UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION **This document relates to:** ***Medical Mutual of Ohio v. Purdue Pharma, L.P., et al.*** **Case No. 1:18-op-45307-DAP**	**MDL No. 2804** **Master Docket No.: 1:17-MD-02804-DAP** **Hon. Judge Dan A. Polster** **JURY TRIAL DEMANDED**

FIRST AMENDED COMPLAINT

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Plaintiff MMO Medical Mutual of Ohio ("MMO") brings this First Amended Complaint against Defendants Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Inc., Cephalon, Inc., Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc., Depomed, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Mallinckrodt Plc, Mallinckrodt LLC, Allergan PLC f/k/a Actavis PLC, Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc., Watson Laboratories, Inc., Actavis, LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., and Insys Therapeutics Inc. ("Manufacturer Defendants"); AmerisourceBergen Drug Corporation, Cardinal Health, Inc., McKesson Corporation, and Miami-Luken, Inc. ("Distributor Defendants"); CVS Health, Inc., Walgreens Boots Alliance, Inc., Rite Aid Corporation, WalMart Stores, Inc., CostCo Wholesale Corporation, Linden Care LLC, Elevate Provider Network, LeaderNET, and AccessHealth ("Pharmacy Defendants"); and John Does Nos. 1-100 ("Doe Defendants") (collectively "Defendants"), alleging civil violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.*, violations of the Ohio Corrupt Practices Act ("OCPA"), Ohio Revised Code §§ 2923.31 *et seq.*, negligent misrepresentation, common law fraud, and unjust enrichment. The facts and information averred herein are based upon Plaintiff MMO's personal knowledge and beliefs and upon investigation of counsel. Plaintiff MMO alleges as follows:

I. INTRODUCTION

1. Plaintiff MMO, a third-party payer ("TPP") based in Cleveland, Ohio, paid or reimbursed all or a portion of its members' and its self-funded customers' members' cost of

prescription opioid drugs that are manufactured, marketed, sold, and/or distributed by Defendants (hereinafter "Opioid Drugs").[1]

2. As alleged herein, the Defendants took part in an aggressive nationwide campaign to fabricate an untreated "pain epidemic" which, conveniently, could be effectively treated with Opioid Drugs. In so doing, Defendants set out to deceptively convince TPPs (including MMO), physicians, and MMO members that Opioid Drugs were, *inter alia*: (i) safe and effective for the treatment of chronic, long-term pain; (ii) rarely, if ever, addictive; (iii) subject to adequate screening tools to prevent, identify, and report drug diversion; and (iv) developed with highly effective "abuse-deterrent technologies" which further minimized addiction risks.

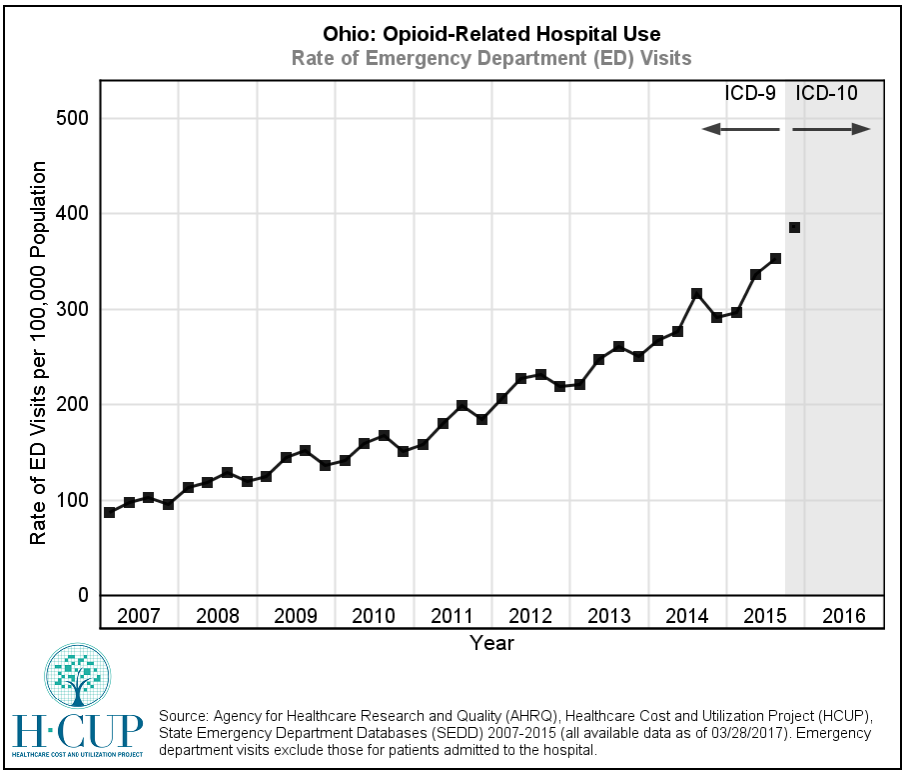
3. The Defendants' audacity cannot be overstated. Defendants even promoted—often through seemingly independent or patient-advocacy focused groups—the idea that traditional signs of physical addiction were actually "pseudoaddiction," a psychological condition effectively treated by higher doses of Opioid Drugs.

4. The result of Defendants' efforts was an opioid epidemic that has caused economic, social, and emotional damage to virtually every community in Ohio and in the United States, and that has dramatically impacted hundreds of thousands of American families. The epidemic is indiscriminate and ruthless. Its impact crosses demographic lines harming every economic class, race, gender and age group. It is killing Americans—almost 100 every day. Prescription and illegal opioids account for more than 60% of overdose deaths in the United States, a toll that has quadrupled over the past two decades, according to the United States

[1] "Opioid Drugs," as defined herein, include OxyContin, OxyContin ADF, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, Targiniq ER, Fentora, Actiq, Duragesic, Nucynta, Nucynta ER, Lazanda, Ultracet, Ultram, Opana, Opana ER, Percocet, Endocet, Percodan, Zydone, Kadian, Norco, Subsys, Roxicodone, Exalgo, Xartemis XR, and generic versions of oxycodone, oxymorphone, hydromorphone, hydrocodone, and fentanyl transdermal systems.

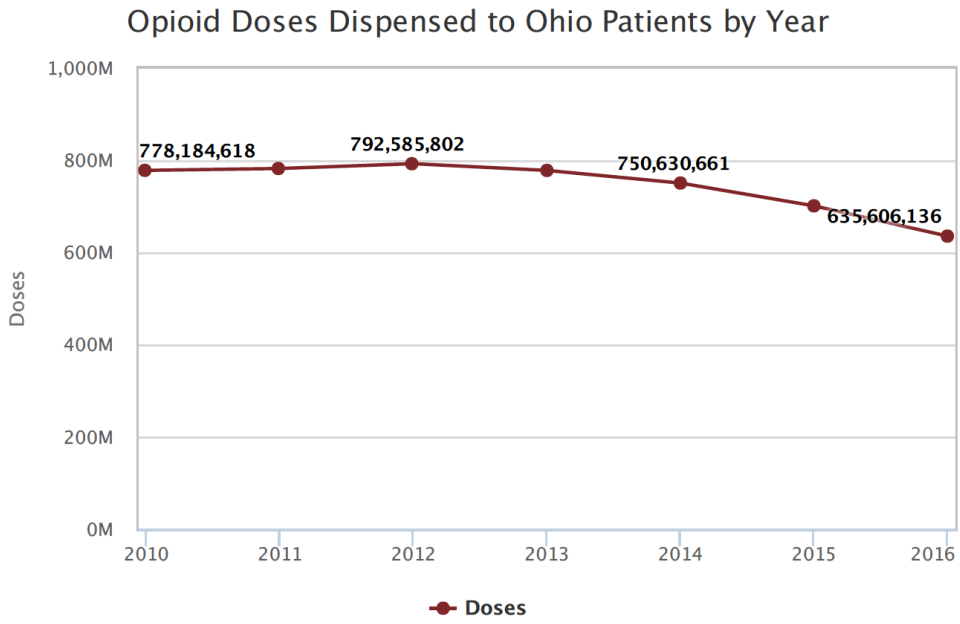
Centers for Disease Control ("CDC"). Drug overdose deaths in 2015 far outnumbered deaths from automobile accidents or guns.

5. Ohio has been especially ravaged by the national opioid crisis. Ohio has an opioid prescription rate of 100.1 per 100 persons, which ranks 12th in the country (U.S. median rate: 82.5) and a benzodiazepine prescription rate of 41.3 per 100 persons, which ranks 20th nationally (U.S. median rate: 37.6).[2] Data maintained by the Agency for Healthcare Research and Quality for 2007 through 2016 document a sharp increase in opioid-related inpatient hospital stays in Ohio. The annual rate of such stays per 100,000 population has continued to increase:



[2] *See* Leonard J. Paulozzi, M.D., et al., *Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines – United States, 2012*, MORBIDITY AND MORTALITY WEEKLY REPORT, CENTERS FOR DISEASE CONTROL (July 1, 2014), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a2.htm. Oxycodone, benzodiazepines, and carisoprodol are referred to as the "holy trinity" and significantly increase the risk of harm to those that abuse prescription pills. *The Perfect Storm: Opioid Risks and 'The Holy Trinity,'* PHARMACY TIMES, (Sept. 24, 2014), http://www.pharmacytimes.com/contributor/jeffrey-fudin/2014/09/the-perfect-storm-opioid-risks-and-the-holy-trinity.

6. The rate of opioid-related emergency department visits increased 106% in Ohio between 2009 and 2014.[3] Ohio has been literally inundated with hundreds of millions of opioid doses. Between 2010 and 2016, there have been between 778 million and 635 million opioid doses per year dispensed in Ohio:[4]



7. The opioid epidemic has ravaged a number of Ohio cities and counties. From 2010 through 2015, the wholesale distributors sold more than 290,000,000 opioids in Hamilton County alone.[5] Cincinnati averages four drug overdoses a day, and in August 2016, it experienced 174 heroin overdoses over a span of six days.[6] In September 2017, The Cincinnati

[3] Audrey J. Weiss, Ph.D., et al., *Healthcare Cost and Utilization Project, Statistical Brief #219, Opioid-Related Inpatient Stays and Emergency Department Visits by State, 2009-2014*, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (December 2016 (Revised January 2017), https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.pdf.

[4] 2016 Ohio Automated Rx Reporting System ("OARRS"), *available at* https://www.ohiopmp.gov/State.aspx.

[5] OARRS, *County Quarterly Data*, https://www.ohiopmp.gov /Reports.aspx, (last visited August 2, 2017).

[6] Katie Mettler, *'This is unprecedented': 174 heroin overdoses in 6 days in Cincinnati*, WASHINGTON POST, (August 29, 2016), https://www.washingtonpost.com/news/morning-mix/wp/2016/08/29/this-is-unprecedented-174-heroin-overdoses-in-6-days-in-cincinnati/?utm_term=.ea35e620cfb1.

Enquirer released a report chronicling the impact of the opioid epidemic in the Cincinnati area.[7] In a single week in July 2017, the Cincinnati area experienced 18 deaths, at least 180 documented overdoses, more than 200 heroin users in jail, and 15 babies born with heroin related medical problems. This devastating week is just a sampling of the ongoing effects wrought on Ohio communities because of the continuing opioid epidemic. Between 2011 and 2016, for example, Cuyahoga County experienced an unintentional drug overdose rate of 23.4 per 100,000 population.[8] Cuyahoga Country experienced a record number of 666 overdose deaths in 2016, some 399 of which directly related to opioids.[9] 2017 deaths in Cuyahoga County were expected to increase 25% to as many as 850.[10] And the problem is "'not getting better" according to County Medical Examiner Thomas Gilson.[11] "And from our discussions with other coroners across the state, it's not getting better in their communities either."[12]

8. Each Defendant group has profited enormously from the Opioid Drugs (too often into the black market) at the expense of TPPs (including MMO), consumers, and communities across Ohio and nationwide. Each acted in its self-interest to move certain drugs over others, to ignore their statutory duties to prevent drug diversion, and to actively conceal from the public the growing evidence of opioid abuse and diversion. And each Defendant bears culpability in the

[7] *Seven Days of Heroin: This is What an Epidemic Looks Like*, CINCINNATI ENQUIRER, (Sept. 10, 2017), *available at* http://www.cincinnati.com/pages/interactives/seven-days-of-heroin-epidemic-cincinnati/.

[8] *2015 Ohio Drug Overdose Data: General Findings*, OHIO DEP'T OF HEALTH, 10-11, *available at* https://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/2015-Overdose-Data/2015-Ohio-Drug-Overdose-Data-Report-FINAL.pdf (last visited March 26, 2018) (18.6 for Ohio Total compared to 35.2 for Clermont).

[9] David Petkiewicz, *Heroin and Fentanyl Killed More People in Cuyahoga County in 2016 than Homicides, Suicides and Car Crashes*, CLEVELAND.COM (May 24, 2017), http://www.cleveland.com/metro/index.ssf/2017/05/heroin_and_fentanyl_killed_mor.html.

[10] Brie Zeltner, *Cuyahoga County Overdose Deaths Predicted to Jump 25 percent in 2017, Could be as High as 850 Deaths*, CLEVELAND PLAIN DEALER, (Nov. 30, 2017), http://www.cleveland.com/healthfit/index.ssf/2017/11/cuyahoga_county_overdose_death.html.

[11] *Id.*

[12] *Id.*

crisis and is a necessary party to addressing the damage it has wreaked, including the costs of abatement of the nuisances they have caused.

9. Given the mechanics of prescription drug reimbursement, Plaintiff MMO and other TPPs are co-payers with their patient members, and as such, are the entities that are most harmed financially by Defendants' fraudulent schemes. As alleged below, Plaintiff MMO and other TPPs were intended targets of Defendants' unlawful strategies, which successfully resulted in excessive and unsafe prescriptions for the Opioid Drugs – the cost of which was paid for by MMO and other TPPs – and gave rise to the direct economic claims set forth herein.

II. PARTIES

A. Plaintiff MMO

10. Plaintiff MMO MEDICAL MUTUAL OF OHIO brings these claims of itself and its subsidiaries, and its self-funded customers. MMO is a not-for-profit mutual insurance company organized under Ohio law with its principal place of business in Cleveland, Ohio. The oldest health care plan in Ohio, MMO provides individual and group health benefits, Medicare supplemental insurance, and other ancillary products, such as vision, dental, and prescription drug coverage. Through its wholly-owned subsidiary Medical Mutual Services, L.L.C. ("MMS"), including Mutual Health Services, the specialty third party administrator division of MMS, MMO also offers administrative services contracts to self-insured groups.

11. At all times material hereto, MMO reimbursed for the Opioid Drugs. Based on preliminary data, MMO has paid for hundreds of thousands of its members' Opioid Drug prescriptions, including payments in all fifty states. MMO paid $108,166,762 for the Manufacturer Defendants' Opioid Drugs since January of 2003, in the following amounts:

- AK $306.99
- AL $82,187.21

- AR $9,240.40
- AZ $135,334.73
- CA $204,700.90
- CO $44,311.49
- CT $7,125.91
- DC $1,549.71
- DE $5,392.30
- FL $686,041.51
- GA $1,214,157.65
- HI $81.85
- IA $18,264.17
- ID $12,445.16
- IL $64,687.54
- IN $1,761,416.09
- KS $12,064.25
- KY $391,491.45
- LA $17,011.54
- MA $7,607.62
- MD $123,124.99
- ME $1,336.27
- MI $568,410.66
- MN $14,055.10
- MO $14,570.62
- MS $8,718.86
- MT $2,884.51
- NC $179,352.15
- ND $6.95
- NE $625.34
- NH $5,062.34
- NJ $346,976.03
- NM $6,589.64
- NV $41,089.98
- NY $637,178.98
- OH $98,750,446.13
- OK $37,304.16
- OR $23,896.44
- PA $670,512.58
- RI $504.93
- SC $927,454.31
- SD $20,345.51
- TN $148,341.89
- TX $90,203.39
- UT $10,615.18
- VA $356,871.68

- VT $371.95
- WA $11,400.45
- WI $16,411.08
- WV $476,489.16
- WY $192.77

12. MMO sustained injury when it purchased, paid for, and/or provided reimbursement for the Opioid Drugs and related medical services (such as addiction treatment costs and opioid induced side effect costs) during the relevant period in the aforementioned states and, therefore, paid more than it would have absent the Defendants' unlawful conduct. As a result of Defendants' concerted conduct, the Opioid Drugs were excessively prescribed, often for uses that were neither safe nor effective or for prescriptions that were known by Defendants to be diverted to the black market.

13. At all times material hereto, each of the Defendants was well aware of the limitations faced by Plaintiff MMO in its ability to control unsafe and unapproved usage of the Opioid Drugs. As a result of Defendants' misrepresentation and concealment of the true safety and efficacy profiles of the Opioid Drugs, Plaintiff MMO was denied the opportunity to make fully informed decisions about whether (and how) to include Opioid Drugs on its formularies and/or paid for far more Opioid Drug prescriptions than it otherwise would have paid absent Defendants' fraudulent and illegal Opioid Drug schemes. Plaintiff MMO has been injured to the extent that it has paid for inappropriate and unsafe use of Opioids.

14. Due to Defendants' illegal enterprises set forth in detail below, a flurry of fraudulent Opioid Drug prescribing activity resulted, which continues to this day. Plaintiff MMO, as a direct and foreseeable result of each Defendant's fraudulent scheme, has been forced and will continue to be forced to reimburse many thousands of Opioid Drug prescriptions even though it has only recently become apparent that, for the vast majority of Opioid Drug patients,

no prescriptions should have or would have been written absent Defendants' unfair conduct and illegal enterprises. In addition to the personal injuries, deaths, and other adverse events associated with Opioid Drug use, which have had serious implications on the health of Americans, the financial impact of each Defendant's false and deceptive conduct has likewise been profound, especially for Plaintiff MMO, which bears the ultimate cost of Opioid Drug prescriptions. As has only recently become clear, Plaintiff MMO was a primary financial victim of Defendants' false and misleading schemes, having been duped by each Defendant into paying millions of dollars for unapproved, ineffective, and unsafe Opioid Drug prescriptions.

15. Each Defendant knew that Plaintiff MMO would reimburse for on-formulary prescriptions of the Opioid Drugs, even if the drugs were being prescribed as a result of their respective covert, systematic, and illegal schemes. Each Defendant knew that Plaintiff MMO bore the financial brunt of Defendants' unlawful Enterprises and activities and as a result, expended huge sums of money related to Defendants' Opioid Drugs.

B. Manufacturer Defendants

16. Defendant PURDUE PHARMA L.P. is a Delaware limited partnership with its principal place of business in Stamford, Connecticut; Defendant PURDUE PHARMA, INC. is a New York corporation with its principal place of business in Stamford, Connecticut and is the general partner of Purdue Pharma L.P.; and Defendant THE PURDUE FREDERICK COMPANY, INC. is a Delaware corporation with its principal place of business in Stamford, Connecticut. The Purdue defendants are collectively referred to herein as "Purdue."

17. Purdue is primarily engaged in the manufacture, promotion, sale, and distribution of opioids, including OxyContin, its largest selling opioid, throughout the nation (including Ohio). Other opioids manufactured, promoted, sold, and distributed by Purdue include MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER. As Purdue developed

OxyContin in the mid-1990s, Purdue, together with other Defendants, promoted prescription opioids by propagating the message both in Ohio and nationwide that chronic pain was undertreated and that its Opioid Drugs were a safe, effective, and generally non-addictive treatment for its long-term management of chronic pain.

18. Since 2009, Purdue's national annual sales have fluctuated between $2.47 billion and $2.99 billion and are primarily derived from OxyContin. Purdue has generated an estimated $35 billion in sales since it launched OxyContin in 1995. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

19. In 2007, Purdue agreed to pay the federal government $635 million, settling criminal and civil charges alleging the misbranding of OxyContin.

20. Defendant TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania, and is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli company.

21. Defendant CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Defendant Cephalon, Inc. through Teva USA. The Teva corporations work closely with Cephalon, Inc., and control and direct Cephalon's business practices. The Teva defendants and Cephalon are collectively referred to herein as "Cephalon."

22. Cephalon is in the business of manufacturing, promoting, selling, and distributing pharmaceutical drugs, including opioids Actiq and Fentora, in Ohio and throughout the nation. In November 1998, the FDA granted restricted marketing approval for Actiq, limiting its lawful marketing to cancer patients experiencing pain "with malignancies who had developed a

tolerance to less dangerous therapies." The FDA specified that Actiq should not be marketed for off-label uses, stating that the drug "must not be used in opioid non-tolerant patients" and must be prescribed solely to cancer patients by oncologists and pain specialists specifically trained in the use of Schedule II opioids to treat pain in cancer patients. In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs for misbranding and agreed to pay $425 million. Cephalon also entered into a five-year Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services.

23. Defendant JOHNSON & JOHNSON is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

24. Defendant JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly-owned subsidiary of Johnson & Johnson. Johnson & Johnson and Janssen Pharmaceuticals, Inc. are collectively referred to herein as "Janssen."

25. Janssen manufactures, promotes, sells, and distributes a range of medical devices and pharmaceutical drugs in Ohio and throughout the nation, including the opioids Duragesic, Nucynta, Nucynta ER, Ultracet, and Ultram. Prior to 2009, Duragesic accounted for more than $1 billion in annual sales. Prior to January 2015, Nucynta and Nucynta ER accounted for over $170 million in sales.

26. Defendant DEPOMED, INC. ("Depomed") is a California corporation with its principal place of business in Newark, California. Depomed describes itself as a specialty pharmaceutical company focused on pain and other central nervous system conditions. Depomed develops, markets, and sells prescription drugs in Ohio and nationally. Depomed acquired the

rights to Nucynta and Nucynta ER for $1.05 billion from Janssen pursuant to a January 15, 2015 Asset Purchase Agreement. This agreement closed on April 2, 2015.

27. Defendant ENDO HEALTH SOLUTIONS, INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania; Defendant ENDO PHARMACEUTICALS, INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania, and is a wholly-owned subsidiary of Endo Health Solutions, Inc. The Endo defendants are collectively referred to herein as "Endo."

28. Endo manufactures, promotes, sells, and distributes prescription drugs, including opioids Opana, Opana ER, Percocet, Endocet, Percodan and Zydone, in Ohio and throughout the nation. These opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana yielded revenue of $1.16 billion between 2008 and 2012, and alone accounted for 10% of Endo's total 2012 revenue.

29. Endo also manufactures and sells generic opioid products (including oxycodone, oxymorphone, hydromorphone, and hydrocodone) in Ohio and across the United States, both for itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

30. Defendant ALLERGAN PLC (formerly known as Actavis plc) is an Irish company with its headquarters and principal place of business in Dublin, Ireland.

31. 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.

32. Defendant ACTAVIS PHARMA, INC. (formerly known as Watson Pharma, Inc.) is a Delaware corporation with its principal place of business in New Jersey; Defendant ACTAVIS, LLC, is a Delaware limited liability company with its principal place of business in

Parsippany, New Jersey. Each of these defendants is owned by Allergan plc, which uses them to market and sell its drugs in Ohio and nationwide. Allergan plc, Watson Laboratories, Inc., Actavis Pharma, Inc., and Actavis LLC are collectively referred to herein as "Actavis."

33. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco (a generic version of Kadian), Opana ER, and generic versions of Duragesic and Opana, throughout the United States, including Ohio. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

34. Defendant INSYS THERAPEUTICS, INC. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona. Since 2012, Insys has been manufacturing and selling Subsys, a spray form of fentanyl, in Ohio and across the United States.

35. Subsys is a highly addictive mouth spray approved for use in cancer patients who are tolerant of other opioids. In 2016, Subsys had a 42% market share of transmucosal immediate-release fentanyl, which generated $300 million in annual U.S. sales for the company. Only 1% of Subsys sales have been generated by oncologists.

36. Defendant MALLINCKRODT PLC is an Irish public limited company with its principal place of business in Staines-upon-Thames, United Kingdom; Defendant MALLINCKRODT LLC is a Delaware limited liability company with its principal place of business in St. Louis, Missouri, and is a wholly-owned subsidiary of Mallinckrodt plc. The Mallinckrodt defendants are collectively referred to herein as "Mallinckrodt."

37. 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.

38. In Ohio and nationwide, Mallinckrodt is engaged in the manufacture, promotion, distribution, and sale of opioids such as Roxicodone, Exalgo, Xartemis XR, as well as oxycodone and other generic opioids.

39. The manufacturer defendants listed above are all engaged in the manufacturing of opioids. The manufacturer defendants listed above are collectively referred to herein as the "Manufacturer Defendants."

40. The Manufacturer Defendants engaged in widespread conduct aimed at vastly increasing profits resulting from the sale of Opioid Drugs by increasing prescriber demand, increasing patient demand, facilitating insurance coverage, and nurturing the thriving black market for Opioid Drugs by concealing evidence of drug diversion.

41. This conduct was inter-related by purpose. For example, increasing TPP formulary coverage was necessary to allow prescribers to write more prescriptions in response to patient demand. Again, by example, TPP formulary coverage, prescriber demand, and consumer demand all depended on the vast dissemination of fraudulent information regarding the safety and efficacy of Opioid Drugs.

42. The unscrupulous strategies employed by the Manufacturer Defendants to obtain insurance coverage for long-term opioid use, along with their aggressive and misleading marketing to prescribers and consumers, development of fake scientific substantiation and literature, and failure to prevent, monitor, identify, and report drug diversion, all contributed to a vast increase in opioid overuse and addiction. The Manufacturer Defendants' conduct thus directly caused a public health crisis, increasing costs for excessive prescribing and addiction-related treatment costs for MMO.

C. Distributor Defendants

43. Defendant AMERISOURCEBERGEN CORPORATION ("Amerisource") is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. Amerisource is also one of the largest distributors of the Opioid Drugs in the United States, including Ohio. At all times material hereto Amerisource has owned Defendant ELEVATE PROVIDER NETWORK and its associated Good Neighbor Network (together herein "Elevate"), one of the largest pharmacy administrative services organizations in the United States, including in Ohio. Elevate is incorporated in Delaware and its principal place of business in Chesterbrook, Pennyslvania.

44. Defendant CARDINAL HEALTH, INC. ("Cardinal") is an Ohio corporation with its principal place of business in Dublin, Ohio. Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including Ohio. Cardinal is also one of the largest distributors of the Opioid Drugs in the United States, including in Ohio. At all times material hereto, Cardinal has owned Defendant CARDINAL LEADERNET, one of the largest pharmacy administrative services organizations in the United States, including in Ohio. Cardinal LeaderNET is incorporated in Ohio and its principal place of business in Dublin, Ohio.

45. Defendant McKESSON CORPORATION ("McKesson") is a Delaware corporation with its principal place of business in San Francisco, California. McKesson distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including Ohio. McKesson is also one of the largest distributors of the Opioid Drugs in the United States, including Ohio. At all times material hereto, Cardinal has owned Defendant ACCESSHEALTH, one of the largest pharmacy administrative services organizations in the

United States, including in Ohio. AccessHealth is incorporated in Delaware, and its principal place of business in New Albany, Ohio.

46. Defendant MIAMI-LUKEN, INC. ("Miami-Luken") is a corporation organized and existing under the laws of the State of Ohio with its principal place of business located in Springboro, Ohio. During all relevant times, Miami-Luken has distributed substantial amounts of prescription opioids to providers and retailers in Ohio. Miami-Luken has engaged in consensual commercial dealings with Ohio and its citizens and has purposefully availed itself of the advantages of conducting business with and within Ohio.

47. The distributor defendants listed above are all engaged in the wholesale distribution of the Opioid Drugs. The distributor defendants listed above are collectively referred to herein as the "Distributor Defendants."

48. The Distributor Defendants' role in facilitating access to Opioid Drugs for long-term use—coupled with their failure to prevent, monitor, identify, and report drug diversion—contributed to a vast increase in opioid overuse and addiction, as well as an increase in costs to TPPs, including MMO. The Distributor Defendants' conduct thus directly caused a public health crisis, increasing costs for excessive prescribing and addiction-related treatment costs for MMO.

D. Pharmacy Defendants

49. Defendant CVS HEALTH CORPORATION ("CVS") is a Delaware corporation with its principal place of business in Woonsocket, Rhode Island. During all relevant times, CVS has sold and continues to sell, in Ohio and nationwide, prescription opioids including the Opioid Drugs at issue in this lawsuit.

50. Defendant WALGREENS BOOTS ALLIANCE, INC. ("Walgreens") is a Delaware corporation with its principal place of business in Deerfield, Illinois. During all

relevant times, Walgreens has sold and continues to sell, in Ohio and nationwide, prescription opioids including the Opioid Drugs at issue in this lawsuit.

51. Defendant RITE AID CORPORATION ("Rite Aid") is a Delaware corporation with its principal place of business in Camp Hill, Pennsylvania. During all relevant times, Rite Aid has sold and continues to sell, in Ohio and nationwide, prescription opioids including the Opioid Drugs at issue in this lawsuit.

52. Defendant COSTCO WHOLESALE CORPORATION ("Costco") is a Washington corporation with its principal place of business in Issaqua, Washington. During all relevant times, Costco has sold and continues to sell, in Ohio and nationwide, prescription opioids including the Opioid Drugs at issue in this lawsuit.

53. Defendant WALMART STORES, INC. ("WalMart") is a Delaware corporation with its principal place of business in Bentonville, Arkansas. During all relevant times, WalMart has sold and continues to sell, in Ohio and nationwide, prescription opioids drugs including the Opioid Drugs at issue in this lawsuit.

54. LINDEN CARE, LLC ("Linden Care") is a foreign limited liability company licensed in Ohio as an out-of-state pharmacy. Linden Care's principal place of business and corporate headquarters is located in Woodbury, New York. At all relevant times, Linden Care served as a concierge pharmacy service specializing in filling, dispensing, and shipping pain medications, including the Opioid Drugs at issue in this lawsuit, throughout the United States, including Ohio, using commercial shipping services. During the relevant time period, Linden Care was reportedly the leading pharmacy dispenser of fentanyl spray. Linden Care does not have physical retail pharmacies in Ohio. Instead, it dispensed and shipped fentanyl spray and other Opioid Drugs to patients throughout the United States, and in Ohio, by Federal Express.

At all times material hereto, Linden Care solicited and received profits from Ohio prescriptions for fentanyl spray and Opioid Drugs.

55. The pharmacy defendants listed above are all engaged in the business of retail selling of opioids. The pharmacy defendants are collectively referred to herein as the "Pharmacy Defendants."

56. The Pharmacy Defendants all participate in MMO's pharmacy network established by its pharmacy benefit manager ("PBM"), Express Scripts, Inc. ("ESI"), through its Provider Agreements and Provider Manual ("the Agreements"). Under the Agreements, the Pharmacy Defendants agreed to fill prescriptions for health plan members (*i.e.*, to MMO's members and the members of ESI's other health plan customers). In exchange, the Pharmacy Defendants get a number of benefits, including access to ESI's client health plan members (like MMO's members) as customers, payment within specified times, dispensing fees, marketing and advertising, as well as on-line determination of member eligibility.

57. The Pharmacy Defendants participating in the MMO pharmacy network in turn agreed to comply with the terms of the Agreements, including requirements that all information submitted to ESI to be accurate and complete and prohibitions against "knowingly making a false claim." The Agreements required the Pharmacy Defendants to identify "fraudulent prescription drug claims or any information in support thereof" and stated the Agreements were terminable if the retail pharmacy is in "violation of any applicable law, rule and/or regulation."

58. The Pharmacy Defendants' role in facilitating access to formulary drugs for long-term opioid use—coupled with their failure to abide by their legal obligation to prevent, monitor, identify, and report drug diversion—all contributed to a vast increase in opioid overuse and addiction, as well as an increase in TPP costs including to MMO. The Pharmacy Defendants'

conduct thus directly caused a public health crisis, increasing costs for excessive prescribing and addiction-related treatment costs for MMO.

59. The Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants are collectively referred to herein as "Defendants."

E. Doe Defendants

60. The true names and capacities, whether individual, corporate, associate, or otherwise of certain vendors, distributors and/or their alter egos, sued herein as DOES 1 through 100 inclusive, are presently unknown to Plaintiff MMO, who therefore sues these Defendants by fictitious names. Plaintiff MMO will seek leave of this Court to amend the First Amended First Amended Complaint to show their true names and capacities when they have been ascertained. Each of the Doe Defendants has taken part in and participated with, and/or aided and abetted, some or all of the other Defendants in some or all of the matters referred to herein, and is therefore liable for same.

III. JURISDICTION AND VENUE

61. This Court has subject matter jurisdiction over all of the claims of Plaintiff MMO pursuant to 28 U.S.C. § 1331, because the claims in this action arise under the laws of the United States; pursuant to 18 U.S.C. § 1964, because this Court has jurisdiction to prevent, remedy, and restrain violations of RICO 18 U.S.C. § 1962; and pursuant to 28 U.S.C. § 1367(a), because this Court has supplemental jurisdiction over all non-federal claims in this action that form part of the same case or controversy as those within the Court's original jurisdiction.

62. This Court has personal jurisdiction over Defendants as they engaged in substantial business activities in Ohio, purposefully directed their wrongful actions toward Ohio, and have the requisite minimum contacts with Ohio. All Defendants received substantial compensation from the sale of the Opioid Drugs in Ohio and this District.

63. Venue is proper in this District under 28 U.S.C. § 1391, because all Defendants engaged in substantial conduct relevant to Plaintiff MMO's claims within this District, and all Defendants have caused harm to Plaintiff MMO in this District. Venue is also proper in this District under 18 U.S.C. § 1965(a), which provides that "[a]ny civil action or proceeding under this chapter against any person may be instituted in the district court of the United States for any district in which such person resides, is found, has an agent, or transacts his affairs."

IV. FACTUAL ALLEGATIONS

A. Background on Opioid Drugs

64. The Food and Drug Administration's ("FDA's") website describes opioids as follows: "Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, they can cause serious harm, including addiction, overdose and death."

65. The term "opioid" includes (a) all drugs derived in whole or in part from the morphine-containing opium poppy plant such as morphine, laudanum, codeine, thebaine, hydrocodone oxycodone and oxymorphone, and (b) synthetic opioids like fentanyl or methadone.

66. Heroin, a semi-synthetic opioid based on the structure of morphine, began being manufactured in 1914. By the 1920s, physicians were aware of the highly addictive nature of opioids and tried to avoid treating patients with them. Heroin was illegal by 1924.

67. The Opioid Drugs manufactured by Defendants are all semi-synthetic or fully synthetic opioids designed and regularly modified in labs. The semi-synthetic versions are common opioids including: OxyContin, Dilaudid, Opana, and Percocet. Janssen and Cephalon

manufacture fully synthetic opioids as variations on Fentanyl. Fentanyl, a totally synthetic and highly potent opiate acting drug, was synthesized by Dr. Paul Janssen in Belgium in 1960.

68. All opioids, semi-synthetic, and synthetic opioids react in the human body in the same way; they are agonists that bind with opioid receptors in the brain, ultimately numbing pain reception and encouraging the release of dopamine, which can result in a euphoric feeling.

69. Over time, the effects of the opioids are dulled due to overexposure. This results in a decrease in the release of dopamine and further induces cravings for the drugs.

70. Prior to the 1990s, HCPs used opioid pain relievers sparingly and only in the short term, for cases of acute injury or illness, during surgery, or for end-of-life ("palliative") care.[13] HCPs' reluctance to use opioids for an extended period of time was due to the legitimate fear of causing addiction.[14]

B. Defendants Engineered the Expansion of the Prescription Market for Opioid Drugs

71. Defendants disregarded and actively sought to destroy this widely regarded medical orthodoxy in order to increase the number of patients treated with Opioid Dugs. In so doing, they massively bolstered their profits while unleashing one of the greatest medical crises in modern history.

72. Beginning in the late 20th century, and continuing through today, the pharmaceutical industry acted to dramatically expand the prescription marketplace for opioids. As set forth below, pharmaceutical actors facilitated this expansion in a number of ways.

73. Pharmaceutical manufacturers, including Manufacturer Defendants, targeted HCPs and the general public with a coordinated (and often clandestine) misinformation

[13] Meldrum ML, *Progress in Pain Research and Management*, Vol. 25 Seattle, WA: IASP Press; 2003.

[14] *Id.*

campaign to alter perceptions about the safe and effective use of Opioid Drugs. The Manufacturer Defendants' goal was simple: to create a medical demand for Opioid Drugs that did not currently exist in the market. The goal was to change perceptions of the class of Opioid Drugs, over and above touting the virtues of a particular drug.

74. Each Defendant has been engaged in a fraudulent and illegal scheme to cause increased prescribing and reimbursement for their Opioid Drugs. As the entities directly reimbursing most, if not all, of the cost of Opioid Drug prescriptions, Plaintiff MMO and other TPPs were intended victims of these fraudulent schemes. Defendants' respective schemes targeted and defrauded Plaintiff MMO and TPPs on a massive scale.

75. The misrepresentations and omissions key to expanding the prescription market for Opioid Drugs all focused on the necessity, efficacy and risks associated with long-term use for the treatment of chronic pain. The Manufacturer Defendants and their allies (co-promoters, third-party marketers and promoters, physician thought leaders, key opinion leaders ("KOLs"), medical ghost writers, medical marketing firms, digital marketers, and Front Groups) invented an "untreated pain epidemic" requiring urgent attention from not only the medical community, but from patients who had decided to live with some chronic pain. Luckily, an uninterrupted life-long regimen of Opioid Drugs was the perfect solution to the nation's chronic pain woes. And finally, the Manufacturer Defendants promulgated the fraudulent messaging that concerns about addiction were overblown: simple screening and monitoring tools would prevent addiction, which incidentally was all the more unlikely due to incredible advancements in abuse-deterrent pill technology. Even if a patient exhibited all the classic symptoms of addiction, those were merely signs that his or her pain was undertreated: the solution was more Opioid Drugs, often ending in an uninterrupted life-long regimen.

76. To disseminate this wildly inaccurate message and grow the prescription market for Opioid Drugs, the Manufacturer Defendants and their allies employed a coordinated and multi-faceted marketing campaign, utilizing different tools and aimed at different targets.

77. First, prescribing physicians were targeted with these deceptive messages. The messages originated from a variety of sources. Some could recognize as originating from the Manufacturer Defendants, such as sales representative pitches, medical journal advertising, and manufacturer websites. Other deceptive messages, however, came from peer physician experts, trade organizations, or hosts of medical education programs that seemed independent but were actually controlled by the Manufacturer Defendants. Prescribing HCPs were also enticed with financial payments or other compensation (such as free trips) as rewards for prescribing Opioid Drugs. The Physician Pull-Through Marketing Enterprises are discussed in greater detail, *infra.*

78. Second, the Manufacturer Defendants also set out to corrupt scientific literature in an effort to expand the prescription market for Opioid Drugs. They employed an endless chain of circular citations in an effort to lend veracity to their unsubstantiated claims. They helped draft guidelines and disseminate medical board standards, and then utilized their Front Group organizations to create medical consensus around those standards. They further paid physicians, Front Groups, and consultants to draft academic or technical papers lauding the safety and efficacy or Opioid Drugs in treating long-term chronic pain. These actors—all paid by the Manufacturer Defendants—often cited and relied on one another's work in an effort to create the illusion of peer review. The Scientific Literature Marketing Enterprises are discussed in greater detail, *infra.*

79. Third, the Manufacturer Defendants also targeted vulnerable consumers (those suffering with chronic pain) with false and misleading marketing to increase patient demand for

Opioid Drugs. These efforts consisted of, *inter alia*, patient brochures, patient-oriented websites, starter coupons or co-pay assistance, media campaigns and initiatives, and the use of Front Groups masquerading as patient advocacy organizations. The Consumer Pull-Through Marketing Enterprises are discussed in greater detail, *infra*.

80. Fourth, *all* Defendants worked tirelessly to manufacture, market, promote, distribute, and sell each of the Opioid Drugs. This often consisted of generating false and misleading information provided to TPPs (including MMO and/or to its contracted PBM) to determine coverage, such as drug dossiers, treatment guidelines, and scientific literature. Once the Manufacturer Defendants obtained (and/or maintained) formulary access, it was key to "pull-through" prescriptions by marketing this favorable formulary status to prescribing HCPs. This meant that the Manufacturer Defendants' sales representatives sold MMO formulary status to HCPs as part of pulling-through formulary prescriptions. To the extent that TPPs attempted to impose formulary limitations, the Manufacturer Defendants' representatives would then "teach" prescribing HCPs various techniques to secure more favorable health plan coverage on behalf of their patients. Health plan efforts to control their formularies through preferred tier placement were stymied by the Manufacturer Defendants' coupons and co-pay assistance programs. All Defendants also suppressed required reporting of adverse addiction events and instances of drug diversion, which would have otherwise influenced MMO coverage decisions. The Formulary Access and Coverage Enterprises are discussed in greater detail, *infra.*

81. The growth in the prescription market for Opioid Drugs was due to the expansion of promoted uses of Opioid Drugs; namely, for the unsafe and unapproved treatment of chronic pain. For example, according to IMS Health Data, the annual number of OxyContin prescriptions

for non-cancer pain increased nearly tenfold between 1997 and 2002, whereas OxyContin prescriptions for cancer pain increased only fourfold during this time.

82. Defendants were thus part of a scheme to dramatically increase the market for the Opioid Drugs. These efforts were wildly successful. The number of Opioid Drug prescriptions increased sharply, reaching nearly 250 million prescriptions in 2013, almost enough for every person in the United States to have a bottle of pills. This represents an increase of 300% since 1999. The scheme was so successful that by 2014 the Defendants had turned the Opioid Drugs into the *most prescribed* class of drugs in the entire nation, generating a whopping $11 billion in revenue.

C. Defendants' Schemes Expanded the Unsafe and Unapproved "Black Market" for the Opioid Drugs

83. The expansion of the prescription market was only one aspect of the Defendants' deceptive scheme to increase their financial gain. All Defendants intentionally flouted federal regulations, concealing evidence of drug diversion in a concerted effort to nurture the expansion of the market for Opioid Drugs as well.

84. Though Defendants collected information relating to suspicious prescribing and pharmacy dispensing patterns, they did not (as they were required by law) provide such information to federal or state agencies. Defendants also encouraged others involved in the scheme to conceal this information from regulatory agencies.

85. Defendants' concealment efforts were not merely aimed at the government. Rather, Defendants knew that TPPs such as MMO would re-evaluate formulary placement for Opioid Drugs if provided evidence of massive drug diversion. For sales not to plummet, it was thus critical to maintain favorable formulary access. To accomplish that, Defendants could not let TPPs like MMO know about the rampant diversion underway.

86. But Defendants did not merely conceal such data. Rather, they shared this information with one another to coordinate micro-targeting opportunities and drive higher sales. In other words, they not only identified where and how the market for Opioid Drugs flourished, but worked to help such markets thrive and expand, thus creating the engine for "black market" diversion.

87. Defendants even continued to supply Opioid Drugs to fulfill demand generated by physicians and pharmacies that their own employees had red-flagged as highly suspicious. Employees who were not "on board" with this scheme were pressured to suppress or even change their opinions.

88. Defendants were thus part of a scheme to protect and nurture the market for Opioid Drugs, which in turn would spin out of control into rampant black market diversion. The Drug Diversion Concealment Enterprises are discussed in greater detail, *infra.*

89. The black market for Opioid Drugs expanded greatly as a result of Defendants' illegal and profit-driven conduct. Much of the data regarding opioid distribution, sales, and consumption is in the hands of Defendants or others. But some publicly available data shows that Ohio as a whole, and certain parts in particular, consume a number of Opioid Drug that can be explained only by the diversion of opioids for criminal and non-medically appropriate uses.

V. THE ILLEGAL, FALSE, AND MISLEADING OPIOID DRUGS ENTERPRISES

90. Defendants engaged in a number of illegal, false, and/or misleading Opioid Drug Enterprises, which commenced at various times and continue through the present. These Enterprises involved cooperation between and among Defendants as well as between Defendants and various third parties, such as peer-influencing physicians and Front Groups.

91. Beginning when their respective Opioid Drugs came to market and continuing to the present, each Manufacturer Defendant implemented a marketing, advertising, and promotion

campaign by combining its own respective personnel and financial resources with other Manufacturer Defendants, co-promoters, peer-influencing physicians, and Front Groups through which the Manufacturer Defendants falsely and deceptively promoted the long-term use of Opioid Drugs for the treatment of chronic pain while concealing and misrepresenting the risks accompanying such treatment. These associations-in-fact created by each Manufacturer Defendant are denominated in this First Amended First Amended Complaint as the Physician Pull-Through Marketing Enterprises, Scientific Literature Marketing Enterprises, and Consumer Pull-Through Marketing Enterprises.

92. For these Enterprises to thrive, each Manufacturer Defendant and its associated participants established and carried out their respective Enterprises to accomplish the common goal of increasing the medical demand (among both prescribers and patients) for Opioid Drugs, thereby expanding the Opioid Drug prescription market to uses that were neither safe nor effective.

93. The Manufacturer Defendants' Enterprises did not develop by accident. Rather, they were the product of comprehensive marketing and business plans developed for each Opioid Drug, as well as a concerted effort to change prescriber and physician attitudes about opioids in general. The goals of these plans were simple: to attract new prescribers and increase the overall prescribing of the Manufacturer Defendants' respective Opioid Drugs.

94. Further, beginning in approximately 1996 when OxyContin came to market (for the Distributor and Pharmacy Defendants) or when their respective Opioid Drugs came to market (for the Manufacturer Defendants), each and every Defendant combined its own respective personnel and financial resources with other Defendants and third parties through which they falsely and deceptively secured TPP coverage and preferred formulary placement for the Opioid

Drugs (including on MMO formularies). Such schemes aimed at TPPs such as MMO included false and deceptive messaging regarding the necessity, safety, efficacy, and likelihood of diversion accompanying long-term Opioid Drug treatment for chronic pain. These associations-in-fact are labeled in this First Amended Complaint as the Formulary Access and Coverage Enterprises.

95. For the Formulary Access and Coverage Enterprises to succeed, each Defendant and its associated participants established and carried out its respective Enterprises to accomplish the common goal of receiving formulary access and coverage from TPPs like MMO, thereby facilitating the expansion of the Opioid Drug prescription market.

96. During the same time frame, each and every Defendant combined its own respective personnel and financial resources with other defendants and third parties through which Defendants intentionally ignored their legal obligations to identify, monitor, and report suspicious activity indicating drug diversion, and actively concealed evidence of same. These associations-in-fact are labeled in this First Amended Complaint as the Drug Diversion Concealment Enterprises.

97. For the Drug Diversion Concealment Enterprises, each Defendant and its associated participants established and carried out its respective Enterprises to accomplish the common goal of protecting the expansion of the Opioid Drug prescription market and nurturing the expansion of the Opioid Drug market.

98. The goals and implementation of these five Enterprises were intentionally complimentary and mutually reinforcing. The Defendants' respective Enterprises, individually and collectively, succeeded in distorting and polluting the discourse surrounding the Opioid Drugs to such a degree that physicians and patients were rendered incapable of making objective

and informed decisions concerning the appropriate use of Opioid Drugs. Likewise, MMO was prevented from making informed decisions on how and whether to reimburse for the costs of Opioid Drugs, and whether to continuing doing so.

99. These five Enterprises, the complete nature and extent of which have only recently been revealed to the public and MMO, are explained in greater detail, *infra*.

A. Physician Pull-Through Marketing Enterprises

100. Once the Manufacturer Defendants had gained (and/or improved) MMO formulary access for their Opioid Drugs, it was key to "pull-through" prescriptions through the Physician Pull-Through Marketing Enterprises.

101. Physicians were actively targeted with false and misleading statements regarding the safety and efficacy of utilizing Opioid Drugs for long-term, chronic pain. Increasing prescriber demand was part of Manufacturer Defendants' greater efforts to expand the prescription market for Opioid Drugs.

102. The Manufacturer Defendants devised multiple schemes to facilitate direct marketing to physicians. The marketing was aggressive, with an emphasis on in-person contact. Pharmaceutical sales representatives bombarded HCPs with messages reinforcing the necessity, safety and efficacy of Opioid Drugs for treatment long-term chronic pain. Physician-oriented advertisements appeared in trade and medical journals. Manufacturer websites included sections for prescribers.

103. Further, in order to successfully execute their Physician Pull-Through Marketing Enterprises and "pull-through" MMO formulary access, each Manufacturer Defendant had to create parallel marketing structures that appeared independent from the ordinary promotion sources. To this end, the Manufacturer Defendants surreptitiously employed KOLs—peer

physicians purportedly focused on patient health—to campaign relentlessly on behalf of the Opioid Drugs, pushing beliefs that many later recanted.

104. The Manufacturer Defendants' synchronized marketing structures also involved the creation, funding, and control of various Front Groups which purported to be medical societies, think tanks, and/or patient advocacy groups. The Manufacturer Defendants funded these groups and were responsible for the content of their messaging, yet carefully concealed their behind-the-scenes roles. Such groups were instrumental in "raising awareness" of a "pain epidemic" afflicting the United States. To combat the scourge of untreated pain, HCPs were urged to prescribe Opioid Drugs to their patients, a legitimate course of treatment that these prestigious organizations backed enthusiastically – all in the name of patient well-being.

105. The Manufacturer Defendants also funded (either directly or indirectly through their front groups and KOLs) marketing presentations that were deceptively presented as unbiased Continuing Medical Education programs ("CMEs"), a requirement for many physicians to maintain their licenses.

106. The deceptive marketing to physicians occurred not only on a macro but a micro-level as well. Physicians with certain prescribing patterns, or those with a patient base likely composed of many chronic pain sufferers, were of particular interest to the Manufacturer Defendants. Their sales representatives made such physicians the targets of even more intense marketing efforts.

107. The Manufacturer Defendants also developed and put into practice a scheme to financially reward HCPs who prescribed their Opioid Drugs. This included the development of "speaker bureaus," whereby high prescribers were paid to give presentations that were in large

part written by the manufacturers themselves. Of course, these "speakers" needed to be "trained;" and their "training" consisted of all-expenses paid trips to lavish resorts.

108. The Manufacturer Defendants' efforts to deceptively influence HCPs' prescribing decisions worked. In an August 2016 open letter to the nation's physicians, the then-U.S. Surgeon General connected the "urgent health crisis" arising from Opioid Drugs to "heavy marketing of opioids to doctors[,] [m]any of whom were taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[15]

109. The Physician Pull-Through Marketing Enterprises bombarded prescribers with various misrepresentations and omissions aimed at increasing prescriber demand for Opioid Drugs, including: (1) the existence of a "pain epidemic" and urgency with which it must be addressed; (2) the efficacy with which long-term Opioid Drug therapy treats or manages long-term chronic pain; (3) the ability of opioids to improve life functions (such as psychological health, health-related quality of life, and quality of life itself); (4) downplaying the serious risk of addiction; (5) creating and promoting the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (6) exaggerating the effectiveness of screening tools to prevent addiction; (7) claiming that opioid dependence and withdrawal are easily managed; (8) denying the risks of higher opioid dosages; (9) exaggerating the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction; and (10) actively concealing, and causing others to conceal, information about the safety (including addiction risk), efficacy, and usefulness of Opioid Drugs to treat long-term chronic pain.

[15] Letter from Vivek H. Murthy, 19th U.S. Surgeon General, to U.S. Doctors (Aug. 2016), *available at* https://turnthetiderx.org/..

110. The tools with which the Physician Pull-Through Marketing Enterprises spread these misrepresentations and omissions (or otherwise increased prescriber demand) were many, and included the use of: (1) pharmaceutical sales representatives who would "detail"[16] prescribers; (2) physician-targeted advertisements (print, video, and online); (3) peer physicians or KOLs; (4) seemingly independent front groups; (5) industry sponsored or controlled CME programs; (6) micro-targeting of physicians with certain prescribing patterns or vulnerable patient populations; and (7) financial incentives for physician to prescribe Opioid Drugs. Each of these characteristics is alleged in greater detail below.

1. False and Misleading Branded Promotion Through Pharmaceutical Sales Representatives

111. Drug companies that make, market, and distribute opioids are subject to generally applicable rules requiring truthful marketing of prescription drugs. A drug company's branded marketing, which identifies and promotes a specific drug, must: (a) be consistent with its label and supported by substantial scientific evidence, (b) not include false or misleading statements or material omissions, and (c) fairly balance the drug's benefits and risks.[17] The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of drugs for their patients.

112. Further, the Federal Food, Drug, and Cosmetic Act ("FDCA") prohibits the sale in interstate commerce of drugs that are "misbranded." A drug is "misbranded" if it lacks

[16] When a sales representative "details" a physician, he or she delivers to the physician (often during a call or in-person) the drug manufacturer's key selling messages for one or more pharmaceutical products. In most cases, the sales pitch is accompanied by written materials and/or other promotional products.

[17] 21 U.S.C. § 352(a); 21 C.F.R. §§ 1.21(a), 202.1(e)(3), 202.1(e)(6).

"adequate directions for use" or if the label is false or misleading "in any particular."[18] "Adequate directions for use" are directions "under which the layman can use a drug safely and for the purposes for which it is intended."[19] "Labeling" includes more than the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug, including promotional material.[20] The term "accompanying" is interpreted broadly to include promotional materials—posters, websites, brochures, books, and the like—disseminated by or on behalf of the manufacturer of the drug.[21] Thus, Defendants' promotional materials are part of their drugs' labels and are required to be accurate, balanced, and not misleading.

113. Labeling is misleading if it is not based on substantial evidence, if it materially misrepresents the benefits of the drug, or if it omits material information about or minimizes the frequency or severity of a product's risks. "The most serious risks set forth in a product's labeling are generally material to any presentation of efficacy." The FDA notes that "[b]ecause people expect to see risk information, there is no reason for them to imagine that the product has important risks that have been omitted . . . especially if some risks are included."[22] Promotion that fails to present the most important risks of the drug as prominently as its benefits lacks fair balance and is therefore deceptive.

114. Each Manufacturer Defendant promoted the use of Opioid Drugs for chronic pain through "detailers," who were sales representatives that visited individual physicians and their staff in their offices and small group speaker programs. By establishing close relationships with

[18] 21 U.S.C. § 352.

[19] 21 C.F.R. § 201.5.

[20] 21 U.S.C. § 321(m).

[21] *See id.*

[22] FDA, Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion, at 14 (May 2009)

HCPs, the Manufacturer Defendants' sales representatives were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate their opioids and to address individual prescribers' concerns about prescribing opioids for chronic pain. Representatives were trained on techniques to build these relationships It is also illegal for drug companies to distribute materials that exclude contrary evidence or information about the drug's safety or efficacy or present conclusions that "clearly cannot be supported by the results of the study."[23] Further, drug companies must not make comparisons between their drugs and other drugs that represent or suggest that "a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience."[24]

115. While the FDA must approve a drug's label, it is the drug company's responsibility to ensure that the material in its label is accurate and complete and is updated to reflect any new information.[25]

116. Promotional materials also must be submitted to the FDA when they are first used or disseminated. The FDA does not have to approve these materials in advance; if, upon review, the FDA determines that materials marketing a drug are misleading, it can issue an untitled letter or warning letter. The FDA uses untitled letters for violations such as overstating the effectiveness of the drug or making claims without context or balanced information. Warning

[23] 21 C.F.R. § 99.101(a)(4).

[24] 21 C.F.R. § 202.1(e)(6)(ii).

[25] *See* 21 C.F.R. § 201.56 (providing general requirements for prescription drug labeling); *see also Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that a drug company bears responsibility for the content of its drug labels at all times); 21 C.F.R. § 314.70(c)(6) (iii)(A-C) (allowing manufacturers to make changes that "strengthen . . . a warning, precaution, or adverse reaction" or "strengthen a statement about drug abuse, dependence, psychological effect, or overdosage").

letters address promotions involving safety or health risks and indicate the FDA may take further enforcement action.

117. Studies have shown that direct-to-physician visits by drug representatives are highly effective tools for increasing prescriptions for any given drug.[26] The Manufacturer Defendants used their sales representatives to detail their Opioid Drugs to HCPs throughout Ohio and the United States, including to HCPs whose patients were insureds of MMO.

118. The Manufacturer Defendants have exerted strict control over the messages their sales force would deliver to prescribers. They have exactingly directed and monitored their sales representatives—through detailed action plans, trainings, tests, verbatims, role-plays, supervisor "ride-alongs," and other means—to ensure that individual detailers actually delivered the desired messages and did not veer off-script. Sales representatives were typically obligated by their employment contracts to adhere to corporate training, and departing from the script could lead to termination of employment.

119. The Manufacturer Defendants also regularly tested the effectiveness of their messaging through third-party research firms to survey physicians to test how well their message was received by prescribers. Further, as alleged below, the Manufacturer Defendants also utilized available market data to identify particularly susceptible prescribers, so as to better focus the efforts of their sales representatives.

[26] *See, e.g.*, Puneet Manchanda & Pradeep K. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 P.K. MKTG. LETTERS 129 (2004), https://doi.org/10.1023/B:MARK.0000047389.93584.09 (detailing has a positive impact on prescriptions written); Ian Larkin, Desmond Ang, Jerry Avorn, and Aaron S. Kesslheim, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33:6 HEALTH AFFAIRS 1014 (June2014), *available at* https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2013.0939 (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); *see also* Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) AM J. PUB. HEALTH 221 (Feb. 2009) *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/ (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

120. In addition to marketing materials, sales representatives were armed with purportedly unbiased "proof" for physicians who may be wary of the sales representatives' advocacy for particular drugs or opioids in general. This "proof" came in the form of the studies, publications, and treatment guidelines that comprised the Scientific Literature Marketing Enterprises, discussed *infra*. As noted below, the true sources of this information were the Manufacturer Defendants or their KOLs or front groups.

121. In an effort to maximize their marketing potential, the Manufacturer Defendants did not limit their detailing to in-person sales details. They sought to reach additional prescribers by expanding beyond traditional sales calls and speaker events to new channels for their messages. For their sales forces, these included marketing to prescribers through voice mail, postcards, and email—so-called "e-detailing." This enabled the Manufacturer Defendants to target hard-to-reach prescribers (including those whose patients were insureds of MMO), such as those at hospitals, academic centers, or other locations that limit or prohibit in-person detailing.

(i) Purdue Sales Representatives Misrepresented the Safety and Efficacy of Its Opioid Drugs to Physicians

122. Purdue promoted its branded opioids—principally, OxyContin, Butrans, and Hysingla—and opioids generally in a campaign that consistently mischaracterized the risk of addiction and made deceptive claims about functional improvement.

123. Following its initial FDA approval, Purdue embarked on an extensive marketing campaign to grow its prescribing base, expanding its sales force to promote OxyContin to high prescribers of its predecessor drug MS Contin and to primary care specialists for chronic non-cancer pain.

124. Purdue doubled its sales force through a 1996 co-promotion agreement with Abbott Laboratories from approximately 300 to 600 representatives.[27] By 2000, Purdue increased its internal sales force to 671 representatives, who were each expected to make about 35 physician calls per week and typically called on each physician every 3 to 4 weeks.

125. Increasing the number of sales representatives, of course, expanded the number of HCPs to whom Purdue could make its false and misleading representations. In 1996, the 300-plus Purdue sales representatives had a total call list of approximately 33,400 to 44,500 physicians. By 2000, the nearly 700 representatives had a total call list of approximately 70,500 to 94,000 physicians.

126. Coming as it did at a time when many in the medical community had come to believe that it was critical that there be drugs to treat chronic pain, when it was launched in 1995, OxyContin provided the cure. The message that accompanied the OxyContin launch was the alleged inadequacy of patient pain treatment and management, and prescriptions grew exponentially. By 2001, OxyContin had become a blockbuster drug with sales exceeding $1 billion and over 7 million prescriptions, becoming Purdue's star product and accounting for 90% of the company's total prescription sales.

127. Purdue also cynically awarded its sales representatives through a lucrative bonus system that had one goal: increase sales of Opioid Drugs (particularly OxyContin). This resulted in a large number of visits by its sales representatives to physicians with high rates of opioid prescriptions, as well as a multifaceted "information" campaign aimed at high volume opioid prescribers. In 2001, in addition to the average sales representative's annual salary of $55,000, annual bonuses averaged $71,500, with a range of $15,000 to nearly $240,000. In 2001 alone,

[27] U.S. Government Accountability Office, GAO-04-110, *OxyContin Abuse and Diversion*, 17 (2003).

Purdue paid approximately $40 million in bonuses to its sales representatives. According to a 2003 government investigation, "[t]he number of total bonuses that Purdue estimated were tied to OxyContin sales increased significantly from about $1 million in 1996, when OxyContin was first marketed, to about $40 million in 2001." The corresponding growth in prescriptions for non-cancer pain outpaced the growth in prescriptions for cancer pain from 1997 to 2002.

128. Through a 1996-2002 co-promotional agreement with Purdue, Abbott was actively engaged in the promotion and distribution of opioids nationally. Under the agreement, Abbott received 25% of all net sales, up to $10 million, for prescriptions written by HCPs its sales representatives called on, and 30% of sales above $10 million. Abbott thus played an instrumental role in Purdue's marketing scheme.

129. Purdue sought out general practitioners that had little experience in treating serious pain or recognizing the signs of drug abuse. By 2003, nearly half of all OxyContin prescribers were primary care physicians who had not been adequately trained in pain management.

130. According to a 2003 U.S. Government Accountability Office report, "Purdue's sales representatives promoted OxyContin to physicians as an initial opioid treatment for moderate-to-severe pain lasting more than a few days, to be prescribed instead of other single-entity opioid analgesics or short-acting combination opioid pain relievers."[28]

131. Purdue's spending on detailing reached its nadir in 2006 and 2007, as the company faced civil and criminal charges for misbranding OxyContin. Since settling those charges in 2007, however, Purdue has sharply increased its quarterly spending on promotion

[28] U.S. Government Accountability Office, GAO-04-110, *OxyContin Abuse and Diversion*, 17 (2003).

through its sales force, from under $5 million in 2007 to more than $30 million by the end of 2014.

132. Although civil claims and criminal charges were brought against Purdue and its executives, the resulting penalties paled in comparison to extended-release oxycodone profits. In May 2007, the company and its president, chief counsel, and former chief medical officer pled guilty to falsely marketing extended-release oxycodone as "less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications."[29] As part of the plea bargain, Purdue agreed to pay the federal government $600 million and 27 states $20 million. The three executives agreed to $34.5 million in fines but avoided jail-time.[30] By contrast, Purdue has earned an estimated $31 billion in total revenues from extended-release oxycodone since its launch.[31] Rather than deterring fraudulent marketing, the penalties simply became a cost of doing business.

133. Purdue's sales representatives and advertising also misleadingly implied that OxyContin provides a full 12 hours of pain relief, and its allied Front Groups and KOLs conveyed the additional deceptive messages about opioids' safety at higher doses, the safety of alternative therapies, and the effectiveness of addiction screening tools.

134. Based on the highly coordinated and uniform nature of Purdue's marketing, Purdue conveyed these deceptive messages nationwide, including to Ohio prescribers. The materials that Purdue generated in collaboration with third parties also were distributed or made available nationwide, including in Ohio. Purdue distributed these messages, or facilitated their

[29] *See* Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. TIMES (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html [https://per ma.cc/AQS4-LW32].

[30] *See* Barry Meier, *3 Executives Spared Prison in OxyContin Case*, N.Y. TIMES (July 21, 2007), http://www.nytimes.com/2007/07/21/business/21pharma.html [https://perma.cc/5QEL- D8RA].

[31] Ryan, et al., *supra* note 40.

distribution, nationwide and in Ohio with the intent that prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

135. Like the other Defendants, Purdue directly disseminated deceptive branded and unbranded marketing focused on minimizing the risks associated with the long-term use of opioids to treat chronic pain. Purdue directed these messages to prescribers and consumers through its sales force and branded advertisements.

136. Purdue engaged in in-person marketing to doctors nationwide, and in Ohio. Until it abruptly announced on February 9, 2018 that it was terminating the promotion of OxyContin,[32] Purdue had over 250 sales representatives, of whom 150 were devoted to promoting sales of OxyContin full time. Like the other Defendants' detailers, Purdue sales representatives visited targeted physicians in Ohio and throughout the nation to deliver sales messages that were developed centrally and deployed, identically, across the country. These sales representatives were critical in delivering Purdue's marketing strategies and talking points to individual prescribers.

137. Purdue's efforts paid off, as its army of sales representatives was instrumental in expanding prescriber demand (and thus the prescription market) for OxyContin. A 2009 study noted that the nearly 10-fold increase in OxyContin prescriptions between 1997 and 2002 correlated with Purdue's doubling of its sales force and tripling its sales calls.

138. Purdue's direct marketing materials also misrepresented that opioids would help patients regain functionality and make it easier for them to conduct everyday tasks like walking, working, and exercising.

[32] Jared Hopkins, *Pain Pill Giant Purdue to Stop Promotion of Opioids to Doctors*, Bloomberg (February 9, 2018), available at https://www.bloomberg.com/news/articles/2018-02-10/pain-pill-giant-purdue-to-stop-promotion-of-opioids-to-doctors.

139. For example, in 2012, Purdue disseminated a mailer to doctors titled "Pain vignettes." These "vignettes" consisted of case studies describing patients with pain conditions that persisted over a span of several months. One such patient, "Paul," is described as a "54-year-old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work. None of these ads, however, disclosed the truth: that there is no evidence that opioids improve patients' lives and ability to function and that there was substantial evidence to the contrary.

140. In 2014 alone, Purdue spent $108 million detailing its branded Opioid Drugs to HCPs.

141. Purdue trained its sales representatives "to carry the message that the risk of addiction was 'less than one percent,'" and "[a] consistent feature in the promotion and marketing of OxyContin was a systematic effort to minimize the risk of addiction in the use of opioids for the treatment of chronic non-cancer-related pain."[33]

142. Purdue's sales representatives also made numerous misleading statements regarding its Opioid Drugs, such as their efficacy in treating long-term chronic pain, the low risk of addiction (and concept of "pseudoaddiction"), the efficacy of 12-hour dosing, and the efficacy of reformulated OxyContin's abuse deterrent technology.

143. Purdue also had sales representatives push the false idea that OxyContin provides 12 hours of pain relief, a representation it knew was false. In reality, OxyContin does not last the full 12 hours, and Purdue only sought the FDA-approved 12-hour dosing label in order to maintain a competitive advantage over more frequently dosed opioids. The dosing label is not

[33] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am. J. Pub. Health 221-27 (Feb. 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/.

equivalent to how long the drug lasts. Purdue knew that, for many patients, the pain relief lasted for as little as eight hours.

144. Though Purdue promoted OxyContin as a 12-hour extended-release opioid, 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 adapted from Purdue's own sales materials:[34]

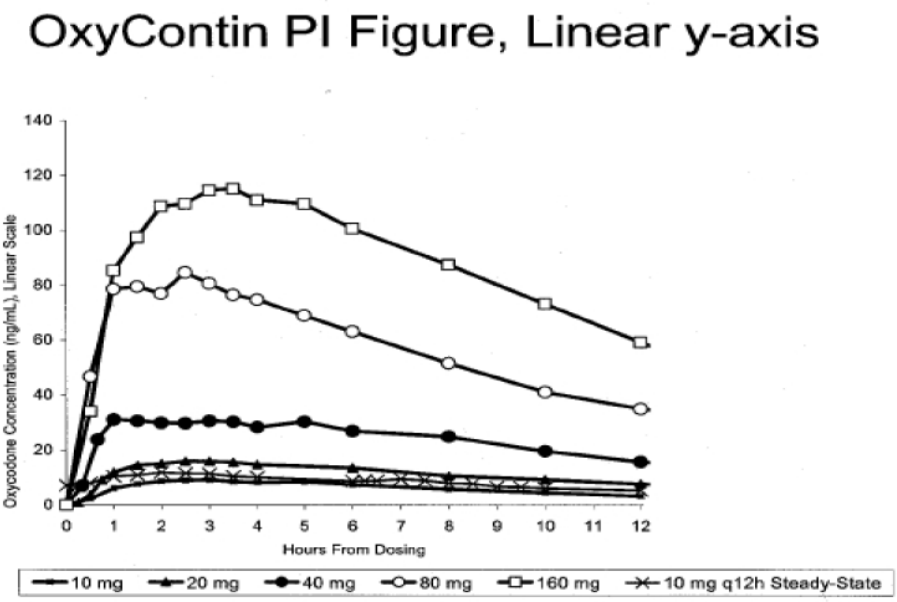


Figure 1

145. The reduced release of the drug over time means that the oxycodone no longer provides the same level of pain relief; as a result, for many patients, OxyContin does not last for the 12 hours for which Purdue promotes it—a fact that Purdue has known at all times relevant to this action.

146. The initial heightened release rate for OxyContin triggers a powerful psychological response that behaves more like an immediate release opioid, which Purdue itself

[34] Jim Edwards, *How Purdue Used Misleading Charts to Hide OxyContin's Addictive Power*, CBSNEWS.COM, (Sept. 28, 2011), https://www.cbsnews.com/news/how-purdue-used-misleading-charts-to-hide-oxycontins-addictive-power/. Purdue's promotional materials in the past displayed a logarithmic scale, which gave the misleading impression the concentration remained constant.

once claimed was more addicting in its original 1995 FDA-approved drug label. This initial release means there is less of the active drug at the end of the dosing period, which results in the drug not lasting for the full 12 hours and leading to withdrawal symptoms and "end of dose" failure. The combination of fast onset and end-of-dose failure makes OxyContin particularly addictive, even compared with other opioids.

147. In following suit with its aggressive marketing of extended-release oxycodone, Purdue made numerous problematic assertions. For example, the company heavily touted the convenience of its drug over other non-extended release opioids. As Purdue noted in its press release announcing FDA approval of extended-release oxycodone: "Unlike short-acting pain medications, which must be taken every 3 to 6 hours—often on an 'as needed' basis—OxyContin Tablets are taken every 12 hours, providing smooth and sustained pain control all day and all night. Dosing with OxyContin Tablets on a regular schedule spare patients from anxious 'clock-watching' when pain must be controlled over long periods."[35]

148. Yet Purdue was aware of the inadequacy of the twelve-hour dosing regimen for many patients. Clinical trial data and follow-up reports from patients who received the drug indicated that the drug often wore off after six to eight hours.[36] Senior management at Purdue nevertheless instructed sales representatives to press prescribers not to prescribe extended-release oxycodone at shorter intervals, fearing that the drug would lose its competitive advantage over alternative opioid medications.[37] As one sales manager commented, shorter-interval prescribing

[35] See Harriet Ryan et al., *You Want a Description of Hell?" OxyContin's 12-Hour Problem*, L.A. TIMES (May 5, 2016), available at http://www.latimes.com/projects/oxycontin-part1/ [https://per ma.cc/N26C-GKVX].

[36] *Id.*

[37] *Id.*

needed to be "nipped in the bud. NOW!!"[38] Instead, prescribers were pressured to write prescriptions for stronger doses.[39]

149. Undaunted, Purdue knowingly caused its sales representatives to falsely advertise and promote OxyContin as effective for the full 12 hours. Purdue had knowledge of the occurrence of end-dose failure from FDA's MEDWATCH Adverse Event reports[40] and was also aware that physicians would prescribe three pills a day to compensate for the loss of therapeutic effect. Purdue's failure to disclose the prevalence of end-of-dose failure left prescribing physicians in the dark and not informed of risks relating to addiction, while increasing the dose or prescribing "rescue" opioids in attempt to compensate.[41]

150. Purdue's 12-hour strategy was motivated by profit, not patient health. Purdue insisted on 12-hour rather than 8-hour FDA approval to maintain its edge on the opioid market. In order to receive FDA approval for twice-daily (or "Q2") dosing, Purdue merely had to show that OxyContin lasted for 12 hours for at least half of patients. Purdue cleared that bar with a single study. OxyContin was approved for Q2 dosing in 1996. Since then, Purdue has been using the label to assert that OxyContin provides round-the-clock relief for 12 hours. Its original press release at launch touted 12-hour dosing as providing "smooth and sustained pain control all day and all night," despite the fact that the FDA had never approved such marketing. In fact, in 2008, the FDA found that a "substantial number" of chronic pain patients taking OxyContin

[38] *Id.*

[39] *Id.*

[40] MEDWATCH refers to the FDA's voluntary adverse event reporting system.

[41] Purdue's *Clinical Issues in Opioid Prescribing*, put out in 2005 under Purdue's unbranded Partners Against Pain banner, states that "it is recommended that a supplementary immediate-release medication be provided to treat exacerbations of pain that may occur with stable dosing." References to "rescue" medication appear in publications Purdue sponsored such as APF's A Policymaker's Guide (2011) and the 2013 CME *Overview of Pain Management Options.*

experienced "end of dose failure," which meant little to no pain relief at the end of the dosing period.

151. Of course, Purdue anticipated physician feedback that for their patients, OxyContin did *not* provide 12 hours of relief. Purdue's sales representatives were instructed to tell prescribers that the answer to end-of-dose failure was not increasing the interval of dosing, but rather higher doses.

152. Purdue also instructed their sales representatives to promote a condition called "pseudoaddiction," which uncannily resembled real addiction, but, according to Purdue's representatives, was actually a sign of under-treatment of pain. "Pseudoaddiction" was invented by Dr. David Haddox, who eventually became Vice President of Health Policy at Purdue.

153. Purdue representatives proffered "pseudoaddiction" as an explanation and incentive to increase the dosage of existing Opioid Drug prescriptions. By emphasizing a new, opioid-specific condition, Defendants convinced physicians to ignore common signs of addiction, including early requests for prescription refills, agitation, etc., and to prescribe a higher dose of the opioid, which feeds the addiction cycle.

154. "Pseudoaddiction" is not a real condition. The CDC rejects the concept of "pseudoaddiction". In its 2016 *Guideline for Prescribing Opioids for Chronic Pain*, it explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment. . . are unlikely to experience pain relief with longer-term use," and treating physicians should "reassess pain and function within 1 month," which will assist them in determining whether to "minimize risks of long-term opioid use by discontinuing opioids" since the patient is "not receiving a clear benefit."[42]

[42] *CDC Guidelines for Prescribing Opioids for Chronic Pain,* CDC.GOV, https://www.cdc.gov/drugoverdose/prescribing/guideline.html (last visited Mar. 26, 2018).

155. Purdue's sales representatives also misled prescribers about the efficacy of its abuse-deterrent opioid formulation ("ADF"). In 2010 Purdue introduced "reformulated" OxyContin ("ADF OxyContin") that had a harder shell meant to make the pills more resistant to crushing. Purdue's sales representatives deceptively marketed ADF OxyContin as a solution to opioid abuse. In 2014, Purdue launched Hysingla ER, an opioid with purportedly similar abuse-deterrent properties.

156. But ADF OxyContin was no solution to opioid abuse. As noted by the FDA, "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." Further, a 2015 study showed that *one-third* of patients were able to defeat the so-called abuse-deterrent properties to inhale or inject the drug.

157. Purdue's sales representatives use these abuse-deterrent properties to distinguish their drugs from competitors. Their specific tactics include:

- claiming that Purdue's ADF opioids *prevent* tampering and could not be crushed or snorted;
- claiming that Purdue's ADF opioids *reduce* abuse and diversion;
- asserting or suggesting that Purdue's ADF opioids are "safer" than other opioids; and
- failing to disclose that Purdue's ADF opioids do not actually impact oral abuse or misuse.

158. Thus, even though Purdue faced increased competition from other Opioid Drugs, it was able to maintain and even expand its sales by convincing HCPs that ADF OxyContin was a safer option. As late as 2015, Purdue's sales representatives were telling physicians ADF OxyContin was "addiction resistant" and had "abuse-deterrent technology."

159. In an effort to substantiate its marketing claims, Purdue sales representatives discussed Treatment Guidelines (*see* Scientific Literature Marketing Enterprises, *infra*) with HCPs during individual sales visits including visits throughout the United States and Ohio.

160. The Purdue sales representatives employed various marketing techniques to detail its Opioid Drugs to HCPs. In some instances, sales representatives would visit individual HCPs and their medical staff in their offices. In other instances, sales reps would create small group speaker programs to reach more physicians.

161. Purdue sales representatives also used gifts, meals, and trips to get facetime with physicians and/or their staff. The DEA reported that Purdue's "swag" strategy was unprecedented for a Schedule II drug regulated by the Controlled Substances Act ("CSA"),[43] and included items such as OxyContin fishing hats, stuffed plush toys, and music compact discs ("Get in the Swing with OxyContin").

162. According to the *Los Angeles Times*, "[s]ales reps showered prescribers with clocks and fishing hats embossed with 'Q12h.' The company invited HCPs to dinner seminars and flew them to weekend junkets at resort hotels, where they were encouraged to prescribe OxyContin and promote it to colleagues back home."[44]

163. Purdue has been fully aware of studies proving that in-person drug detailing was the most effective marketing technique to influence prescribing habits. Despite this, the Purdue-funded the AstroTurf organization, the Center for Lawful Access and Abuse Deterrence (euphemistically called "CLADD," apparently a play on MADD, "Mothers Against Drunk Drivers"), maintains a website that states that it is a myth that "[i]ncreased access to controlled substances is directly related to… aggressive marketing tactics to prescribers by pharmaceutical sales representatives."

[43] 21 U.S.C. § 801 *et seq.*

[44] Harriet Ryan, Lisa Girion and Scott Glover, *You Want a Description of Hell? Oxycontin's 12-hour Problem*, L.A. TIMES (May 5, 2016) http://www.latimes.com/projects/oxycontin-part1/.

(ii) Cephalon Sales Representatives Misrepresented the Safety and Efficacy of Its Opioid Drugs to Physicians

164. Cephalon sales representatives' visits to non-oncologists to pitch its fentanyl drug Actiq increased six-fold between 2002 and 2005. When visiting non-oncologists, the representatives would provide up to 60 to 70 coupons, each good for six free Actiq lozenges, and encourage the prescribers to try Actiq on non-cancer patients,[45] which is off-label marketing.

165. Cephalon's efforts to increase Actiq sales in this way were highly successful. In 2000, Actiq generated $15 million in sales.[46] By 2002, Cephalon experienced a 92% increase in Actiq prescriptions and attributed it to a "dedicated sales force for ACTIQ" and "ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists."[47] Actiq only has narrow FDA approval, but by 2005 its sales had jumped to $412 million, making it Cephalon's second-best selling drug. In 2006, sales exceeded $500 million.

166. Fentora was developed as a follow-on product to Actiq – that is, as a way for Cephalon to mitigate the expected loss of revenue on Actiq due to generic competition, which entered the market in late 2006. The financial success of Actiq, which was also indicated for the treatment of breakthrough cancer pain in opioid-tolerant patients, had been predominantly driven by an unsafe and unapproved marketing campaign for use in other forms of breakthrough pain. Despite paying a significant settlement as a result of its off-label promotion of Actiq and entering a Corporate Integrity Agreement designed to prevent continued off-label promotion, the

[45] John Carreyrou, *Narcotic "Lollipop" Becomes Big Seller Despite FDA Curbs,* WALL ST. J. (Nov. 3, 2006), https://www.wsj.com/articles/SB116252463810112292.

[46] *Id*.

[47] Cephalon, Inc. Annual Report (Form 10-K), (Mar. 31, 2003),, *available at* https://www.sec.gov/Archives/edgar/data/873364/000104746908001920/a2183048z10-k.htm.

"FENTORA 2011 Brand Plan" clearly reflects that Cephalon has built on its unsafe and unapproved promotion of Actiq as the basis for its promotion of Fentora.

167. The central tactic in Cephalon's unsafe and unapproved promotional scheme for both Actiq and Fentora was, and is, to promote the drugs to pain specialists, despite the Company's knowledge that pain specialists do not treat breakthrough cancer pain. In 2007, the company conducted a market research study to determine which physicians actually treat breakthrough cancer pain.

168. In 2007, the company conducted a market research study to determine which physicians actually treat breakthrough cancer pain. That study concluded that in 90% of instances, oncologists themselves treat breakthrough cancer pain, and almost never refer patients to a pain specialist. Another study in 2009 confirmed this result. Nonetheless, despite having received repeated information confirming that pain specialists do not treat patients for Fentora's on-label use, Cephalon made pain specialists its primary target for its promotion of Fentora.

169. Cephalon targeted the same non-oncologists it had with Actiq. In a call with investors, the Cephalon CEO alleged the opportunity to use Fentora for non-cancer pain: "[t]he other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower back pain and breakthrough neuropathic pain."[48]

170. Cephalon trained its sales representatives on techniques to prompt HCPs into off-label conversations. In 2008, the FDA found that Cephalon had illegally promoted Actiq to physicians for long-term treatment of chronic pain, rather that Actiq's indicated use: to treat breakthrough pain in opioid-tolerant cancer patients who are already receiving around-the-clock opioid therapy. Cephalon, however, had been marketing Actiq for uses such as migraine

[48] Transcript of Q1 2007 Cephalon, Inc. Earnings Conference Call, 6-7(May 1, 2007), *available at* http://seekingalpha.com/article/34163-cephalon-q1-2007-earningscall-transcript?all=true&find =Q1% 2B2007%2BCephalon%2BMay%2B1%2C% 2B2007).

headaches and other non-cancer pain, such as sickle-cell pain crises, and in anticipation of changing dressings or radiation therapy.

171. For example, Cephalon instructed its sales representatives to ask non-cancer doctors whether they have the potential to treat cancer pain. Even if the doctor answered "no," a decision tree provided by Cephalon instructed the sales representatives to give these physicians free Actiq coupons to pass on to their patients.

172. Cephalon sales representatives also utilized the assistance of outside pain management specialists when visiting non-cancer physicians to pitch Actiq. For instance, a Cephalon salesperson would bring along a retained "independent" pain management specialist when making a sales call on a non-cancer physician. The "independent" pain management specialist would misrepresent to the physician that Actiq does not cause patients to experience a "high" and, unlike other narcotic painkillers, carries a low risk of diversion toward recreational use.

173. Many of these physicians who did not treat breakthrough cancer pain lack or lacked the experience with opioids intended for opioid-tolerant patients necessary to fully appreciate the dangers of Fentora as compared to other pain medications. Cephalon marketed Fentora for unapproved uses primarily through direct calls by sales representatives on these non-oncologists, while visiting oncologists — who actually see patients with breakthrough cancer pain — only approximately 20% of the time. An internal presentation to Cephalon management in 2009 documented that 44% of Fentora prescriptions were written by pain doctors, 20% by PCPs, 14% by nurse practitioners and physician's assistants, 12% by "other" HCPs, 6% by neurologists, and that oncologists accounted for only 4% of all Fentora prescriptions.

174. Cephalon used the same sales tactics, despite receiving a Warning Letter from the FDA in 2009, for its drug Fentora. The FDA alleged a Fentora internet advertisement was 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." Fentora was only approved for those that were already opioid tolerant. The FDA went on to criticize Fentora advertising because Cephalon failed to disclose the risks associated with using the drug.

175. Cephalon's strategy was to promote Fentora for the treatment of various breakthrough pain conditions, none of which was part of its approved indication. Cephalon did so not only despite the fact that Fentora is only approved for treatment of breakthrough cancer pain in opioid-tolerant patients, but also despite the fact that the FDA specifically refused to expand this indication to include other forms of breakthrough pain. Cephalon, however, designed and implemented a marketing plan for Fentora that was targeted primarily at pain specialists, even though the Company was fully aware that it is oncologists, and almost never pain specialists, who treat breakthrough cancer pain.

176. Cephalon sought to convert pain specialists, who prescribed Actiq off-label as a result of the Company's former promotional effort for Actiq, to prescribe Fentora instead for those same unsafe and unapproved uses. In summarizing its previously established objectives for 2010, Cephalon's first-listed objective was to "minimize prescriber losses / re-activate former prescribers." Given that the vast majority of prescribers of both Actiq and Fentora were pain specialists who did not prescribe Actiq for its on-label use (breakthrough cancer pain or "BTCP"), the Company's goal was to maintain market share among these prescribers. The Brand

Plan signaled that, for 2010, that objective was successfully met with "a positive trend and stabilization in the FENTORA business."

