Chain Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity *(i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Supply Chain Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Supply Chain Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Supply

Chain Enterprise. The RICO Supply Chain Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

707. The RICO Supply Chain Defendants also conducted and participated in the conduct of the affairs of the Opioid Supply Chain Enterprise through a pattern of racketeering activity by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

708. The RICO Supply Chain Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

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

710. The RICO Supply Chain Defendants' predicate acts of racketeering (18 U.S.C. § 19610)) include, but are not limited to:

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

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

711. Controlled Substance Violations: The RICO Supply Chain Defendants who are Distributor Defendants violated 21 U.S.C. § 823 by knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the DEA.

712. The RICO Supply Chain Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

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

714. The RICO Supply Chain Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the reality of the suspicious orders that the RICO Supply Chain Defendants

were filling on a daily basis — leading to the diversion of hundreds of millions of doses of prescriptions opioids into the illicit market.

715. The RICO Supply Chain Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

716. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding manufacturing prescription opioids and refusing to report suspicious orders.

717. As described herein, the RICO Supply Chain Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

718. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs' business and property, while simultaneously generating billion-dollar revenue and profits for the RICO Supply Chain Defendants. The predicate acts were committed or caused to be committed by the RICO Supply Chain Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

719. The pattern of racketeering activity alleged herein and the Opioid Supply Chain Enterprise are separate and distinct from each other. Likewise, the RICO Supply Chain Defendants are distinct from the enterprise.

720. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

721. Many of the precise dates of the RICO Supply Chain Defendants' criminal actions at issue here have been hidden by Defendants and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Supply Chain Enterprise alleged herein depended upon secrecy.

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

723. It was foreseeable to the RICO Supply Chain Defendants that Plaintiffs would be harmed when they refused to report and halt suspicious orders, because their violation of the duties imposed by the CSA and Code of Federal Regulations allowed the widespread diversion of prescription opioids out of appropriate medical channels and into the illicit drug market—causing the opioid epidemic that the CSA intended to prevent.

724. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

725. The RICO Supply Chain Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff ERISA Plans' injuries in

their business and property. The RICO Supply Chain Defendants' pattern of racketeering activity, including their refusal to identify, report and halt suspicious orders of controlled substances, logically, substantially and foreseeably cause an opioid epidemic. Plaintiffs were injured by the RICO Supply Chain Defendants' pattern of racketeering activity and the opioid epidemic that they created.

726. The RICO Supply Chain Defendants knew that the opioids they manufactured and supplied were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. [177] Nevertheless, the RICO Supply Chain Defendants engaged in a scheme of deception, that utilized the mail and wires as part of their fraud, in order to increase sales of their opioid products by refusing to identify, report suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse, and were actually being diverted into the illegal market.[178]

727. The RICO Supply Chain Defendants' predicate acts and pattern of racketeering activity were a cause of the opioid epidemic which has injured Plaintiffs in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic.

[177] *Travelers Prop. Cas. Co. of Am.* v. *Actavis, Inc.*, 16 Cal. App. 5th 1026, 1030 (2017).
[178] *City of Everett v. Purdue Pharma L.P.*, Case No. 17-cv-00209, 2017 WL 4236062, *2 (W.D. Wash. Sept. 25, 2017)

728. Specifically, the Plaintiff ERISA Plans' injuries and resulting damages, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

a. the cost of unnecessary opioid prescriptions paid by the Plans;

b. the cost of healthcare, medical care, therapeutic care, prescription drug purchases, and other medical costs and treatments for Plan participants and beneficiaries suffering from opioid-related addiction or disease, including overdoses and deaths, paid by the Plans;

c. the cost of mental-health services, treatment, counseling, rehabilitation services, and social services to Plan participants and beneficiaries who are victims of the opioid epidemic, paid by the Plans; and

d. the cost of providing treatment of infants who are Plan beneficiaries, who were born with opioid-related medical conditions, or born dependent on opioids due to opioid drug use by the mother during pregnancy, paid by the Plans; and

729. The Plaintiff ERISA Plans' injuries were proximately caused by Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of Plaintiffs' injuries. But for the opioid-addiction epidemic created by Defendants' conduct, the Plaintiff ERISA Plans would not have lost money or property.