177. Moving forward into 2011, the Company planned to pursue a similar strategy of leveraging relationships with pain specialists to drive sales of Fentora, despite the knowledge that pain specialists do not prescribe Fentora for its on-label use. Facing ever-increasing competition from other fentanyl-based drugs such as Onsolis, Abstral, and PecFen, Cephalon conducted a competitive strategy workshop in order to determine how to best differentiate Fentora from these competing drugs. Among the three "key areas" identified by the workshop to differentiate Fentora were "existing relationships with pain community," yet again emphasizing the centrality of this primarily demographic in Cephalon's promotional strategy for Fentora.

178. Likewise, Cephalon targeted speakers, advocates, and consultants who are primarily from the pain management field, rather than from the oncology field. The "Pain Knowledge Mapping Project" is a project specifically designed to "identify and profile prominent experts in the field of pain management," and an "[e]ditorial board" of "[t]op-tier advisors" is to be composed entirely of "5-6 pain specialists." These pain specialists were to facilitate Cephalon's broader targeting of pain specialists by "advis[ing] the marketing team on marketing projects, initiatives, [and] messages."

179. While the Fentora Brand Plan also contains objectives to increase promotions to oncologists, these objectives serve to emphasize the very limited extent to which Cephalon has targeted oncologists in the past. The "Advisory Board Plan of Action" lists as a focus, "Engage oncology experts," elaborating that "[m]ore needs to be done to gain feedback from oncologists and oncology nurses as we continue to expand our commercial presence with these important groups."

180. More importantly, though, these efforts to expand promotion to oncologists remain secondary to Cephalon's efforts to expand and continue promotion to pain specialists – despite, once again, Cephalon's awareness that pain specialists almost exclusively prescribe Fentora for unsafe and unapproved uses. The Fentora Brand Plan includes a goal of broadening the targeted audience beyond the current group of 1,800 HCPs ("HCPs") to include an additional 750 rapid-onset-opioid-("ROO") prescribing oncologists and another 1,235 non-ROO prescribing oncologists. While that indeed constitutes a significant expansion in the Company's promotion to oncologists, that expansion is nonetheless dwarfed by Cephalon's promotional expansion to 5,500 other ROO-prescribing HCPs.

181. According to the Fentora Brand Plan itself, Cephalon's unsafe and unapproved promotion of Fentora had been successful. The Brand Plan stated that "[r]epresentative driven detailing activities . . . have demonstrated a significant impact[,] driving 29% of FENTORA sales historically." Given that only 7% of total Fentora prescriptions were written by oncologists, see CEPHALON_002978, and that these 7% almost entirely constituted the on-label market for the drug, this statement is a surprisingly explicit admission that Cephalon's sales representatives have been instrumental at driving off-label market share for Fentora.

182. In fact, that 29% figure likely understated the significance of sales representatives' effect on prescriptions of Fentora, as the Brand Plan attributes the remaining 71% of Fentora sales to "carryover as a result of physician loyalty and past promotion," namely the Cephalon's former unsafe and unapproved promotion of Actiq.

183. In apparent recognition of the significant impact of its sales representatives' promotion of Fentora to pain specialists, Cephalon planned to allocate even more resources to targeting pain specialists. The Brand Plan recommends that for 2011 that Cephalon "[i]ncrease &

reallocate marketing spend based on historical responsiveness of physician segment," recognizing that "there is an opportunity to refine the allocation of key sales force activities to optimize that return on investment."

184. In accordance with its marketing plans, Cephalon sales representatives marketed Fentora for unapproved and unsafe pain applications well beyond the narrow scope of Fentora's FDA marketing approval for breakthrough cancer pain, or its approved uses found in the statutorily named Compendia.

185. Cephalon also used its sales representatives to influence HCPs to prescribe higher and higher doses of its products (which resulted in more profits for Cephalon). For example, while Actiq's label calls for a maximum dosage of six lollipops containing a 200- microgram dose of fentanyl for patients starting off on the drug, the government investigation revealed that Cephalon encouraged physicians to ignore the label, and instead start patients off with 24 lollipops containing 400 micrograms of the powerful narcotic.

186. Marketing executives directed the Fentora sales force to "stay out of oncology, and go directly to pain," and focus its targeting on HCPs who were high-prescribers of opioids and narcotics such as pain specialists. Indeed, all the physician targeting lists focused on the level of opioid prescribing by the doctor. There was no instruction to call on HCPs who were engaged in treating cancer patients.

187. These marketing executives included a senior marketing director and an associate marketing director. This instruction was mirrored by sales managers, including a regional sales director, who would instruct sales representatives to focus on non-oncology HCPs.

188. In addition to pain specialists, Fentora was marketed for unsafe and ineffective uses to a larger group of HCPs, including psychiatry or rehabilitation specialists,

anesthesiologists, internal medicine, general practitioners, family medicine practitioners, and other primary care physicians who have prescribing patterns similar to those of pain specialists.

189. Despite Fentora's limited approval for only breakthrough cancer pain, Cephalon's pain sales force aggressively promoted the drug for unsafe and unapproved uses, particularly for non-cancer breakthrough pain. In addition, Fentora was also marketed to physicians known by Cephalon sales management to use the drug for unsafe and unapproved uses in a pre- or perioperative setting, such as for preoperative sedation or as an adjunct to anesthesia. There are no directions or dosage recommendations for the use of Fentora in this perioperative setting. In fact, the use of Fentora in perioperative setting is contraindicated for use for such short-term pain by the FDA for several reasons as set forth in the Black Box Warning on the label, which specifically states that "[d]ue to the risk of fatal respiratory depression, FENTORA is contraindicated in opioid non-tolerant patients . . . [and] postoperative pain."

190. Cephalon, like Purdue, devoted a large amount of resources to direct visits from sales representatives to HCPs and their staff. In 2014 alone, Cephalon spent approximately $13 million detailing its Opioid Drugs to prescribers.

191. As a result of Cephalon's promotional activities, physicians prescribed and submitted false claims for reimbursement of Fentora for unsafe and unapproved use to TPP health care programs, including MMO. Cephalon's own marketing documents demonstrate that more than 80% of Fentora sales are associated with unsafe and unapproved uses.

(iii) Janssen Sales Representatives Misrepresented the Safety and Efficacy of Its Opioid Drugs to Physicians

192. Janssen downplayed the risk of patient addiction, abuse, and misuse, and marketed the opioid drugs Nucynta, Nucynta ER, and Ultram ER as natural and less addictive than other drugs. Although evidence was building up that long-acting extended release ("ER")

opioids should only be used as a last resort for pain management, Janssen ignored the signs and continued to push these highly addictive drugs using misleading terms.

193. Janssen promoted the dangerous and contraindicated idea that pain should be treated first by taking long-acting opioids like Nucynta ER and Ultram ER continuously and then by taking short-acting, rapid onset opioids on top of that. Extended release formulas are only indicated where shorter-acting formulas are inadequate. Meanwhile, despite the short acting nature of the drug, the marketing efforts for Nucynta were concentrated on high volume pain prescribers such as pain management specialists and rheumatologist that primarily treat chronic pain patients. Short-acting Nucynta (November 20, 2008) went on the market about three (3) years before the long-acting form, Nucynta ER (August 25, 2011). The drug was marketed based on its so-called ascending and descending pathways, part of a claim that the drug was non-addictive, and avoided withdrawal symptoms.

194. While it was once thought that long-acting opioids would not be as susceptible to abuse and addiction as short-acting ones, this view has been discredited by innumerable adverse reaction reports. Since it claimed there was an ascending and descending pathway component to the opioid, Janssen told HCPs the risk would be small.

195. The emphasis on descending and ascending pathway served to ensure that the risk for addiction was minimal even with long-term use, and thus ignoring the potential for addiction, tolerance, and the Schedule II nature of the product.

196. Janssen trained, managed and instructed its sales representatives to expand the label by advising physicians to stack Nucynta in addition to other long-acting opioids for additional pain relief. Physicians were encouraged to prescribe Nucynta as a part of an "opioid rotation regimen" whereby it is indicated that risk of tolerance would be decreased if the patient

rotates through medications. This information is unsubstantiated in the clinical literature, nor is there any adequate clinical evidence supporting the notion that adding additional Nucynta on a long acting opioid would be safe and effective for the patient.

197. A 2008 Janssen marketing piece for detailing pharmacists emphasized neuroplasticity, that theoretically someone using Nucynta could change pain chemistry and prevent "neuronal remodeling" to prohibit the progression into chronic pain:

SAMPLE MESSAGE

As a pharmacist, you are a key member of a patient's pain relief team. I'm sure you see a lot of patients who are looking for relief of pain that they've had for weeks, months, or even years. Wouldn't you agree that unresolved acute pain can have significant clinical consequences?

Did you know that unresolved acute pain may lead to the development of chronic pain? In fact, the severity of acute pain is often a risk factor for the development of chronic pain. This has been documented in patients with low back pain, suggesting that moderate to severe pain should be resolved as quickly as possible.

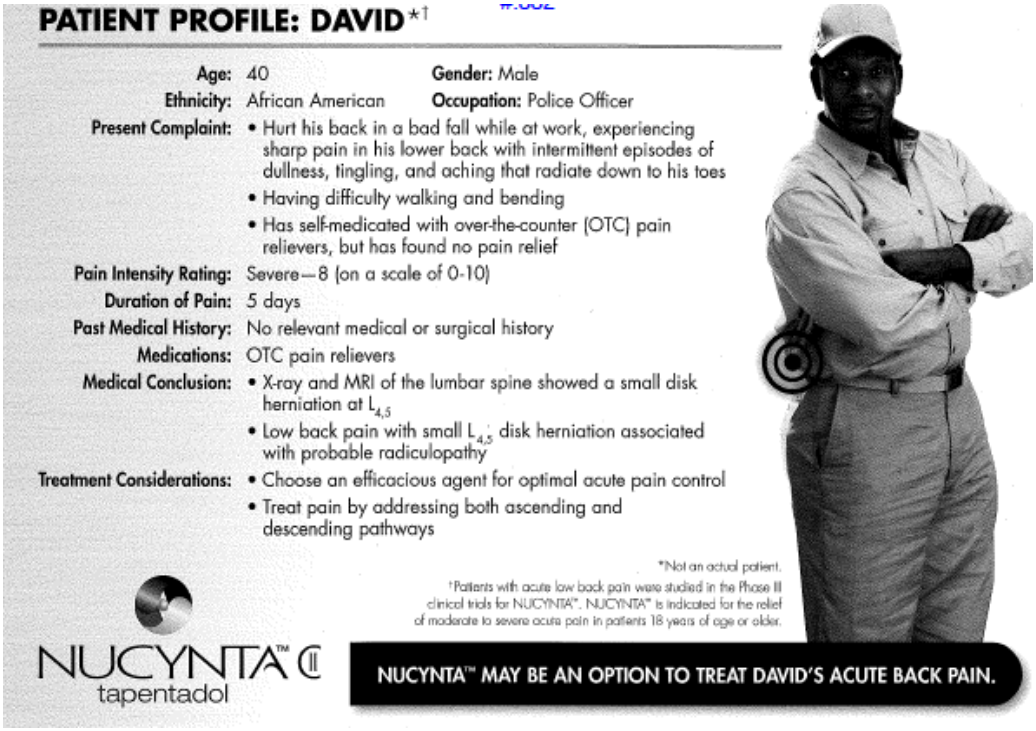
*The cascade of events that leads from acute pain to chronic pain can begin in even less than an hour of injury. This schematic shows how an acute injury can lead to **sensitization** and **neuronal remodeling*** that results in chronic pain. Yet, early intervention and effective management of acute pain may improve long-term outcomes in pain patients. For more information on the chronicity of pain, you can visit www.neopathwaysinpain.com.*

Does this information provide evidence to you of the importance of early, effective treatment of acute pain?

198. Essentially, this is a claim that Nucynta would help patients actually get better, not just treat their pain. Chronic pain develops when a patient is in pain so long that their brain undergoes "neuronal remodeling" which basically means that the brain resets to be in a pain state constantly. Claiming that Nucynta would prevent this neuronal remodeling implies that Nucynta would somehow address the underlying cause of the pain, which is totally unsubstantiated.

199. Likewise, Janssen denied that Nucynta ER was an opioid, and said it had "weak" mu-opioid activity, and the majority of the pain relief was the result of adjuvant activity from serotonin and norepinephrine re-uptake, rather than any opioid effect.

200. One 2009 Nucynta promo piece profiles a 40-year-old African American male police officer who was hurt on the job. It recommends Nucynta for lower risk pain relief, due to its treatment of pain "by addressing both ascending and descending pathways" and its combination of "opioid and non-opioid activity in one centrally acting oral analgesic."



201. Janssen sales representatives were instructed to tell prescribers that Nucynta ER and Ultram ER "reach steady state, and essentially there's no dumping of the medication in the central nervous system." The intent was to tell HCPs that neither drug produced a rush or euphoric effect, and therefore were less addictive and less likely to be abused. Janssen trained and directed its sales representatives to use a similar statement for immediate release Nucynta – a

marketing line that it had a "dual mode of action," and that it was safer due to the "neuroplasticity of the brain."

202. Janssen sales representatives were instructed to emphasize to physicians that the majority of Nucynta's pain relief came from serotonin and norepinephrine, and that it has a weak affinity to mu-opioid receptors. They were told to claim that it was about "1/50th" of the effect of morphine on the mu-opioid receptors," and that "it tickles the mu-opioid receptors." This is not true, however, as Nucynta's label notes that the drug contains tapentadol, an opioid agonist and Schedule II substance with abuse liability similar to other opioid agonists, legal or illicit.

203. The sales message was that Nucynta has weak activity on the mu-opioid receptor and achieves the majority of its adjuvant pain relief properties from norepinephrine and serotonin inhibition. This fact was repeated to tout the low potential for addiction to the medication. This is a claim that is not supported by the label, but was used to encourage broad adoption of Nucynta in patient populations where its use is not warranted and is not deemed safe and effective by the label.

204. Janssen's sales representatives told prescribers that Nucynta's unique properties virtually eliminated the risk of addiction associated with the drug.

205. This marketing exploitation is further supported by the compensation structure of Janssen's sales representatives. Janssen representatives were paid by baseline growth of Nucynta prescriptions, not by the number of new prescriptions, suggesting that sales representatives were rewarded for getting physicians to have their patients on medication above and beyond the on label 90-day period. Since both compensation and retention of employment were based on the representatives' sales numbers, sales representatives understood their employment and livelihood depended on patients using Nucynta beyond its label.

206. In discussions with prescribers, Janssen sales representatives omitted discussion of addiction risks related to many other of Janssen's Opioid Drugs. Janssen's sales representatives left REMS packages ("REMS" or Risk Management Protocol that is released for opiates) for the physicians without additional explanation of what that necessarily meant for the patient and the physician. In fact, in a Quality Assurance training session Janssen asserted that this was the package that is necessary for new compounds with no indication that there is an additional risk for addiction may be the actual reason for the REMS program.

207. Beginning in or about 2008, Janssen then trained, managed, and instructed its sales representatives to market to prescribers that Nucynta's unique properties virtually eliminated the risk of addiction associated with the drug. Janssen told physicians that Nucynta's unique properties virtually eliminated the risk of addiction associated with the drug. In discussions with prescribers, Janssen sales representatives omitted discussion of addiction risks related to Janssen's Opioid Drugs.

208. This "core message" of a lack of withdrawal symptoms runs throughout Janssen's sales training materials. For example, Janssen's "Licensed to Sell" Facilitator's Guide instructs those conducting Janssen sales trainings to evaluate trainees, in part, on whether they remembered that "[w]ithdrawal symptoms after abrupt cessation of treatment with NUCYNTA ER were mild or moderate in nature, occurring in 11.8% and 2% of patients, respectively" and whether they were able to "accurately convey" this "core message." Janssen further claimed in 2008 that "low incidence of opioid withdrawal symptoms" was an advantage of the tapentadol molecule.

209. Janssen's sales force was trained to trivialize addiction risk. A June 2009 Nucynta training module warns that physicians are reluctant to prescribe controlled substances like

Nucynta because of their fear of addicting patients, but this reluctance is unfounded because "the risks . . . are [actually] much smaller than commonly believed." Janssen also encouraged its sales force to misrepresent the prevalence of withdrawal symptoms associated with Nucynta. A Janssen sales training PowerPoint titled *Selling Nucynta ER and Nucynta* indicates that the "low incidence of opioid withdrawal symptoms" is a "core message" for its sales force. The message was touted at Janssen's Pain District Hub Meetings, in which Janssen periodically gathered its sales force personnel to discuss sales strategy.

210. Janssen sales representatives told prescribers that Nucynta and Nucynta ER were "weak opioids" in a class of their own, implying that the risks of addiction and other adverse outcomes associated with opioids were not applicable to Janssen's Opioid Drugs. In truth, however, as set out in Nucynta's FDA-mandated label, Nucynta "contains Tapentadol, an opioid agonist and Schedule II substance with abuse liability similar to other opioid agonists, legal or illicit."

211. A February 2009 Janssen coaching sheet for training its sales representatives indicated that the low incidence of nausea and vomiting and the low the incidence of constipation, CNS, dizziness, somnolence, and pruritus are important sales messages. Additionally, sales representatives were coached to push the "low discontinuation rates due to" adverse events, and a "low incidence of opiate withdrawal symptoms."

212. A document called the *Nucynta Launch Vis Aid – An Annotated Guide* from 2009 was also used to coach sales representatives on their Nucynta messages. This document also promoted the "low composite incidence of nausea and vomiting," low discontinuation rates, and "low incidence of withdrawal symptoms." These statements did not accurately reflect the studies

they referenced, which did not address patients on the drug for more than ninety (90) days or with chronic pain – a large target for the Nucynta sales team.

213. Another 2009 sales training booklet, called *Opioid Efficacy Meets Unexpected Tolerability* made the same claims of low rates of discontinuation, adverse events, and withdrawal symptoms in the same flawed manner based on the same studies.

214. Similarly, a Nucynta Clinical Studies Facilitator's Guide instructs individuals training Janssen's sales representatives to ask trainees to describe a "key point"—that "83% of patients reported no withdrawal symptoms after abruptly stopping treatment without initiating alternative therapy"—"as though he/she is discussing it with a physician."

215. This misrepresentation regarding withdrawal was one of the key messages Janssen imparted to employees in the *Retail ST 101 Training* delivered to Nucynta sales representatives. Indeed, training modules between 2009 and 2011 instruct training attendees that "most patients [who discontinued taking Nucynta] experienced no withdrawal symptoms" and "[n]o patients experienced moderately severe or severe withdrawal symptoms."

216. Janssen sales representatives told prescribers that patients on Defendants' drugs were less susceptible to withdrawal than those on other opioids. Janssen sales representatives told prescribers that Nucynta was not an opioid, making it a good choice for chronic pain patients who previously were unable to continue opioid therapy due to excessive side effects. This statement was misleading because Nucynta is an opioid and has the same effects as other opioids.

217. Nucynta IR and ER were combined for commissions; Janssen expected patients to be on Nucynta IR long-term, and they were compensating sales representatives based on long-term Nucynta IR prescriptions.

218. In or around 2012, on a field ride with the Nucynta Product Director, Haya Teitel, Dr. Avrom Gart asserted that he had a patient that had experienced temporary blindness while on Nucynta. The Marketing Director requested that the representative not report the incident as it would "jeopardize the launch" of the medication. Regardless, the representative reported the incident under "visual disturbance." This is parallel to company's overall culture to further expand the indication of the medications while simultaneously reducing the perceived rate of occurrence of side effects to encourage physicians' comfort in prescribing Opioid Drugs broadly despite the off-label use and the clinical appropriateness for the patients.

219. During the very time Janssen was instructing its sales force to trivialize the risks of addiction and withdrawal associated with the use of Nucynta to treat chronic pain, it knew or should have known, that significant numbers of patients using opioids to treat chronic pain experienced issues with addiction. Janssen knew or should have known that its studies on withdrawal were flawed and created a misleading impression of the rate of withdrawal symptoms and, as a result, the risk of addiction.

220. The misleading messages and materials Janssen provided to its sales force were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, irrespective of the risks, benefits, and alternatives. This deception was national in scope and included Ohio. Janssen's nationwide messages reached Ohio prescribers in a number of ways, including through its sales force in detailing visits, as well as through websites and advertisements. They were also delivered to Ohio prescribers by Janssen's paid speakers, who were required by Janssen policy and by FDA regulations to stay true to Janssen's nationwide messaging.

221. A Janssen PowerPoint presentation used for training its sales representatives titled *Selling Nucynta ER* indicates that the "low incidence of withdrawal symptoms" is a "core message" for its sales force. This message is repeated in numerous Janssen training materials between 2009 and 2011. The studies supporting this claim did not describe withdrawal symptoms in patients taking Nucynta ER beyond 90 days or at high doses and would therefore not be representative of withdrawal symptoms in the chronic pain population. Patients on opioid therapy long-term and at high doses will have a harder time discontinuing the drugs and are more likely to experience withdrawal symptoms. In addition, in claiming a low rate of withdrawal symptoms, Janssen relied upon a study that only began tracking withdrawal symptoms in patients two to four days after discontinuing opioid use; Janssen knew or should have known that these symptoms peak earlier than that for most patients. Relying on data after that initial window painted a misleading picture of the likelihood and severity of withdrawal associated with chronic opioid therapy. Janssen also knew or should have known that the patients involved in the study were not on the drug long enough to develop rates of withdrawal symptoms comparable to rates of withdrawal suffered by patients who use opioids for chronic pain—the use for which Janssen promoted Nucynta ER.

222. Janssen sales representatives told Ohio prescribers that its drugs were "steady state," the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.

223. Janssen sales representatives told Ohio prescribers that Nucynta and Nucynta ER were "not opioids," implying that the risks of addiction and other adverse outcomes associated with opioids were not applicable to Janssen's Opioid Drugs. In truth, however, as set out in

Nucynta's FDA-mandated label, Nucynta "contains tapentadol, an opioid agonist and Schedule II substance with abuse liability similar to other opioid agonists, legal or illicit."

224. The experiences of specific prescribers confirm both that Janssen's national marketing campaign included the misrepresentations, and that the company disseminated these same misrepresentations to Ohio prescribers and consumers. In particular, these prescriber accounts reflect that Janssen detailers claimed that Nucynta was "not an opioid" because it worked on an "alternate receptor"; claimed that Janssen's drugs would be less problematic for patients because they had anti-abuse properties and were "steady state"; claimed that patients on Janssen's drugs were less susceptible to withdrawal; omitted or minimized the risk of opioid addiction; claimed or implied that opioids were safer than NSAIDs; and overstated the benefits of opioids, including by making claims of improved function.

225. The following statements were made on December 8, 2010, at the American Society of Health-System Pharmacists Midyear Clinical Meeting and Exhibition in Anaheim, CA. The unsubstantiated claims made by Janssen's sales representatives include, *inter alia*:

- "Nucynta provides 10 mg of opioid/oxycodone pain control, similar to Tramadol, but with less GI, constipation, nausea, and vomiting," which is misleading and implied that Nucynta is clinically superior compared to oxycodone and Tramadol for certain patients; and
- When physicians prescribe Nucynta they "won't have to put patients on docusate or senna [and] patients get out of the hospital a day earlier which saves thousands of dollars because they are going to be able to have a bowel movement," which is misleading and implied that treatment with Nucynta has been shown to reduce the length of a hospital stay in comparison to oxycodone and Tramadol.

226. On August 26, 2011, Janssen received a warning letter regarding its Opioid Drug, Nucynta. The letter informed Janssen that the FDA had become aware of oral statements made by a Janssen sales representative that promoted an unapproved use for its opioid Nucynta, made unsubstantiated superiority claims about the drug, and minimized the serious risks associated with Nucynta.

227. Janssen also focused much of its time and resources on detailing its Opioid Drugs to prescribing physicians. Sales representatives would visit individual HCPs, as well as their staff, in office visits as well as small group speaker programs. In 2014 alone, the company spent approximately $34 million in detailing its Opioid Drugs

228. After annual sales of $166 million, in January 2015, Janssen sold its rights to market to Nucynta and Nucynta ER in the United States, including in Ohio to Depomed for $1 billion

(iv) Depomed Sales Representatives Misrepresented the Safety and Efficacy of Its Opioid Drugs to Physicians

229. Depomed has, since at least October 2011, engaged in unsafe and/or unapproved marketing of Lazanda and (with the acquisition from Janssen in January 2015) of Nucynta and Nucynta ER.

(a) Depomed Sales Representatives Promoted Lazanda for Unsafe and Unapproved Uses

230. Lazanda is only indicated "for the management of breakthrough pain in cancerpatients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." Despite the drug's explicit limitation, Depomed actively promoted Lazanda to physicians who do not treat cancer patients. Not only did Depomed instruct sales representatives to promote Lazanda to non-cancer treating physicians, the Company also discouraged sales representatives from marketing the drug to

physicians treating cancer patients, even if the sales representatives were successful in gaining these doctors' business.

231. When it launched Lazanda in 2011, the Company's management, from the start, disregarded the FDA's limitations concerning Lazanda's usage, instructing its sales representatives to target pain management physicians, particularly those who historically wrote large numbers of ROOs and Lazanda-like drugs.

232. Sales representatives were pressured to target pain management physicians. Area managers at Depomed regularly supplied sales representatives with lists of target physicians containing few, if any, physicians treating cancer patients. Of the typical call list containing approximately 100 physicians, under five generally treated cancer patients.

233. Depomed also strongly discouraged sales representatives from targeting physicians treating cancer patients. Sales representatives had to "make a case" for using any portion of their allotted marketing money to call on cancer treating physicians. And employees who did call on cancer treating physicians were disciplined.

234. One Depomed sales representative, who worked in the Los Angeles area, was chastised by management for targeting, almost exclusively, physicians treating cancer patients despite the fact that he had been very successful in generating business from these physicians. This representative was reprimanded for targeting physicians who could prescribe Lazanda for its indicated use, and was told to stop targeting these physicians, and to think about how well he could be doing if he was targeting potentially higher writers.

235. Depomed explicitly told sales representatives to market only to non-cancer treating physicians by their managers, most notably Todd Wittenbach, the company's then head of sales for the United States.

236. Depomed sales representatives were also trained to deal with (rightful) pushback from physicians. For example, when confronted with the common statement from a physician that "it's extremely rare that we see cancer patients," Depomed trained sales representatives to divert the conversation to the physician's use of other, similar medications. For example, sales representatives were trained to respond by saying "well tell me about your patients taking Actiq," and then extol the relative benefits of switching those patients to Lazanda.

237. Due to the worsening headwinds within the opioid market, Depomed ultimately sold Lazanda to Slán Medicinal Holdings on November 7, 2017.[49]

(b) Depomed Sales Representatives Promoted Nucynta and Nucynta ER for Unsafe and Unapproved Uses

238. On April 2, 2015, Depomed acquired from Janssen and its affiliates the U.S. rights to the Nucynta franchise of pharmaceutical products for $1.05 billion in cash. The Nucynta franchise is an opioid that includes Nucynta ER (tapentadol) extended release tablets indicated for the management of pain, including neuropathic pain associated with diabetic peripheral neuropathy (DPN), severe enough to require daily, around-the-clock, long-term opioid treatment, Nucynta IR (tapentadol), an immediate release version of tapentadol, for management of moderate to severe acute pain in adults, and Nucynta (tapentadol) oral solution, an approved oral form of tapentadol that has not been commercialized.

239. Nucynta's annual sales increased in the U.S. from $189.9 million in 2015 to approximately $281.3 million in 2016, quickly becoming Depomed's best-selling product. This marked a 48% year-over-year growth in sales of Nucynta in just one year.

[49] Press Release, *Depomed and Slán Medicinal Holdings Ltd Announce Strategic Asset Transactions*, November 7, 2017, available at https://globenewswire.com/news-release/2017/11/07/1176771/0/en/Depomed-and-Slán-Medicinal-Holdings-Ltd-Announce-Strategic-Asset-Transactions.html

240. The marketing strategy causing the astronomical growth in sales, however, was fueled by Depomed's illegal practices in connection with its marketing of Nucynta for unsafe and unapproved uses. In particular, Depomed promoted the use of opioids for all manner of pain management while downplaying the drug's addictive nature, often promoting the drug as a safer alternative to opioids, despite this not being on the FDA label.

241. Further, Depomed promoted an increase in dosage while focusing on family physicians and internal medicine doctors who were less knowledgeable about the dangers of opioids. In February 2017, Depomed's former CEO increased its sales force for the specific purpose of targeting primary care physicians.

242. The FDA-approved labels for both Nucynta IR and Nucynta ER describe the tapentadol molecule as "a substance with a high potential for abuse similar to other opioids including fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and oxymorphone." Nowhere on the FDA-approved label does it say or mention that Nucynta is safer, more tolerable, less abusive, or less addictive than other opioids. Despite this, Nucynta has a long history of its manufacturer (formerly Janssen, *see supra*) claiming these benefits in its sales pitches and marketing.

243. Nonetheless, Depomed directed its sales representatives to market Nucynta for unsafe and unapproved uses as a safer, less abusive, less addictive opioid that did not create the same euphoric feeling as other opioids, even though this was not on the FDA-approved label.

244. Depomed management knew that the FDA-approved label for Nucynta contained no information about it being safer, more tolerable, less addictive, or less abusive than alternative opioids, and knew they could not market Nucynta this way.

245. On June 23, 2015 investor call, August Moretti, Depomed's Senior Vice President and Chief Financial Officer, stated that "[a]lthough not in the label, there's a very low abuse profile and side effect rate."

246. Additionally, in a March 14, 2015 presentation at the ROTH Conference, then Depomed CEO Schoeneck stated: "The addiction profile is thought to be better. I can't make a claim around that because we don't actually have that in the label." In February 2017, Schoeneck also told investors that Depomed was "initiating label enhancement studies, aimed at further differentiating Nucynta by highlighting its respiratory depression and abuse potential profile. These labeling studies will focus on the properties of the tapentadol molecule, and its uniqueness in the pain marketplace." The purpose of this was to "be able to get it hopefully into the label."

247. Depomed's marketing push was "Think Differently." Sales representatives were told that Nucynta is a "safer opioid." They were told to tell physicians about Nucynta and its value to patients in terms of, among other things, improved safety relative to other opioids on the market.

248. Depomed actively targeted primary care physicians with marketing presentations that described Nucynta as a safer, less addictive, less abusive opioid that did not contain the same euphoric feeling as other opioids. Depomed did not have FDA-approval to market Nucynta in this manner, and also did not have any independent scientific evidence to support these claims.

249. Depomed represented that Nucynta was uniquely positioned to combat the negative public sentiment against Opioids. Former President and CEO James Schoeneck described to investors that Nucynta had "different properties than the other opioids, particularly when it comes to the kind of activity that the CDC and others are most concerned about" and that

"there'll be relatively little impact on [Depomed] compared to where some other companies may fall in at."

250. Depomed knew that it could not promote Nucynta as a safer, less addictive, less abusive opioid that did not have the same euphoric feeling on patients because these properties were not on its FDA-approved label. Despite this knowledge, Depomed trained its sales representatives to use these marketing tactics to sell Nucynta, using the same sales team as Janssen had to promote Nucynta, knowing that Janssen was being sued for, among other things, improperly marketing Nucynta.

251. Due to the worsening headwinds within the Opioid market, Depomed ultimately entered into a commercialization agreement with Collegium Pharmaceutical, Inc., for the NUCYNTA brand on December 4, 2017.

(v) Endo Sales Representatives Misrepresented the Safety and Efficacy of Its Opioid Drugs to Physicians

252. Endo knew that its marketing reached physicians repeatedly because it tracked their exposure. Internal Endo documents dated August 23, 2006, demonstrate that the following percentages of physicians would view an Endo journal insert (or paid supplement) at least three times in an eight-month period: 86% of neurologists; 86% of rheumatologists; 85% of oncologists; 85% of anesthesiologists; 70% of targeted primary care physicians; and 76% of OB/GYNs.

253. Endo distributed *Case Challenges in Pain Management: Opioid* Therapy for Chronic Pain to 116,000 prescribers in 2007, including primary care physicians in Ohio.

254. In a 2007 Sales Tool that was intended to be shown by Endo sales personnel to physicians during their detailing visits, Endo highlighted a hypothetical patient named "Bill," a 40-year-old construction worker who was reported to suffer from chronic low back pain.

According to the Sales Tool, Opana ER will make it more likely that Bill can return to work and support his family.

255. Similarly, training materials for sales representatives from March 2009 ask whether it is true or false that "[t]he side effects of opioids prevent a person from functioning and can cause more suffering than the pain itself." The materials indicate that this is "[f]alse," because "[t]he overall effect of treatment with opioids is very favorable in most cases."

256. Endo was not only able to reach physicians through its marketing, but also successfully impart its marketing messages. The company found that its promotional materials tripled prescribers' ability to recall the sales message and doubled their willingness to prescribe Opana ER in the future. This was true of marketing that contained deceptions.

257. For example, according to internal Endo documents, up to 10% of physicians it detailed were able to recall, without assistance, the message that Opana ER had "Minimal/less abuse/misuse" potential than other drugs. The Endo message that prescribers retained was a plain misrepresentation: that use of Opana ER was unlikely to lead to abuse and addiction. Although Opana ER always has been classified under Schedule II as a drug with a "high potential for abuse," the largest single perceived advantage of Opana ER, according to a survey of 187 physicians who reported familiarity with the drug, was "perceived low abuse potential," cited by 15% of doctors as an advantage. Low abuse potential was among the deceptive messages that Ohio prescribers received, and retained, from Endo sales representatives.

258. Endo's promotion of Opana ER relied heavily on in-person marketing, including to Ohio prescribers. In the first quarter of 2010 alone, sales representatives made nearly 72,000 visits to prescribers nationwide to detail Opana ER. Between 2007 and 2013, Endo spent between $3 million and $10 million each quarter to promote opioids through its sales force.

259. Endo's sales representatives, like those of the other Defendants, targeted physicians to deliver sales messages that were developed centrally and deployed uniformly across the country. These sales representatives were critical in transmitting Endo's marketing strategies and talking points to individual prescribers.

260. Endo specifically directed its sales force to target physicians who would prescribe its drugs to treat chronic pain. For example, an Opana Brand Tactical Plan dated August 2007 aimed to increase "Opana ER business from [the Primary Care Physician] community" more than 45% by the end of that year. Indeed, Endo sought to develop strategies that would be most persuasive to primary care doctors—strategies that sought to influence the prescribing behavior of primary care physicians through the use of subject matter experts. A February 2011 Final Report on Opana ER Growth Trends, for example, predicted that Endo's planned "[u]se of Pain Specialists as local thought leaders should affect increased primary care adoption."

261. Endo trained its sales force to make a number of misrepresentations to physicians nationwide, including to physicians in Ohio. Endo's sales representatives were trained to represent to these prescribers that Opana ER would help patients regain function they had lost to chronic pain; that Endo opioids had a lower potential for abuse because they were "designed to be crush resistant," despite the fact that "clinical significance of INTAC Technology or its impact on abuse/misuse ha[d] not been established for Opana ER;" and that drug-seeking behavior was a sign of undertreated pain rather than addiction.

262. Nevertheless, Endo knew that its marketing was extremely effective in turning physicians into prescribers. Nationally, the physicians Endo targeted for in-person marketing represented approximately 84% of all prescribers of Opana ER in the first quarter of 2010. Endo also observed that the prescribers its sales representatives visited wrote nearly three times as

many prescriptions per month for Opana ER as those physicians who were not targeted for Endo's marketing—7.4 prescriptions per month versus 2.5. The most heavily targeted prescribers wrote nearly 30 prescriptions per month. Internal Endo documents from May 2008 indicate that Endo expected that each of its sales representatives would generate 19.6 prescriptions per week by the end of 2008. As summarized by a February 2011 report on Opana ER growth trends, Endo's "[a]ggressive detailing [is] having an impact."

263. Endo also employed its sales representatives to market Opana ER as tamper / crush resistant and therefore less prone to misuse and abuse, despite the fact that the FDA rejected Endo's petition to approve Opana ER as abuse-deterrent in 2012. The FDA warned in a 2013 letter that there was no evidence to support the claim that Opana ER "would provide a reduction in oral, intranasal or intravenous abuse."

264. Similarly, the N.Y. Attorney General found that statements that Opana ER was "designed to be, or is crush resistant" were false and misleading because there was no difference in the ability to extract the narcotic from the drug.

265. Endo's own internal documents acknowledged the misleading nature of these statements, conceding that "Opana ER has an abuse liability similar to other opioid analgesics as stated in the [FDA-mandated] box warning." A September 2012 Opana ER Business Plan similarly stated that Endo needed a significant investment in clinical data to support comparative effectiveness, scientific exchange, benefits and unmet need, while citing lack of "head-to-head data" as a barrier to greater share acquisition.

266. More broadly, Endo's sales trainings and marketing plans demonstrate that its sales force was trained to provide prescribers with misleading information regarding the risks of opioids when used to treat chronic pain. Foremost among these messages were misleading claims

that the risks of addiction, diversion, and abuse associated with opioids—and Endo's products in particular—were low, and lower than other opioids.

267. Endo also focused much of its time and resources on detailing its Opioid Drugs to prescribing physicians. Sales representatives would visit individual HCPs, as well as their staff, in office visits as well as small group speaker programs. In 2014 alone, the company spent approximately $10 million in detailing its Opioid Drugs.

268. By way of illustration, Endo's Opana ER INTAC Technology Extended-Release Sell Sheet Implementation Guide, which instructs Endo sales personnel how to effectively "support key messages" related to the marketing of Opana ER, states that it is an "approved message" for sales representatives to stress that Opana ER was "designed to be crush resistant," even though this internal document conceded that "the clinical significance of INTAC Technology or its impact on abuse/misuse has not been established for Opana ER."

269. Other Endo documents acknowledge the limitations on Opana ER's INTAC technology, conceding that while Opana ER may be resistant to pulverization, it can still be "ground" and "cut into small pieces" by those looking to abuse the drug. Endo's claims about the crush-resistant design of Opana ER also made their way to the company's press releases. 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 Ohio patients and prescribers.

270. The only reason to promote the crush resistance of Opana ER was to persuade doctors that there was less risk of abuse, misuse, and diversion of the drug. The idea that Opana ER was less addictive than other drugs was the precise message that Ohio prescribers took from Endo's marketing.

271. In an effort to substantiate their marketing claims, Endo sales representatives discussed Treatment Guidelines (*see* Scientific Literature Marketing Enterprises, *infra*) with HCPs during individual sales visits including visits throughout the United States and Ohio. Endo spent approximately $246,620 to buy copies of FSMB's treatment guidelines (discussed *infra*), which were distributed by Endo's sales force.

272. Even Endo's own internal studies showed that Opana ER could still be ground or chewed, which it failed to disclose. Despite this, and repeated warnings, Endo's sales representatives continued to assert to physicians that Opana ER is harder to abuse. Regional surveys have confirmed that Endo sales representatives marketed the drug as "crush resistant."

273. Endo trained its sales force in 2012 that use of long-acting opioids resulted in increased patient compliance, without any supporting evidence.

274. Endo further misled patients and prescribers by downplaying the risks of opioids in comparison to other pain relievers. For example, in Ohio and elsewhere, Endo distributed a presentation titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*. This study held out as a representative example one patient who had taken NSAIDs for more than eight years and, as a result, developed "a massive upper gastrointestinal bleed." The presentation recommended treating this patient with opioids instead. By focusing on the adverse side effects of NSAIDs, while omitting discussion of serious side effects associated with opioids, this presentation misleadingly portrayed the comparative risks and benefits of these drugs.

275. A sales training video dated March 8, 2012, that Endo produced and used to train its sales force makes the same types of claims. A patient named Jeffery explains in the video that he suffers from chronic pain and that "chronic pain [. . .] reduces your functional level." Jeffery claims that after taking Opana ER, he "can go out and do things" like attend his son's basketball

game, and "[t]here's no substitute for that." This video was shown to Endo's sales force, which adopted its misleading messaging in its nationwide sales approach, including the approach it used in Ohio.

276. Claims of improved functionality were central to Endo's marketing efforts for years. A 2012 Endo Business Plan lists way to position Opana ER, and among them is the claim that Opana ER will help patients "[m]aintain[] normal functionality, sleep, [and] work/life/performance productivity" and have a positive "[e]ffect on social relationships." Indeed, that business plan describes the "Opana ER Vision" as "[t]o make the Opana franchise (Opana ER, Opana, Opana Injection) the choice that maximizes improvement in functionality and freedom from the burden of moderate-to-severe pain."

277. On June 8th, 2017, in an unprecedented move, the FDA officially requested that Endo remove Opana ER from the market. The FDA cited its reasoning as "its concern that the benefits of the drug may no longer outweigh its risks."[50] The FDA acknowledged 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 consequence of its abuse."[51]

(vi) Actavis Sales Representatives Misrepresented the Safety and Efficacy of Its Opioid Drugs to Physicians

278. Like the other Manufacturer Defendants, Actavis encouraged its sales representatives to develop close relationships not only with physicians, but with their staff as well. The company even provided its sales representatives with an "Own the Nurse" kit as a "door opener" to time with HCPs. Actavis's sales representatives targeted physicians to deliver sales messages that were developed centrally and deployed uniformly across the country. These

[50] FDA News Release *FDA requests removal of Opana ER for risks related to abuse,"* available at https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm562401.htm

[51] *Id.*

sales representatives were critical in delivering Actavis's marketing strategies and talking points to individual prescribers.

279. Actavis's strategy and pattern of deceptive marketing is evident in its internal training materials. A sales education module titled *Kadian Learning System* trained Actavis's sales representatives on the marketing messages—including deceptive claims about improved function, the risk of addiction, the false scientific concept of "pseudoaddiction," and opioid withdrawal—that sales representatives were directed and required, in turn, to pass on to prescribers, nationally and in Ohio.

280. The expanded market also included internists and general practitioners who were low- to mid-volume prescribers. Actavis, for example, rolled out a plan in 2008 to move beyond "loyalists" to an "expanded audience" of "low morphine writers."

281. The sales training module, dated July 1, 2010, includes the misrepresentations documented in this Amended Complaint, starting with its promise of improved function. The sales training instructed Actavis sales representatives that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy," when, in reality, available data demonstrate that patients on chronic opioid therapy are less likely to participate in daily activities like work. The sales training also misleadingly implied that the dose of prescription opioids could be escalated without consequence and omitted important facts about the increased risks of high dose opioids.

282. First, Actavis taught its sales representatives, who would pass the message on to doctors, that pain patients would not develop tolerance to opioids, which would have required them to receive increasing doses: "Although tolerance and dependence do occur with long-term

use of opioids, many studies have shown that tolerance is limited in most patients with [chronic pain]."

283. Second, Actavis instructed its sales personnel that opioid "[d]oses are titrated to pain relief, and so no ceiling dose can be given as to the recommended maximal dose." Actavis failed to explain to its sales representatives and, through them, to doctors, the greater risks associated with opioids at high doses.

284. Further, the 2010 sales training module highlighted the risks of alternate pain medications without providing a comparable discussion of the risks of opioids, painting the erroneous and misleading impression that opioids are safer. Specifically, the document claimed that "NSAIDs prolong the bleeding time by inhibiting blood platelets, which can contribute to bleeding complications" and "can have toxic effects on the kidney." Accordingly, Actavis coached its sales representatives that "[t]he potential toxicity of NSAIDs limits their dose and, to some extent, the duration of therapy" since "[t]hey should only be taken short term." By contrast, the corresponding section related to opioids neglects to include a single side effect or risk associated with the use of opioids, including from long-term use.

285. This sales training module also severely downplayed the main risk associated with Kadian and other opioids—addiction. It represented that "there is no evidence that simply taking opioids for a period of time will cause substance abuse or addiction" and, instead, "[i]t appears likely that most substance-abusing patients in pain management practices had an abuse problem before entering the practice." This falsely suggests that few patients would become addicted, that only those with a prior history of abuse are at risk of opioid addiction, and that doctors could screen for those patients and safely prescribe to others. To the contrary, opioid addiction affects a significant population of patients; while patients with a history of abuse may

be more prone to addiction, all patients are at risk, and doctors may not be able to identify, or safely prescribe to, patients at greater risk. The sales training also noted that there were various "signs associated with substance abuse," including past history or family history of substance or alcohol abuse, frequent requests to change medication because of side effects or lack of efficacy, and a "social history of dysfunctional or high-risk behaviors including multiple arrests, multiple marriages, abusive relationships, etc." This is misleading, as noted above, because it implies that only patients with these kinds of behaviors and history become addicted to opioids.

286. Further, the sales training neglected to disclose that no risk-screening tools related to opioids have ever been scientifically validated. The Agency for Healthcare Research and Quality ("AHRQ") recently issued an Evidence Report that could identify "[n]o study" that had evaluated the effectiveness of various risk mitigation strategies—including the types of patient screening implied in Actavis's sales training—on outcomes related to overdose, addiction, abuse or misuse.

287. The sales training module also directed representatives to counsel doctors to be on the lookout for the signs of "[p]seudoaddiction," which were defined as "[b]ehaviors (that mimic addictive behaviors) exhibited by patients with inadequately treated pain." However, the concept of "pseudoaddiction" is unsubstantiated and meant to mislead doctors and patients about the risks and signs of addiction. The 2010 national training materials trivialized the harms associated with opioid withdrawal by explaining that "[p]hysical dependence simply requires a tapered withdrawal should the opioid medication no longer be needed." This, however, overlooks the fact that the side effects associated with opioid withdrawal are severe and a serious concern for any person who wishes to discontinue long-term opioid therapy.

288. Actavis's documents also indicate that the company continued to deceptively market its drugs after 2010. Specifically, a September 2012 Kadian Marketing Update, and the "HCP Detail" aid contained therein, noted that Kadian's "steady state plasma levels" ensured that Kadian "produced higher trough concentrations and a smaller degree of peak-to-trough fluctuations" than other opioids.

289. Actavis also commissioned surveys of prescribers to ensure Kadian sales representatives were promoting the "steady-state" message. That same survey—paid for and reviewed by Actavis—found repeated instances of prescribers being told by sales representatives that Kadian had low potential of abuse or addiction. This survey also found that prescribers were influenced by Actavis's messaging. A number of Kadian prescribers stated that they prescribed Kadian because it was "without the addictive potential" and would not "be posing high risk for addiction." As a result, Actavis's marketing documents celebrated a "perception" among doctors that Kadian had "low abuse potential."

290. A July 2010 "Dear Doctor" letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion." According to the FDA, "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients

may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[52]

291. In an effort to substantiate their marketing claims, Actavis sales representatives discussed Treatment Guidelines (*see* Scientific Literature Marketing Enterprises, *infra*) with HCPs during individual sales visits including visits throughout the United States and Ohio.

292. Actavis sales representatives trained with a uniform, nationally used, education model called "Kadian Learning System," which trained representatives on the marketing messages they were required to pass onto prescribers, including deceptive claims about improved function, the risk of addiction, and withdrawal.

293. Actavis also devoted time and resources to detailing its Opioid Drugs. In 2011 alone, Actavis expended $6.7 million on drug detailing. In 2014, Actavis spent at least $2 million.

294. Actavis trained its sales force that increasing and restoring function is an expected outcome of chronic Kadian therapy, including physical, social, vocational, and recreational function.

295. Likewise, Actavis trained its sales force that discontinuing opioid therapy can be handled "simply" and that it can be done at home. Actavis's sales representative training claimed opioid withdrawal would take only a week, even in addicted patients.

296. Actavis sales representatives told Ohio prescribers that prescribing Actavis's Opioid Drugs would improve their patients' ability to function and improve their quality of life.

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

297. Kadian sales representatives told Ohio prescribers that Kadian was "steady state" and had extended release mechanisms, the implication of which was that it did not produce a rush or euphoric effect, and therefore was less addictive and less likely to be abused.

298. Kadian sales representatives told Ohio prescribers that the contents of Kadian could not be dissolved in water if the capsule was opened, implying that Kadian was less likely to be abused—and thereby less addictive—than other opioids.

299. Kadian sales representatives omitted any discussion of addiction risks related to Actavis's Opioid Dugs to Ohio prescribers.

(vii) Insys Sales Representatives Misrepresented the Safety and Efficacy of Subsys to Physicians

300. Fentanyl is a powerful drug that can cause serious side effects, including death. For this reason, the TIRF REMS Access Program advises all "stakeholders" to "[p]romptly report suspected adverse events associated with the use of a TIRF medicine including misuse, abuse, and overdose directly to the TIRF REMS Access program . . . [and/or] to the FDA MedWatch Reporting System."[25] Between August 13, 2011, and August 12, 2014, there were a total of 13,196 cases and 48,323 incidents, with 2,356 deaths reported through the FDA Adverse Event Reporting System ("FAERS") in which one of the drugs reported contained fentanyl as an active ingredient - not necessarily Subsys.

301. In order to increase the number of Subsys prescriptions for which it received reimbursement and to obtain reimbursement for unsafe and unapproved prescriptions of Subsys, Insys directed and engaged in a conspiracy with prescribers to increase the number of Subsys prescriptions written and to provide material misrepresentations during the prior-authorization process regarding whether patients had breakthrough cancer pain and/or were opioid tolerant in order to obtain reimbursements for those prescriptions.

302. The top ten prescribers of Subsys were paid handsomely for their participation in the speaker program – collectively receiving more than $870,000 in speaker fees in 2013 and 2014 alone.

303. Two physicians in Mobile, Alabama, operated a pain management clinic and between 2012, when Subsys became available, and 2013, they became among the top prescribers in the United States. However, of the thousands of patients they treated, very few had cancer, which indicated they had a prominent role in the scheme.[53]

304. In October 2013, the clinic prescribed Subsys more than any other medicine. During that month, the physicians — Dr. John Couch and Dr. Xiulu Ruan — together wrote 110 prescriptions. Furthermore, of those prescriptions, 33 were for patients who had previously never been prescribed the medicine, and nearly all were written off-label to patients who did not have cancer.[54]

305. Insys compensated these two physicians for the prescribing practices by paying them nearly $210,000, mostly in speaking and consulting fees, in 2013 and 2014, according to the Open Payments database, which tracks payments made by drug makers to physicians.[55]

306. But Insys's efforts to funnel illegal kickbacks to Subsys prescribers were not limited to speaker fees. The company also offered valuable administrative services to prescribers' offices at no charge in exchange for Subsys prescriptions. To that end, Insys created a "reimbursement unit" that was deployed to prescriber practices to handle the prior-authorization process. As discussed in greater detail below, these free services not only benefited

[53] Ed Silverman, *Former sales rep for opioid drug maker pleads guilty to kickbacks*, Pharmalot, (February 22, 2016), available at https://www.statnews.com/pharmalot/2016/02/22/insys-therapeutics-sales-rep-opioid-kickbacks/.

[54] *Id.*

[55] *Id.*

the prescribers, but also allowed Insys to control the (false) messaging to health plans, including MMO.

307. In addition, Insys was engaged in a scheme to promote Subsys for unapproved and unsafe uses in order to increase the number of Subsys prescriptions written.

308. Insys sales representatives aggressively targeted high-volume opioid drug prescribers without regard to the suitability of the patient population for the approved use of Subsys.

309. Insys misrepresented to prescribers and patients the approved use and dosage parameters for Subsys.

310. Insys sales representatives encouraged prescribers to disregard FDA approved indications and FDA mandated dosing, instead marketing Subsys for breakthrough pain generically.

311. Then, once the prescriptions were written, using its "reimbursement unit," Insys conspired with prescribers to fraudulently obtain prior authorizations for non-covered prescriptions.

312. Insys's fraudulent scheme has received much scrutiny by the federal and state governments.

313. In December of 2016, several of Insys's pharmaceutical executives and managers were indicted for, *inter alia*, conspiracy to mislead and defraud health insurance providers who were reluctant to approve payment for the drug when prescribed for non-cancer patients.

314. According to the indictment, Insys achieved its goal of increasing prescriptions by setting up its "reimbursement unit,' which was dedicated to obtaining prior authorization directly from health plans and pharmacy benefit managers.

315. Among other things, the executives were charged with conspiracy to commit racketeering, conspiracy to commit wire and mail fraud, and RICO conspiracy.

(viii) Mallinckrodt Sales Representatives Misrepresented the Safety and Efficacy of Its Opioid Drugs to Physicians

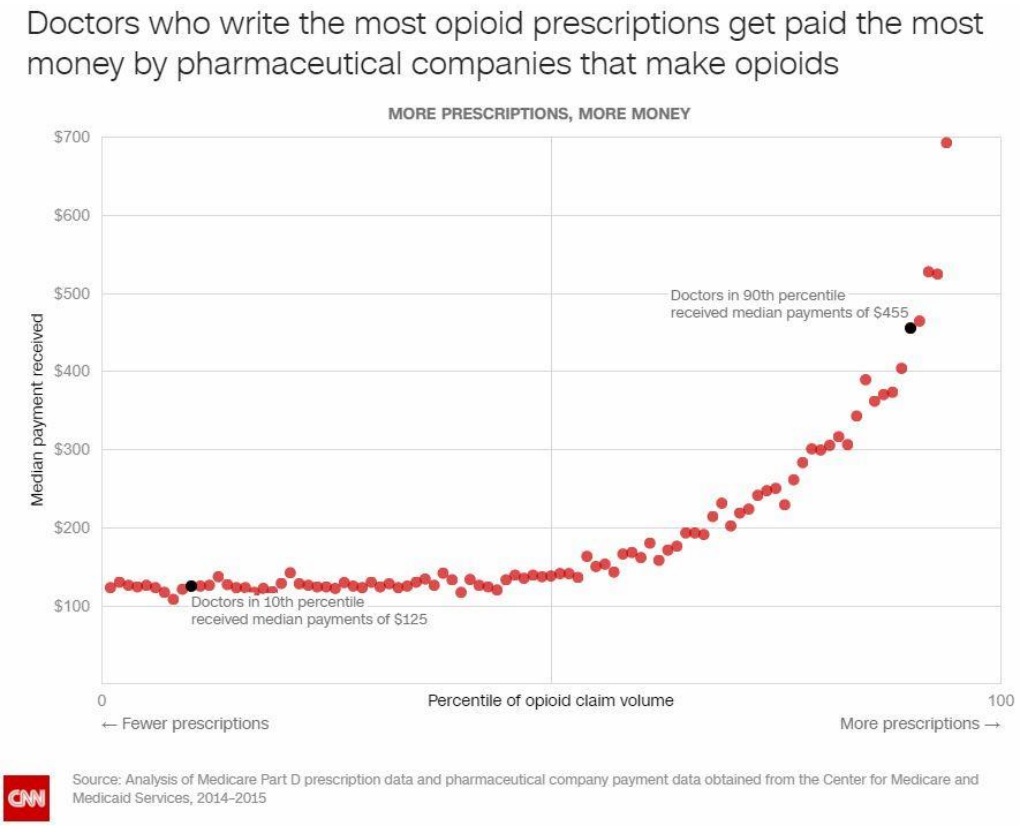
316. Upon information and belief, each Manufacturer Defendant, including Mallinckrodt, promoted the use of opioids for chronic pain through "detailers," who were sales representatives who visited individual physicians and their staff in their offices and small group speaker programs.

2. False and Misleading Branded Promotion Through Speaker Programs

317. The Manufacturer Defendants' branded marketing efforts to physicians also included financial incentives for physicians to prescribe opioids. Such payments are typically disguised as speaking or consulting fees.

318. A March 2018 Harvard University / CNN study looked at opioid manufacturer payments to prescribing physicians in 2014-2015 and found some startling results. Not only did "opioid manufacturers [pay] hundreds of HCPs sums in the six figures, while thousands more were paid over $25,000," but "the more opioids a doctor prescribes, the more money he or she gets paid by those same manufacturers,"[56] as the following chart illustrates:

[56] *The More opioids doctors prescribe, the more they get paid*, HARVARD SCHOOL OF PUBLIC HEALTH (Mar. 2018), available at https://www.hsph.harvard.edu/news/hsph-in-the-news/opioids-doctors-prescriptions-payments/.



319. As noted by one industry watchdog, "[t]his is the first time we've seen this, and it's really important."[57] The Executive Director of Physicians for Responsible Opioid Prescribing noted that it "smells like doctors being bribed to sell narcotics[.]"[58]

320. In all, between 2014 and 2015, *more than 200,000* doctors who wrote Opioid Drug prescriptions received payments from manufacturers, including the Manufacturer Defendants.[59]

321. Predictably, the Manufacturer Defendants counted on their Front Groups to handle spin control. In a recent CNN interview, AAPM President Dr. Steven Stanos downplayed the study's link between high prescribers and high payments, because high prescribers "know

[57] Aaron Kessler and Elizabeth Cohen, *The more opioids doctors prescribe, the more money they make*, CNN (Mar. 12, 2018), https://www.cnn.com/2018/03/11/health/prescription-opioid-payments-eprise/index.html.

[58] *Id.*

[59] *Id.*

those medicines, and so they're going to be more likely to prescribe those because they have a better understanding." He then went on to hit another Front Group talking point, that the payments may have been to HCPs to educate other HCPs about "abuse-deterrent" opioids.[60]

322. One common way such payments are made are through the Manufacturer Defendants' selection of a high prescriber to serve on paid "speakers' bureaus" and/or to attend programs with free meals and other amenities. Although these meal-based speaker events are more expensive to host and typically have lower attendance than CMEs, they are subject to less professional scrutiny and thus afford Defendants greater freedom in the messages they present. Indeed, the two were combined in many cases, such that the paid members of the "speakers bureau" would receive an all-expenses-paid "training" at lavish resorts.

323. The Defendants regularly used speaker program monies to reward "high writer" Ohio doctors: For example, Cleveland, Ohio pain doctor Dr. Riad Laham was a regular speaker for the Defendants, receiving between 2013 and 2016 some $549,341.09 from eight of the defendants: Insys, Teva, Depomed, Mallinckrodt, Janssen, Purdue, and Endo.[61] Dr. Laham has been a regular prescriber of the Opioid Drugs, including Nucynta, fentanyl, oxycodone, and hydrocodone.[62] According to Cleveland.com, Dr. Laham in 2013 wrote a letter to the FDA opposing limits on the use of Opioids, stating his view that Opioids are the "corner stone" of

[60] *Id.*

[61] "Physician Profile - Open Payments Data - CMS | Riad Laham." *OpenPaymentsData.CMS.gov*, openpaymentsdata.cms.gov/physician/105419/summary.

[62] Prescriber Checkup - RIAD LAHAM MD." *Prescriber Checkup*, ProPublica, projects.propublica.org/checkup/providers/1316900210.

treating and managing pain, declaring that the long-term negative effects of opiate treatment are "acceptable" and "manageable."[63]

324. Fairfield, Ohio, pain doctor Dr. Hammam Akbik is among the top 10 prescribers of Nucynta in the country and has received some $79,648.76 between 2013 and 2016 from eight of the defendants: Insys, Teva, Depomed, Mallinckrodt, Janssen, Purdue, Endo., and Actavis.[64] Eighty-nine percent of this provider's patients filled at least one prescription for an opioid including Nucynta, oxycodone, hydrocodone, oxycodone HCL, fentanyl, and OxyContin.[65]

325. Cincinnati, Ohio pain doctor Dr. Rajbir Minhas is among the top 10 prescribers of Oxycodone-Acetaminophen in the country and has received some $145,281.11 between 2013 and 2016 from eight of the defendants: Insys, Teva, Depomed, Mallinckrodt, Janssen, Purdue, Endo, and Actavis.[66] Dr. Minhas has been a regular prescriber of the Opioid Drugs, including Nucynta, oxycodone, hydrocodone, fentanyl, oxycodone HCL, Butrans, Opana ER, OxyContin, Endocet, and oxymorphone HCL ER.[67]

326. Toledo, Ohio pain doctor Dr. James Otting was a regular speaker for the Defendants, receiving between 2013 and 2016 some $134,749.67 from eight of the defendants: Insys, Teva, Depomed, Mallinckrodt, Janssen, Purdue, Endo, and Actavis.[68] Dr. Otting has been a regular prescriber of the Opioid Drugs, including Nucynta, Nucynta ER, oxycodone,

[63] Koff, Stephen. "Painkiller-Abuse Proposal Divides Healthcare Community, Even in Same Hospitals." *Cleveland.com*, Mar. 3, 2013, www.cleveland.com/open/index.ssf/2013/03/proposed_painkiller-abuse_rule.html.

[64] Open Payments, https://openpaymentsdata.cms.gov/physician/82191/summary

[65] Prescriber Checkup, https://projects.propublica.org/checkup/providers/1821041674.

[66] Open Payments, https://openpaymentsdata.cms.gov/physician/187065/summary

[67] Prescriber Checkup, https://projects.propublica.org/checkup/providers/1134175409

[68] OpenPayments, *OpenPaymentsData.CMS.gov*,https://openpaymentsdata.cms.gov/physician /113772/summary

oxycodone HCL, fentanyl, OxyContin, oxymorphone HCL ER, Zohydro ER, Butrans, Opana ER, and oxymorphone HCL.[69]

327. Hamilton, Ohio, pain doctor Dr. Nilesh Jobalia received some $105,008.82 between 2013 and 2016 from six of the defendants: Insys, Teva, Depomed, Mallinckrodt, Purdue, and Endo.[70] Dr. Jobalia is one of the top 10 prescribers in the country of multiple Opioid Drugs, including Hysingla ER, hydromorphone ER, oxymorphone HCL, and OxyContin.[71] Dr. Jobalia also prescribes Opana ER, oxycodone HCL, oxycodone, hydrocodone, fentanyl, oxymorphone HCL ER, Subsys, and Endocet.[72]

328. Toledo, Ohio pain doctor Dr. Nadeem Moghal was a regular speaker for the Defendants, receiving some $236,888.23 between 2013 and 2016 from eight of the Defendants: Insys, Teva, Depomed, Mallinckrodt, Janssen, Purdue, Endo, and Actavis.[73] Dr. Moghal has been a regular prescriber of the Opioid Drugs, including oxycodone, hydrocodone, oxycodone HCL, fentanyl, Nucynta, and OxyContin.[74]

329. Sandusky, Ohio pain doctor Dr. Gregory Gerber received some $177,757.92 between 2013 and 2016 from six of the Defendants: Insys, Teva, Depomed, Mallinckrodt, Purdue Transdermal Technologies L.P., Endo.[75] Most notably, Insys Therapeutics Inc. contributed some $176,864.48 towards that sum. Ninety-six percent of this provider's patients

[69] Prescriber Checkup, https://projects.propublica.org/checkup/providers/1497953749

[70] Open Payments, https://openpaymentsdata.cms.gov/physician/268125/summary

[71] Prescriber Checkup, https://projects.propublica.org/checkup/providers/1902884455

[72] Prescriber Checkup, https://projects.propublica.org/checkup/providers/1902884455

[73] Open Payments, https://openpaymentsdata.cms.gov/physician/288441/summary

[74] Prescriber Checkup, https://projects.propublica.org/checkup/providers/1376529578

[75] Open Payments, https://openpaymentsdata.cms.gov/physician/105460/summary

filled at least one prescription for an opioid, including Opana ER, oxycodone HCL, OxyContin, Fentanyl, oxymorphone HCL ER, and hydrocodone.[76]

330. Westerville, Ohio, pain doctor Dr. Jimmy Henry received some $79,480.74 between 2013 and 2016 from nine of the Defendants: Insys, Teva, Depomed, Mallinckrodt, Janssen, Purdue, Endo, and Actavis.[77] Dr. Henry has been a regular prescriber of the Opioid Drugs, including Opana ER, oxycodone HCL, oxycodone, fentanyl, hydrocodone, and Subsys.[78]

331. Cuyahoga Falls, Ohio, pain doctor Dr. Syed Ali received $66,833.59 between 2013 and 2016 from six of the Defendants: Teva, Depomed, Mallinckrodt, Purdue, and Endo.[79] Dr. Ali has been a regular prescriber of the Opioid Drugs, including oxycodone, hydrocodone, oxycodone HCL, fentanyl, Butrans, and OxyContin.

332. A Dayton pain doctor with a surrendered medical license, Dr. Morris Brown, has been among one of the top 10 prescribers of Endocet in the country and has received some $82,675.93 from nine of the Defendants, with Janssen Pharmaceuticals contributing $81,783.38 to that sum.[80] The Defendants include Teva, Janssen, Johnson & Johnson Health Care Systems Inc., Purdue, Endo, Actavis., Forest Pharmaceuticals, Inc., and Actavis Pharma Inc.[81] Dr. Brown has prescribed the Opioid Drugs hydrocodone, oxycodone, Endocet, oxycodone HCL, fentanyl, and OxyContin.[82] In May of 2017, Ohio's State Medical Board accused and then concluded that

[76] Prescriber Checkup, https://projects.propublica.org/checkup/providers/1336228022

[77] Open Payments, https://openpaymentsdata.cms.gov/physician/70236/summary

[78] Prescriber Checkup, https://projects.propublica.org/checkup/providers/1548483670

[79] Open Payments, https://openpaymentsdata.cms.gov/physician/56015/summary

[80] Open Payments, https://openpaymentsdata.cms.gov/physician/52920/summary

[81] Open Payments, https://openpaymentsdata.cms.gov/physician/52920/summary

[82] Prescriber Checkup, https://projects.propublica.org/checkup/providers/1184608267

Dr. Brown prescribed dangerous combinations of opioids and practiced below minimal standards of care.[83]

333. Richmond Heights, Ohio, pain doctor Dr. Sami Moufawad received some $72,557.24 between 2013 and 2016 from seven of the Defendants: Teva, Depomed, Mallinckrodt, Janssen, Purdue, and Endo.[84] Dr. Moufawad has been a regular prescriber of the Opioid Drugs, including oxycodone, hydrocodone, oxycodone HCL, and OxyContin.

334. Marysville, Ohio, pain doctor, Dr. Kedar Deshpande, received some $53,459.16 between 2013 and 2016 from nine of the Defendants: Insys, Teva, Depomed, Mallinckrodt, Janssen, Purdue, Endo, and Actavis.[85] Eighty-six percent of this provider's patients filled at least one prescription for an opioid, including oxycodone, oxycodone HCL, hydrocodone, fentanyl, and OxyContin.[86]

(i) Purdue's Use of Speaker Programs as Part of Its False and Misleading Branded Promotion of Its Opioid Drugs

335. From the beginning, much of Purdue's marketing was directed at prescribers. By 2000, Purdue had approximately 94,000 doctors on its physician call list.[87] Purdue also recruited and paid respected health care professionals as "speakers" who presented Purdue-approved programs to other prescribers at lunch and dinner events. From 1996 to 2001, Purdue held more than 40 national conferences and more than 5,000 physicians, pharmacist, and nurses attended these speaker conferences.[88] In addition to speaker programs, Purdue targeted doctors with

[83] Riepenhoff, Jill. "Case Study: Dr. Morris Brown." *WTOL Toledo News Weather and Sports*, 19 Feb. 2018, www.wtol.com/story/37540348/case-study-dr-morris-brown.

[84] Open Payments, https://openpaymentsdata.cms.gov/physician/342625/summary

[85] Open Payments, https://openpaymentsdata.cms.gov/physician/81302/summary

[86] Prescriber Checkup, https://projects.propublica.org/checkup/providers/1801891007

[87] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. J. Pub. Health 221–227 (2009).

[88] *Id.*

"educational" programing and funded more than 20,000 pain-related educational programs through direct sponsorship or financial grants by July 2002.[89]

336. During that same five-year period, Purdue sponsored dozens of all-expenses paid national pain-management and speaker-training conferences attended by thousands of physicians, pharmacists, and nurses, who were then recruited and trained for the pharmaceutical company's national speaker bureau. Purdue sent sales representatives out to physicians across the country, plying them with marketing materials and distributing promotional items branded with the OxyContin name to such a degree that, according to the DEA, it was unprecedented for a Schedule II narcotic.[90]

337. It was a highly coordinated effort to convince medical professionals that OxyContin was safe and effective for patients with chronic pain. And, it worked. When the FDA was struggling to come up with an opioid policy, it relied on a panel of doctors, many of whom had financial relationships with Purdue Pharma and other drug makers.[91] Pain brings more people into contact with medical professionals than any other problem. The most common medical treatment for all forms of pain became opioid medications (the so-called "painkillers"), such as hydrocodone (Vicodin, Lortab) and oxycodone (Percoset, OxyContin).

(ii) Cephalon's Use of Speaker Programs as Part of Its False and Misleading Branded Promotion of Its Opioid Drugs

338. Cephalon utilized similar techniques. Its "Pain Knowledge Mapping Project" was a project specifically designed to "identify and profile prominent experts in the field of pain

[89] *Id.*

[90] *Id.*

[91] General Accounting Office, Publication GAO-04-110, Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem (Washington, DC: General Accounting Office, 2003).

management," and an "[e]ditorial board" of "[t]op-tier advisors" to be composed entirely of "5-6 pain specialists."

339. Beginning after the Fentora launch in 2006, Cephalon's pain sales force set up hundreds of speaker programs for HCPs during which unapproved and unsafe promotional presentations were offered that flouted the FDA prohibitions on such conduct. The programs were rife with illegal promotional activities. The sales force chose the topics and the speakers, who in many instances were chosen because they were also high-decile prescribers. Fentora had nearly 200 speakers, that were paid an honoraria of $1,500 to $2,000 per event, and could give two to three events per day, with some speakers earning tens of thousands of dollars per year. As such, the speaker monies were an improper effort to develop KOL product allegiance and improve the relationships between the speakers and Cephalon.

340. For example, as he was directed to do by his manager, former Cephalon sales manager, Alec Burlakoff, organized numerous speaker programs in the Florida region in order to promote unsafe and unapproved sales of Fentora for the treatment of breakthrough pain.

341. Cephalon provided the selected physician speakers with training and a Cephalon-approved Fentora promotional speaker slide deck. Speakers, however, were permitted to create and add their own slides into the presentation. These slides would discuss the doctor's personal experience with prescribing Fentora, which included discussions of how they used Fentora for unsafe and unapproved uses in their own practice. Although sales representatives and sales managers were aware that these slides promoted prohibited off-label prescribing, Cephalon turned a blind eye, believing apparently that speakers were, as a practical matter, less likely to get caught, since attending physicians would be more likely to report an objectionable unsafe and

unapproved message delivered by a sales representative than one delivered by a physician colleague.

342. Cephalon did not enforce the legal requirements that paid physician speakers limit their promotional presentations to on-label uses (as was required of Cephalon's sales representatives). Cephalon instructed its Fentora sales force that, if HCPs were speaking to one another—even a Cephalon-selected and paid speaker—off-label discussions were the intended and acceptable outcome.

343. Indeed, Cephalon *expected* that the speakers would initiate off-label discussions, and Cephalon's sales representatives understood that they were *not* to interrupt those discussions, or report them to their supervisors, or prevent the use of speaker-created slides concerning unsafe and unapproved use since doing so would limit the effectiveness of the underlying sales pitch, thereby placing their jobs in jeopardy. There was no compliance review of the numerous speaker events that would even permit such oversight of off-label content.

344. Cephalon retained numerous physicians as Fentora speakers who do not generally (or at all) treat breakthrough cancer pain. For example, the Company retained internal medicine, general practitioners, family medicine practitioners, and other primary care physicians who have prescribing patterns similar to those of pain specialists.

345. The following are examples of some of the physicians retained by Cephalon's pain sales force as speakers in order to promote Fentora for unapproved and unsafe uses:

- Dr. Stephen Landy, a neurologist from Cordova, Tennessee, gave Fentora speaker programs and was paid $98,600 in honoraria in 2009, and $90,979 in speaking and travel fees in 2010. As a neurologist, Dr. Landy did not generally treat cancer patients.
- Dr. Donald R. Taylor, an anesthesiologist from Marietta, Georgia gave Fentora speaker programs and was paid $142,050 in honoraria in 2009. He primarily prescribed Fentora for unsafe and unapproved uses.

- Dr. Wayne Anderson, a neurologist from San Francisco, California gave some 37 Fentora speaker programs for Cephalon in 2009 and 2010 and was paid $173,950. He runs a neurology, pain, headache clinic and is not likely to treat cancer patients.
- Dr. Paul Brown, an internal medicine doctor and rheumatologist gave some 20 Fentora speaker programs for Cephalon in 2009 and 2010, and was paid $99,800. He is not likely to treat cancer patients.
- Dr. James McMillen, an internal medicine doctor and rheumatologist gave some 19 Fentora speaker programs for Cephalon in 2009 and 2010, and was paid $126,000. He is not likely to treat cancer patients.
- Dr. Riad Laham, a pain management and anesthesiologist at the Cleveland Clinic in Cleveland, Ohio, was paid $95,900 in 2009 and 2010 for speaker programs. He is not likely to treat cancer patients.

346. Cephalon used Fentora speaker programs to intentionally target the broader range of non-oncologists in an effort to expand the use of Fentora beyond its lone approved indication.

(iii) Janssen's Use of Speaker Programs as Part of Its False and Misleading Branded Promotion of Its Opioid Drugs

347. Janssen did not stop at disseminating its misleading messages regarding chronic opioid therapy through its sales force. It also hired speakers to promote its drugs and trained them to make the very same misrepresentations made by its sales representatives.

348. In order to increase sales of its opioid drugs Nucynta, Nucynta ER, and Ultram ER, Janssen provided monetary and other incentives for physicians who were willing to prescribe the drugs. Janssen trained, managed, and instructed its sales representatives, business and marketing managers, and other executives to offer physicians cash payments, expensive trips and meals, expensive gifts, and entertainment as kickbacks in exchange for the physicians' agreement to prescribe Janssen's Opioid Drugs Nucynta, Nucynta ER, and Ultram ER.

349. Janssen's marketing and sales strategy documents show that at least on a weekly basis Janssen were tracking prescription volume by doctor, and tracking the percentage change in prescribing habits of physicians for Janssen's drugs. In addition, Janssen tracked the return on investment ("ROI") of paid travel and expensive meals for physicians. Janssen's sales

representatives were instructed to ask physicians for additional prescriptions when the physicians were paid to speak at a lavish meal event, and told to track follow-up prescriptions by the physician, and to hold the physicians accountable if the physicians did not increase prescriptions of Janssen's Opioid Drugs.

350. Physicians were made aware by sales representatives that the physicians would not continue to be invited to lavish meals if the physicians did not remain in the high volume prescriber range, and if the physicians did not prescribe Janssen's Opioid Drugs. Physicians who did not continue to prescribe Janssen's Opioid Drugs were tracked on a quarterly basis by Janssen's marketing and sales personnel, and were sometimes penalized by being taken off target lists for invitations to future lavish meals and offers of speaking engagements, paid research opportunities, and other perks. Janssen's pushed "prescribe to play," quid pro quo-focused sales strategies, which are based entirely on the amount of prescriptions written by the physicians and the ability of the physician to influence other physicians to begin prescribing Janssen's drugs. The recipients of these awards and benefits were selected by Janssen's marketers based on the recipients' ability to prescribe its Opioid Drugs Nucynta, Nucynta ER, and Ultram ER, and to influence other doctors to do so.

351. Janssen's speakers worked from slide decks—which they were required to present—reflecting the deceptive information about the risks, benefits, and superiority of opioids outlined above. For example, a March 2011 speaker's presentation titled *A New Perspective For Moderate to Severe Acute Pain Relief: A Focus on the Balance of Efficacy and Tolerability* set out the following adverse events associated with use of Nucynta: nausea, vomiting, constipation, diarrhea, dizziness, headache, anxiety, restlessness, insomnia, myalgia, and bone pain. It completely omitted the risks of misuse, abuse, addiction, hyperalgesia, hormonal dysfunction,

decline in immune function, mental clouding, confusion, and other known, serious risks associated with chronic opioid therapy. The presentation also minimized the risks of withdrawal by stating that "more than 82% of subjects treated with tapentadol IR reported no opioid withdrawal symptoms."

352. An August 2011 speaker presentation titled *New Perspectives in the Management of Moderate to Severe Chronic Pain* contained the same misleading discussion of the risks associated with chronic opioid therapy. It similarly minimized the risks of withdrawal by reporting that 86% of patients who stopped taking Nucynta ER "abruptly without initiating alternative opioid therapy" reported no withdrawal symptoms whatsoever. The same deceptive claims regarding risks of adverse events and withdrawal appeared in a July 2012 speaker's presentation titled *Powerful Pain Management: Proven Across Multiple Acute and Chronic Pain Models.*

353. These speakers' presentations were part of Janssen's nationwide marketing efforts. A number of these events were available to and were intended to reach Ohio prescribers

(iv) Depomed's Use of Speaker Programs as Part of Its False and Misleading Branded Promotion of Its Opioid Drugs

354. In yet another attempt to increase revenue and market share, Depomed paid speaker fees to physicians to induce them to write Lazanda or Nucynta prescriptions that were reimbursed through TPP health plans. As a façade for this arrangement, Depomed conducted speaker programs that were actually vehicles for paying monies to physicians under the guise of honoraria. These financial benefits were offered with the understanding that, in exchange, the physicians would preferentially prescribe or indicate the use of Lazanda or Nucynta to treat their patients. Through Depomed's speaker programs, physician speakers were ostensibly paid to speak at ongoing speaking engagement events to educate other doctors and health care

professionals about Lazanda or Nucynta. In practice, however, Depomed's speaker program exists to induce physicians to increase the quantity of Lazanda or Nucynta prescriptions they write.

355. Specifically, Depomed offered ongoing speaker positions to pain management physicians, whom it deemed "high writers" – physicians writing five or more prescriptions per month. These speaking arrangements usually consisted of dinners with colleagues. Significantly, these speaking engagements never included physicians who treat cancer patients.

356. The qualifications of the physicians hired as speakers by Depomed demonstrate that its speaker program was nothing more than a mechanism to facilitate kickbacks in return for writing Lazanda or Nucynta prescriptions. The criteria used to determine which physicians to offer speaker positions to depended primarily upon the volume of Lazanda or Nucynta prescriptions written.

357. As Lazanda's indicated use is pain management for cancer patients, it would be reasonable to expect that the physicians Depomed selected to educate and inform other physicians and health care professionals about the drug would be oncologists, or otherwise have at least some level of expertise in dealing with cancer patients. And yet, Depomed did not condition its selection of speakers on whether they had a pedigree that included cancer treatment. Instead, Depomed focused solely on those physicians who wrote the most prescriptions for Lazanda.

358. And, because Depomed's focus was on rewarding high writers and not on actually educating, Depomed did not screen speakers based on academic or clinical accomplishments. Where a speaker's curriculum vitae ("CV") was relatively unspectacular, Depomed would simply not provide it to the speaker's "audience." In one example, a high writer/speaker's CV was never

circulated before his speaking engagements because he attended medical school at the Universidad Aut6noma de Guadalajara (Guadalajara Medical School), a school that was not prestigious enough.

359. In addition, Depomed's speaker program also demonstrated its intent to induce physicians to preferentially prescribe or indicate Lazanda to their patients. The speakers selected by Depomed were incapable of prescribing (or at best, highly unlikely to prescribe) Lazanda for its indicated use because their patient populations did not have cancer. Moreover, Depomed selected speakers who were high writers of Lazanda and attempted to conceal the fact that they had virtually no experience treating cancer patients. Indeed, Depomed's selection of non-cancer treating physicians, as well as its attempt to conceal this fact, demonstrates that Depomed intended and did, in fact, utilize its speaker program to fraudulently induce Lazanda prescriptions by providing illegal compensation to prescribing physicians.

(v) Endo's Use of Speaker Programs as Part of Its False and Misleading Branded Promotion of Its Opioid Drugs

360. In addition to its sales representatives' visits to doctors, Endo also used deceptive science and speaker programs to spread its deceptive messages.

361. Endo leaned heavily on its speakers' bureau programs. In 2008 alone, Endo spent nearly $4 million to promote up to 1,000 speakers' programs around the country. Endo contracted with a medical communications firm to operate its speakers' bureau program, planning to hold a total of 500 "fee-for-service . . . peer-to-peer promotional programs" for Opana ER in just the second half of 2011, including dinners, lunches and breakfasts. These programs were attended by sales representatives, revealing their true purpose as marketing, rather than educational, events.

362. In 2009, Endo wrote a talk titled *The Role of Opana ER in the Management of Chronic Pain.* The talk included a slide titled "Use of Opioids is Recommended for Moderate to Severe Chronic Non-cancer Pain," which cited the 2009 AAPM/APS Guidelines ("2009 Guidelines")—and their accompanying misstatements regarding the likelihood of addiction (by claiming that addiction risks were manageable regardless of patients' past abuse histories) while omitting their disclaimer regarding the lack of supporting evidence in favor of that position. This dangerously misrepresented to doctors the force and utility of the 2009 Guidelines.

363. These speakers' bureau presentations included the very same misrepresentations Endo disseminated through its sales representatives. A 2012 speaker slide deck for Opana ER—on which Endo's recruited speakers were trained and to which they were required to adhere to in their presentations—misrepresented that the drug had low abuse potential, in addition to suggesting that as many as one-quarter of the adult population could be candidates for opioid therapy.

364. Endo's internal reporting stated that the "return on investment" turned positive 8-12 weeks after such programs. Endo measured that return on investment in numbers of prescriptions written by physicians who attended the events. One internal Endo document concluded: "[w]e looked at the data for [the] 2011 program and the results were absolutely clear: physicians who came into our speaker programs wrote more prescriptions for Opana ER after attending than they had before they participated. You can't argue with results like that."

365. In addition, a 2013 training module directed speakers to instruct prescribers that "OPANA ER with INTAC is the only oxymorphone designed to be crush resistant" and advised that "[t]he only way for your patients to receive oxymorphone ER in a formulation designed to be crush resistant is to prescribe OPANA ER with INTAC." This was a key point in

distinguishing Opana ER from competitor drugs. Although Endo mentioned that generic versions of oxymorphone were available, it instructed speakers to stress that "[t]he generics are not designed to be crush resistant." This was particularly deceptive given that Opana ER was not actually crush-resistant.

366. The misleading messages and materials Endo provided to its sales force and its speakers were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, irrespective of the risks, benefits, and alternatives. This deception was national in scope and included Ohio. Endo's nationwide messages would have reached Ohio prescribers in a number of ways. For example, they were carried into Ohio by Endo's sales representatives during detailing visits as well as made available to Ohio patients and prescribers through websites and ads. They also have been delivered to Ohio prescribers by Endo's paid speakers, who were required by Endo policy and by FDA regulations to stay true to Endo's nationwide messaging.

367. Endo, for instance, sought to use specialists in pain medicine—including high prescribers of its drugs—as local thought leaders to market Opana ER to primary care doctors. Such invitations are lucrative to the physicians selected for these bureaus; honorarium rates range from $800 to $2,000 per program, depending on the type of event, and even speaker training typically is compensated at $500 per hour

(vi) Actavis's Use of Speaker Programs as Part of Its False and Misleading Branded Promotion of Its Opioid Drugs

368. Actavis also increasingly relied on speakers—physicians whom Actavis recruited to market opioid to their peers—to convey similar marketing messages. Actavis set a goal to train 100 new Kadian speakers in 2008 alone, with a plan to set up "power lunch teleconferences" connecting speakers to up to 500 participating sites nationwide. Actavis sales

representatives, who were required to make a certain number of sales visits each day and week, saw the definition of sales call expanded to accommodate these changes; such calls now included physicians' "breakfast & lunch meetings with Kadian advocate/speaker."

369. A training program for Actavis speakers included training on many of the same messages found in the Kadian Learning System, as described below. The deceptive messages in Actavis's speakers' training are concerning for two reasons: (a) the doctors who participated in the training were, themselves, prescribing doctors, and the training was meant to increase their prescriptions of Kadian, and (b) these doctors were trained, paid, and directed to deliver these messages to other doctors who would write prescriptions of Kadian.

370. Consistent with the training for sales representatives, Actavis's speakers' training falsely minimized the risk of addiction posed by long-term opioid use. Actavis claimed, without scientific foundation, that "[o]pioids can be used with minimal risk in chronic pain patients without a history of abuse or addiction." The training also deceptively touted the effectiveness of "Risk Tools," such as the Opioid Risk Tool, in determining the "risk for developing aberrant behaviors" in patients being considered for chronic opioid therapy. In recommending the use of these screening tools, the speakers' training neglected to disclose that none of them had been scientifically validated.

371. The speakers' training also made reference to "pseudoaddiction" as a "[c]ondition characterized by behaviors, such as drug hoarding, that outwardly mimic addiction but are in fact driven by a desire for pain relief and usually signal undertreated pain." It then purported to assist doctors in identifying those behaviors that actually indicated a risk of addiction from those that did not. Behaviors it identified as "[m]ore suggestive of addiction" included "[p]rescription forgery," "[i]njecting oral formulations," and "[m]ultiple dose escalations or other nonadherence

with therapy despite warnings." Identified as "[l]ess suggestive of addiction" were "[a]ggressive complaining about the need for more drugs," "[r]equesting specific drugs," "[d]rug hoarding during periods of reduced symptoms," and "[u]napproved use of the drug to treat another symptom." By portraying the risks in this manner, the speakers' training presentation deceptively gave doctors a false sense of security regarding the types of patients who can become addicted to opioids and the types of behaviors these patients exhibit.

372. The speakers' training downplayed the risks of opioids, while focusing on the risks of competing analgesics like NSAIDs. For example, it asserted that "Acetaminophen toxicity is a major health concern." The slide further warned that "Acetaminophen poisoning is the most common cause of acute liver failure in an evaluation of 662 US Subjects with acute liver failure between 1998-2003," and was titled "Opioids can be a safer option than other analgesics." However, in presenting the risks associated with opioids, the speakers' training focused on nausea, constipation, and sleepiness, and ignored the serious risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness; increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines. As a result, the training exaggerated the risks of NSAIDs, both absolutely and relative to opioids, to make opioids appear to be a more attractive first-line treatment for chronic pain.

373. The speakers' training also misrepresented the risks associated with increased doses of opioids. For example, speakers were instructed to "[s]tart low and titrate until patient reports adequate analgesia" and to "[s]et dose levels on [the] basis of patient need, not on predetermined maximal dose." However, the speakers' training neglected to warn speakers (and

speakers bureau attendees) that patients on high doses of opioids are more likely to suffer adverse events.

(vii) Insys's Use of Speaker Programs as Part of Its False and Misleading Branded Promotion of Subsys

374. Insys made payments to clinicians to induce them to write unsafe and unapproved prescriptions of Subsys. Some of these payments were made pursuant to a sham "speaker program" that Insys created to shield the illegality of its financial arrangements with the conspiring prescribers.

375. Through this "speaker program," Insys paid prescribers to give presentations on Subsys, purportedly to increase brand awareness via peer-to-peer educational lunches and dinners.

376. Insys's speaker programs were poorly disguised kickbacks. Insys hired selected doctors to give talks in promotional settings about Subsys. Insys sought "coachable" doctors willing to laud Subsys' effectiveness to other doctors. In addition, speakers were offered honoraria, ranging from $800 to $1200 per program, for their speaking engagements. Insys's payments to these doctors greatly exceeded the fair market value and reasonable compensation ordinarily given to a speaker in a typical arms-length transaction, particularly as presentations were often short and the audiences small.

377. Most of the presentations, however, would make only a cursory mention of Subsys, and in some there was no mention of Subsys at all. And many were attended only by the prescriber and sales representatives or others individuals who had no authority to prescribe the drug – thereby eliminating any question of the program's utility beyond masking Insys's real intent to pay prescribers for prescriptions.

378. Some speakers were chosen as a reward for prescribing drugs. In fact, as soon as Alec Burlakoff took over as Southeast Regional Sales Manager in June 2012, Burlakoff told the sales representatives under his direction that "speaker programs would be the key to their success" and that "the purpose of the speaker programs was to get money in the doctor's pocket." On September 12, 2012, Burlakoff was promoted to Vice President of Sales. As Vice President of Sales, Burlakoff continued to push the message that speakers should be writing one prescription a day in order to remain a Subsys speaker, particularly in light of the Company's view that speakers should have clinical experience with Subsys or be removed from the speaker program.

379. On September 19, 2012, Insys held a national meeting for all of its sales representatives in Phoenix, Arizona, where Insys's headquarters are located. The same day, Joe Rowan, who took over as the Southeast Regional Manager for Insys, sent an e-mail to the Southeast Region sales representatives, stating that they each needed to schedule six speaker programs over the next two weeks. When sales representatives told Rowan that they may not be able to meet this goal because some doctors were not writing more prescriptions after becoming speakers. Rowan responded that if he is "not putting pen to paper, we need to get rid of him."

380. Insys's kickback strategy raised the total cost assumed by MMO and other TPPs because doctors, blinded by Insys's remunerations, prescribed Subsys: (a) when they would not have otherwise if not for the kickbacks; or (b) when medically unnecessary and ineffective.

381. The prescribers chosen for these lucrative speaking opportunities are further evidence of the true motivation behind the program. Insys targeted prescribers running pain clinics – particularly those who were high-volume opioid prescribers – for these "speaker

programs," as opposed to oncologists treating patients that met the conditions set forth in the label.

382. Insys formed a sham speakers' bureau, the primary purpose of which was to facilitate peer-to-peer educational lunches and dinners to increase brand awareness. The Indictment against Insys alleges that executives would meet with, make telephone calls, and send text messages to Insys sales representatives informing them that the key to sales was using the speakers' bureau to pay practitioners to prescribe Subsys. One vice president for sales texted one of his sales representatives regarding potential physician speakers: "[t]hey do not need to be good speakers, they need to write a lot of [Subsys prescriptions.]" As such, Insys would actively recruit physicians known to have questionable prescribing habits.[92]

383. The Indictment further alleges that the speakers' bureaus were often simply social gatherings at expensive restaurants that involved neither education or presentations and often included repeat attendees, including physicians not licensed to prescribe Subsys. Many of the meetings had no attendees, in which case sales representatives were instructed to falsify a list of names and signatures on the sign-in sheets.

384. Speakers were not selected to share their expertise, but were rather paid to follow the slide decks provided to them by the Manufacturer Defendants. This is important because the FDA regards promotional talks as part of product labeling, and requires their submission for review. Speakers thus give the appearance of providing independent, unbiased presentations on opioids, when in fact they are presenting a script prepared by Defendants' marketing

[92] U.S. Attorney's Office for the District of Massachusetts, Press Release, Pharmaceutical Executives Charged in Racketeering Scheme (Dec. 8, 2016), *available at* https://www.justice.gov/usao-ma/pr/pharmaceutical-executives-charged-racketeering-scheme.

departments. Endo's speaker rules, for example, provide that "all slides must be presented in their entirety and without alterations . . . and in sequence."

385. Insys, working together with Linden Care, conducted a nationwide illegal scheme to market and sell Subsys, which also directly targeted Ohio citizens. Through kickbacks and bribes to doctors and other health care professionals, and other fraudulent means, Insys and Linden Care collectively made hundreds of millions of dollars while exposing Plaintiff MMO's members to the drug's extraordinary risks, including addiction, abuse, and, in many cases, death.

(viii) Mallinckrodt's Use of Speaker Programs as Part of Its False and Misleading Branded Promotion of Its Drugs

386. Mallinckrodt also made thousands of payments to physicians nationwide, including to Ohio physicians. Mallinckrodt paid physicians $1.2 million between 2014 and 2015 for consulting, promotional speaking events, and other services and support relating to its Opioid Drug Xartemis XR. The company made similar payments to physicians relating to Exalgo between 2013 and 2015 totaling $376,000.

3. The Manufacturer Defendants Used Physician-Targeted Advertisements, Websites and Pamphlets to Convey Their Misleading Branded Messages

387. The Manufacturer Defendants also engaged in false and misleading marketing to physicians by way of their physician-targeted advertisements, websites, pamphlets, and other promotional materials.[93] The Manufacturer Defendants placed advertisements in trade journals meant to reach prescribing physicians.

388. The advertisements were printed in various medical journals, including those aimed at specialists (such as the *Journal of Pain* and *Clinical Journal of Pain*) as well as a

[93] Unlike other physician-directed marketing materials, these were official advertisements wherein the Defendants were clearly listed as the sponsor.

broader array of medical professionals (such as the *Journal of the American Medical Association*)

389. In 2011 alone, the Manufacturer Defendants spent more than $14 million on medical journal advertising of opioids, nearly triple what they spent in 2001.

390. These advertisements contained deceptive messages regarding the safety and efficacy of the Opioid Drugs as a long-term treatment of chronic pain.

(i) Purdue Advertisements Convey Misleading Safety and Efficacy Messages

391. Purdue former CEO, Arthur Sackler, made his name in pharmaceutical advertising, which at the time consisted almost exclusively of pitches from so-called "detail men" who sold drugs to doctors door-to-door. Sackler intuited that print ads in medical journals could have a revolutionary effect on pharmaceutical sales, especially given the excitement surrounding the "miracle drugs" of the 1950s—steroids, antibiotics, antihistamines, and psychotropics. In 1952, the same year that he and his brothers acquired Purdue, Arthur became the first adman to convince the *Journal of the American Medical Association*, one of the profession's most august publications, to include a color "advertorial" brochure.[94]

392. When OxyContin hit the market in 1996, Purdue took out numerous ads in medical journals. One such ad featured a spotlight illuminating two dosage cups, one marked 8 AM, and the other 8 PM. "REMEMBER, EFFECTIVE RELIEF JUST TAKES TWO" the ad said, a representation Purdue knew at the time was false and misleading.

393. Advertisements and websites by Purdue have been the extensive subjects of FDA violations and Warning Letters for overstating efficacy and minimizing risks. In May 2000, the

[94] Christopher Glazek, *The Secretive Family Making Billions From The Opioid Crisis*, Esquire (Oct. 16, 2017), available at https://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/

FDA called out Purdue for the misrepresentations and violations of the FD&C Act. Specifically, that the advertisement misleadingly suggested that "OxyContin could be used as an initial therapy for the treatment of osteoarthritis pain without substantial evidence to support this claim, and the advertisement promoted OxyContin in a selected class of patients – the elderly – without presenting risk information applicable to that class of patients." Purdue subsequently agreed to cease dissemination of the advertisement.

394. In January 2003, the FDA again issued a warning letter to Purdue for minimizing risks (failing to include the boxed warning on potentially fatal risks and abuse potential) while concealing "important information about the limitations on the indicated use of OxyContin" in two professional medical journal advertisements

395. Purdue advertisements that ran in 2005 and 2006 issues of the Journal of Pain depicted a sample prescription for OxyContin with "Q12h" handwritten. Another advertisement Purdue ran in 2005 in the Journal of Pain touted OxyContin's "Q12h dosing convenience" and displayed two paper dosing cups, one labeled "8 am" and one labeled "8 pm," implying that OxyContin is effective for the 12-hour period between 8 a.m. and 8 p.m. Similar ads appeared in the March 2005 Clinical Journal of Pain.

396. Purdue ran a 2005 OxyContin advertisement in the *Journal of Pain* portraying the drug as an "around-the-clock analgesic . . . for an extended period of time." The advertisement featured a man and boy fishing, and proclaimed that "There Can Be Life With Relief." This depiction falsely implied that OxyContin provides both effective long-term pain relief and functional improvement, claims that, as alleged below, are unsubstantiated and contradicted in the medical literature.

397. Similar advertisements ran in 2005 and 2006 issues of the *Journal of Pain* depict a sample prescription for OxyContin with "Q12h" handwritten. To this day, Purdue includes prominent 12-hour dosing instructions in its branded advertising, such as in a 2012 Conversion and Titration Guide, which states: "Because each patient's treatment is personal / Individualize the dose / Q12h OxyContin Tablets." Similar ads appeared in the March 2005 *Clinical Journal of Pain.*

398. Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad allegedly described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. This advertisement, and others like them, promoted the false message that OxyContin was safe and effective for the long-term treatment of chronic pain.

399. Purdue's misleading messages were effective, and its annual spending on OxyContin advertisements skyrocketed from approximately $700,000 in 1996 to $4.6 million in 2001. Purdue's marketing messages—which were subsequently adopted by the other Manufacturer Defendants—were the subject of numerous FDA letters warning Purdue that its ads overstated the efficacy and minimized the risk of long-term Opioid Drug treatment for chronic pain.

400. Purdue's annual spending for OxyContin advertisements also skyrocketed from approximately $700,000 in 1996 to $4.6 million in 2001. In 2011, Purdue spent approximately $8.3 million in medical journal advertising.

401. In 2011, Purdue published a prescriber and law enforcement education pamphlet titled *Providing Relief, Preventing Abuse*, which deceptively portrayed the signs—and therefore

the prevalence—of addiction. However, Purdue knew, as described above, that OxyContin was used non-medically by injection less than 17% of the time. Yet, *Providing Relief, Preventing Abuse* prominently listed side effects of injection like skin popping and track marks as "Indications of Possible Drug Abuse"—downplaying much more prevalent signs of addiction associated with OxyContin use such as asking for early refills, making it seem as if addiction only occurs when opioids are taken illicitly.

402. *Providing Relief, Preventing Abuse* also deceptively camouflaged the risk of addiction by falsely supporting the idea that drug-seeking behavior could, in fact, be a sign of "pseudoaddiction" rather than addiction itself. Specifically, it noted that the concept of "pseudoaddiction" had "emerged in the literature" to describe "[drug-seeking behaviors] in patients who have pain that has not been effectively treated." Nowhere in *Providing Relief, Preventing Abuse* did Purdue disclose the lack of scientific evidence justifying the concept of "pseudoaddiction," or that the phrase itself had been coined by a Purdue vice president.

403. *Providing Relief, Preventing Abuse* was available nationally and was intended to reach Ohio prescribers. As described below, the deceptive statements in *Providing Relief, Preventing Abuse* regarding addiction were the very same messages Purdue directed at Ohio prescribers through its sales force.

(ii) Cephalon Advertisements Convey Misleading Safety and Efficacy Messages

404. Cephalon's medical journal advertising peaked in 2007-2008, when the company spent approximately $2 million each year.

405. Cephalon also promoted the unsafe and unapproved use of Fentora through "supplements" to medical journals. These supplements were not peer-reviewed publications but were essentially paid promotional vehicles disguised to look like medical journals, and offered

Cephalon another venue to market Fentora beyond its approved labeling. These supplements were frequently prepared in conjunction with a CME set up for Cephalon by a Medical Education and Communication Company ("MECC") to present information that appeared to be—but in reality was not—free from Cephalon's influence.

406. In December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)," a supplement to Anesthesiology News, Clinical Oncology News, and Pain Medicine News.

407. The advertorial supplement was prepared by McMahon Publishing and "supported" by Cephalon. Anesthesiology News is mailed monthly free of charge to all 44,832 anesthesiologists and anesthesiology residents in the United States. Clinical Oncology News is mailed monthly free of charge and/or is available in an online edition provided to oncologists, hematologists, and oncology nurses. Pain Medicine News is mailed monthly to 50,000 of "the highest-prescribers of pain medication."

408. Although the Special Report is designed so that it appears to be objective educational material, it is blatantly promotional and is aimed simply as a marketing piece which was then distributed to well over 100,000 anesthesiologists, oncologists, pain doctors and nurses. It contains three articles, all written by Cephalon employees, purportedly describing the new REMS procedures that were soon to be implemented by the FDA in early 2012 for Fentora and the fentanyl class of drugs.

409. Even though the FDA's REMS for the fentanyl class of drugs specifically makes clear that these drugs are *only* to be prescribed for breakthrough cancer pain in patients who are opioid tolerant, the Special Report ignores this limitation and instead openly promotes Fentora

for non-cancer breakthrough pain. For example, in an article written by Cephalon employee Arvind Narayana, he states that "[f]entanyl buccal tablet has been shown to be effective in the treatment of BTP associated with multiple causes of pain." While he does discuss the serious risk of abuse associated with Fentora, and thus the importance of patient selection, he then fails to note that the REMS itself and the Fentora label limit use only to breakthrough cancer pain. Moreover, Narayana fails to point out to readers that the FDA had specifically rejected the Company's request to expand the label to non-cancer breakthrough pain.

410. The Special Report was also circulated by Cephalon through a free journal supplement sent out by Pharmacy Times in January 2012. Pharmacy Times has a circulation of 174,104 pharmacists throughout the United States.

(iii) Janssen Advertisements Convey Misleading Safety and Efficacy Messages

411. Janssen also targeted physicians through medical journal advertising. In 2011, the company spent approximately $4.9 million in such ads.

412. Janssen's physician-targeted advertisements were similarly deceptive, as evidenced by a September 2, 2004 FDA Warning Letter. That letter was in relation to Janssen's Duragesic patch. The FDA found that a file card used by Janssen in connection with that patch contained false and misleading claims regarding the efficacy and abuse potential of Duragesic. The FDA noted Janssen's representations could encourage the unsafe use of the drug, potentially resulting in serious or life-threatening hypoventilation, or even death.

413. The marketing materials in question included the following misleading or unsubstantiated claims:

- "low reported rate of mentions in [Drug Abuse Warning Network ("DAWN") data" along with comparisons to other Opioid Drugs, which suggested that Duragesic is less abused than other opioids;

- "minimizes the potential for local GI side effects by avoiding GI absorption," which suggested that Duragesic is associated with less constipation, nausea, and vomiting than oral opioids;
- "demonstrated effectiveness in chronic back pain with additional patient benefits" which was based on an open-label, single arm trial with no control group which is clearly inadequate to support such a claim;
- "86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep," "all patients who experienced overall benefit from Duragesic would recommend it to others with chronic low back pain," "significantly reduced nighttime awakenings" and "significant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index" which were again based on an open-label, single arm trial with no control group—which is inadequate to support such claims;
- "Improved patient outcomes: Open-label, crossover comparison study," "Significant improvement in physical functioning summary score," and "Significant improvement in social functioning," which are based on an open label study lacking sufficient support for the cited claims; and
- "1,360 loaves…and counting," "Work, uninterrupted," "Life, uninterrupted," "Game, uninterrupted," "Chronic pain relief that supports functionality," "Helps patients think less about their pain," and "Improvements in physical and social functioning," which imply that patients will experience improved social or physical functioning, a claim for which Janssen lacked support for.

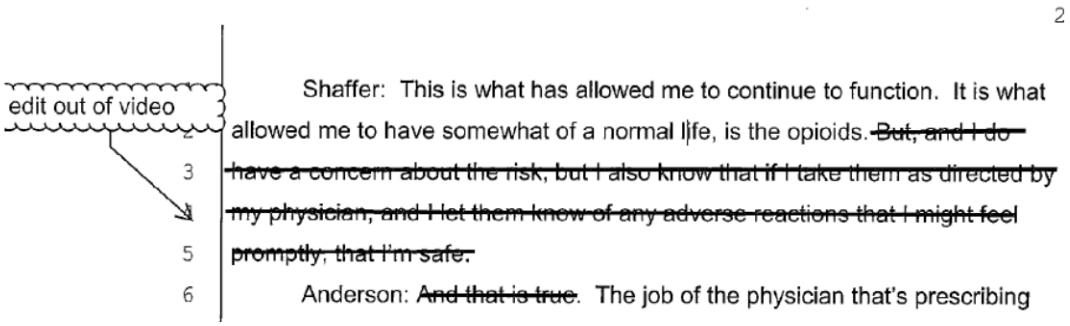
414. The FDA stated they were not aware of any substantial evidence or clinical experience to support these claims.

415. Most prominent among Janssen's efforts was the *Let's Talk Pain* website. Janssen sponsored *Let's Talk Pain* in 2009, acting in conjunction with APF, American Academy of Pain Management, and American Society of Pain Management Nursing. Janssen financed and orchestrated the participation of these groups in the website.

416. Janssen exercised substantial control over the content of the *Let's Talk Pain* website. Janssen's internal communications always referred to *Let's Talk Pain* as promoting

tapentadol, the molecule it sold as Nucynta and Nucynta ER. Janssen regarded *Let's Talk Pain* and another website—*Prescriberesponsibly.com*— as integral parts of Nucynta's launch:

417. Janssen documents also reveal that Janssen personnel viewed APF and AAPM as "coalition members" in the fight to increase market share. To this end, Janssen and APF entered into a partnership to "keep pain and the importance of responsible pain management top of mind" among prescribers and patients. They agreed to work to reach "target audiences" that included patients, pain management physicians, primary care physicians, and KOLs. One of the roles Janssen assumed in the process was to "[r]eview, provide counsel on, and approve materials." Janssen did in fact review and approve material for the *Let's Talk Pain* website, as evidenced by the following edits by a Janssen executive to the transcript of a video that was to appear on the site:



418. The final version of the video on *Let's Talk P*ain omitted the stricken language above.

419. This review and approval authority extended to the *Let's Talk Pain* website. Emails between Janssen personnel and a consultant indicate that, even though the *Let's Talk Pain* website was hosted by APF, Janssen had approval rights over its content. Moreover, emails describing Janssen's review and approval rights related to *Let's Talk Pain* indicate that this right extended to "major changes and video additions."

420. As a 2009 Janssen memo conceded, "[t]he Let's Talk Pain Coalition is sponsored by PriCara, a Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc." and "[t]he Coalition and Pricara maintain editorial control of all Let's Talk Pain materials and publications."

421. A 2011 Consulting Agreement between Janssen and one of APF's employees, relating to the dissemination of national survey data, demonstrates the near-total control Janssen was empowered to exercise over APF in connection with the *Let's Talk Pain* website, including requiring APF to circulate and post Janssen's promotional content. The agreement required APF to "participate in status calls between Janssen, APF, AAPM, ASPMN, and Ketchum as requested by Janssen" and required APF to "respond to requests to schedule status calls within 48 hours of the request" (emphasis in original). APF also was required to "[r]eview and provide feedback to media materials, including a press release, pitch email, a key messages document, and social media messages, within one week of receipt."

422. From 2009 to 2011, Janssen's website, *Let's Talk Pain*, stated that "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated" and that "[p]seudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

423. *Let's Talk Pain* contained a number of misrepresentations. For example, Let's Talk Pain misrepresented that the use of opioids for the treatment of chronic pain would lead to patients regaining functionality. Let's Talk Pain featured an interview claiming that opioids were what allowed a patient to "continue to function." This video is still available today on YouTube.com and is accessible to Ohio prescribers and patients.

424. A Janssen-funded brochure was also distributed to doctors and patients in Ohio during the relevant time period described the "Opioid Myths" compared to NSAID drugs. The disclosed risks of NSAIDs include bleeding in the stomach or intestine, kidney or liver damage, and an increased risk of heart attack and stroke. In contrast, the side effects of opioids include an upset stomach, sleepiness, and constipation, though even these side effects often go away or can be managed. The brochure makes the claims that "Opioids are *rarely* addictive. . . ." and the unfounded claim that patients should not have to increase the dose of the opioid taken over time.

425. Janssen's marketing campaign for Nucynta was particularly deceptive in that it promoted Nucynta's "tolerability," which is completely at odds with and misrepresents its serious side effects. In October 2009, Janssen began to run an advertisement in *Medical Economics* that proclaimed: "OPIOID EFFICACY MEETS UNEXPECTED TOLERABILITY," even though the risk of addiction and serious side effects make opioids intolerable for most patients. While the "tolerability" to which Janssen referred was a lack of GI-related side effects (*e.g.*, nausea and vomiting), a reader could only learn this after examining a bar chart

representing the study's results. Thus, the all-caps claim of "unexpected tolerability" falsely implied that Nucynta could be taken without severe side effects or consequences.

(iv) Depomed Advertisements Convey Misleading Safety and Efficacy Messages

426. Likewise, on a website that was designed to market Nucynta, Depomed promoted Nucynta ER as more tolerable because of fewer "discontinuation rates due to treatment-emergent adverse events." The website set forth a number of treatment emergent adverse events and how they compare to one competitor, oxycodone. The website also claimed that Nucynta ER is safe because only 4.8% of Nucynta ER-treated patients experienced mild or moderate withdrawal. However, none of this appears on the FDA-approved label for Nucynta.

(v) Endo Advertisements Convey Misleading Safety and Efficacy Messages

427. Endo also targeted physicians through medical journal advertising. In 2011, the company spent approximately $1.1 million in such ads.

428. Endo's advertisements for the 2012 reformulation of Opana ER claimed it was designed to be crush resistant, in a way that conveyed that it was less likely to be abused. This claim was false; the FDA warned in a May 10, 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse," and Endo's "post-"post-marketing date submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse." Further, Endo instructed its sales representatives to repeat this claim about "design," with the intention of conveying Opana ER was less subject to abuse.

429. Endo advertised its Opana ER (or extended release) drug by depicting a professional chef and a construction worker, each with chronic lower back pain, smiling and working as a result of Opana ER.

430. Endo sought to minimize the risk of abuse by misrepresenting their drugs' susceptibility to tampering. In 2012, Endo asked the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, meaning that it was protected against manipulation that would allow users to snort or inject it. It also sought permission to withdraw its previous approval for Opana ER in favor of its newer, purportedly safer version. The FDA denied both requests, explaining in a May 10, 2013 letter that there was no evidence the new design "would provide a reduction in oral, intranasal or intravenous abuse" and that Endo's "post-marketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse[.]" Yet, Endo advertised, and advised its sales representatives and speakers' bureau doctors, to market reformulated Opana ER as "the only oxymorphone extended release tablets that are *designed to be crush resistant*." (emphasis added). Endo chose its words carefully, but the misleading impression it created – that Opana is tamper-resistant and therefore less subject to abuse – was no doubt deliberate.

431. Endo also worked with various KOLs to disseminate various misleading statements about chronic opioid therapy. For example, Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy titled *Understanding your Pain: Taking Oral Opioid Analgesics.* This pamphlet deceptively minimized the risks of addiction by stating that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems," implying that patients who are taking opioids for pain are not at risk of addiction.

432. *Understanding your Pain: Taking Oral Opioid Analgesics* also misleadingly omitted any description of the increased risks posed by higher doses of opioid medication. Instead, in a Q&A format, the pamphlet asked "[i]f I take the opioid now, will it work later when

I really need it?" and responded that "[t]he dose can be increased . . . [y]ou won't 'run out' of pain relief."

(vi) Actavis Advertisements Convey Misleading Safety and Efficacy Messages

433. Actavis also targeted physicians through medical journal advertising. Such advertising hit its peak in 2005, when Actavis spent over $11 million advertising in medical journals.

434. Actavis had a patient education brochure distributed in 2007 that claimed addiction is possible, but it is "less likely if you have never had an addiction problem." Although the term "less likely" is not defined, the overall presentation suggests the risk is so low as not to be a worry.

435. Actavis distributed a product advertisement that claimed that use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and cause patients to enjoy their lives. The FDA warned Actavis that such claims were misleading, writing: "We are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[95]

[95] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18. 2010), *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatory Information/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259240.htm.

4. Unbranded Promotion of the Opioid Drugs

436. In addition to their direct marketing efforts, the Manufacturer Defendants used unbranded, third-party marketing, which they deployed as part of their national marketing strategies for their branded drugs. Each Defendant executed these strategies through a network of third-party KOLs and Front Groups, with which it acted in concert by funding, assisting, encouraging, and directing their efforts. At the same time, the Manufacturer Defendants exercised substantial control over the content of the messages third parties generated and disseminated, and distributed certain of those materials themselves. As with their other marketing strategies, Manufacturer Defendants' unbranded marketing created, and relied upon, an appearance of independence and credibility that was undeserved but central to its effectiveness. Unlike their direct promotional activities, Manufacturer Defendants' unbranded marketing allowed them to evade the oversight of federal regulators and gave them greater freedom to expand their deceptive messages.

437. Drug companies that make, market, and distribute opioids are subject to generally applicable rules requiring truthful marketing of prescription drugs. A drug company's branded marketing, which identifies and promotes a specific drug, must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks. The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of drugs for their patients.

438. Further, the Federal Food, Drug, and Cosmetic Act ("FDCA") prohibits the sale in interstate commerce of drugs that are "misbranded." A drug is "misbranded" if it lacks

"adequate directions for use" or if the label is false or misleading "in any particular." "Adequate directions for use" are directions "under which the layman can use a drug safely and for the purposes for which it is intended." "Labeling" includes more than the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug, including promotional material. "The term "accompanying" is interpreted broadly to include promotional materials—posters, websites, brochures, books, and the like—disseminated by or on behalf of the manufacturer of the drug. Thus, Manufacturer Defendants' promotional materials are part of their drugs' labels and are required to be accurate, balanced, and not misleading.

439. Labeling is misleading if it is not based on substantial evidence, if it materially misrepresents the benefits of the drug, or if it omits material information about or minimizes the frequency or severity of a product's risks. "The most serious risks set forth in a product's labeling are generally material to any presentation of efficacy." The FDA notes that "[b]ecause people expect to see risk information, there is no reason for them to imagine that the product has important risks that have been omitted . . . especially if some risks are included." Promotion that fails to present the most important risks of the drug as prominently as its benefits lacks fair balance and is therefore deceptive. It is also illegal for drug companies to distribute materials that exclude contrary evidence or information about the drug's safety or efficacy or present conclusions that "clearly cannot be supported by the results of the study." Further, drug companies must not make comparisons between their drugs and other drugs that represent or suggest that "a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience."

440. While the FDA must approve a drug's label, it is the drug company's responsibility to ensure that the material in its label is accurate and complete and is updated to reflect any new information. Promotional materials also must be submitted to the FDA when they are first used or disseminated. The FDA does not have to approve these materials in advance; if, upon review, the FDA determines that materials marketing a drug are misleading, it can issue an untitled letter or warning letter. The FDA uses untitled letters for violations such as overstating the effectiveness of the drug or making claims without context or balanced information. Warning letters address promotions involving safety or health risks and indicate the FDA may take further enforcement action.

(i) Drug Manufacturer Websites Convey Misleading Unbranded Safety and Efficacy Messages

441. The Manufacturer Defendants also utilized "for prescribers" sections on their websites to market Opioid Drugs to prescribers (or otherwise offered information on their websites specifically for HCPs). These websites rehashed many of the long-term efficacy / safety misrepresentations detailed above.

442. Dr. Webster's bogus "Opioid Risk Tool," discussed *infra*, appeared on or was linked to websites operated by Purdue, Endo, and Janssen.

443. With the exception of Insys, every Manufacturer Defendant's website (at least through 2012) contained prescriber information about the fictitious concept of "pseudoaddiction."

444. Purdue operated a *Partners Against Pain* website, which it allegedly described as "a comprehensive resource that offers a wide range of information about various chronic pain conditions including osteoarthritis, low back pain and cancer; pain measurement and assessment tools; pain policy, legislation and community relations; and links to other relevant Web sites."

Purdue's websites, the company explained, were meant to "address [the] growing public health crisis" of an untreated pain epidemic.[96] On this website, Purdue provided an informational guide, *Clinical Issues in Opioid Prescribing* that pushed the concept of "pseudoaddiction." This was eventually converted into a pamphlet, and is discussed in greater detail, *infra.*

445. Purdue extended its deceptive messaging by launching its *Team Against Opioid Abuse* website in August of 2015, "designed to help HCPs and laypeople alike learn about different abuse-deterrent technologies and how they can help in the reduction of misuse and abuse of opioids."[97] Days after launching the website, Purdue reached a settlement with the N.Y. Attorney General "in which the company agreed to be more transparent about how it promotes itself in 'unbranded' websites."[98]

446. Purdue's websites for physicians were also the subject of various FDA warnings. In 2003, the FDA reprimanded Purdue regarding deceptive information on its *Partners Against Pain* website. The website suggested OxyContin could be used to treat a wide array of ailments, not just postoperative pain. And the website omitted the fact that the drug is not indicated for use in the "immediate postoperative period" or "for patients not previously taking the drug, because its safety in this setting has not been established."

447. Janssen also "owned or controlled"[99] a *Prescribe Responsibly* website, that propagates numerous false or misleading statements concerning the safety of opioids and fails to

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[96] Purdue Pharm., Press Release, *Online Tool Helps Pain Advocacy Community Address Growing Public Health Crisis*, PURDUEPHARMA.COM (Jul 24, 2008), http://www.purduepharma.com/news-media/2008/07/online-tool-helps-pain-advocacy-community-address-growing-public-health-crisis/.

[97] Purdue L.P., Press Release, *New Resource Aimed at Educating About Opioid Analgesics with Abuse-Deterrent Properties and Team Efforts to Deter Abuse of Prescription Medicines*, PURDUEPHARMA.COM (Aug. 17, 2005), http://www.purduepharma.com/news-media/2015/08/purdue-pharma-l-p-launches-teamagainstopioidabuse-com/.

[98] Pat Anson, *Purdue Pharma's 'Misleading' Websites,* PAIN NEWS NETWORK (August 21, 2005), https://www.painnewsnetwork.org/stories/2015/8/21/purdue-pharmas-misleading-websites.

[99] Legal Notice, PRESCRIBE RESPONSIBLY, https://www.prescriberesponsibly.com/legal-notice (last visited March 27, 2018).

address the risks associated with taking them. It states that prescribers' trepidation about prescribing opioids is largely due to "questions of addiction" and such concerns "are often overestimated. According to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesic[] . . . therapy."[100] The website also falsely stated that opioid addiction "can usually be managed" with tools like Opioid Agreements between the physician and patient.

448. Janssen's *Prescribe Responsibly* also noted that "pseudoaddiction" is "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately, the inappropriate behavior ceases."[101] Essentially, "pseudoaddiction" is a condition that requires the prescription of more or stronger opioids.

449. *Prescribe Responsibly* also misleadingly asserted that Nucynta ER had a low incidence of withdraw symptoms.

450. Janssen funded and edited another website, *Let's Talk Pain*, which in 2009 stated that "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 nationwide until May 2012.

451. Endo sponsored two websites, painknowledge.com and painaction.com, which claimed as of 2004 and 2015, respectively, that "[p]eople who take opioids as prescribed usually

[100] *Use of Opioid Analgesics in Pain Management*, PRESCRIBE RESPONSIBLY, http://www.prescriberesponsibly.com/ articles/opioid-pain-management (last visited Dec. 14, 2017).

[101] *What a Prescriber Should Know Before Writing the First Prescription*, PRESCRIBE RESPONSIBLY, https://www.prescriberesponsibly.com/articles/before-prescribing-opioids (last visited March 27, 2018).

do not become addicted" and "[m]ost chronic pain patients do not become addicted to the opioid medications that are prescribed for them."[102]

452. Endo also represented that "[t]aking opioids for pain relief is not addiction" and that "[a]ddiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problem." In the same publication, Endo suggested that patients use the following test to determine whether they are addicted to opioids: "Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons—to relieve pain and improve your function. You are not addicted."[103]

453. Until at least February 2009, Mallinckrodt provided funding to *Pain-Topics.org*, a now-defunct website that touted itself as "a noncommercial resource for HCPs, providing open access to clinical news, information, research, and education for a better understanding of evidence-based pain-management practices."[104]

454. Among other content, the website included a handout entitled *Oxycodone Safety Handout for Patients*, which advised practitioners that: "Patients' fears of opioid addiction should be dispelled."[105] The handout included several false and misleading statements concerning the risk of addiction associated with prescription opioids:

> Will you become dependent on or addicted to oxycodone?

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[102] Endo Pharmaceuticals, *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004), https://perma.cc/QN86-62PK.

[103] *Id.*

[104] *Pain Treatment Topics*, Pain-Topics.org, http://web.archive.org/web/20070104235709/http://www.pain-topics.org:80 / (last visited Apr. 22, 2018).

[105] Lee A. Kral & Stewart B. Leavitt, *Oxycodone Safety Handout for Patients*, Pain-Topics.org (June 2007), *available at* http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.

> After a while, oxycodone causes physical dependence. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.
>
> This is not the same as addiction, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.[106]

455. Additionally, the FAQ section of *Pain-Topics.org* relayed Manufacturer Defendants' fictitious marketing message concerning "pseudoaddiction," downplaying the dangers and risks of prescription opioid use while indirectly promoting higher dosages and overprescribing:

> **Pseudoaddiction** – has been used to describe aberrant patient behaviors that may occur when pain is undertreated (AAPM 2001). Although this diagnosis is not supported by rigorous investigation, it has been widely observed that patients with unrelieved pain may become very focused on obtaining opioid medications, and may be erroneously perceived as "drug seeking." Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated. Along with this, two related phenomena have been described in the literature (Alford et al. 2006):
>
> **Therapeutic dependence** – sometimes patients exhibit what is considered drug-seeking because they fear the reemergence of pain and/or withdrawal symptoms from lack of adequate medication; their ongoing quest for more analgesics is in the hopes of insuring a tolerable level of comfort.
>
> **Pseudo-opioid-resistance** – other patients, with adequate pain control, may continue to report pain or exaggerate its presence, as if their opioid analgesics are not working, to prevent reductions in their currently effective doses of medication.
>
> Patient anxieties about receiving inadequate pain control can be profound, resulting in demanding or aggressive behaviors that are

[106] *Id.*

> misunderstood by healthcare practitioners and ultimately detract from the provision of adequate pain relief.[107]

456. Also available on *Pain-Topics.org* was a document titled *Commonsense Oxycodone Prescribing & Safety*, which falsely suggested that generic oxycodone is less prone to abuse and diversion than branded oxycodone. The document stated: "Anecdotally, it has been observed that generic versions of popularly abused opioids usually are less appealing; persons buying drugs for illicit purposes prefer brand names because they are more recognizable and the generics have a lower value 'on the street,' which also makes them less alluring for drug dealers."[108]

(ii) Physician Pamphlets and Videos Convey Misleading Unbranded Safety and Efficacy Messages

457. The Manufacturer Defendants also utilized pamphlets, videos, and similar marketing materials to falsely and deceptively market their Opioid Drugs directly to prescribers.

458. Purdue published a pamphlet in 2011 entitled *Providing Relief Preventing Abuse*, which, described "pseudoaddiction" as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated." The pamphlet depicted the signs of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa—under the heading, "Indications of Possible Drug Abuse," despite the fact that it knew that drug addicts that resort to these extremes are uncommon and people far more typically become addicted through oral use. Thus, these misrepresentations wrongly assured prescribers that their patients are not abusing or addicted to opioids in the absence of the aforementioned signs.

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[107] *FAQs*, Pain-Topics.org, https://web.archive.org/web/20070709031530/http://www/pain-topics.org:80/faqs/index1.php#tolerance (last accessed in 2009).

[108] Lee A. Kral, *Commonsense Oxycodone Prescribing & Safety*, Pain-Topics.org (June 2007), *available at* http://paincommunity.org/blog/wp-content/uploads/OxycodoneRxSafety.pdf .

459. Purdue also provided two promotional videos to physicians that, according to FDA, appear to have made unsubstantiated claims and minimized the risks of OxyContin. The first video was available for about 3 years without being submitted to FDA for review.

460. Purdue brochures or similar marketing materials disseminated by its sales representatives across the country misleadingly represented the efficacy of 12-hour dosing. A "Conversion and Titration Guide" provided to HCPs touted OxyContin's "12-hour AcroContin Delivery System" which was "designed to deliver oxycodone over 12 hours," offering patients "life with Q12H relief." Those same marketing materials included a timeline graphic with little white paper pill cups only at "8AM" and, further down the line, at "8PM." They also proclaimed that OxyContin provides "Consistent Plasma Levels Over 12 Hours" and set forth charts demonstrating absorption measured on a logarithmic scale, which fraudulently made it appear levels of oxycodone in the bloodstream slowly taper over a 12-hour time period.

461. Starting in 2006, Purdue distributed to physicians a pamphlet entitled *Clinical Issues in Opioid Prescribing*, which claimed that "illicit drug use and deception" were not indicia of addiction, but rather indications that a patient's pain was undertreated. The publication indicated that "[p]seudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated." In other words, Purdue suggested that when faced with drug-seeking behavior from their patients, HCPs should prescribe more opioids—turning evidence of addiction into an excuse to sell and prescribe even more drugs.

462. In 2003, the FDA issued a warning letter to Purdue for spreading inaccurate information in OxyContin advertisements, and for failing to inform the public of important safety information about the drug. The letter found Purdue was in violation of the FDCA, 21 U.S.C. §§ 331(a) and (b), 352 (n).

463. While Purdue did withdraw the offensive promotional materials, rather than distributing a Dear HCP ("DHCP") letter correcting the misinformation or altering the labeling for OxyContin, Purdue doubled down and instructed their sales force to "refocus" physicians if and when they learn that physician was misinformed regarding the addictive qualities of their products.

464. The misinformation Purdue pushed out violated federal criminal law. On May 9, 2007, Defendant Purdue pleaded guilty, in federal court, to violations of 21 U.S.C. §§ 331(a) and 331(a)(2) for marketing and promoting OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.

465. For another example, Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) in conjunction with the AAPM, ACPA, and APF, which, as set forth in the excerpt below, described as a "myth" the fact that opioids are addictive, and asserts as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

466. Although the term "rarely" is not defined, the overall presentation suggests that the rate is so low as to be immaterial. The language also implies that as long as a prescription is given, opioid use is unlikely to lead to addition, which is untrue. The guide states as a "fact" that "Many studies" show that opioids are *rarely* addictive when used for chronic pain. In fact, no such studies exist.

467. Endo distributed a pamphlet, *Living with Someone with Chronic Pain,* which stated that most health care providers agree that most people do not develop an addiction.

468. Actavis was notified by the FDA in 2010 that certain brochures it was providing to prescribers were "false or misleading because they omit and minimize the serious risks

associated with the drug, broaden and fail to present the limitations to the approved indication of the drug, and present unsubstantiated superiority and effectiveness claims." The FDA also found that "[t]hese violations are a concern from a public health perspective because they suggest that the product is safer and more effective than has been demonstrated."

469. Rather than honestly disclose the risk of addiction, the Manufacturer Defendants attempted to portray those who were concerned about addiction as callously denying treatment to suffering patients. To increase pressure on doctors to prescribe chronic opioid therapy, Defendants turned the tables: they suggested that doctors who *failed* to treat their patients' chronic pains with opioids were failing their patients and risking professional discipline, while doctors who relieved their pain using long-term opioid therapy were following the compassionate (and professionally less risky) approach. Defendants claimed that purportedly overblown worries about addiction cause pain to be under- treated and opioids to be over-regulated and under-prescribed. The Treatment Options guide funded by Purdue and Cephalon states "[d]espite the great benefits of opioids, they are often underused." The APF publication funded by Purdue, *A Policymaker's Guide to Understanding Pain & Its Management*, laments that: "Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include . . . misconceptions about opioid addiction."

(iii) Manufacturer Defendants Employ Physician Key Opinion Leaders to Convey Misleading Unbranded Safety and Efficacy Messages

470. The Manufacturer Defendants also employed small circle of physicians who held themselves out as experts in the pain management field. These KOLs were selected, cultivated, and elevated to prominence by the manufacturers.

471. In order to spread their fraudulent and deceptive science to bolster their marketing schemes, the Manufacturer Defendants enlisted the help of such KOLs to espouse pro-opioid misinformation for practicing doctors, and most importantly, general practitioners.

472. Pro-opioid HCPs are one of the most important avenues that the Manufacturer Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. The Manufacturer Defendants know that HCPs rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website *In the Face of Pain* failed to disclose that HCPs who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.[109]

473. Further, by maintaining an illusion of independence, KOLs are less subject to FDA oversight and regulations regarding marketing. Without the air of independence, KOLs (and Front Groups) would be subject to the FDA's promotional rules, which state in part:

> FDA's regulation of prescription drug product promotion extends both to promotional activities that are carried out by the firm itself, and to promotion conducted on the firm's behalf.
>
> Therefore, a firm is responsible for the content generated by its employees or any agents acting on behalf of the firm who promote the firm's product. For example, if an employee or agent of a firm, such as a medical science liaison or paid speaker (e.g., a key

[109] The NY AG, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the NY AG found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo continues to make these false statements elsewhere.

> opinion leader) acting on the firm's behalf, comments on a third-party site about the firm's product, the firm is responsible for the content its employee or agent provides. A firm is also responsible for the content on a blogger's site if the blogger is acting on behalf of the firm.

474. The laundry list of KOL activities done at the behest of the Manufacturer Defendants were crucial in disseminating their campaign for long-term opioid use for chronic pain. KOLs have written, consulted on, edited, and supplied their names for books and articles, and given speeches and CMEs in support of long-term opioid use to treat chronic pain. They have also served on committees that helped develop guidelines for chronic pain opioid use and on boards of pro-opioid groups and professional societies charged with selecting and preparing CMEs. They have also served as paid consultants to the Manufacturer Defendants.

475. To garner their support, Defendants provided these KOLs with money, prestige, recognition, research funding, and avenues to publish, all at the expense of the patients they were obligated to protect. Defendants' manipulative scheme allowed the KOLs to exert an increasing amount of influence on the medical community. Since 2000, Cephalon alone has paid HCPs more than $4.5 million for programs related to its Opioid Drugs.

476. Although some KOLs initially may have advocated for more permissive opioid prescribing with honest intentions, Defendants cultivated and promoted only those KOLs who could be relied on to help broaden the chronic opioid therapy market. Defendants selected, funded, and elevated those HCPs whose public positions were unequivocal and supportive of using opioids to treat chronic pain. These HCPs' reputations were then dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the drug companies.

477. According to the Brand Plan when Cephalon launched Fentora in 2006, they would focus on KOLs because they help shape, among other things, managed care access, and they were the number one reason for changing prescribing patterns:

> KOLs are luminary HCPs and academicians who play a vital role in the success of a brand throughout its life cycle, especially with new and innovative therapies coming to market. **KOLs help shape the following**: clinical development plans, product positioning, brand development, life cycle management, prescribing practices, publications, medical education, **managed care**, etc. Studies for more than 25 years have shown that **the number 1 reason a physician/HCP changes prescribing habits is peer-to-peer influenc**e. For this reason, it is important to work with these individuals to generate awareness, understanding, and appropriate use of [Fentora] for [Breakthrough Pain]. (emphasis added)

478. Defendants cited and promoted favorable studies or articles by these KOLs. By contrast, Defendants did not support, acknowledge, or disseminate the publications of HCPs critical of the use of chronic opioid therapy. Indeed, one prominent KOL, Russell Portenoy, stated that he was told by a drug company that research critical of opioids (and the HCPs who published that research) would never obtain funding. Some KOLs have even gone on to become direct employees and executives of Defendants, like Dr. David Haddox, Purdue's Vice President of Risk Management, or Dr. Bradley Galer, Endo's former Chief Medical Officer.

479. Defendants kept close tabs on the content of the misleading materials published by these KOLs. In many instances, they also scripted what these KOLs said (as they did with all their recruited speakers). The KOLs knew or deliberately ignored the misleading way in which they portrayed the use of opioids to treat chronic pain to patients and prescribers, but they continued to publish those misstatements to benefit themselves and Defendants, all the while causing harm to prescribers, patients, and TPPs.

480. Defendants utilized many KOLs, and often used the same ones, collaborating on their message. Four of the most prominent KOLs are Drs. Russell Portenoy, Lynn Webster, Perry Fine, and Scott Fishman.

(a) KOL Russell Portenoy, M.D.

481. Dr. Russell Portenoy, former Chair of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, was one of the most prominent KOLs used by the Manufacturer Defendants. He received research support, counseling fees and/or honoraria from Purdue, Cephalon, Janssen, and Endo (among others), and was a paid consultant to Cephalon and Purdue.

482. Dr. Portenoy was even told by one drug company that any research critical of opioids and the HCPs that authored it would never receive funding from the company. To ensure such critical research was never published, Defendants often selected topics and approached KOLs to participate when the research was well underway. Dr. Portenoy regularly agreed to author articles in this manner.

483. As admitted in 1994 by Dr. Russell Portenoy, a KOL who went on to tirelessly promote opioid therapy for the treatment of chronic non-cancer pain (also called chronic nonmalignant pain), the medical consensus before Defendants' "reeducation" campaign was decidedly against the use of opioids to treat chronic non-cancer pain:

> ***The traditional approach to chronic nonmalignant 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.[110]

484. The studies that Portenoy and other paid KOLs executed, with funding from and in connection with Defendants, worked to create a discussion in the 1990s around making pain treatment "a priority for all patients."[111] With funding from Defendants funneled through Front Groups under Portenoy's influence, pain became the "fifth vital sign" for physicians to monitor. Portenoy also served to popularize the concept of "pseudoaddiction."

485. In addition to his limited study (which he in large part disavowed, as discussed below), he authored articles, hosted CMEs, gave interviews, and performed lectures promoting false and misleading messages regarding Opioid Drugs. Most of these were targeted at fellow physicians.

486. Dr. Portenoy also served on a number of "Front Groups" (discussed below). He served on the APS and AAPM Consensus Statement Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of the American Pain Foundation, where he (alongside other KOLs) reviewed its publications and policy statements.

487. Dr. Portenoy made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on *Good Morning America* in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely watched program, broadcast across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the

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[110] Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Research & Mgmt. 247 (H.L. Fields and J.C. Liebeskind eds., 1994).

[111] Sonia Moghe, *Opioid history: From 'wonder drug' to abuse epidemic,* CNN, (Oct. 14, 2016), https://www.cnn.com/2016/05/12/health/opioid-addiction-history/index.html.

family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[112]

488. In 2012, Dr. Portenoy even admitted that the information he spread to physicians and the public at large had been deceptive. In a 2012 interview, he acknowledged giving innumerable lectures in the late 1980s and 1990s about addiction that weren't true. [113] These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks.[114] Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[115] Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well…I guess I did."[116]

(b) KOL Lynn Webster, M.D.

489. Another prominent KOL was Dr. Lynn Webster, co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah.

490. Like Dr. Portenoy, Dr. Webster also served in leadership roles for various Front Groups and developed numerous CMEs sponsored by Purdue, Cephalon, and Endo. These included but are not limited to the *Opioid Treatment for Breakthrough Pain*; *Managing Patients' Opioid Use* CMEs; and National Initiative on Pain Control (NIPC) eNewsletter CMEs, discussed *infra*.

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

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

[114] *Id.*

[115] *Id.*

[116] *Id.*

491. KOL Webster developed a basic five-question risk screening tool called the "Opioid Risk Tool." 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 as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to doctors in Ohio during the relevant period.

492. In 2013, Dr. Webster served as AAPM's President, a Front Group to which he is currently a board member. He is Senior Editor of *Pain Medicine*, a medical journal employed by the Manufacturer Defendants to advertise their Opioid Products.

493. Dr. Webster also served on the APF Board.

494. During his time sitting on these purportedly non-biased boards, Dr. Webster received significant funding from the Manufacturer Defendants (including nearly $2 million from Cephalon).

495. Remarkably, a portion of Dr. Webster's time as KOL was marked by an active DOJ investigation for overprescribing, which led to his Utah clinic being raided in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients have died of opioid overdoses.

496. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, 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 pre-sort 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 Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue.

497. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to *increase* a patient's dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), a book that is still available online, when faced with signs of aberrant behavior, increasing the dose "in most cases…should be the clinician's first response." Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[117]

(c) KOL Perry Fine, M.D.

498. Dr. Perry Fine was another Manufacturer Defendant KOL, and received his financial support from Purdue, Cephalon, Janssen, and Endo. Through articles, CMEs, studies, and participation in various Front Groups, Dr. Fine contributed to the Manufacturer Defendants' ability to push false and misleading representations regarding the safety and efficacy of long-term opioid therapy for chronic pain.

499. Dr. Fine authored a CME, sponsored by Cephalon, titled *Opioid-Based Management of Persistent and Breakthrough Pain*, which Cephalon subsequently paid to have published in a 2009 supplement to *Pain Medicine News*. It instructed prescribers that "clinically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility," and recommended dispensing "rapid onset opioids" for "episodes that occur

[117] John Fauber, *Networking Fuels Painkiller Boom*, BANGOR DAILY NEWS (Feb. 19, 2012), http://bangordailynews.com/2012/02/19/health/networking-fuels-painkiller-boom/.

spontaneously" or unpredictably, including "oral transmucosal fentanyl," i.e., Actiq, and "fentanyl buccal tablet," i.e., Fentora, including in patients with chronic non-cancer pain.

500. Dr. Fine also served as editor for of various NIPC eNewsletter CMEs, discussed *infra*. Many of these were authored by Dr. Webster.

501. Dr. Fine not only served on the APS / AAPM Consensus Statement Committee discussed herein, but also served as AAPM's past president. He also served on APF's Board.

502. AAPM's publications note that at some point during 2012, Dr. Fine served on advisory boards for both Purdue and Actavis and also performed consultant work for Johnson & Johnson (now Janssen) and Mylan.[118] Dr. Fine received compensation from these Manufacturer Defendants.

503. However, just as the U.S. Senate Finance Committee launched its investigation in May 2012 into makers of narcotic painkillers and their relationships with doctors and advocacy groups, including APF, that have championed them, suddenly APF announced it was dissolving "due to irreparable economic circumstances."

(d) KOL Scott Fishman, M.D.

504. Dr. Scott Fishman also served the Manufacturer Defendants as a KOL.

505. Dr. Scott Fishman, another KOL whose work was long supported by opioid makers, acknowledged that data supporting the contention that addiction is rare:

> [The data] have been found to be inadequate and seriously flawed. Although we currently do not know the exact rate of addiction in patients legitimately prescribed opioids for pain or the rate of overall misuse, we know that rates are

[118] Perry Fine & Lynn Webster, *American Academy of Pain Medicine Response to PROP Petition to the FDA that Seeks to Limit Pain Medications for Legitimate Noncancer Pain Sufferers*, Pain Medicine (2012) at p.1. Accessed at: http://paindr.com/wp-content/uploads/2012/09/AAPM-journal-ARTICLE_Response-to-PROP_2012.pdf.

> high enough that they should be considered a significant potential adverse effect.[119]

506. Similarly, in his book, *Responsible Opioid Prescribing* (2007), which was funded by Defendants Cephalon, Endo, and Purdue, and is still distributed in Ohio, Dr. Scott Fishman asserts: "It may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications. But other causes of non-adherence should be considered before a judgment is made." Thus, according to Dr. Fishman, even patients at high risk for opioid addiction should be given the benefit of the doubt (and more opioids).

507. Dr. Fishman was tapped to author a companion piece, titled *Responsible Opioid Prescribing: A Physician's Guide* (2007). The *Guide* was sponsored by Defendants Endo, Cephalon, and Purdue and was distributed to state medical boards, healthcare regulatory boards, medical organizations, hospitals and physicians across the country, including in Ohio. The *Physician's Guide* contained many of the misrepresentations alleged herein, notably the concept of "pseudoaddiction" and the claim that opioids improve function.

508. He also (upon information and belief) served as past president to AAPM, as well as an APF board member.

(iv) Manufacturer Defendants Use Front Groups to Convey Misleading Unbranded Safety and Efficacy Messages

509. Among the strategies intentionally designed to obscure the actual sources and amounts of funding for promotional activities, the Manufacturer Defendants developed relationships with various "Front Groups"—*i.e.*, industry-funded grassroots, consumer advocacy,

[119] Scott M. Fishman, *Responsible Opioid Prescribing: A Clinician's Guide*, 15, The Fed'n of State Med. Bds. Found., 2nd ed. (2012).

research, and educational organizations whose primary goal is to promote marketing, influence regulations, or advance other industry interests.

510. The Manufacturer Defendants utilized non-profit organizations (such as the APF) as Front Groups to further their own self-interest of increasing market share for the Opioid Drugs. The Manufacturer Defendants' funding and partnering with the APF and/or other similar organizations was designed to accomplish through a non-profit organization what the Manufacturer Defendants could not do on their own: give the appearance of independent analysis and a grassroots movement encouraging FDA approval and expanding the use, including unapproved uses, for Opioid Drugs.

511. As with KOLs, Front Groups—as purportedly independent organizations—helped lend credibility to the Manufacturer Defendants' deceptive marketing. As one physician adviser to Defendants noted, third-party documents not only had greater credibility, but broader distribution, as HCPs did not "push back" at having materials from, for example, the non-profit APF on display in their offices, as they might with first party, drug company pieces.

512. Further, Front Groups—like KOLs—evaded FDA oversight and regulations regarding marketing due to their illusory independence from the Manufacturer Defendants.

513. The large number of these organizations (a recent U.S. Senate Committee Report found 14)[120] was no accident. The groups, who often had shared board members, reviewed and approved of each other's work or collaborated on projects. In this way, the Manufacturer Defendants were able to build an illusion of medical consensus around their false and misleading marketing claims.

[120] U.S. Senate Homeland Security & Governmental Affairs Committee, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, 115th Cong., 1 (Feb. 12, 2018), https://www.hsgac.senate.gov/media/minority-media/breaking-millions-in-payments-among-findings-of-mccaskill-opioid-investigation-into-ties-between-manufacturers-and-third-party-advocacy-groups-.

514. These Front Groups were funded in large part by the Manufacturer Defendants, had "corporate councils" with Manufacturer Defendant representatives, had a "revolving door" between industry employment and Front Group advocacy, and/or were comprised of individuals with financial ties to the Manufacturer Defendants.

515. The Manufacturer Defendants also cut-out the middleman and made huge payments directly to the board members and other decision-makers at these organizations, thereby creating egregious conflicts of interest aimed at driving those groups' messaging. Between 2013 and 2017, Manufacturer Defendants made substantial payments to Front Group affiliated individuals. For example, Dr. Charles Argoff, current AAPM President, received over $600,000 in payments.

516. The Manufacturer Defendants were involved in numerous Front Groups. Some of the most prominent Front Groups were the APF, AAPM, and the APS. In an effort to create an impression of medical consensus, these groups often "collaborated" on various initiatives and publications, such as the Pain Care Forum ("PCF") and FSMB projects.

(a) American Pain Foundation

517. The most prominent nonparty advocate for opioids, funded by Defendants, was the APF, which falsely held itself out to be an independent patient advocacy organization. In reality, APF advocates for opioid manufacturers, even accepting grants from manufacturers meant to "strategically align [the manufacturer's] investment in nonprofit organization that share [its] business interests."

518. Its media campaign led it in some instances to merely re-stamp their name on opioid manufacturer materials. For example, APF put out media packet—*APF Reporter's Guide: Covering Pain and its Management* (2009)—that simply recycled text previously used by a (non-defendant) drug manufacturer in its media relations. The "Reporter's Guide" also graciously

offered to "connect reporters with a wide array of leading pain experts," who (upon information and belief) consisted of the Manufacturer Defendants' KOLs.

519. Essentially the same drug company that was making general grants to APF was then directing APF on how to use them. In response to one particular APF request for funding to address a potentially damaging state Medicaid decision related to pain medications generally, one company's representative responded, "I provided an advocacy grant to APF this year—this would be a very good issue on which to use some of that. How does that work?"

520. APF received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million.

521. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. Even notorious KOL Dr. Portenoy admitted that the lack of funding diversity was a big problem for APF.

522. APF's board, which developed its messaging and reviewed its publications, was comprised in large part of KOLs sponsored by the Manufacturer Defendants. This includes Dr. Fine, Dr. Portenoy, and Dr. Fishman (discussed *supra*). Its board also included one or more individuals who also worked for public relations firms that represented certain Manufacturer Defendants.

523. APF issued "education guides" for physicians, patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks,

particularly the risk of addiction. It even provided "patient representatives" to participate in industry marketing campaigns.

524. APF also developed the National Initiative on Pain Control (NIPC), which ran a facially unaffiliated website called www.painknowledge.org and put on CME programs. NIPC was substantially controlled by Endo through funding of NIPC projects; in developing, directing specifics of, and reviewing content; and distribution of NIPC materials.

525. NIPC held itself out to be an education initiative and promoted its expert leadership team that included purported experts in the pain management field. Its website, painknowledge.org informed readers that while using 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." It also included improved quality of life and functions as benefits of opioid uses throughout the website. It falsely stated that "people that have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted" and did not rule out the possibility of those with a history of opioid addiction continuing to use the drugs.

526. APF also engaged in a significant multimedia campaign—through radio, television, and the internet—to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach Ohio physicians, patients, and TPPs.

527. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes—including death—among returning soldiers.

528. It also engaged in purported grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors.

529. APF took audacious stances in an effort to convince HCPs that the country was suffering from an epidemic of untreated pain—and that opioids were the solution. It even urged tracking of this so-called epidemic.

530. APF's activities were guided or controlled by various Manufacturer Defendants. In many instances, opioid manufacturer representatives—usually at informal meetings—"suggested" activities and publications for APF to pursue. APF would then submit a grant proposal seeking funding for these "suggested" activities, knowing that the drug companies would provide financial support.

531. APF caught the attention of the United States Senate Finance Committee in May 2012, as the Committee sought to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation raised red flags as to APF's credibility as an objective and neutral third party; the Manufacturer Defendants stopped funding it. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."

(b) The American Academy of Pain Medicine

532. AAPM, which falsely held itself out to be a professional society, was another one of the Manufacturer Defendants' Front Groups. Between 2012 and 2017, opioid manufacturers collectively submitted over $2.7 million in payments to AAPM.[121]

[121] U.S. Senate Homeland Security & Governmental Affairs Committee, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, 115th Cong., 1 (Feb. 12, 2018), https://www.hsgac.senate.gov/media/minority-media/breaking-millions-in-payments-among-findings-of-mccaskill-opioid-investigation-into-ties-between-manufacturers-and-third-party-advocacy-groups-.

533. AAPM's past presidents included numerous KOLs sponsored by the Manufacturer Defendants. This includes Dr. Fine, Dr. Portenoy, Dr. Webster, and Dr. Fishman (discussed *supra*).

534. With the assistance, prompting, and involvement of the Manufacturer Defendants (as well as other Front Groups), AAPM served the Manufacturer Defendants' financial interests. Through treatment guidelines, policies, and similar messaging, AAPM deceptively promoted opioids for the long-term treatment of chronic pain. AAPM issues guidelines and policies minimizing the risk of addition.

535. Additionally, AAPM lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for over-prescription and misbranding.

536. AAPM also sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic opioid therapy

537. AAPM was laser focused on promoting the use of Opioid Drugs for long-term treatment of chronic pain and minimizing the risk of addiction. At one conference alone, 37 out of 40 of the conference sessions were opioid-focused. Dr. Fishman, a past AAPM president, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are…small and can be managed."[122] AAPM even issued a statement in 1997 that endorsed opioids and claimed that the risk of opioid addiction in people taking prescription opioids was low.

538. The Manufacturer Defendants were able to use AAPM and other Front Groups to overestimate the prevalence of pain suffering and need for opioid therapy. Eleven AAPM

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

members were on the roster for the IOM Committee working on the 2011 report finding chronic pain affects over 100 million people. As AAPM member Dr. Sean Mackey deceptively notes, this influential report "clearly reinforce[s] that the overall burden of pain is just astronomically high."[123] Mackey also commented on the "clear overlap between the recommendations outlined in the [IOM] report and much of the vision of the [AAPM]."[124]

539. According to AIPM's website, they "greatly value…relationships with…commercial sponsors."[125] Corporate council benefits are said to "increase in value as the level of corporate support increases."[126] In exchange for funds, corporate council Defendants receive access to leadership and data the organization collects, including: "Executive Reports of Member and Patient Surveys," "Advised Input Into Planned Surveys," and "Monthly Email to Members Listing Sponsors Open Clinical Trials."[127] The benefits also included allowing members to present educational programs at off-site dinner symposia in connections with AAPM's marquee event – its annual meeting. Defendants Purdue, Cephalon, Endo and Actavis were members of the council and presented deceptive programs to HCPs who attended this annual event. Finally, corporate council members allowed drug company executives and

[123] The American Academy of Pain Medicine, *Shared Vision on Future of Pain Care*, 26 PAIN MEDICINE NETWORK 2, 4 (Fall 2011 / Winter 2012). *available at* http://www.painmed.org/files/network-newsletter-2011-fall-2012-winter.pdf.

[124] *Id.* at 1.

[125] Corporate Council Members, ACADEMY OF INTEGRATIVE PAIN MANAGEMENT, https://integrativepainmanagement.site-ym.com/page/CorporateCouncil, (last visited March 5, 2018).

[126] *Id.*

[127] Corporate Council Program, ACADEMY OF INTEGRATIVE PAIN MANAGEMENT, https://integrativepainmanagement.site-ym.com/page/CorpCouncilProgram (last visited March 5, 2018).

marketing staff to meet in an intimate setting, allowing an opportunity to align their fraudulent messages.[128]

540. As noted in greater detail below, AAPM also sought to undermine both the FDA and CDC's efforts to limit opioid prescribing contrary to the Manufacturer Defendants marketing plan.

541. In 2012, KOLs Dr. Fine and Dr. Webster co-authored the AAPM's response to the FDA's efforts to limit opioid medications to severe and cancer pain indications. The response circularly references the AAPM/APS 2009 Guidelines, written by KOLs and sponsored/funded by the Manufacturer Defendants, admitting the guidelines "are based on lower quality evidence" but maintaining that "[a]t best, the literature has shown inconsistent effectiveness of opioids for chronic pain." Parroting the opioid industry's message, the response further misleadingly states that mental health and substance-abuse comorbidities are "not a reason to deny people with pain an opioid."

(c) American Pain Society

542. APS was another of the Manufacturer Defendants' Front Groups. In 1996, the APS first introduced the concept of "pain as the 5th vital sign" to exaggerate and misinform the medical community that "pain assessment is as important assessment of the standard four vital signs and that clinicians need to take action when patients report pain."[129] As a result of equating subjective pain as a vital sign, physicians are forced to come up with a reliable and effective treatment if and when a patient gives a subjectively high pain rating on the scale.[130]

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[128] *Id.*

[129] National Pharmaceutical Council, *Section II: Assessment of Pain, available at* http://americanpainsociety.org/uploads/education/section_2.pdf (last visited March 26, 2018).

[130] Myles Gart, M.D., *Pain is not the fifth vital sign*, MEDICAL ECONOMICS (May 20, 2017), http://medicaleconomics.modernmedicine.com/medical-economics/news/pain-not-fifth-vital-sign.

543. According to a 2018 Senate Committee investigation, various Manufacturer Defendants combined to pay APS more than $1 million between 2012 and 2017.[131]

544. The APS website specifies that its "Corporate Council" contributors donate between $7,500 and $25,000. Various Manufacturer Defendants "served" on the Corporate Council during the relevant time period.

545. APS also publishes *The Journal of Pain*, which according to APS's website "aims to improve the care of patients in pain by providing a platform in which clinical researchers, basic scientists, clinicians, and other health professionals can publish original research. *JOP* is the second ranked pain journal in the world and has a current impact factor of 4.519 on 2013 Journal Citation Reports, which rises every year."[132] The Manufacturer Defendants utilized the *Journal of Pain* to disseminate their false and misleading statements regarding the safety and efficacy of Opioid Drugs for the long-term treatment of chronic pain.

546. In addition to its journal, APS has also generated and disseminated an electronic newsletter which also misleadingly marketed Opioid Drugs to prescribers.

547. APS also hosted a number of CMEs or other "educational" courses for physicians which were used by the Manufacturer Defendants to misleadingly market their Opioid Drugs to physicians. These include, *inter alia*, the *APS Resident's Course* sponsored by Endo, alleged in great detail, *infra*.

548. APS has several connections to other Front Groups through which the Manufacturer Defendants have funneled money and influence. For example, APS along with

[131] U.S. Senate Homeland Security & Governmental Affairs Committee,. *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, 115th Cong., 7 (Feb. 12, 2018), https://www.hsgac.senate.gov/media/minority-media/breaking-millions-in-payments-among-findings-of-mccaskill-opioid-investigation-into-ties-between-manufacturers-and-third-party-advocacy-groups-.

[132] American Pain Society, JOURNAL OF PAIN, *available at* http://americanpainsociety.org/education/the-journal-of-pain/overview (last accessed Mar. 20, 2018).

AAPM discussed herein were largely responsible for the misleading 1997 and 2009 treatment guidelines and consensus statements.

(d) Federation of State Medical Boards

549. Even where the Manufacturer Defendants did not completely control an organization, they were able to hijack that organization's messaging on pain treatment through the use of grants and lobbying. One example is the FSMB, an organization representing the various state medical boards in the United States (which in turn have the power to license, investigate, and discipline physicians).

550. The FSMB received funding from numerous Manufacturer Defendants, both to its general fund and to bankroll opioid promotion campaigns. FSMB in turn utilized these grants from the Manufacturer Defendants to finance various opioid- and pain-specific programs.

551. The FSMB is most well-known for its adoption of Treatment Guidelines and Model Policies, which are in turn adopted by many state medical boards. These policies are not only distributed to prescribing physicians (which certain Manufacturer Defendants funded), but form the standards against which state medical boards might discipline prescribing HCPs.

552. As explained *infra*, the FSMB's Treatment Guidelines and Model Policies were funded by industry and had a significant impact on prescribing behavior. The standards, not surprisingly, advocated for the use of opioids in the long-term treatment of chronic pain, minimized the risk of addiction, and promoted false concepts such as "pseudoaddiction".

(e) Pain Care Forum

553. The PCF was yet another attempt by Defendants to push false and misleading messages about the existence of a pain epidemic in America, the safety and efficacy of long-term opioid drug therapy in treating said epidemic, and other typical claims. In addition to utilizing the tools used by other Front Groups, PCF aggressively used lobbying to achieve these ends.

554. In 2004, the Front Groups combined with the Manufacturer Defendants to form the PCF, which began as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and to "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe allegedly described the forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

555. PCF is comprised of representatives from opioid manufacturers and distributors (including, *inter alia*, Purdue, Cephalon, Janssen, and Endo); HCPs and nurses in the field of pain care; professional organizations (including AAPM, APS, and American Society of Pain Educators); patient advocacy groups (including APF and American Chronic Pain Association (ACPA)); and other like-minded organizations, almost all of which received substantial funding from Defendants.

556. For example, the PCF organized a Capitol Hill briefing entitled "*The Epidemic of Pain in America*" in June of 2006, which included misleading statements, such as: "[a]ppropriate use of opioid medications like oxycodone is safe and effective and unlikely to cause addiction in people who are under the care of a doctor and who have no history of substance abuse."[133]

557. In or around 2007, the PCF specifically "agreed to pay a public relations consultant $85,000 to prep speakers, draft patient testimonials and coordinate an educational initiative focused on elected officials and the state medical board."[134] At the same time, the PCF Education Subgroup, including Purdue and APF, developed a plan to address perceived "lack of

[133] Matthew Perrone and Ben Wieder, *Pro-painkiller echo chamber shaped policy amid drug epidemic*, THE CENTER FOR PUBLIC INTEGRITY (Sept. 19, 2016),https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic.

[134] Geoff Mulvihill and Liz Essley Whyte, *Drugmakers fought domino effect of Washington opioid limits*, THE CENTER FOR PUBLIC INTEGRITY (Sept. 21, 2016), https://www.publicintegrity.org/2016/09/18/20202/drugmakers-fought-domino-effect-washington-opioid-limits.

coordination" among the industry and pro-opioid organizations. PCF members agreed to develop simplified "key" messages for public education purposes. These messages are reflected in NIPC's *Let's Talk Pain* (put together by Endo and APF) and Purdue's *In the Face of Pain* (both discussed below). According to APF meeting minutes, as early as 2008, the PCF was developing lobbying strategies to influence and "inform the process" at the FDA.[135]

558. PCF also sought to influence and undermine the FDA's 2009 REMS for long-acting opioids, discussed *infra*. For example, in response to the FDA requiring drug companies to fund CMEs related to opioid risks in accordance with its REMS, PCF lobbied to ensure that it would not be mandatory for prescribers to attend the CMEs. A survey was circulated among Endo, Janssen and Purdue which predicted the rates of doctors who prescribe opioids for chronic pain would fall by 13% if more than four hours of mandatory patient education were required.

559. PCF was heavily involved in lobbying. Purdue's Washington lobbyist, Burt Rosen, helped co-found the PCF and coordinates the group's monthly meetings, which include dozens of lobbyists and executives of opioid pharmaceutical manufacturer defendants. PCF met regularly in-person and via teleconference, and shared information through an email listserv.[136]

560. According to a report by the Associated Press and the Center for Public Integrity, the pharmaceutical companies and allied groups that comprise the PCF "spent more than $880 million from 2006 to 2015 on campaign contributions and lobbying expenses at the state and federal levels" to preserve the status quo of aggressive opioid prescribing.[137] Front Groups like PCF, the report noted, served as "advocates spreading opioid-friendly narratives – with their

[135] Matthew Perrone and Ben Wieder, *Pro-painkiller echo chamber shaped policy amid drug epidemic*, THE CENTER FOR PUBLIC INTEGRITY (Sept. 19, 2016),https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic.

[136] *Id.*

[137] *Politics of Pain: A decade of opioid lobbying,* ASSOCIATED PRESS & THE CENTER FOR PUBLIC INTEGRITY, (Sept. 19, 2016), http://data.ap.org/projects/2016/cpi_ap_opioids/indexcpiap.html

links to drug companies going unmentioned – or by persuading pharma-friendly lawmakers to introduce legislation drafted by the industry."[138]

561. PCF engaged in efforts to defeat proposed opioid prescribing guidelines, meeting with health advisers to discuss the "unintended consequences" of Washington state's stricter opioid prescribing guidelines discouraging high doses.[139]

562. PCF participants spent nearly $19 million on lobbying efforts that included the legislation requiring federal research on pain and the Institute of Medicine ("IOM") report that first highlighted the figure that more than 100 million Americans suffer from debilitating pain.[140] Nearly half the experts assembled by the IOM to write the 364-page report had served as leaders in PCF-affiliated groups, such as the APF, the APS and the AAPM — all supported by industry funding.[141] Essentially the IOM report derived from legislation drafted and pushed by PCF members that their experts had helped author. After the report's release in June of 2011, the APF received $150,000 from Purdue to promote its findings through the PCF.[142] To further highlight the manipulated information and perpetuate the myth that chronic pain in America was a "crisis of epidemic proportions," PCF sent a letter to U.S. senators in 2012 to promote a hearing on the influential IOM report.

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[138] *Id.*

[139] Geoff Mulvihill and Liz Essley Whyte, *Drugmakers fought domino effect of Washington opioid limits*, THE CENTER FOR PUBLIC INTEGRITY (Sept. 21, 2016),https://www.publicintegrity.org/2016/09/18/20202/drugmakers-fought-domino-effect-washington-opioid-limits.

[140] Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research*, NATIONAL ACADEMIES PRESS (2011), https://www.ncbi.nlm.nih.gov/books/NBK92516/#ch2.s1.

[141] Matthew Perrone and Ben Wieder, *Pro-painkiller echo chamber shaped policy amid drug epidemic*, THE CENTER FOR PUBLIC INTEGRITY (Sept. 19, 2016), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic.

[142] *Id.*

563. PCF was also instrumental in lobbying for state bills mandating coverage for abuse-deterrent formulations.[143] PCF has influenced the passage of more than 100 state bills (at least 81 in the 2015-2016 timeframe) with at least 21 containing nearly identical language.

(f) Alliance for Patient Access

564. The Alliance for Patient Access ("APA") was founded in 2006. The APA is a self-described patient advocacy and health professional organization comprised of "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care."[144] It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.[145] As of June 2017, the APA listed 30 "Associate Members and Financial Supporters," including Defendants Endo, Mallinckrodt, Purdue and Cephalon.

565. Between 2013 and 2015, APA board members directly received over $2 million in funding from pharmaceutical companies, including Manufacturer Defendants Endo, Insys, Purdue, Cephalon, and Mallinckrodt.[146]

566. The APA issued a white paper entitled *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*,[147] which among other things, parrots the Manufacturer Defendants' sentiments criticizing prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy, stating:

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[143] *Id.*

[144] *About APA*, The Alliance for Patient Access, http://allianceforpatientaccess.org/about-afpa/#membership (last visited Apr. 23, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

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

[146] *See* ProPublica's Dollars for Docs database, *available at* http://projects.propublica.org/docdollars/.

[147] *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, Institute for Patient Access (Oct. 2013), http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/01/PT_White-Paper_Finala.pdf.

> 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.

567. Again aligning itself with pro-opioid industry marketing and messages, the APA's white paper laments the stigma associated with prescribing and taking pain medication (termed by the industry as "opioidphobia"):

> 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.[148]

568. The white paper also deceptively concludes 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."[149]

569. The APA's white paper further purports to express concern about policies enacted in response to the prevalence of "pill mills," claiming such policies make it "difficult for legitimate pain management centers to operate." The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the

[148] *Id.* at 6.

[149] *Id.* at 7.

DEA to police pill mills by enforcing the "suspicious orders" provision of the CSA.[150] The AAPM, another front group, is also a signatory to this letter. An internal DOJ memo stated that the proposed bill "could actually result in increased diversion, abuse, and public health and safety consequences"[151] and, according to the DEA chief administrative law judge John J. Mulrooney, the law would make it "all but logically impossible" to defend prosecutions of manufacturers and distributors, like the Manufacturer Defendants here, in the federal courts.[152] The law passed both houses of Congress and was signed into law in 2016.

(g) The American Academy of Integrative Pain Management

570. The Academy of Integrative Pain Management ("AIPM") was yet another Front Group that receives significant funding from the Defendants. Formerly the American Academy of Pain Management, the AIPM represents itself as a "diverse community of healthcare providers representing more than 30 distinct disciplines who are dedicated to *using all appropriate therapeutic approaches* to reduce pain, and achieve optimal health and healing."[153] Despite the name change and this ostensibly holistic goal, the former American Academy of Pain Management received approximately $1.2 million in funding from the Defendants between 2012 and 2017.

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[150] Letter from Alliance for Patient Access, et al., to Congressman Tom Marino, Marsha Blackburn, Peter Welch, and Judy Chu (Jan. 26, 2015), *available at* http://www.hoparx.org/images/hopa/advocacy/advocacy-activities/FINAL_Patient_Access_Letter_of_Support_House_Bill.pdf.

[151] Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS NEWS (Oct. 17, 2017), https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/.

[152] John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101(2) Marquette L. Rev. 333-451 (Winter 2017), http://scholarship.law.marquette.edu/cgi/viewcontent.cgi?article=5348&context=mulr.

[153] Corporate Council Members, ACADEMY OF INTEGRATIVE PAIN MANAGEMENT, https://integrativepainmanagement.site-ym.com/page/CorporateCouncil, (last visited March 5, 2018).

571. According to AIPM's website, they "greatly value…relationships with…commercial sponsors." Corporate council benefits are said to "increase in value as the level of corporate support increases." In exchange for funds, corporate council Defendants receive access to leadership and data the organization collects, including: "Executive Reports of Member and Patient Surveys," "Advised Input Into Planned Surveys," and "Monthly Email to Members Listing Sponsors Open Clinical Trials." The benefits also included allowing members to present educational programs at off-site dinner symposia in connections with AAPM's marquee event – its annual meeting. Defendants Purdue, Cephalon, Endo and Actavis were members of the council and presented deceptive programs to HCPs who attended this annual event. Finally, corporate council members allowed drug company executives and marketing staff to meet in an intimate setting, allowing an opportunity to align their fraudulent messages.

(v) Each Manufacturer Defendant Used Front Groups to Deliver Its Misleading Unbranded Message

(a) Purdue's Use of Front Groups

572. Between 2012 and 2017, Purdue made payments to many Front Groups, including the AIPM ($1,091,024), AAPM ($725,584), APS ($542,249), U.S. Pain Foundation (USPF) ($359,300), ACPA ($312,470), American Society of Pain Management Nursing (ASPMN) ($242,535), American Society of Pain Educators (ASPE) ($30,000), APF ($25,000), American Geriatric Society (AGS) ($11,785), and others. During those years, Purdue's payments to Front Groups exceeded $4 million.

573. Between 2012 and 2017, Purdue (combined with Janssen, Insys, Depomed, and Mylan) also made payments to individuals affiliated with Front Groups, including: National Pain Foundation ("NPF") ($839,848), AAPM ($330,636), ASPE ($280,765), APS ($95,474), ACPA ($31,265), and AIPM ($30,223).

574. Between 2007 and 2012, APF received approximately $1.7 million from Purdue. Purdue also made payments to persons on APF's board (who also reviewed and approved its publications), including Dr. Fine, Dr. Portenoy, Dr. Fishman, and Dr. Webster. Another APF board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF. Purdue utilized APF "patient representatives" in its promotional activities, including its *Partners Against Pain* campaign. As early as 2011, Purdue told APF that the basis of its grant to APF was its desire to "strategically align its investments in nonprofit organizations that share [its] business interests." As alleged in greater detail, *infra*, the agreement between Purdue and APF with respect to the *Partners Against Pain* campaign gave exclusive control of content to Purdue.

575. Purdue also sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The sole reference for the functional improvement claim noted the absence of long-term studies and actually stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids."

576. Purdue also used staff and board members from APF, ACPA, and AAPM to appear on its patient-oriented *In The Face of Pain* website. They were presented as "Voices of Hope" – "champions passionate about making a difference in the lives of people who live with pain" and providing "inspiration and encouragement" to pain patients. This website is discussed in greater detail, *infra*.

577. Purdue, who sat on AAPM's corporate council (for an annual cost of $25,000), eventually hired AAPM's Past President (Dr. David Haddox) as Vice President of Health Policy

at Purdue. Purdue also made payments to persons who served as AAPM Presidents, including Dr. Portenoy and Dr. Webster. Purdue used its AAPM corporate council membership to make false and misleading presentations to prescribing physicians at AAPM's annual meetings. One of Purdue's KOLs, Dr. Portenoy, was the sole consultant to AAPM's 1997 Consensus Statement, discussed *infra.*

578. Purdue also sat on APS's Corporate Council, donating between $7,500 and $25,000 to APS annually. This was true for 2012 and in numerous other years as well. A 2018 investigation by a U.S. Senate Committee revealed that between 2012 and 2017, various Manufacturer Defendants (including Purdue) paid approximately $1 million to APS. Approximately $542,259 of these contributions came from Purdue.

579. Since at least 2011, APS's electronic newsletter has been sponsored by Purdue.[154]

580. Purdue also sponsored various APS CMEs aimed at prescribing physicians, including *inter alia, Pain: Current Understanding of Assessment, Management and Treatments*, discussed *infra.*

581. Purdue was a main contributor to the FSMB, both generally as well as for opioid-specific promotion campaigns. Between 1997 and 2012, Purdue paid the FSMB over $800,000.

582. Purdue spent at least $100,000 to pay for the distribution of the FSMB's Model Policy concerning opioids to approximately 700,000 prescribing HCPs. Purdue also made payments to Scott Fishman, one of its KOLs, who was hired by FSMB to convert the Model Policy into a book. In addition to payments to Dr. Fishman, Purdue also paid FSMB to fund his book. The book, *Responsible Opioid Prescribing: A Physician's Guide*, was then cited by the Manufacturer Defendants, along with their KOLs and Front Groups, as "evidence" supporting

[154] AMERICAN PAIN SOCIETY, APS E-NEWS, (Dec. 2011), *available at* http://www.americanpainsociety.org/enews/2011/dec/.

their false and misleading marketing claims. Purdue then funded CMEs based on the Model Guidelines.

583. Purdue also provided grants for the production and distribution of the AGS's 2009 treatment guidelines, *Pharmacological Management of Persistent Pain in Older Persons*.

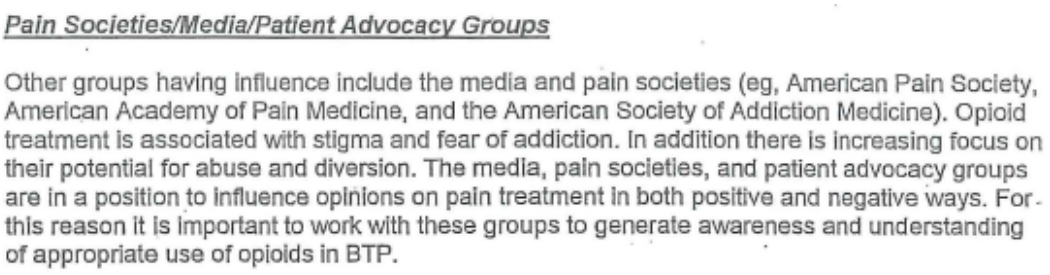
584. Purdue helped initiate and/or fund the PCF, the "collaborative" project aimed at creating an illusion of medical consensus around the Manufacturer Defendants' marketing themes.

585. Purdue, combined with five other opioids manufacturers, made payments exceeding $140,000 to ten members of the ACPA Advisory Board.

586. Purdue was also a member (and a contributor) to the Healthcare Distribution Alliance ("HDA"), an association of pharmaceutical manufacturers and distributors that worked tirelessly to protect the market for Opioid Drugs by fighting regulatory efforts to crack down on drug diversion. The HDA is alleged in greater detail *infra*.