730. The Plaintiff ERISA Plans' injuries were directly caused by the RICO Supply Chain Defendants' pattern of racketeering activities.

731. The Plaintiff ERISA Plans are most directly harmed and there are no other Plaintiffs better suited to seek a remedy for the economic harms at issue here.

732. The Plaintiff ERISA Plans' seek all legal and equitable relief as allowed by law, including, *inter alia,* actual damages; treble damages; equitable and/or injunctive

relief; forfeiture or disgorgement of profits; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest.

THIRD CLAIM FOR RELIEF (BROUGHT BY FIDUCIARY PLAINTIFFS)

ERISA Equitable Relief (Enforcement of ERISA)
(29 U.S.C. § 1132(a)(3))

733. The Plaintiff ERISA Plans are administered based on trust principles. See U.S.C. §1103(a); *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 110-11 (1989).

734. The Fiduciary Plaintiffs are fiduciaries of their respective Plaintiff ERISA Plans because they exercise discretionary authority or discretionary control respecting management of such Plans and exercise authority or control respecting management or disposition of the respective Plans' assets, and because they have discretionary authority or discretionary responsibility in the administration of their respective Plans. See 29 U.S.C. §1002(21)(A).

735. As fiduciaries under ERISA, the Fiduciary Plaintiffs have a legal duty and obligation (i) to protect their respective Plans from incurring improper losses and (ii) when a third party causes improper expenses/losses to the Plans, to seek recovery of such expenses/losses from the third party. See, e.g., 29 U.S.C. §1103(a); §1104(a)(1)(A)(ii) & (C); 1109(a).

736. The Plaintiff ERISA Plans have incurred direct losses as a result of Defendants' improper and fraudulent conduct. As described above, these losses include, for example, paying for opioids that were unnecessary (over-prescription and addict

doctor shopping) and paying for opioid-related treatment and therapy for participants and beneficiaries who became addicted to opioids or which resulted from opioid use.

737. Having become aware of the Defendants' improper and fraudulent conduct, and the losses it has caused to the Plaintiff ERISA Plans, the Fiduciary Plaintiffs are required to discharge their ERISA fiduciary duties to prevent further improper losses to the Plaintiff ERISA Plans and to preserve the Plans' assets and legal rights to reimbursement and subrogation.

738. Specifically, the Fiduciary Plaintiffs, as fiduciaries, bring this action under 29 U.S.C. § 1132(a)(3)(A), to enjoin and abate Defendants' continuing wrongful and fraudulent acts and practices (which have caused improper losses to the Plaintiff ERISA Plans) and which violate subchapter I of ERISA (improper losses to the Plans).

739. The Fiduciary Plaintiffs also bring this action under 29 U.S.C. § 1132(a)(3)(B)(i), to obtain appropriate equitable relief, which includes declaratory relief, to redress the aforementioned violations of subchapter I of ERISA.

740. The Fiduciary Plaintiffs also bring this action under 29 U.S.C. § 1132(a)(3)(B)(ii), to obtain appropriate equitable relief (injunction, abatement, and declaratory relief) to enforce the provisions of ERISA and provisions in the ERISA Plans which require ERISA plan fiduciaries to protect their plans against improper losses. Specifically, with respect to relief under 29 U.S.C. § 1132(a)(3)(B)(ii), the Fiduciary Plaintiffs seek a declaration that:

> The Plaintiff ERISA Plans and many of the members in Class A have subrogation rights, interests and/or liens which are provided to them under their Plan documents. Therefore, to the extent the Plaintiff ERISA Plans and any ERISA Plan within Class A has such rights through their Plans, then

> with respect to (a) any settlement proceeds that are paid by any of the Defendants named in this lawsuit or (b) damages are awarded, (c) to any plaintiff in any lawsuit in *In re: National Prescription Opiate Litigation*, Cause 1:17-md-2804 (N.D. Ohio) against any of the Defendants named in this lawsuit, in which the plaintiff is an individual ERISA Plan participant or beneficiary of a Plan within Class A, then the Plan applicable to that individual plaintiff or plaintiffs has a contractual right of subrogation or lien against any such settlement proceeds or damages award, as provided under the applicable Plan documents.