(b) Cephalon's Use of Front Groups

587. Cephalon's Brand Plan at the time it launched Fentora in 2006 made clear they would focus on "Pain Societies/Media/Patient Advocacy Groups" to "influence opinions on pain treatment":



Pain Societies/Media/Patient Advocacy Groups

Other groups having influence include the media and pain societies (eg, American Pain Society, American Academy of Pain Medicine, and the American Society of Addiction Medicine). Opioid treatment is associated with stigma and fear of addiction. In addition there is increasing focus on their potential for abuse and diversion. The media, pain societies, and patient advocacy groups are in a position to influence opinions on pain treatment in both positive and negative ways. For this reason it is important to work with these groups to generate awareness and understanding of appropriate use of opioids in BTP.

588. Cephalon provided funding to APF before withdrawing its support due to the Senate investigation. During that time, Cephalon made payments to persons on APF's board

(who also reviewed and approved its publications), including Dr. Fine, Dr. Portenoy, and Dr. Fishman.

589. Cephalon representatives sat on AAPM's corporate council, whose membership cost Cephalon $25,000 per year. Cephalon used its AAPM corporate council membership to make false and misleading presentations to prescribing physicians at AAPM's annual meetings. It further also made payments to persons who served as AAPM President, including Dr. Portenoy, Dr. Fishman, and Dr. Webster. One of Cephalon's KOLs, Dr. Portenoy was the sole consultant to AAPM's 1997 Consensus Statement, discussed *infra.*

590. Cephalon also sat on APS' Corporate Council, donating between $7,500 and $25,000 to APS annually. This was true for 2012, and in numerous other years as well. A 2018 investigation by a U.S. Senate Committee revealed that between 2012 and 2017, various Manufacturer Defendants (including Cephalon) paid approximately $1 million to APS.

591. Between 1997 and 2012, Cephalon provided approximately $180,000 to FSMB. Cephalon helped fund FSMB's project to convert the organization's opioid friendly Model Guidelines into a book by Dr. Fishman, *Responsible Opioid Prescribing: A Physician's Guide*. Dr. Fishman was also a notorious Cephalon (and Purdue) KOL. Cephalon spent $150,000 to purchase copies of the book in bulk and distributed the book through its pain sales force to 10,000 prescribers and 5,000 pharmacists.

592. Cephalon helped initiate and/or fund PCF, the "collaborative" project aimed at creating an illusion of medical consensus around the Manufacturer Defendants' marketing themes.

593. Cephalon was also a member (and a contributor) to the HDA, an association of pharmaceutical manufacturers and distributors that worked tirelessly to protect the market for

opioids by fighting regulatory efforts to crack down on drug diversion. The HDA is alleged in greater detail *infra*.

(c) Janssen's Use of Front Groups

594. Between 2012 and 2017, Janssen made payments to many Front Groups including AIPM ($128,000), APS ($88,500), AAPM ($83,975), ASPMN ($55,177), ACPA ($50,000), USPF ($41,500), and others. During those years, Janssen's payments to Front Groups were nearly $500,000.

595. Between 2012 and 2017, Janssen (combined with Purdue, Insys, Depomed, and Mylan) also made payments to individuals affiliated with Front Groups, including: NPF ($839,848), AAPM ($330,636), ASPE ($280,765), APS ($95,474), ACPA ($31,265), and AIPM ($30,223).

596. Janssen also made payments to persons on APF's board (who also reviewed and approved its publications), including Dr. Fine and Dr. Portenoy. Janssen utilized APF "patient representatives" in its promotional activities, including its *Let's Talk Pain* campaign. Janssen funded and controlled the content of the *Let's Talk Pain* website, while orchestrating (through financing) the "involvement" of APF, AAPM, and ASPMN.

597. Janssen sat on AAPM's corporate council board, at an annual cost of $25,000. It used this position to make false and misleading presentations to prescribing physicians at AAPM's annual meetings. Janssen also made payments to Dr. Portenoy, who served at one time as AAPM's President. Dr. Portenoy was the sole consultant to AAPM's 1997 Consensus Statement, discussed *infra.*

598. Janssen also worked with various Front Groups to create and disseminate brochures and guides. Ostensibly aimed at "educating" HCPs and patients, these materials were

nothing more than a medium by which Janssen made misleading statements regarding the safety and efficacy of long-term Opioid Drug use.

599. For example, Janssen worked with AAPM and AGS to create a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) (discussed in greater detail, *infra*).

600. Janssen also worked with AAPM to purchase and distribute copies of *Finding Relief.* The money behind these and many other "educational" efforts, led to widespread lack of skepticism on the part of leading physicians about the hazards of opioids. It also led these physicians to accept without adequate scrutiny published studies that, while being cited to support the safety of opioids, were, in fact, of such poor methodological quality that they would not normally be accepted as adequate scientific evidence.

601. *Finding Relief* is rife with deceptive content. *Finding Relief* misrepresents that opioids increase function by featuring a man playing golf on the cover and listing examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The guide states as a "fact" that "opioids may make it easier for people to live normally." The functional claims contained in *Finding Relief* are textbook examples of Defendants' use of third parties to disseminate messages the FDA would not allow them to say themselves.

602. *Finding Relief* also trivialized the risks of addiction describing as a "myth" the fact that opioids are addictive, and asserting as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

603. *Finding Relief* further misrepresented that opioids were safe at high doses by listing dose limitations as "disadvantages" of other pain medicines and omitting any discussion

of risks from increased doses of opioids. The publication also falsely claimed that it is a "myth" that "opioid doses have to be bigger over time."

604. Finally, *Finding Relief* deceptively overstated the risks associated with alternative forms of treatment. It juxtaposed the advantages and disadvantages of NSAIDs on one page, with 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 "increase[d] . . .risk of heart attack and stroke." Conversely, the only adverse effects of opioids listed by *Finding Relief* are "upset stomach or sleepiness," which the brochure claims will go away, and constipation. The guide never mentions addiction, overdose, abuse, or other serious side effects of opioids.

605. Janssen was not merely a passive sponsor of *Finding Relief*. Instead, Janssen exercised control over its content and provided substantial assistance to AGS and AAPM to distribute it. A "Copy Review Approval Form" dated October 22, 2008 indicates that key personnel from Janssen's Advertising & Promotion, Legal, Health Care Compliance, Medical Affairs, Medical Communications, and Regulatory Departments reviewed and approved Finding Relief. All six Janssen personnel approving the publication checked the box on the approval form indicating that *Finding Relief* was "Approved With Changes." After the publication was modified at the behest of Janssen personnel, Janssen paid to have its sales force distribute 50,000 copies of *Finding Relief* throughout the nation. Thus, *Finding Relie*f is considered labeling for Janssen's opioids within the meaning of 21 C.F.R. § 1.3(a).

606. Janssen also sat on APS's Corporate Council, donating between $7,500 and $25,000 to APS annually. This was true for 2012 and in numerous other years as well. A 2018 investigation by a U.S. Senate Committee revealed that between 2012 and 2017, various

Manufacturer Defendants (including Janssen) paid approximately $1 million to APS. Approximately $88,500 of these contributions came from Janssen.

607. Janssen also utilized APS's *Journal of Pain* to disseminate marketing materials directed at physicians. For example, Janssen[155] conducted a survey entitled *Clinicians' Attitudes and Beliefs about Opioids Surveys (CAOS): Instrument Development and Results of National Physician Survey* which was published in APS's Journal of Pain in June 2013.[156] The authors concluded that the survey results showed "that negative physician attitudes about opioids are closely associated with lower rates of prescribing and more favorable attitudes are linked with higher prescribing levels."[157] This study shows how the Manufacturer Defendants recognized the importance of changing HCPs' attitudes. Formulary status was thus also relevant to HCPs' attitudes.

608. Janssen helped initiate and/or fund PCF, the "collaborative" project aimed at creating an illusion of medical consensus around the Manufacturer Defendants' marketing themes.

609. Janssen and/or its subsidiaries was also a member (and a contributor) to the HDA, an association of pharmaceutical manufacturers and distributors, that worked tirelessly to protect the market for Opioid Drugs by fighting regulatory efforts to crack down on drug diversion. The HDA is alleged in greater detail *infra*.

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[155] Janssen Scientific Affairs.

[156] Hilary D. Wilson, et al., *Clinicians' Attitudes and Beliefs About Opioids Survey (CAOS): Instrument Development and Result of a National Physician Survey*, 6 The Journal of Pain 613 (2013); *see also* AMERICAN PAIN SOCIETY, APS E-NEWS, (June 2013), http://www.americanpainsociety.org/enews/2013/june.html.

[157] *Id.*

(d) Endo's Use of Front Groups

610. Between 2007 and 2012, APF received more than $5 million from Endo. Endo also made payments to persons on APF's board (who also reviewed and approved its publications), including Dr. Fine and Dr. Portenoy.

611. Endo also funded and substantially controlled APF's National Initiative on Pain Control (NIPC).

612. Endo also made payments to Dr. Portenoy, who served as AAPM's President. Dr. Portenoy was the sole consultant to AAPM's 1997 Consensus Statement, discussed *infra.*

613. Endo representatives sat on AAPM's corporate council, whose membership cost Endo $25,000 per year. Endo used its AAPM corporate council membership to make false and misleading presentations to prescribing physicians at AAPM's annual meetings.

614. In 2008, Endo spent $1 million per year to attend conventions of these pro-opioid medical societies, including meetings of AAPM. Endo also worked with AAPM, which it viewed internally as "Industry Friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications.

615. Endo also provided grants for the production and distribution of the AGS's 2009 treatment guidelines, *Pharmacological Management of Persistent Pain in Older Persons*. Endo went on to fund AGS efforts to develop and conduct CME(s) based on these guidelines. Endo contracted with the AGS's 2009 treatment guidelines to produce a CME promoting the 2009 guidelines for the Pharmacological Management of Persistent Pain in Older Persons. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids, and there is no such evidence. Endo was aware of the AGS guidelines' content when it agreed to

provide this funding, and AGS drafted the guidelines with the expectation it would seek drug-company funding to promote them after their completion.

616. Endo also sat on APS's Corporate Council, donating between $7,500 and $25,000 to APS annually. This was true for 2012 and in numerous other years as well.

617. Between 1997 and 2012, Endo has contributed at least $350,000 to FSMB. Endo helped fund (paying approximately $50,000) FSMB's project to convert the organization's opioid friendly Model Guidelines into a book by Dr. Fishman, *Responsible Opioid Prescribing: A Physician's Guide*. Endo also funded CMEs based on the book and Model Guidelines, including CMEs offered by the University of Wisconsin's Pain & Policy Group.

618. Endo helped initiate and/or fund PCF, the "collaborative" project aimed at creating an illusion of medical consensus around the Manufacturer Defendants' marketing themes.

619. Endo, combined with five other opioid manufacturers, made payments exceeding $140,000 to ten members of the ACPA Advisory Board.

620. Endo was also a member (and a contributor) to the HDA, an association of pharmaceutical manufacturers and distributors that worked tirelessly to protect the market for Opioid Drugs by fighting regulatory efforts to crack down on drug diversion. The HDA is alleged in greater detail *infra*.

(e) Actavis's Use of Front Groups

621. Actavis representatives sat on AAPM's corporate council, whose membership cost Actavis $25,000 per year. Actavis used its AAPM corporate council membership to make false and misleading presentations to prescribing physicians at AAPM's annual meetings.

622. Actavis also sat on APS' Corporate Council, donating between $7,500 and $25,000 to APS annually. This was true for 2012 and in numerous other years as well.

623. Actavis (Teva), combined with five other opioids manufacturers, made payments exceeding $140,000 to ten members of the ACPA Advisory Board.

624. Actavis also presented at various Front Group meetings. For example, Actavis presented papers concerning Kadian at an annual meeting of AGS because AGS's guidelines, according to Actavis documents, "support the use of opioids."

625. Actavis was also a member (and a contributor) to the HDA, an association of pharmaceutical manufacturers and distributors that worked tirelessly to protect the market for Opioid Drugs by fighting regulatory efforts to crack down on drug diversion. The HDA is alleged in greater detail *infra*.

(f) Insys's Use of Front Groups

626. Between 2012 and 2017, Insys made payments to Front Groups, including USPF ($2,500,000), NPF ($562,500), AAPM ($57,750), APS ($22,965), and AIPM ($3,050). During those years, Insys's payments to Front Groups exceeded $3.1 million.

627. Between 2012 and 2017, Insys (combined with Purdue, Janssen, Depomed, and Mylan) also made payments to individuals affiliated with Front Groups, including: NPF ($839,848), AAPM ($330,636), ASPE ($280,765), APS ($95,474), ACPA ($31,265), and AIPM ($30,223).

628. Insys representatives sat on AAPM's corporate council, whose membership cost Actavis $25,000 per year. Insys used its AAPM corporate council membership to make false and misleading presentations to prescribing physicians at AAPM's annual meetings.

629. Insys also made presentations (and/or exhibits) at APS annual scientific meetings, including in 2013 and 2014. These presentations dealt with the use of Insys's Opioid Drugs for the long-term treatment of chronic pain.

630. Between 2013 and 2016, Insys further paid NPF Chairman and founder Dr. Daniel Bennett more than $170,000.

631. Insys was also a member (and a contributor) to the HDA, an association of pharmaceutical manufacturers and distributors that worked tirelessly to protect the market for Opioid Drugs by fighting regulatory efforts to crack down on drug diversion. The HDA is alleged in greater detail *infra*.

(g) Mallinckrodt's Use of Front Groups

632. Like the other Manufacturer Defendants, Mallinckrodt provided substantial funding to purportedly neutral organizations which disseminated false messaging about opioids. For example, until at least February 2009, Mallinckrodt provided an educational grant to *Pain-Topics.org*, a now-defunct website that touted itself as "a noncommercial resource for HCPs, providing open access to clinical news, information, research, and education for a better understanding of evidence-based pain-management practices."[158]

633. In November 2016, Mallinckrodt paid Dr. Scott Gottlieb ("Gottlieb"), the new commissioner of the FDA, $22,500 for a speech in London, shortly after the U.S. presidential election. Gottlieb has also received money from the HDA, an industry-funded organization that pushes the agenda of large pharmaceutical wholesalers, and he has often criticized efforts aimed at regulating the pharmaceutical opioid market.

634. Over the years, Mallinckrodt has paid at least $100,000 to FSMB.

635. Mallinckrodt, combined with five other opioids manufacturers, made payments exceeding $140,000 to ten members of the ACPA Advisory Board.

[158] Pain Treatment Topics, Pain-Topics.org, https://web.archive.org/web/ 20070104235709/http://www.pain-topics.org:80/ (last visited Oct. 10, 2017).

636. Mallinckrodt was also a member (and a contributor) to the HDA, an association of pharmaceutical manufacturers and distributors that worked tirelessly to protect the market for Opioid Drugs by fighting regulatory efforts to crack down on drug diversion. The HDA is alleged in greater detail *infra*.

(vi) The Impact of the Manufacturer Defendants' Use of Front Groups to Deliver Their False and Misleading Unbranded Messages

637. A lack of funding transparency was key to the success of these Front Groups in marketing Opioid Drugs. Due to their classification under the U.S. tax code, the Front Groups had no legal obligation to disclose their donors publicly in their I.R.S. Form 990 filings. And whereas other professional groups feel an ethical obligation to disclose any potential conflicts of interest, the Front Groups did not.

638. As noted in the Senate Report, of the 14 Front Groups profiled, "no organization…provides an online list linking donors, their specific donations, and the projects or events benefiting from each donation for each of the years between 2012 and 2017."[159]

639. Funding from Manufacturer Defendants shaped in large part the message of these groups. "The necessary conditions for [the opioid] crisis," the Senate Report noted, "may have arisen, in part, due to the financial relationships between opioid manufacturers and patient advocacy groups and medical professional societies[.]"[160]

640. The Manufacturer Defendants' payments to these organizations coincided with their financial interest in the opioids market, destroying any notion that their contributions were for any reasons other than their own financial interest. For example, Insys payments rose

[159] U.S. Senate Homeland Security & Governmental Affairs Committee,. *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, 115th Cong., 11-12 (Feb. 12, 2018), https://www.hsgac.senate.gov/media/minority-media/breaking-millions-in-payments-among-findings-of-mccaskill-opioid-investigation-into-ties-between-manufacturers-and-third-party-advocacy-groups-.

[160] *Id.* at 2.

significantly starting in 2012, when the company received FDA approval for Subsys. And payments from Janssen dropped sharply to $0 in 2015, coinciding with its sale of its U.S. licensing rights for its blockbuster opioid Nucynta to Depomed for $1.05 billion.

641. The Front Groups were involved in numerous activities aimed at increasing the medical market for Opioid Drugs, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain. Much of this work was comprised of CMEs, Treatment Guidelines, pamphlets for patients, and "Consensus Statements," discussed *infra*.

642. APS, for example, campaigned to make pain the "fifth vital sign" that HCPs should monitor, alongside blood pressure, temperature, heartbeat and breathing. The addition of "pain" as a vital sign was simply part of Manufacturer Defendants' greater efforts to create an "epidemic of pain" in the United States. Shortly after APS's campaign, the U.S. Department of Veterans Affairs adopted such a standard into their national pain management strategy. On June 16, 2016, at its annual meeting in Chicago, the American Medical Association (AMA)—a legitimate medical organization—urged physicians to eliminate pain as the fifth vital sign

643. Some Front Groups also lobbied to change laws directed at curbing opioid use and challenged legal efforts to hold physicians and industry executives accountable for overprescribing and misbranding.

644. The impact of these groups as part of Manufacturer Defendants' marketing scheme was significant. A U.S. Senate Committee investigation found that "[i]nitiatives from the groups…often echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of opioid manufacturers. These groups have issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain,

lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for over prescription and misbranding."

5. False and Misleading Marketing Disguised as Unbranded Continuing Medical Education

645. The Manufacturer Defendants also funded a number of Continuing Medical Education Programs that were little more than face-to-face marketing sessions between their agents and prescribing physicians. The aim of these CMEs was to ensure that Manufacturer Defendants' long-term opioid use agenda was spread effectively.

646. Because industry-sponsored CMEs are typically delivered by KOLs, whose presentations are expected to reflect their medical expertise and "cutting edge" practices, HCPs who attend these CMEs are particularly susceptible to Defendants' messaging.

647. In other instances, the Manufacturer Defendants' would hide their involvement in the CMEs with Front Groups. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, the Manufacturer Defendants could expect messages to be favorable to them, as these organizations were otherwise dependent on the Manufacturer Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy.

648. Manufacturer Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and the Manufacturer Defendants measured the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

649. Further, in addition to using CMEs to propagate the false messages, the Manufacturer Defendants took effective steps to suppress other CMEs which (accurately) contradicted their marketing message. In 2009, the FDA sought to convince state medical boards

to require all physicians take a vetted CME accurately representing the efficacies and risks. The Manufacturer Defendants undertook a study and found that such a requirement would result in at least a 13% reduction in opioid drug prescription rates. To protect their market, these manufacturers (through the PCF which they controlled) lobbied and successfully had the measure killed.

650. The American Medical Association ("AMA") has recognized 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 educational subject matter."[161] The Manufacturer Defendants-sponsored CMEs fell short of these standards.

651. The influence of Manufacturer Defendants' funding on the content of these CMEs is clear. One study by a Georgetown University Medical Center professor compared the messages retained by medical students who reviewed an industry-funded CME article on opioids versus another group who reviewed a non-industry-funded CME article. The industry-funded CME did not mention opioid-related death once; the non-industry-funded CME mentioned opioid-related death 26 times. Students who read the industry-funded article more frequently noted the impression that opioids were underused in treating chronic pain. The "take—aways" of those reading the non-industry-funded CME mentioned the risks of death and addiction much more frequently than the other group. Neither group could accurately identify whether the article

[161] *Financial Relationships with Industry in Continuing Medical Education*, AM. MED. ASS'N (Nov. 2011), *available at* https://www.ama-assn.org/delivering-care/financial-relationships-industry-continuing-medical-education.

they read was industry- funded, making clear the difficulty health care providers have in screening and accounting for source bias.[162]

(i) Purdue Sponsored CMEs to Deliver Its Misleading Safety and Efficacy Messages

652. From 1996 to 2001, Purdue conducted more than 40 national pain-management and speaker training conferences at resorts across the country. More than 5,000 medical providers attended these all-expenses-paid symposia, where they not only received CME credit but were recruited and trained for Purdue's national speaker bureau with the intent of influencing prescribing patterns towards prescribing opioids more liberally for non-cancer related chronic pain.

653. In 2007, Purdue sponsored a CME entitled *Overview of Management Options* that was available for CME credit and available until at least 2012. It taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

654. AGS contracted with Purdue, along with Janssen and Endo, to sponsor a number of CMEs based on the 2009 AGS Treatment Guidelines, discussed *infra.*

655. Purdue also utilized KOLs including Dr. Lynn Webster to author numerous CMEs. For example, Dr. Webster in 2011 presented a webinar (hosted by Purdue) entitled *Managing Patient's Opioid Use: Balancing the Need and the Risk.* The CME fraudulently taught prescribers that screening tools (including his Opioid Risk Tool), urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."

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

[162] Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME,* PHARMEDOUT (June 25, 2010), *available at* pharmedout.galacticrealms.com/Fugh-BermanPrescriptionforConflict6-25-10.pdf (unable to locate, archived).

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

657. During that time, Purdue funded more than 20,000 pain-related educational programs through direct sponsorship or financial grants. In so doing, Purdue exerted enormous influence on physicians' prescribing practices throughout the country.

658. Purdue also sponsored an APS CME entitled *Pain: Current Understanding of Assessment, Management and Treatments*. This CME including misleading statements such as "[b]arriers to the appropriate assessment and management of pain include…fear of…addiction." The CME also teaches that opioids "play a major role in treating acute…and some types of chronic non-cancer pain" while highlighting the adverse effects of NSAIDs.[163]

(ii) Cephalon Sponsored CMEs to Deliver Its Misleading Safety and Efficacy Messages

659. Cephalon also utilized various CMEs (often featuring KOLs) as a means to spread false and deceptive marketing to prescriber physicians.

660. For example, Cephalon sponsored the 2003 CME titled *Pharmacologic Management of Breakthrough or Incident Pain*, and posted it on Medscape, a nationally accessible website, which taught:

> [C]hronic pain is often undertreated, particularly in the non-cancer patient population…The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the

[163] *Pain: Current Understanding of Assessment, Management and Treatments*, AMERICAN PAIN SOCIETY (2018), *available at* http://americanpainsociety.org/uploads/education/posttest.pdf (The Posttest for CME Credit remains on APS's website, but is "no longer being offered for continuing education credit. It is available here as a resource for pain professionals' use.").

> 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 under treatment 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.** (emphasis added in cite)

661. Cephalon also sponsored a CME written by KOL Dr. Lynn Webster, titled *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007, through December 15, 2008. The CME taught that Cephalon's Actiq and Fentora improved patients' quality of life and allowed for more activities when taken in conjunction with long-acting opioids.

662. The CME recommends prescribing a "short-acting opioid" (e.g., morphine, hydromorphone, oxycodone) "when pain can be anticipated," or a rapid-onset opioid when it cannot. The only examples of rapid-onset opioids then on the market were oral transmucosal fentanyl citrate *(i.e.,* Actiq) or fentanyl effervescent buccal tablet *(i.e.,* Fentora): "Both are indicated for treatment of [breakthrough pain] in opioid-tolerant cancer patients *and are frequently prescribed to treat [breakthrough pain] in non-cancer patients as well.*" (emphasis added). The CME also minimized the risks associated with increased opioid doses by explaining that NSAIDs were less effective than opioids for the treatment of breakthrough pain because of their dose limitations, without disclosing the heightened risk of adverse events on high-dose opioids. Around the same time, Dr. Webster was receiving nearly $2 million in funding from Cephalon. The CME was available online and intended to reach prescribers.

663. Cephalon also sponsored a CME authored by KOL Dr. Fine, titled *Opioid-Based Management of Persistent and Breakthrough Pain*, which implored physicians to cast aside the

"broad classification of pain syndromes as either cancer- or non-cancer related" as having "limited utility." Not surprisingly, he went on to suggest Actiq, Cephalon's primary Opioid Drug, for treatment of non-cancer chronic pain.

664. A Cephalon-controlled seminar in New York included the discussion topic: "Opioid Use in Headache." Another Cephalon-controlled meeting in Las Vegas included the topic: "Use of Actiq in Opioid-Naïve Patients."

665. Cephalon was also one of four Manufacturer Defendants responsible for the PCF's successful attempt to thwart the FDA's 2009 efforts to convince state medical boards to require corrective CME training for all physicians relating to opioid prescribing.

(iii) Janssen Sponsored CMEs to Deliver Its Misleading Safety and Efficacy Messages

666. Janssen also utilized various CMEs (often featuring KOLs) as a means to spread false and deceptive marketing to prescriber physicians.

667. AGS contracted with Janssen, along with Purdue and Endo, to sponsor a number of CMEs based on the 2009 AGS Treatment Guidelines, discussed *infra*.

668. As part of its scheme to promote its opioid drugs Nucynta, Nucynta ER, and Ultram ER, Janssen sought out influential physicians and proffered hefty payments to them in return for conducting research and implementing policies promoting the use of its drugs for unsafe and unapproved uses. Most of this "research" consisted of paying a physician to prescribe Defendants' opioid drugs Nucynta, Nucynta ER, and Ultram ER, and report some simple findings. The Janssen marketing department made the decisions on which doctors to pay to do case studies and be involved in research protocols based on their drug prescribing volume, showing that Janssen was not paying those doctors for a legitimate research purpose. Janssen paid these influential physicians to prescribe their patients with Janssen drugs in order to expand

its market share. Janssen also paid these KOLs and "Champions" to promote the use of opioid drugs Nucynta, Nucynta ER, and Ultram ER at seminars and other events for referring physicians and clinic staff.

669. Similar to CMEs, Janssen also offered "training materials" on its *PrescribeResponsibly.com* website, which made various false and/or misleading statements regarding the safety and efficacy of its Opioid Drugs.

670. Janssen was also one of four Manufacturer Defendants responsible for the PCF's successful attempt to thwart the FDA's 2009 efforts to convince state medical boards to require corrective CME training for all physicians relating to opioid prescribing.

(iv) Endo Sponsored CMEs to Deliver Its Misleading Safety and Efficacy Messages

671. Endo also utilized various CMEs (often featuring KOLs) as a means to spread false and deceptive marketing to prescriber physicians.

672. Through its substantive control over NIPC, Endo sponsored, developed, and/or distributed CME programs (ostensibly hosted by NIPC) aimed at marketing false and misleading claims to prescribing physicians.

673. Endo also sponsored CMEs based on the AGS Treatment Guidelines (discussed *infra*). AGS panel member Dr. Bruce Ferrell authored a CME in 2007 on treating pain in the elderly that was funded by Endo and spoke favorably about opioid use. And a year after the AGS guidelines came out, Dr. Ferrell was listed as a paid speaker for Endo and he helped conduct a CME on treating osteoarthritis pain that was funded by Purdue.

674. Endo sponsored and NIPC distributed a number of eNewsletter CMEs that focused on "key topic[s] surrounding the use of opioid therapy" and were intended to quell physician fears in prescribing opioids. Dr. Webster authored a number of these, while Dr. Fine

served as editor. Endo estimated that roughly 60,000 prescribers viewed each one, which were available to prescribers. Before-and-after surveys, summarized in the chart below, showed that prescriber comfort with prescribing opioids ranged from 27% to 62% before exposure to the CME, and from 76% to 92% afterwards:

Topic	Comfort level *prior to reading the article*	Comfort level *after reading the article*
Patient Selection and Initiation of Opioid Therapy as a Component of Pain Treatment	47%	87%
Informed Consent and Management Plans to Optimize Opioid Therapy for Chronic Pain	48%	81%
Risk Stratification and Evaluation of High-Risk Behaviors for Chronic Opioid Therapy	28%	76%
Integration of Nonpharmacologic and Multidisciplinary Therapies Into the Opioid Treatment Plan	42%	85%
Addressing Patients' Concerns Associated With Chronic Pain Treatment and Opioid Use	62%	92%
Opioid Therapy in Patients With a History of Substance Use Disorders	35%	85%
Urine Drug Testing: An Underused Tool	54%	86%
Appropriate Documentation of Opioid Therapy: The Emergence of the 4As and Trust and Verify as the Paradigm	44%	86%
Opioid Rotation	27%	92%
Discontinuing Opioid Therapy: Developing and Implementing an "Exit Strategy"	37%	90%

675. AGS contracted with Endo, along with Purdue and Janssen, to sponsor a number of CMEs based on the 2009 AGS Treatment Guidelines, discussed *infra*. One such 2009 CME, *The Role of Opana ER in the Management of Chronic Pain*, includes a slide titled *Use of Opioids is Recommended for Moderate to Severe Chronic Non-cancer Pain*. That slide cites the Guidelines, which contain a number of misstatements as noted elsewhere herein, while omitting their disclaimer regarding the lack of supporting evidence. This dangerously misrepresented to HCPs the force and utility of the 2009 Guidelines. The CME was approved by Endo's Medical Affairs Review Committee.

676. Endo also funded CMEs, such as those put on by the University of Wisconsin's Pain & Policy Group that were based on Dr. Fishman's *Responsible Opioid Prescribing* book.

677. Endo sponsored CMEs published by APF's NIPC, of which Endo was the sole funder, titled Persistent Pain in the Older Adult and Persistent Pain in the Older Patient. These CMEs claimed that opioids used by elderly patients present "possibly less potential for abuse than in younger patients[,]" which lacks evidentiary support and deceptively minimizes the risk of addiction for elderly patients. Therein, physicians were "taught" that withdrawal can be avoided if they taper the dosage by 10-20% for ten days. This statement is false and misleading.

678. Endo also utilized CMEs to push the concept of "pseudoaddiction" onto prescribers. For example, Endo sponsored an NIPC CME in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*. The program promoted "pseudoaddiction" by teaching that a patient's aberrant behavior was the result of untreated pain.

679. Endo also sponsored the *APS Residence's Course* through the efforts of Dr. Galer, who at the time had left the University of Washington and was working for Endo Pharmaceuticals and others.[164] Endo "graciously agreed to support this program, which initially included approximately 30 residents" and continued to sponsor the course until at least 2011.[165] The reasoning for the course as stated in APS publication:

> [T]hat we could develop a…pain management course that, even if the participating resident did not pursue a career in pain medicine, nevertheless that resident would feel comfortable in the assessment and initial treatment of a person with acute or chronic pain and be able to make appropriate and timely referrals as needed. Given how prevalent acute and chronic pain are and how prevalent the underassessment and under treatment of acute and chronic pain are, we felt this was an extremely needed education priority for residents.

[164] *APS Bulletin*, AMERICAN PAIN SOCIETY, Vol. 18, Issue 3 (2008), *available at* http://americanpainsociety.org/uploads/APS08_NwsWinter.pdf.

[165] American Pain Society, APS E-NEWS, (Jan. 2011), *available at* http://www.americanpainsociety.org/enews/2011/jan/.

680. Endo was also one of four Manufacturer Defendants responsible for the PCF's successful attempt to thwart the FDA's 2009 efforts to convince state medical boards to require corrective CME training for all physicians relating to opioid prescribing.

681. Endo also funded a CME (developed by KOLs Portenoy and Fine) promoting the use of opioid rotation claiming "[t]his view has been advocated by expert groups, e.g., in the 2009 evidence-based guidelines developed by [APS and AAPM], as well as by the [AGS]."[166]

6. Micro-targeting Physicians with Certain Prescribing Patterns

682. All Manufacturer Defendants utilized prescription and marketing data to micro-target certain physicians with prescribing patterns and/or patient populations likely suffering from chronic pain. Purdue was the industry pioneer in developing these tactics, which (upon information and belief) the other Manufacturer Defendants adopted.

683. Purdue compiled (or purchased from other defendants) detailed prescription data for the opioids market, including in Ohio. Purdue's data collection allowed it to build prescriber profiles tied to individual HCPs, and identify the highest and lowest prescribers by drug class in a particular zip code, county, state, or nationwide. It also enabled Purdue to identify HCPs with a large number of chronic pain patients.

684. Armed with this data, Purdue's sales representatives set out to target the highest prescribers of opioids in the country, HCPs with liberal prescription records, and HCPs with the most vulnerable patient populations.

685. Purdue's practices became the common practices of all the Manufacturer Defendants. The Manufacturer Defendants would purchase and closely analyze prescription sales data from IMS Health that allows them to track, precisely, the rates of initial prescribing and

[166] Perry Fine and Robert Portenoy, *Strategies for Opioid Rotation: Decision Support in Chronic Pain Management*, MEDSCAPE (March 30, 2010) *available at* https://www.medscape. org/viewarticle/717832. The CME was available from March 30, 2010 through March 30, 2011.

renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their appeals.

686. The Manufacturer Defendants in particular relied upon "influence mapping," i.e.., using decile rankings or similar breakdowns to identify the high-volume prescribers as to whom detailing would have the greatest sales impact. Endo, for example, identified prescribers representing 30% of its nationwide sales volume (decile Nos. 8 through 10) and planned to visit these physicians three times per month. Defendants also closely monitored HCPs' prescribing after a sales representative's visit to allow them to refine their planning and messaging and to evaluate and compensate their detailers.

B. Scientific Literature Marketing Enterprises

687. The Manufacturer Defendants understood that scientific substantiation (or the illusion thereof) was key to bolstering the effectiveness of their marketing messages. They therefore set out to manufacture a body of scientific literature, again concealing its source. This scheme was part of Manufacturer Defendants' greater efforts to expand the prescription market for Opioid Drugs.

688. Regarding clinical proof, the Manufacturer Defendants and their KOL / Front Group agents often pointed to scientific "evidence" backing their claims of efficacy and safety. However, such "evidence" consisted of nothing but a letter-to-the-editor and a widely-debunked observational study. Both authors of this "scientific evidence" were industry-paid KOLs.

689. Acting directly or with and through third parties, each of the Manufacturer Defendants claimed that the potential for addiction from its drugs was relatively small, or non-existent, even though there was no scientific evidence to support those claims, and the available research contradicted them. A recent literature survey found that while ranges of "problematic use" of opioids ranged from <1% to 81%, abuse averaged between 21% and 29% and addiction

between 8% and 12%.[167] These estimates are well in line with Purdue's own studies, showing that between 8% and 13% of OxyContin patients became addicted, but on which Purdue chose not to rely, instead citing the Porter-Jick letter.

690. The FDA has found that 20% of opioid patients use two or more pharmacies, 26% obtain opioids from two or more prescribers, and 16.5% seek early refills—all potential "red flags" for abuse or addiction.[168] The FDA in fact has ordered manufacturers of long-acting opioids to "[c]onduct one or more studies to provide quantitative estimates of the serious risks of misuse, abuse, addiction, overdose and death associated with long-term use of opioid analgesics for management of chronic pain," in recognition of the fact that it found "high rates of addiction" in the medical literature.[169]

691. Of course, the significant (and growing) incidence of abuse, misuse, and addiction to opioids is also powerful evidence that Defendants' statements regarding the low risk of addiction were, and are, untrue. This was well-known to Defendants who had access to sales data and reports, adverse event reports, federal abuse and addiction-related surveillance data, and other sources that demonstrated the widening epidemic of opioid abuse and addiction.

692. Acting directly or through and with third parties, each of the Defendants claimed that the potential for addiction even from long-term use of its drugs was relatively small, or non-existent, despite the fact that the contention was false and there was no scientific evidence to support it.

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[167] Kevin Vowels, *et al*., *Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis*, 156 PAIN 569-76 (April 2015).

[168] Len Paulozzi, M.D., "Abuse of Marketed Analgesics and Its Contribution to the National Problem of Drug Abuse," available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndLifeSupportDrugsAdvisoryCommittee/UCM233244. pdf

[169] September 10, 2013 letter from Bob Rappaport, M.D., to NDA applicants of ER/LA opioid analgesics, available at http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrug Class/UCM367697.pdf; Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

693. The Manufacturer Defendants, through their financial influence and control over Front Groups, played a major role in the development of "Consensus Statements," FSMB Guidelines and Model Policies, and "Treatment Guidelines."

694. The Manufacturer Defendants paid KOLs to churn out academic and research papers pointing to a "pain epidemic" that could be successfully treated through a long-term regimen of Opioid Drugs. In some instances, a manufacturer would instruct the KOL as to the "outcome" of study and paper *before* the KOL started the project.

695. Consultants were even hired by some manufacturers to help engineer an academic publication strategy. This strategy advocated the use of circular sourcing, whereby the same unsubstantiated materials would all cite to one another and then be "adopted" by Front Groups who would issue "Consensus Statements," demonstrating the medical community's consensus around the false representations.

696. Front Groups were also involved, issuing bogus "consensus recommendations" purporting to reflect consensus among the medical community. These consensus recommendations were meant to influence state medical board policies or undercut various FDA REMS. They were in some instances reprinted in medical journals relied on by subscribers.

697. Front Groups also "peer reviewed" industry-sponsored articles and papers authored by KOLs, thereby bolstering those works' legitimacy.

698. Front Groups also brought attention to and lent credence to one another's works. When one Front Group issued consensus recommendations, other Front Groups would promote them, in some instances lauding them as breakthroughs in the medical community.

699. It was actually the Manufacturer Defendants who were coordinating this 'peer-review' process. The Manufacturer Defendants—who drafted (or directed the drafting) of

various groups' publications—then essentially 'peer reviewed' themselves. This was nothing but a sham aimed at creating an air of legitimacy and scientific consensus around their absurd marketing claims. The Manufacturer Defendants' sales representatives, for example, would point to consensus recommendations as backing up their claims.

700. In addition to promoting opioid products, the literature was also used to combat messaging (most originating from government agencies) that contradicted the Manufacturer Defendants' claims regarding the safety and efficacy of long-term Opioid Drug therapy to treat chronic pain.

701. Through the Scientific Literature Marketing Enterprises, the Manufacturer Defendants also undertook a concerted effort to undermine the 2016 CDC Guidelines, which reject many of the Manufacturer Defendants' false and misleading marketing claims.

702. The scientific, academic, official and quasi-official publications also served a key role in that they were relied upon by TPPs (including by MMO) in determining coverage and formulary placement.

703. The Manufacturer Defendants' Scientific Literature Marketing Enterprises were comprised of four main categories: (1) clinical "proof"; (2) Treatment Guidelines and Consensus Statements; (3) "academic" publications; and (4) attempts to undermine the FDA and CDC. The overall effectiveness of these enterprises were and are amplified by the Manufacturer Defendants' use of circular sourcing to create a façade of real peer review. Each of these characteristics of the Scientific Literature Marketing Enterprises are alleged in greater detail below.

1. Clinical "Proof"

704. The Manufacturer Defendants' campaign of deception regarding the safety and efficacy of long-term opioid treatment for chronic paid was rooted in two pieces of purportedly

"scientific" evidence. The first piece of evidence was a five-sentence letter to the editor published in 1980 in the New England Journal of Medicine.

705. The letter was drafted by Hershel Jick, a doctor at Boston University Medical Center, with the help of a graduate student, Jane Porter. It noted, anecdotally, that a review of "current files" did not indicate high levels of addiction among hospitalized medical patients who received narcotic preparation treatment. In full, the letter reads:

> Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients 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, 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.[170]

706. Notably, since the letter was written in 1980, then-current opioid prescribing practices likely meant that the "medical patients" regularly receiving opioids were likely sufferers of acute, cancerous, or end-of-life pain. The Manufacturer Defendants were aware or should have been aware that this "study" was completely inapplicable to the safety and efficacy of long-term opioid treatment of chronic pain.

707. Further, while the letter says that patient records were reviewed (resulting in few references to signs of addiction), there is no indication that the caregivers generating those records were instructed to assess or document signs of addiction. Though the Manufacturer Defendants were aware or should have been aware of the serious limitations of this "study," those limitations (upon information and belief) were not communicated to prescribers.

[170] *Addiction rate in patients treated with narcotics,* 302(2) New Eng. J. Med. 123 (Jan. 10, 1980).

708. Purdue had "start[ed] using the letter's data" based on a highly unrepresentative cohort "to say that less than one percent of patients treated with opioids became addicted"[171] in promotional videos. One video entitled *"I Got My Life Back"* featured people suffering from chronic pain and deceptively taught that OxyContin has a very minimal risk of addiction and could give them their lives back. The video was distributed to 15,000 HCPs in 1998. Purdue's ad campaign in 2000 included similar unsubstantiated claims, which were distributed to physicians.[172]

709. In 2003, a former sales manager, William Gergely, told the South Florida Sun Sentinel "[t]hey told us to say things like it is 'virtually' non-addicting…You'd tell the doctor there is a study, but you wouldn't show it to him."[173] In Purdue's weeks of sales training – they would ask representatives one question about concerns over the risk of addiction: "[t]he correct answer was 'less than one percent.'"[174]

710. Currently on *NEJM's* website, the Porter & Jick letter is qualified by an editor's note stating: "For reasons of public health, readers should be aware that this letter has been 'heavily and uncritically' cited as evidence that addiction is rare with opioid therapy."

711. The Manufacturer Defendants—often working through their KOLs or Front Groups—saw that the "study" was cited throughout the academic literature. It is cited 856 times in Google Scholar, including 86 citations since 2010. It was cited by the Manufacturer

[171] *Id. See also* Purdue L.P., "I got my life back," *available at* https://www.youtube.com/watch?v=Er78Dj5hyeI (last visited March 26, 2018).

[172] Jerry Mitchell and Clarion Ledger, *How the FDA helped pave the way for an opioid epidemic*, USA TODAY NETWORK (Jan. 26, 2018), https://www.clarionledger.com/story/news/2018/01/26/opioid-epidemic-how-fda-helped-pave-way/950561001/.

[173] Fred Schulte, *OxyContin Was Touted as Virtually Nonaddictive, Newly Released State Records Show*, SUN SENTINEL (March 6, 2003), http://articles.sun-sentinel.com/2003-03-06/news/0303051301_1_purdue-pharma-oxycontin-william-gergely.

[174] Sam Quinones, DREAMLAND: THE TRUE TALE OF AMERICA'S OPIATE EPIDEMIC (2015).

Defendants in various industry-sponsored CMEs. It appears as a reference in two CME programs in 2012 sponsored by Purdue and Endo.[175]

712. The second major piece of "evidence" used by the Manufacturer Defendants was a 1986 study by soon-to-be-KOL Dr. Portenoy in the medical journal *Pain*. The study, which had a patient cohort of merely 38 patients, claimed that opioids could be used for long periods of time to treat non-cancer related chronic pain without any risk of addiction. The rationale behind the study was that patients in pain would not become addicted to opioids because their pain drowned out the euphoria associated with opioids. As such, the study concluded that opioids should be freely administered to patients with fibromyalgia, headaches, finicky backs, and a host of other issues. According to Portenoy and his co-author, Dr. Kathleen Foley, "opioid maintenance therapy can be a safe, salutary and more humane alternative ... in those patients with intractable non-malignant pain and no history of drug abuse."[176] Portenoy's study also cited Jick's one-paragraph letter to the New England Journal of Medicine and Portenoy himself admitted that he gave innumerable lectures citing the statistic that less than 1% of opioid users became addicted.[177]

713. In the years that have followed, both the *New England Journal of Medicine* letter and Portenoy's 1986 study have been expressly disavowed. Neither actually demonstrates that opioids can be safely prescribed for long-term, chronic pain.

714. In a taped interview in 2011, Portenoy admitted:

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[175] AAPM, *Safe Opioid Prescribing Course*, February 25-26, 2012, sponsored by Purdue and Endo; *Chronic Pain Management and Opioid Use*, October 11, 2012, sponsored by Purdue.

[176] Robert Portenoy and K.M. Foley, *Chronic use of opioid analgesics in non-malignant pain: report of 38 cases*, 25 PAIN 171 (1986).

[177] Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, WALL ST. J., (Dec. 17, 2012), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

> 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. I would cite 6 to 7 maybe 10 different avenues of thought or evidence, ***none of which represents 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 toto and feel more comfortable about opioids in a way they hadn't before ... Because the primary goal was to de-stigmatize, ***we often left evidence behind."***
>
> ***It was clearly the wrong thing to do*** and to the extent that some of the adverse outcomes now are as bad as they have become in terms of endemic occurrences of addiction and unintentional overdose death, it's quite scary to think about how the growth in that prescribing driven by people like me led, in part, to that occurring.

Live interview with Dr. Russell Portenoy.[178]

715. As to the *New England Journal of Medicine* letter, Dr. Jick, in an interview with Sam Quinones decades after the letter was published, stated: "[t]hat particular letter, for me, is very near the bottom of a long list of studies that I've done. It's useful as it stands because there's nothing else like it on hospitalized patients. But if you read it carefully, it does not speak to the level of addiction in outpatients who take these drugs for chronic pain."

716. *The New England Journal of Medicine* itself has since disavowed the letter, stating "[the letter] was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy."[179] "We believe," the journal provided, "that this citation pattern contributed to the 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."

717. Indeed, the letter—because it was just a letter—did not describe how the data was gathered, the duration of the patients' treatment, or the purpose behind their treatment in the first

[178] Physicians for Responsible Opioid Prescribing, "Opioids for Chronic Pain: Addiction is NOT Rare," *available at* https://www.youtube.com/watch?v=DgyuBWN9D4w (last visited March 26, 2018).

[179] *New Eng. J. Med.* 2194, 2194-95 (2017).

place. But the *New England Journal of Medicine* is one of the premier medical journals in the country. And, given the journal's prestige, the five-sentence letter, combined with Portenoy's later study, was exactly what opioid manufacturers needed to push their products.

718. The Manufacturer Defendants (or their Front Groups) cited these pieces of "evidence" time and time again, even after they had come to be rejected by their source.

2. Treatment Guidelines, Medical Board Policies, and Consensus Statements

719. The Manufacturer Defendants also used Front Group "Consensus Statements," Treatment Guidelines, and FSMB Model Policies to further the narrative that its marketing themes were actually the result of sound science and peer review. All of these "scientific" or "academic" publications, however, were heavily influenced if not drafted by persons with financial ties to the Manufacturer Defendants. This scheme targeted not only physicians, but policymakers, regulators, and the academic community.

720. The scheme aimed at building "consensus" around the Manufacturer Defendants' deceptive marketing claims was multi-tiered. First, Front Groups would issue landmark consensus statements. Next, the FSMB, relying on the consensus in the medical and scientific community, would develop its Treatment Guidelines and Model Policies. The Model Policies would in turn be adopted by state medical boards, to which the Front Groups and Manufacturer Defendants would point to when drafting additional Treatment Guidelines.

721. Through their Front Groups, the Manufacturer Defendants also worked to build an illusion of medical consensus around the Guidelines and Policies. Front Groups would put out "Consensus Statements" endorsing the practices in the FSMB Treatment Guidelines and Model Policy. Often, these statements involved the collaboration between multiple Front Groups,

further underscoring the theme of medical consensus. This illusion of medical consensus influenced the state medical boards' decision to adopt the FSMB Model Policy.

722. As alleged above, AAPM and APS were two Front Groups which received substantial funding from the Manufacturer Defendants. In 1997, the two organizations came together and issued a joint landmark Consensus Statement, *The Use of Opioids for the Treatment of Chronic Pain,* that endorsed opioids to treat chronic pain and claimed that the there was little risk of addiction or overdose in pain patients.[180] The 1997 statement misleadingly recommended the use of opioids to treat chronic pain, despite limited evidence, and concluded that the risk of addiction is manageable for patients regardless of past abuse histories.

723. The publication, sub-titled "A consensus statement from the American Academy of Pain Medicine and American Pain Society," was approved by AAPM's Board of Directors on June 29, 1996, followed by APS' Executive Committee on August 20, 1996.

724. The Chair of the Committee was none other than Dr. David Haddox, a KOL who at that time was a paid speaker for Purdue. The sole consultant to the Committee (and fellow author of the "landmark" consensus statement) was Dr. Portenoy, whose paid work on behalf of the Manufacturer Defendants is well documented.

725. The FSMB authored a Treatment Guidelines in 1998, which it conceded was produced "in collaboration with pharmaceutical companies." It was based in large part on the APM / AAPS "Consensus Statement."

726. The Treatment Guidelines proclaimed that opioids were "essential" for the effective treatment of chronic pain but failed to mention risks relating to respiratory depression and overdose, and discussed addiction only in the sense that "inadequate understanding" of

[180] *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997), *available at* http://www.jpain.org/article/S1082-3174(97)80022-0/pdf (last accessed Mar. 14, 2018).

addiction can lead to "inadequate pain control," insinuating that the risk of addiction should not hinder higher dose prescriptions.

727. FSMB then adopted those guidelines as a Model Policy in 2004, which the majority of state medical boards adopted. Thus, this Model Policy, which was developed by FSMB with industry grants, was especially impactful on prescriber behavior. Since medical boards were the agency responsible for disciplining HCPs, the Model Policies came to be seen as "rules of the road" for opioid prescribing.

728. Following the publication of FSMB's Model Policy, Purdue then provided a $100,000 grant to "help" pay for the printing and distribution of that policy to 700,000 practicing doctors. That $100,000 was but a down payment on the $3.1 million that FSMB estimated it would cost for its campaign to get out the word about "safe" use of opioid analgesics in treatment of chronic pain.

729. Instead of protecting patients from over-prescribing HCPs, many of those medical boards were duped by FSMB's pharma-funded campaign into encouraging aggressive prescribing. This in turn made it more difficult for medical boards to discipline pill mill operators and reckless HCPs.

730. FSMB then turned to Scott Fishman, a notorious industry KOL, to translate their model policy into a guidebook: *Responsible Opioid Prescribing: A Physician's Guide*. The project was underwritten by various Manufacturer Defendants, including Purdue, Cephalon, Endo, and others. The Manufacturer Defendants than sponsored CMEs based on these guidelines (as further filtered through Dr. Fishman's book).

731. The *Responsible Opioid Prescribing* guide promoted the use of opioid pain relievers for both acute and chronic pain and severely minimized the risk of addiction, even

claiming that opioids could be used safely (just with additional care) in patients assessed to have a risk of substance abuse. The guide promoted the widespread use of opioids, stating that "[p]atients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient." The guideline advised physicians that denying high doses of opioids to patients is a "bad medical decision."

732. Additionally, the guide presented symptoms of genuine addiction as "pseudoaddiction" and taught HCPs that the symptoms of addiction—such as demanding or manipulative behavior and obtaining opioid prescriptions from more than one physician—are actually "pseudoaddiction," rather than addictive behavior that would necessitate the withdrawal of opioid treatment. Instead, HCPs faced with "pseudoaddiction" in patients should prescribe higher doses of Opioid Drugs.

733. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers. It was drafted by Medical Writer X hired by Conrad & Associates (who later worked with Janssen, AAPM, and AGS to create *Finding Relief*). The Medical Writer X now acknowledges that the list of adverse effects from chronic opioid use in publications he authored were "ridiculous" and "prime examples" of leaving out facts that the pharmaceutical company sponsors and KOLs knew at the time were true. His writings repeatedly alleged that the risk of addiction as low. The Medical Writer X stated that he understood that the goal was to promote opioids and, as a result, discussing addiction would be "counterproductive."

734. 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 CME activity for prescribers of opioid medications."

735. The most disturbing effect of Defendants' manipulation of the FSMB was the instilled fear of discipline. The FSMB Guidelines, by favoring higher dose prescriptions, conveyed the 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 such prescription decisions were documented. Since the Model Policy had been adopted by state medical boards, many physicians viewed them as standards of care regulating their prescribing conduct.

736. In other words, the Manufacturer Defendants created an environment where over-prescription of Opioid Drugs, even in instances leading to death, created less liability risk than untreated pain. The Guidelines and Model Policy not only offered physicians a carrot but threatened them with a stick.

737. Indeed, the Manufacturer Defendants' Front Groups even filed at least one amicus brief in support of HCPs who had been criminally convicted of illegally prescribing opioids. In 2005, one such brief was filed by APF and NPF at the United States Court of Appeals for the Fourth Circuit. Therein, the Front Groups argued that "there is no 'ceiling dose' for opioids."[181]

738. As noted above, the Manufacturer Defendants not only played a key role in the development of the FSMB Treatment Guidelines and Model Policy, but their dissemination (through physician mailings, physician-oriented advertising, sales representatives, books authored by KOLs, and CME programs).

739. AAPM and APS then put out their own Treatment Guidelines in 2009 and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel

[181] Brief of the APF, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474, 9 (4th Cir. Sept. 8, 2005).

members who drafted the 2009 Guidelines, including Dr. Portenoy and Dr. Fine, received support from Purdue, Cephalon, Janssen, and Endo.

740. The 2009 AAPM / APS Guidelines promote opioid drugs as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache and Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members.

741. The 2009 AAPM / APS guidelines contain only four recommendations "viewed as supported by even moderate quality evidence,"[182] with nearly all recommendations based on "low-quality" evidence.[183] While admitting that "well-conducted studies have not examined these benefits," the guideline misleadingly suggests that the: "[p]roposed benefits of transitioning to long-acting opioids….include[s]…a lower risk of addiction or abuse."[184] Another "strong recommendation" based on "low-quality evidence" is consideration of chronic opioid therapy for patients with chronic non-cancer pain and a history of drug abuse if monitored.[185]

742. The guidelines similarly falsely suggest that screening tools are capable of assessing potential addiction risks for patients.[186] The claimed ability to pre-sort patients likely to

[182] Roger Chou, *et al*., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain,* 10 JOURNAL OF PAIN, 113,124 (Feb. 2009), *available at* http://www.jpain.org/article/S1526-5900(08)00831-6/pdf.

[183] *Id.* at p. 124. *See* Appendix 2: *Grading Evidence and Recommendations.* Low-quality evidence is defined as "insufficient to assess effects on health outcomes because of the limited number or power of studies, large and unexplained inconsistency between higher quality studies, important flaws in study design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes."

[184] *Id.* at 117.

[185] *Id.* at 112.

[186] *Id.* at 116.

become addicted is an important tool in giving HCPs confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry supported guidelines. Versions of KOL Dr. Webster's Opioid Risk Tool appear on, or are linked to websites run by Endo, Janssen and Purdue and also coincidentally appear in 2009 Defendant influenced guidelines.

743. The Manufacturer Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions.

744. The AAPM / APS Consensus Statement (1997) and Treatment Guidelines (2009) have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited over 700 times in academic literature, were disseminated to MMO, are still available online and were reprinted in the *Journal of Pain.*

745. Meanwhile, the AGS put out its own guidelines in 2009 titled *Pharmacological Management of Persistent Pain in Older Persons* ("AGS Treatment Guidelines"). Similar to AAPM / APS guidelines, the AGS Treatment Guidelines doled out strong recommendations favorable to opioid use based on low-quality evidence, with known KOLs serving on its expert panel. Additionally, AAPM provided peer review of a preliminary draft of the guideline.[187]

746. AGS is yet another organization that was provided funding to push the Manufacturer Defendants' unsubstantiated claims regarding Opioid Drugs.

747. At the time of the AGS Treatment Guidelines, the preferred treatment of chronic pain in older adults was acetaminophen. The AGS Treatment Guidelines strongly recommended

[187] *Id.* at 1343.

opioids—as opposed to aspirin or ibuprofen—for those unable to gain relief from Tylenol or similar products.

748. The AGS Treatment Guidelines also included the following recommendations: "All patients with moderate to severe pain…should be considered for opioid therapy (low quality of evidence, strong recommendation)," and that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[188] These recommendations, which continue to appear on AGS's website, are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited 278 times in Google Scholar since their 2009 publication.

749. Known KOL and AGS panel member Dr. Fine was receiving payments as a consultant or speaker "for at least six opioid companies at the time the guidelines came out," including Defendants Purdue, Cephalon, and Endo.[189] Additionally, Dr. Fine disclosed he had a "commercial interest" with Cephalon.[190] Indeed, half of the experts on the ten-member AGS Treatment Guidelines panel disclosed financial ties to Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by Defendants, receiving grants from Defendants, and investing in Defendants' stock. The Institute of Medicine recommends that, to ensure an unbiased result, fewer than 50% of the members of a guidelines committee should have financial relationships with drug companies.

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[188] *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. AM. GERIATRICS SOC'Y 1331, 1339, 1342 (2009), *available at* https://geriatricpain.org/sites/geriatricpain.org/files/wysiwyg_uploads/ags_pharmacological_management_of_persistent_pain_in_olders_persons_2009_2.pdf.

[189] John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, MILWAUKEE J.SENTINEL, (May 30, 2012), https://www.medpagetoday.com/geriatrics/painmanagement/32967.

[190] American Geriatric Society, *Pharmacological Management of Persistent Pain in Older Persons*, JAGS, Vol. 57, No. 8, at 1331-1346 (Aug. 2009), *available at* https://geriatricpain.org/sites/geriatricpain.org/files/wysiwyg_uploads/ags_pharmacological_management_of_persistent_pain_in_olders_persons_2009_2.pdf.

750. AGS sought and obtained grants from Endo and Purdue to distribute and promote the AGS Treatment Guidelines beginning July 15, 2009. Internal AGS discussions in August 2009 reveal that it did not want to receive up-front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate the publication. However, by drafting the guidelines knowing that pharmaceutical company funding would be needed, and allowing these companies to determine whether to provide support only after they have approved the message, AGS ceded significant control to these companies. According to one news report, AGS has received $344,000 in funding from opioid makers since 2009.[191]

751. Endo then funded AGS efforts in December 2009 to create a CME based on the AGS Treatment Guidelines. After having sponsored it, Endo's internal documents indicate that Endo's sales representatives discussed the AGS guidelines with HCPs during individual sales visits.

752. Most if not all of the Manufacturer Defendants trained their sales representatives to invoke various Treatment Guidelines when detailing their respective Opioid Drugs to prescribers.

753. The extent of the Manufacturer Defendants' influence on treatment guidelines is demonstrated by the fact that independent guidelines — the authors of which did not accept drug company funding — reached very different conclusions.

754. The 2012 Guidelines for *Responsible Opioid Prescribing* in Chronic Non-Cancer Pain, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that "[t]he recent revelation that the pharmaceutical industry was involved in the development of

[191] John Fauber and Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, MILWAUKEE J. SENTINEL, (May 30, 2012).

opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it." ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain." ASIPP recommends long-acting opioids in high doses only "in specific circumstances with severe intractable pain" and only when coupled with "continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvements in physical and functional status and minimal adverse effects."[192]

755. Similarly, the 2011 Guidelines for the Chronic Use of Opioids, issued by the American College of Occupational and Environmental Medicine, recommend against the "routine use of opioids in the management of patients with chronic pain," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence."[193]

756. The Clinical Guidelines on Management of Opioid Therapy for Chronic Pain, issued by the United States Department of Veterans Affairs ("VA") and Department of Defense ("DOD") in 2010 notes that their review revealed a lack of solid evidence-based research on the efficacy of long-term opioid therapy.[194]

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[192] Laxmaiah Manchikanti, *et al*., American Society of Interventional Pain Physicians (ASIPP), *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment,* 15 PAIN PHYSICIAN (Special Issue) S1-S66; *Part 2 — Guidance,* 15 PAIN PHYSICIAN (Special Issue) S67-S116 (2012).

[193] AMERICAN COLLEGE OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE'S GUIDELINES FOR THE CHRONIC USE OF OPIOIDS (2011).

[194] MANAGEMENT OF OPIOID THERAPY FOR CHRONIC PAIN WORKING GROUP, VA/DOD CLINICAL PRACTICE GUIDELINE FOR MANAGEMENT OF OPIOID THERAPY FOR CHRONIC PAIN (MAY 2010).

757. Under pressure from legitimate advocacy groups, it was not until June 2017 that FSMB updated its Model Policy regarding opioids. The current policy, based off the CDC's March 2016 *Guidelines for Prescribing Opioids for Chronic Pain*, is a complete reversal of FSMB's previous Model Policy which promoted the long-term use of opioids while downplaying the risk of addiction.

758. The Manufacturer Defendants' Treatment Guidelines, along with the FSMB Model Policy, were instrumental in securing TPP coverage of Opioid Drugs. Treatment Guidelines directly inform HCPs' prescribing practices, and are especially important because they are relied upon more by general practitioners and family doctors, who—as Manufacturer Defendants' marketing research concluded—were typically less informed about opioids and thus more susceptible to marketing messages. These prescribers included nurse practitioners and physician assistants, who, a 2012 Endo business plan noted, were "share acquisition" opportunities because they were "3x times more responsive than MDs to details" and wrote "96% of [their] prescription…without physician consult."

759. Such guidelines were crucial for giving legitimacy to the explosion of opioid prescriptions and providing HCPs with a framework to work within and to allay their fears that such prescriptions were inappropriate.

760. TPPs (including MMO) also utilized the guidelines to determine whether or not they should cover treatments (including opioid prescriptions for management) for specific conditions. The more HCPs that were prescribing a given opioid medication within the recommended framework, the more likely it was that the insurance companies would cover the drug for that purpose.

3. The Manufacturer Defendants' Creation of Misleading Clinical Literature Supporting Use of Opioids to Treat Chronic Pain

761. The Manufacturer Defendants aimed to create a body of academic literature that its sales force, KOLs, and Front Groups could rely on as "evidence" of their false and misleading claims relating to the Opioid Drugs.

762. The Manufacturer Defendants' Front Groups also published a number of seemingly academic peer-reviewed articles in medical journals, which were utilized by the Manufacturer Defendants to misleadingly market their Opioid Drugs to physicians.

763. The proliferation of academic articles promoting the long-term use of opioids in treating chronic pain was the result of orchestrated publication campaigns developed by the Manufacturer Defendants as part of their overall marketing strategy.

764. To accomplish this, Manufacturer Defendants—sometimes through third-party consultants and/or advocacy organizations—commissioned, edited, and arranged for the placement of favorable articles in academic journals. The Manufacturer Defendants' internal documents reveal plans to submit research papers and "studies" to long lists of journals, including back-up options and last resort, "fast-track" application journals that they could use if the pending paper was rejected everywhere else.

4. The Manufacturer Defendants' False and Misleading Publications

765. The Manufacturer Defendants coordinated the timing and publication of manuscripts, abstracts, posters/oral presentations, and educational materials in peer-reviewed journals and other publications to support the launch and sales of their drugs. The plans for these materials did not originate in the departments within the manufacturers' organizations that were responsible for research, development or any other area that would have specialized knowledge

about the drugs and their effects on patients, but in their marketing departments (and from their marketing and PR consultants).

766. The Manufacturer Defendants' misrepresentations about increased function are particularly misleading for specific indications for which they promoted opioids, such as migraines and lower back pain. For instance, research indicates that as many as 30% of patients who suffer from migraines have used opioids to treat their headaches.[195] Despite this, users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non- opioid users.[196] A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.[197] Studies of the use of opioids long-term for chronic lower back pain similarly have been unable to demonstrate an improvement in patients' function.[198]

767. There also is evidence that, over the long-term, opioid therapy fails to lessen, and sometimes increases, patients' pain – important facts that Defendants fail to include in their marketing literature. For example, Defendants have failed to disclose scientific evidence that establishes that many patients on chronic opioid therapy continue to experience significant pain

[195] Dawn C. Buse, *Opioid Use and Dependence Among Persons With Migraine: Results of the AMPP Study*, 52 Headache: The Journal of Head & Face Pain, 18-36 (Jan. 2012).

[196] *Id.*

[197] *Press Kits – Migraine Patients Taking Addictive Or Non Approved FDA Migraine Treatment*, National Headache Foundation (May 15, 2007), available at http://www.headaches.org/press/NHF_Press_Kits/Press_Kits__Migraine_Patients_Taking_Addictive_Or_Non_Approved_FDA_Migraine_Treatments.

[198] Luis E. Chaparro, *Opioids compared to placebo or other treatments for chronic low-back pain*, 8 Cochrane Database of Systematic Reviews (2013).

and dysfunction.[199] Defendants also have failed to disclose research and clinical experience demonstrating that: (1) the analgesic (pain relieving) efficacy of opioids often declines over time; (2) patients on opioids long-term may develop greater sensitivity to pain ("hyperalgesia"); and (3) because they develop tolerance to the medication over time, many chronic non-cancer pain patients require ever higher doses of opioids to obtain relief and are on doses that doctors have described as "frighteningly high."[200]

768. Consistently, in their marketing, Defendants failed to disclose the lack of evidence to establish that opioids are safe and effective long-term, as well as the growing body of evidence that the risks of opioids increase and their benefits decline over time. The studies relied on by Defendants in marketing their drugs are short-term, typically for less than 12 weeks.

769. As a pain specialist noted in an article titled, *Are We Making Pain Patients Worse?*, "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 control pain, and these patients are unable to function normally." Instead, at higher doses, patients are much more likely to develop dependence or addiction, experience pain deterioration due to hyperalgesia, and are three to nine times more likely to die from opioid-related causes than those on low doses.[201] Additionally, epidemiological

[199] Mark D. Sullivan et al., *Problems and concerns of patients receiving chronic opioid therapy for chronic non-cancer pain*, 149(2) Pain, 345-353 (2010); Jørgen Erikson et al., *Critical issues on opioids in chronic non-cancer pain*, 125(1-2) Pain, 172-179 (2006); *see also Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research*, Institute of Med. Comm. on Advancing Pain Research, Care, & Educ. Board on Health Sci. Policy, (2011). K.S. Dillie et al., *Quality of life associated with daily opioid therapy in a primary care chronic pain sample*, 21(2) Journal of the Am. Bd. Of Family Med., 108-117 (Mar.-Apr., 2008).

[200] Mitchell H. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170(16) Archives of Internal Med., 1422-1424 (Sept. 13, 2010).

[201] Tara Gomes et al., *Opioid dose and drug-related mortality in patients with nonmalignant pain*, 171(17) Archives of Internal Med., 686-691 (Apr. 11, 2011); Kate M. Dunn et al. *Opioid prescriptions for chronic pain and overdose: a cohort study*, 152(2) Annals of Internal Med., 85- 92 (Jan. 19, 2010).Most overdoses were medically serious and 12% were fatal. *Id*. *See also* J.B. Braden et al., *Emergency Department visits among recipients of*

data suggest that only a minority of patients on chronic opioid therapy benefit from the drugs and most continue to suffer significant pain and limitations on their activities. Defendants have never disclosed these facts.

(i) Purdue False and Misleading Literature Marketing Enterprise

770. Purdue misrepresented the risks associated with long-term opioid use by promoting scientific studies in a deceptive way. In 1998, Purdue funded two articles by Dr. Lawrence Robbins, which showed that between 8% and 13% of the patients he studied became addicted to opioids—a troubling statistic for Purdue, whose market, and marketing, depended upon the claim that opioids were rarely addictive. Purdue had these articles placed in headache-specific journals where they would be less likely to be encountered by pain specialists or general practitioners.

771. Purdue supported a May 2002 article in *Pain Report* on how pain is undertreated in minority patients and "prudent opioid prescribing" in "meeting the challenges of chronic back pain."[202] Along the same vein, Purdue sponsored another *Pain Report* article focusing on "achieving pain relief in osteoarthritis and management of pain in patients with HIV/AIDS" issued in June 2002.[203] Purdue also supported an associated CME entitled *Osteoarthritis Pain: APS Guideline Offers New Help for Case Managers* which promoted opioid therapy for unsafe and unapproved indications.[204]

772. The first of these articles has been cited a mere 16 times; the second does not even appear on Google scholar. Five years later, Purdue funded a study of OxyContin in diabetic

chronic opioid therapy, 170(16) Archives of Internal Med., 1425-1432 (Sept. 13, 2010) (finding that higher doses of opioids doubled the risk of adverse drug events).

[202] PURDUE, MEDICAL EDUCATION RESOURCE CATALOG, ISSUE 2 (July 2003) at 11, *available at* http://www.aamcn.org/Online_Education/PDF%20-%20Catalog%20Issue%202_Purdue.pdf.

[203] *Id.*

[204] *Id.* at 15.

neuropathy patients, which was published in 2003. Notwithstanding the fact that Purdue-funded studies, testing Purdue's own drugs, had previously indicated that addiction rates were between 8% and 13%, Purdue's 2003 article reached back to the 1980 Porter-Jick Letter to support its claim that OxyContin was not commonly addictive. This article was placed in a prominent pain journal and has been cited 487 times. While this article was drafted over a decade ago, it continues to be relied upon to further the misrepresentations that opioids are not addictive.

773. Rather than rigorously test the safety and efficacy of opioids for long-term use, Purdue created scientific support for its marketing claims by sponsoring studies that were methodologically flawed, biased, and drew inappropriate conclusions from prior evidence. It then published studies with favorable outcomes and suppressed the problematic ones. The result was a body of literature whose primary purpose was to support the use of opioids for chronic pain, but was passed off as legitimate scientific research. Subsequent studies then cited—and continue to cite—this research to insidious effect: the body of evidence on which physicians rely to prescribe opioids now fully incorporates Purdue's skewed science.

774. For example, Purdue-sponsored studies, and Purdue marketing materials that cited them, regularly made claims that the risk of psychological dependence or addiction is low absent a history of substance abuse. One such study, published in the *Journal of Pain* in 2003 and widely referenced since (with nearly 600 citations in Google Scholar)[205] ignored previous Purdue-commissioned research showing addiction rates between 8% and 13%—far higher than Purdue acknowledged was possible in its mainstream marketing.

775. Purdue relegated those earlier studies to less-prominent headache journals, where it knew they would be less widely read. Instead, to support the claim that OxyContin rarely was

[205] C. Peter, N. Watson, et al., *"Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial in painful diabetic neuropathy,"* 105 J. Pain 71 (2003).

addictive, the Pain article reached back to a 1980 letter to the editor—not an article, but a letter—in the New England Journal of Medicine. That letter, J. Porter & H. Jick, "Addiction Rare in Patients Treated with Narcotics," 302(2) New England Journal of Medicine 123 (1980) ("Porter-Jick Letter"), is reproduced in full below:

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.

JANE PORTER
HERSHEL JICK, M.D.
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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.

776. The Porter-Jick Letter does not reflect any study, but simply describes a review of the charts of hospitalized patients who had received opioids. The Porter-Jick Letter notes that the review found almost no references to signs of addiction, though there is no indication that staff were instructed to assess or document signs of addiction. And because the opioids were administered in a hospital, there was no risk of patients taking more or higher doses than were prescribed.

777. The Porter-Jick Letter has become a mainstay in scientific literature, with more than 1,000 citations in Google Scholar. Purdue, for example, has cited it in support of Purdue's patently false marketing claim that "less than 1%" of opioid patients become addicted, most prominently in its 1998 "I Got My Life Back" video. Yet Purdue failed to disclose both the

nature of the citation (a letter, not a study) and any of its serious limitations. Dr. Jick later complained that drug companies "pushing out new pain drugs" had misused the Letter—citing it to conclude that their opioids were not addictive, even though "that's not in any shape or form what we suggested in our letter." In June 2017, the New England Journal of Medicine, citing a new analysis of the Porter-Jick Letter's citation history, added this editor's note to its online version of the Letter: "For reasons of public health, readers should be aware that this letter has been 'heavily and uncritically cited' as evidence that addiction is rare with opioid therapy."

778. Purdue published other research supporting chronic opioid therapy that was just as flawed as the 2003 Pain article. One such Purdue-sponsored study, which featured two Purdue authors and appeared in the Journal of Rheumatology in 1999, misleadingly suggested that OxyContin was safe and effective as a long-term treatment for osteoarthritis. Patients were given OxyContin only for 30 days, only 106 of the 167 patients continued the study after their appropriate dose was determined, and most who left did so due to ineffective pain control or side effects from the drug. While acknowledging the short-term nature of the trial, the authors still drew the unsupported conclusion that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term."

779. Another Purdue-authored study, published in the *Clinical Journal of Pain* in 1999, misleadingly implied that OxyContin was safe and effective as a long-term treatment of back pain. This study, too, had a high dropout rate, and although it concerned a chronic condition, it followed patients on OxyContin only between four and seven days. The study was not set up to consider long-term risks, including the risk of addiction, but blithely concluded that

"common opioid side effects can be expected to become less problematic for the patient as therapy continues."

780. In spite of the complete lack of scientific basis, in 2011, Purdue sponsored *A Policymaker's Guide to Understanding Pain & Its Management*, published by the APF, which asserted that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic non-cancer pain patients. To support this claim, APF cited *Opioids for chronic non-cancer pain: a meta-analysis of effectiveness and side effects*, a study published in 2006 in the Canadian Medical Association Journal. However, the study concludes: "For functional outcomes, the other analgesics were significantly more effective than were opioids." The Purdue-sponsored *Guide* failed to disclose this conclusion, as well as the fact that the study was conducted only for five weeks, and therefore could not support the long-term use of opioids, or the study's findings that opioids were actually less effective than alternative treatments.

(ii) Cephalon False and Misleading Literature Marketing Enterprise

781. Cephalon also knew that its misleading messages would be more likely to be believed by prescribers if they were corroborated by seemingly neutral scientific support.

782. Employing these tactics, Cephalon caused the term "breakthrough pain"—a term it seeded in the medical literature—to be used in articles published by practitioners and clinicians it supported. With funding from Cephalon, for example, Dr. Portenoy wrote an article that purported to expand the definition of breakthrough cancer pain to non-cancer indications, vastly expanding the marketing potential of Cephalon's Fentora. The article was published in the nationally circulated Journal of Pain in 2006 and helped drive a surge in Fentora prescriptions.

783. The concept of "breakthrough pain" ultimately formed the sole basis for the central theme of promotional messages Cephalon cited to support the approval and marketing of Actiq and Fentora, rapid-acting opioids which begin to work very quickly but last only briefly. Neither of these drugs had a natural place in the treatment of chronic pain before Cephalon's marketing campaign changed medical practice. A recent literature survey of articles describing non-cancer breakthrough pain calls into question the validity of the concept, suggesting it is not a distinct pain condition but a hypothesis to justify greater dosing of opioids.

784. In other words, Cephalon conjured the science of breakthrough pain in order to sell its drugs. As one scholar has pointed out, references to breakthrough pain in articles published on the MEDLINE bibliographic database spiked in 1998 and again in 2006. These spikes coincide with FDA's approval of Actiq and Fentora.

785. A government investigation revealed that two studies touted by Cephalon tested fewer than 28 patients and had no control group whatsoever. Further, the doctors who conducted the studies were anything but independent of Cephalon. One of the doctors also had paid speaking arrangements with Cephalon to pitch its products; the other doctor received help from Cephalon with conducting his study. Cephalon then used these bogus studies to promote and misrepresent the efficacy of Actiq for conditions where no real scientific substantiated existed. At least one of the studies was published in the medical journal *Headache*.

786. A clinical study evaluating the effect of Fentora in opioid tolerant *non-cancer patients* for breakthrough pain concluded that the drug showed clinically important analgesic effects and was generally well tolerated even for long-term treatment. The primary author, Dr. Srinivas Nalamachu, a physical medicine and rehabilitation specialist from Overland Park, Kansas, had been paid over $440,000 dollars by Cephalon in speaking fees, consulting fees,

travel and meals between 2009 and 2011. The other two authors listed on the study, Drs. Narayana and Janka, were Cephalon employees.[206]

787. Cephalon funded these studies to promote the unsafe and unapproved use of Fentora. During the Fentora launch and through the first year of sales, these clinical studies were presented by the marketing division to the Fentora sales force at national sales meetings and trainings to suggest that the FDA was moving towards approving certain unsafe and unapproved uses such as for non-cancer breakthrough pain, migraine pain, and general chronic pain. In reality, these studies were provided to sales representatives to encourage them to promote Fentora for unsafe and unapproved use to physicians on the misunderstanding that these uses would shortly be approved by the FDA.

788. Although these clinical studies were provided as reference materials to the sales force, during this period Cephalon did not institute any guidelines or restrictions on their use as promotional materials to be used on sales calls with physicians. Thus, sales representatives would discuss these off-label clinical studies and articles with physicians to encourage or increase unsafe and unapproved prescribing.

789. Cephalon also sponsored a number of journal articles based on their sham clinical studies, discussed *supra*. A review of the journal articles discussing the use of Fentora in non-cancer breakthrough pain reveals that Cephalon is either directly or indirectly involved in nearly all of those publications, either by sponsoring the study, "supporting" the writing of the article, or having the paper authored or the study conducted by a Cephalon employee or paid consultant. Thus, despite the overwhelming risk of addiction that even limited on-label BTCP use of Fentora

[206] *See* Srinivas R. Nalamachu, Arvind Narayana and L. Janka, *Long-term dosing, safety, and tolerability of fentanyl buccal tablet in the management of non-cancer-related breakthrough pain in opioid-tolerant patients*, 27(4) CURRENT MEDICAL RESEARCH & OPINION 751-760 (2011), *available at* https://www.ncbi.nlm.nih.gov/pubmed/21288055(last visited Feb. 19, 2014).

presented, Cephalon actively set out to build a consensus around the notion its marketing plans had set out to achieve, use of Fentora for all forms of breakthrough pain.

790. For example, one non-peer reviewed article, concluded after a review of clinical studies that Fentora should be used in opioid tolerant patients for breakthrough pain regardless of whether the patient had cancer versus non-cancerous reasons for pain—directly in opposition to the FDA and Drug Compendia's indicated uses. The article was funded by Cephalon, authored in part by two Cephalon employees (Drs. Messina and Darwish), and medically reviewed by another Cephalon employee (Dr. Narayana).[207]

791. In addition to promoting the unsafe and ineffective use of Fentora for non-cancer breakthrough pain, Cephalon also attempted to promote the use of the drug to alleviate certain psychiatric symptoms in opioid-tolerant patients with chronic pain or breakthrough pain.[208] Although the clinical study concluded that Fentora "did not reduce anxiety to a clinically meaningful extent," it clearly demonstrates Cephalon's attempt to broaden the market for unsafe and unapproved uses of Fentora well beyond the boundaries of indicated usage approved by the FDA. Of the authors of the clinical study, two (Drs. Messina and Xie) were Cephalon employees. As mentioned above, Dr. Nalamachu is a paid Cephalon consultant and Dr. Lynn Webster is also a paid consultant, having earned over $18,000 in 2009-2010 for speaking fees, consulting, and research.

[207] *See* Darwish, M. et al., *Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain: Pharmacokinetics of Buccal Mucosa Delivery and Clinical Efficacy*, PERSPECTIVES IN MEDICINAL CHEMISTRY, 4, 11 (2010), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC290 1636/pdf/pmc-2010-011.pdf.

[208] *See* Lynn R. Webster, John Messina, Frank Xie, & Srinivas Nalamachu, *Effect of fentanyl buccal tablet on pain-related anxiety: a 4-week open-label study among opioid-tolerant patients with chronic and breakthrough pain*, 7 Journal of Opioid Management, 297-308 (2010).

(iii) Janssen False and Misleading Literature Marketing Enterprise

792. In another example, Janssen on its *Prescribe Responsibly* website claimed that Nucynta ER had a low incidence of withdraw symptoms. The basis for this false and misleading claim was a purported study of withdraw symptoms occurring two to four days after discontinuing use. In reality, withdrawal symptoms peak earlier than that.

793. An ad that Janssen ran, including on its website, claims that Nucynta ER has "Efficacy you need, Tolerability you want." However, each of the studies included in the drug's approval was only conducted over a 12-week period, using a pre-selected patient group; thus, none provide support for a claim of long-term efficacy in the population at large. Indeed, Janssen also failed to disclose that it submitted a fourth study for the FDA's consideration that did not show pain reduction over placebo and was thus omitted from the approval.

794. Janssen sponsored the *Let's Talk Pain* talk show—which is still available online—which made deceptive claims regarding the scientific evidence concerning the long-term use of Opioids. In the very first episode of this talk show, the following exchange, from a script edited and approved by Janssen, took place:

> **Teresa Shaffer (APF Action Network Leader)**: As a person who has been living with pain for over 20 years, opioids are a big part of my pain treatment. And I have been hearing such negative things about opioids and the risk factors of opioids. Could you talk with me a little bit about that?
>
> **Dr. Al Anderson (AAPM Board of Directors):** The general belief system in the public is that the opioids are a bad thing to be giving a patient. Unfortunately, it's also prevalent in the medical profession, so patients have difficulty finding a doctor when they are suffering from pain for a long period of time, especially moderate to severe pain. And that's the patients that we really need to use the opioids methods of treatment, because they are the ones who need to have some help with the function and they're the ones who need to have their pain controlled enough so that they can increase their quality of life.

> **Teresa Shaffer**: This is what has allowed me to continue to function and is what has allowed me to have somewhat of a normal life, is the opioids.

There simply is no scientific evidence that opioids taken long-term improve function or quality of life for chronic non-cancer pain patients, and significant evidence that opioids impose significant risks and adverse outcomes on long-term users, none of which is disclosed in this video interview.

(iv) Endo False and Misleading Literature Marketing Enterprise

795. Endo also sought to promote opioids for the treatment of chronic pain through the use of key opinion leaders and biased, misleading science.

796. Endo distributed copies of a book by KOL Dr. Webster entitled *Avoiding Opioid Abuse While Managing Pain* (2007). Endo's internal planning documents describe the purpose of distributing this book as to "[i]ncrease the breadth and depth of the Opana ER prescriber base." The book claims that when faced with signs of aberrant behavior, the doctor should regard it as "pseudoaddiction" and thus, increasing the dose *in most cases . . . should be the clinician's first response*." (emphasis added).

797. Endo documents indicate that, around 2007, the company purchased at least 50,000 copies of the book for distribution. Internal Endo documents demonstrate that the book had been approved for distribution by Endo's sales force, and Endo had fewer than 8,000 copies on hand in March of 2013. Based on the nationwide and uniform character of Endo's marketing, and the book's approval for distribution, this book was available to and was intended to reach prescribers.

798. KOL Dr. Lynn Webster later conceded this information was deceiving: "[Pseudoaddiction] obviously became too much of an excuse to give patients more

medication…It led us down a path that caused harm. It is already something we are debunking as a concept."

799. Endo's 2010 publication plan for Opana ER identified a corporate goal of making Opana ER the second-leading branded product for the treatment of moderate-to-severe chronic pain (after OxyContin). Endo sought to achieve that goal by providing "clinical evidence for the use of Opana ER in chronic low back pain and osteoarthritis," and subsequently successfully had articles on this topic published.

800. These studies suffered from the limitations common to the opioid literature—and worse. None of the comparison trials lasted longer than three weeks. Endo also commissioned a six-month, open label trial during which a full quarter of the patients failed to find a stable dose, and 17% of patients discontinued, citing intolerable effects. In open label trials, subjects know which drug they are taking; such trials are not as rigorous as double-blind, controlled studies in which neither the patients nor the examiners know which drugs the patients are taking.

801. In the years that followed, Endo sponsored articles authored by Endo consultants and Endo employees, which argued that the metabolic pathways utilized by Opana ER, compared with other opioids, were less likely to result in drug interactions in elderly low back and osteoarthritis pain patients. In 2010, Endo directed its publication manager to reach out to a list of consultants conducting an ongoing Endo-funded study, to assess their willingness to respond to an article[209] that Endo believed emphasized the risk of death from opioids, "without [] fair balance."

802. Endo's reliance on flawed, biased research is also evident in its 2012 marketing materials and strategic plans. A 2012 Opana ER slide deck for Endo's speakers' bureaus—on

[209] Susan Okie, *A Flood of Opioids, a Rising Tide of Deaths*, 363 NEW ENGL. J. MED. 1981 (2010) (finding that opioid overdose deaths and opioid prescriptions both increased by roughly 10-fold from 1990 to 2007).

which these recruited physician speakers were trained and to which they were required to adhere—misrepresented that the drug had low abuse potential and suggested that as many as one-quarter of the adult population could be candidates for opioid therapy. Although the FDA requires such speaker slide decks to reflect a "fair balance" of information on benefits and risks, Endo's slides reflected one-sided and deeply biased information. The presentation's 28 literature citations were largely to "data on file" with the company, posters, and research funded by, or otherwise connected to, Endo. Endo's speakers relayed the information in these slides to audiences that were unaware of the skewed science on which the information was based.

803. A 2012 Opana ER Strategic Platform Review suffered from similar defects. Only a small number of the endnote referenced in the document, which it cited to indicate "no gap" in scientific evidence for particular claims, were to national-level journals. Many were published in lesser or dated journals, and written or directly financially supported by opioid manufacturers. Where the strategy document did cite independent, peer-reviewed research, it did so out of context. For example, it cited a 2008 review article on opioid efficacy for several claims, including that "treatment of chronic pain reduces pain and improves functionality," but it ignored the article's overall focus on the lack of consistent effectiveness of opioids in reducing pain and improving functional status.[210]

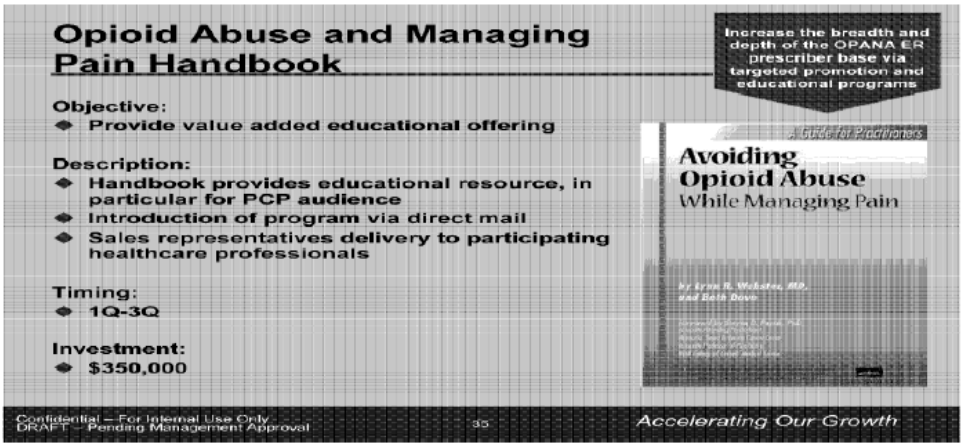
804. Notwithstanding Endo's reliance upon dubious or cherry-picked science, in an Opana ER brand strategy plan it internally acknowledged the continuing need for a significant investment in clinical data to support comparative effectiveness. Endo also cited a lack of "head-to-head data" as a barrier to greater share acquisition, and the "lack of differentiation data" as a challenge to addressing the "#1 Key Issue" of product differentiation. This acknowledged lack of

[210] Andrea M. Trescot, *et al*., *Opioids in the management of non-cancer pain: an Update of American Society of the Interventional Pain Physicians, Pain Physician*, 2008 Opioids Special Issue, 11:S5-S62.

support did not stop Endo from directing its sales representatives to tell prescribers that its drugs were less likely to be abused or be addictive than other opioids.

805. Endo sponsored a paper that falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that HCPs and patients nationwide, and in Ohio, would look to opioids first for the treatment of chronic pain. The paper deceptively describes the risks from NSAIDs while failing to disclose the risks from opioids.[211]

806. A slide from an Opana ER business plan contemplated distribution of the book as part of Endo's efforts to "[i]ncrease the breadth and depth of the OPANA ER prescriber base via targeted promotion and educational programs." The slide indicates that the book would be particularly effective "for [the] PCP audience" and instructed "[s]ales representatives [to] deliver [the book] to participating health care professionals." The slide, shown below, demonstrates Endo's express incorporation of this book by a KOL into its marketing strategy:



(v) Actavis False and Misleading Literature Marketing Enterprise

807. Actavis also exemplifies the Manufacturer Defendants' practice of commissioning a KOL research article with a conclusion pre-determined by the manufacturer. For example,

[211] *See, e.g., Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, PAIN MED. NEWS (Apr. 2007) , *available at* http://www.painmedicinenews.com/download /BtoB_Opana_WM.pdf (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids, and supported by Endo).

Actavis ordered three manuscripts to be written in 2005, all three of which had planned outcomes. The contents were to be written as follows: "[t]he neuropathic pain manuscript will provide evidence demonstrating KADIAN is as effective in patients with presumptive neuropathic pain as it is in those with other pain types;" "[t]he elderly subanalysis…will provide clinicians with evidence that KADIAN is efficacious and well tolerated in appropriately selected elderly patients" and will "be targeted to readers in the geriatrics specialty;" and "[t]he QDF/BID manuscript will…call attention to the fact that KADIAN is the only-sustained release opioid to be labeled for [once or twice daily] use." Articles matching these descriptions later appeared in the *Journal of Pain* and the *Journal of the American Geriatrics Society*, which as discussed herein received significant funding from the Manufacturer Defendants.

808. In 2005, Actavis commissioned a report from one of its consultants regarding the barriers to market entry for its branded drug Kadian. The report concluded that the major barriers to opioid manufacturers were (i) overcoming "concerns regarding the safety and tolerability" of opioids, and (ii) the fact that "physicians have been trained to evaluate the supporting data before changing their respective practice behavior."

809. In order to change physicians practice behavior, the report recommended a "[p]ublication strategy based on placing in the literature key data that influence members of the target audience," with an "emphasis…on ensuring that the message is believable and relevant to the needs of the target audience." Such a strategy requires the creation of "effective copy points…back by published references" and "developing and placing publications that demonstrate [the] efficacy [of opioids] and [their] safety/positive side effect profile." In this way physicians would be able to "reach[] a mental agreement" and change their behavior without having first evaluated supporting data, which of course did not exist. Such manufactured

literature would "provide greater support for the promotional message and add credibility to the brand's advocates" based on "either actual or perceived 'scientific exchange'" in relevant medical literature, which essentially admits Actavis knew their messaging was false and deceptive.

5. The Manufacturer Defendants' Efforts to Deflect FDA and CDC Concerns

810. As part of their coordinated efforts to deflect concerns about the Opioid Drugs' contribution to the epidemic, the Manufacturer Defendants, through their Front Groups, issued official statements and critical reviews of positions taken by both the FDA and CDC aimed at reigning in the long-term prescribing of Opioid Drugs for chronic pain.

811. In 2009 the FDA mandated REMS for opioids to be distributed to prescribers and patients. PCF developed and disseminated "consensus recommendations" in order to ensure that the REMS did not go too far in narrowing the uses or benefits or highlighting the risks of opioid therapy for chronic pain, which would significantly undermine the Defendants' marketing efforts. The recommendations claimed that opioids were "essential" to the management of pain and that it would behoove the REMS to "acknowledge the importance of opioids in the management of pain and…not introduce new barriers." Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain their deceptive marketing of opioids for chronic pain.

812. As noted above, one successful effort by the Manufacturer Defendants (through PCF) was to thwart the FDA's efforts to *require* physicians take a CME which accurately informs them of the efficacy and risks of long-term opioid treatment for chronic pain. PCF was controlled in large part by Purdue, Cephalon, Janssen, and Endo.

813. In 2012, KOLs Dr. Fine and Dr. Webster co-authored the AAPM's response to the FDA's efforts to limit opioid medications to severe and cancer pain indications, relying on the AAPM's own 2009 guidelines (that they assisted in drafting) as evidence. Therein they made the unsubstantiated statements that "[a]t best, the literature has shown inconsistent effectiveness of opioids for chronic pain" and a predisposition to substance abuse is "not a reason to deny people with pain an opioid."

814. AAPM subsequently spearheaded a campaign criticizing the CDC's drafted prescribing guidelines in 2015, claiming "[b]y only addressing how to limit or avoid opioids, the new guidelines will inevitably result in fewer prescriptions overall – including those needed by patients with legitimate medical needs."[212] In its letter, the AAPM questions the CDC's methodology of evidence review claiming the proposed CDC guidelines restricting opioid use "are not an evidence-based practice guideline in the conventional sense."[213] Not surprisingly, AAPM champions for the continued use of industry funded misrepresentations in its 2009 Guideline which they now characterize as an approach "relying on the 'best available evidence'." While downplaying the public health risks associated with opioid prescriptions, AAPM stressed the Manufacturer Defendants' favorite message - that chronic pain is "a national healthcare crisis." In 2016, past president of the AAPM, Daniel Carr, also criticized the prescribing

[212] Mary Rechtoris, *Pain Groups Critique CDC's Prescribing Guidelines—6 Points*, BECKER'S SPINE REVIEW (Sept. 13, 2915), https://www.beckersspine.com/spine/item/27319-http-www-painnewsnetwork-org-stories-2015-9-22-chronic-pain-groups-blast-cdc-for-opioid-guidelines.html.

[213] Letter to Thomas Frieden, MD, MPH, Nat't Ctr. for Injury Prevention & Control, Ctrs. for Disease Control & Prevention, from the American Academy of Pain Medicine (Jan. 12, 2016), at 2, *available at* http://www.painmed.org/files/aapm-letter-to-cdc-proposed-2016-guidelines-for-prescibing.pdf.

guidelines, stating "that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence."[214]

815. On March 15, 2016 the CDC issued the guidelines, "explaining that non-opioid therapies are preferred for chronic pain and recommended that physicians prescribe immediate-release opioids at the lowest effective dosage and evaluate the benefits and harms of continued opioid use within one to four weeks of starting opioid therapy."[215] As Dr. Andrew Kolodny, executive director of Physicians for Responsible Opioid Prescribing, has explained, "[t]he opioid lobby has very actively blocked interventions that might result in more cautious prescribing or reduced prescribing. They've very clearly defended their financial stake in the status quo."

816. Relatedly, in a March 2017 article published in JAMA Internal Medicine, researchers from Johns Hopkins University and Brandeis University examined industry payments to over 150 organizations that had submitted comments on the draft CDC guidelines.[216] After coding guideline comments by supportiveness and reviewing financial disclosures, including annual reports, tax returns, and self-reported information, researchers found "opposition to the guidelines was significantly more common among organizations with funding from opioid manufacturers than those without funding from the life sciences industry."[217]

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[214] *Responses and Criticisms Over New CDC Opioid Prescribing Guidelines*, PRACTICAL PAIN MGMT., https://www.practicalpainmanagement.com/resources/news-and-research/responses-criticisms-over-new-cdc-opioid-prescribing-guidelines (last visited Sept. 28, 2017).

[215] DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL AND PREVENTION, CDC GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN – UNITED STATES, 2016 (Mar. 15, 2016), *available at* www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1er.pdf.

[216] Dora H. Lin *et al.*, *Financial Conflicts of Interest and the Centers for Disease Control and Prevention's 2016 Guideline for Prescribing Opioids for Chronic Pain*, JAMA INTERNAL MEDICINE (Mar. 2017).

[217] *Id.* (emphasis added).

817. Likewise, the 2018 government report notes: "[t]he fact that these groups registered their opposition while receiving funding from the opioids industry raises the appearance—at the very least—of a direct link between corporate donations and the advancement of opioids-friendly messaging."[218]

818. Accordingly, a "major concern is that opposition to regulatory, payment, or clinical policies to reduce opioid use may originate from groups that stand to lose financially if opioids sales decline."[219] In an extended version of their findings, the researchers are more explicit: "[O]pposition to more conservative opioid use may, at least in part, be financially motivated."[220]

6. The Manufacturer Defendants' Circular Sourcing Strategy

819. The Scientific Literature Marketing Enterprises relied on a circular sourcing strategy, whereby information coming from one source was presented as if coming from multiple sources. The "evidence" cited in support of published material was in reality the source of the published material itself: Manufacturer Defendants. This strategy successfully elevated unsubstantiated (and false) claims to the level of peer-reviewed and adequately sourced work, when in fact nothing could be further from the truth.

820. For example, KOL Dr. Fine authored an article suggesting urine testing could prevent opioid drug diversion in patients on long-term opioid therapy for the treatment of chronic pain.[221] In that 2012 article, titled *Recommendations for Urine Drug Monitoring as a Component*

[218] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office, Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups, (Feb. 13, 2018), at 14.

[219] *Id.*

[220] DORA H. LIN ET AL., POTENTIAL FINANCIAL CONFLICTS OF INTEREST AND FEDERAL OPIOID GUIDELINES: A CROSS-SECTIONAL STUDY (2017).

[221] Perry Fine *et al.*, *Recommendations for Urine Drug Monitoring as a Component of Opioid Therapy in the Treatment of Chronic Pain*, 13 PAIN MED. 886 (2012).

of Opioid Therapy in the Treatment of Chronic Pain, Dr. Fine relies heavily on the 2009 APS / AAPM Treatment Guidelines, which were written in part by Dr. Fine.

821. Another technique by the Manufacturer Defendants was the frequent citation of source material that lacked evidentiary support. The sheer number of citations to the unsubstantiated source material was meant to create the impression among the public and medical community that the source material was based on sound evidence. In this way, a letter-to-the-editor was transformed into a landmark study justifying the Manufacturer Defendants' outlandish claims.

822. These strategies were by design, not accident. In 2005, Actavis commissioned a report from one of its consultants regarding the barriers to market entry for its branded drug Kadian. The report concluded that the major barriers to opioid manufacturers were (i) overcoming "concerns regarding the safety and tolerability" of opioids, and (ii) the fact that "physicians have been trained to evaluate the supporting data before changing their respective practice behavior."

823. In order to change physicians' prescribing behavior, the report recommended a "[p]ublication strategy based on placing in the literature key data that influence members of the target audience," with an "emphasis…on ensuring that the message is believable and relevant to the needs of the target audience." Such a strategy requires the creation of "effective copy points…back by published references" and "developing and placing publications that demonstrate [the] efficacy [of opioids] and [their] safety/positive side effect profile." In this way physicians would be able to "reach[] a mental agreement" and change their behavior without having first evaluated supporting data, which of course did not exist. Such manufactured literature would "provide greater support for the promotional message and add credibility to the

brand's advocates" based on "either actual or perceived 'scientific exchange'" in relevant medical literature, which essentially admits Actavis knew its messaging was false and deceptive.

824. The Manufacturer Defendants all understood that circular sourcing and medical consensus was key to the success of the Opioid Drugs, and thus all contributed to the 'greater good' with their own sham KOLs, CMEs, Front Group statements, publications and the like. The success of the strategy—and it was indeed successful—depended on each Defendant Manufacturer doing their part. In an ocean of deception aimed at tricking HCPs, patients, and TPPs, a rising tide lifts all boats.

C. Consumer Pull-Through Marketing Enterprises

825. Beginning in the early 1990's, there was a significant philosophical shift in the way prescription drugs were marketed. Twenty years ago, direct appeals to consumers by prescription drug manufacturers via print and broadcast media was a new phenomenon in the health sector. This approach, known as direct-to-consumer ("DTC") marketing, has taken an increasingly important position in terms of public awareness of prescription drug products. Surveys have shown that over 90% of the public reports seeing prescription drug advertisements.

826. In 1989, the drug industry collectively spent only $12 million on DTC marketing, compared to $2.38 billion in 2001, an increase of almost 200-fold in only 12 years. A total of 105 prescription drugs were advertised directly to consumers in 2001

827. As a result of this change in marketing, the Institute for Safe Medication Practices reports 78% of primary care physicians have been asked for drugs that their patients saw advertised on television and 67% concede that they sometimes grant patients' requests for medications that are not clinically indicated. Therefore, many patients may be using medications unnecessarily and/or are overmedicated.

828. Direct marketing of controlled prescription drugs to patients is designed to increase the demand for a particular medication among those seeking it for legitimate (i.e., medical) purposes. Unfortunately, it may increase demand among those seeking drugs for abusive (*i.e.*, diversion) purposes as well.

829. There are no federal prohibitions against DTC advertising of controlled prescription drugs. DTC advertising of any controlled prescription drug, however, is prohibited by Article 10 of the 1971 International Convention on Psychotropic Substances which states: "Each Party *[to the treaty]* shall, with due regard to its constitutional provisions, prohibit the advertisement of such substances *[controlled psychotropic substances]* to the general public."[222] Because DTC advertising in general has to date been deemed protected by a Constitutional First Amendment right to commercial speech, the U.S. government has not prohibited drug manufacturers from advertising their drugs to consumers.

830. The Manufacturer Defendants knew they could not create a new market for a drug by convincing HCPs alone. The Manufacturer Defendants therefore unleashed a torrent of deceptive marketing on consumers as well, promising sufferers of chronic pain that greener pastures were on the horizon. Increasing consumer demand was thus part of the Manufacturer Defendants' greater efforts to expand the prescription market for Opioid Drugs.

831. The emphasis on patient marketing was based on the Manufacturer Defendants' market research and business plans. Pharmaceutical industry marketing experts see patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in "increas[ing] market share…by bringing awareness to a particular disease that the drug treats."[223]

[222] Convention on Psychotropic Substances, art. 10, ¶ 2, Feb. 21, 1971, 32 U.S.T. 543.

[223] Kanika Johar, Comment, *An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices*, 76 ALB. L. REV. 299, 308 (2013).

Evidence also demonstrates that physicians are willing to acquiesce to patient demands for a particular drug—even for opioids and for conditions for which they are not generally recommended.[224]

832. These observations were not lost on the Manufacturer Defendants. Endo's research, for example, found that patient-oriented advertising resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations. An Actavis marketing plan similarly noted that "[d]irect-to-consumer marketing affects prescribing decisions."

833. The Consumer Pull-Through Marketing Enterprise took many forms, including patient-focused "educational" materials, such as pamphlets, videos, websites, print advertisements in magazines available in physician offices, and Front Group messages targeting pain sufferers.

834. The Manufacturer Defendants created information campaigns – including literature, websites, community groups, and programs – targeting individuals who suffer from chronic non-cancer pain from illnesses such as low back pain, shingles, migraines, osteoarthritis, phantom limb pain, fibromyalgia, multiple sclerosis, among others. Many individuals affected by these conditions have formed affinity groups and on-line communities that provide support to people seeking to address conditions that produce persistent pain or that may necessitate long-term treatment. The Manufacturer Defendants targeted these communities and used these community-building efforts to promote the unsafe and unapproved use of opioids for treating these conditions. The Manufacturer Defendants did so despite the fact that there was little or no

[224] According to one study, nearly 20% of sciatica patients requesting oxycodone would receive a prescription for it, compared with 1% making no request. More than half of patients requesting a strong opioid received one. J.B. McKinlay et al., *Effects of Patient Medication Requests on Physician Prescribing Behavior: Results of a Factorial Experiment*, 52(2) MED. CARE 294 (2014).

scientific evidence supporting the use of opioids for these conditions, and little or no evidence supporting or even suggesting that the use of opioids for these conditions would provide more pain relief than harm from the many known and significant opioid treatment risks.

835. Further, the Manufacturer Defendants employed rebates, co-pay assistance, and free trials to lower the cost for patients seeking relief from chronic pain and to encourage the patients to fill the prescriptions.

836. The Consumer Pull-Through Marketing Enterprises bombarded patients with various misrepresentations and omissions aimed at increasing patient demand for Opioid Drugs, including: (1) the existence of a "pain epidemic" and urgency with which it must be addressed; (2) that living with pain is a "choice"; (3) the efficacy with which long-term Opioid Drug therapy treats or manages long-term chronic pain; (4) downplaying the serious risk of addiction; (5) suggesting patients "advocate" for themselves with their doctors, should not "take no for an answer," and threaten to leave prescribers who did not provide Opioid Drugs; and (6) actively concealing, and causing others to conceal, information about the safety (including addiction risk), efficacy, and usefulness of Opioid Drugs to treat long-term chronic pain.

837. The tools with which the Consumer Pull-Through Marketing Enterprises spread these misrepresentations and omissions (or otherwise increased patient demand) included: (1) direct marketing or advertising to consumers; (2) indirect marketing through bogus Front Groups; (3) media campaigns or otherwise influencing media coverage, and (4) financial incentives for would-be patients (such as coupons or rebates). The Manufacturer Defendants further targeted particularly vulnerable patient populations (namely, the elderly and wounded veterans). Each of these characteristics is explained in greater detail below.

1. Indirect Marketing to Consumers through Front Groups

838. As noted above, the Manufacturer Defendants entered into arrangements with numerous Front Groups to promote their Opioid Drugs, particularly as an appropriate long-term treatment for chronic pain. While some of these Front Groups focused their messaging solely on prescribers, others—masquerading as "patient advocacy" groups—sought to "educate" consumers suffering from chronic pain.

839. For example, APF issued education guides for patients that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. Its patient guide found on its website even went so far as to discourage the use of non-opioid pain killers citing harmful side-effects, all while encouraging the use of opioids and minimizing the far more crippling side-effects and debilitating risk of addiction.

840. APF's *Treatment Options: A Guide for People Living with Pain*, misleadingly told patients that addiction was limited to extreme cases of unauthorized dose escalations, getting opioids from multiple sources, or theft.

841. APF also engaged in a significant multimedia campaign—through radio, television, and the internet—to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach Ohio consumers, physicians, patients, and TPPs.

842. AGS and AAPM also developed materials focused on patients, such as their "education" pamphlet entitled *Finding Relief: Pain Management for Older Adults* (discussed *infra*).

843. NIPC also undertook various initiatives containing false and misleading statements aimed at consumers, such as its *painknowledge.org* website (discussed *infra*).

2. Media Campaigns and Influencing Media Coverage

844. The Manufacturer Defendants also developed public relations strategies with respect to how opioids—and the so-called "epidemic of pain"—were covered by media organizations who served the public at large (and thus patients).

845. The Manufacturer Defendants were also well aware that media organizations would be understandably skeptical of claims originating from the manufacturers themselves, and thus enlisted the help of their Front Groups. The Front Groups held themselves out as an independent resource for reporters writing stories on opioids.

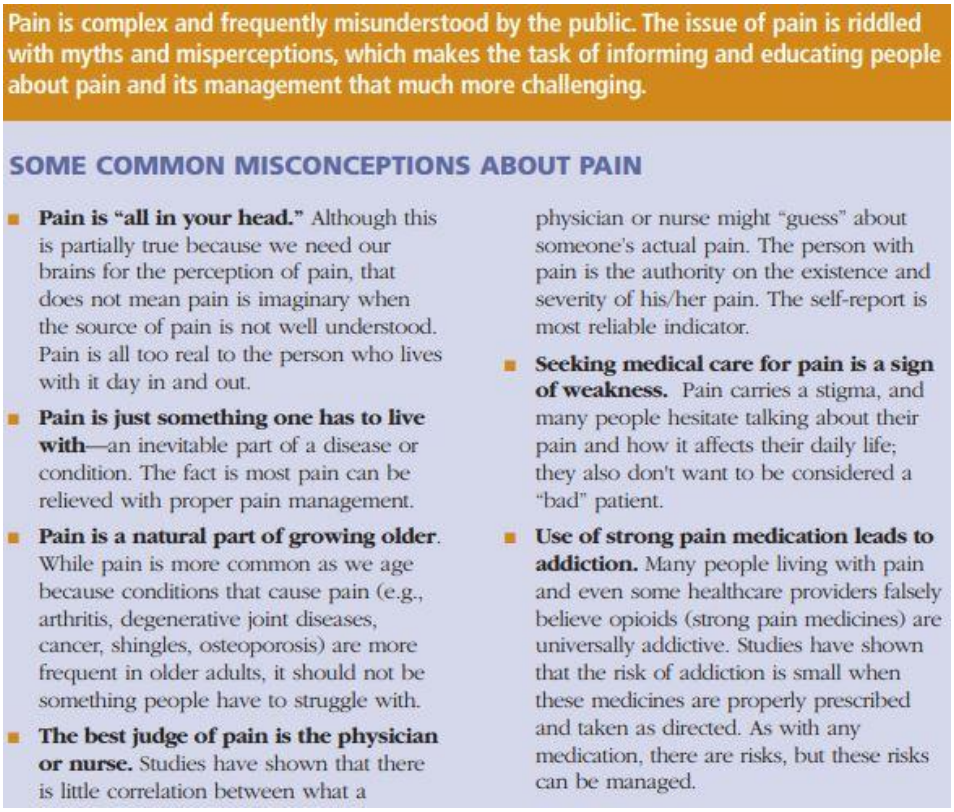
846. One example is *A Reporter's Guide: Covering Pain and Its Management*, published by APF exclusively for reporters.[225] APF developed the Guide "as a primer on pain and pain management to help meet the informational needs of busy reporters, editors and producers covering the pain story." APF even offered to "connect reporters with a wide array of leading pain experts" (which upon reasonable belief included various KOLs).[226]

847. Indeed, the very busy reporter need not even read the nearly 50-page guide, since the first page, noting that pain is "frequently misunderstood by the public," listed the "common misconceptions about pain" that the media can help dispel through solid reporting:[227]

[225] *A Reporter's Guide: Covering Pain and Its Management,* AM. PAIN FOUND. (Oct. 2008), *available at* https://assets.documentcloud.org/documents/277606/apf-reporters-guide.pdf.

[226] *Id.* at 3.

[227] *Id.* at 1.



Pain is complex and frequently misunderstood by the public. The issue of pain is riddled with myths and misperceptions, which makes the task of informing and educating people about pain and its management that much more challenging.

SOME COMMON MISCONCEPTIONS ABOUT PAIN

- **Pain is "all in your head."** Although this is partially true because we need our brains for the perception of pain, that does not mean pain is imaginary when the source of pain is not well understood. Pain is all too real to the person who lives with it day in and out.
- **Pain is just something one has to live with**—an inevitable part of a disease or condition. The fact is most pain can be relieved with proper pain management.
- **Pain is a natural part of growing older**. While pain is more common as we age because conditions that cause pain (e.g., arthritis, degenerative joint diseases, cancer, shingles, osteoporosis) are more frequent in older adults, it should not be something people have to struggle with.
- **The best judge of pain is the physician or nurse.** Studies have shown that there is little correlation between what a physician or nurse might "guess" about someone's actual pain. The person with pain is the authority on the existence and severity of his/her pain. The self-report is most reliable indicator.
- **Seeking medical care for pain is a sign of weakness.** Pain carries a stigma, and many people hesitate talking about their pain and how it affects their daily life; they also don't want to be considered a "bad" patient.
- **Use of strong pain medication leads to addiction.** Many people living with pain and even some healthcare providers falsely believe opioids (strong pain medicines) are universally addictive. Studies have shown that the risk of addiction is small when these medicines are properly prescribed and taken as directed. As with any medication, there are risks, but these risks can be managed.

848. The guide also warned reporters of the "challenges" of reporting on pain, including the "stigma of pain management, especially among legal and governmental regulatory bodies." In other words, the media should turn to APF—not the FDA, CDC or other agencies—in the search for "unbiased, credible information about pain."[228] One such unbiased source of information is Perry Fine, who is quoted in the Guide as saying "[w]hen opioids are prescribed for pain control in adequately evaluated, selected, and monitored patients, addiction is rare."[229]

849. The Manufacturer Defendants' KOLs also appeared on television programming with a broad audience including patients. One example is Dr. Portenoy's appearance on *Good Morning America*, discussed *supra*.

[228] *Id.* at 2.

[229] *Id.* at 29.

850. The Manufacturer Defendant KOLs also gave interviews for print publications with a broad audience (encompassing chronic pain sufferers). For example, Dr. Portenoy in 2008 gave an interview to *Health Magazine*, in which he said that many chronic pain sufferers resistant to treatment "tend to underreport" their pain. This situation, he explained, "can be improved a great deal if the person brings a spouse or another family member to the [doctor's] appointment."

3. Financial Assistance for Consumer Co-payments and Deductibles

851. The Manufacturer Defendants also knew that one of the largest obstacles to patients starting and remaining on their branded opioids—including by switching from a competitor's drug—was out-of-pocket cost. They recognized they could overcome this obstacle by providing patients financial assistance with their insurance co-payments, and each of the Defendants did so through vouchers and coupons distributed during detailing visits with prescribers.

4. Targeting Vulnerable Patient Populations

852. The Manufacturer Defendants also targeted vulnerable subgroups of the population at large; namely, the elderly and wounded war veterans.

853. Guidelines published by the Manufacturer Defendants' Front Group AGS promoted the idea that "[a]ll patients with moderate to severe pain…should be considered for opioid therapy."[230] There has never been any scientifically-based evidence to support this audacious claim.

854. The Manufacturer Defendants' marketing misleadingly minimized the particular risks affecting the elderly population. Elderly patients are at greater risk of adverse drug effects

[230] *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. AM. GERIATR. SOC'Y 1331,1339, 1342 (2009), *available at* http://onlinelibrary.wiley.com/doi/10.1111/j.1526-4637.2009.00699.x/full.

and interactions; indeed, a 2010 paper in the Archives of Internal Medicine reported that elderly patients who used opioids had a significantly higher rate of death, heart attacks, and strokes than users of NSAIDs. While these risks are acknowledged somewhat in the Manufacturer Defendants' labeling, they are (upon information and belief) downplayed in the marketing aimed at the elderly population.

855. The Manufacturer Defendants also promoted the notion—also without adequate scientific foundation—that the elderly are particularly unlikely to become addicted to opioids. AGS's 2009 Guidelines, for example, which the Manufacturer Defendants publicized, alleged the risk of addiction as "exceedingly low in older patients with no current or past history of substance abuse."[231] Yet, a 2010 study examining overdoses among long-term opioid users found that patients 65 or older were among those with the largest number of serious overdoses.

856. Defendants' efforts have paid off. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59.

857. Another group aggressively targeted by the Manufacturer Defendants are veterans, for which Opioid Drugs are particularly dangerous.

858. According to a study published last year in the 2013 Journal of American Medicine, veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, like overdoses and self-inflicted and accidental injuries; 40% of veterans with post-traumatic stress disorder received opioids and benzodiazepines (anti-anxiety drugs) that, when mixed with alcohol, can cause respiratory depression and death. Yet, according to a VA Office of Inspector General Report, 92.6% of veterans who were prescribed opioid drugs were also prescribed benzodiazepines. Again, as with

[231] *Id.*

elderly patients, Defendants both purposefully sought to increase opioid prescribing to this vulnerable group and omitted from their promotional materials the known, serious risks opioids posed to them.

859. *Clinical Guidelines on Management of Opioid Therapy for Chronic Pain*, issued by the DOD, discloses that its review "revealed the lack of solid evidence-based research on the efficacy of long-term opioid therapy. Almost all of the randomized trials of opioids for chronic non-cancer pain were short-term efficacy studies. Critical research gaps…include: lack of effectiveness studies on long-term benefits and harms of opioids…; insufficient evidence to draw strong conclusions about optimal approaches to risk stratification…; lack of evidence on the utility of informed consent and opioid management plans…; and treatment of patients with chronic non-cancer pain at higher risk for drug abuse or misuse." These disclosures are missing from the Manufacturer Defendants' marketing to veterans.

860. The Manufacturer Defendants' marketing to veterans has had devastating consequences. A 2008 survey showed prescription drug abuse among military personnel doubled from 2002 to 2005, and then nearly tripled again over the next three years. In 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills—four times as many as they did in 2001. Further, one-third of veterans prescribed opioids as of 2012 remained on take-home opioids for more than 90 days. Although many of these veterans are returning from service with traumatic injuries, the increase in opioid prescribing is disproportionate to the population and, in far too many cases, unsuited for their treatment.

861. Among former service members receiving VA services nationally in a single year (2005), 1,013 had died of accidental drug overdoses—double the rate of the civilian population.

5. Strategies Used by Particular Defendants Aimed at Deceiving Consumers

(i) Marketing by Purdue Aimed at Deceiving Consumers

862. Purdue utilized advertisements, websites, Front Groups, bogus "initiatives," and financial assistance to increase patient demand for Opioid Drugs by falsely representing the safety and efficacy of long-term opioid therapy for the treatment of chronic pain. These patient-oriented marketing measures are in addition to those (alleged above) undertaken by the Front Groups, with whom Purdue was intertwined.

863. In 1999, Purdue provided its sales representatives with 14,000 copies of a promotional video entitled *From One Pain Patient to Another: Advice from Patients Who Have Found Relief*. The video was provided to physicians as an "educational" video to show to their patients, to be used in physician waiting rooms, as a 'check out' item for an office's patient education library, or as an educational tool for office or hospital staff to utilize with patients and their families. It was also available through Purdue's *Partners Against Pain* website through July 2001.

864. The video encouraged patients to report their pain to their doctors, and also sought to alleviate patient concerns about the risk of addiction. It even told would-be customers that opioid analgesics were shown to cause addiction in less than 1 percent of patients, a claim the FDA later criticized as unsubstantiated.

865. Purdue also provided financial assistance to would-be users of their Opioid Drugs. This included, *inter alia*, a starter coupon program to provide patients with a free limited-time (typically 7 or 30 days) prescription. By 2001, approximately 34,000 coupons had been redeemed nationally.

866. Purdue co-sponsored APF's *Treatment Options: A Guide for People Living with Pain (2007)* brochure, which suggests that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative prescriptions, or theft. This publication is available today.[232]

867. Purdue also sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* — which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." The same guide taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.[233]

868. Purdue operated a patient-focused website, *In The Face of Pain*. Thereon, Purdue's KOLs and Front Group affiliates appeared as "Voices of Hope"—"champions passionate about making a difference in the lives of people who live with pain" and providing "inspiration and encouragement" to pain patients. Consistent with Purdue's efforts to portray opioid treatment as "essential" for the proper treatment of chronic pain and label skepticism related to chronic opioid therapy as an "inadequate understanding" that leads to "inadequate pain control."

869. *In the Face of Pain* criticized policies that limited access to opioids as being "at odds with best medical practices" and encouraged patients to be "persistent" in finding HCPs who will treat their pain. This was meant to imply that patients should keep looking until they find a doctor willing to prescribe opioids. Such messaging effectively condones physician shopping, which is generally considered a sign of addiction.

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[232] *Treatment Options: A Guide for People Living with Pain*, AM. PAIN FOUND., *available at* https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

[233] *A Policymaker's Guide to Understanding Pain & Its Management*, AM. PAIN FOUND., *available at* https://www.documentcloud.org/documents/277603-apf-policymakers-guide.

870. The "Voices of Hope" featured on the website included staff and board members from APF, ACPA, AAPM – as well as KOL Dr. Webster.

871. In 2010, Purdue obtained approval for an "abuse-deterrent" formulation ("ADF") of OxyContin but deceptively marketed it to doctors and consumers, claiming:

- Purdue's ADF opioids could not be crushed or snorted, which is false.
- Purdue's ADF opioids reduced opioid abuse and diversion, which is false. Purdue failed to tell consumers that its ADF opioids had no impact on oral abuse.
- Purdue's ADF opioids were safer than other opioids, which is false.

872. Along with the launch of reformulated OxyContin, Purdue also launched a new campaign—capitalizing upon growing concern about the rising tide of opioid addiction, overdose, and death—falsely promoting the effectiveness of its abuse-deterrent opioids in preventing abuse. Like "pseudoaddiction," this marketing was intended to, and did, reassure prescribers and consumers who became concerned about addiction that they not only could continue to prescribe and take opioids, but in fact needed to switch to Purdue's opioids because they were safer.

873. Purdue also targeted vulnerable patient populations. For example, Purdue in 2009 sponsored a publication distributed by Front Group APF entitled *Exit Wounds*. The publication, which was written from a veteran's person narrative, touted the effectiveness of opioids and called them the "gold standard of pain medications." It explained to readers that opioids "increase a person's level of functioning" and that "[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medication." Veterans and returning service members are eager to return to normalcy and as such are more susceptible to promises of increased functionality and safety.

874. Most disturbing is that *Exit Wounds* asserts "[d]enying a person opioid pain medication because he or she has a history of substance abuse or addiction is contrary to the model guidelines for prescribing opioids, published by the U.S. Federation of State Medical Boards."

875. When compared to the guidelines published by the VA and the Department of Defense in 2010 and 2011, the deceptive nature of *Exit Wounds* stands out. In contrast, the unbiased publication, free from the Manufacturer Defendants' influence, *Taking Opioids Responsibly*,[234] describes opioids as "dangerous," cautions against taking extra doses, and mentions the risk of overdose and the dangers of interactions with alcohol. It lists the side effects of opioids including decreased hormones, sleep apnea, hyperalgesia (the condition of becoming more sensitive to painful stimuli), addiction, immune system changes, birth defects, and death.

876. APF mailed copies of *Exit Wounds* to non-profits who worked with disabled or wounded veterans.

877. Purdue even enlisted celebrities. In one 2011 Press Release, Purdue proudly announced that "[m]ovie icon, dancing star and patient advocate Jennifer Grey has joined forces with Partners Against Pain to launch a new national initiative called Hands On Approach for Pain Management. The program highlights the importance of open and honest communication between people living with chronic pain and their HCPs in developing an individualized treatment plan."[235]

878. Purdue used celebrities to get access to local news interviews to push their marketing message. In one 2012 interview, Ms. Grey was introduced as a movie star who was

[234] Available at https://www.ethics.va.gov/docs/policy/Taking_Opioids_Responsibly_2013528.pdf

[235] *Id.*

"giving back too with a non-profit called Partners for Pain."[236] She went on to describe how she has been suffering for years from "chronic pain from a car accident many years before." But she was able to persevere because while "pain is just part of life,…suffering is optional."

879. Ms. Grey went on to describe PAP as an "educational program…meant to help people become advocates for themselves"; specifically, people "who are in chronic pain." She repeatedly directed viewers to the *Partners Against Pain* website, and even stated that she "didn't know [she] was in pain until the pain stopped." In a 2011 appearance on HealthCentral, Ms. Grey told a curiously well-prepared caller that in dealing with her chronic pain, "if my doctor is not responsive, I'm gonna switch doctors."[237] At no point in these interviews was Ms. Grey disclosed as a paid spokesperson.

880. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. 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. Even for projects not produced during the terms of this Agreement, the Agreement demonstrates APF's lack of independence and

[236] *Partners Against Pain*, YOUTUBE.COM (Jan 22, 2012), *available at* https://www.youtube.com/watch?v=WEeoFKVyyak.

[237] *Jennifer Grey Interview on Living with Chronic Pain*, YOUTUBE.COM (Oct. 4, 2011), https://www.youtube.com/watch?v=OGrpURS4GNQ.

willingness to harness itself to Purdue's control and commercial interests, which would have carried across all of APF's work.

881. In 2011, Purdue hired an APF employee to consult on the *Partners Against Pain* rollout, to orchestrate the media campaign associated with the launch of certain content on the website, and to make public appearances promoting the website along with a celebrity spokesperson. Purdue contemplated paying this consultant $7,500 in fees and expenses for 26 hours of work. Purdue would require this consultant to "discuss and rehearse the delivery of [Purdue's] campaign messages" and Purdue committed that "[m]essage points will be provided to [the] Consultant in advance and discussed on [a planned] call." At all times, decisions regarding the final content on the *Partners Against Pain* website were "at the sole discretion of Purdue."

882. Purdue exercised complete control over APF on projects where the two purportedly collaborated. Indeed, Purdue personnel participated in a March 2011 call with APF's "Corporate Roundtable," where they suggested that APF "[s]end ambassadors to talk about pain within companies and hospitals." Thus, Purdue suggested what role APF could play that would complement its own marketing efforts. On that call, Purdue personnel also committed to provide APF with a list of "industry state advocates" who could help promote chronic opioid therapy, individuals and groups that APF reached out to. Purdue personnel remained in constant contact with their counterparts at APF.

883. Purdue knew, and evidence showed, that Purdue's reformulated OxyContin, and its later-released Hysingla, which it also promoted as abuse-deterrent could be easily defeated, did not affect oral use, which is the most common means of abuse, and increased harmful

outcomes. In 2012, Purdue filed a Citizen Petition,[238] seeking a ruling from the FDA that Purdue's removal of the original OxyContin was for safety reasons and generic products approved as bioequivalent to the older formulation should be removed from the market unless they could demonstrate similar tamper resistance. This effort was successful and allowed Purdue to defeat generic competition for the drug just one day before Purdue faced loss of patent protection. Yet, there were no long-term studies to support Purdue's claims, and tellingly, after it successfully removed generic competition, Purdue in 2015 abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff were to release its assessment of the application. A FDA review acknowledged that "unusual means" could result in extraction of the active ingredient for snorting or injection.

884. According to a 2015 Assurance of Voluntary Compliance ("AVC") between Purdue and the New York Attorney General ("NY AG"), *Inthefaceofpain.com* received 251,648 page views between March 2014 and March 2015. Except in one document linked to the website, *Inthefaceofpain.com* made no mention of opioid abuse or addiction. Purdue's copyright appears at the bottom of each page of the website, indicating its ownership and control of its content. The AVC claims there is no other indication that 11 of the individuals who provided testimonials on *Inthefaceofpain.com* received $231,000 in payments from Purdue for their participation in speakers' programs, advisory meetings and travel costs between 2008 and 2013. The NY AG found Purdue's failure to disclose its financial connections with these individuals had the potential to mislead consumers because of the potential bias of these individuals.

885. Even today, the website (which upon information and belief was deactivated due to regulatory and/or legal pressure) takes no corrective measures, providing visitors with the

[238] Available at: http://www.hpm.com/pdf/blog/FDA-2012-P-0760.pdf.

following nostalgic message: "Dear Pain Advocates: *In the Face of Pain* has been proud to serve the pain community since 2001. Please note that we have deactivated the website on October 1, 2015. It is our sincere hope that the information and materials available on this website have informed, equipped, and inspired you on your pain advocacy journey."[239]

886. Purdue's "education" of patients included *Partners Against Pain* ("PAP"), which Purdue describes as a "national education program [that] helps patients, caregivers, and HCPs alleviate unnecessary suffering by advancing standards of pain care through education and advocacy."[240] In addition to its website, PAP developed initiatives, conducted surveys, issued press releases, held live events, and conducted media blitzes.

887. When it was not enlisting celebrities, Purdue used "patient representatives" to speak to chronic pain sufferers. These were often (if not always) provided to Purdue from APF. Exactly who the "patient representative" was representing is suspect. On one back pain project, Purdue contracted with APF to provide a "patient representative" who agreed to attend a Purdue-run "media training session."

888. Many of the "Front Groups" supported by Purdue either pretended to be "patient advocacy" organizations or otherwise had programs and/or initiatives aimed at "educating" patients themselves (with false and misleading statements).

889. In addition to the *Partners Against Pain* program, Purdue undertook another direct-to-consumer marketing initiative entitled *Understanding & Coping with Lower Back Pain*. One of the consultants was APF's paid employee, Mickie Brown. The consultant's services

[239] IN THE FACE OF PAIN, http://inthefaceofpain.com/ (Deactivated as of October 1, 2015).

[240] *Actress Jennifer Grey Spearheads National Initiative to Promote Effective Communication Between People Living with Pain and Healthcare Professionals*, PURDUEPHARMA.COM (Sep. 27, 2011), http://www.purduepharma.com/news-media/2011/09/actress-jennifer-grey-spearheads-national-initiative-to-promote-effective-communication-between-people-living-with-pain-and-healthcare-professionals/

would be provided in return for a $10,000 in consulting fees for APF and $1,500 in honoraria for the spokesperson. All documents used by the consultant in her media appearances would be reviewed and approved by individuals working for Purdue. Purdue initiated this project, and it was not until later that APF worried about "how Purdue sees this program fitting in with our [existing] grant request."

(ii) Marketing by Cephalon Aimed at Deceiving Consumers

890. Cephalon utilized advertisements, websites, Front Groups, and bogus "initiatives" to increase patient demand for Opioid Drugs by falsely representing the safety and efficacy of long-term opioid therapy for the treatment of chronic pain. These patient-oriented marketing measures are in addition to those (alleged above) undertaken by the Front Groups, with whom Cephalon was intertwined.

891. Cephalon co-sponsored APF's *Treatment Options: A Guide for People Living with Pain (2007)*, which suggests that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative prescriptions, or theft. This publication is available today.[241]

892. Cephalon also targeted vulnerable patient populations in an effort to expand their market share. In 2007, Cephalon launched a plan to target elderly chronic pain patients, via a multi-city tour with stops at AARP events, YMCAs, and senior living facilities.

893. In March of 2009, the FDA issued a Warning Letter to Cephalon asserting that the company-sponsored links for Fentora on Google and other internet search engines were "misleading because they make representations and/or suggestions about the efficacy of Fentora, but fail to communicate any risk information associated with the use" of the drug.

[241] *Treatment Options: A Guide for People Living with Pain*, AM. PAIN FOUNDATION, https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

894. Cephalon also provided financial assistance to would-be users of their Opioid Drugs.

(iii) Marketing by Janssen Aimed at Deceiving Consumers

895. Janssen utilized advertisements, websites, Front Groups, and bogus "initiatives" to increase patient demand for Opioid Drugs by falsely representing the safety and efficacy of long-term opioid therapy for the treatment of chronic pain. These patient-oriented marketing measures are in addition to those (alleged above) undertaken by the Front Groups, with whom Janssen was intertwined.

896. Janssen sponsored, developed, and approved content of a website, *Let's Talk Pain* in 2009, acting in conjunction with the APF, AAPM, and ASPMN, whose participation in *Let's Talk Pain* Janssen financed and orchestrated. This website featured an interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," inaccurately implying her experience would be representative. This video is still available today on YouTube.

897. Janssen worked with AAPM and AGS to create a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described a "myth" that opioids are addictive, and asserts as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain." Although the term "rarely" is not defined, the overall presentation suggests the risk is so low as not to be a concern. The language also implies that as long as a prescription is given, opioid use is not a problem.

898. In doing so, Janssen contracted with a medical publishing firm, Conrad & Associates, LLC. The content was drafted by a writer ("Medical Writer X") hired by Conrad & Associates and funded by Janssen. These materials were reviewed, in detail, by Janssen's

medical-legal review team, which conducted detailed reviews and gave him editorial feedback on his drafts, which was adopted in the published version.

899. Medical Writer X understood, without being explicitly told, that since his work was funded and reviewed by Janssen, the materials he was writing should aim to promote the sale of more drugs by overcoming the reluctance to prescribe or use opioids to treat chronic pain. He knew that the publication was undertaken in connection with the launch of a new drug and was part of its promotional effort. Medical Writer X knew of the drug company sponsoring the publication, and he would go to the company's website to learn about the drug being promoted. He also knew that his clients—including Janssen—would be most satisfied with his work if he emphasized that: (a) even when used long-term, opioids are safe and the risk of addiction is low; (b) opioids are effective for chronic pain; and (c) opioids are under-prescribed because HCPs are hesitant, confused, or face other barriers.

900. *Finding Relief* promises: "Used properly, opioid medications may make it possible for people with chronic pain to 'return to normal' – get back to work, walk or run, and play sports, and participate in other activities." *Finding Relief* describes opioids as "rarely addicting when used properly for the management of chronic pain" and assures that "unless the underlying cause of your pain gets worse…you will probably remain on the same dose or only need small increases over time." These contentions are wholly lacking in scientific or clinical support.

901. Janssen also targeted vulnerable patient populations. It provided significant funding to APF for the distribution of *Exit Wounds*, which (as alleged *supra*), aggressively and misleadingly targeted wounded war veterans suffering from chronic pain.

902. Janssen also provided financial assistance to would-be users of their Opioid Drugs. For example, in 2012, Janssen planned to distribute 1.5 million savings cards worth $25 each.

(iv) Marketing by Endo Aimed at Deceiving Consumers

903. Endo utilized advertisements, websites, Front Groups, and bogus "initiatives" to increase patient demand for Opioid Drugs by falsely representing the safety and efficacy of long-term opioid therapy for the treatment of chronic pain. These patient-oriented marketing measures are in addition to those (alleged above) undertaken by the Front Groups, with whom Endo was intertwined.

904. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain,* which stated that "[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem."

905. Endo also distributed a pamphlet edited by KOL Dr. Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004). 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."[242]

906. Endo, on information and belief, has distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement.

907. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled *Pain*

[242] Margo McCaffery and Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004), http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf.

Management Dilemmas in Primary Care: Use of Opioids, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

908. The CDC Guideline confirms the falsity of Defendants' claims about the utility of patient screening and management strategies in managing addiction risk.[243] The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse, or misuse."[244] The CDC Guideline recognizes that available risk screening tools "show *insufficient accuracy* for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[245]

909. Through its substantive control of NIPC, Endo upon information and belief was responsible for the content on the patient-oriented *painknowledge.org* website. That website make numerous false and misleading representations, such as: "[While using 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" and that "people that have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted." It did not even rule out the possibility that those with a history of opioid addiction should steer clear of Opioid Drugs.

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[243] CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), http://www.cdc.gov/washington/testimony/2014/t20140429.htm; Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at http://turnthetiderx.org.

[244] *Id.*

[245] *Id.*

910. The *Pain Knowledge* website in 2009 claimed that opioid dosages may be increased until "you are on the right dose of medication for your pain."

911. Another Endo website, *PainAction.com*, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on *PainAction.com* that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

912. Endo also targeted vulnerable patient populations. It provided significant funding to APF for the distribution of *Exit Wounds*, which (as alleged *supra*), aggressively and misleadingly targeted wounded war veterans suffering from chronic pain.

913. Endo also provided financial assistance to would-be users of their Opioid Drugs.

(v) Marketing by Actavis Aimed at Deceiving Consumers

914. Actavis utilized advertisements, websites, Front Groups, bogus "initiatives," and financial incentives to increase patient demand for Opioid Drugs by falsely representing the safety and efficacy of long-term opioid therapy for the treatment of chronic pain. These patient-oriented marketing measures are in addition to those (alleged above) undertaken by the Front Groups, with whom Actavis was intertwined.

915. For example, Actavis's predecessor caused a patient education brochure, *Managing Chronic Back Pain*, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." The term "less likely" is never defined and gives the reader the impression that the risk is so low as to not be a concern. The brochure also stated that "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Based on Actavis's acquisition of its predecessor's

marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.

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

917. Actavis also targeted vulnerable patient populations. As noted *supra*, Actavis sponsored "studies" with pre-determined outcomes. One of these studies was undertaking to show that its Opioid Drug was well tolerated in elderly patients (which it was not), and was published in the *Journal of the American Geriatrics Society.*

918. Actavis also provided financial assistance to would-be users of their Opioid Drugs. A 2008 Actavis business review, for example, highlighted co-pay assistance, good for up to $600 per patient per year, as a way to drive conversions to Kadian from competitor drugs like Avinza and MS Contin.

919. Actavis also used its co-pay assistance program as a vehicle with which to deliver more false and misleading information directly to consumers. On February 18, 2010, the FDA issued a warning letter to Actavis for distributing a false and misleading co-pay assistance brochure and comparison detailer.

920. The FDA's findings were based on Actavis's omissions and its minimization of serious risks associated with Kadian in its brochure; Actavis's failure to present the limitations to Kadian's approved indication for use and its suggestions that it could be used for broader purposes than indicated; and its unsubstantiated claims of superiority and effectiveness.

921. The brochure presented several effectiveness claims regarding Kadian, but failed to present any contraindications and, additionally, omitted several warnings, precautions, drug

interactions, and adverse events. It also failed to present risk information with a prominence and readability that is reasonably comparable to the presentation of benefit information.

922. The brochure also minimized the serious and significant risks associated with the use of Kadian by describing the serious and potentially fatal risks in highly complex, medically technical language not likely to be understood by consumers. The brochure simply included the following language, "Please see accompanying complete Prescribing Information" in an effort to mitigate the misleading omission and/or minimization of risk information.

923. In what amounted to direct marketing to consumers, Kadian's brochure included the following erroneous claims:

- "Allow for less breakthrough pain and more consistent pain relief for patients";
- "Better pain control ...";
- "Allow patients to live with less pain ..."; and
- "Less pain. More options."

924. The FDA informed Actavis that its brochure and detailer were false and misleading because they omitted and minimized the serious risks associated with Kadian, broadened and fail to present the limitations to the approved indication of Kadian, and presented unsubstantiated claims of superiority and effectiveness.

925. The FDA found Actavis's brochure and detailer for Kadian failed to include important and serious risk information including contraindications, adverse events, and warnings regarding potentially fatal abuse of opioids.

926. The FDA also found Actavis's brochure and detailer presented broad claims about Kadian's use in treating pain, therefore implying that Kadian was appropriate for use in a broader range of patients than the patients for which FDA approval was granted.

927. Finally, the FDA found Actavis's detailer included efficacy claims and presentations which were unsubstantiated, misleading and implied Kadian was superior to other opioid therapies.

928. Prior to the co-pay assistance program, as noted in the 2003 GAO Report, Actavis also used a coupon program for Kadian similar to that of Purdue, which provided a free introductory prescription for which no co-pay paid by the customer was required.

(vi) Marketing by Insys Aimed at Deceiving Consumers

929. Insys utilized advertisements, websites, Front Groups, and bogus "initiatives" to increase patient demand for Opioid Drugs by falsely representing the safety and efficacy of long-term opioid therapy for the treatment of chronic pain. These patient-oriented marketing measures are in addition to those (alleged above) undertaken by the Front Groups, with whom Insys was intertwined.

930. Insys also provided financial assistance to would-be users of their Opioid Drugs. For example, Insys contributed $2.5 million to the USPF's "Gain Against Pain" patient assistance program, which provided financial assistance for patients' medical copays.

D. Formulary Access and Coverage Enterprises

931. Of course, no amount of patient and doctor enthusiasm for the 'breakthrough' treatment of chronic pain mattered if there was no health plan prepared to pay for it. Gaining both access to and preferred placement on TPP formularies (including MMO's) were thus a priority; and for this the Manufacturer Defendants would enlist the help of the Distributor and the Pharmacy Defendants. Ensuring formulary access was part of all Defendants' efforts to expand the Opioid Drug market. The Manufacturer Defendants understood how prescribing HCPs were more likely to prescribe Opioid Drugs if covered on a formulary. And the

Manufacturer Defendants further understood how TPPs (including MMO) made coverage decisions, and devised schemes to influence that process.

932. Given the mechanics of prescription drug reimbursement, TPPs like Plaintiff MMO are thus the entities that are often the most harmed financially by Defendants' fraudulent schemes. As alleged below, TPPs like Plaintiff MMO were the intended targets of Defendants' unlawful strategies aimed at MMO's members and its self-funded customers' members, which successfully resulted in excessive and unnecessary prescriptions for the Opioid Drugs and giving rise to its direct economic claims set forth herein.

933. As alleged in detail below in the Formulary Access and Coverage Enterprises for each Manufacturer Defendant, each of the Defendant's strategic plans included multi-pronged targeting of Plaintiff MMO. As alleged herein, Defendants' common tactics included comprehensive business plans that carefully tracked Plaintiff MMO's coverage decisions – e.g., whether one or more Opioid Drugs was on formulary, what tier, and any restrictions.

934. As alleged herein below, the Defendants' direct misleading promotion aimed at MMO and its employees, including in face-to-face meetings with Defendants' managed care account executives, involved the misrepresentations as alleged in the Formulary Access and Coverage Enterprises. These misrepresentations were embraced and shared by each Manufacturer Defendant. Each was aware that Plaintiff MMO wanted to control access to the Opioid Drugs on its formularies. To circumvent these controls, Defendants planned and implemented false and misleading marketing campaigns to target Plaintiff MMO to ensure formulary access for the Opioid Drugs without limitation, including for unsafe and unapproved uses.

935. To execute their Formulary Access and Coverage Enterprises successfully, each Manufacturer Defendant provided Plaintiff MMO's managed pharmaceutical personnel directly, through intermediaries, and/or through marketing (including Scientific Literature Marketing Enterprise publications), materials that discussed or suggested that the Opioid Drugs were safe and/or effective for the long-term treatment of chronic pain. TPPs (including Plaintiff MMO and/or its contracted PBM) relied on these materials in making coverage and formulary placement decisions.

936. Further, concepts such as "pseudoaddiction" were key not only to increasing prescriber demand, but important for securing formulary access. Had the Manufacturer Defendants not pushed the notion of "pseudoaddiction"—that addiction was not really addiction—there would have been far more addiction-related adverse events reported with respect to the Opioid Drugs. This in turn would have impacted MMO's and/or its contracted PBM's review of Opioid Drugs with respect to both formulary access and preferred status, compared to other painkillers that would have exhibited a lower rate of addiction-related adverse events.

937. Similarly, the Manufacturer Defendants also advised prescribers of "techniques" to ensure health plan reimbursement. These included both the way Opioid Drugs were prescribed (amount vs. frequency of dosage) and the reported conditions for which they were prescribed in the first place. Upon reasonable belief, physicians writing Opioid Drug prescriptions reimbursed by Plaintiff MMO utilized these techniques.

1. Background Regarding TPPs and Prescription Drug Coverage

938. Although the physician prescribes the Opioid Drugs, it is the patients and their TPP insurance company which pay their costs. Plaintiff MMO generally pays 75-90% of the retail cost of brand name drugs, while the patient is responsible for a small copayment. The

physician pays nothing and bills the patient's insurance company for associated office visits. Accordingly, MMO has been the primary and intended financial victims of Defendants' fraudulent marketing.

939. Absent prescription drug coverage, patients are responsible for paying 100% of the cost of their prescribed Opioid Drugs. Physicians were either opposed or reluctant to prescribe Opioid Drugs if their patients were responsible for money out of pocket when the Opioid Drugs were not "on formulary" (or were but with very high copayments or restrictions).

940. Defendants knew that gaining prescription drug coverage, as well as favorable formulary status, was essential to both growing the entire market for opioids as well as the sales of their respective Opioid Drugs, as physicians based their prescribing on the Opioid Drugs formulary coverage.

941. Plaintiff MMO provides medical and pharmacy benefits to a wide range of organizations nationally, including employers, state and local governments and Medicaid programs through insurance contracts and through self-funded contracts with employers.

942. Plaintiff MMO's PBM provides point-of-service ("POS") claim processing services as alleged below. In addition, MMO's contracted PBM contracts with retail pharmacies, provides mail order pharmacy services, negotiates rebates with drug manufacturers, develops formularies, and conducts drug utilization review activities. The PBM services are performed for the benefit of Plaintiff MMO.

943. There exist a number of programs or tools available to Plaintiff MMO (often working with its contracted PBM) to manage drug utilization within the insured population. The primary tools available for this purpose are formulary placement after review by the appropriate

pharmacy and therapeutics ("P&T") committee, cost sharing, claim edits and prior authorization. Several of these are discussed below.

944. The P&T committee is an entity established for Plaintiff MMO's benefit by its contracted PBM for the purpose of evaluating products that are being considered for formulary placement and developing programs to promote appropriate utilization of pharmaceuticals. The use of the P&T committee is a requirement for health plan accreditation and is widely used and accepted as the basis for decisions related to a formulary. P&T committees are an established component of health care delivery throughout the TPP sector, including at PBMs, health plans, and government agencies.

945. The P&T committee meets periodically throughout the year, often bi-monthly or once per calendar quarter. When considering drugs in a therapeutic class or new products for consideration on the formulary, P&T committee members are provided with relevant clinical information about the product, often in the form of a formulary packet or monograph. The information included in this packet is often derived from published medical literature, manufacturer-supplied materials, treatment guidelines, comments from FDA proceedings (including approval status), and the TPP or PBM's drug utilization experience. The P&T committee packet is intended to help committee members as they decide which products to include or exclude from formularies and when considering drug management options.

946. The P&T committee performs no independent clinical research or laboratory analysis. P&T committees make recommendations as to which drugs should be included or excluded from formulary. They also provide guidance and approval regarding the use of any tools, such as quantity limits or prior authorization, used in managing the insurance coverage of a

specific drug or class of drugs. P&T committee members do not control prescribing, nor do they prevent or mandate the prescribing of any drug for a specific condition.

947. The identity of the P&T committee membership is highly sought by pharmaceutical companies, and by the Defendants. Because the purpose of drug marketing is to influence prescribing habits, drug makers like the Manufacturer Defendants have perceived that direct marketing to P&T committee members benefit their drug products during the formulary evaluation process. Pharmaceutical companies, including the Manufacturer Defendants, are anxious to know the schedule adopted by the P&T committee for review of their products. Using this information, they aggressively seek opportunities to promote their products directly to P&T committee members immediately prior to these review dates.

948. P&T committee members are often invited to participate in advisory board meetings and other informational sessions sponsored by manufacturers, including Defendants, during which information about products is disseminated. While these sessions can provide valid clinical information about a product, to the extent that information provided by pharmaceutical companies is incorrect or misleading, such information can improperly influence the members of the P&T committee as they consider formulary initiatives.

949. The 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, with the Opioid Drugs classified as Narcotic Analgesics on Plaintiff MMO's formulary.

950. In addition to the formulary, Plaintiff MMO often limits coverage of some classes of medication based on the conditions being treated.

951. Plaintiff MMO can utilize its formulary (and corresponding higher or lower copays) to promote compliance with national treatment guidelines, to discourage undocumented or non-medical uses of drug therapies, and to educate prescribers regarding the cost-effectiveness of drug treatment options; however, their ability to effectively do so is subject to practical limitations discussed below.

952. The development of the formulary, and of formulary management initiatives, is conducted under the direction of the P&T committee of MMO's contracted PBM that it uses for this purpose. The use of the P&T committee is meant to assure that the formulary is clinically sound, is sufficiently robust to meet the medical needs of the population being served, and is not unduly burdensome to providers and patients when accessing care.

953. The decision whether to place a given pharmaceutical product on a drug formulary is first and foremost a clinical decision. The P&T committee will review the FDA approved clinical indications for the product or products in question and FDA comments associated with the approval of the products. The P&T committee relies on published studies and other materials that evaluate product efficacy, safety and, when available, directly compare the product to other agents in the appropriate therapeutic category or with comparable clinical uses.

954. Manufacturers often submit a formulary dossier and other materials about their drug products for use by the P&T committee during the drug review process. The P&T committee will also review any existing utilization of the product, or of comparable products, by health plan members. The P&T committee's evaluation is limited to a review of published medical information, such as clinical studies published in peer-reviewed articles and the formulary dossier provided by the manufacturer, and drug utilization data. The P&T committee does not engage in primary research and cannot detect instances in which information about a

drug may have been suppressed by a manufacturer, is unpublished, or is inaccurately represented in the medical literature or other information provided by the manufacturer.

955. ESI, MMO's contracted PBM, has at all times material hereto acted as a conduit to MMO and its Pharmacy Quality Management ("PQM") Committee. ESI regularly passes on information to MMO for MMO and its PQM Committee to consider in connection with MMO's coverage and formulary decision-making. This information includes the medical appropriateness underpinning ESI's formulary drug and coverage criteria recommendations.

956. ESI has regularly conveyed information to MMO in multiple ways, including (1) face-to-face meetings (ESI and MMO have regularly scheduled "Formulary Consulting" meetings); (2) by email, (3) via mailed news and publications, such as ESI's "Sales & Marketing" weekly newsletter (summarizing recent FDA and prescription drug news); (4) distribution of studies and clinical information, including information provided by drug manufacturers; and (5) other regular communications.

2. Plaintiff MMO's Use of Cost-Sharing Tools to Control Drug Costs

957. Plaintiff MMO uses cost-sharing as a tool when promoting cost-effective utilization of pharmaceuticals. MMO typically achieves member cost-sharing through three different methods: (a) deductibles in which the patient pays his or her entire prescription cost until a specific dollar amount has been paid out of pocket; (b) coinsurance, or percentage co-payment, the percentage of the prescription cost which the patient pays for each prescription; or (c) co-payments, fixed dollar amounts which members pay for each prescription.

958. Plans can have a single co-payment or co-insurance regardless of the drug type or use a tiered design that allows for different payment amounts for different types of drugs (e.g., generics and brands). Plans may also combine the use of deductibles, co-payments and co-insurance within their benefit programs.

959. Of the various cost-sharing designs used by Plaintiff MMO, tiered benefits have been widely accepted for many years, and accounted for over 80% of benefit programs offered in 2006. Formularies are often tied to tiered benefits to encourage utilization of lower cost products, particularly for brand and generic medication.

960. In MMO's most common four-tiered incentive formulary, a low co-pay is charged for generic products and a modest co-pay is applied to preferred brand medications, while the highest co-payment levels are reserved for branded medications for which a generic equivalent is available and for non-preferred branded medications. Other benefit plans that are utilized within the insurance industry include three- and five-tier benefits, co-insurance (where the patient typically pays a flat percentage of the cost of the drug), and programs with annual and maximum deductibles.

961. Cost-sharing is aligned with MMO's formulary in an effort to promote the use of low-cost products and to maximize rebates and discounts on medications, particularly for those drugs which are clinically comparable. For example, proton pump inhibitors ("PPIs"), medications used for the treatment of heartburn, are widely considered to be clinically equivalent. Examples of PPIs include Prilosec, Nexium, Acifex, and Prevacid. While all of these products are very effective, the cost of the products can differ significantly. Prilosec is available in generic form and as an over-the-counter medication. The P&T committee used by MMO's contracted PBM has adopted programs to establish generic drugs as first-line agents, with minimal cost-sharing. Because the remaining products are clinically similar, the P&T committee may consider product cost and rebates offered by manufacturers when selecting a preferred brand product for the formulary. Preferred products are often subject to moderate cost-sharing, while non-preferred agents are subject to higher cost-sharing.

962. Opioid Drugs have been widely accepted on the formularies used by MMO and are subject to modest branded cost sharing requirements. MMO and/or its contracted PBM have relied on various representations and omissions made by Defendants regarding the addictiveness (or lack thereof) of Opioid Drugs to provide formulary access. Due to Defendants' misrepresentations regarding addictiveness and concealment of drug diversion evidence, MMO believed that the Opioid Drugs were clinically safe and effective.

963. Prior authorization is a drug management tool that is used by MMO when the drug coverage process requires information that cannot be readily obtained through the claim processing system. Such criteria may include diagnosis, laboratory values or other clinical parameters. For example, a health plan may wish to cover Opioid Drugs for the treatment of acute cancer-related pain, but would wish to exclude Opioid Drugs when they are being prescribed for the treatment of chronic pain. When a prior authorization is applied, the claim is rejected at the pharmacy and the pharmacist is notified that the prescriber must contact MMO or its contracted PBM to obtain approval for coverage, much in the same manner that pre-certification is required for the use of certain health care services.

964. At all times material hereto, neither Plaintiff MMO (and/or its contracted PBM) had access to the patient's diagnosis as a component of the claim transaction through the POS system. It would therefore be impossible for Plaintiff MMO and/or its contracted PBM to know the reasons (whether for long-term chronic pain or acute cancer-related pain) for which Opioid Drugs were being prescribed when claims are being processed. As a result, a diagnosis code is not included as a component of typical claim transactions and is unknown to Plaintiff MMO and/or contracted PBM.

965. Further, MMO would have required strict formulary control (prior authorizations, step edits, days quantity supply limits) but for Defendants' misrepresentations and concealment of drug diversion evidence, which Defendants were legally obligated to report, but failed to do so.

3. Plaintiff MMO Was Targeted by the Defendants

966. Plaintiff MMO's healthcare business involves managing the full spectrum of its employer-customers' health benefits, including the pharmacy benefit. MMO employs a team of medical and pharmacy professionals who oversee the quality and cost of the benefits provided to its covered patients.

967. MMO employs clinical best practices criteria in evaluating a drug's coverage status: efficacy, safety and cost. In addition, because a drug's coverage status may change, its formulary status is periodically reviewed. MMO has modified its formulary to add or delete certain drugs, to designate certain drugs as "preferred" or "non-preferred," or to require that certain drugs be subject to conditions such as step therapy,[246] prior authorization, or other limits such as quantity limits or refill-too-soon.

968. At all relevant times, including following the FDA approval of the Manufacturer Defendants' various Opioid Drugs, MMO has provided oversight of its pharmacy programs by various means including through its PQM Committee, which is MMO's equivalent of a P&T committee. MMO's PQM Committee regularly reviews and approves the MMO prescription drug formulary and provides ongoing oversight and direction to MMO's drug program and drug management initiatives as it relates to clinical and quality issues. PQM Committee

[246] Step therapy is the process whereby a preferred drug must be used first, and fail, before a more expensive drug will be covered under the formulary.

responsibilities include assisting in the development, evaluation and support of drug management initiatives, and monitoring clinical quality direction over all pharmacy benefit initiatives.

969. The MMO PQM Committee, which meets at least nine times annually, is comprised of 15 members, including pharmacists, physicians, practicing participating providers, as well as representatives from MMO's Pharmacy, Clinical, and Medical Management departments. The PQM Committee is chaired by MMO's Pharmacy Director. In addition, the PQM Committee includes pharmacist and medical representatives from its PBM partner.

970. MMO's pharmacy benefit administration is aided by consultation with MMO's PBM partner, formerly Medco Health Solutions ("Medco"), from 1999 until Medco was merged with another PBM, ESI in 2013. Medco, and now ESI, consult with MMO to make decisions concerning formulary development, including prescription painkillers, which includes the Opioid Drugs at issue in this case. ESI representatives, comprised of pharmacists and physicians, have close working relationships with their counterparts at MMO.

971. Together with its PBM partner, MMO provides simplified administration and streamlined prescription drug coverage to its customers and their members. For example, MMO consolidates aspects of both the medical and prescription drug benefit. Operationally, MMO customers send MMO their patient eligibility files, and in turn MMO sends each eligible patient one ID card with both medical and prescription drug coverage information.

972. At all relevant times hereto, MMO has, along with its PBM partner Medco/ESI, made decisions, based on FDA approvals, manufacturer-supplied information and clinical studies, to include or exclude new or existing prescription drugs from its formulary, or to implement tools to control utilization or to modify coverage criteria.

973. Medco/ESI has at all times material hereto acted as a conduit to MMO and its PQM Committee. Medco/ESI regularly passes on information to MMO for MMO and its PQM Committee to consider in connection with MMO's coverage and formulary decision-making. This information includes the medical appropriateness underpinning ESI's formulary drug and coverage criteria recommendations.

974. Although Medco/ESI has regularly consulted with MMO on formulary and coverage criteria, MMO at the same time has regularly conducted its own evaluation, and does not always follow Medco/ESI's recommendations.

975. Medco/ESI has regularly conveyed information to MMO in multiple ways, including (1) face-to-face meetings (Medco/ESI and MMO have regularly scheduled "Formulary Consulting" meetings); (2) by email, (3) via mailed news and publications, such as ESI's "Sales & Marketing" weekly newsletter (summarizing recent FDA and prescription drug news); (4) distribution of studies and clinical information, including information provided by drug manufacturers; and (5) other regular communications.

976. Other TPPs relied on similar misrepresentations by the Defendants. For example, following a review of the Opioid Analgesics / Pain Therapeutic drug class review, MedImpact Healthcare Systems, Inc. made its recommendations to TPP Members in November of 2009. MedImpact's written recommendation, based on the Manufacturer Defendants' false and misleading information, included citations to Manufacturer Defendant-sponsored and Front Group or KOL written treatment guidelines and articles and Manufacturer Defendant-sponsored studies, including: (i) Chou R, Fanciullo GJ, Fine PG, et al., American Pain Society – American Academy of Pain Medicine Opioids Guidelines Panel, *Clinical guidelines for the use of chronic opioid therapy in chronic non-cancer pain,* J. Pain. 2009;10(2):113-30; (ii) Roper Starch

Worldwide for the American Academy of Pain Medicine, American Pain Society, and Janssen Pharmaceutica, *Chronic Pain in America: Roadblocks to Relief*, 1999; and (iii) Gordon DB, Dahl JL, Miaskowski C, et al., *American Pain Society quality of care task force.*, Arch Intern Med. 2005;165(14):1574-80.

977. Similarly, MMO's PBM, ESI, made its opioid formulary recommendations to Plaintiff MMO in 2014 and 2015 based on the Manufacturer Defendants' (or those of their KOLs of Front Groups) false and misleading information, including: (i) Raffa BR, Pergolizzi JV, *Opioid formulations designed to resist / deter abuse*, Drugs, 2010;70(13):1657-1675; (ii) Chou R, Fanciullo GJ, Fine PG, et al., American Pain Society – American Academy of Pain Medicine Opioids Guidelines Panel, *Clinical guidelines for the use of chronic opioid therapy in chronic non-cancer pain*, J. Pain. 2009;10(2):113-30; (iii) American Pain Society, *Guidelines for the use of chronic opioid therapy in chronic non-cancer pain* (2009); and (iv) Taylor DR, Webster LR, Chun SY, et al., *Impact of breakthrough pain on quality of life in patients with chronic, non-cancer pain; patient perceptions and effect of treatment with oral transmucosal fentanyl citrate* (OTFC, ACTIQ), Pain Med. 2007:8(3):281-288.

978. Plaintiff MMO had access to (and received) these and other Defendant-sponsored studies and articles and relied on them when making formulary status determinations with respect to the Opioid Drugs.

979. Following the issuance of the 2016 CDC Guidelines illuminating Defendants' misrepresentations, MMO implemented formulary management utilization tools to further restrict and limit opioid drug product coverage. Indeed, MMO in 2016 "created a plan to monitor opioid utilization and correct use of products."

4. Defendants Made or Caused to be Made Direct Misrepresentations to MMO

980. As alleged in detail herein, each and every Defendant, through its various Enterprises, targeted MMO with false and misleading statements in order to secure formulary status for the Opioid Drugs. As alleged herein, Defendants' common tactics included comprehensive business plans that carefully tracked Plaintiff MMO's coverage decisions – *e.g.*, whether one or more of the Opioid Drugs was on formulary, what tier, and any restrictions.

981. As alleged herein below, each of Defendants' managed markets account managers coordinated and reported the success of their multiple contacts with Plaintiff MMO 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.

982. As alleged herein below, the Defendants' direct misleading promotion aimed at MMO and its employees, including in face-to-face meetings with Defendants' managed care account executives, involved the misrepresentations as alleged in the Formulary Access and Coverage Enterprises. These misrepresentations were embraced and shared by each Defendant. Defendants were aware that Plaintiff MMO wanted to restrict availability of highly addictive opioid medications to those suffering from cancer pain. Defendants were further aware that healthcare and related costs associated with opioid use was of paramount importance to MMO. To circumvent these concerns, Defendants planned and implemented false and misleading marketing campaigns to target Plaintiff MMO and the TPPs to ensure formulary access for chronic non-cancer pain and other conditions, (notwithstanding lack of evidence of safety or efficacy) – e.g., misrepresentations that the opioid drugs were effective over the long-term and would not result in addiction, withdrawal or other serious safety risks, when knowing the opposite was true.

983. All Defendants were also aware that the growing evidence of Opioid Drug diversion—*i.e.*, the bourgeoning black market for Opioid Drugs—would have led MMO to make decisions that would have drastically reduced the Opioid Drugs' access to MMO's formulary, or led MMO to implement controls that would have prevented drug diversion. However, all Defendants were making significant money from the Opioid Drug market, and suppressed non-cancer evidence of diversion so as to maintain formulary access and status for Opioid Drugs.

984. Defendants frequently contacted MMO personnel to discuss formulary coverage for their respective drugs. In 2009, MMO documented a recent March 16, 2009 meeting with Purdue Regional Account Executive ("RAE"), Kendra Price, who contacted MMO to discuss gaining favorable formulary access for Purdue's "[n]ew drug coming out [in] '09 for moderate pain." According to MMO's notes, Purdue's RAE Ms. Price, served as a "[r]esource for info on pain med[ications]" including "(OxyContin et al.)."

985. Defendants often discussed formulary management options with MMO in order to obtain and maintain favorable formulary status for opioid medications, employing the misrepresentations alleged herein. Defendants were fully aware of MMO's concerns over rising healthcare costs, and aimed to score formulary coverage for their abuse-deterrent formulations by overly stating the effectiveness against abuse and addiction and presenting misleading information on the healthcare cost savings with abuse-deterrent and extended-release formulations to Plaintiff MMO.

986. Defendants also tried to manipulate and influence MMO's use of potential utilization management restrictions through direct misrepresentations or through misleading publications intended for managed care audiences. For example, Endo sales representatives, Todd Berner and Ken Vergara, engaged in discussions with MMO on September 3, 2009

regarding the formulary status for opioid drugs, providing MMO personnel with information on "pain mgmt controls." Defendants presented similar information through AMCP events and publications alleged herein.

(i) MMO Pharmacy Personnel Were Attendees at Conferences as well as Recipients of AMCP Publications Where the Manufacturer Defendants Promoted the Unsafe and Ineffective Use of the Opioid Drugs

987. As alleged in more detail below, MMO's Pharmacy, Clinical and 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 membership 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."

988. 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.

989. 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.

990. 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 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.

991. Plaintiff MMO, and many of its employees, including its Clinical Director and Medical Director, are members of AMCP and regularly attend AMCP meetings as well as regularly receive and read communications from AMCP. Many TPPs are also actively involved as AMCP members. PBMs, including Medco and ESI, are also members and regularly attend meetings.

992. For example, Sonny Asuncion D. Borja-Barton, MMO's former Vice President of Pharmacy Management, presented at AMCP's Specialty Pharmacy Conference in Tampa, Florida, on April 1-2, 2014, which was held immediately before AMCP's 2014 Annual Meeting & Expo.

993. Marko Blagojevic, Plaintiff MMO's Manager of Clinical Programs, attended AMCP's Managed Care & Specialty Pharmacy Annual Meeting in Denver, Colorado, in March of 2017. Prior to attending, another opioid drug manufacturer contacted Mr. Blagojevic to inquire about "meet[ing] up with [him] for a few minutes" to "**brief** you on this new Abuse Deterrent agent" because "when we met [with] Becky [she] mentioned MMO would be doing a Pain Class review in the coming months." (emphasis in original). The Regional Account

Manager ("RAM") for this opioid manufacturer "thought this could be good timing." A month later the RAM followed up with Mr. Blagojevic again via email confirming their discussions in Denver and asking if he could "get an appointment scheduled, and it [he] could bring a member of [their] Medical team in to discuss the ADF aspects" with the MMO "team." He thought MMO would "find it of real interest as it seems there is a lot of discussion going on now in the Pain space." The RAM later contacted Mr. Blagojevic in July of 2017 to "set a time" to review an "Immediate Release abuse deterrent formulation" writing "I think you will agree there is a lot of need for an IR ADF pain medication[], we have had a lot of interest so far."

994. As alleged in detail below, drug manufacturers, including Defendants and their representatives, have at all times material hereto regularly attended AMCP events, exhibiting information about their opioid drug products as well as giving or sponsoring presentations to managed care and PBM representatives. Defendants' AMCP event attendees regularly included sales representatives, national account directors, and managed markets / managed care personnel whose explicit aim was to influence opioid drug formulary access.

995. Several Defendants submitted abstracts for publication in AMCP's *Journal of Managed Care & Specialty Pharmacy.* According to the journal, most abstracts are submitted as poster presentations "so interested AMCP meeting attendees" like MMO "can view the findings and query the authors."[247] 2014 abstract posters were submitted on categories directly impacting managed care including "Economic Models" and "Solving Problems in Managed Care" including the following Defendant sponsored and written abstracts:

- Mallinckrodt Pharmaceuticals in conjunction with PRA Health Sciences funded the research and the editorial and medical writing support for the development of an abstract entitled, *Correlation of*

[247] *Meeting Abstracts, Academy of Managed Care Pharmacy*, 20 J. OF MANAGED CARE & SPECIALTY PHARMACY, S31 (Oct. 2014).

Pharmacodynamic and Pharmacokinetic Parameters to Assess the Abuse Liability of Orally Administered Extended-Release Oxycodone/Acetaminophen Tablets Versus Immediate-Release Oxycodone/Acetaminophen Tablets in Recreational Users of Prescription Opioids.[248] This Defendant-sponsored and KOL co-authored abstract concludes, based on "subjective and objective PD effects correlated with PK parameter estimates," that crushing the extended release formulation of oxycodone/acetaminophen tablets results in slowed release of the drug, delayed Tmax and decreased Cmax with "less intense subjective effects" than an intact tablet, and falsely and conclusory states that the extended release formulation "has lower liability for abuse."[249]

- Janssen Scientific Affairs, L.L.C. sponsored a study and the development of an abstract entitled *Economic Outcomes of Chronic Pain Patients Treated with Tapentadol ER or Oxycodone* which concluded that patients on Nucynta were "less likely to be hospitalized or visit the emergency department and had significantly lower total health care costs" than their oxycodone controlled release counterparts.[250] Janssen states the "decade-long growth in U.S. opioid prescribing has increased the need for health plans to understand the economic impact of chronic pain patients on managed care pharmacy and medical budgets."[251]

996. For example, in April 2015, Defendants, sponsored, submitted and likely presented similar abstracts to TPPs at the AMCP Nexus event in San Diego, California.[252] Janssen Scientific Affairs funded a study entitled, *Cost of Opioid Overutilization in a Medicare Population Under Alternative Definitions of Overutilization.* The study found that setting more restrictive thresholds for overutilization (at 3 for prescribers and pharmacies) resulted in higher healthcare cost per member than less restrictive thresholds, allowing members to obtain opioid

[248] *Id.* at S32.

[249] *Id.*

[250] *Id.* at S62.

[251] *Id.*

[252] *Meeting Abstracts, AMCP's 27th Annual Meeting & Expo, April 7-10 San Diego 2015*, 21 JOURNAL OF MANAGED CARE & SPECIALTY PHARMACY (April 2015).

prescriptions from up to 6 prescribers and 6 pharmacies.[253] Janssen's abstract concludes that: "[c]hanging thresholds for number of prescribers and number of pharmacies or adding a dosage criterion changes the population size and cost of patients meeting opioid overutilization criteria. This information can help managed care plans assess trade-offs in the design of interventions to improve appropriate use of opioids."[254] The abstract deceptively recommends that TPPs (such as MMO) will save money per member if they opt for more lenient opioid utilization management tools.

997. As alleged in further detail below, at all times material hereto, Defendants' AMCP exhibits and presentations were calculated to be received and reviewed by the TPPs in attendance, including MMO Pharmacy and Medical employees, and thereby influencing their decisions to continue coverage of the opioid drugs on their formularies.

(ii) MMO Regularly Received Managed Care Periodicals which Included Defendants' False and Misleading Representations Concerning the Safety and Efficacy of the Opioid Drugs

998. Plaintiff MMO's 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. MMO employees regularly reviewed what they reasonably believed were

[253] *Id.* at S45

[254] *Id.*

reputable publications as part of gathering relevant information in their opioid coverage decision making.

5. The Manufacturer Defendants' False and Misleading Messages to Managed Care Plans, Including MMO

999. Defendants utilized these and other managed care periodicals to disseminate their false and misleading messages concerning opioid drugs to Plaintiff MMO and the TPPs. Many of Defendants' marketing messages appeared in these publications.

(i) Purdue's False and Misleading Messages to TPPs, Including MMO

1000. As part of the Purdue's Formulary Access and Coverage Enterprise, it developed a dedicated "managed care" (also called "Regional Account Executives" or "Managed Markets") sales group, many of whom had advanced science degrees, whose job it was to call on TPP pharmacy directors and P&T committees, including on MMO pharmacy personnel. These specialized Managed Markets representatives presented false and misleading studies/abstracts to Plaintiff MMO to influence placement of Purdue's drugs on its formularies.

1001. Some misrepresentations made to prescribers were more about securing health plan coverage than about increasing prescriber demand. For example, Purdue's misleading focus on 12-hour dosing (where sales reps pleaded with physicians to increase dosage rather than shorten dosing intervals) was motivated almost solely with insurance coverage in mind. Purdue feared managed care companies would not provide coverage for more frequent dosing intervals and knew higher dosages equated more profits. In a 2001 workshop presentation, Purdue expressed concerns that managed care companies would "deny[] or will start denying shorter prescriptions."[255] And according to Purdue's own 2001 sales data, the company charged on

[255] Harriet Ryan, Lisa Girion & Scott Glover, *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, LA TIMES (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/.

average about $97 for a bottle of the 10-milligram pills, the smallest dosage, while the maximum strength, 80 milligrams, ran more than $630."[256] Moreover, Purdue sales representatives were told that "raising dosage strength was the key to a big payday" as bonuses and performance evaluations "were based in part on the proportion of sales from high-dose pills."[257]

1002. As noted extensively above, Defendant Purdue sponsored studies and publications containing deceptive statements as to the efficacy, safety and healthcare cost savings of opioid drug products often appeared in AMCP publications circulated to MMO. One example of a publication touting the health care savings managed care would experience with abuse-deterrent formulations in AMCP's Daily Dose was sent via email to MMO personnel, including Kathryn Canaday, on April 28, 2014. The AMCP publication highlighted an article from the Boston Business Journal entitled *Analyst Says Abuse-Resistant Opioid Painkiller Helps Save Millions of Dollars.* The article stated that "research suggests 'that such a [ADF] reformulation would not only reduce addiction, but also save millions in national healthcare costs." More specifically, "$430 [million] a year because of reformulation of another opioid OxyContin."