741. The Fiduciary Plaintiffs and the members in Class B are entitled to equitable, injunctive, declaratory, and other relief to ensure that any proceeds that rightfully belong to the Plaintiff ERISA Plans and the members of Class A as set forth in plan documents, are paid to those Plans and not to other parties such as Plan participants, personal representatives of participants, or other persons claiming entitlement to payment of funds that rightfully belong to the Plaintiff ERISA Plans.

742. With respect to relief under ERISA, 29 U.S.C. § 1132(a)(3)(B)(ii), declaratory relief and/or other equitable relief is necessary to preserve the Plaintiff ERISA Plans' assets prior to any distribution of settlement proceeds and/or payment of damages that may be paid by any of the Defendants named herein, to, or on behalf of, any plan participant or beneficiary in the Plaintiff ERISA Plans or in any ERISA Plan in the Class A class. See ERISA Opinion Letter 92-24A, p.2, 11/6/1992.

743. Accordingly, the Fiduciary Plaintiffs seek injunctive and other appropriate equitable relief, individually and on behalf of Class B, under 29 U.S.C. § 1132(a)(3).

PRAYERS FOR RELIEF

744. The Plaintiff ERISA Plans, individually, and on behalf of all Class A members, respectfully request that this Court enter an order of judgment granting all relief requested in this complaint and/or allowed at law or in equity, including:

a. granting class certification at an early practicable time with respect to the claims brought by the Plaintiff ERISA Plans on behalf of Class A, ordering that same may be maintained as a class action under Fed. R. Civ. P. 23(a) and 23(b)(3); appoint the Plaintiff ERISA Plans and their counsel to represent the class; and maintain this action as a class action for purposes of notice, trial, and resolution;

b. entering judgment against Defendants and in favor of Plaintiffs and Class A;

c. awarding compensatory damages in an amount sufficient to fairly and completely compensate Plaintiffs and the Class for all damages;

d. awarding treble damages;

e. awarding equitable and injunctive relief;

f. awarding forfeiture, disgorgement, restitution and/or divestiture of proceeds and assets;

g. awarding attorneys' fees pursuant to RICO, 18 U.S.C. § 1964;

h. awarding costs and expenses of suit;

i. awarding pre- and post-judgment interest; and

j. awarding such other and further relief as this Court deems appropriate.

745. The Fiduciary Plaintiffs, individually, and on behalf of all Class B members, respectfully request that this Court enter an order of judgment granting all relief requested in this complaint, and/or allowed at law or in equity, including:

a. granting class certification at an early practicable time with respect to the claims brought by the Fiduciary Plaintiffs on behalf of Class B, ordering that same may be maintained as a class action under Fed. R.

Civ. P. 23(a) and 23(b)(2); appoint the Fiduciary Plaintiffs and their counsel to represent the class; and maintain this action as a class action for purposes of notice, trial, and resolution;

b. entering judgment against Defendants and in favor of Plaintiffs and Class B;

c. with respect to Count III (ERISA), awarding the Fiduciary Plaintiffs appropriate equitable relief under 29 U.S.C. §1132(a)(3), which includes but it not limited to, declaratory relief with respect to the Plaintiff ERISA Plans' subrogation rights which are provided by ERISA and the provisions of the ERISA Plans and/or injunctive relief with respect to Defendants' conduct which is continuing to cause improper losses to the Plans;

d. awarding attorneys' fees pursuant to ERISA, 29 U.S.C. § 1132(g)(1);

e. awarding costs and expenses of suit;

f. awarding pre- and post-judgment interest; and

g. awarding such other and further relief as this Court deems appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs, on behalf of themselves and the Proposed Classes, demand a trial by jury on all issues so triable.

Respectfully submitted,

/s/ Henry D. Hoss
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CERTIFICATE OF SERVICE

I hereby certify that on the 9th day of October, 2018, pursuant to 29 U.S.C. §1132(h), a true and correct copy of the foregoing was mailed, certified mail, return receipt requested, to the following:

The Secretary
Department of Labor
Frances Perkins Building
200 Constitution Ave., NW
Washington, DC 20210

The Secretary
Department of the Treasury
1500 Pennsylvania Avenue, NW
Washington, D.C. 20220

s/Henry D. Hoss