1003. MMO relied on these and other statements when making decisions regarding the access to and status of Opioid Drugs on MMO's formulary.

1004. It was not apparent from the AMCP Daily Dose email, but the study was both funded by Purdue and co-authored by a Purdue employee.[258] The Purdue-sponsored study purported to provide "evidence that reformulated ER oxycodone [was] associated with

[256] *Id.* The 2001 sales data was disclosed in litigation with the state of West Virginia. *See State of West Virginia ex rel., et al. v. Purdue Pharma L.P., et al.,* Civil Action No. 01-C-137-5, Circuit Court of McDowell County, West Virginia.

[257] Ryan, *supra.*

[258] Rossiter, et al., *Medical cost savings associated with an extended-release opioid with crush-resistant technology in the U.S.*, 17 J. MED. ECON. 279 (Apr. 2014).

reductions in abuse rates" and substantial $430 million abuse-related medical cost savings.[259] Purdue intended for this study, which overstates and misrepresents the effectiveness of ADF drugs to deter abuse, to reach TPPs including MMO. As the study further concluded that "[p]ayers and policy-makers should consider these benefits as they devise and implement new guidelines and policies in this therapeutic area."[260]

1005. In September 2014, Purdue doubled down on the misrepresentations, funding an extension of the study, which was published in Front Group AAPM's Journal of Pain Medicine and entitled *Societal Economic Benefits Associated with an Extended-Release Opioid with Abuse-Deterrent Technology in the United States.*[261] The commentary on the extension again stated, without solid evidentiary support to back it up, that "[r]eformulated ER oxycodone may reduce…abuse-related costs as well."[262] It also parroted Defendants' mantra regarding the under treatment of pain, exaggerating the prevalence of chronic pain conditions in American adults (i.e. over 100 million suffer), and notes staggering healthcare costs of "$560-635 billion annually."[263]

1006. The extension estimates indirect cost savings for the reformulation as follows: societal benefits of "$96 million in cost savings to the criminal justice system," "$209 million for reductions in premature deaths," "$181 million for reduction in lost wages and employment," "$34 million for reductions in excess medically related absenteeism costs, $15 million in

[259] *Id.*

[260] *Id.*

[261] Noam Y. Kirson, *et al*., *Societal Economic Benefits Associated with an Extended-Release Opioid with Abuse-Deterrent Technology in the United States*, 15 J. PAIN MEDICINE 1450 (Sept. 2014), *available at* https://academic.oup.com/painmedicine/article/15/9/1450/1892618.

[262] *Id.*

[263] *Id.*

reductions in excess disability costs, and $38 million for reductions in presentation costs."[264] In addition, the study calculated annual savings of $33 million for "excess medical and drug costs for caregivers of opioid abuse patients."[265]

1007. The research for both misleading studies was funded by Purdue and both publications were also co-authored by Purdue employee Rami Ben-Joseph, Ph.D. Defendant's misrepresentations regarding the cost savings as to reformulated opioids were calculated to reach managed care organizations like Plaintiff MMO and create the false sense of security, when in reality the same or greater abuse potential exists for the ADF.

(ii) Cephalon's False and Misleading Messages to TPPs, Including MMO

1008. As part of Cephalon's Formulary Access and Coverage Enterprise, it developed a dedicated "managed care" (also called "Regional Account Executives" or "Managed Markets") sales group, many of whom had advanced science degrees, whose job it was to call on TPP pharmacy directors and P&T committees, including on MMO pharmacy personnel. These specialized Managed Markets representatives presented false and misleading studies/abstracts to Plaintiff MMO to influence placement of Cephalon's drugs on its formularies.

1009. From the time Cephalon launched Fentora in 2006 to replace its drug Actiq, a key focus was access on TPP formularies to secure "favorable reimbursement for a branded opioid analgesic." The Brand Plan at the time spelled this out clearly:

[264] Noam Y. Kirson, *et al*., *Societal Economic Benefits Associated with an Extended-Release Opioid with Abuse-Deterrent Technology in the United States*, 15 J. PAIN MEDICINE 1450 (Sept. 2014), *available at* https://academic.oup.com/painmedicine/article/15/9/1450/1892618.

[265] *Id.*

Managed Care/Third-Party Payers

Many chronic pain patients remain marginalized by BTP because BTP is underrecognized and the economic and social value of rapid onset analgesia has not been established. A recent publication of BTP treatment guidelines indicates that the optimal treatment for BTP is a rapid ROO; unfortunately this will need ongoing validation and understanding with TPPs. Also, the chronic pain market is a highly genericized market. TPPs continually seek to control costs by driving utilization to generics or lower cost branded products. TPPs use tools such as tiered co-pays, prior authorization, step edits, and/or quantity limits to impact drug utilization. Therefore, it will be extremely important for Cephalon to continue to improve its relationship with TPPs in order to secure favorable reimbursement for a branded opioid analgesic. For this reason, a comprehensive managed markets plan will need to be executed in order to achieve favorable reimbursement status and access to FEBT for appropriate physicians and patients.

1010. The 2011 Brand Plan specifically targeted "payers" in order to "maintain current formulary status for FENTORA in the face of emerging competition in the ROO market. The primary tactic is a proposed regional targeting effort to appropriately support the reimbursement process."

1011. The 2011 Brand Plan also featured a Fentora Reimbursement Program which, in Cephalon's own words, "provides tools and services that may facilitate the reimbursement process." According to Cephalon's website, the Fentora Reimbursement Program is designed to help patients and physicians with pre-authorizations and denied claims. In reality, however, the Fentora Reimbursement Program is a program that Cephalon has used primarily to help physicians overturn adverse Fentora coverage decisions by payers.

1012. The Fentora Reimbursement Program is provided free of cost to HCPs, and it has been a key resource for sales representatives in their unsafe and unapproved promotions of Fentora. Without assistance, reimbursement issues may be costly to physicians in two ways. First, in the event of a denied claim for coverage, a medical practice must bill the patient for drugs already provided. Given the high cost of many oncology drugs, the patient may be unable to afford payment. If this cost is beyond the patient's means, the practice may then be required to assume the cost itself.

1013. Second, even in the event that coverage is eventually approved, the process of obtaining that coverage can be costly for physicians and their staffs, requiring time-consuming interaction with payers. In a recent study published by the Zitter Group in September 2010, the average time required to process a typical oncology prior authorization was nearly one hour. The study further revealed that prior authorizations have a direct impact on prescribing decisions. Oncologists and practice managers reported that prior authorizations are the one payer management tool that most affects therapy utilization. Prior authorizations may be costly for patients as well, requiring them to postpone treatment until a coverage decision is reached. For all of these reasons, reimbursement concerns have been a frequent physician objection against prescribing Fentora.

1014. Such objections were particularly prevalent with regard to unsafe and unapproved uses of the drug. When prescribing drugs for on-label indications, coverage denials are relatively unlikely, and the reimbursement process is simple and straightforward. However, when prescribing a drug for unapproved uses, coverage denials are increasingly likely, and the reimbursement process becomes correspondingly more time-consuming and complicated. A physician who writes a prescription for an unapproved use may be required to spend considerable time interacting with the patient's insurance payer, arguing that the particular circumstances of the patient justify coverage of the unsafe and unapproved prescription. The difficulty of arguing the physician's case increases when the alternative on-label therapy is significantly cheaper than the unapproved use. All else being equal, physicians are, understandably, inclined to prescribe the cheaper, on-label regime rather than the more expensive, unsafe and unapproved combination in order to simplify the reimbursement process.

1015. Cephalon has been required to counter physicians' inclination not to prescribe a powerful opioid for the treatment of certain unsafe and unapproved, non-cancer breakthrough pain. Thus, Cephalon needed a mechanism to remove the reimbursement burden from physicians' shoulders. The Fentora Reimbursement Program has accomplished this objective.

1016. Cephalon acknowledged internally that one of the biggest obstacles to growing Fentora sales is the lack of reimbursement for breakthrough pain. Cephalon increased the size of its reimbursement support team to minimize this obstacle, spending over $3 million per year (with nearly $4 million budgeted for 2011) to provide customized reimbursement support services to doctors and their office managers, including a Fentora Hotline. Cephalon performed numerous interventions on behalf of healthcare providers seeking to be reimbursed for unsafe and unapproved Fentora prescriptions.

1017. When a physician or physician's office contacts Cephalon's hotline for reimbursement support to overturn a denial for unsafe and unapproved uses, the company used a pre-populated form with all relevant data and studies it has identified supporting the use and reimbursement of Fentora for those uses. The pre-populated form allows physicians or their staff to only fill in the patient specific information and send it to the payer, requesting that the payer reimburse for such unsafe and unapproved use of Fentora. Importantly, Cephalon has generated a pre-populated form for non-cancer breakthrough pain to aid physicians in making their case for unsafe and unapproved reimbursement.

1018. Cephalon's use of the Fentora Reimbursement Program to reverse reimbursement denials for unsafe and unapproved prescriptions of Fentora was part of its scheme to induce physicians to prescribe and utilize Fentora for unsafe and unapproved uses without concern for

the time, resources or lost profits associated with addressing reimbursement issues raised by payers, such as MMO, themselves.

(iii) Janssen's False and Misleading Messages to TPPs, Including MMO

1019. As part of Janssen's Formulary Access and Coverage Enterprise, it developed a dedicated "managed care" (also called "Regional Account Executives" or "Managed Markets") sales group, many of whom had advanced science degrees, whose job it was to call on TPP pharmacy directors and P&T committees, including on MMO pharmacy personnel. These specialized Managed Markets representatives presented false and misleading studies/abstracts to Plaintiff MMO to influence placement of Janssen's drugs on its formularies.

1020. The Janssen Managed Markets representatives were specifically trained to initiate the Company's rehearsed false and misleading safety and efficacy messages designed to cause the P&T committee to add Janssen's drugs to its formularies.

1021. The Company trained sales representatives through role-playing exercises to promote its drugs based on false and misleading safety and efficacy statements that had been rejected by the FDA.

1022. The Janssen Managed Markets representatives did as they were trained and instructed, and the Janssen Formulary Access and Coverage Enterprise succeeded in deceiving Plaintiff MMO into adding Janssen's drugs to its formulary.

1023. Janssen's sales representatives were encouraged to be involved with prior authorization process with Ultram ER, Nucynta and Nucynta ER in order to evade TPP drug formulary restrictions. Prior authorization manipulation was part of their business plans. Defendants' District Managers touted that the number one sales representative in the country in 2012 got prescriptions by going to physician offices and simply flagging the charts with Ultram

ER stickers and doing prior authorizations for each patient. This practice was encouraged by the Regional Business Director and other District Managers.

1024. Janssen's sales representative involvement in the prior authorization process endangered the patients' HIPAA rights and was designed to bypass the existing formulary process to gain the prescription.

1025. Janssen's territory business plans often included tracking of doctors by their volume of private insurance patients, average duration of treatment, and the average revenue from Janssen drugs. Janssen management utilized this private insurance volume information in order to determine which doctors to target for expensive meals and cash payment.

(iv) Endo's False and Misleading Messages to TPPs, Including MMO

1026. As part of Endo's Formulary Access and Coverage Enterprise, it developed a dedicated "managed care" (also called "Regional Account Executives" or "Managed Markets") sales group, many of whom had advanced science degrees, whose job it was to call on TPP pharmacy directors and P&T committees, including on MMO pharmacy personnel. These specialized Managed Markets representatives presented false and misleading studies/abstracts to Plaintiff MMO to influence placement of Endo's drugs on its formularies.

1027. The Endo Managed Markets representatives were specifically trained to initiate the Company's rehearsed false and misleading safety and efficacy messages designed to cause the P&T committee to add Endo's drugs to its formularies.

1028. For example, the Company trained them through role-playing exercises to promote its drugs based on false and misleading safety and efficacy statements that had been rejected by the FDA.

1029. The Endo Managed Markets representatives did as they were trained and instructed, and the Endo Formulary Access and Coverage Enterprise succeeded in deceiving Plaintiff MMO into adding Endo's drugs to its formulary.

1030. In another example, Endo sponsored publications specifically aimed at seeking access to TPP formularies. One such article, *Pain Management*, appeared in the P&T Digest, a "Peer-Reviewed Compendium of Formulary Considerations."[266] The self-described "Tool for Formulary Decision Makers" explained its utility:

> The purpose of this publication is to provide P&T committees with an understanding of options for addressing patients' chronic pain. This peer-reviewed digest examines current guidelines for pain management, therapeutic approaches to care, and strategies for managing patients with various types of pain. In consolidating this information, it serves as a valuable tool for formulary committees and is an important contribution to the medical literature.

1031. Among its many misrepresentations aimed at securing formulary access, *Pain Management* stated that most specialists in pain medicine and addiction medicine agree that patients treated with prolonged opioid therapy do not usually develop addictive disorders.[267] The term usually was never defined, but the presentation as a whole suggested that the rate of addiction was so low as to be immaterial

(v) Actavis's False and Misleading Messages to TPPs, Including MMO

1032. As part of Actavis's Formulary Access and Coverage Enterprise, it developed a dedicated "managed care" (also called "Regional Account Executives" or "Managed Markets") sales group, many of whom had advanced science degrees, whose job it was to call on TPP pharmacy directors and P&T committees, including on MMO pharmacy personnel. These

[266] *Pain Management*, 14 P&T Digest: 4 (Dec. 2005), http://www.managedcaremag.com/sites/default/files/supplements/0512_PTD_pain/PTD_pain_MC.pdf.

[267] *Id.* at 35.

specialized Managed Markets representatives presented false and misleading studies/abstracts to Plaintiff MMO to influence placement of Actavis's drugs on its formularies.

1033. The Actavis Managed Markets representatives were specifically trained to initiate the Company's rehearsed false and misleading safety and efficacy messages designed to cause the P&T committee to add Actavis's drugs to its formularies.

1034. For example, the Company trained them through role-playing exercises to promote its drugs based on false and misleading safety and efficacy statements that had been rejected by the FDA.

1035. The Actavis Managed Markets representatives did as they were trained and instructed, and the Actavis Formulary Access and Coverage Enterprise succeeded in deceiving Plaintiff MMO into adding Actavis's drugs to its formulary.

(vi) Insys's False and Misleading Messages to TPPs, Including MMO

1036. The lengths to which the Manufacturer Defendants would go to defraud TPPs is best exemplified by Insys. Insys Therapeutics was co-founded in 2002 by Dr. John Kapoor, a serial pharmaceutical industry entrepreneur "known for applying aggressive marketing tactics and sharp price increases on older drugs."[268] In 2012, Insys received U.S. Food and Drug Administration (FDA) approval for Subsys, a fentanyl sublingual spray product designed to treat breakthrough cancer pain, and the drug proved incredibly successful financially.[269] Insys had "the best-performing initial public offering in 2013," and, over the next two years, revenues

[268] *Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids*, Wall Street Journal (Nov. 22, 2016), available at www.wsj.com/articles/fentanyl-billionaire-comes-under-fire-as-death-toll-mounts-from-prescription-opioids-1479830968.

[269] *Id.*

tripled and profits rose 45%.[270] The value of company stock increased 296% between 2013 and 2016.[271]

1037. As noted in a Permanent Subcommittee on Investigations report Sen. McCaskill and Sen. Rob Portman issued on October 4, 2016, the prior authorization process "requires additional approval from an insurer or its pharmacy benefit manager before dispensing. ... Prior authorization policies can also impose 'step therapy,' which requires beneficiaries to first use less expensive medications before moving on to a more expensive approach."[272]

1038. With regard to Insys specifically, recent court filings explain that insurers have "required that a prior authorization be obtained before a claim [can] be submitted for a Subsys prescription."[273] This 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 those factors was not present, the prior authorization would be denied ... meaning no reimbursement would be due."[274] These screening processes reportedly raised significant obstacles to Subsys prescriptions shortly after Insys introduced the drug. According to a criminal indictment filed against former Insys CEO Michael Babich and five other Insys

[270] *Id.*

[271] An Opioid Spray Showered Billionaire John Kapoor in Riches. Now He's Feeling the Pain, Forbes (Oct. 4, 2016) (www.forbes.com/sites/matthewherper/2016/10/04/death-kickbacks-and-a-billionaire-the-story-of-a-dangerous-opioid/).

[272] Senate Permanent Subcommittee on Investigations, Combatting the Opioid Epidemic: A Review of Anti-Abuse Efforts in Medicare and Private Health Insurance Systems (Oct. 4, 2016); see also Department of Health and Human Services, Centers for Medicare & Medicaid Services, How Medicare Prescription Drug Plans & Medicare Advantage Plans with Prescription Drug Coverage (MA-PDs) Use Pharmacies, Formularies, & Common Coverage Rules (Oct. 2015).

[273] Complaint (July 12, 2017), *Blue Cross of California, Inc., et al. v. Insys Therapeutics, Inc*., D. Ariz. (No. 2:17 CV 02286).

[274] *Id.*

executives, an internal company analysis in November 2012 revealed that insurers and PBMs approved reimbursements for Subsys in only approximately 30% of cases.[275]

1039. In response to these challenges, Insys created a prior authorization unit, known at one point as the Insys Reimbursement Center (IRC), to intervene with PBMs and secure reimbursements between January 2013 and October 2016.[276] Led by an Insys employee, IRC employees reportedly received significant financial incentives and management pressure—including quotas and group and individual bonuses—to boost the rate of Subsys authorizations.[277] According to a former Insys employee, they personally pressured IRC employees to improve the rate of prescription approvals, noting that "Dr. Kapoor's not happy, we have to get these approvals up."[278]

1040. The PA Team was trained and directed to conduct various techniques to gain approval. According to one former employee, when the PBM called to ask what Subsys was being prescribed for and if the patient had tried other medications due to "step therapy" policies, the PA Team was instructed to lie about the other drugs the patient had taken; the PA Team was given the cheat sheet lists of other drugs, and they were trained to tell the PBM that the patient had taken drugs from that list, even though the patient had not taken the drugs. This former employee stated that the PA Team was "helping" the prescriber by handling all of the paperwork involved in getting prior authorization from the insurance company, paperwork that would normally have to be done by the doctor's staff. Sometimes the insurance companies would call

[275] Indictment (Dec. 6, 2016), *United States v. Babich, et al*., D. Mass. (No. 1:16 CR 10343).

[276] *See* Complaint (July 12, 2017), *Blue Cross of California, Inc., et al. v. Insys Therapeutics, Inc*., D. Ariz. (No. 2:17 CV 02286).

[277] *Murder Incorporated: Insys Therapeutics, Part I*, Southern Investigative Reporting Foundation (Dec. 3, 2015) (sirf-online.org/2015/12/03/murder-incorporated- the-insys-therapeutics-story/); *see also* Indictment (Dec. 6, 2016), *United States v. Babich, et al.*, D. Mass. (No. 1:16 CR 10343).

[278] *Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids*, WALL STREET JOURNAL (Nov. 22, 2016).

doctors' offices to determine that the Insys employee was a valid employee of the doctor's office. According to CW6, many prescribers had informed their staff to affirm that the Insys employees were indeed employees of the doctor's office.

1041. This former employee also stated that the PA Team was directed to tell PBMs that a prescription had been written for a three-month supply even when the prescription specified a one-month supply.

1042. Some PBMs became suspicious that their caller IDs displayed that the PA Team member was calling from an Arizona area code but claimed to be calling from a doctor's office located in another state. When the PA Team informed CEO Babich of this problem, CEO Babich said he would arrange for the PA Team to get a phone system that would mask the outgoing phone number. On or about February 28, 2013, when the PA Team moved into new offices across the street from Insys headquarters, a new phone system had been installed which masked their numbers from appearing on caller ID.

1043. Insys knew that Subsys usage was primarily off-label because the PA Team was given the patient's information with the diagnosis and the list of the drugs that the patient had already taken. The majority of prescriptions were written for peripheral neuropathy caused by diabetes, lower back pain, and sciatica, in that order. Only 10% of the prescriptions reflected cancer as a diagnosis, and it was such a rare occurrence that every time the PA Team saw cancer as a patient's diagnosis, they would get "stoked."

1044. The PA Team was involved in the training of the sales representatives so that the sales representatives knew what to tell prescribers regarding which diagnoses would get authorized so that the physician did not exclude off-label use. For example, one former employee said that the sales representatives were taught to say things such as "Subsys works great on this

diagnoses (like lower back pain), too." During the training then-VP of Marketing instructed the sales representatives to use the term "breakthrough pain" instead of "breakthrough cancer pain" with HCPs.

1045. Insys's 2013 "Brand Plan" specifically included strategies with which to "mitigate prior authorization barriers."[279] Some TPPs (acting either directly or through their PBMs) required prior authorization for Subsys prescriptions to ensure it was prescribed for cancer patients only. In response, Insys adopted an elaborate scheme aimed at misleading PBMs and health plans as to patients' medical histories, successfully misleading TPPs or their PBMs as to the condition for which Subsys was prescribed.[280]

1046. Insys management was aware that only about 10% of prescriptions approved through the Prior Authorization Department were for cancer patients. An Oregon Department of Justice Investigation found that 78% of preauthorization forms submitted by Insys on behalf of Oregon patients were for unsafe and unapproved uses.[281] Physicians are allowed to prescribe medications for indications outside of FDA guidelines if they see fit, but it is illegal for pharmaceutical companies to market a drug for unsafe and unapproved use.

1047. The core of the Insys scheme was outright lying in getting prior authorizations approved for Subsys. Insys's prior authorization unit did this by changing patients' diagnoses to cancer. Absent the alleged changes, MMO and other TPPs would have never paid for the Subsys prescriptions. The result has been that MMO and other TPPs have approved reimbursement

[279] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office, Fueling An Epidemic: Insys Therapeutics And The Systematic Manipulation Of Prior Authorization (Sep. 1, 2017), at Ex. A.

[280] *Id.* at 2-3.

[281] Gusovsky, Dina. The Pain Killer: *A drug Company Putting Profits Above Patients,* CNBC, available at https://www.cnbc.com/2015/11/04/the-deadly-drug-appeal-of-insys-pharmaceu ticals.html).

of prescriptions for Subsys at vastly higher rates than those of its rivals in the Fentanyl marketplace.

1048. The Insys prior authorization unit was set up to assist patients with complex insurance paperwork. Its goal was simple: The patient signed a few forms and Insys handled the messy paperwork. Patients would get the Subsys, prescribers would not have to scramble for an alternate medication, and Insys would book thousands of dollars in revenue per prescription.[282]

1049. In reality what the Insys prior authorization unit did was take advantage of PBM approvals to work a type of bureaucratic alchemy whereby a torrent of unsafe and unapproved Subsys prescriptions would be transformed into ones associated with medically urgent cancer diagnoses.

1050. Unmistakably, its prior authorization unit was the key piece in helping Insys to double the size of the Fentanyl marketplace to more than $500 million in less than two years. Lost in the cascade of prescriptions, however, has been the human toll from peddling Subsys like a new piece of software or an improved detergent.[283] Since Subsys was launched in January 2012, the FDA's Adverse Events Reporting System lists hundreds of deaths for which medical providers have pointed to Subsys as the probable candidate for triggering an adverse reaction.

1051. Instead of answering "yes" to questions about breakthrough cancer pain, Insys prior authorization unit employees were to answer, "yes, they have breakthrough pain," which was both an affirmative answer but ambiguous enough to mean virtually anything.[284]

[282] Roddy Boyd, *Murder Incorporated: Insys Therapeutics, Part I*, Southern Investigative Reporting Foundationi, The Investigator, December 3, 2015, available at http://sirf-online.org/2015/12/03/murder-incorporated-the-insys-therapeutics-story/

[283] *Id.*

[284] *Id.*

1052. Through the spring of 2014, Subsys prior authorization approval rates remained impressive, but pharmacy benefit managers began to push back, sometimes demanding to speak with the physician about the diagnosis. If the pharmacy benefit manager called the prescriber, that was a big problem in and of itself as the prior authorization unit was in no way "from" any doctor's office.[285]

1053. To reverse the trend of a slowdown in number of approvals, Insys developed what prior authorization employees called "the spiel," a series of dialogues (to commit to memory), designed to address detailed questions about whether a patient had breakthrough pain and cancer. When someone from a pharmacy benefit management office asked about a patient's having breakthrough pain from cancer, the Insys prior authorization employee would reply, "The physician has stated that Subsys is approved for treating breakthrough cancer pain so (he or she) is treating breakthrough pain." Prior authorization employees, per their instructions, would invent conversation to suggest they were right inside the prescriber's office — something along the lines of "You should see this guy. It's a real sad case and the doctor is upset about it."[286]

1054. Insys's prior authorization unit (also known internally as the "insurance reimbursement center" or "IRC") employees were trained and rewarded for saying anything, including purportedly inventing patient diagnoses, to get Subsys approved.[287]

1055. Materials produced by Insys to the Senate minority staff suggest that Insys was aware of the danger of its problematic practices towards MMO and other TPPs. Specifically, on

[285] *Id.*

[286] *Id.*

[287] Roddy Boyd, *The Brotherhood of Thieves: Insys Therapeutics*, Southern Investigative Reporting Foundation, The Investigator, January 25, 2016, available at http://sirf-online.org/2016/01/25/the-brotherhood-of-thieves-insys-therapeutics-2/

February 18, 2014, Compliance Implementation Services (CIS)—a healthcare consultant—issued a draft report to Insys titled, "Insys Call Note, Email, & IRC Verbatim Data Audit Report."[288] The introduction to the report explained that "CIS was approached by INSYS'S legal representative … on behalf of the Board of Directors for Insys to request that CIS support in review of certain communications with HCPs and INSYS employees, and report how there were being documented."[289] Insys had expressed concerns "with respect to communications with HCPs by INSYS employees being professional in nature and in alignment with INSYS approved topics regarding off or on-label promotion of an INSYS product, and general adherence to INSYS documentation requirements."[290] An additional concern "stemmed from the lack of monitoring of commercial activities where these types of interactions could occur."[291]

1056. Similarly, Insys management was urged to formally draft specific standard operating procedures "specific to each job function within the IRC [Insys Reimbursement Center]," accompanied by "adequate training and understanding of these processes."[292] To ensure compliance with standards, Insys was also directed to create an electronic system to allow management "to monitor both live and anonymously IRC employee communications both incoming and outgoing."[293] Finally, CIS recommended that Insys institute a formal process for revising and updating "IRC documentation used for patient and HCP data."[294]

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[288] U.S. Senate Homeland Security & Governmental Affairs Committee, *Insys Therapeutics and the Systemic Manipulation of Prior Authorization* (quoting Compliance Implementation Services, Insys Call Note, Email & IRC Verbatim Data Audit Report (Feb. 18, 2014) (INSYS_HSGAC_00007763)).

[289] *Id.* at INSYS_HSGAC_00007765.

[290] *Id.*

[291] *Id.*

[292] INSYS_HSGAC_00007771.

[293] *Id.*

[294] *Id.*

1057. Yet within a year of this conclusion, according to a recording, an Insys IRC employee appeared to have misled a PBM representative regarding the IRC employee's affiliation and the diagnosis applicable to the patient. The alleged result, in that case, was death due to inappropriate and excessive Subsys prescriptions.

1058. One former Insys sales representative described the motto of this approach to patients as "[s]tart them high and hope they don't die."[295]

1059. Insys's unlawful promotion of Subsys included the specific targeting of prescribers and TPPs in Cleveland, Ohio, where MMO is headquartered. According to a nurse practitioner working for a pain physician responsible for one of the highest number of Subsys prescriptions in the state, Insys instructed its sales representatives to manipulate prior authorization forms in order to circumvent restrictions on reimbursement erected by TPPs, including Medical Mutual of Ohio. Specifically, Insys sales representatives were directed to modify or fabricate diagnosis codes on a patient's prior authorization form in an effort to ensure payment by TPPs. For example, if the patient was suffering from low back pain, the physician's office completed the prior authorization form using an appropriate pain-related diagnosis code and then sent the form along to Insys. Insys would then add a cancer-related diagnosis code to the patient's form before submitting the claim for payment to Ohio TPPs, including to MMO. This was all done despite the fact that the physician was not an oncologist and the patient was not being treated for any cancer-related conditions. Insys's conduct was designed to obtain payment from TPPs, including MMO, for the unsafe and unapproved use of Insys, irrespective of the patient's underlying medical condition.

[295] INSYS_HSGAC_00007772.

(vii) Mallinckrodt's False and Misleading Messages to TPPs, Including MMO

1060. As part of Mallinckrodt's Formulary Access and Coverage Enterprise, it developed a dedicated "managed care" (also called "Regional Account Executives" or "Managed Markets") sales group, many of whom had advanced science degrees, whose job it was to call on TPP pharmacy directors and P&T committees, including on MMO pharmacy personnel. These specialized Managed Markets representatives presented false and misleading studies/abstracts to Plaintiff MMO to influence placement of Mallinckrodt's drugs on its formularies.

1061. The Mallinckrodt Managed Markets representatives were specifically trained to initiate the Company's rehearsed false and misleading safety and efficacy messages designed to cause the P&T committee to add Mallinckrodt's drugs to its formularies.

1062. For example, the Mallinckrodt trained representatives through role-playing exercises to promote its drugs based on false and misleading safety and efficacy statements that had been rejected by the FDA.

1063. The Mallinckrodt Managed Markets representatives did as they were trained and instructed, and the Mallinckrodt Formulary Access and Coverage Enterprise succeeded in deceiving Plaintiff MMO into adding Mallinckrodt's drugs to its formulary.

6. Concerted Efforts of All Defendants to Suppress Evidence of Diversion

1064. A critical component of the Formulary Access and Coverage Enterprise was *all* of the Defendants' concerted efforts to illegally suppress evidence of drug diversion, which they were obligated to report. Absent this concealment, payers like Plaintiff MMO would have been on notice that a significant amount of the Opioid Drugs for which it had paid were not prescribed for legitimate medical need, but rather made their way to the black market. This would have led MMO to employ various fraud fighting tools to thwart 'market prescribing,' and also affected its

formulary access and status decisions regarding Opioid Drugs. It would also have revealed to MMO that representations regarding the non-addictive properties of Opioid Drugs were false. In short, Defendants' Drug Diversion Concealment Enterprise (discussed *infra*) was a key component of Defendants' Formulary Access and Coverage Enterprise.

1065. Absent this concealment, health plans like Plaintiff MMO would not have made the coverage and formulary placement decisions it did with respect to Opioid Drugs, and would have expended far less money on the reimbursement of Opioid Drugs.

1066. The success of the Drug Diversion Concealment Enterprise (discussed *infra*) hinged on *all actors* in the supply chain working to conceal evidence of drug diversion. Thus, in additional to the Manufacturer Defendants, the Distributor Defendants and Pharmacy Defendants were key integral players in the success of the Formulary Access and Coverage Enterprises.

7. Manufacturer Defendants Used Managed Care Contracts to Garner Favorable Formulary Access and Coverage Without Restrictions

1067. In addition to coverage decisions, the Manufacturer Defendants also worked to ensure preferred formulary status for Opioid Drugs. In doing so, the Manufacturer Defendants made numerous misrepresentations to TPPs themselves (or those acting on their behalf) to achieve a formulary placement that they would not have otherwise received. This is also true with respect to Plaintiff MMO.

1068. Recently released court documents illustrate that blocking any limits on Opioid Drug prescribing, including Purdue's OxyContin, was a top priority for the Manufacturer Defendants. For example, Purdue official Bernadette Katsur confirmed in an interview that Purdue negotiated "national contracts" with PBMs in exchange for ensuring "favorable" treatment for OxyContin on formularies (meaning without prior authorization and with low

copayments).[296] Katsur explained: "[Purdue] would negotiate a certain rebate percentage for keeping it on a certain tier related to copay or whether it has prior authorization" because of Purdue's intense desire to "keep prior authorization[s] off of any drug."[297] Internal memos confirm that "stop[ping] any preauthorization efforts for OxyContin" and working with PBMs to "try to make parameters less stringent" were of the utmost importance to the success of OxyContin, and upon information and belief other Opioid Drugs.[298]

1069. Once Defendants obtained formulary access for their Opioid products, they initiated a variety of marketing initiatives to increase prescription sales by disseminating information regarding the formulary access of their drugs, typically described as "pull through" efforts. Defendants accomplished this by misleading consumers and physicians alike into believing that the Opioid drugs could be safely and effectively used treat all forms of pain. The scheme to perpetrate the Opioids myth was multi-faceted, and multi-pronged.

1070. Defendants also blocked MMO's use of formulary tiers (and resulting in higher co-pay amounts paid by policyholders) and other managed care limitations to influence sound prescribing practices (prior authorization, quantity limits, and step therapy). This included the Manufacturer Defendants' programs such as free-trials, coupons, and copay assistance vouchers (discussed in greater detail, *supra*).

8. Enlisting KOLs to Blame TPPs for the Opioid Crisis

1071. As part of their scheme to deflect blame for their central role in the Opioid crisis, Defendants have enlisted their KOLs to blame TPPs.

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[296] David Armstrong, *Drug maker thwarted plan to limit OxyContin prescriptions at dawn of opioid epidemic*, STAT (October 26, 2016), https://www.statnews.com/2016/10/26/oxycontin-maker-thwarted-limits/

[297] *Id.*

[298] *Id.*

1072. For example, KOL Webster (who has served as a consultant for most of the Manufacturer Defendants, including has consulted or received research grants from Insys Therapeutics, Mallinckrodt, Teva) joined with others with ties to the Defendants to author an article entitled *The health insurance industry: perpetuating the opioid crisis through policies of cost-containment and profitability*, published in the Journal of Pain Research.

1073. Webster and his colleagues point the finger of blame at TPPs: "[I]n the interests of cost-containment and profitability, the health insurance industry has contributed to the opioid crisis in the USA by refusing to pay for therapies to reduce the harm associated with opioid prescribing."[299]

1074. Not surprisingly, given their ties to the Manufacturer Defendants, Webster and his colleagues' solution is that the federal government should require "health insurance carriers (including Medicare and Medicaid) to provide coverage for the opioid formulations that have the potential to substantially ameliorate the nation's persisting prescription opioid crisis."[300]

E. Drug Diversion Concealment Enterprises

1075. As noted above, Defendants' profit was not merely tied to the prescription market for Opioid Drugs, but also to the black market. All Defendants worked together to conceal evidence of drug diversion, ensuring the protection and expansion of the black market for Opioid Drugs, from which all Defendants were profiting. The Drug Diversion Concealment Enterprise was critical to the success of the Formulary Access and Coverage Enterprise (which bolstered and secured all Defendants' profits resulting from the Opioid Drugs).

[299] *Id.*, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4370920/

[300] *Id.*

1. Defendants' Statutory Duty to Identify, Monitor, and Report Drug Diversion, Potential Misuse

(i) Duties under the Controlled Substances Act of Manufacturers, Distributors and Retail Pharmacies to Report Diversion

1076. The opioid supply chain begins with manufacturers (including the Manufacturer Defendants), who manufacture and package the pills. The Manufacturer Defendants then transfer the opioids to wholesale distributors (including the Distributor Defendants). Wholesale Distributors then dispense the opioids to hospitals and pharmacies. Those entities (which include the Pharmacy Defendants) who then dispense drugs to patients.

1077. Recognizing that there is a need for greater scrutiny over controlled substances, like opioids, due to their potential for abuse and danger to public health and safety, Congress enacted the CSA in 1970.[301] 21 U.S.C. § 801 *et seq.* In doing so, Congress specifically designed a closed chain of distribution, with multiple ways of identifying and preventing diversion through active participation of registrants at each link in the chain, to prevent the "widespread diversion of [legally produced controlled substances] into the illicit market."[302] Realizing and anticipating that highly addictive drugs like opioids could easily be abused and diverted to the black market, Congress in the CSA set forth two important controls on such drugs.

1078. First, the DEA sets limits on the quantity of schedule II controlled substances—such as opioids—that may be produced in the United States in any given year. See 21 U.S.C. § 826(a). 28 C.F.R. § 0.100. This quota system was intended to reduce or eliminate diversion from

[301] Joseph T. Rannazzisi Decl. ¶ 4, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185, ECF No. 14-2 (February 10, 2012).

[302] *Gonzalez v. Raich*, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801(20; 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970). See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files /Rannazzisi%20Testimony_0.pdf); Statement of Joseph T. Rannazzisi before the Caucus on International Narcotics Control United States Senate, July 18, 2012 (available at https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea-rannazzisi.pdf).

"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."[303] When determining production quotas, the DEA considers a variety of data including: sales, production, inventories, exports, disposals, and inventories. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.[304]

1079. Second, the CSA requires every actor within the closed system of drug distribution and opioid supply chain (i.e. manufacturers, wholesale distributors, and retailers) to register with the DEA. Every registrant, in turn, is charged with being be vigilant in deciding whether a customer, whether a pharmacy, wholesaler, or end customer, can be trusted to deliver or use controlled prescription narcotics only for lawful purposes. 21 U.S.C. § 823(e).

1080. As the Supreme Court explains, "Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic."[305] This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances, like opioid drugs, has a substantial and detrimental effect on the health and general welfare of the American people.

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[303] H.R. Rep. No. 91-1444, *reprinted in* 1970 U.S.C.C.A.N. 4566, 4589; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi %20Testimony_0.pdf).

[304] H.R. Rep. No. 91-1444, *reprinted in* 1970 U.S.C.C.A.N. 4566, 4615 (citing 21 U.S.C. § 842(b)).

[305] *United States v. Moore*, 423 U.S. 122, 135 (1975).

1081. Every registrant is required to "maintain effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1). Further, the Code of Federal Regulations requires all registrants to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21. C.F.R. § 1301.74(b). Federal law also imposes a duty upon Defendants to comply with applicable State and local laws. *See* 21 U.S.C. § 823(b)(2). When determining if a distributor has provided effective controls, the DEA Administrator refers to the security requirements set forth in §§ 130 1.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. *See* 21 C.F.R. § 1301.71.

1082. In addition to the requirement of implementing a system for diversion control, the CSA and its implementing regulations require all registrants to: (1) report suspicious orders of prescription opioids to the DEA and (2) perform required due diligence *prior to filling* any suspicious orders. (emphasis added) *See* 21 U.S.C. § 823(b)(1); 21 C.F.R. § 1301.74(b). A "suspicious order" is defined as including "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

1083. To further prevent unauthorized users from obtaining opioids, the CSA creates a distribution monitoring system for controlled substances. At the heart of this system are registration and tracking requirements imposed upon anyone authorized to handle controlled substances. The DEA's Automation of Reports and Consolidation Orders System ("'ARCOS") is an automated drug reporting system which monitors the flow of Schedule II controlled substances from their point of manufacture through commercial distribution channels to point of sale. ARCOS accumulates data on the Manufacturer and Distributor Defendants' controlled substances acquisition/distribution transactions, which are then summarized into reports used by

the DEA to identify any diversion of controlled substances into illicit channels of distribution. Each person or entity that is registered to distribute ARCOS Reportable controlled substances must report acquisition and distribution transactions to the DEA.

1084. Acquisition and distribution transaction reports must provide data on each acquisition to inventory (identifying whether it is, *e.g.*, by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, *e.g.*, by sale or transfer, theft, destruction or seizure by Government agencies) for each ARCOS Reportable controlled substance. *See* 21 U.S.C. § 827(d)(l); 21 C.F.R. §§ 1304.33(e), (d). Inventory that has been lost or stolen must also be reported separately to the DEA within one business day of discovery of such loss or theft.

1085. In addition to filing acquisition/distribution transaction reports, each registrant is required to maintain on a current basis a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. *See* 21 U.S.C. §§ 827(a)(3), 1304.2 1(a), 1304.22(b). It is unlawful for any person to negligently fail to abide by the recordkeeping and reporting requirements.

1086. Reflecting the importance of CSA compliance, the DEA has repeatedly provided guidance to registrants emphasizing their obligations under the CSA. A DEA letter dated September 27, 2006, sent to every commercial entity in the United States registered with the DEA, outlined specific circumstances that might be indicative of diversion: a) Ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs. b) Ordering a Limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered. c) Ordering excessive quantities of a limited

variety of controlled substances in combination with excessive quantities of lifestyle drugs. d) Ordering the same controlled substance from multiple distributors.

1087. Additionally, the letter implored the Distributor Defendants to know their pharmacy customers, including the Pharmacy Defendants, and to follow up with said pharmacy customers, including the Pharmacy Defendants, regarding: a) What percentage of the pharmacy's business does dispensing controlled substances constitute? b) Is the pharmacy complying with the laws of every state in which it is dispensing controlled substances c) Is the pharmacy soliciting buyers of controlled substances via the internet or is the pharmacy associated with an internet site that solicits orders for controlled substances? d) Does the Pharmacy, or Internet site affiliated with the pharmacy, offer to facilitate the acquisition of a prescription for a controlled substance from a practitioner with whom the buyer has no pre-existing relationship? e) Does the pharmacy fill prescriptions issued by practitioners based solely on an on-line questionnaire without a medical examination or bona-fide doctor-patient relationship? f) Are the prescribing practitioners licensed to practice medicine in the jurisdictions to which the controlled substances are being shipped, if such a license is required by state law? g) Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy? h) Does the pharmacy offer to sell controlled substances without a prescription? i) Does the pharmacy charge reasonable prices for controlled substances? j) Does the pharmacy accept insurance payment for purchases of controlled substances made via the internet?

1088. In 2007, the DEA sent letters to every registered manufacturer or distributor of controlled substances, including Defendants. As stated in the letter, "the purpose of [the] letter [wa]s to reiterate the responsibilities of controlled substance manufacturers and distributors to inform the DEA of suspicious orders in accordance with 21 C.F.R. 1301.74(b)."

1089. In the letter, the DEA expressly warned that the regulation "requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant." The DEA also warned that "[r]egistrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted."

1090. In addition, the DEA warned that the "regulation specifically states that suspicious orders include orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a 'normal pattern' to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the order patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry."

(ii) Duties of the Distributor Defendants Under the Controlled Substances Act

1091. The same legal duties under the CSA to prevent diversion, and to monitor, report, and prevent suspicious orders of prescriptions opioids that were incumbent upon the Manufacturer and Pharmacy Defendants are also legally required of the Distributor Defendants.

All opioid distributors are required to maintain effective controls against opioid diversion. They are required to create and use a system to identify and report to law enforcement downstream suspicious orders of controlled substances, such as orders of unusually large size, orders that are disproportionate, orders that deviate from a normal pattern, and/or orders of unusual frequency. To comply with these requirements, distributors must know their customers, must conduct due diligence, must report suspicious orders, and must terminate orders if there are indications of diversion.

1092. As part of the legal obligation to maintain effective controls against diversion, the distributor is required to exercise due care in confirming the legitimacy of each and every order prior to filling. Circumstances that could be indicative of diversion include ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; ordering a disproportionate amount of controlled substances versus non-controlled prescription drugs; ordering excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs; and ordering the same controlled substance from multiple distributors.

1093. Reporting an order as suspicious will not absolve a distributor of responsibility if the distributor knew, or should have known, that the prescription opioids were being diverted. Indeed, reporting a suspicious order, then filling said order with knowledge it may be suspicious constitutes a failure to maintain effective controls against diversion under 21 U.S.C. §§ 823 and 824.

1094. The DEA has repeatedly provided guidance on compliance with the foregoing CSA regulations to effectively combat opioid diversion. Since 2006 the DEA has conducted one-on-one briefings with distributors regarding downstream customer sales, due diligence, and regulatory responsibilities. The DEA also provides distributors with data on controlled substance

distribution patterns and trends, including data on the volume and frequency of orders and the percentage of controlled versus non-controlled purchases. The DEA has also hosted conferences for opioid distributors and has participated in numerous meetings and events with trade associations.

(iii) Duties of the Pharmacy Defendants Under the Controlled Substances Act

1095. Pharmacists are the "last line of defense" in keeping drugs from entering the illicit market. Since they are the final point of sale for pharmaceuticals and the interface between the supply chain and the consumer, pharmacies generate the data that manufacturers, as well as wholesale distributors, rely upon to measure consumer activity for sales purposes. Moreover, pharmacists are meant to be the drug experts in the healthcare delivery system and as such have considerable duties and responsibility in the oversight of patient care. Pharmacists are the gatekeepers of a closed system of prescription drug distribution designed to protect the health, safety and welfare of our citizens through limited access to drugs that can have serious and lethal adverse consequences. They cannot blindly fill prescriptions written by a doctor, even one registered under the CSA to dispense opioids, if the prescription is not for a legitimate medical purpose.

1096. The CSA imposes duties and requirements on the conduct of the Pharmacy Defendants. These requirements, along with their related regulations and agency interpretations, set a standard of care for pharmacy conduct.

1097. The CSA requires pharmacists to review each controlled substance prescription and, prior to dispensing medication, make a professional determination that the prescription is effective and valid.

1098. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." *See* 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."

1099. Therefore, pharmacists are required to ensure that prescriptions for controlled substances are valid, and that they are issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.

1100. The DEA's 2010 "Practitioner's Manual" section on "Valid Prescription Requirements" instructs that "[a]n order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription." Filling such a prescription is illegal. The manual states: "The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted."

1101. The DEA (as well as state pharmacy boards and national industry associations) have provided extensive guidance to pharmacists concerning their duties to the public. The guidance teaches pharmacists how to identify red flags, which indicate to the pharmacist that there may be a problem with the legitimacy of a prescription presented by a patient. The guidance also tells pharmacists how to resolve the red flags and what to do if the red flags are unresolvable.

1102. The industry guidance tells pharmacists how to recognize stolen prescription pads; prescription pads printed using a legitimate doctor's name, but with a different call back

number that is answered by an accomplice of the drug-seeker; prescriptions written using fictitious patient names and addresses, and so on.

1103. Questionable or suspicious prescriptions include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible; (5) prescriptions with quantities or dosages that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwritings. Most of the time, these attributes are not difficult to detect or recognize; they should be apparent to an adequately trained pharmacist.

1104. Signs that a customer is seeking opioids for the purpose of diversion include customers who: (1) appear to be returning too frequently; (2) are seeking to fill a prescription written for a different person; (3) appear at the pharmacy counter simultaneously, or within a short time, all bearing similar prescriptions from the same physician; (4) are not regular patrons or residents of the community, and show up with prescriptions from the same physician; (5) drive long distances to have prescriptions filled; (6) seek large volumes of controlled substances in the highest strength in each prescription; (7) seek a combination of other drugs with opioids such as tranquilizers and muscle relaxers that can be used to create an "opioid cocktail"; and (8) pay large amounts of cash for their prescriptions rather than using insurance. Ignoring these signs violates industry standards and DEA guidelines.

1105. Other "red flags" include when prescriptions that lack the technical requirements of a valid prescription, such as a verifiable DEA number and signature; prescriptions written in excess of the amount needed for proper therapeutic purposes; prescriptions obtained through disreputable or illegal web-based pharmacies; and patients receiving multiple types of narcotic pain killers on the same day. All of these issues have been presented by the DEA in pharmacist training programs throughout the United States and have been used as examples by individual state boards of pharmacy and the National Association of Boards of Pharmacy.

1106. Industry standards require pharmacists to contact the prescriber for verification or clarification whenever there is a question about any aspect of a prescription order. If a pharmacist is ever in doubt, he or she must ask for proper identification. If a pharmacist believes the prescription is forged or altered, he or she should not dispense it and call the local police. If a pharmacist believes he or she has discovered a pattern of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

2. The Healthcare Distribution Alliance

1107. The HDA is an association of pharmaceutical manufacturers and distributors. The HDA states its mission is to "protect patient safety and access to medicines through safe and efficient distribution" and acts as the pharmaceutical "convener of the supply chain," representing 35 drug distributors and 130 drug manufacturers. Members of the HDA included Manufacturer Defendants Purdue, Endo, Johnson & Johnson (Janssen's parent company), Actavis, and Teva (Cephalon's parent company), and the Distributor Defendants McKesson, Cardinal, Amerisource and Miami-Luken. These Defendants are members, participants, and/or sponsors of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity. The HDA and the PCF (discussed *infra*) 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 Manufacturer and Distributor Defendants were intimately involved in communication and cooperation.

1108. Not surprisingly, each of the Manufacturer and Distributor Defendants who stood to profit from expanded prescription opioid use is a member of and/or participant in the PCF.[306] In 2012, membership and participating organizations included the HDA (of which all Manufacturer and Distributor Defendants are members).[307] Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.[308] The Distributor Defendants participated directly in the PCF as well.

1109. Additionally, the HDA led to the formation of interpersonal relationships and an organization between the Manufacturer and Distributor Defendants. The HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Manufacturer Defendants by advocating for the many benefits of members, including "**strengthening . . . alliances**."[309] (emphasis added).

1110. 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

[306] *PAIN CARE FORUM: 2012 Meetings Schedule*, (last updated December 2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf.

[307] *Id*. Mallinckrodt became an active member of the PCF sometime after 2012.

[308] *Id*. The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for Amerisource Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. *Executive Committee*, Healthcare Distribution Alliance, (last visited Mar. 26, 2018), https://www.healthcaredistribution.org/about/executive-committee.

[309] *Manufacturer Membership Benefits*, HEALTHCARE DISTRIBUTION ALLIANCE, (last visited Mar. 26, 2018), https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en.

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."[310] Clearly, the HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships and "alliances" between the Manufacturers and Defendants.

1111. The application for manufacturer membership in the HDA further indicates the level of connection between the Defendants and the level of insight that they had into each other's businesses.[311] 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.

1112. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information

1113. Manufacturer Members were asked to identify their "most recent year end net sales" through wholesale distributors, including the Distributor Defendants Amerisource, Cardinal, and McKesson and their subsidiaries.

1114. The closed meetings of the HDA's councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

1115. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA, and the Distributor Defendants advertise these conferences to

[310] *Id.*

[311] *Manufacturer Membership Application Instructions*, HEALTHCARE DISTRIBUTION ALLIANCE, (last visited Mar. 26, 2018), https://www.healthcaredistribution.org/~/media/pdfs/membership/ manufacturer-membership-application.ashx?la=en.

the Manufacturer 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."[312] The conferences also gave the Manufacturer and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[313] The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. It is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.[314]

1116. In addition, the Distributor Defendants and the Manufacturer Defendants 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.[315] For example, on April 27, 2011, the HDA offered a Webinar to "accurately and effectively exchange business transactions between distributors and manufacturers…":

[312] *Business and Leadership Conference – Information for Manufacturers*, HEALTHCARE DISTRIBUTION ALLIANCE, https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers (last accessed on September 14, 2017).

[313] *Id.*

[314] *2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-distribution-management-conference (last accessed on September 14, 2017).

[315] *Webinar Leveraging EDI: Order-to-Cash Transactions*, Healthcare Distribution Alliance, (Apr. 27, 2011), https://www.healthcaredistribution.org/resources/webinar-leveraging-edi.

Webinar Leveraging EDI: Order-to-Cash Transactions CD Box Set

(Webinar held: April 27, 2011) Using EDI to accurately and efficiently exchange business transactions (i.e., purchase orders, acknowledgements, ship notices, invoices, etc.) between distributors and manufacturers in the healthcare supply chain is critical. The development and use of voluntary guidelines for specific EDI standards provide industry trading partners with a means to effectively convey the necessary information.

Hear updates on HDMA's Order-to-Cash Guidelines for Electronic Data Interchange (EDI) in the Healthcare Product Supply Chain, including the 810 Invoice; 850 Purchase Order; 855 Purchase Order Acknowledgement; and the 856 Ship Notice/Manifest.

1117. The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

1118. And, through the HDA, Manufacturer Members were asked to identify their "most recent year end net sales" through wholesale distributors, including the Distributor Defendants as follows:

Company	Most Recent Year End Net Sales
Henry Schein, Inc.	
Henry Schein Distribution Centers (7)	
Hospital Pharmaceutical Consulting (1)	
KeySource Medical, Inc. (1)	
Louisiana Wholesale Drug Co. Inc. (1)	
McKesson Corporation (71)	
McKesson Supply Solutions (25)	
McKesson Canada (12)	
McKesson Corporation (4)	
McKesson Specialty Health (1)	
McKesson Strategic Redistribution Center (1)	
McKesson Medical Surgical (1)	
Physician Sales & Service (PSS) (25)	
US Oncology (1)	
DeVictoria Healthcare, Inc. PR (1)	
Miami-Luken, Inc. (1)	
Morris & Dickson Co., LLC (1)	
Mutual Wholesale Drug Co. (1)	
PBA Health (1)	
Prescription Supply, Inc. (1)	
Prodigy Health Supplier Corporation (1)	
Quality Care Products, LLC (1)	
RDC (3)	
R&S Northeast LLC (2)	
Richie Pharmacal Co., LLC (1)	
Seacoast Medical LLC (1)	
Smith Drug Company, Div. JM Smith Corporation (4)	
Burlington Drug Company, Inc. (1)	
Smith Drug Company, Div. JM Smith Corporation (3)	
Top Rx (4)	
Value Drug Company (1)	
VaxServe (1)	
TOTAL SALES (millions)	$ 0

Company	Most Recent Year End Net Sales
Henry Schein, Inc.	
Henry Schein Distribution Centers (7)	
Hospital Pharmaceutical Consulting (1)	
KeySource Medical, Inc. (1)	
Louisiana Wholesale Drug Co. Inc. (1)	
McKesson Corporation (71)	
McKesson Supply Solutions (25)	
McKesson Canada (12)	
McKesson Corporation (4)	
McKesson Specialty Health (1)	
McKesson Strategic Redistribution Center (1)	
McKesson Medical Surgical (1)	
Physician Sales & Service (PSS) (25)	
US Oncology (1)	
DeVictoria Healthcare, Inc. PR (1)	
Miami-Luken, Inc. (1)	
Morris & Dickson Co., LLC (1)	
Mutual Wholesale Drug Co. (1)	
PBA Health (1)	
Prescription Supply, Inc. (1)	
Prodigy Health Supplier Corporation (1)	
Quality Care Products, LLC (1)	
RDC (3)	
R&S Northeast LLC (2)	
Richie Pharmacal Co., LLC (1)	
Seacoast Medical LLC (1)	
Smith Drug Company, Div. JM Smith Corporation (4)	
Burlington Drug Company, Inc. (1)	
Smith Drug Company, Div. JM Smith Corporation (3)	
Top Rx (4)	
Value Drug Company (1)	
VaxServe (1)	
TOTAL SALES (millions)	$ 0

1119. Members of the PCF (discussed *infra*) and the HDA also lobbied for the passage of legislation to weaken the DEA's enforcement authority to further the common goals of the Defendants' Opioid Diversion Enterprise. To this end, the Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations, which allowed Defendants to continue filling and dispensing excessive amounts of opioids and better follow-through on their shared scheme to expand the opioid market.[316] The HDA and other members of the PCF contributed substantial

[316] *See HDMA is now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, (July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; 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-

amounts of money to political campaigns for federal candidates, state candidates, political action committees and political parties. The PCF and its members and HDA, poured millions into such efforts.

3. Characteristics

(i) Failure of the Manufacturer Defendants to Identify, Monitor, and Report Drug Diversion, Potential Misuse

1120. Defendants disseminated false and misleading statements to state and federal regulators claiming that (1) the quotas for prescription opioids should be increased, (2) they were complying with their obligations to maintain effective controls against diversion of their prescription opioids, (3) they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids, (4) they were complying with their obligation to timely notify the DEA of any suspicious orders or diversion of their prescription opioids and (5) they did not have the capability to identify suspicious orders of controlled substances despite their possession of national, regional, state, and local prescriber- and patient-level data that allowed them to track prescribing patterns over time, which the Defendants obtained 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"). Defendants further created inter-personal relationships among themselves,

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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, https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html .

cooperating with one another to encourage high-volume-and-increased-profits business models throughout the entire Opioid Drug supply chain, and sharing ordering information in exchange for rebates and discounts on the Opioid Drugs to facilitate further expansion of the black market

1121. The opioid epidemic was further fueled by all Defendants' failure to follow the specific mandates in the CSA requiring them to help ensure that highly addictive drugs are not diverted to illegal use. The brunt of the opioid epidemic could have been, and should have been, prevented by had Defendants fulfilled their duties set by statute and common law. Defendants, who operate at every level of the opioid supply chain, had an obligation and duty to act. They did not—and the country, including MMO, who paid the price.

1122. Defendants knowingly, recklessly, and/or negligently supplied suspicious quantities of prescription opioids to obviously suspicious physicians and pharmacies, without disclosing suspicious orders as required by regulations and otherwise circumventing their statutory obligations under federal and state laws.

1123. Defendants' refusal to report and investigate suspicious orders had far-reaching effects. As mentioned above, the DEA is required to annually set production quotas for regulated drugs. In the context of opioids, however, DEA has cited the difficulty of determining an appropriate production level to ensuring that adequate quantities are available for legitimate medical use. That is because there are no direct measures available to establish legitimate medical need. DEA's difficulty in setting production quotas was compounded by the fact that the Manufacturer, Distributor, and Pharmacy Defendants failed to report suspicious orders of opioids—and failed to maintain effective controls against diversion. Defendants' deliberate failures thus prevented the DEA from realizing the full extent of opioid diversion for years.

1124. Defendants could have (and should have) reported and stopped the flow of prescription opioids into the black market. But Defendants intentionally, recklessly, and/or negligently failed to investigate, report, and halt suspicious orders. Accordingly, as a direct result of Defendants' misconduct, substantial and dangerous quantities of prescription opioids were illegally diverted to and overprescribed.

1125. 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."[317]

1126. 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.[318] The "know your customer" questionnaires informed the Distributor Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are 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.

1127. The Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from the Data Vendors that allowed them to track prescribing trends, identify

[317] *See Id.*

[318] Suggested Questions a Distributor should ask prior to shipping controlled substances, DRUG ENFORCEMENT ADMINISTRATION, *available at* https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf (last visited March 27, 2018); Richard Widup, Jr. and Kathleen H. Dooley, Esq. *Pharmaceutical Production Diversion: Beyond the PDMA*, Purdue and McGuireWoods LLC, *available at* https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf (last visited March 27, 2018).

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 competitor's sales, and to compare and analyze market share information.[319]

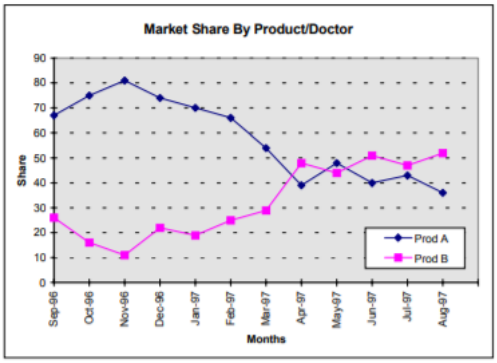
1128. IMS, for example, IMS provided the Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.[320]

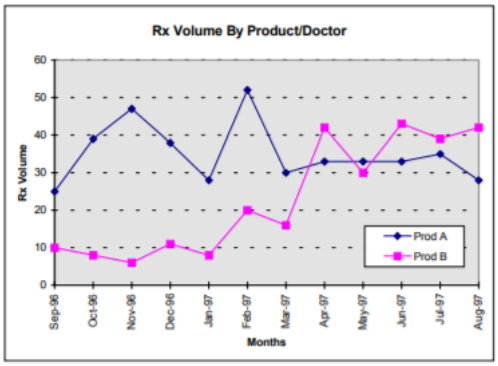
Figure 2:

Physician Targeting Report

Company:	XYZ
Product:	A
Time Period:	September 1996 - August 1997
Market:	Anti-ulser
Name:	John Smith
DEA NUMBER:	AA0012345
Speciality:	OBSTETRICS
Address	150 Main Street, Chester, PA
Number of Samples:	5
Number of Details:	2
Product Switched:	B
PLANS ASSOCIATED:	A, B, C
Reasons for Switch:	Less Drug Interactions, More Cost effective

	Market Share			Rx Volume		
	Period	Prod A	Prod B	Period	Prod A	Prod B
	Sep-96	67	26	Sep-96	25	10
	Oct-96	75	16	Oct-96	39	8
	Nov-96	81	11	Nov-96	47	6
	Dec-96	74	22	Dec-96	38	11
	Jan-97	70	19	Jan-97	28	8
	Feb-97	66	25	Feb-97	52	20
	Mar-97	54	29	Mar-97	30	16
	Apr-97	39	48	Apr-97	33	42
	May-97	48	44	May-97	33	30
	Jun-97	40	51	Jun-97	33	43
	Jul-97	43	47	Jul-97	35	39
	Aug-97	36	52	Aug-97	28	42





1129. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal (ArcLight), provided the Defendants with charts analyzing the weekly prescribing patterns of multiple physicians,

[319] A Verispan representative testified that the Manufacturer Defendants use the prescribing information to "drive market share." *Sorrell v. IMS Health Inc.*, 2011 WL 661712, *9-10 (Feb. 22, 2011).

[320] Paul Kallukaran and Jerry Kagan, *Data Mining at IMS HEALTH: How we Turned a Mountain of Data into a Few Information-rich Molehills*, Figure 2 at 3, *available at*, http://www2.sas.com/proceedings/sugi24/Dataware/p127-24.pdf (last visited February 15, 2018).

organized by territory, regarding competing drugs, and analyzed the market share of those drugs.[321]

3. Territory Summary Report shows Prescriber Roster information aggregated at a territory level

Territory Summary

Name	Spec	Zip	Product A NRX	Product A MM Share	Product A Rank	Market NRX	Market Rank
ABNEY, RAY C.	P	05302	6	10.7%	43	56	38
ALLISTER, ROBERT	P	03820	6	18.8%	43	32	63
ALTMAN, LEE S.	P	01655	34	14.0%	3	247	3
BALLARD, HARLOW	P	05801	0	0.0%	93	8	96
BARNEY, CHRISTINE A.	P	03766	6	26.1%	43	23	85
BARTON, GAIL	P	03755	13	32.5%	18	40	50
BERNSTEIN, RICHARD A.	P	05401	0	0.0%	93	14	94
BOHNERI, MICHAEL	P	03060	3	4.5%	73	66	29
BOSTIC, JEFFERY O.	CHP	03079	5	10.9%	55	45	44
BREITHOLTZ, TIMOTHY	P	03870	13	34.2%	18	38	52
BROWN, KENNETH	P	03941	4	10.0%	61	40	50
BUCHANAN, KEVIN	P	05701	5	16.1%	55	31	70
CARMAN, MEGAN W.	P	03246	10	12.3%	28	81	18
CARSEN, MARJORIA	P	05701	6	18.2%	43	33	59
CATPANO-FRIEDMAN, LISA	P	05201	5	8.6%	43	70	25
CLARKE-RUBIN, LORNA	P	12901	8	24.2%	32	33	59
COHEN, DEVRA H.	CHP	03060	3	6.5%	73	46	44
COLE, STEPHEN A.	P	05101	5	13.2%	55	38	52
COTTON, PAUL G.	P	05401	13	28.3%	18	46	44
CUSI, PRISCILLA M.	P	03104	17	7.9%	14	215	5
DAVISON, MARTHA F.	P	03110	14	11.3%	16	124	8
DEJONG, JACOB	P	03067	0	0.0%	93	21	87
DELFAUSSE, PETER O.	P	03301	6	35.3%	43	17	90
DENNETT, DOUGLAS E.	CHP	05401	0	0.0%	93	33	59
DEPPE, SUSAN L.	P	05401	1	0.3%	87	300	2
DEVENDERRAO, T.	P	03060	7	9.6%	37	73	21

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[321] *Sorrell v. IMS Health Inc.*, 2011 WL 705207, *467-471 (Feb. 22, 2011).

3. Territory Summary Report shows Prescriber Roster information aggregated at a territory level

Territory Summary

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ABNEY, RAY C.	P	05302	6	10.7%	43	56	38
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DEVENDERRAO, T.	P	03060	7	9.6%	37	73	21

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1130. This information allowed the Defendants to track and identify instances of, overprescribing.[322] In fact, one of the Data Vendors' experts testified that a manufacturer of "narcotic analgesics" used the Data Vendors' information to track, identify, report and halt suspicious orders of controlled substances.[323]

[322] *See Sorrell v. IMS Health Inc.*, 2011 WL 1449043, *37-38 (March 24, 2011) (arguing that data had been used to . "identify overuse of antibiotics in children," and "whether there is a wide use of anthrax prophylactic medicines after the scares happened in 2001."). The Data Vender Respondents also cited evidence from the trial court proving that "because analysis of PI data makes it possible to 'identify overuse of a pharmaceutical in specific conditions, the government employs the data to monitor usage of controlled substances." *Id*.

[323] *Id*. at *38. Eugene "Mick" Kolassa testified as an expert on behalf of the Data Vender stating 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." *Id*; *see also* Joint Appendix in *Sorrell v. IMS Health*, 2011 WL 687134, at *204 (Feb. 22, 2011).

> [455] Q. Besides marketing and promotion, are there any other uses for prescriber-identifiable data?
>
> A. There's a number of other uses.
>
> Q. And what are those?
>
> A. The one that I was most impressed with was a firm that used it to identify – 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 and they would use that to notify the DEA and other authorities of potential problems.

1131. The Defendants were, therefore, collectively aware of the suspicious orders that flowed daily from their manufacturing and distribution facilities.

1132. The 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. The Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012[324] and 117 recommended decision 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.[325]

1133. Defendants' scheme had a decision-making structure driven by the Manufacturer Defendants and corroborated by the Distributor and Pharmacy Defendants. The Manufacturer

[324] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

[325] *Id.*

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.

1134. The Defendants worked together to control the flow of information and influence state and federal governments and political candidates to pass legislation that was pro-opioid. The Manufacturer and Distributor Defendants did this through their participation in the PCF and HDA.

1135. 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. The Defendants influenced the DEA production quotas in several ways.

1136. The scheme devised and implemented by the Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

1137. Manufacturers are the source of the prescription drugs in the pharmaceutical supply chain. The pharmaceutical manufacturing industry is composed of two distinct business models: manufacturers of brand-name drugs and manufacturers of generic drugs. Manufacturers manage the actual distribution of drugs from manufacturing facilities to drug wholesalers, and in some cases, directly to retail pharmacy chains, mail-order and specialty pharmacies, hospital chains, and some health plans. Manufacturers may also distribute products directly to government purchasers, such as the Veterans Administration. The Manufacturer Defendants

collected, tracked, and monitored extensive data concerning suspicious physicians and pharmacies through third-party organizations and through defendant distributors and defendant pharmacies in exchange for rebates or other consideration to better drive sales.

1138. With knowledge that Pharmacy Defendants and prescribing HCPs were facilitating diversion, the Manufacturer Defendants failed to report each instance of diversion to the DEA while rolling out marketing campaigns to churn its prescription opioid sales.

1139. Indeed, the Manufacturer Defendants withheld from the DEA information about suspicious orders—and induced Distributor Defendants and Pharmacy Defendants to do the same—to obfuscate the extent of the opioid epidemic. The Manufacturer Defendants knew that if they or the other defendants disclosed suspicious orders, the DEA would become aware that many opioids were being diverted to illegal channels, and would refuse to increase the production quotas for opioids.

1140. The impact of this failure to report suspicious sales in Ohio has been devastating. Former West Shore Family Practice doctor Ronald Celeste is just one example. On April 4, 2016, the Westlake, Ohio, internist was sentenced to three years for running a pill mill. He reportedly wrote 33,000 fraudulent prescriptions for OxyContin, Percocet, Valium, and other prescription pills.[326]

1141. Prior to that, David Kirkwood, 59, and Beverly Kirkwood, 47, pled guilty to conspiracy and distributing prescription pills and health care fraud. According to the indictment filed in Dayton U.S. District Court, Kirkwood charged $100 per office visit and "examined" 60 to 100 patients per day. The indictment states that the object of the conspiracy was "to make as much money as possible by distributing and dispensing controlled substances such as diazepam,

[326] Westlake doctor sentenced to prison for running 'pill mill,' Cleveland.com (April 5, 2016), available at http://www.cleveland.com/metro/index.ssf/2016/04/westlake_doctor_sentenced_to_p.html

carisoprodol, methadone, opana, hydrocodone, oxycodone, and alprazolam, to patients, other drug users, and conspirators."[327] The indictment alleges that the drug distributions by the Kirkwoods have resulted in numerous overdoses, and, in some cases, deaths to customers, including, but not limited to: Eula Hoskins, Deborah Goff, Ronald Jackson, Tyrone Redavide, Gregory Spurlock, Norma Shepherd, and Gary Durham. The drugs were allegedly dispensed in Ohio, Florida, Kentucky, Oklahoma, South Carolina, Tennessee, Texas and West Virginia.[328]

1142. A year earlier, a federal arrest warrant was issued for Dr. Syed Jawad Akhtar-Zaidi of Solon, Ohio, who had run the Pain Management of Northern Ohio clinic in Solon. Between 2011 and 2013, he allegedly illegally prescribed 1,131,920 dosage units of oxycodone and 217,897 dosage units of morphine.[329] Among the drugs prescribed to undercover DEA agents by Dr. Zaidi were 308 tablets of Percocet, 84 tablets of OxyContin 10 mg, and 126 tablets of OxyContin 15 mg for a claim by the first undercover officer of a nagging stiffness/discomfort in the officer's back during a four month period; 434 tablets of Percocet, 84 tablets of OxyContin 10 mg, and 84 tablets of OxyContin 15 mg to a second undercover officer who claimed a nagging stiffness/discomfort in the officer's back during a six month period; and 224 tablets of Vicodin and 224 tablets of Percocet to a third undercover officer who complained of a dull ache in the left knee during a four month period. In no case did any of the undercover officers ever claim unbearable pain, the undercover officers having reported the pain to be no more than a four on a pain scale of one to ten, with ten being the worst. Zaidi continued to prescribe Schedule II

[327] Indictment, *United States v. Kirkwood*, Crim. No. 3:14-cr-168 (Dec. 11, 2014).

[328] *Id.*

[329] *Id.*

and Schedule III pain medication drugs even though the undercover officers would report as low as two on the pain scale during many of their visits.[330]

1143. Other doctors practicing in Ohio and/or prescribing opioids to Ohio residents have been similarly arrested and arraigned for writing an egregiously high number of opioid prescriptions.

(a) Purdue Failed to Report Suspicious Sales as Required

1144. Purdue could have used the ARCOS data to identify diversion as required under federal law, to satisfy its duties of "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." *See* 21 U.S.C. 823(b)(1).

1145. Instead, Purdue utilized the data to understand which regions, and which HCPs, to encourage laser-focused targeting of promotions and marketing through its sales force to further increase sales. Purdue, referred to such overprescribing HCPs or doctors engaged in diversion as "whales."

1146. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Through its extensive network of sales representatives, Purdue had and continues to have knowledge of the prescribing practices of thousands of HCPs and could identify HCPs who displayed red flags for diversion such as those whose waiting rooms were overcrowded, whose parking lots had numerous out-of-state vehicles, and whose patients seemed young and healthy or homeless. Using this information, Purdue has since 2002 maintained a database of HCPs suspected of inappropriately prescribing its drugs.[331]

[330] *United States v. $506,069 Seized from First Merit Bank, et al.*, 1:14-cv-0023 (E.D. Ohio Jan. 6, 2014).

[331] *See* Scott Glover and Lisa Girion, *OxyContin maker closely guards its list of suspect doctors*, LOS ANGELES TIMES, (Aug. 11, 2013), http://articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811

1147. Rather than report these HCPs to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*,[332] Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers.

1148. Purdue was clearly aware of the obvious diversion – what its own district manager described internally as "an organized drug ring."[333] Despite its knowledge, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about [a pill mill] until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals."[334]

1149. But despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

1150. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services, said in a *Los Angeles Times* article, "Any drug company that has information about

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[332] *See* Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminal and addicts. What the drugmaker knew*, L. A. TIMES, (Jul. 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/

[333] *Id.*

[334] *Id.*

physicians potentially engaged in illegal prescribing or prescribing that is endangering people's lives has a responsibility to report it."[335]

1151. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015, Purdue's sales representatives, at various times, failed to timely report suspicious prescribing and continued to detail those prescribers even after they were placed on a "no-call" list.[336] Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

1152. Purdue is a "registrant" under the federal CSA, 21 C.F.R. §1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

1153. Purdue failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders.

1154. Purdue's failure to timely report these and other suspicious sales violated the CSA.

(b) Cephalon Failed to Report Suspicious Sales as Required

1155. Cephalon is a "registrant" under the federal CSA, 21 C.F.R. §1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

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[335] Glover and Girion, *supra* note 118. *See* Scott Glover and Lisa Girion, *OxyContin maker closely guards its list of suspect doctors*, L. A. TIMES, (Aug. 11, 2013), http://articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811

[336] *See* NY Purdue Settlement, at 6-7, *available at* https://www.seattle.gov/documents/departments/cityAttorney/opioidLitigation/NY-PurdueSettlement-August%202015.pdf.

1156. Cephalon failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders.

1157. The Cephalon's actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids.

(c) Janssen Failed to Report Suspicious Sales as Required

1158. Janssen is a "registrant" under the federal CSA, 21 C.F.R. §1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

1159. Janssen failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders.

1160. Janssen's failure to timely report these and other suspicious sales violated the CSA.

1161. Janssen's actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids.

(d) Endo Failed to Report Suspicious Sales as Required

1162. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY AG found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who

were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.[337]

1163. The NY AG's investigation further revealed that, in certain cases where Endo's sales representatives detailed prescribers who were convicted of illegal prescribing of opioids, those representatives could have recognized potential signs of diversion and reported those prescribers but failed to do so. Certain Endo sales representatives testified that "they did not know about any policy or duty to report problematic conduct observed in [HCPs'] offices, and did not report anyone, even when they saw suspicious behavior."[338]

1164. Endo is a "registrant" under the federal CSA, 21 C.F.R. §1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

1165. Endo failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders.

1166. Endo's failure to timely report these and other suspicious sales violated the CSA.

(e) Actavis Failed to Report Suspicious Sales as Required

1167. Actavis is a "registrant" under the federal CSA, 21 C.F.R. §1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section

[337] *See* New York State Office of the Attorney General, Press Release, *A.G. Schneiderman Announces Settlement With Endo Health Solutions Inc. & Endo Pharmaceuticals Inc. Over Marketing Of Prescription Opioid Drugs,* (March 3, 2016), https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals ; Attorney General of the State of New York, *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No.: 15-228 Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 (March 1, 2016), https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

[338] *Id.*

823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

1168. Actavis failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders.

1169. Actavis's actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids.

1170. Actavis's failure to timely report these and other suspicious sales violated the CSA,

(f) Insys Failed to Report Suspicious Sales as Required

1171. Insys is a "registrant" under the federal CSA, 21 C.F.R. §1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

1172. Insys failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders.

1173. Insys's failure to timely report these and other suspicious sales violated the CSA.

1174. The Insys Defendants' actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids.

(g) Mallinckrodt Failed to Report Suspicious Sales as Required

1175. In 2008, the DEA and federal prosecutors launched an investigation into Mallinckrodt, charging that the company ignored red flags and supplied – and failed to report suspicious orders for its generic oxycodone between 2008 and 2012.[339] The U.S. Attorney's office in Detroit, handled the case. The investigation uncovered that from 2008 to 2012, Mallinckrodt sent, for example, 500 million tablets of oxycodone into a single state, Florida – "66 percent of all oxycodone sold in the state."[340] According to the internal government documents obtained by the Washington Post, Mallinckrodt's failure to report could have resulted in "nearly 44,000 federal violations and exposed it to $2.3 billion in fines."[341]

1176. Despite learning from the DEA that generic opioids seized in a Tennessee drug operation were traceable to one of its Florida distributors, Sunrise Wholesale ("Sunrise") of Broward County, Mallinckrodt in the following six weeks sent 2.1 million tablets of oxycodone to Sunrise. In turn, Sunrise sent at least 92,400 oxycodone tablets to a single doctor over an 11-month period, who, in one day, prescribed 1,000 to a single patient.[342]

1177. On July 11, 2017, Manufacturer Defendant Mallinckrodt agreed to pay $35 million to the United States Department of Justice ("DOJ") to settle charges stemming from violations of certain provisions of the CSA, such as (1) 21 C.F.R. 1301.74(b) for failing to design and operate a system to disclose to the registrant suspicious orders of controlled substances and to inform the DEA Field Division office of such suspicious orders when discovered, (2) 21

[339] Lenny Bernstein & Scott Higham, *The government's struggle to hold opioid manufacturers accountable*, Wash. Post (Apr. 2, 2017), https://www.washingtonpost.com/graphics/ investigations/dea-mallinckrodt/?utm_ term=.7ce8c975dd86.

[340] *Id.*

[341] *Id.*

[342] *Id.*

C.F.R. 1301.71(a) for failing to provide effective controls and procedures to guard against theft and diversion of controlled substance.[343]

1178. As the DOJ Press Release highlights: "This is the first settlement of its magnitude with a manufacturer of pharmaceuticals resolving nationwide claims that the company did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic."[344]

1179. The Memorandum of Agreement entered into by Mallinckrodt ("2017 Mallinckrodt MOA") avers "[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."[345]

1180. With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's allegedly failed to distribute these controlled substances in a manner authorized by its registration and failed to operate an effective suspicious order monitoring system and failed to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:

a. conduct adequate due diligence of its customers;
b. detect and report to the DEA orders of unusual size and frequency;
c. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in

[343] U.S. Department of Justice, Press Release, *Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations,* (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

[344] *Id.*

[345] *See* Press Release, U.S. Dep't of Justice, *Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations* (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:

1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products; and
3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;

d. use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

e. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[346]

1181. Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007." Mallinckrodt further agreed that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and 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. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[347]

[346] 2017 Mallinckrodt MOA at p. 2-3.

[347] *Id*. at 3-4.

1182. 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." Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[348]

1183. The same duties imposed by federal law on Mallinckrodt were imposed upon all Defendants.

1184. The same business practices utilized by Mallinckrodt regarding "charge backs" and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including the other Distributor Defendants.

1185. Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007."[349]

1186. But Mallinckrodt chose to ignore such information and its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012. Federal prosecutors summarized the case by saying that Mallinckrodt's response was that everyone knew what was going on in Florida, but they had no duty to report it.

1187. According to documents obtained by the Washington Post, investigators also found "scores of alleged violations" at Mallinckrodt's plant in Hobart, New York. Those

[348] *Id.* at p.5.

[349] *Administrative Memorandum of Agreement* at 2–3 (July 7, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download.

violations included the failure to keep accurate records, to document transfers of drugs and to secure narcotics.[350]

1188. During the DEA's investigation, Mallinckrodt sponsored the HDA (known as the Healthcare Distribution Management Association ("HDMA") until 2016), an industry-funded organization that represents pharmaceutical distributors.[351] The HDA initiated the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (enacted April 19, 2016), which requires the DEA to give notice of violations and an opportunity to comply, to pharmacies and distributors, before withdrawing licenses. This Act substantially lessened the DEA's ability to regulate manufacturers and wholesalers.[352]

1189. In May 2014, Mallinckrodt posted a video titled "Red Flags: Pharmacists Anti-Abuse Video." The video is a thinly veiled attempt to divert responsibility for the opioid epidemic away from manufacturers and wholesalers, and toward individual pharmacists. The video was sponsored by the Anti-Diversion Industry Working Group, which is composed of Cardinal, Actavis, McKesson, Mallinckrodt, Amerisource, and Qualitest—all of whom are conveniently missing from the list of those responsible.[353]

1190. In addition to the significant monetary penalty, the DOJ settlement also included "a groundbreaking parallel agreement with the DEA, as a result of which the company will analyze data it collects on orders from customers down the supply chain to identify suspicious

[350] Lenny Bernstein & Scott Higham, *The government's struggle to hold opioid manufacturers accountable*, Wash. Post (Apr. 2, 2017), https://www.washingtonpost.com/graphics/ investigations/dea-mallinckrodt/?utm_term=.7 ce8c975dd86.

[351] Sponsors: HDA's Annual Circle Sponsors, Healthcare Distribution Alliance, https://www.healthcare distribution.org/hda-sponsors (last visited Oct. 5, 2017).

[352] Chris McGreal, Opioid epidemic: ex-DEA official says Congress is protecting drug makers, Guardian (Oct. 31, 2016, 9:26 EDT), https://www. theguardian.com/us-news/2016/oct/31/opioid-epidemic-dea-official-congress-big- pharma.

[353] Mallinckrodt Pharmaceuticals, Red Flags: Pharmacists Anti-Abuse Video, YouTube (May 27, 2014), https://www.youtube.com/watch?v=fdv0B210bEk&t=1s

sales. The resolution advances the DEA's position that controlled substance manufacturers need to go beyond 'know your customer' to use otherwise available company data to 'know your customer's customer' to protect these potentially dangerous pharmaceuticals from getting into the wrong hands."[354]

1191. Finally, the agreement settled charges stemming from allegations by the DOJ that Mallinckrodt was guilty of record-keeping violations at its manufacturing facility in upstate New York, which created discrepancies between the actual number of oxycodone tablets manufactured in a batch and the number of tablets Mallinckrodt reported on its records.[355]

1192. Mallinckrodt is a "registrant" under the federal CSA, 21 C.F.R. §1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

1193. Mallinckrodt failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders.

1194. Mallinckrodt's failure to timely report these and other suspicious sales violated the CSA.

(ii) Failure of the Distributor Defendants to Track and Report Suspicious Sales of the Opioid Drugs

1195. The Distributor Defendants purchase prescription opioids from the Manufacturer Defendants to distribute to a variety of customers, including Pharmacy Defendants (retail and

[354] *Id.*

[355] *Id.*

mail-order), hospitals, long-term care, and other medical facilities (e.g., community clinics, physician offices and diagnostic laboratories).

1196. The top three wholesale distributors, McKesson, Cardinal, and Amerisource, account for almost 90 percent of the entire wholesale drug market. This consolidation has forced the industry to change its revenue model, evolving its core distribution business into a low-margin enterprise that makes money by maximizing economies of scale, i.e. the more opioids they distribute the lower their margins.

1197. The Distributor Defendants utilize "just-in-time" delivery methods. In order to keep inventory and liability of pharmaceutical drugs as low as possible, most pharmacies receive drug deliveries from distributors every day of the week. This allows the pharmacy to hold as little inventory of pharmaceutical drugs on site as possible. In making just-in-time deliveries, sometimes multiple times a day to a single pharmacy, distributors know precisely how many opioid prescriptions and individual pills they are delivering to a specific pharmacy.

1198. The Distributor Defendants supplied the Manufacturer Defendants with distribution data in exchange for rebates or other consideration so the Manufacturer Defendants could better drive sales.

1199. The Distributor Defendants report the sale of all prescription opioids, including those to Pharmacy Defendants in Ohio, to the ARCOS database. The ARCOS database's purpose is to monitor the flow of DEA controlled substances from their point of manufacture through commercial distribution channels but does not include prescription or doctor data.

1200. The ARCOS database does not alert the DEA to the suspicious nature of a particular order. The DEA investigators regard the database as unwieldy because it encompassed

dozens of drugs sold by more than a thousand companies and is frequently six months out of date.

1201. Distributors are a crucial link in the closed system envisioned by Congress in enacting the CSA. Wholesale distributors are the closest link to pharmacies in the pharmaceutical supply chain, as such, they are best situated to determine whether a pharmacy is facilitating the diversion of prescription opioid pills.

1202. Industry compliance guidelines established by the HDMA, the trade association of pharmaceutical distributors, explain that distributors, including the Distributor Defendants, are "[a]t the center of a sophisticated supply chain" and, therefore, "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."

1203. The Distributor Defendants are a key link in the pharmaceutical supply chain, as they that have the power to determine that an order is not being diverted before filling suspicious orders— thereby preventing diversion before it can even occur.

1204. Reporting an order as suspicious will not absolve a distributor, including the Distributor Defendants, of responsibility if the registrant and distributor knew, or should have known, that the prescription opioids were being diverted. Indeed, reporting a suspicious order, then filling said order with knowledge it may be suspicious constitutes a failure to maintain effective controls against diversion under 21 U.S.C. §§ 823 and 824.

1205. Once the DEA started to enforce suspensions of registrations to distribute controlled substances, rather than comply, manufacturers and defendants spent at least $102 million to undermine the DEA's ability to do so.

1206. On February 19, 2014, acting at the behest of industry lobbyists, Representative Tom Marino introduced the "Ensuring Patient Access and Effective Drug Enforcement Act" as a supposed effort to define "imminent danger" in the 1970 act. A DEA memo noted that this bill would essentially destroy the agency's power to file an immediate suspension order of any suspicious drug shipments.

1207. This bill required that the DEA show the company's actions had shown "substantial likelihood of an immediate threat," whether in death, serious bodily harm or drug abuse before a suspension order can be sought. It also gave drug companies the ability to submit "corrective action" plans before any penalties could be issued. The law essentially makes it impossible for the DEA to halt any suspicious narcotic shipments before opioids are diverted to the illegal black market.

1208. Despite their duties to prevent diversion, the Distributor Defendants have knowingly or negligently allowed diversion.[356] The DEA has repeatedly taken action to attempt to force compliance, including 178 registrant actions between 2008 and 2012, 76 orders to show cause issued by the Office of Administrative Law Judges, and 41 actions involving immediate suspension orders.[357] The Distributor Defendants' wrongful conduct and inaction have resulted in numerous civil fines and other penalties.

[356] Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, WASH. POST, (Oct. 15, 2017),https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.eff03e845e7a; Lenny Bernstein, David S. Fallis, and Scott Higham, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* WASH. POST, (Oct. 22, 2016), https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegalusers-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html ?utm_term=.3076e67a1a28

[357] *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6, Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, (May 2014), https://oig.justice.gov/reports/2014/e1403.pdf.

1209. Specifically, the Distributor Defendants fraudulently concealed the existence of Plaintiff MMO's claims by affirmatively seeking to convince the public that their legal duties had been satisfied through public assurances that they were working to curb the opioid epidemic.

(a) Amerisource Failed to Track and Report Suspicious Sales of the Opioid Drugs

1210. Amerisource is a wholesale distributor of pharmaceuticals, including controlled substances and non-controlled prescription medications. It handles the distribution of approximately 20% of all pharmaceuticals sold and distributed in the U.S. through a network of 26 pharmaceutical distribution centers, including centers in Columbus and Lockbourne, Ohio.

1211. In 2007, Amerisource lost its license to send controlled substances from a distribution center in Florida amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies.

1212. Amerisource was again implicated for CSA violations in 2012 for failing to protect against diversion of controlled substances into non-medically necessary channels.

1213. In 2012, West Virginia sued Amerisource and Cardinal, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance. Unsealed court records from that case demonstrate that Amerisource, along with McKesson and Cardinal, together shipped 423 million pain pills to West Virginia between 2007 and 2012. Amerisource itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that time period. Moreover, public documents also demonstrate that that the average dose of each tablet distributed grew substantially during that time period. The Distributor Defendants, including Amerisource, shipped large quantities of oxycodone and hydrocodone tablets to the state. In 2016, Amerisource agreed to settle the West Virginia lawsuit by paying $16 million to the state,

with the funds set aside to fund drug treatment programs in order to respond to the opioid addiction crisis

(b) Cardinal Failed to Track and Report Suspicious Sales of the Opioid Drugs

1214. Cardinal is a significant distributor of opioids in the United States and has three pharmaceutical distribution centers located in Ohio including: 5532 Spellmire Drive, Cincinnati, OH 45246; 5260 Naiman Parkway Solon, OH 44139; and 2320 McGaw Road Obetz, OH 43207.

1215. As evidenced below, Cardinal has repeatedly ignored its responsibilities as a distributor under the CSA and federal law to prevent abuse and diversion of opioid medications. Cardinal has been the subject of numerous DEA Order to Show Cause and Immediate Suspension Orders, including:

- On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal facility in Auburn, Washington, for failure to maintain effective controls against diversion. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal facility in Lakeland, Florida, for failure to maintain effective controls against diversion.
- On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal facility in Swedesboro, New Jersey, for failure to maintain effective controls against diversion.
- On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal facility in Stafford, Texas, for failure to maintain effective controls against diversion.
- On February 2, 2012, the DEA issued another Order to Show Cause and Immediate Suspension Order against a Cardinal facility in Lakeland, Florida, for failure to maintain effective controls against diversion.

1216. Cardinal has also entered into several settlements, incurring small monetary penalties compared to its enormous profits derived from the excessive distribution of opioids,

including a 2008 agreement to pay $34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States.

1217. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states.

1218. In 2012, West Virginia sued Amerisource and Cardinal, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance. Unsealed court records from that case demonstrate that Amerisource, along with McKesson and Cardinal, together shipped 423 million pain pills to West Virginia between 2007 and 2012. Moreover, public documents also demonstrate that that the average dose of each tablet distributed grew substantially during that time period. The Distributor Defendants, including Cardinal, shipped large quantities of oxycodone and hydrocodone tablets to the state.

1219. Cardinal again reached a settlement agreement with the DOJ in December of 2016, paying a $44 million dollar penalty for similar violations of the CSA. In connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Wisconsin that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000 doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year.

1220. Cardinal, through an executive, falsely assured the public that its diversion controls were effective, claiming that it used "advanced analytics" to monitor the supply chain

and falsely represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

1221. In the settlement agreement, Cardinal admitted, accepted and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to: (a) "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)"; (b) "maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA's regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5)"; and (c) "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA Form 222 order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305."

1222. In the press release announcing the settlement agreement, U.S Attorney for the District of Maryland, Rod Rosenstein, stated: "Pharmaceutical suppliers violate the law when they fill unusually large or frequent orders for controlled substances without notifying the DEA … Abuse of pharmaceutical drugs is one of the top federal law enforcement priorities. Cases such as this one, as well as our $8 million settlement with CVS in February 2016, reflect the federal commitment to prevent the diversion of pharmaceutical drugs for illegal purposes."

1223. In another press release, DEA's Washington Division Special Agent-in-Charge, Karl Colder, further clarified that the settlement specifically concerned oxycodone: "[The] DEA is responsible for ensuring that all controlled substance transactions take place within DEA's regulatory closed system. All legitimate handlers of controlled substances must maintain strict accounting for all distributions and Cardinal failed to adhere to this policy … Oxycodone is a

very addictive drug and failure to report suspicious orders of oxycodone is a serious matter. The civil penalty levied against Cardinal should send a strong message that all handlers of controlled substances must perform due diligence to ensure the public safety …"

(c) McKesson Failed to Track and Report Suspicious Sales of the Opioid Drugs

1224. In May 2008, McKesson entered into a $13.25 million dollar settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the Country, resulting in millions of doses of controlled substances being diverted. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer.

1225. As a result, McKesson developed a Controlled Substance Monitoring Program ("CSMP") but nevertheless failed to design and implement an effective system to detect and report "suspicious orders" for controlled substances distributed to its independent and small chain pharmacy customers – *i.e.*, orders that are unusual in their frequency, size or other patterns. McKesson continued to fail to detect and disclose suspicious orders of controlled substances. 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.

1226. Despite the CSMP, a DEA investigation revealed that between 2008 and 2013, McKesson continued to fail to inform the DEA about a plethora of suspicious orders of

prescription opioids. In that time period, a single warehouse in Aurora, Colorado filled 1.6 million prescription orders and reported only .001% as suspicious.

1227. In 2012, West Virginia sued Amerisource and Cardinal, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance. Unsealed court records from that case demonstrate that Amerisource, along with McKesson and Cardinal, together shipped 423 million pain pills to West Virginia between 2007 and 2012. Amerisource itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that time period. Moreover, public documents also demonstrate that that the average dose of each tablet distributed grew substantially during that time period. The Distributor Defendants, including McKesson Amerisource, shipped large quantities of oxycodone and hydrocodone tablets to the state.

1228. As recently as December 17, 2017 facts continue to emerge regarding McKesson's misdeeds. According to both the Washington Post Article and "60 Minutes," McKesson's failures from 2008 to 2013 were so egregious that members of the DEA believed that it warranted a criminal case against the drug distribution company. Apparently, members of the DEA thought prison sentences for McKesson executives would be warranted.

1229. The DEA's Denver field division, in conjunction with a local law enforcement investigation into Platte Valley Pharmacy in Brighton, Colo., ascertained that the vast majority of pills prescribed at the Platte Valley Pharmacy originated at McKesson's warehouse in Aurora, CO. According to local law enforcement, a single pharmacist, Jeffrey Clawson, was selling as many as 2,000 opioids a day.

1230. None of the 16 suspicious orders that McKesson actually reported from 2008 to 2013 were related to the Platte Valley Pharmacy, or to Jeffrey Clawson.

1231. This was in spite of the fact that, from 2008-2011, the percentage increase for oxycodone 30 mg orders supplied by McKesson to Platte Valley Pharmacy was approximately 1,469%. Jeffrey Clawson was eventually indicted and convicted of drug trafficking charges and was given a 15 year prison sentence.

1232. McKesson eventually did report Jeffrey Clawson's suspicious orders, but only after he had already been convicted and the Platte Valley Pharmacy closed and was no longer a source of revenue.

1233. Like Cardinal, McKesson fraudulently concealed the existence of Plaintiff MMO's claims by affirmatively seeking to convince the public that their legal duties had been satisfied through public assurances that they were working to curb the opioid epidemic. McKesson stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claims that it is "deeply passionate about curbing the opioid epidemic in our country." Given each Distributor Defendant's sales volumes and history of violations, these false statements were made intentionally and fraudulently or recklessly without regard to the truth and as a positive assertion.

1234. In a recent 2017 Administrative Memorandum of Agreement between McKesson and the DEA, McKesson admitted that it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." McKesson was fined $150,000,000. McKesson further admitted that it failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by

sales to certain customers in violation of the CSA and its implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at McKesson distribution centers including its Washington Court House facility located in Ohio.

(d) Miami-Luken Failed to Track and Report Suspicious Sales of the Opioid Drugs

1235. On November 23, 2015, the DEA issued an Order to Show Cause to begin the process of revoking Miami-Luken's Certificate of DEA Registration.[358].

1236. In its revocation proceeding, the DEA has alleged that Miami-Luken failed to maintain effective controls against diversion of controlled substances and that the company failed to operate a system to disclose suspicious orders of controlled substances when it shipped controlled substances, particularly oxycodone and hydrocodone, to customers in southern Ohio, eastern Kentucky, and southern West Virginia.[359]

1237. In early 2016, Miami-Luken agreed to pay the state of West Virginia $2.5 million to resolve allegations that the company knowingly shipped opioids to West Virginia pharmacies without exercising sufficient monitoring or control.[360]

(iii) Failure of the Pharmacy Defendants to Report Diversion of the Opioid Drugs

1238. Pharmacies are the final step on the pharmaceutical supply chain before drugs reach the consumer/patient. Pharmacies purchase drugs from wholesalers, and occasionally directly from manufacturers, and then take physical possession of the drug products.

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[358] *DEA Suspends Orlando Branch of Drug Company from Distributing Controlled Substances*, DEA.GOV (Apr. 24, 2007), https://www.dea.gov/pubs/states/newsrel/mia042407.html.

[359] *See*, Letter from the U.S. House of Representatives Committee on Energy and Commerce (September 25, 2017), *available at* https://energycommerce.house.gov/wp-content/uploads/2017/09/2010925Miami_Luken.pdf.

[360] *W. Va. public safety, public health departments welcome $2.5 million drug settlement news,* West Virginia Department of Military Affairs and Public Safety, (Feb. 3, 2016), https://dmaps.wv.gov/News-Announcements/Pages/W.Va.-public-safety,-public-health-departments-welcome-$2.5-million-drug-settlement-news.aspx.

1239. Since they are the final point of sale for pharmaceuticals and the interface between the supply chain and the consumer, pharmacies generate the data that manufacturers as well as wholesale distributors rely upon to measure consumer activity for sales purposes.

1240. The Pharmacy Defendants had knowledge of not just the widespread public coverage of the prescription opioid epidemic, but also had industry-specific knowledge of the particular risks and harms from filling prescriptions for non-medical purposes and the resulting widespread opioid abuse.

1241. The DEA,[361] state pharmacy boards,[362] and national industry associations[363] have provided extensive guidance to pharmacists concerning their duties to the public. The guidance teaches pharmacists how to identify red flags, which indicate to the pharmacist that there may be a problem with the legitimacy of a prescription presented by a patient.[364] The guidance also tells pharmacists how to resolve the red flags and what to do if the red flags are unresolvable.

1242. For instance, the industry guidance tells pharmacists how to recognize (a) stolen prescription pads; (b) prescription pads printed using a legitimate doctor's name, but with a different call back number that is answered by an accomplice of the drug-seeker; (c)

[361] Michele Leonhart et al., *Pharmacist's Manual: An informational outline of the controlled substances act*, Drug Enf't Admin., Diversion Control Div. (Revised 2010), https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/.

[362] Tex. State Bd. Of Pharmacy, *Abuse & Misuse of Prescription Drugs* (last visited Aug. 11, 2017), https://www.pharmacy.texas.gov/SB144.asp; Fla. Bd. of Pharmacy, *DEA Guidelines to Prescription Fraud* (June 12, 2013), http://floridaspharmacy.gov/latest-news/dea-guidelines-to-prescription-fraud/; Va. Bd. of Pharmacy, *Prescription Drug Abuse: Red flags for pharmacists and pharmacy technicians* (Aug. 6, 2014), https://youtu.be/j5CkhirlZk8.

[363] Philip Brummond et al., *American Society of Health-Systems Pharmacists Guidelines on Preventing Diversion of Controlled Substances*, 74 Am. J. of Health-Sys. Pharmacy e10 (Jan. 2017), http://www.ajhp.org/content/early/2016/12/22/ajhp160919

[364] Va. Bd. of Pharmacy, *Prescription Drug Abuse: Red flags for pharmacists and pharmacy technicians* (Aug. 6, 2014), https://youtu.be/j5CkhirlZk8; Philip W. Brummond et al., *American Society of Health-Systems Pharmacists Guidelines on Preventing Diversion of Controlled Substances*, 74 Am. J. of Health-System Pharmacy e10 (Jan. 2017), http://www.ajhp.org/content/early/2016/12/22/ajhp160919.

prescriptions written using fictitious patient names and addresses; and (d) other similar red flags.[365]

1243. The Pharmacy Defendants, through their words or actions set forth in news reports and other public documents, have acknowledged these risks and assured the public that issues affecting public health and safety are their highest priority.

1244. In 2015, CVS publicly stated that, "the abuse of controlled substance pain medication is a nationwide epidemic that is exacting a devastating toll upon individuals, families and communities. Pharmacists have a legal obligation under State and Federal law to determine whether a controlled substance was issued for a legitimate purpose and to decline to fill prescriptions they have reason to believe were issued for a non-legitimate purpose."[366]

1245. Similarly, in 2016, Walgreens issued a press release captioned "Walgreens Leads Fight Against Prescription Drug Abuse with New Programs to Help Curb Misuse of Medications and the Rise in Overdose Deaths."[367]

1246. Despite knowing and even warning of these risks, the Pharmacy Defendants recklessly or negligently permitted diversion to occur. In failing to take adequate measures to prevent substantial opioid-related injuries to Plaintiff MMO, the Pharmacy Defendants have breached their common law duties under the "reasonable care" standard (including violating a voluntarily-undertaken duty to the public which they have assumed by their own words and

[365] Fla. Bd. of Pharmacy, *DEA Guidelines to Prescription Fraud* (June 12, 2013), http://floridaspharmacy.gov/latest-news/dea-guidelines-to-prescription-fraud/; Mass. Bd. of Registration in Med., Policy 15-05, *Prescribing Practices Policy and Guidelines* (Oct. 8, 2015), http://www.mass.gov/eohhs/docs/borim/policies- guidelines/policy-15-05.pdf.

[366] *Patients Profiled at Pharmacy Counters*, KTNV (Feb. 23, 2015), http://contact1846.rssing.com/chan-30860085/all_p11.html#item217.

[367] Press Release, Walgreens, Walgreens Leads Fight Against Prescription Drug Abuse with New Programs to Help Curb Misuse of Medications and the Rise in Overdose Deaths (Feb. 9, 2016), http://news.walgreens.com/press-releases/general-news/walgreens-leads-fight-against-prescription-drug-abuse-with-new-programs-to-help-curb-misuse-of-medications-and-the-rise-in-overdose- deaths.htm.

actions), professional duties under the relevant standards of professional practice, and requirements established state and federal laws and regulations.

1247. The Pharmacy Defendants were on notice of their ongoing negligence or reckless misconduct towards the Plaintiff MMO in part because of their history of being penalized for violating their duties and legal requirements.

1248. Pharmacies have the most accurate data on individual HCPs' prescribing habits. The Pharmacy Defendants provided the Manufacturer Defendants with prescribing data regarding individual HCPs in exchange for rebates, or other forms of consideration.

1249. The Pharmacy Defendants all participate in the pharmacy networks established by MMO's PBM, ESI, and as such had a duty to submit only non-fraudulent claims. The Pharmacy Defendants are members of ESI's pharmacy provider network pursuant to the Agreements. Under the terms of the Agreements, the Pharmacy Defendants all agreed to comply with the ESI provider's contract(s), including but not limited to Section 2.4 of the Network Provider Manual (requiring all information submitted to ESI to be "accurate and complete"), and Section 6.2 of the Network Provider Manual (prohibiting a Provider from "knowingly making a false claim").

1250. The Agreements also require the Defendants to identify "fraudulent prescription drug claims or any information in support thereof," and states the agreement is terminable if the Provider is in "violation of any applicable law, rule and/or regulation."

1251. Because Plaintiff MMO in turn is responsible for payment for all claims the Pharmacy Defendants have submitted for its health plan members, MMO relies on the Pharmacy Defendants to identify fraudulent claims and deter potential diversion.

1252. The Pharmacy Defendants' role in facilitating access to formulary drugs (i.e., access to drugs on MMO's formularies) for long-term opioid use—coupled with their failure to

prevent, monitor, identify, and report drug diversion—all contributed to a vast increase in opioid overuse and addiction. The Pharmacy Defendants' conduct thus directly contributed to the public-health crisis, increasing costs for excessive prescribing and addiction-related treatment costs for Plaintiff MMO.

1253. Most pharmacies purchase their drug supply from a wholesale distributor, although some retailers are large institutional and retail chain pharmacies that obtain drugs directly from a manufacturer. These organizations can deal directly with manufacturers because they already possess the operational infrastructure necessary to bypass wholesalers – warehousing facilities, distribution vehicles, and inventory control systems. Once a pharmacy takes possession of the drug products it distributes the products to physicians or directly to consumers.

1254. The Pharmacy Defendants' policies of speed over accuracy were negligent. Adopting performance metrics and quotas placed significant and unrealistic time pressures on pharmacists. Many Pharmacy Defendants required pharmacists to fill one prescription every three minutes or more than 600 prescriptions per work shift. All measurements focus on productivity with the end goal of maximizing the Pharmacy Defendants' profits. Meeting such unrealistic goals would violate the law regarding professional responsibilities and governing practice rules. To satisfy these increased productivity demands with decreased staffing required pharmacists employed by the Pharmacy Defendants to cut corners in their performance of due diligence obligations and violate their legal obligations under federal and state laws. The Pharmacy Defendants' high-volume-and-increased-profits business model also led to a greater number of errors in dispensing, which can result in significant harm to pharmacy customers.

1255. The Pharmacy Defendants failed to adequately train their pharmacists and pharmacy techs on how to properly and adequately handle prescriptions for opioids, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal.

1256. The Pharmacy Defendants failed to instruct their pharmacists and pharmacy techs on how to address situations in which they are forced to decline filling a prescription for a customer who submitted a prescription which a pharmacist has identified as suspicious.

1257. The Pharmacy Defendants have failed to train their pharmacists and pharmacy techs on how to properly exercise their judgment and intuition with respect to determinations about whether a prescription is one that should be filled, or whether, under the applicable laws, the pharmacist should refuse to fill it.

1258. The Pharmacy Defendants failed to adequately use data available to them to identify HCPs that were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids.

1259. The Pharmacy Defendants failed to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that contributed to the opioid crisis. The Pharmacy Defendants failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

1260. The Pharmacy Defendants failed to conduct internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly. The Pharmacy Defendants failed to have trained personnel monitoring media and journal publications regarding issues with all drugs being sold, including opioids.

1261. The Pharmacy Defendants failed to heed communications from government agencies, to the public and to MMOs specifically, and take action.

1262. The Pharmacy Defendants failed to effectively respond to concerns from raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

1263. The Pharmacy Defendants' own sales representatives, agents, employees, contractors, and other persons who rendered services in furtherance of selling more of the Pharmacy Defendants' drugs, raised a significant number of complaints, statements of concern, and observations of regarding suspicious prescriptions, which the Pharmacy Defendants failed to investigate, act upon, and in some cases even acknowledge or create records of.

1264. The Pharmacy Defendants knew, reasonably should have known, or, if they did not know, intentionally remained willfully blind to the fact of the media and journal attention published about the opioid epidemic. They intentionally remained willfully blind to the fact that pill diversion and pill mills were increasing at an alarming rate. And, the Pharmacy Defendants failed to act.

1265. The Pharmacy Defendants failed to track or observe increase in antidote sales, which would have triggered suspicion in a reasonable person or a reasonable sales representative that levels of prescription drug abuse were rampant. The Pharmacy Defendants failed to observe,

take notice of, and take into account, government communications to the public and to those involved in the opioid supply chain, such as the Pharmacy Defendants, and take action.

1266. The Pharmacy Defendants failed to track profit changes for opioids, which skyrocketed once the epidemic was truly underway and would have signaled to any reasonable person, pharmacist, or executive that a crisis involving narcotic drugs was underway.

1267. The Pharmacy Defendants in fact knew of massive sales and negotiated purchase contracts more favorable to them, which in turn create d further pressure on sales representatives.

1268. The Pharmacy Defendants knew that supply procedures had to change to address the ever increasing volume of drugs being sold—which was so patently obvious that it required an update to a larger physical storage space for the volume of pills being moved.

1269. The Pharmacy Defendants intentionally, maliciously, and repeatedly failed to investigate or act upon complaints, statements of concern and observations of employees.

1270. The Pharmacy Defendants clearly knew that an opioid epidemic existed as that they considered and/or implemented changes to their security procedures to address retail outlet concerns regarding customers who were, may have been, or had the potential to become addicts.

(a) CVS Failed to Track and Report Suspicious Sales of the Opioid Drugs

1271. CVS is a "registrant" under the federal CSA, 21 C.F.R. §1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section 823, in turn, requires pharmacies dispensing Schedule II controlled substances to register with the DEA.

1272. The Agreements also required CVS to identify "fraudulent prescription drug claims or any information in support thereof," and states the agreement is terminable if the Provider is in "violation of any applicable law, rule and/or regulation."

1273. Contrary to its duties as a registrant and under the Agreements, CVS adopted a performance metrics system it calls The Metrics System ("The Metrics") where pharmacists are directed to meet unobtainable prescription filling goals. If met, those goals would violate the law regarding professional responsibilities and governing practice rules. Due to The Metrics and other similar systems, pharmacists cannot meet their directives and are forced to decide whether they violate the law and regulations pharmacists must comply with, or attempt to meet company directives. Such directives that favor speed over accuracy result in dispensing errors, including errors in dispensing dangerous Opioid Drugs.

1274. CVS has been implicated in other Manufacturer Defendant settlements with the DEA including the 2011 Cardinal investigation "which…sent millions of doses of oxycodone to a small number of pharmacies in Florida, including two CVS stores in Sanford."[368]

1275. Furthermore, the Pharmacy Defendants, including CVS, have been subject to multiple DEA investigations regarding their failure to meet their obligations under the CSA as DEA registrants. For example, in 2013, CVS paid $11,000,000 in fines for violations of the CSA. According to the DEA press release: "The United States has alleged that from October 6, 2005 to October 5, 2011, CVS pharmacy retail stores violated the CSA and the record- keeping regulations by":

a. Creating, entering and maintaining invalid "dummy" DEA registration numbers or numbers other than the valid DEA registration number of the prescribing practitioner on dispensing records, which were at times provided to state prescription drug monitoring programs;
b. Filling prescriptions for certain prescribers whose DEA registration numbers were not current or valid; and

[368] Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA,* WASH. POST (Oct. 15, 2017), https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.6140a39686bd.

c. Entering and maintaining CVS dispensing records, including prescription vial labels, in which the DEA registration numbers of non-prescribing practitioners were substituted for the DEA registration numbers of the prescribing practitioners."

1276. CVS also entered into an $8 million dollar settlement with the DEA in 2016, "reflect[ing] the federal commitment to prevent the diversion of pharmaceutical drugs for illegal purposes."[369] According to the settlement agreement, CVS acknowledged that between 2008 and 2012 certain CVS pharmacy stores dispensed controlled substances, including oxycodone, fentanyl and hydrocodone, in a manner not fully consistent with their compliance obligations under the CSA and related regulations."[370] This included "failing to comply with a pharmacist's liability to ensure the controlled substance prescriptions were issued for a legitimate medical purpose."[371]

1277. CVS has had knowledge and/or notice of the opioid problem since at least 2002. At any time since CVS had knowledge and/or notice of the opioid problem it could have unilaterally taken steps to curtail and prevent expansion of the problem, but it failed to do so.

1278. Rather than act to curb the expansion of opioid use that CVS knew was occurring at a breathtaking pace, CVS chose not to undertake and/or failed to take action to induce internal consideration of any of the measures it was capable of taking.

1279. In addition to measures alleged above, CVS could and should have unilaterally taken action, and/or offered a program to TPPs, which had the effect of: (a) limiting to 7 days the supply of opioids dispensed for certain acute prescriptions; (b) reducing the dispensing of

[369] United States Attorney's Office District of Maryland, Press Release, *United States Reaches $8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances* (Feb. 12, 2016), https://www.justice.gov/usao-md/pr/united-states-reaches-8-million-settlement-agreement-cvs-unlawful-distribution-controlled

[370] *Id.*

[371] *Id.*

stronger and extended release opioids; (c) enhancing pharmacist counseling for new opioid patients; (d) limiting the daily dosage of opioids dispensed based on the strength of the opioid; and (e) requiring the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

1280. CVS could have and should have implemented these measures at any point in the last 15 years.

1281. CVS considered some of these measures prior to June 2017, but chose not to act on their implementation until September 2017.

1282. Having knowledge and/or notice of the damages that CVS' conduct had caused to Plaintiff MMO and others, CVS failed to take other steps to help curb the damages already incurred by Plaintiff MMO. Such steps CVS could have taken included, among other things: (a) donating medication disposal units to community police departments across the country to ensure unused opioid painkillers are disposed of properly rather than taken by individuals to whom the prescription was not written or otherwise diverted or abused; (b) implementing a program that consists of providing counseling to patients who are receiving an opioid prescription for the first time, such as by discussing the risks of dependence and addiction associated with opioid use and discussing and answering any questions or concerns such patients may have; and (c) running a public education campaigns in which CVS Pharmacists' Teach Program share facts about opioid abuse with students and parents.

(b) Walgreens Failed to Track and Report Suspicious Sales of the Opioid Drugs

1283. Walgreens is a "registrant" under the federal CSA, 21 C.F.R. §1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section

823, in turn, requires pharmacies dispensing Schedule II controlled substances to register with the DEA.

1284. The Agreements also required Walgreens to identify "fraudulent prescription drug claims or any information in support thereof," and states the agreement is terminable if the Provider is in "violation of any applicable law, rule and/or regulation."

1285. Contrary to its duties as a registrant and under the Agreements, in 2013, as a result of a multi-jurisdictional investigation by the DOJ, including the Eastern District of Michigan, Walgreens was fined $80 million for its violations of the CSA.

1286. According to the investigation Walgreens committed an unprecedented number of record-keeping and dispensing violations under the CSA. According to documents filed in the underlying administrative actions, Walgreens negligently all owed controlled substances listed in Schedules II – V of the Act, such as oxycodone and other prescription pain killers, to be diverted for abuse and illegal black market sales.

1287. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000)[372] and Massachusetts ($200,000).[373] The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of patients who were considered high-risk. Such patients are supposed to obtain all prescriptions from only one pharmacy, and that pharmacy is required to track the patient's pattern of prescription use. Some of the state's 160 Walgreens accepted cash for controlled substances from patients in

[372] Caleb Stewart, *Kroger, CVS, and Walgreens Settle Lawsuit with West Virginia for $3 Million*, WHSV (Aug. 16, 2016), http://www.whsv.com/content/news/Kroger-CVS-and-Walgreens-settle-lawsuit- with-West-Virginia-for-3-million-390332992.html.

[373] Felice J. Freyer, *Walgreens to Pay $200,000 Settlement for Lapses with Opioids*, The Boston Globe (Jan. 19, 2017),https://www.bostonglobe.com/metro/2017/01/18/walgreens-agrees-better-monitor-opioid-dispensing/q0B3FbMo2k3wPt4hvmTQrM/story.html.

MassHealth (the state's combined program for Medicaid and Children's Health Insurance), rather than seeking approval from the agency. In some cases, MassHealth had rejected the prescription; at other times, MassHealth was never billed. In response, Walgreens simply agreed to update its policies and procedures and train its staff to ensure that pharmacists properly monitor and not accept cash payments from patients deemed high-risk.

1288. On September 20, 2017, Walgreens announced that the pharmacy was launching its "#ItEndsWithUs" campaign to educate teens about the opioid epidemic. As part of that initiative, the company created a website that serves as an online "#ItEndsWithUs" hub and resource center aimed at disseminating the risks of opioid abuse, guides on how to properly dispose of unused opioids, and even testimonials from individuals who personally overcame opioid addictions.

1289. Additionally, the "#ItEndsWithUs" hub provides the locations of free-to-use medication-disposal kiosks where individuals can deposit their unused medication into a safe-box, the contents of which will be later disposed of in a safe and proper manner.

1290. In the wake of a recent $500,000 fine, Walgreens adopted a "good faith dispensing" policy that allows a pharmacist to refuse to dispense pain relievers if the pharmacist feels that the prescriber failed to write a prescription for a legitimate medical purpose.

1291. In a letter issued to prescribing physicians, Walgreens stated: "According to 21 C.F.R. 1306.04, pharmacists are required to ensure that prescriptions for controlled substances are issued for a legitimate medical purpose." The precise text of the regulation to which Walgreens' letter referred, in pertinent part, is as follows:

> The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued

> not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

1292. Walgreens also took additional steps to combat the opioid crisis, although such efforts were admittedly late in the game including launching a safe medication disposal program in which the company installed drug disposal kiosks in more than 500 Walgreens drugstores in states and Washington D.C., as well as eliminating the requirement persons present a prescription before being permitted to obtain the life-saving medication, Naloxone (in 35 states including Washington, D.C.). When a patient receives naloxone, Walgreens provides mandatory counseling on the risks of opioids, risk factors for and how to avoid overdose, how to identify and respond to an overdose, and how to use and administer Naloxone.

1293. In addition to measures alleged above, Walgreens could and should have unilaterally taken action that and/or offered a program to TPPs to accept that: (a) limited to 7 days the supply of opioids dispensed for certain acute prescriptions; (b) reduced the dispensing of stronger and extended release opioids; (c) enhanced pharmacist counseling for new opioid patients; (d) limited the daily dosage of opioids dispensed based on the strength of the opioid; and (e) required the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

1294. Having knowledge and/or notice of the damages that Walgreens conduct had caused to Plaintiff MMO and others, Walgreens failed to take other steps to help curb the damages already incurred by Plaintiff MMO due to Defendants, including Walgreens, could have: (a) donated medication disposal units to community police departments across the country

to ensure unused opioid painkillers are disposed of properly rather than taken by individuals to whom the prescription was not written or otherwise diverted or abused; (b) implemented a program that consists of providing counseling to patients who are receiving an opioid prescription for the first time, such as by discussing the risks of dependence and addiction associated with opioid use and discussing and answering any questions or concerns such patients may have; (c) ran public education campaigns in which Walgreens ran public education programs; (d) limited to 7 days the supply of opioids dispensed for certain acute prescriptions; (e) reduced the dispensing of stronger and extended release opioids; (f) enhanced pharmacist counseling for new opioid patients; (g) limited the daily dosage of opioids dispensed based on the strength of the opioid; and (h) required the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

1295. Walgreens could have and should have implemented these measures at any point in the last 15 years.

1296. And the failure to take such steps that Walgreens should have taken was negligent and did result in significant damages to Plaintiff MMO.

1297. Walgreens had knowledge and/or notice of the damages caused and continuing to be caused by its conduct and could and should have taken measures, including but not limited to those set forth herein, to curb opioid expansion of opioid use and to prevent or minimize the cascading damages caused by its wrongful conduct.

(c) Rite Aid Failed to Track and Report Suspicious Sales of the Opioid Drugs

1298. Rite Aid is a "registrant" under the federal CSA, 21 C.F.R. §1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section

823, in turn, requires pharmacies dispensing Schedule II controlled substances to register with the DEA.

1299. The Agreements also required Rite Aid to identify "fraudulent prescription drug claims or any information in support thereof," and states the agreement is terminable if the Provider is in "violation of any applicable law, rule and/or regulation."

1300. Contrary to its duties as a registrant and under the Agreements, in 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined $5 million in civil penalties for its violations of the CSA.

1301. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and federal regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated. Rite Aid failed to notify the DEA of losses of controlled substances in violation of 21 USC 842(a)(5) and 21 C.F.R 1301.76(b).

1302. In an effort to preserve good will, Rite Aid, in partnership with Albertsons announced in February 2017 that it was expanding access to naloxone, the opioid antagonist drug that is extremely effective at reversing the effects of an opioid overdose and saving the lives of those affected.

1303. In addition to measures alleged above, Rite Aid could and should have unilaterally taken action that and/or offered a program to TPPs to accept that: (a) limited to 7 days the supply of opioids dispensed for certain acute prescriptions; (b) reduced the dispensing of stronger and extended release opioids; (c) enhanced pharmacist counseling for new opioid patients; (d) limited the daily dosage of opioids dispensed based on the strength of the opioid;

and (e) required the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

1304. Having knowledge and/or notice of the damages that Rite Aid conduct had caused to Plaintiff MMO and others, Rite Aid failed to take other steps to help curb the damages already incurred by Plaintiff MMO due to Defendants, including Rite Aid, could have: (a) donated medication disposal units to community police departments across the country to ensure unused opioid painkillers are disposed of properly rather than taken by individuals to whom the prescription was not written or otherwise diverted or abused; (b) implemented a program that consists of providing counseling to patients who are receiving an opioid prescription for the first time, such as by discussing the risks of dependence and addiction associated with opioid use and discussing and answering any questions or concerns such patients may have; (c) run public education campaigns in which Rite Aids ran public education programs; (d) limited to 7 days the supply of opioids dispensed for certain acute prescriptions; (e) reduced the dispensing of stronger and extended release opioids; (f) enhanced pharmacist counseling for new opioid patients; (g) limited the daily dosage of opioids dispensed based on the strength of the opioid; and (h) required the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

1305. Rite Aid could have and should have implemented these measures at any point in the last 15 years.

1306. And the failure to take such steps that Rite Aid should have taken was negligent and did result in significant damages to Plaintiff MMO.

1307. Rite Aid had knowledge and/or notice of the damages caused and continuing to be caused by its conduct and could and should have taken measures, including but not limited to

those set forth herein, to curb opioid expansion of opioid use and to prevent or minimize the cascading damages caused by its wrongful conduct.

(d) Costco Failed to Track and Report Suspicious Sales of the Opioid Drugs

1308. Costco is a "registrant" under the federal CSA, 21 C.F.R. §1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section 823, in turn, requires pharmacies dispensing Schedule II controlled substances to register with the DEA.

1309. The Agreements also required Costco to identify "fraudulent prescription drug claims or any information in support thereof," and states the agreement is terminable if the Provider is in "violation of any applicable law, rule and/or regulation."

1310. Contrary to its duties as a registrant and under the Agreements, in 2017, Costco Wholesale was fined $11.75 million as a result of a multijurisdictional investigation by the DOJ relating to CSA violations.

1311. According to the investigation, Costco pharmacies filled prescriptions that were incomplete, lacked valid DEA registration numbers or were for substances beyond various doctors' scope of practice. Additionally, the settlement resolves allegations that Costco failed to keep and maintain accurate records for controlled substances at its pharmacies.

1312. Between January 1, 2012 and December 31, 2015, certain Costco pharmacies dispensed controlled substances inconsistent with their compliance obligations under the CSA and its implementing regulations. The violations include: filling prescriptions from practitioners who did not have a valid DEA number, incorrectly recording the practitioner's DEA number, filling prescriptions outside the scope of a practitioner's DEA registration, filling prescriptions that did not contain all the required information, failing to maintain accurate dispensing records,

and failing to maintain records for their central fill locations in Sacramento, California and Everett, Washington.

1313. According to U.S. Attorney Eileen M. Decker: "These are not just administrative or paperwork violations – Costco's failure to have proper controls in place in its pharmacies played a role in prescription drugs reaching the black market…."

1314. Furthermore, Costco could and should have unilaterally taken action that and/or offered a program to TPPs to accept that: (a) limited to 7 days the supply of opioids dispensed for certain acute prescriptions; (b) reduced the dispensing of stronger and extended release opioids; (c) enhanced pharmacist counseling for new opioid patients; (d) limited the daily dosage of opioids dispensed based on the strength of the opioid; and (e) required the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

1315. Having knowledge and/or notice of the damages that Costco's conduct had caused to Plaintiff MMO and others, Costco failed to take other steps to help curb the damages already incurred by Plaintiff MMO due to Defendants, including Costco, could have: (a) donated medication disposal units to community police departments across the country to ensure unused opioid painkillers are disposed of properly rather than taken by individuals to whom the prescription was not written or otherwise diverted or abused; (b) implemented a program that consists of providing counseling to patients who are receiving an opioid prescription for the first time, such as by discussing the risks of dependence and addiction associated with opioid use and discussing and answering any questions or concerns such patients may have; (c) run public education campaigns in which Costco ran public education programs; (d) limited to 7 days the supply of opioids dispensed for certain acute prescriptions; (e) reduced the dispensing of stronger and extended release opioids; (f) enhanced pharmacist counseling for new opioid patients; (g)

limited the daily dosage of opioids dispensed based on the strength of the opioid; and h) required the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

1316. Costco could have and should have implemented these measures at any point in the last 15 years.

1317. And the failure to take such steps that Costco should have taken was negligent and did result in significant damages to Plaintiff MMO.

(e) WalMart Failed to Track and Report Suspicious Sales of the Opioid Drugs

1318. WalMart is a "registrant" under the federal CSA, 21 C.F.R. §1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section 823, in turn, requires pharmacies dispensing Schedule II controlled substances to register with the DEA.

1319. The Agreements also required WalMart to identify "fraudulent prescription drug claims or any information in support thereof," and states the agreement is terminable if the Provider is in "violation of any applicable law, rule and/or regulation."

1320. Other Pharmacy Defendants, including WalMart, have engaged in similar conduct in violation of their responsibilities to prevent diversion.

1321. In 2009, WalMart paid $637,000 to resolve allegations of numerous record keeping violations at its pharmacies in Texas. Those allegations included that WalMart had failed to timely file records indicating loss or theft of drugs to the DEA, in violation of the CSA.[374]

[374] *See generally* Emma Perez-Trevino, *WalMart Fined for Alleged Recording Keeping Violations*, Brownsville Herald, Jan. 7, 2009, *Walmart Fined for Pharmacy Record-Keeping Violations*, Ozarks First, Jan. 7, 2009, http://www.ozarksfirst.com/news/health-and-medical/walmart-fined-for-pharmacy-record-keeping-violations.

1322. WalMart's actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of Opioid Drugs.

1323. Furthermore, WalMart could and should have unilaterally taken action that and/or offered a program to TPPs to accept that: (a) limited to 7 days the supply of opioids dispensed for certain acute prescriptions; (b) reduced the dispensing of stronger and extended release opioids; (c) enhanced pharmacist counseling for new opioid patients; (d) limited the daily dosage of opioids dispensed based on the strength of the opioid; and (e) required the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

1324. Having knowledge and/or notice of the damages that WalMart's conduct had caused to Plaintiff MMO and others, WalMart failed to take other steps to help curb the damages already incurred by Plaintiff MMO due to Defendants, including WalMart, could have: (a) donated medication disposal units to community police departments across the country to ensure unused opioid painkillers are disposed of properly rather than taken by individuals to whom the prescription was not written or otherwise diverted or abused; (b) implemented a program that consists of providing counseling to patients who are receiving an opioid prescription for the first time, such as by discussing the risks of dependence and addiction associated with opioid use and discussing and answering any questions or concerns such patients may have; (c) run public education campaigns in which WalMart ran public education programs; (d) limited to 7 days the supply of opioids dispensed for certain acute prescriptions; (e) reduced the dispensing of stronger and extended release opioids; (f) enhanced pharmacist counseling for new opioid patients; (g) limited the daily dosage of opioids dispensed based on the strength of the opioid; and h) required

the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

1325. WalMart could have and should have implemented these measures at any point in the last 15 years.

1326. And the failure to take such steps that WalMart should have taken was negligent and upon information and belief, did result in significant damages to Plaintiff MMO.

(f) Linden Care Failed to Track and Report Suspicious Sales of the Opioid Drugs

1327. Linden Care is a "registrant" under the federal CSA, 21 C.F.R. §1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section 823, in turn, requires pharmacies dispensing Schedule II controlled substances to register with the DEA.

1328. Linden Care was formed in New York in 2006 to provide concierge pharmacy services. It has specialized in filling, dispensing, and shipping pain medications including Opioid Drugs throughout the country via mail/commercial shipping services, most of which related to treatment of chronic disease and pain management.

1329. In essence, Linden Care was engaged in the practice of mail order pharmacology, by and through its agents and employees, who were obligated to use professional skill, knowledge and care from their education, training and standards.

1330. At all times relevant to the First Amended Complaint, Linden Care ignored and subverted its legal duties in dispensing fentanyl spray and other Opioid Drugs and was willfully blind and reckless in the manner in which it operated.

1331. The Insys scheme to profit by marketing and promoting Subsys included one other player: a pharmacy willing to dispense such large amounts of the medication and look the

other way. Linden Care, a New York pharmacy specializing in supplying opioids and pain medicine, was just the pharmacy. It turned a blind eye to what Insys was doing and shipped Subsys to patients throughout the United States and in Ohio. Linden Care filled approximately 50% of the sales of Subsys in the United States and in Ohio.

(g) The PSAO Defendants Failed to Track and Report Suspicious Sales of the Opioid Drugs

1332. To address independent pharmacies' need for assistance with TPP interactions, both existing entities—such as drug wholesalers—as well as new entities began providing a variety of administrative services to independent pharmacies. These administrative services included managing independent pharmacies' submission of claims to and receipt of payments from TPPs like MMO. Entities that provide administrative services to independent pharmacies to assist them in interacting with TPPs are called pharmacy services administrative organizations ("PSAO").[375]

1333. PSAOs develop networks of independent pharmacies by signing contractual agreements with them. These agreements set forth the duties and obligations of the PSAO to each independent pharmacy and vice versa, and generally authorize PSAOs to interact with TPPs on behalf of the independent pharmacies in their network. Among the responsibilities established between the PSAO and the independent pharmacy, the PSAO is frequently given the responsibility to contract on behalf of the pharmacy with TPPs.

1334. The three large wholesalers own the three largest PSAOs in the United States: Amerisource owns Elevate Health Network (4,500 independent pharmacies), Cardinal owns

[375] *See generally* GAO Report, PRESCRIPTION DRUGS: The Number, Role, and Ownership of Pharmacy Services Administrative Organizations, GAO-13-176 (January 2013).

Cardinal LeaderNET (5,600 independent pharmacies), and McKesson owns AccessHealth (5,900independent pharmacies).

1335. Each has failed to track and report suspicious sales of the Opioid Drugs.

(1) Elevate Provider Network Failed to Track and Report Suspicious Sales of the Opioid Drugs

1336. At all times material hereto, MMO has had regular (either directly or through its contracted PBM) interaction with Amerisource through its wholly owned Elevate Provider Network and its associated Good Neighbor Network (together herein "Elevate").

1337. Elevate is a PSAO. It performs a variety of administrative services including, for example, managing independent pharmacies' submission of claims for payment and then distributing payments received from TPPs, including from MMO.

1338. Elevate has developed a network of 4,500 independent pharmacies throughout the nation and in Ohio by signing contractual agreements with independent pharmacies. These agreements set forth the duties and obligations of Elevate to each pharmacy and vice versa, and authorize Elevate to interact with TPPs on behalf of the network of independent pharmacies. Among the responsibilities established between Elevate and the independent pharmacies, Elevate has been given the responsibility to contract with TPPs.

1339. Elevate contracts nationwide and in Ohio to establish a pharmacy provider network pursuant to agreements with independent pharmacies. Under the Elevate agreement, Elevate agreed to solicit contracts with various employers, unions, insurance companies and other groups providing pharmaceutical benefits to participate in the managed care program on behalf of its members. Independent pharmacies agree to become part of the Elevate network, and obtain the benefit of being included in-network with various insurance providers.

1340. Elevate aggregates claims on behalf of the independent pharmacies, submits them for payment by the TPP, and then receives aggregated, single payments from a TPP on behalf of the independent pharmacies. Elevate then distributes individual payments to the independent pharmacies from the single payment made by the TPP.

1341. Elevate is a "registrant" under the federal CSA, 21 C.F.R. §1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section 823, in turn, requires pharmacies dispensing controlled substances to register with the DEA.

1342. Elevate, in turn, has entered into Agreements with ESI to be a participating pharmacy network that would be available to ESI's customers, including MMO. Under the terms of the Agreements with ESI, Elevate agreed to comply with the ESI provider's contract(s), including but not limited to Section 2.4 of the Network Provider Manual (requiring all information submitted to ESI to be "accurate and complete"), and Section 6.2 of the Network Provider Manual (prohibiting a Provider from "knowingly making a false claim").

1343. The Agreements also required Elevate to identify "fraudulent prescription drug claims or any information in support thereof," and states the agreement is terminable if the Provider is in "violation of any applicable law, rule and/or regulation."

1344. In its capacity as a PSAO, Elevate must comply with state and federal regulations related to the prescription and disbursement of drugs. This is particularly true for the Opioid Drugs that require the strict direction and guidance of a physician to prevent abuse.

1345. This wholly profit-driven business model made the complicated process of pharmaceutical claims administration and processing more efficient, but it failed to properly implement a system that was designed to protect the people who were in need of its services.

1346. Because Plaintiff MMO is responsible for payment of all claims that Elevate has submitted for reimbursement, MMO has relied on Elevate to identify fraudulent claims and deter potential diversion of the Opioid Drugs.

1347. At all times material hereto, Amerisource (and its subsidiary Elevate) failed to track and report suspicious sales, to identify fraudulent claims, and to deter potential diversion of the Opioid Drugs.

(2) Cardinal LeaderNET Failed to Track and Report Suspicious Sales of the Opioid Drugs

1348. At all times material hereto, MMO has had regular (either directly or through its contracted PBM) interaction with Cardinal through its wholly owned Cardinal LeaderNET.

1349. Cardinal LeaderNET is a PSAO. It performs a variety of administrative services including, for example, managing independent pharmacies' submission of claims for payment and then distributing payments received from TPPs, including from MMO.

1350. Cardinal LeaderNET has developed a network of 5,600 independent pharmacies throughout the nation and in Ohio by signing contractual agreements with independent pharmacies. These agreements set forth the duties and obligations of Cardinal LeaderNET to each pharmacy and vice versa, and authorize Cardinal LeaderNET to interact with TPPs on behalf of the network of independent pharmacies. Among the responsibilities established between Cardinal LeaderNET and the independent pharmacies, Cardinal LeaderNET has been given the responsibility to contract with TPPs.

1351. Cardinal LeaderNET contracts nationwide and in Ohio to establish a pharmacy provider network pursuant. Under the Cardinal Health Cardinal LeaderNET Agreement, Cardinal LeaderNET agreed to solicit contracts with various employers, unions, insurance companies and other groups providing pharmaceutical benefits to participate in the Leader Managed Care

Program on behalf of the independent pharmacies. The independent pharmacies agree to become part of AccessHealth's managed care program, and obtain the benefit of being included in-network with various insurance providers.

1352. Cardinal LeaderNET is a "registrant" under the federal CSA, 21 C.F.R. §1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section 823, in turn, requires pharmacies dispensing Schedule II controlled substances to register with the DEA.

1353. Cardinal LeaderNET aggregates claims on behalf of the independent pharmacies, submits them for payment by the TPP, and then receives aggregated, single payments from a TPP on behalf of the independent pharmacies. Cardinal LeaderNET then distributes individual payments to the independent pharmacies from the single payment made by the TPP.

1354. Cardinal LeaderNET in turn, has entered into Agreements with ESI to be a participating pharmacy network that would be available to ESI's customers, including MMO. Under the terms of its Agreements with ESI, Cardinal LeaderNET agreed to comply with the ESI provider's contract(s), including but not limited to Section 2.4 of the Network Provider Manual (requiring all information submitted to ESI to be "accurate and complete"), and Section 6.2 of the Network Provider Manual (prohibiting Provider from "knowingly making a false claim").

1355. The Agreements also required Cardinal LeaderNET to identify "fraudulent prescription drug claims or any information in support thereof," and states the agreement is terminable if the Provider is in "violation of any applicable law, rule and/or regulation."

1356. In its capacity as a PSAO, Cardinal LeaderNET must comply with state and federal regulations related to the prescription and disbursement of drugs. This is particularly true

for the Opioid Drugs that require the strict direction and guidance of a physician to prevent abuse.

1357. This wholly profit-driven business model made the complicated process of pharmaceutical claims administration and processing more efficient, but it failed to properly implement a system that was designed to protect the people who were in need of its services.

1358. Because Plaintiff MMO in turn is responsible for payment for all claims that Cardinal LeaderNET has submitted for reimbursement, MMO has relied on the Cardinal LeaderNET to identify fraudulent claims and deter potential diversion.

1359. At all times material hereto, Cardinal (and its subsidiary Cardinal LeaderNET) failed to track and report suspicious sales, to identify fraudulent claims, and to deter potential diversion of the Opioid Drugs.

(3) AccessHealth Failed to Track and Report Suspicious Sales of the Opioid Drugs

1360. At all times material hereto, MMO has had regular (either directly or through its contracted PBM) interaction with McKesson through its wholly owned AccessHealth.

1361. AccessHealth is a PSAO, and performs a variety of administrative services including, for example, managing independent pharmacies' submission of claims for payment and then distributing payments received from TPPs, including from MMO.

1362. AccessHealth has developed a network of 5,900 independent pharmacies throughout the nation and in Ohio by signing contractual agreements with independent pharmacies. These agreements set forth the duties and obligations of AccessHealth to each independent pharmacy and vice versa, and authorize AccessHealth to interact with TPPs on behalf of the network of independent pharmacies. Among the responsibilities established

between AccessHealth and the independent pharmacies, AccessHealth has been given the responsibility to contract with TPPs.

1363. AccessHealth contracts nationwide and in Ohio to establish a pharmacy provider network. Under the AccessHealth agreement with its community pharmacy participants, AccessHealth agreed to solicit contracts with various employers, unions, insurance companies and other groups providing pharmaceutical benefits to participate in the AccessHealth network on behalf of the independent pharmacies. The independent pharmacies agree to become part of AccessHealth's managed care program, and obtain the benefit of being included in-network with various insurance providers.

1364. AccessHealth is a "registrant" under the federal CSA, 21 C.F.R. §1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section 823, in turn, requires pharmacies dispensing Schedule II controlled substances to register with the DEA.

1365. AccessHealth holds itself out as an "expert third-party contracting" service provider, helping members "increase revenue, save time and eliminate hassles through centralized third-party contracting, consolidated reimbursements, electronic funds transfers, audit-assistance services, and a call center that contacts PBMs on our members' behalf."

1366. This wholly profit-driven business model made the complicated process of pharmaceutical claims administration and processing more efficient, but it failed to properly implement a system that was designed to protect the people who were in need of its services.

1367. AccessHealth contracts nationwide and in Ohio to establish a pharmacy provider network pursuant to the Agreements. AccessHealth holds over 9,000 contracts with more than 40 pharmacy benefit managers, including all major third parties, Blue Cross and Blue Shield plans,

and HMOs and maintained preferred status in 56 Medicare Part D Medicare Advantage Prescription Drug ("MAPD") plans and Prescription Drug Plans ("PDPs") across the country.

1368. AccessHealth aggregates claims on behalf of the independent pharmacies, submits them for payment by the TPP, and then receives aggregated, single payments from a TPP on behalf of the independent pharmacies. AccessHealth then distributes individual payments to the independent pharmacies from the single payment made by the TPP.

1369. In its capacity as a PSAO, AccessHealth must comply with state and federal regulations related to the prescription and disbursement of drugs. This is particularly true for Opioid Drugs that require the strict direction and guidance of a physician to prevent abuse.

1370. AccessHealth in turn, has entered into Agreements with ESI to be a participating pharmacy network that would be available to ESI's customers, including MMO. Under the terms of the Agreements with ESI, AccessHealth agreed to comply with the ESI provider's contract(s), including but not limited to Section 2.4 of the Network Provider Manual (requiring all information submitted to ESI to be "accurate and complete"), and Section 6.2 of the Network Provider Manual (prohibiting a Provider from "knowingly making a false claim").

1371. The Agreements also required AccessHealth to identify "fraudulent prescription drug claims or any information in support thereof," and states the agreement is terminable if the Provider is in "violation of any applicable law, rule and/or regulation."

1372. Because Plaintiff MMO in turn is responsible for payment for all claims that AccessHealth has submitted for reimbursement, MMO has relied on the AccessHealth to identify fraudulent claims and deter potential diversion of Opioid Drugs.

1373. At all times material hereto, McKesson and its subsidiary AccessHealth failed to track and report suspicious sales, to identify fraudulent claims, and to deter potential diversion of the Opioid Drugs.

VI. CONSPIRACY IN VIOLATION OF FEDERAL RICO LAW AND OHIO CORRUPT PRACTICES ACT

1374. The Defendants have engaged in multiple conspiracies to artificially and unlawfully broaden the market for their Opioid Drugs. Defendants' entered agreements to conspire (a) among Defendants themselves, in a deceptive marketing campaign, (b) between Defendants and their co-promoters, and (c) between Defendants and their third party marketers and promoters, which as alleged in this First Amended Complaint include physician thought leaders, KOLs, medical ghost writers, medical marketing firms, digital marketers, and Front Groups.

1375. The Defendants' conspiracy injured Plaintiff MMO by the commission of overt acts in furtherance of the conspiracy, involving activity directed toward Plaintiff MMO, which actually and proximately caused Plaintiff MMO injuries in paying for excessive prescriptions of Opioid Drugs and paying for prescriptions of Opioid Drugs diverted into the black market.

1376. The Defendants knew but ignored that the campaign's foundation was built on deception; and that to succeed, Defendants' synchronized marketing strategies needed to specifically target pain physicians and other health care providers with the false message that their Opioid Drugs were not addictive.

1377. The Defendants, acting in concert, entered into agreements with, utilized and compensated third parties, comprising, for example, HCPs, medical societies, and marketing and media firms. Ostensibly engaged in raising public awareness about underdiagnosed and undertreated problems related to chronic pain, these third parties were paid to promote a view of

treatment of pain as a particular condition, which was widespread, serious, and treatable with the Opioid Drugs. Defendants knew that these unregulated "disease awareness" campaigns are commonly linked to companies' marketing strategies, they operate to expand markets and increase prescribing.

1378. One of the Defendants' unified goals was to create the impression that the treatment of pain was a vastly underdiagnosed but prevalent condition. Defendants cooperatively agreed and worked to inflate the treatment of pain prevalence numbers by grossly understating the Opioids epidemic.

1379. The Defendants acted in concert to implement their pain awareness basic strategies: (1) lower the bar for diagnosis (turning chronic pain into a treatable condition), (2) raise the stakes, so that people want to get treated, and (3) spin the evidence about Opioid Drug benefits and harms.

1380. The Defendants acted in concert in communications to Plaintiff MMO, physicians and patients who reasonably and justifiably relied on Defendants' misrepresentations that chronic pain was treatable with Opioid Drugs, yet were not informed that scant evidence exists from randomized trials as to the safety and efficacy of these drugs.

1381. The Defendants acted in concert in using deception not just in their message, but in their messengers, often funding the same KOLs to legitimize misleading promotion.

1382. Although these KOLs may have been relatively neutral in tone and did not mention specific products, none were skeptical, none questioned the reliability of the data on which claims were being made, and none included the views of clinicians who dissented from the emerging paradigm about treatment of chronic pain with Opioid Drugs.

1383. As alleged in this First Amended Complaint, which allegations are incorporated herein, Defendants at various times conspired with co-marketing partners, individuals, marketing companies and others to implement Defendants' conspiratorial unbranded marketing campaign whose supposed mission was to advocate for and educate consumers about health and pain management issues.

1384. Organizations such as such as the APF, the AAPM, the PCF and others conspired with the Defendants in their ubiquitous campaign. The APF described itself as one of the nation's largest advocacy group for pain patients. At the heart of its messaging, created in coordination and often times coming directly from the Defendants, was that the risk of opioid addiction was overblown and opioids were underused as a treatment for pain, which often appeared in Defendants' promotional materials.

1385. The Manufacturer Defendants contributed millions of dollars in funding to APF until the organization immediately shut down on May 8, 2012, the same day the U.S. Senate Finance Committee sent a letter to APF inquiring about its ties to drug manufacturers. Likewise, AAPM who also received substantial funding from Defendants issued guidelines, statements, CMEs, and other publications that repeatedly claimed that the risk of opioid addiction in people taking prescription Opioid Drugs was low, inventing and promoting the pseudoscience of "pseudoaddiction" (the idea that opioid-seeking patients are not actually addicted to opioids but are "undertreated" – requiring higher doses of opioids). In 2009, the APS, jointly with the AAPM, issued guidelines promoting Opioid Drugs to treat chronic pain, concluding that the risk of addiction was manageable in patients regardless of prior histories of abuse. The majority of the panel members drafting the APS/AAPM guidelines received substantial funding and had substantial ties with the Manufacturer Defendants.

1386. The Manufacturer and Distributor Defendants also funded and utilized organizations, such as the HDA, to effectively lobby against DEA enforcement actions and coordinate a fraudulent scheme to profit from unlawful sales of diverted Opioid Drugs.

1387. The Manufacturer Defendants frequently gave institutions hundreds of thousands of dollars over the years styled as "unrestricted educational grants," but the true purpose was to sully the scientific literature with Defendants' false marketing messages about the low risk of addiction and the effectiveness of Opioid Drugs for chronic pain – and to ultimately increase Opioid Drug prescriptions and profits. The Manufacturer Defendants regularly awarded the requested grant amount, and often made additional payments to KOLs in connection with the grants.

1388. The Manufacturer and Distributor Defendants utilized these "non-profit" organizations as middlemen to further their mutual interests and expand the disease market.

1389. As alleged in this First Amended Complaint, the Defendants conspired in a fraudulent and unlawful marketing scheme to cause increased prescribing and concealment of Opioid Drug diversion to further expand the market and increase prescriptions and MMO payments for their Opioid Drugs. As the entity directly reimbursing the cost of Opioid Drug prescriptions for its members, Plaintiff MMO was the primary and intended victim of Defendants' conspiracy.

1390. The Defendants and their co-conspirators knew that their marketing and promotion was deceptive and their concealment of drug diversion was fraudulent, and knowingly agreed to facilitate, and cooperate with, the activities of their co-conspirators. The Defendants' conspiracy injured MMO by the commission of overt acts in furtherance of the conspiracy, involving activity directed toward Plaintiff MMO, which actually and proximately caused

Plaintiff MMO injuries in paying for excessive prescriptions of Opioid Drugs and related medical services.

1391. As described and alleged in this First Amended Complaint, the common deceptive marketing strategy and diversion concealment employed by Defendants and the members of their various Enterprises created an explosion in the prescribing of the Opioid Drugs by artificially creating the perception that the Opioid Drugs were effective and safe for chronic pain.

1392. By virtue of agreements with the members of their respective enterprises as alleged in this First Amended Complaint, Defendants entered into conspiracies to artificially and unlawfully expand the market for Opioid Drugs (the "Enterprise Conspiracies").

1393. The systematic linkages and interrelationships between and among the physicians, KOLs, Front Groups, vendors, third parties and Defendants all were established for a common and conspiratorial purpose: to aid in deceptively marketing and conceal the known diversion of the Opioid Drugs to increase profits. Each participant of the respective Enterprise Conspiracies —physicians, KOLs, medical marketing firms, third party vendors, Front Groups, Manufacturer, Distributor, and Pharmacy Defendants — received substantial revenue from the scheme to promote and conceal the diversion of the Opioid Drugs. Such revenue was exponentially greater than it would have been if the Opioid Drugs had been marketed and distributed appropriately. All participants were aware of the Defendants' control over the content of the presentations, speeches, promotional events, and articles that involve the marketing of the Opioid Drugs. And all participants were aware of the Defendants' control and directives in the exchange of information and lobbying efforts and turned a blind eye to suspicious ordering and maintaining effective controls, to conceal Opioid Drug diversion. Furthermore, each portion of the Enterprises benefited from the existence of other parts. For example, the Science Literature

Marketing and Consumer Pull-Through Marketing Enterprises provided literature and advertising which lent an air of academic legitimacy and buttressed the claims being made by the promotion and detailing of the Physician Pull-Through Marketing Enterprise. And, the Physician Pull-Through Marketing Enterprise generated direct contacts with the medical and healthcare community and Plaintiff MMO to spread the word regarding the Opioid Drugs, which provided other Enterprises with greater interest in their work. Likewise, the Drug Diversion Concealment Enterprise bolstered other Enterprises by disguising the true and actual medical need for Opioid Drugs and further supporting the Defendants' misleading and coordinated messages that chronic pain is drastically under treated and Opioid Drugs are safe and effective for the same. Standing alone and together these Enterprises then provided support and credibility for the crucial Formulary Enterprise which targeted Plaintiff MMO, because formulary access and coverage for Opioid Drugs was essential to every other Enterprise and vital to Opioid Drugs' success.

1394. This common fraudulent purpose was effectuated through this broad network of Manufacturer Defendants, Front Groups, vendors, physicians, KOLs, Pharmacy Defendants and Distributors Defendants. That network was held together by the funneling of funds through and to the Enterprise participants, the content controlled by Defendants, which made up the Enterprise Conspiracies that furthered the fraudulent marketing scheme.

1395. Plaintiff MMO has been injured in its property by reason of the various Enterprise Conspiracies, and has paid millions of dollars in payments for the Opioid Drugs that it would not have made had Defendants not engaged in the Enterprise Conspiracies.

VII. INJURY

1396. The Defendants, collectively, and each of them, agreed with one another by words, deeds, and consciously parallel actions to commit the wrongs alleged herein. Both circumstantial and limited direct evidence of such as meetings, common tactics, and shared

motivations support the finding of an actionable implied agreement. As set forth herein, Plaintiff MMO suffered injury as a result of Defendants' agreements and concerted efforts.

1397. Plaintiff MMO, an entity that provides prescription drug benefits to their insured patients and that reimburses all or a portion of the cost of Opioid Drugs – was directly harmed and suffered an economic loss as a result of Defendants' multi-layered and inter-connected schemes which have led to a significant increase in opioid prescriptions and in turn, a significant increase in opioid addiction.

1398. When listed on the formulary, Plaintiff MMO reimburses approximately 75%-90% of the cost of Opioid Drugs. Thus, garnering favorable access to Plaintiff MMO's formularies was integral to the success of Defendants' unlawful marketing and diversion concealment campaigns, and as one of the primary payers for Opioid Drug prescriptions, MMO suffered a direct economic loss. According to MMO internal documents, with hundreds of thousands of claims being submitted to MMO and payments reaching tens of millions of dollars. The startling increase in Opioid Drug prescriptions and sales correlates directly to the Defendants' physician pull-through efforts as well as through consumer marketing, deceptive science, and diversion scheme timelines.

1399. The Defendants and their Enterprises were designed to cause, and did cause, Plaintiff MMO to pay for excessive Opioid Drug prescriptions to treat conditions for which the drugs are not FDA-approved, for which there was no reliable scientific evidence that they were safe or effective. On top of this, there was reliable evidence (and Defendants were fully aware) that Opioid Drugs have a high risk of addiction and were not safe for long-term use in non-cancer pain, and Defendants acting in concert and separately concealed this information from the public and from Plaintiff MMO. Even worse, the Defendants not only had ready access to data

and information to expose suspicious ordering and identify excessive quantities of opioids entering the community, they orchestrated a plan to work together to conceal this information from the DEA, governmental officials, the public and Plaintiff MMO to prevent them from discovering the causes of action asserted herein. Patients, including those whose prescription drug charges were paid by Plaintiff MMO, and who were prescribed Opioid Drugs for non-indicated and unsafe uses, received no therapeutic benefit and were subject to life threatening side effects. Likewise, Plaintiff MMO paid for worthless Opioid Drug prescriptions, many of which were diverted to the black market. Absent Defendants' jointly and coordinated conduct, Plaintiff MMO would not have paid for the Opioid Drugs.

1400. The Defendants' deceptive and misleading marketing schemes and blatant disregard for CSA and related federal regulations drastically increased the number of prescriptions and distribution of Opioid Drugs written and filled. Because the Manufacturer Defendants withheld material information about the true safety and efficacy, and manipulated medical literature leaving a whirlwind of flat out false propaganda regarding the risks of addiction associated with Opioid Drugs, the prescribing physicians did not have the knowledge necessary to make informed decisions regarding Opioid Drug prescriptions. Plaintiff MMO, unaware of Defendants' schemes, paid for these prescriptions. The Manufacturer Defendants' promotion and marketing of Opioid Drugs safety and effectiveness has been highly successful, resulting in Defendants receiving unprecedented billions of dollars in profits, representing ill-gotten gains to which Defendants were not entitled and leaving a ravaged, opioid-addicted population in its wake.

1401. Plaintiff MMO reasonably and justifiably relied on the Defendants and their co-conspirators to comply with CSA regulations and to provide truthful, scientifically-based and

clinically relevant information when deciding to include Opioid Drugs on its formularies or to provide coverage for payment of Opioid Drug prescriptions. Ultimately, Plaintiff MMO has shouldered the responsibility of paying for the Opioid Drug prescriptions, the costs of monitoring and processing excessive use of Opioid Drugs fueled by Defendants schemes, associated medical claims and costs, and the inevitable costs of addiction treatment facilities and associated medication that follows.

1402. These costs are not limited to drug users. The over-prescription of Opioid Drugs has also had a significant impact on children. Children of all ages have access to prescriptions in their homes and ingest them either accidentally or recreationally. Babies are born addicted to opioids, children are neglected when their parents spiral into addiction, which often results in behavioral and mental health issues requiring treatment.

1403. The impact of the Drug Diversion Concealment Enterprise has been particularly devastating. Ohio has the 12th highest opioid prescription rate in the county, with approximately 100.1 opioid prescriptions written for every 100 persons in Ohio.[376] Although the number of pills dispensed in Ohio slightly decreased from the peak number of 793 million doses of opioids to 631 million doses (an approximately 20% decrease), the total number of pills dispensed in Ohio between 2011 and 2016 is staggering. As reported by the Ohio Department of Health, there were over 4.4 billion solid doses (excluding liquid doses) of prescription opioids dispensed in Ohio between 2011 and 2016.[377]

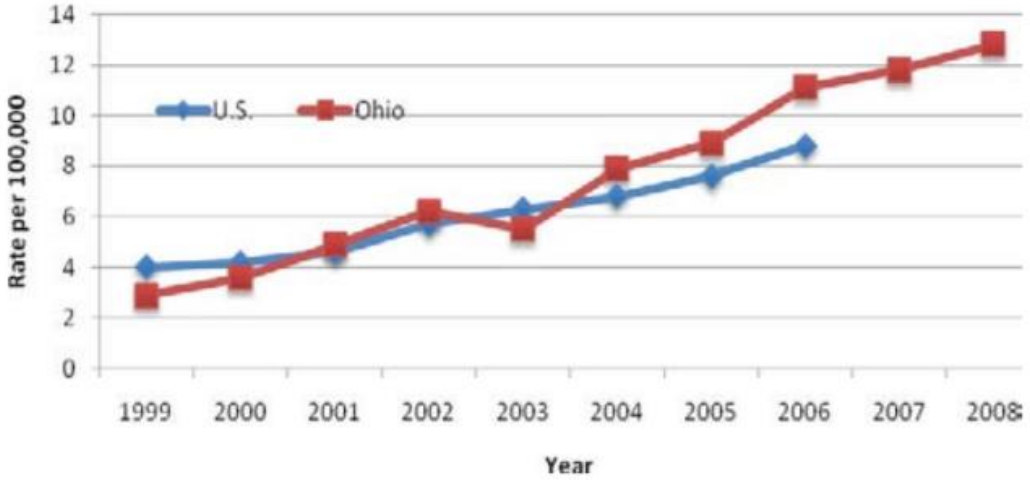
[376] *See* Leonard J. Paulozzi, M.D., *et al., Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines – United States, 2012*, Morbidity and Mortality Weekly Report, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (July 4, 2014). The combination of hydrocodone, oxycodone, and benzodiazepines is referred to as the "holy trinity" and significantly increases the risk of harm to those that abuse prescription pills.

[377] *2016 Ohio Drug Overdose Data: General Findings*; OHIO DEPARTMENT OF HEALTH, STATE OF OHIO BOARD OF PHARMACY, OHIO AUTOMATED RX REPORTING SYSTEM, https://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/2016-Ohio-Drug-Overdose-Report-FINAL.pdf (last visited on March 3, 2018).

1404. "Ohio's death rate has grown faster than the national rate."[378]

Ohio's death rate has grown faster than the national rate. In 1999, Ohio's unintentional drug overdose death rate was 2.9 per 100,000 compared to the national rate of 4.0 per 100,000 (Figure 1). In 2006, Ohio's unintentional drug poisoning death rate had risen to 11.1 per 100,000, compared to the national rate of 8.8 per 100,000. By 2008, Ohio's death rate rose to almost 13 per 100,000.[2]

Figure 1. Ohio[3] and U.S.[4] Unintentional Drug Overdose Death Rates per 100,000 Population, 1999-2006 (2008 for Ohio).



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1405. The death toll is staggering. From 2000 to 2015, Ohio's death rate due to unintentional drug poisonings increased 642 percent, driven largely by opioid-related overdoses.[380] In 2015, there were 3,050 Ohio overdose deaths, up 20.5 percent from 2,531 Ohio overdose deaths in 2014.[381] In 2016, there were over 4,000 overdose deaths.[382]

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[378] *Id.*

[379] *Id.*

[380] Prevalence and Trends in Unintentional Drug Overdose, OHIO DEPARTMENT OF HEALTH, https://www.odh.ohio.gov/health/vipp/drug/dpoison.aspx (last visited Sept. 15, 2017).

[381] *See* Governor's Cabinet Opiate Action Team, *available at* http://fightingopiateabuse.ohio.gov/ (last visited September 17, 2017).

[382] *2016 Ohio Drug Overdose Data: General Findings*; OHIO DEPARTMENT OF HEALTH, STATE OF OHIO BOARD OF PHARMACY, OHIO AUTOMATED RX REPORTING SYSTEM, https://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/2016-Ohio-Drug-Overdose-Report-FINAL.pdf (last visited on March 3, 2018).

Overview

Unintentional drug overdose continued to be the leading cause of injury-related death in Ohio in 2015, ahead of motor vehicle traffic crashes – a trend which began in 2007.

Unintentional drug overdoses caused the deaths of 3,050 Ohio residents in 2015,[1] the highest number on record, compared to 2,531 in 2014. The number of overdose deaths increased 20.5 percent from 2014 to 2015, which is similar to the increase from 2013 to 2014.

[383]

1406. Eighty-five percent of these overdoses involved opioids.[384] The problem is only getting worse: between 2015 and 2016, overdose deaths in Ohio rose by nearly 33 percent.[385] And the overall number of drug overdose deaths attributable to all opioids rose from 85% in 2015 to 86.3 percent in 2016.[386]

[383] *Id.*

[384] *Id.*

[385] *2016 Ohio Drug Overdose Data: General Findings*; OHIO DEPARTMENT OF HEALTH, STATE OF OHIO BOARD OF PHARMACY, OHIO AUTOMATED RX REPORTING SYSTEM, https://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/2016-Ohio-Drug-Overdose-Report-FINAL.pdf (last visited on March 3, 2018).

[386] *Id.*

Table 1. Number of Unintentional Drug Overdose Deaths Involving Specific Drug(s), As Mentioned on Death Certificate, by Year, 2004-2016 [1-3]

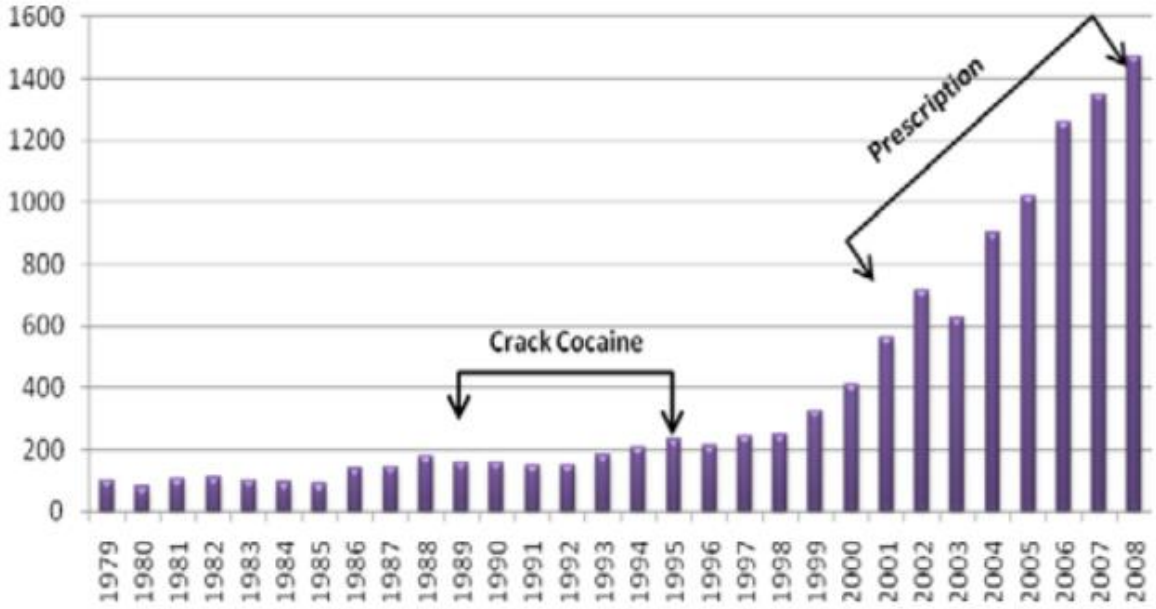
Drug Category	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	% of 2016 deaths
All opioids*	429	489	551	631	733	783	980	1,163	1,272	1,539	2,020	2,590	3,495	86.3%
Fentanyl & related drugs				75^	65^	72^	77^	73^	75	84	503	1,155	2,357	58.1%
Heroin	124	131	117	146	233	283	338	431	680	983	1,196	1,424	1,444	35.7%
Cocaine	221	223	317	287	252	220	213	309	326	405	517	685	1,109	27.4%
Prescription opioids**	319	388	462	435^	480^	482^	622^	724^	628	644	672	667	564	13.9%
Benzodiazepines	69	90	121	133	154	211	300	376	311	328	420	504	553	13.7%
Alcohol***	38	58	89	135	181	173	195	226	282	304	383	380	539	13.3%
Psychostimulants**** (e.g., Methamphetamines)	6	9	4	7	7	9	10	28	30	49	59	96	233	5.8%
Hallucinogens	8	8	10	13	14	9	26	31	31	43	49	61	100	2.5%
Methadone	116	144	161	176	168	169	155	156	123	112	103	108	94	2.3%
Barbiturates	3	5	3	7	3	5	13	11	6	10	6	19	14	0.3%
Other/unspecified drugs only*****	256	289	378	453	475	396	343	373	389	319	274	194	182	4.5%
Multiple Drug Involvement							888	980	1,016	1,014	1,321	1,747	2,451	60.5%
Total unintentional poisoning deaths	904	1,020	1,261	1,351	1,473	1,423	1,544	1,772	1,914	2,110	2,531	3,050	4,050	
Age-adjusted annual death rate per 100,000	7.9	8.9	11.0	11.8	12.9	12.7	13.7	15.4	17.0	18.7	22.7	27.7	36.8	

Source: Ohio Department of Health, Bureau of Vital Statistics; analysis conducted by ODH Violence and Injury Prevention Program.

1407. These figures make the opioid epidemic in Ohio one of the deadlier epidemics, measured by deaths and mortality rates. In 2010, mortality rates were four to five times higher than the rates during the "black tar" heroin epidemic in the mid-1970s and more than three times what they were during the peak years of the crack cocaine epidemic in the early 1990s.[387]

[387] Final Report, OHIO PRESCRIPTION DRUG ABUSE TASK FORCE, (October 1, 2010), https://www.odh.ohio.gov/health/vipp/drug/~/media/1F1DD52D1CA24ADBB98551AD588114EC.ashx.

Figure 4. Epidemics of unintentional drug overdoses in Ohio, 1979-2008.[12,13,14]



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1408. The death toll in Ohio is so staggering, that in 2016 a coroner's office had to use refrigerated trucks to store bodies for an entire week because the city was unable to process cases as fast as individuals were fatally overdosing.[389] In 2017, the same coroner's office requested, for the first time, that a local funeral parlor provide temporary storage for bodies that it simply lacked the capacity to hold.[390] Specifically, the Defendants' predicate acts and pattern of racketeering activity caused the opioid epidemic which has injured Plaintiff MMO in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic.

1409. The Manufacturer Defendants falsely promoted Opioid Drugs as safe and effective directly to Plaintiff MMO and through its contracted PBM in order to get Opioid Drugs

[388] *Id.*

[389] Kimiko de Freytas-Tamura, *Amid Opioid Overdoses, Ohio Coroner's Office Runs Out of Room for Bodies*, N.Y. TIMES (Feb. 2, 2017).

[390] *Id.*

placed more favorably on MMO formularies and thereby obtain critical coverage they needed to further common goals of expanding the market and increasing their bottom line – profits (over people).

1410. The Manufacturer Defendants' misrepresentations of Opioid Drugs' safety and efficacy had a foreseeable impact on Plaintiff MMO, its contracted PBM, physicians, the medical community and the general public. Physicians relied on the Manufacturer Defendants' misrepresentations of Opioid Drugs' safety and efficacy in prescribing the drug for their patients. Plaintiff MMO and its contracted PBM relied on the Defendants' misrepresentations regarding safety and efficacy when placing Opioid Drugs on its formularies, and further relied on those misrepresentations and the concealment of diversion in reimbursing and/or paying for prescriptions of Opioid Drugs for its plan members, along with associated consequential damages of excessive Opioid Drugs on the street and the plague of related heroin addiction and treatment.

1411. The Defendants have superior access to information about the Opioid Drugs in terms of safety and efficacy, especially in the post-marketing phase, and in terms of addiction and diversion rates, and are under a special duty to investigate and report adverse effects and suspicious orders. Defendants' duty to disclose also arises when a Defendant makes partial or ambiguous statements about their Opioid Drugs that require further disclosure in order to avoid being misleading.

1412. The Defendants' nondisclosure or concealment, including when they make partial representations and suppresses some material facts, was done intentionally and with a common purpose.

1413. The Manufacturer Defendants also had a duty to disclose the lack of safety and efficacy of the Opioid Drugs for chronic non-cancer pain management as they were marketing the Opioid Drugs to alleviate something the Manufacturer Defendants over-exaggerated and over-hyped as a "chronic pain epidemic." The Manufacturer Defendants' failure to disclose the lack of safety and efficacy and adequately forewarn of the grave adverse risks associated with the Opioid Drugs is particularly egregious given the complete lack of substantial scientific evidence supporting the same and given the inescapable negative side effects of addiction and related consequences, which are all too often fatal.

1414. Truthful information, rather than Defendants' misrepresentations, would have been material to MMO in making its coverage decisions and managing its formularies, as MMO relied on receiving accurate scientific information about Opioid Drugs, including evidence-based medical studies, and further relied on the integrity of the published literature to determine whether a pharmaceutical product is effective and safe. Defendants' untruthfulness deceived a reasonable health plan like MMO.

1415. Therefore, the Defendants' failure to adequately inform consumers, Plaintiff MMO, and those in the medical community that the use of Opioid Drugs is associated with a risk of abuse and addiction along with other serious adverse events, their false and misleading promotion of Opioid Drugs' safety and efficacy, which are neither safe nor effective except for a very few patients, and which were excessively being diverted into the black market and of little to no value, caused Plaintiff MMO to pay for excessive Opioid Drug prescriptions.

1416. But for the Defendants' actions, Plaintiff MMO would not have paid for excessive Opioid Drug prescriptions that were of no therapeutic benefit or were further diverted into the black market. Moreover, but for thw Defendants' actions, Plaintiff MMO would not have had to

pay for the costs of care related to its members' adverse medical, behavioral, mental and addiction-treatment related events. Here are representative examples of the injury suffered by Plaintiff MMO resulting from the Defendants' false and misleading promotion of Opioid Drugs and concealment of the diversion of Opioid Drugs into the black market:

1417. Plaintiff MMO's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

a. Losses caused by purchasing and/or paying reimbursements for the Manufacturer Defendants' Opioid Drug prescriptions that Plaintiff MMO would not have paid for or reimbursed but for the Defendants' conduct, including excessive Opioid Drug prescriptions and also Opioid Drug prescriptions diverted to the black market;

b. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

c. Costs associated with providing Naloxone – an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

d. Costs associated with emergency and/or first responders to opioid overdoses;

e. Costs for providing mental-health services, treatment, counseling, and rehabilitation services to victims of the opioid epidemic and their families; and

f. Costs for providing treatment of infants born with opioid-related medical conditions, or born addicted to opioids.

1418. Defendants used, and knowingly caused the use of, mail and interstate wire communications to create, execute, and manage and further their fraudulent schemes. This scheme involved national marketing and sales plans and programs and encompassed physicians and consumers across the country.

1419. The Defendants' use of, and causing the use of, the mails and wires in furtherance of their schemes to defraud involved thousands of communications and transmissions all over Ohio and throughout the country, including:

- Transmission through mail and wire marketing and advertising materials about the non-indicated and unsafe uses of their Opioid Drug(s) to physicians across the country;
- Communications and transmissions, including financial payments, from Defendants or vendors to participants in the Physician Pull-Through Marketing, Scientific Literature Marketing, Consumer Pull-Through Marketing, Opioid Drug Diversion Concealment Enterprises, including physicians and medical marketing vendors, discussing and relating to the production and publication of articles and dissemination of materials and speeches misrepresenting the non-indicated uses and safety and efficacy of their Opioid Drugs;
- Communications with Plaintiff MMO and its members, inducing payments for Opioid Drugs to be made based on misrepresentations concerning their safety, efficacy, effectiveness, lack of addiction and unsubstantiated patient benefits; and
- Communications, payments and monetary transfers using the wires concerning the receipt and distribution of the proceeds of Defendants' improper schemes.

1420. In addition, the Defendants' respective corporate headquarters have communicated, and knowingly caused communications, by United States mail, telephone and facsimile with or by various local district managers, medical liaisons, and pharmaceutical representatives, in furtherance of Defendants' schemes.

VIII. PLAINTIFF MMO'S CLAIMS ARE TIMELY

1421. The claims set forth herein are timely because – among other reasons – Plaintiff MMO in the exercise of reasonable diligence was unable to discover their injuries and because Defendants' fraudulently concealed their illegal conduct and aggressively countered any negative publicity regarding Defendants' promotion of the Opioid Drugs. As such, the extent of Defendants' concealment of Opioid Drug diversion was unknown, even to government officials, until just recently.

1422. As evidenced by the allegations in this First Amended Complaint, Defendants have concealed and/or failed to adequately disclose the Opioid Drugs' propensity to cause abuse and addiction, have employed and continue to employ practices and techniques of secrecy and public denial in order to avoid detection of and to assuage potential concern, and have fraudulently hidden their deceptive and conspiratorial behavior regarding the safety and efficacy of Opioid Drugs.

1423. As such, Plaintiff MMO had not been effectively alerted to the existence and scope of this industry-wide fraud and thus was not on notice of their potential claims until shortly prior to the filing of this First Amended Complaint.

1424. The accrual of Plaintiff MMO's claims is tied to the recent discovery of diversion concealment and disclosures regarding the true rates of addiction to and efficacy of Opioid Drugs. In pursuit of their efforts to promote Opioid Drugs and conceal the diversion of Opioid Drugs for non-medically legitimate purposes, Defendants concealed and failed to disclose the known or reasonably knowable serious adverse side effects, rates of addiction and lack of long-term efficacy for chronic non-cancer pain described above. Plaintiff MMO could not have known, nor could it have reasonably discovered Opioid Drugs' propensity to cause the same, for the data and information for which was exclusively within the hands of Defendants and were not generally known until very recently.

1425. Plaintiff MMO could not have acquired such knowledge through the exercise of reasonable diligence. Defendants' self-concealing schemes, including their public statements, marketing, and advertising, were designed to prevent Plaintiff MMO from discovering its injuries. Defendants affirmative conduct to perpetuate their fraud deprived Plaintiff MMO of

actual or presumptive knowledge of facts sufficient to put them on notice as to its potential claims.

1426. The false and misleading Physician Pull-Through Marketing, Science-Literature Marketing, Consumer Pull-Through Marketing, Formulary Access and Coverage, and Drug Diversion Enterprises, and their respective marketing, publications, Front Groups, and illegal kickback schemes, depended on the Defendants' concealment of their involvement because of the various prohibitions on manufacturers in promoting their products for unapproved uses, and the obvious illegality of bribing physicians in the form of kickbacks and conspiring to conceal Opioid Drug diversion. Indeed, Defendants' CME and promotional speaker programs as well as the medical literature and publishing programs, were only successful because Defendants managed to hide the true extent of their control over these activities. Defendants strove to make these CME seminars, medical journal articles, and speaking events appear as independent and legitimate as possible, when in reality the physicians and researchers participating in the schemes were merely the paid mouthpieces for Defendants' false and misleading promotions. And, of course, the written materials were in large part less explicitly false and misleading promotion, even though Defendants trained their sales force to deliver explicit unapproved and unsafe pitches during sales calls. The result of this concealment was a body of medical literature and a roster of well-respected teaching physicians supporting the unsafe uses, and concealing the lack of efficacy and risk of addiction of Opioid Drugs.

1427. As alleged in the Enterprises, the Defendants jointly and acting in concert sought to create the impression to Plaintiff MMO, to patients, and to physicians that the increased utilization of Opioid Drugs was safe and effective for pain that was simply underdiagnosed. Defendants, however, knew and understood that promotion of the Opioid Drugs for chronic pain

and other conditions was inappropriate and that Defendants' own data and studies suggested that Opioid Drug use in these populations, as well as others, was inappropriate and dangerous, and likely to be diverted from proper distribution channels and lead to addiction and abuse. Defendants failed to make adequate disclosures because the vast majority of Opioid Drug prescribing and distribution, and reimbursement never would have occurred had adequate disclosures and warnings been made.

1428. To the extent that anyone publicly called into question Defendants' false and fraudulent promotional activities or diversion concealment schemes, Defendants were highly aggressive in their attacks against such negative media.

1429. To ensure that Defendants' counter-messaging reached its intended subjects, Defendants had equipped their sales forces with counter-messaging and talking points to reassure patients, physicians, and Plaintiff MMO with respect to Opioid Drug therapy, thereby creating a market for drugs that weren't necessary.

1430. MMO was thus not put on inquiry notice of any injuries by articles and publications on account of Defendants' extreme and successful efforts to attack and undermine negative media reports. Moreover, it was not until just recently when ARCOS data revealed the slightest inkling as to Defendants' elaborate concealment scheme that Opioid Drug diversion became public. Defendants have demonstrated an unparalleled ability to further lobby and conceal such Opioid Drug diversion tactics that exponentially increased the number of Opioid Drug prescriptions entering the market.

1431. Likewise, the Defendants' involvement in their primary false and fraudulent promotional activities as well as in their attacks on any negative press and diversion concealment was hidden because Defendants largely used intermediaries and Front Groups to deliver their

deceptive messages. These activities, and others described above, concealed Defendants' false and misleading promotional activities and deceptive concealment of Opioid Drug diversion. They were designed such that MMO could not have discovered the alleged scheme or their causes of action earlier in the exercise of reasonable diligence. Much of the scheme – to this day – remains concealed.

1432. Furthermore, due to their illegality, physician kickbacks for prescriptions were concealed or disguised as payments for other purposes through a number of artifices described above, including sham "honoraria," bogus "speaker program fees" and other methods.

1433. Thus, any applicable statutes of limitation have not commenced and/or have been tolled by Defendants' knowing and active concealment and public denials of the facts alleged herein. MMO has been kept in ignorance of vital information essential to the pursuit of these claims without any fault or lack of diligence on its part, and as part of each Defendant's scheme. MMO could not have reasonably discovered the fraudulent nature of Defendants' conduct, and in fact was prevented from discovering the fraudulent nature of Defendants' conduct on account of Defendants' respective schemes to prevent Plaintiff MMO from discovering that Opioid Drugs were for ineffective, unsafe, and unapproved uses. Accordingly, Defendants are estopped from relying on any statute of limitations to defeat any of Plaintiff MMO's claims.

1434. The Defendants' motives in concealing the serious adverse side effects and negative safety profiles of the Opioid Drugs; along with turning a blind eye to CSA regulations mandating effective diversion controls and reporting of suspicious ordering; and in controlling and operating the various Enterprises described herein, was to obtain additional revenues from the illegal, false, and misleading marketing and concealment of the diversion of Opioid Drugs into the black market. Had the Opioid Drugs only been sold for approved indications, had their

true safety and efficacy profiles been marketed appropriately, and the grave risk of abuse and addiction been disclosed, sales would have been significantly lower. Due to the conduct described herein, the Defendants achieved billions of dollars in combined sales.

IX. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Violation of 18 U.S.C. § 1962(c)
(Physician Pull-Through Marketing Enterprises)
Against the Manufacturer Defendants

1435. Plaintiff MMO incorporates by reference all preceding paragraphs, as if fully set forth herein.

1436. Plaintiff MMO brings this Claim against the Manufacturer Defendants, because of the impact of this scheme on Plaintiff MMO as described herein.

1437. The Manufacturer Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who participated in the conduct of the affairs of the Physician Pull-Through Marketing Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

1438. The Physician Pull-Through Marketing Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of (i) the Manufacturer Defendants, defined above, including their employees and agents, (ii) advocacy groups and professional societies known herein as Front Groups, and (iii) physicians associated with the Manufacturer Defendants (or their Front Groups) known herein as KOLs.

1439. The Front Groups include the AIPM, the AAPPM, the ACPA, the AGS, the APF, the APS, the ASPE, the ASPMN, the FSMB, the PCF, the USPF and the APA, and others whose identities are not yet known but will be learned in discovery.

1440. The KOLs include Dr. Russell Portenoy, Dr. Lynn Webster, Dr. Perry Fine, Dr. Scott Fishman, Dr. David Haddox, Dr. Bradley Galer, Dr. Charles Argoff, Dr. Sean Mackey, Dr.

Daniel Bennett, Dr. Bruce Ferrell, Dr. Steven Stanos, and others whose identities are not yet known but will be learned in discovery.

1441. The Physician Pull-Through Marketing Enterprise is an ongoing organization that functions as a continuing unit. It was created and used by each Manufacturer Defendant as a tool to effectuate a pattern of racketeering activity. The Manufacturer Defendant "persons" are distinct from the Physician Pull-Through Marketing Enterprise. The Manufacturer Defendants were aware of the essential nature and scope of this Enterprise and intended to participate in and/or conduct it.

1442. The Physician Pull-Through Marketing Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" associated together for the common purpose of promoting Opioid Drugs to prescribers for unsafe uses and earning profits therefrom.

1443. The Manufacturer Defendants have conducted and participated in the affairs of the Physician Pull-Through Marketing Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, described herein. The false and misleading predicate acts of racketeering activity committed, or caused to be committed, by the Manufacturer Defendants number in the hundreds if not thousands, and the Manufacturer Defendants committed, or caused to be committed, at least two of the predicate acts within the requisite ten (10) year period.

1444. The Physician Pull-Through Marketing Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, or provided Opioid Drugs to thousands of entities and individuals throughout the United States and engaged in the prohibited conduct alleged herein throughout the United States.

1445. The Manufacturer Defendants exerted control over the Physician Pull-Through Marketing Enterprise, and the Manufacturer Defendants participated in the operation or management of the affairs of the Physician Pull-Through Marketing Enterprise, through a variety of actions including the following:

- the Manufacturer Defendants controlled the content of the messages being delivered by the Physician Pull-Through Marketing Enterprise by its sales representatives, who met individually or telephonically with prescribing physicians, nurses, and/or their staff;
- the Manufacturer Defendants controlled the content of the messages being delivered by the by the Physician Pull-Through Marketing Enterprise in advertisements in trade publications or medical journals read by prescribing HCPs;
- the Manufacturer Defendants controlled the content of the messages being delivered by the Physician Pull-Through Marketing Enterprise on the Manufacturer Defendants' own websites, which included information for prescribing HCPs;
- the Manufacturer Defendants controlled the content of the messages being delivered by the Physician Pull-Through Marketing Enterprise by exerting control over the communications to prescribing HCPs concerning Opioid Drugs by various KOLs;
- the Manufacturer Defendants controlled the content of the messages being delivered by the Physician Pull-Through Marketing Enterprise by exerting control over the communications to prescribing HCPs concerning Opioid Drugs by various Front Groups (as identified above);
- the Manufacturer Defendants paid the KOLs and Front Groups for their participation in the Physician Pull-Through Marketing Enterprise;
- the Manufacturer Defendants concealed their relationship and control of Front Groups from HCPs which made the Physician Pull-Through Marketing Enterprise more effective;
- the Manufacturer Defendants concealed their relationship and control of KOLs from HCPs, which made the Physician Pull-Through Marketing Enterprise more effective;
- the Manufacturer Defendants controlled the content of the messages being delivered by the Physician Pull-Through Marketing Enterprise at CME events—or similar purportedly "educational" events for prescribing physicians—funded or hosted by Manufacturer Defendants, their Front Groups, or featuring KOLs;

- the Manufacturer Defendants selected the prescribing HCPs targets of the false and misleading communications delivered by the Physician Pull-Through Marketing Enterprise;
- the Manufacturer Defendants used sophisticated data to micro-target prescribing HCPs with certain prescribing patterns or vulnerable patient populations for communications delivered by the Physician Pull-Through Marketing Enterprise;
- the Manufacturer Defendants provided financial and/or other consideration to prescribing HCPs to write prescriptions for Opioid Drugs; and
- the Manufacturer Defendants placed their own employees and agents in positions of authority and control over the Physician Pull-Through Marketing Enterprise.

1446. As detailed above, the Manufacturer Defendants' Physician Pull-Through Marketing Enterprise, in an effort to increase prescriber demand for Opioid Drugs, made various misrepresentations and omissions to prescribing HCPs: (1) the existence of a "pain epidemic" and urgency with which it must be addressed; (2) the efficacy with which long-term Opioid Drug therapy treats or manages long-term chronic pain; (3) the ability of Opioid Drugs to improve life functions (such as psychological health, health-related quality of life, and quality of life itself); (4) downplaying the serious risk of addiction; (5) creating and promoting the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more Opioid Drugs; (6) exaggerating the effectiveness of screening tools to prevent addiction; (7) claiming that opioid dependence and withdrawal are easily managed; (8) denying the risks of higher Opioid Drug dosages; (9) exaggerating the effectiveness of "abuse-deterrent" Opioid Drug formulations to prevent abuse and addiction; (10) actively concealing, and causing others to conceal, information about the safety (including addiction risk), efficacy, and usefulness of Opioid Drugs to treat long-term chronic pain; and (11) promoting favorable MMO formulary status during "pull-through" sales details with physicians to encourage Opioid Drug prescribing.

1447. The illegal activities of the Physician Pull-Through Marketing Enterprise required extensive use of the wires and mails by each of the Manufacturer Defendants, Front Groups, and KOLs including, *inter alia*: (1) making travel arrangements for sales representatives (booking of hotels, airplane tickets, arranging meals, etc.); (2) teleconferences or telephonic training for sales representatives; (3) email communications between sales representatives and their superiors; (4) the development and dissemination of sales representative training materials; (5) telephonic surveys of prescribers by third-party research firms; (6) the dissemination of marketing materials to sales representatives (and ultimately prescribers); (7) the mailing of marketing materials directly to prescribers; (8) "e-detailing" (by way of sales calls, voice mails, postcards, and emails); (9) developing advertising content for medical journals (which were subsequently mailed); (10) developing websites for marketing to physicians; (11) developing and disseminating newsletters containing marketing material; (12) making travel arrangements for KOLs to give speeches or make presentations (booking of hotels, airplane tickets, arranging meals, etc.); (13) developing and coordinating content of the presentations made at conferences or CMEs; (14) publishing and disseminating CME materials; (15) mailing proposals to CME accrediting institutions; (16) disseminating press releases; (17) collecting data used to "micro-target" certain HCPs; (18) paying "honoraria" to prescribers (such as the mailing of checks or wiring of funds); (19) paying general funds or grants to Front Groups; (20) making travel arrangements for HCPs for "speakers bureau" training events (booking of hotels, airplane tickets, arranging meals, etc.); and (21) disseminating through the wires and mails in interstate commerce of formulary cards, detail pieces, and advisory board materials.

1448. Many of the precise dates of the fraudulent uses of the wires and mails by each Manufacturer Defendant are concealed from Plaintiff MMO and cannot be alleged with more

particularity without discovery and access to the Manufacturer Defendants' books, records and other documents. However, Plaintiff MMO has described the types of predicate acts of mail and wire fraud that occurred. The secretive nature of the Physician Pull-Through Marketing Enterprise's activities make the unlawful tactics alleged herein even more deceptive and harmful.

1449. The Manufacturer Defendants' Physician Pull-Through Marketing Enterprise and related publications were aimed at increasing prescriber demand and securing formulary placement for Opioid Drugs. The "targets" of the misrepresentations and omissions contained in the Physician Pull-Through Marketing Enterprise publications included both HCPs and individuals responsible for making formulary and coverage decisions on behalf of TPPs (including Plaintiff MMO and its contracted PBM).

1450. The Manufacturer Defendants' schemes and the above-described racketeering activities amounted to common courses of conduct intended to cause Plaintiff MMO to pay for excessive amounts of Opioid Drugs. Within the Physician Pull-Through Marketing Enterprise, each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff MMO. The Manufacturer Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to Plaintiff MMO.

1451. The Manufacturer Defendants and the other members of the Physician Pull-Through Marketing Enterprise created and maintained systematic links for the common purpose of gaining revenue from marketing Opioid Drugs for the long-term treatment of chronic pain (including revenue from Plaintiff MMO). Each of the members of the Physician Pull-Through Marketing Enterprise received substantial revenue (including from Plaintiff MMO) from misleadingly marketing Opioid Drugs in this manner. Such revenue (including from Plaintiff

MMO) was exponentially greater than it would have been if Opioid Drugs had been marketed appropriately.

1452. The Physician Pull-Through Marketing Enterprise has a hub and spoke organizational, decision-making structure, with the Manufacturer Defendants serving as the hub.

1453. All members of the Physician Pull-Through Marketing Enterprise were aware of the Manufacturer Defendants' control over its activities. Furthermore, each member of the Physician Pull-Through Marketing Enterprise benefited from the existence of the other members.

1454. The pattern of racketeering activities alleged herein and the Physician Pull-Through Marketing Enterprise are separate and distinct from each other. The Manufacturer Defendants engaged in a pattern of racketeering activities alleged herein for the purpose of conducting the affairs of the Physician Pull-Through Marketing Enterprise.

1455. Plaintiff MMO has been injured in its property by reason of these violations. Through the Physician Pull-Through Marketing Enterprise, Manufacturer Defendants caused prescribing physicians to write far more prescriptions for Opioid Drugs than they would otherwise have written absent the Physician Pull-Through Marketing Enterprise's racketeering activities. This led Plaintiff MMO to make millions of dollars in payments for Opioid Drugs—as well as payments for Opioid Drug-related addiction treatment services—that it would not have made otherwise.

1456. Plaintiff MMO thus suffered direct, consequential, and concrete financial loss flowing from the injury to its property by expending these funds, and thereby suffered out-of-pocket losses. And but for the predicate acts committed or caused to be committed by the Manufacturer Defendants, Plaintiff MMO would not have suffered its RICO injuries.

1457. Plaintiff MMO's injuries were directly and proximately caused by the Manufacturer Defendants' racketeering activity, as described above. Plaintiff MMO's injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; its injuries were a foreseeable and natural consequence of the Manufacturer Defendants' scheme; and there are no others, more directly injured, that could vindicate Plaintiff MMO's claims.

1458. By virtue of these violations of 18 U.S.C. § 1962(c), the Manufacturer Defendants are jointly and severally liable to Plaintiff MMO for three times the damages Plaintiff MMO has sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

SECOND CLAIM FOR RELIEF

Violation of 18 U.S.C. § 1962(c)
(Scientific Literature Marketing Enterprises)
Against the Manufacturer Defendants

1459. Plaintiff MMO incorporates by reference all preceding paragraphs, as if fully set forth herein.

1460. Plaintiff MMO brings this Claim against the Manufacturer Defendants, because of the impact of this scheme on Plaintiff MMO described herein.

1461. The Manufacturer Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who participated in the conduct of the affairs of the Scientific Literature Marketing Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

1462. The Scientific Literature Marketing Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of (i) the Manufacturer Defendants, including their employees and agents, (ii) advocacy groups and professional societies known herein as Front

Groups defined above, and (iii) physicians associated with Manufacturer Defendants (or their Front Groups) known herein as KOLs defined above.

1463. The Scientific Literature Marketing Enterprise is an ongoing organization that functions as a continuing unit. It was created and used by each Manufacturer Defendant as a tool to effectuate a pattern of racketeering activity. The Manufacturer Defendant "persons" are distinct from the Scientific Literature Marketing Enterprise. The Manufacturer Defendants were aware of the essential nature and scope of this Enterprise and intended to participate in it.

1464. The Scientific Literature Marketing Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of groups of "persons" associated together for the common purpose of producing, promoting, and disseminating publication materials of a scientific or academic nature which promoted Opioid Drugs for unsafe uses and earning profits therefrom.

1465. The Manufacturer Defendants have conducted and participated in the affairs of the Scientific Literature Marketing Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described herein. The false and misleading predicate acts of racketeering activity committed, or caused to be committed, by the Manufacturer Defendants number in the hundreds if not thousands, and the Manufacturer Defendants committed, or caused to be committed, at least two of the predicate acts within the requisite ten (10) year period.

1466. The Scientific Literature Marketing Enterprise engaged in and affected interstate commerce, because, *inter alia*, it operated through trade publications and medical journals with national subscribership, disseminated reprints of studies, articles, Treatment Guidelines, Consensus Statements, and Model Policies to sales representatives and physicians across the

nation, were used as part of the Physician Pull-Through Marketing Enterprise, which, *inter alia*, marketed, sold, or provided Opioid Drugs to thousands of entities and individuals throughout the United States.

1467. The Manufacturer Defendants exerted control over the Scientific Literature Marketing Enterprise, and the Manufacturer Defendants participated in its operation or management of the affairs of the Scientific Literature Marketing Enterprise, through a variety of actions including the following:

- the Manufacturer Defendants controlled the content of the Scientific Literature Marketing Enterprise publications, and the marketing messages contained therein, promulgated by the Scientific Literature Marketing Enterprise, including the misinformation and false statements described herein;
- the Manufacturer Defendants selected and approved KOLs to serve as "authors" of publications comprising Scientific Literature Marketing Enterprise publications;
- the Manufacturer Defendants funded KOLs to write publications comprising Scientific Literature Marketing Enterprise publications;
- the Manufacturer Defendants controlled the content of KOL-drafted publications comprising Scientific Literature Marketing Enterprise publications;
- the Manufacturer Defendants concealed their relationship and control of KOLs publishing Scientific Literature Marketing Enterprise publications, which made the Scientific Literature Marketing Enterprise more effective;
- the Manufacturer Defendants funded Front Groups to write publications comprising Scientific Literature Marketing Enterprise publications;
- the Manufacturer Defendants concealed their relationship and control of Front Groups disseminating Scientific Literature Marketing Enterprise publications, which made the Scientific Literature Marketing Enterprise more effective;
- the Manufacturer Defendants controlled the content of Front Group-drafted publications comprising Scientific Literature Marketing Enterprise publications;
- the Manufacturer Defendants funded the dissemination of the Scientific Literature Marketing Enterprise publications;
- their funding of particular publications aside, the Manufacturer Defendants paid and therefore sponsored KOLs who participated in the Scientific Literature Marketing Enterprise;

- the Manufacturer Defendants placed their own employees and agents in positions of authority and control over the Scientific Literature Marketing Enterprise;
- the Manufacturer Defendants promoted the Scientific Literature Marketing Enterprise publications by utilizing such publications in CMEs;
- the Manufacturer Defendants promoted the Scientific Literature Marketing Enterprise publications by sponsoring speeches and conferences where KOLs would make presentations based on their respective Scientific Literature Marketing Enterprise publications; and
- the Manufacturer Defendants concealed their involvement in the Scientific Literature Marketing Enterprise such that its publications would have a veneer of credibility as independent and unbiased scientific research.

1468. As detailed above, the Manufacturer Defendants' Scientific Literature Marketing Enterprise publications consisted primarily of: (1) clinical studies; (2) Consensus Statements; (3) Treatment Guidelines; (4) Model Policies; (5) academic journal publications; and (6) Front Group reviews and official statements criticizing FDA and CDC initiatives.

1469. The Manufacturer Defendants' Scientific Literature Marketing Enterprise and related publications were aimed at increasing prescriber demand and securing formulary placement for Opioid Drugs. The "targets" of the misrepresentations and omissions contained in the Scientific Literature Marketing Enterprise publications included both HCPs and individuals responsible for making formulary and coverage decisions on behalf of TPPs (including Plaintiff MMO and its contracted PBM).

1470. The misrepresentations and omissions included in the Scientific Literature Marketing Enterprise publications, on which prescribers and TPPs (including Plaintiff MMO) relied to that end, included: (1) the existence of a "pain epidemic" and urgency with which it must be addressed; (2) the efficacy with which long-term Opioid Drug therapy treats or manages long-term chronic pain; (3) the ability of Opioid Drugs to improve life functions (such as

psychological health, health-related quality of life, and quality of life itself); (4) downplaying the serious risk of addiction; (5) creating and promoting the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more Opioid Drugs; (6) exaggerating the effectiveness of screening tools to prevent addiction; (7) claiming that opioid dependence and withdrawal are easily managed; (8) denying the risks of higher Opioid Drug dosages; (9) exaggerating the effectiveness of "abuse-deterrent" Opioid Drug formulations to prevent abuse and addiction; and (10) actively concealing, and causing others to conceal, information about the safety (including addiction risk), efficacy, and usefulness of Opioid Drugs to treat long-term chronic pain.

1471. The illegal activities of the Scientific Literature Marketing Enterprise required extensive use of the wires and mails by each of the Manufacturer Defendants, Front Groups, and KOLs including, *inter alia*: (1) developing content for Scientific Literature Marketing Enterprise publications; (2) emailing and/or engaging in telephonic conversations between Manufacturer Defendants and KOLs wherein Manufacturer Defendants exerted influence over the misleading content in a forthcoming Scientific Literature Marketing Enterprise publication; (3) emailing and/or engaging in telephonic conversations between Manufacturer Defendants and Front Groups wherein Manufacturer Defendants exerted influence over the misleading content in a forthcoming Scientific Literature Marketing Enterprise publication; (4) paying KOLs (such as the mailing of checks or wiring of funds) to generate Scientific Literature Marketing Enterprise publications; (5) Paying Front Groups (such as the mailing of checks or wiring of funds) to generate Scientific Literature Marketing Enterprise publications; (6) widespread distributing and disseminating of Scientific Literature Marketing Enterprise publications (either by printing and mailing or emailing); and (7) making travel arrangements (booking of hotels, airplane tickets,

arranging meals, etc.) for KOLs to conduct presentations based on various Scientific Literature Marketing Enterprise publications.

1472. Many of the precise dates of the fraudulent uses of the wires and mails by each Manufacturer Defendant are concealed from Plaintiff MMO and cannot be alleged with more particularity without discovery and access to the Manufacturers' books, records and other documents. However, Plaintiff MMO has described the types of predicate acts of mail and wire fraud that occurred. The secretive nature of the Scientific Literature Marketing Enterprise's activities make the unlawful tactics alleged herein even more deceptive and harmful.

1473. The Manufacturer Defendants' schemes and the above-described racketeering activities amounted to common courses of conduct intended to cause Plaintiff MMO to pay for excessive amounts of Opioid Drugs. Within the Scientific Literature Marketing Enterprise, each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff MMO. The Manufacturer Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to Plaintiff MMO. The Manufacturer Defendants and the other members of the Scientific Literature Marketing Enterprise created and maintained systematic links for the common purpose of gaining revenue from marketing Opioid Drugs for the long-term treatment of chronic pain (including revenue from Plaintiff MMO). Each of the members of the Scientific Literature Marketing Enterprise received substantial revenue (including from Plaintiff MMO) from misleadingly marketing Opioid Drugs in this manner. Such revenue was exponentially greater than it would have been if Opioid Drugs had been marketed appropriately.

1474. The Scientific Literature Marketing Enterprise has a hub and spoke organizational, decision-making structure, with the Manufacturer Defendants serving as the hub.

1475. All members of the Scientific Literature Marketing Enterprise were aware of the Manufacturer Defendants' control over its activities. Furthermore, each member of the Scientific Literature Marketing Enterprise benefited from the existence of the other members.

1476. The pattern of racketeering activities alleged herein and the Scientific Literature Marketing Enterprise are separate and distinct from each other. The Manufacturer Defendants engaged in a pattern of racketeering activities alleged herein for the purpose of conducting the affairs of the Scientific Literature Marketing Enterprise~~,~~.

1477. Plaintiff MMO has been injured in its property by reason of these violations. Through the Scientific Literature Marketing Enterprise, Manufacturer Defendants caused prescribing physicians to write far more prescriptions for Opioid Drugs than they would otherwise have written absent the Scientific Literature Marketing Enterprise's racketeering activities. Further, through the Scientific Literature Marketing Enterprise, Manufacturer Defendants caused TPPs (including Plaintiff MMO) to make coverage and formulary decisions that they would not have otherwise made absent the Scientific Literature Marketing Enterprise's racketeering activities. This led Plaintiff MMO to make millions of dollars in payments for Opioid Drugs—as well as payments for Opioid Drug-related addiction treatment services—that it would not have made otherwise.

1478. Plaintiff MMO thus suffered direct, consequential, and concrete financial loss flowing from the injury to its property by expending these funds, and thereby suffered out-of-pocket losses. And but for the predicate acts committed or caused to be committed by the Manufacturer Defendants, Plaintiff MMO would not have suffered its RICO injuries.

1479. Plaintiff MMO's injuries were directly and proximately caused by the Manufacturer Defendants' racketeering activity, as described above. Plaintiff MMO's injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; its injuries were a foreseeable and natural consequence of the Manufacturer Defendants' scheme; and there are no others, more directly injured, that could vindicate Plaintiff MMO's claims.

1480. By virtue of these violations of 18 U.S.C. § 1962(c), the Manufacturer Defendants are jointly and severally liable to Plaintiff MMO for three times the damages Plaintiff MMO has sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

THIRD CLAIM FOR RELIEF

Violation of 18 U.S.C. § 1962(c)
(Consumer Pull-Through Marketing Enterprises)
Against the Manufacturer Defendants

1481. Plaintiff MMO incorporates by reference all preceding paragraphs, as if fully set forth herein.

1482. Plaintiff MMO brings this Claim against the Manufacturer Defendants, because of the impact of this scheme on MMO described herein.

1483. The Manufacturer Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who participated in the conduct of the affairs of the Consumer Pull-Through Marketing Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

1484. The Manufacturer Defendants participated in the conduct of the affairs of the Consumer Pull-Through Marketing Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

1485. The Consumer Pull-Through Marketing Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of (i) the Manufacturer Defendants, including their employees and agents, (ii) advocacy groups and professional societies known herein as Front Groups, and (iii) physicians associated with Manufacturer Defendants (or their Front Groups) known herein as KOLs.

1486. The Consumer Pull-Through Marketing Enterprise is an ongoing organization that functions as a continuing unit. It was created and used by each Manufacturer Defendant as a tool to effectuate a pattern of racketeering activity. The Manufacturer Defendant "persons" are distinct from the Consumer Pull-Through Marketing Enterprise. The Manufacturer Defendants, however, were aware of the essential nature and scope of this Enterprise and intended to participate in and/or conduct it.

1487. The Consumer Pull-Through Marketing Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" associated together for the common purpose of promoting Opioid Drugs for unsafe uses and earning profits therefrom.

1488. The Manufacturer Defendants have conducted and participated in the affairs of the Consumer Pull-Through Marketing Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described herein. The false and misleading predicate acts of racketeering activity committed, or caused to be committed, by the Manufacturer Defendants number in the hundreds if not thousands, and the Manufacturer Defendants committed, or caused to be committed, at least two of the predicate acts within the requisite ten (10) year period.

1489. The Consumer Pull-Through Marketing Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, or provided Opioid Drugs to thousands of entities and individuals throughout the United States and engaged in the prohibited conduct alleged herein throughout the United States.

1490. The Manufacturer Defendants exerted control over the Consumer Pull-Through Marketing Enterprise, and the Manufacturer Defendants participated in the operation or management of the affairs of the Consumer Pull-Through Marketing Enterprise, through a variety of actions including the following:

- the Manufacturer Defendants controlled the content of the Consumer Pull-Through Marketing Enterprise, and the marketing messages contained therein, promulgated by the Consumer Pull-Through Marketing Enterprise, including the misinformation and false statements described herein;
- the Manufacturer Defendants controlled the content of the messages being delivered by the Consumer Pull-Through Marketing Enterprise by pamphlets and other "educational" written materials that were provided directly to consumers at their physicians' offices;
- the Manufacturer Defendants controlled the content of the messages being delivered by the Consumer Pull-Through Marketing Enterprise on the Manufacturer Defendants' own Opioid Drug websites, which included information for consumers suffering from chronic pain (and/or their family members);
- the Manufacturer Defendants controlled the content of the messages being delivered by the Consumer Pull-Through Marketing Enterprise by exerting control over the content of "education guides" (or similar information material) provided to consumers suffering from chronic pain by various Front Groups (as identified above);
- the Manufacturer Defendants controlled the content of various media appearances and media campaigns—meant to reach a broad base of the population including consumers suffering from chronic pain—operated by their Front Groups;
- the Manufacturer Defendants funded the Front Groups for their participation in the Consumer Pull-Through Marketing Enterprise;
- the Manufacturer Defendants concealed their relationship and control of Front Groups disseminating information to consumers

suffering from chronic pain, which made the Consumer Pull-Through Marketing Enterprise more effective;

- the Manufacturer Defendants controlled the content of KOLs who made media appearances meant to reach a broad base of the population including consumers suffering from chronic pain;
- the Manufacturer Defendants funded KOLs to make media appearances meant to reach a broad base of the population including consumers suffering from chronic pain;
- the Manufacturer Defendants concealed their relationship and control of KOLs making media appearances meant to reach a broad base of the population including consumers suffering from chronic pain, which made the Consumer Pull-Through Marketing Enterprise more effective;
- the Manufacturer Defendants funded and encouraged Front Groups to target elderly consumers with false and misleading statements regarding Opioid Drugs, through media campaigns, "educational" material available online, published "educational" pamphlets, and direct contact with the elderly and/or groups advocating on the elderly's behalf;
- the Manufacturer Defendants funded and encouraged Front Groups to target wounded veteran consumers with false and misleading statements regarding Opioid Drugs, through media campaigns, "educational" material available online, published "educational" pamphlets, and direct contact with the wounded veterans and/or groups advocating on the elderly's behalf;
- the Manufacturer Defendants—in furtherance of the Consumer Pull-Through Marketing Enterprise—created financial incentives to attract consumers to the use of Opioid Drugs, including co-payment assistance, coupons, and vouchers; and
- the Manufacturer Defendants placed their own employees and agents in positions of authority and control over the Consumer Pull-Through Marketing Enterprise.

1491. As detailed above, the Manufacturer Defendants' Consumer Pull-Through Marketing Enterprise, in an effort to increase patient demand for Opioid Drugs, made various misrepresentations and omissions to potential customers suffering from chronic pain as to: (1) the existence of a "pain epidemic" and urgency with which it must be addressed; (2) that living with pain is a "choice"; (3) the efficacy with which long-term Opioid Drug therapy treats or manages long-term chronic pain; (4) downplaying the serious risk of addiction; (5) suggesting patients "advocate" for themselves with their HCPs, and should not 'take no for an answer,' and

threaten to leave prescribers who did not provide Opioid Drugs; and (6) actively concealing, and causing others to conceal, information about the safety (including addiction risk), efficacy, and usefulness of Opioid Drugs to treat long-term chronic pain.

1492. The illegal activities of the Consumer Pull-Through Marketing Enterprise required extensive use of the wires and mails by each of the Manufacturer Defendants, Front Groups, and KOLs including, *inter alia*: (1) making travel arrangements for KOLs to make media appearances (booking of hotels, airplane tickets, arranging meals, etc.); (2) e-mailing communications between Manufacturer Defendants and Front Groups regarding the substance of various media campaigns and/or media appearances; (3) e-mailing communications between Manufacturer Defendants and KOLs regarding the substance of various media appearances; (4) disseminating consumer marketing materials (including pamphlets and videos) to sales representatives who provided them for consumers at various physician offices; (5) mailing of consumer marketing materials (including pamphlets and videos) to physicians who provided them to consumers at various physician offices; (6) mailing of consumer marketing materials by Front Groups to various advocacy groups representing the interests of the elderly or wounded veterans; (7) mailing of consumer rebates, co-pay assistance vouchers, or coupons to physicians who provided them to consumers suffering from chronic pain; (8) developing Opioid Drug websites that included marketing materials aimed at consumers suffering from chronic pain; (9) developing Front Group websites that included marketing materials aimed at consumers suffering from chronic pain; and (10) television broadcasting of various KOL interviews aimed at disseminating marketing material to consumers suffering from chronic pain.

1493. Many of the precise dates of the fraudulent uses of the wires and mails by each Manufacturer Defendant are concealed from Plaintiff MMO and cannot be alleged with more

particularity without discovery and access to the Manufacturers' books, records and other documents. However, Plaintiff MMO has described the types of predicate acts of mail and wire fraud that occurred. The secretive nature of the Consumer Pull-Through Marketing Enterprise's activities make the unlawful tactics alleged herein even more deceptive and harmful.

1494. As detailed above, the Manufacturer Defendants' Consumer Pull-Through Marketing Enterprise and related publications were aimed at increasing patient demand and securing formulary placement for Opioid Drugs. The "targets" of the misrepresentations and omissions contained in the Consumer Pull-Through Marketing Enterprise publications included both patients and individuals responsible for making formulary and coverage decisions on behalf of TPPs (including Plaintiff MMO and its contracted PBM).

1495. The Manufacturer Defendants' schemes and the above-described racketeering activities amounted to common courses of conduct intended to cause Plaintiff MMO to pay for excessive amounts of Opioid Drugs. Within the Consumer Pull-Through Marketing Enterprise, each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff MMO. The Manufacturer Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to Plaintiff MMO.

1496. The Manufacturer Defendants and the other members of the Consumer Pull-Through Marketing Enterprise created and maintained systematic links for the common purpose of gaining revenue from marketing Opioid Drugs to consumers for the long-term treatment of chronic pain (including revenue from Plaintiff MMO). Each of the members of the Consumer Pull-Through Marketing Enterprise received substantial revenue (including from Plaintiff MMO) from misleadingly marketing Opioid Drugs in this manner. Such revenue (including from

Plaintiff MMO) was exponentially greater than it would have been if Opioid Drugs had been marketed appropriately.

1497. The Consumer Pull-Through Marketing Enterprise has a hub and spoke organizational, decision-making structure, with the Manufacturer Defendants serving as the hub.

1498. All members of the Consumer Pull-Through Marketing Enterprise were aware of the Manufacturer Defendants' control over its activities. Furthermore, each member of the Consumer Pull-Through Marketing Enterprise benefited from the existence of the other members.

1499. The pattern of racketeering activities alleged herein and the Consumer Pull-Through Marketing Enterprise are separate and distinct from each other. The Manufacturer Defendants engaged in a pattern of racketeering activities alleged herein for the purpose of conducting the affairs of the Consumer Pull-Through Marketing Enterprise.

1500. Plaintiff MMO has been injured in its property by reason of these violations. Through the Consumer Pull-Through Marketing Enterprise, the Manufacturer Defendants—by increasing not only patient demand but aggressive lobbying by patients of their physicians—caused prescribing physicians to write far more prescriptions for Opioid Drugs than they would otherwise have written absent the Consumer Pull-Through Marketing Enterprise's racketeering activities. Thus, through the Consumer Pull-Through Marketing Enterprise, Manufacturer Defendants caused TPPs (including Plaintiff MMO) to make coverage and formulary decisions that they would not have otherwise made absent the Consumer Pull-Through Marketing Enterprise racketeering activities. This led Plaintiff MMO to make millions of dollars in payments for Opioid Drugs—as well as payments for Opioid Drug-related addiction treatment services—that it would not have made otherwise.

1501. Plaintiff MMO thus suffered direct, consequential, and concrete financial loss flowing from the injury to its property by expending these funds, and thereby suffered out-of-pocket losses. And but for the predicate acts committed or caused to be committed by the Manufacturer Defendants, Plaintiff MMO would not have suffered its RICO injuries.

1502. Plaintiff MMO's injuries were directly and proximately caused by the Manufacturer Defendants' racketeering activity, as described above. Plaintiff MMO's injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; its injuries were a foreseeable and natural consequence of the Manufacturer Defendants' scheme; and there are no others, more directly injured, that could vindicate Plaintiff MMO's claims.

1503. By virtue of these violations of 18 U.S.C. § 1962(c), the Manufacturer Defendants are jointly and severally liable to Plaintiff MMO for three times the damages Plaintiff MMO has sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

FOURTH CLAIM FOR RELIEF

Violation of 18 U.S.C. § 1962(c)
(Formulary Access and Coverage Enterprises)
Against all Defendants

1504. Plaintiff MMO incorporates by reference all preceding paragraphs, as if fully set forth herein.

1505. Plaintiff MMO brings this Claim against the following Defendants, as defined above: the Manufacturer Defendants, the Distributor Defendants, and the Pharmacy Defendants (collectively for purposes of this Claim "Defendants"), because of the impact of this scheme on MMO described herein.

1506. The Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who participated in the conduct of the affairs of the Formulary Access and Coverage Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

1507. The Defendants participated in the conduct of the affairs of the Formulary Access and Coverage Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

1508. The Formulary Access and Coverage Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of (i) Defendants, including their employees and agents, (ii) advocacy groups and professional societies known herein as Front Groups, and (iii) physicians associated with Manufacturer Defendants (or their Front Groups) known herein as KOLs.

1509. The Formulary Access and Coverage Enterprise is an ongoing organization that functions as a continuing unit. It was created and used by each Defendant as a tool to effectuate a pattern of racketeering activity. The Defendant "persons" are distinct from the Formulary Access and Coverage Enterprise. The Defendants, however, were aware of the essential nature and scope of this Enterprise and intended to participate in and/or conduct it.

1510. The Formulary Access and Coverage Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" associated together for the common purpose of promoting Opioid Drugs for unsafe uses, securing formulary access and preferred formulary placement for Opioid Drugs, and earning profits therefrom.

1511. The Defendants have conducted and participated in the affairs of the Formulary Access and Coverage Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation

of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described herein. The false and misleading predicate acts of racketeering activity committed, or caused to be committed, by the Defendants number in the hundreds if not thousands, and the Defendants committed, or caused to be committed, at least two of the predicate acts within the requisite ten (10) year period.

1512. The Formulary Access and Coverage Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, or provided Opioid Drugs to thousands of entities and individuals throughout the United States and engaged in the prohibited conduct alleged herein throughout the United States.

1513. The Defendants exerted control over the Formulary Access and Coverage Enterprise, and the Defendants participated in the operation or management of the affairs of the Formulary Access and Coverage Enterprise, through a variety of actions including the following:

- the Defendants controlled the content of the Formulary Access and Coverage Enterprise, and the messages contained therein, promulgated by the Formulary Access and Coverage Enterprise, including the misinformation, concealments, and false statements described herein;
- the Defendants controlled the content of the messages being delivered by the Formulary Access and Coverage Enterprise at MMO and PQM committee meetings and at P&T committee meetings with its contracted PBM;
- certain Defendants controlled the stream of information disseminated by the Formulary Access and Coverage Enterprise concerning Opioid Drugs by exerting control over the communications concerning Opioid Drugs by managed care sales groups, KOLs, and/or Front Groups that were made to Plaintiff MMO or its contracted PBM;
- certain Defendants funded the KOLs and/or Front Groups responsible for communications concerning Opioid Drugs made to Plaintiff MMO or its contracted PBM;
- the Defendants controlled the content of misleading messages aimed at Plaintiff MMO that were published in periodicals to which TPPs (including Plaintiff MMO) subscribed, including, *inter alia*: 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;

- the Defendants controlled the content (or lack thereof) of information regarding drug diversion reported to the appropriate federal agencies, as required under the CSA;
- the Defendants utilized the Formulary Access and Coverage Enterprise to target Plaintiff MMO, its PQM committees and P&T meetings of its contracted PBM, by concealing the significant evidence of drug diversion, which deceived them into placing Opioid Drugs on their formularies and giving them preferred status; and
- the Defendants placed their own employees and agents in positions of authority and control over the Formulary Access and Coverage Enterprise.

1514. As detailed above, Defendants' Formulary Access and Coverage Enterprise, in an effort to secure and protect formulary access and status for Opioid Drugs, made various misrepresentations and omissions to MMO, its PQM committees, to MMO's contracted PBM and its P&T committees and relevant decision-makers, including statements regarding: (1) the efficacy with which long-term Opioid Drug therapy treats or manages long-term chronic pain; (2) the ability of Opioid Drugs to improve life functions (such as psychological health, health-related quality of life, and quality of life itself), which in turn would save expenditures by TPPs including MMO; (3) downplaying the serious risk of addiction; (4) exaggerating the effectiveness of screening tools to prevent drug diversion; and (5) actively concealing information relating to the rampant drug diversion affecting Opioid Drugs.

1515. The illegal activities of the Formulary Access and Coverage Enterprise required extensive use of the wires and mails by each of the Defendants, Front Groups, and KOLs including, *inter alia*: (1) making travel arrangements for Defendants and/or KOLs to attend conferences which were attended by TPPs including MMO (booking of hotels, airplane tickets,

arranging meals, etc.); (2) engaging in telephonic meetings whereby certain Defendants provided MMO misleading information regarding Opioid Drugs; (3) e-mailing communications wherein certain Defendants provided MMO misleading information regarding Opioid Drugs; (4) providing false and misleading content regarding Opioid Drugs to numerous journals or similar publications which were in turn mailed to TPPs including MMO; and (5) providing false and misleading content regarding Opioid Drugs to various e-mail newsletters, which were in turn transmitted to TPPs including MMO.

1516. Many of the precise dates of the fraudulent uses of the wires and mails by each of the Defendants are concealed from Plaintiff MMO and cannot be alleged with more particularity without discovery and access to the Defendants' books, records and other documents. However, Plaintiff MMO has described the types of predicate acts of mail and wire fraud that occurred. The secretive nature of the Formulary Access and Coverage Enterprise's activities make the unlawful tactics alleged herein even more deceptive and harmful.

1517. The Defendants' schemes and the above-described racketeering activities amounted to common courses of conduct intended to cause Plaintiff MMO to pay for excessive amounts of Opioid Drugs. Within the Formulary Access and Coverage Enterprise, each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff MMO. The Defendants' illegal activities, such as the concerted concealment of drug diversion data, are part of their ongoing business and constitute a continuing threat to Plaintiff MMO.

1518. The Defendants and the other members of the Formulary Access and Coverage Enterprise created and maintained systematic links for the common purpose of securing Opioid Drug access and preferred status on MMO's formulary. This allowed each of the members of the

Formulary Access and Coverage Enterprise to receive substantial revenue (including from Plaintiff MMO). Such revenue was exponentially greater than it would have been if Opioid Drugs had been marketed appropriately, or if Defendants had complied with their obligations to identify, monitor, and report evidence of drug diversion.

1519. The Formulary Access and Coverage Enterprise has a hub and spoke organizational, decision-making structure, with the Defendants serving as the hub.

1520. All members of the Formulary Access and Coverage Enterprise were aware of the Defendants' control over its activities. Furthermore, each member of the Formulary Access and Coverage Enterprise benefited from the existence of the other members.

1521. The pattern of racketeering activities alleged herein and the Formulary Access and Coverage Enterprise are separate and distinct from each other. The Defendants engaged in a pattern of racketeering activities alleged herein for the purpose of conducting the affairs of Formulary Access and Coverage Enterprise.

1522. Plaintiff MMO has been injured in its property by reason of these violations. Through the Formulary Access and Coverage Enterprise, Defendants secured and protected access and status with respect to MMO's formulary, which increased both prescriber and patient demand for Opioid Drugs. Defendants' illegal conduct through the Formulary Access and Coverage Enterprise led TPPs (including MMO) to make coverage and formulary decisions that they would not have otherwise made absent the Formulary Access and Coverage Enterprise racketeering activities. This led Plaintiff MMO to make millions of dollars in payments for Opioid Drugs—as well as payments for Opioid Drug-related addiction treatment services—that it would not have made otherwise.

1523. Plaintiff MMO thus suffered direct, consequential, and concrete financial loss flowing from the injury to its property by expending these funds, and thereby suffered out-of-pocket losses. And but for the predicate acts committed or caused to be committed by the Defendants, Plaintiff MMO would not have suffered its RICO injuries.

1524. Plaintiff MMO's injuries were directly and proximately caused by the Defendants' racketeering activity, as described above. Plaintiff MMO's injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; its injuries were a foreseeable and natural consequence of the Defendants' scheme; and there are no others, more directly injured, that could vindicate Plaintiff MMO's claims.

1525. By virtue of these violations of 18 U.S.C. § 1962(c), the Defendants are jointly and severally liable to Plaintiff MMO for three times the damages Plaintiff MMO has sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

FIFTH CLAIM FOR RELIEF

Violation of 18 U.S.C. § 1962(c)
(The Drug Diversion Concealment Enterprises)
Against all Defendants

1526. Plaintiff MMO incorporates by reference all preceding paragraphs, as if fully set forth herein.

1527. Plaintiff MMO brings this Claim against the following Defendants, as defined above: the Manufacturer Defendants, the Distributor Defendants, and the Pharmacy Defendants (collectively for purposes of this Claim "Defendants"), because of the impact of this scheme on MMO as described herein.

1528.

1529. The Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who participated in the conduct of the affairs of the Drug Diversion Concealment Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

1530. The Defendants participated in the conduct of the affairs of Drug Diversion Concealment Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c). Specifically, Defendants engaged in a conspiracy to expand the market for Opioid Drugs—thus inflating their own profits—by intentionally violating their legal requirements to identify, detect, monitor, and report evidence of Opioid Drug diversion.

1531. The Drug Diversion Concealment Enterprise is legal association and/or association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of at a minimum, a Manufacturer Defendant, a Distributor Defendant, and a Pharmacy Defendant (or a smaller and/or local pharmacy not named as a defendant in the instant case). These legal associations and/or associations in fact are, for purposes of the RICO Act, an enterprise (hereinafter, for purpose of this count, an "Enterprise," a "Drug Diversion Concealment Enterprise," or collectively, the "Enterprises").

1532. Under the present facts, each Defendant either (a) agreed to operate or manage the enterprise that did and does feloniously deal in controlled substances, an offense punishable under the laws of the United States, or (b) if a co-conspirator did not agree to operate or manage the enterprise, each co-conspirator knowingly agreed to facilitate others who did and do operate or manage the enterprise of felonious dealing in controlled substances, an offense punishable under the laws of the United States.

1533. To illustrate the concept of an Enterprise, consider the following example. A Manufacturer Defendant manufactures Opioid Drugs. The Manufacturer Defendant then sells the

same Opioid Drugs to a Distributor Defendant. The Distributor Defendant then distributes, or sells, the same Opioid Drugs to a Pharmacy Defendant. Finally, the Pharmacy Defendant sells the same Opioid Drugs to the Pharmacy Defendant's customers who have been provided a prescription for the Opioid Drugs.

1534. To the Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants, what the customer does with the Opioid Drugs once the final sale has been made is irrelevant. He may ingest the Opioid Drugs for legitimate medical purposes, such as to treat severe acute or chronic pain; he may abuse the Opioid Drugs personally by ingesting them for recreational purposes or to support a drug habit; or he may give or sell them to a third-party abuser who ingests them recreationally or out of habit to support an addiction, thus supporting the black market for Opioid Drugs.

1535. Members of the Drug Diversion Concealment Enterprise systematically violated their statutory duty to maintain effective controls against diversion of their Opioid Drugs, to design and operate a system to identify suspicious orders of their Opioid Drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders. Consequently, Defendants allowed hundreds of millions of pills to enter the illicit market, which allowed the Defendants to derive and be unjustly enriched by obscene profits.

1536. In addition to their statutory duties, the Pharmacy Defendants violated their contractual duty to MMO (and/or its PBM) to refrain from knowingly submitting claims to ESI that were false or were not accurate or otherwise complete.

1537. The Drug Diversion Concealment Enterprise is an ongoing organization that functions as a continuing unit. It was created and used by each Defendant as a tool to effectuate a pattern of racketeering activity. The Defendant “persons” are distinct from the Drug Diversion

Concealment Enterprise. The Defendants, however, were aware of the essential nature and scope of this Enterprise and intended to participate in and/or conduct it.

1538. The Drug Diversion Concealment Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" associated together for the common purpose of promoting Opioid Drugs for unsafe uses, nurturing a diversion-based market for Opioid Drugs (to increase their profits), and secure formulary access and preferred formulary placement for Opioid Drugs by denying TPPs such as MMO the knowledge needed to make informed formulary decisions.

1539. The Defendants have conducted and participated in the affairs of the Drug Diversion Concealment Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) and § 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, described herein. The false and misleading predicate acts of racketeering activity committed, or caused to be committed, by the Defendants number in the hundreds if not thousands, and the Defendants committed, or caused to be committed, at least two of the predicate acts within the requisite ten (10) year period.

1540. The Drug Diversion Concealment Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, sold, or provided Opioid Drugs to thousands of entities and individuals throughout the United States and engaged in the prohibited conduct alleged herein throughout the United States.

1541. The Defendants exerted control over the Drug Diversion Concealment Enterprise, and the Defendants participated in the operation or management of the affairs of the Drug Diversion Concealment Enterprise:

- through their memberships in various industry groups, such as the PCF and the HDA;
- through their own contractual relationships;
- without regard to their obligations under the CSA and other state and federal laws and regulations, such as the obligation to report suspicious orders;
- without regard to whether the prescriptions presented by purchasers are for legitimate purposes;
- without regard to whether the size of individual doses or collective volume of doses in individual prescriptions is appropriate, or extremely inappropriate, given the conditions for the Opioid Drug prescription;
- without regard to whether the purchasers did in the past or continue to exhibit drug seeking behavior;
- without regard to whether the purchasers have a known history of criminal activity inside the Pharmacy Defendants' stores, or on or near their property;
- without regard to whether an individual customer presents multiple Opioid Drug prescriptions from different doctors, who are unaware of each other, during a single month; and
- without regard to whether prescriptions were written by doctors who presently have a known history of engaging in suspicious or downright fraudulent over-prescribing.

1542. It was further part of said scheme and artifice that Defendants' communications directed toward government officials and courts would be and were designed to preserve and increase the market for prescription opioids while concealing Defendants' role in supporting an illegal market for Opioid Drugs, which in turn protected formulary access and placement for the Opioid Drugs.

1543. Throughout the existence of the Drug Diversion Concealment Enterprise, the Defendants purposefully failed to comply with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids—all the while espousing to the general public, to Congress, to federal and state agencies, and to TPPs (including Plaintiff MMO) their commitment to preventing diversion of prescription opioids.

1544. The felonious dealing described herein were made in furtherance of the Defendants' unified scheme to increase and maintain profits from unlawful sales of Opioid Drugs while thwarting the ability of federal and state regulators, as well as TPPs (including Plaintiff MMO) to prevent diversion. This unified scheme was furthered by (1) habitual noncompliance with federal and state law; (2) intensive lobbying of federal and state official to evade further regulation; and (3) increasing and/or maintaining high production quotas for their prescription Opioid Drugs from which Defendants could profit for as long as possible.

1545. The Defendants unlawfully, knowingly and intentionally combined, conspired, confederated, and agreed together with each other, and with others whose names are both known and unknown, to conduct and participate, directly and indirectly, in the overall objective of their unified scheme, and participated in the common course of conduct to fail to prevent the overprescribing and diversion of prescription Opioid Drugs.

1546. Each of the Defendants had to agree to implement similar tactics regarding marketing prescription Opioid Drugs and refusing to report suspicious orders. If any Defendants had properly disclosed and/or withheld suspicious orders, the conspiracy would be endangered.

1547. The illegal activities of the Drug Diversion Concealment Enterprise required extensive use of the wires and mails by each of the Defendants including, *inter alia*: (1) Defendants' practice of asserting their commitment to preventing Opioid Drug diversion by various representations and statements in national publications; (2) providing false information by mail and/or wires (including the electronic submission of information) to federal agencies such as the DEA; (3) using webinars hosted by the HDA designed for Defendants to exchange detailed information regarding their prescription Opioid Drug sales, including purchase orders, acknowledgements, ship notices, and invoices; (4) using wires to transmit false acquisition and

distribution transaction reports (as required by the CSA); (5) using wires to transmit false information to the DEA's ARCOS; (6) mailing and/or electronically transmitting orders of Opioid Drugs that Defendants knew would promote the Drug Diversion Concealment Enterprise.

1548. Many of the precise dates of the fraudulent uses of the wires and mails by each of the Defendants are concealed from Plaintiff MMO and cannot be alleged with more particularity without discovery and access to the Defendants' books, records and other documents. However, Plaintiff MMO has described the types of predicate acts of mail and wire fraud that occurred. The secretive nature of the Drug Diversion Concealment Enterprise's activities make the unlawful tactics alleged herein even more deceptive and harmful.

1549. The Defendants' schemes and the above-described racketeering activities amounted to common courses of conduct intended to cause Plaintiff MMO to pay for excessive amounts of Opioid Drugs. Within the Drug Diversion Concealment Enterprise, each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff MMO. The Defendants' illegal activities, aimed at the concerted concealment of drug diversion data, are part of their ongoing business and constitute a continuing threat to Plaintiff MMO.

1550. The Defendants and other potential members of the Drug Diversion Concealment Enterprise created and maintained systematic links for the common purpose of securing Opioid Drug access on MMO's formulary. This allowed each of the members of the Drug Diversion Concealment Enterprise to receive substantial revenue (including from Plaintiff MMO). Such revenue was exponentially greater than it would have been if Defendants had complied with their obligations to identify, monitor, and report evidence of drug diversion.

1551. The Drug Diversion Concealment Enterprise has a hub and spoke organizational, decision-making structure, with the Defendants serving as the hub.

1552. All members of the Drug Diversion Concealment Enterprise were aware of the Defendants' control over its activities. Furthermore, each member of the Drug Diversion Concealment Enterprise benefited from the existence of the other members.

1553. The pattern of racketeering activities alleged herein and the Drug Diversion Concealment Enterprise are separate and distinct from each other. The Defendants engaged in a pattern of racketeering activities alleged herein for the purpose of conducting the affairs of Drug Diversion Concealment Enterprise.

1554. Plaintiff MMO has been injured in its property by reason of these violations. Through the Drug Diversion Concealment Enterprise, Defendants secured and protected access and status with respect to MMO's formulary, which increased both prescriber and patient demand for Opioid Drugs. Defendants' illegal conduct through the Drug Diversion Concealment Enterprise led TPPs (including MMO) to make coverage and formulary decisions that they would not have otherwise made absent the Drug Diversion Concealment Enterprise racketeering activities. This led Plaintiff MMO to make millions of dollars in payments for Opioid Drugs—as well as payments for Opioid Drug-related addiction treatment services—that it would not have made otherwise.

1555. Plaintiff MMO thus suffered direct, consequential, and concrete financial loss flowing from the injury to its property by expending these funds, and thereby suffered out-of-pocket losses. And but for the predicate acts committed or caused to be committed by the Defendants, Plaintiff MMO would not have suffered its RICO injuries.

1556. Plaintiff MMO's injuries were directly and proximately caused by the Defendants' racketeering activity, as described above. Plaintiff MMO's injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; its injuries were a foreseeable and natural consequence of the Defendants' scheme; and there are no others, more directly injured, that could vindicate Plaintiff MMO's claims.

1557. By virtue of these violations of 18 U.S.C. § 1962(c), the Defendants are jointly and severally liable to Plaintiff MMO for three times the damages Plaintiff MMO has sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

SIXTH CLAIM FOR RELIEF

Violation of 18 U.S.C. § 1962(d)
(Civil RICO Conspiracy to Violate 18 U.S.C. § 1962(c))
Against all Defendants

1558. Plaintiff MMO incorporates by reference all preceding paragraphs, as if fully set forth herein.

1559. Plaintiff MMO brings this Claim against the following Defendants, as defined above: the Manufacturer Defendants, the Distributor Defendants, and the Pharmacy Defendants) (collectively, for purpose of this Claim, the "Defendants"), because of the impact of this scheme on MMO described herein.

1560. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provision of subsection (a), (b), or (c) of this section."

1561. The Manufacturer Defendants have violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of the conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the Physician Pull-Through Marketing

Enterprise, the Scientific Literature Marketing Enterprise, and the Consumer Pull-Through Marketing Enterprise through a pattern of racketeering activity.

1562. Further, all Defendants have violated §1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of the conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the Formulary Access and Coverage Enterprise and Drug Diversion Concealment Enterprise through a pattern of racketeering activity.

1563. Defendants' co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including the numerous material misrepresentations and omissions described in detail herein.

1564. The nature of the above-described Defendants' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent acts have been and are part of an overall pattern of racketeering activity.

1565. As a direct and proximate result of Defendants' overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), MMO has been and continues to be injured in its business or property as set forth more fully above.

1566. Defendants sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts:

- multiple instances of mail and wire fraud violations of 18 U.S.C. § 1341 and § 1342; and
- multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

1567. Defendants' violations of the above federal laws and the effects thereof detailed above are continuing and will continue into the future unless enjoined by this Court.

1568. Plaintiff MMO has been injured in its property by reason of these violations in that MMO has millions of dollars for Opioid Drugs and addiction-related costs that it would not have paid had Defendants not conspired to violate 18 U.S.C. § 1962(c).

1569. Injuries suffered by Plaintiff MMO were directly and proximately caused by Defendants' racketeering activity as described above.

1570. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are liable to Plaintiff MMO for compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

SEVENTH CLAIM FOR RELIEF

Violation of the Ohio Corrupt Practices Act
Ohio Revised Code §§ 2923.31, et seq.
(Physician Pull-Through Marketing Enterprises)
Against the Manufacturer Defendants

1571. Plaintiff MMO incorporates by reference all preceding paragraphs, as if fully set forth herein. For efficiency and to avoid repetition, for purposes of this claim, Plaintiff MMO specifically incorporates by reference the paragraphs of Plaintiff MMO's First Claim for Relief concerning the Physician Pull-Through Marketing Enterprise, and further alleges as follows.

1572. Plaintiff MMO brings this Claim against the Manufacturer Defendants (as defined above), because of the impact of this scheme on MMO described herein.

1573. The Manufacturer Defendants are "persons" within the meaning of Ohio Revised Code § 2923.31(G) who participated in the conduct of the affairs of the Physician Pull-Through Marketing Enterprise through a pattern of "corrupt activity" in violation of Ohio Revised Code Chapter 2923.

1574. Plaintiff MMO is a "person," as that term is defined in Ohio Revised Code § 2923.31(G), who was injured as a result of each Manufacturer Defendants' wrongful conduct. Ohio Revised Code § 2923.34(A).

1575. The Physician Pull-Through Marketing Enterprise is an association-in-fact enterprise within the meaning of Ohio Revised Code § 2923.31(C) consisting of: (i) the Manufacturer Defendants, including their employees and agents, (ii) advocacy groups and professional societies known herein as Front Groups, and (iii) physicians associated with Manufacturer Defendants (or their Front Groups) known herein as KOLs.

1576. The Physician Pull-Through Marketing Enterprise is an ongoing organization that functions as a continuing unit. It was created and used by each Manufacturer Defendant as a tool to effectuate a pattern of "corrupt activity." The Manufacturer Defendant "persons" are distinct from the Physician Pull-Through Marketing Enterprise. The Manufacturer Defendants were aware of the essential nature and scope of this Enterprise and intended to participate in it.

1577. The Physician Pull-Through Marketing Enterprise falls within the meaning of Ohio Revised Code § 2923.31(C) and consists of groups of "persons" associated together for the common purpose of promoting Opioid Drugs to prescribers for unsafe uses and earning profits therefrom.

1578. The Manufacturer Defendants conducted and participated in the conduct of the affairs of the Physician Pull-Through Marketing Enterprise through "corrupt activity" as defined in Ohio Revised Code § 2923.31(I) to mean "engaging in, attempting to engage in, conspiring to engage in, or soliciting, coercing, or intimidating another person to engage in" any conduct defined as "racketeering activity" under the Organized Crime Control Act of 1970, 84 Stat. 941, 18 U.S.C. 1961(1)(B), (1)(C), (1)(D), and (1)(E), as amended.

1579. As previously alleged, the Manufacturer Defendants engaged in a pattern of racketeering activity within the meaning of 18 U.S.C. § § 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, described herein. The false and misleading predicate acts of racketeering activity committed, or caused to be committed, by the Manufacturer Defendants number in the hundreds if not thousands. The Manufacturer Defendants committed, or caused to be committed, at least two of the predicate acts, within the requisite six (6) year period.

1580. The Physician Pull-Through Marketing Enterprise affected commerce in this jurisdiction and other jurisdictions throughout the nation, because, *inter alia*, it marketed, sold, or provided Opioid Drugs to thousands of entities and individuals throughout the United States, including in Ohio, and engaged in the prohibited conduct alleged herein throughout the United States, including in Ohio.

1581. The Manufacturer Defendants exerted control over the Physician Pull-Through Marketing Enterprise, and the Manufacturer Defendants participated in its operation or management of the affairs of the Physician Pull-Through Marketing Enterprise, through a variety of actions including the following:

- the Manufacturer Defendants controlled the content of the messages being delivered by the Physician Pull-Through Marketing Enterprise by its sales representatives, who met individually or telephonically with prescribing physicians, nurses, HCPs and/or their staff;
- the Manufacturer Defendants controlled the content of the messages being delivered by the Physician Pull-Through Marketing Enterprise in advertisements in trade publications or medical journals read by prescribing HCPs;
- the Manufacturer Defendants controlled the content of the messages being delivered by the Physician Pull-Through Marketing Enterprise on the Manufacturer Defendants' own websites, which included information for prescribing HCPs;

- the Manufacturer Defendants controlled the content of the messages being delivered by the Physician Pull-Through Marketing Enterprise by exerting control over the communications to prescribing HCPs concerning Opioid Drugs by various KOLs;
- the Manufacturer Defendants controlled the content of the messages being delivered by the Physician Pull-Through Marketing Enterprise by exerting control over the communications to prescribing HCPs concerning Opioid Drugs by various Front Groups (as identified above);
- the Manufacturer Defendants paid the KOLs and Front Groups for their participation in the Physician Pull-Through Marketing Enterprise;
- the Manufacturer Defendants concealed their relationship and control of Front Groups from physicians, which made the Physician Pull-Through Marketing Enterprise more effective;
- the Manufacturer Defendants concealed their relationship and control of KOLs from HCPs, which made the Physician Pull-Through Marketing Enterprise more effective;
- the Manufacturer Defendants controlled the content of the messages being delivered by the Physician Pull-Through Marketing Enterprise at CME events—or similar purportedly "educational" events for prescribing HCPs—funded or hosted by Manufacturer Defendants, their Front Groups, or featuring KOLs;
- the Manufacturer Defendants selected the prescribing HCP targets of the false and misleading communications delivered by the Physician Pull-Through Marketing Enterprise;
- the Manufacturer Defendants used sophisticated data to micro-target prescribing HCPs with certain prescribing patterns or vulnerable patient populations for communications delivered by the Physician Pull-Through Marketing Enterprise;
- the Manufacturer Defendants provided financial and/or other consideration to prescribing HCPs to write prescriptions for Opioid Drugs; and
- the Manufacturer Defendants placed their own employees and agents in positions of authority and control over the Physician Pull-Through Marketing Enterprise.

1582. As detailed above, the Manufacturer Defendants' Physician Pull-Through Marketing Enterprise, in an effort to increase prescriber demand for Opioid Drugs, made various

misrepresentations and omissions to prescribing HCPs as to: (1) the existence of a "pain epidemic" and urgency with which it must be addressed; (2) the efficacy with which long-term Opioid Drug therapy treats or manages long-term chronic pain; (3) the ability of Opioid Drugs to improve life functions (such as psychological health, health-related quality of life, and quality of life itself); (4) downplaying the serious risk of addiction; (5) creating and promoting the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more Opioid Drugs; (6) exaggerating the effectiveness of screening tools to prevent addiction; (7) claiming that opioid dependence and withdrawal are easily managed; (8) denying the risks of higher Opioid Drug dosages; (9) exaggerating the effectiveness of "abuse-deterrent" Opioid Drug formulations to prevent abuse and addiction; (10) actively concealing, and causing others to conceal, information about the safety (including addiction risk), efficacy, and usefulness of Opioid Drugs to treat long-term chronic pain; and (11) promoting favorable MMO formulary status during "pull-through" sales details with HCPs to encourage Opioid Drug prescribing.

1583. The illegal activities of the Physician Pull-Through Marketing Enterprise required extensive use of the wires and mails by each of the Manufacturer Defendants, Front Groups, and KOLs including, *inter alia*: (1) making travel arrangements for sales representatives (booking of hotels, airplane tickets, arranging meals, etc.); (2) teleconferences or telephonic training for sales representatives; (3) emailing communications between sales representatives and their superiors; (4) developing and disseminating sales representative training materials; (5) engaging in telephonic surveys of HCPs by third-party research firms; (6) disseminating marketing materials to sales representatives (and ultimately HCPs); (7) mailing of marketing materials directly to HCPs; (8) "e-detailing" (by way of sales calls, voice mails, postcards, and emails); (9)

developing advertising content for medical journals (which were subsequently mailed); (10) developing websites for marketing to HCPs; (11) developing and disseminating newsletters containing marketing material; (12) making travel arrangements for KOLs to give speeches or make presentations (booking of hotels, airplane tickets, arranging meals, etc.); (13) developing and coordinating content of the presentations made at conferences or CMEs; (14) publishing and disseminating CME materials; (15) mailing of proposals to CME accrediting institutions; (16) disseminating press releases; (17) collecting data used to "micro-target" certain HCPs; (18) paying "honoraria" to HCPs (such as the mailing of checks or wiring of funds); (19) paying general funds or grants to Front Groups; (20) making travel arrangements for HCPs for "speakers bureau" training events (booking of hotels, airplane tickets, arranging meals, etc.); and (21) disseminating through the wires and mails in this jurisdiction and other jurisdictions throughout the nation formulary cards, detail pieces, and advisory board materials.

1584. Many of the precise dates of the fraudulent uses of the wires and mails by each Manufacturer Defendant are concealed from Plaintiff MMO and cannot be alleged with more particularity without discovery and access to the Manufacturer Defendants' books, records and other documents. However, Plaintiff MMO has described the types of predicate acts of mail and wire fraud that occurred. The secretive nature of the Physician Pull-Through Marketing Enterprise's activities make the unlawful tactics alleged herein even more deceptive and harmful.

1585. The Manufacturer Defendants' Physician Pull-Through Marketing Enterprise and related publications were aimed at increasing prescriber demand and securing formulary placement for Opioid Drugs. The "targets" of the misrepresentations and omissions contained in the Physician Pull-Through Marketing Enterprise publications included both HCPs and

individuals responsible for making formulary and coverage decisions on behalf of TPPs (including Plaintiff MMO and its contracted PBM).

1586. The Manufacturer Defendants' schemes and the above-described racketeering activities amounted to common courses of conduct intended to cause Plaintiff MMO to pay for excessive amounts of Opioid Drugs. Within the Physician Pull-Through Marketing Enterprise, each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff MMO. The Manufacturer Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to Plaintiff MMO.

1587. The Manufacturer Defendants and the other members of the Physician Pull-Through Marketing Enterprise created and maintained systematic links for the common purpose of gaining revenue from marketing Opioid Drugs for the long-term treatment of chronic pain (including revenue from Plaintiff MMO). Each of the members of the Physician Pull-Through Marketing Enterprise received substantial revenue (including from Plaintiff MMO) from misleadingly marketing Opioid Drugs in this manner. Such revenue (including from Plaintiff MMO) was exponentially greater than it would have been if Opioid Drugs had been marketed appropriately.

1588. The Physician Pull-Through Marketing Enterprise has a hub and spoke organizational, decision-making structure, with the Manufacturer Defendants serving as the hub.

1589. All members of the Physician Pull-Through Marketing Enterprise were aware of the Manufacturer Defendants' control over its activities. Furthermore, each member of the Physician Pull-Through Marketing Enterprise benefited from the existence of the other members.

1590. The pattern of "corrupt activity" alleged herein and the Physician Pull-Through Marketing Enterprise are separate and distinct from each other. The Manufacturer Defendants engaged in a pattern of "corrupt activity" alleged herein for the purpose of conducting the affairs of the Physician Pull-Through Marketing Enterprise ~~Physician Pull Through Marketing Enterprise~~.

1591. Plaintiff MMO has been injured in its property by reason of these violations. Through the Physician Pull-Through Marketing Enterprise, the Manufacturer Defendants caused prescribing HCPs to write far more prescriptions for Opioid Drugs than they would otherwise have written absent the Physician Pull-Through Marketing Enterprise's racketeering activities. This led Plaintiff MMO to make millions of dollars in payments for Opioid Drugs – as well as payments for Opioid Drug-related addiction treatment services – that it would not have made otherwise.

1592. Plaintiff MMO thus suffered direct, consequential, and concrete financial loss flowing from the injury to its property by expending these funds, and thereby suffered out-of-pocket losses. And but for the predicate acts committed or caused to be committed by the Manufacturer Defendants, Plaintiff MMO would not have suffered its OCPA injuries.

1593. Plaintiff MMO's injuries were directly and proximately caused by the Manufacturer Defendants' racketeering activity, as described above. Plaintiff MMO's injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; its injuries were a foreseeable and natural consequence of the Manufacturer Defendants' scheme; and there are no others, more directly injured, that could vindicate Plaintiff MMO's claims.

1594. By virtue of these violations of Ohio Revised Code §§ 2923.31, *et seq*., the Manufacturer Defendants are jointly and severally liable to Plaintiff MMO for triple the actual damages Plaintiff MMO has sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

EIGHTH CLAIM FOR RELIEF

Violation of the Ohio Corrupt Practices Act
Ohio Revised Code §§ 2923.31, et seq.
(Scientific Literature Marketing Enterprises)
Against the Manufacturer Defendants

1595. Plaintiff MMO incorporates by reference all preceding paragraphs, as if fully set forth herein. For efficiency and to avoid repetition, for purposes of this claim, Plaintiff MMO specifically incorporates by reference the paragraphs of Plaintiff MMO's Second Claim for Relief concerning the Scientific Literature Marketing Enterprise, and further alleges as follows.

1596. Plaintiff MMO brings this Claim against the Manufacturer Defendants, because of the impact of this scheme on MMO described herein.

1597. The Manufacturer Defendants are "persons" within the meaning of Ohio Revised Code § 2923.31(G) who participated in the conduct of the affairs of the Scientific Literature Marketing Enterprise through a pattern of "corrupt activity" in violation of Ohio Revised Code Chapter 2923.

1598. Plaintiff MMO is a "person," as that term is defined in Ohio Revised Code § 2923.31(G), who was injured as a result of each Manufacturer Defendant's wrongful conduct. Ohio Revised Code § 2923.34(A).

1599. The Scientific Literature Marketing Enterprise is an association-in-fact enterprise within the meaning of Ohio Revised Code § 2923.31(C) consisting of: (i) the Manufacturer Defendants, including their employees and agents, (ii) advocacy groups and professional

societies known herein as Front Groups, and (iii) physicians associated with Manufacturer Defendants (or their Front Groups) known herein as KOLs.

1600. The Scientific Literature Marketing Enterprise is an ongoing organization that functions as a continuing unit. It was created and used by each Manufacturer Defendant as a tool to effectuate a pattern of "corrupt activity." The Manufacturer Defendant "persons" are distinct from the Scientific Literature Marketing Enterprise. The Manufacturer Defendants were aware of the essential nature and scope of this Enterprise and intended to participate in it.

1601. The Scientific Literature Marketing Enterprise falls within the meaning of Ohio Revised Code § 2923.31(C) and consists of groups of "persons" associated together for the common purpose of producing, promoting, and disseminating publication materials of a scientific or academic nature which promoted Opioid Drugs for unsafe uses and earning profits therefrom.

1602. The Manufacturer Defendants conducted and participated in the conduct of the affairs of the Scientific Literature Marketing Enterprise through "corrupt activity" as defined in Ohio Revised Code § 2923.31(I) to mean "engaging in, attempting to engage in, conspiring to engage in, or soliciting, coercing, or intimidating another person to engage in" any conduct defined as "racketeering activity" under the Organized Crime Control Act of 1970, 84 Stat. 941, 18 U.S.C. 1961(1)(B), (1)(C), (1)(D), and (1)(E), as amended.

1603. As previously alleged, the Manufacturer Defendants engaged in a pattern of racketeering activity within the meaning of 18 U.S.C. § § 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, described herein. The false and misleading predicate acts of racketeering activity committed, or caused to be committed, by the Manufacturer Defendants

number in the hundreds if not thousands. The Manufacturer Defendants committed, or caused to be committed, at least two of the predicate acts, within the requisite six (6) year period.

1604. The Scientific Literature Marketing Enterprise affected commerce in this jurisdiction and other jurisdictions throughout the nation, because, inter alia, it operated through trade publications and medical journals with national subscribership, disseminated reprints of studies, articles, Treatment Guidelines, Consensus Statements, and Model Policies to sales representatives and physicians across the nation including in Ohio, which were used as part of the Scientific Literature Marketing Enterprise, which, *inter alia*, marketed, sold or provided Opioid Drugs to thousands of entities and individuals throughout the United States, including in Ohio.

1605. The Manufacturer Defendants exerted control over the Scientific Literature Marketing Enterprise, and the Manufacturer Defendants participated in its operation or management of the affairs of the Scientific Literature Marketing Enterprise, through a variety of actions including the following:

- the Manufacturer Defendants controlled the content of the Scientific Literature Marketing Enterprise publications, and the marketing messages contained therein, promulgated by the Scientific Literature Marketing Enterprise, including the misinformation and false statements described herein;
- the Manufacturer Defendants selected and approved KOLs to serve as "authors" of publications comprising Scientific Literature Marketing Enterprise publications;
- the Manufacturer Defendants funded KOLs to write publications comprising Scientific Literature Marketing Enterprise publications;
- the Manufacturer Defendants controlled the content of KOL-drafted publications comprising Scientific Literature Marketing Enterprise publications;
- the Manufacturer Defendants concealed their relationship and control of KOLs publishing Scientific Literature Marketing Enterprise publications, which made the Scientific Literature Marketing Enterprise more effective;

- the Manufacturer Defendants funded Front Groups to write publications comprising Scientific Literature Marketing Enterprise publications;
- the Manufacturer Defendants concealed their relationship and control of Front Groups disseminating Scientific Literature Marketing Enterprise publications, which made the Scientific Literature Marketing Enterprise more effective;
- the Manufacturer Defendants controlled the content of Front Group-drafted publications comprising Scientific Literature Marketing Enterprise publications;
- the Manufacturer Defendants funded the dissemination of the Scientific Literature Marketing Enterprise publications;
- their funding of particular publications aside, the Manufacturer Defendants paid and therefore sponsored KOLs who participated in the Scientific Literature Marketing Enterprise;
- the Manufacturer Defendants placed their own employees and agents in positions of authority and control over the Scientific Literature Marketing Enterprise;
- the Manufacturer Defendants promoted the Scientific Literature Marketing Enterprise publications by utilizing such publications in CMEs;
- the Manufacturer Defendants promoted the Scientific Literature Marketing Enterprise publications by sponsoring speeches and conferences where KOLs would make presentations based on their respective Scientific Literature Marketing Enterprise publications; and
- the Manufacturer Defendants concealed their involvement in the Scientific Literature Marketing Enterprise such that its publications would have a veneer of credibility as independent and unbiased scientific research.

1606. As detailed above, the Manufacturer Defendants' Scientific Literature Marketing Enterprise publications consisted primarily of: (1) clinical studies; (2) Consensus Statements; (3) Treatment Guidelines; (4) Model Policies; (5) academic journal publications; and (6) Front Group reviews and official statements criticizing FDA and CDC initiatives.

1607. The Manufacturer Defendants' Scientific Literature Marketing Enterprise and related publications were aimed at increasing prescriber demand and securing formulary placement for Opioid Drugs. The "targets" of the misrepresentations and omissions contained in the Scientific Literature Marketing Enterprise publications included both prescribers and

individuals responsible for making formulary and coverage decisions on behalf of TPPs (including Plaintiff MMO and its contracted PBM).

1608. The misrepresentations and omissions included in the Scientific Literature Marketing Enterprise publications, on which prescribers and TPPs (including Plaintiff MMO) relied to that end, included: (1) the existence of a "pain epidemic" and urgency with which it must be addressed; (2) the efficacy with which long-term Opioid Drug therapy treats or manages long-term chronic pain; (3) the ability of Opioid Drugs to improve life functions (such as psychological health, health-related quality of life, and quality of life itself); (4) downplaying the serious risk of addiction; (5) creating and promoting the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocating that the signs of addiction should be treated with more Opioid Drugs; (6) exaggerating the effectiveness of screening tools to prevent addiction; (7) claiming that opioid dependence and withdrawal are easily managed; (8) denying the risks of higher Opioid Drug dosages; (9) exaggerating the effectiveness of "abuse-deterrent" Opioid Drug formulations to prevent abuse and addiction; and (10) actively concealing, and causing others to conceal, information about the safety (including addiction risk), efficacy, and usefulness of Opioid Drugs to treat long-term chronic pain.

1609. The illegal activities of the Scientific Literature Marketing Enterprise required extensive use of the wires and mails by each of the Manufacturer Defendants, Front Groups, and KOLs including, *inter alia*: (1) developing content for Scientific Literature Marketing Enterprise publications; (2) emailing and/or engaging in telephonic conversations between Manufacturer Defendants and KOLs wherein Manufacturer Defendants exerted influence over the misleading content in a forthcoming Scientific Literature Marketing Enterprise publication; (3) emailing and/or engaging in telephonic conversations between Manufacturer Defendants and Front

Groups wherein Manufacturer Defendants exerted influence over the misleading content in a forthcoming Scientific Literature Marketing Enterprise publication; (4) paying KOLs (such as the mailing of checks or wiring of funds) to generate Scientific Literature Marketing Enterprise publications; (5) paying Front Groups (such as the mailing of checks or wiring of funds) to generate Scientific Literature Marketing Enterprise publications; (6) widespread distributing and disseminating of Scientific Literature Marketing Enterprise publications (either by printing and mailing or emailing); and (7) making travel arrangements (booking of hotels, airplane tickets, arranging meals, etc.) for KOLs to conduct presentations based on various Scientific Literature Marketing Enterprise publications.

1610. Many of the precise dates of the fraudulent uses of the wires and mails by each Manufacturer Defendant are concealed from Plaintiff MMO and cannot be alleged with more particularity without discovery and access to the Manufacturers' books, records and other documents. However, Plaintiff MMO has described the types of predicate acts of mail and wire fraud that occurred. The secretive nature of the Scientific Literature Marketing Enterprise's activities make the unlawful tactics alleged herein even more deceptive and harmful.

1611. The Manufacturer Defendants' schemes and the above-described racketeering activities amounted to common courses of conduct intended to cause Plaintiff MMO to pay for excessive amounts of Opioid Drugs. Within the Scientific Literature Marketing Enterprise, each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff MMO. The Manufacturer Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to Plaintiff MMO. The Manufacturer Defendants and the other members of the Scientific Literature Marketing Enterprise created and

maintained systematic links for the common purpose of gaining revenue from marketing Opioid Drugs for the long-term treatment of chronic pain (including revenue from Plaintiff MMO). Each of the members of the Scientific Literature Marketing Enterprise received substantial revenue (including from Plaintiff MMO) from misleadingly marketing Opioid Drugs in this manner. Such revenue was exponentially greater than it would have been if Opioid Drugs had been marketed appropriately.

1612. The Scientific Literature Marketing Enterprise has a hub and spoke organizational, decision-making structure, with the Manufacturer Defendants serving as the hub.

1613. All members of the Scientific Literature Marketing Enterprise were aware of the Manufacturer Defendants' control over its activities. Furthermore, each member of the Scientific Literature Marketing Enterprise benefited from the existence of the other members.

1614. The pattern of "corrupt activity" alleged herein and the Scientific Literature Marketing Enterprise are separate and distinct from each other. The Manufacturer Defendants engaged in a pattern of "corrupt activity" alleged herein for the purpose of conducting the affairs of the Scientific Literature Marketing Enterprise.

1615. Plaintiff MMO has been injured in its property by reason of these violations. Through the Scientific Literature Marketing Enterprise, the Manufacturer Defendants caused prescribing physicians to write far more prescriptions for Opioid Drugs than they would otherwise have written absent the Scientific Literature Marketing Enterprise's racketeering activities. Further, through the Scientific Literature Marketing Enterprise, Manufacturer Defendants caused TPPs (including Plaintiff MMO) to make coverage and formulary decisions that they would not have otherwise made absent the Scientific Literature Marketing Enterprise's racketeering activities. This led Plaintiff MMO to make millions of dollars in payments for

Opioid Drugs—as well as payments for Opioid Drug-related addiction treatment services—that it would not have made otherwise.

1616. Plaintiff MMO thus suffered direct, consequential, and concrete financial loss flowing from the injury to its property by expending these funds, and thereby suffered out-of-pocket losses. And but for the predicate acts committed or caused to be committed by the Manufacturer Defendants, Plaintiff MMO would not have suffered its OCPA injuries.

1617. Plaintiff MMO's injuries were directly and proximately caused by the Manufacturer Defendants' racketeering activity, as described above. Plaintiff MMO's injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; its injuries were a foreseeable and natural consequence of the Manufacturer Defendants' scheme; and there are no others, more directly injured, that could vindicate Plaintiff MMO's claims.

1618. By virtue of these violations of Ohio Revised Code §§ 2923.31, et seq., the Manufacturer Defendants are jointly and severally liable to Plaintiff MMO for triple the actual damages Plaintiff MMO has sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

NINTH CLAIM FOR RELIEF

Violation of the Ohio Corrupt Practices Act
Ohio Revised Code §§ 2923.31, et seq.
(Consumer Pull-Through Marketing Enterprises)
Against the Manufacturer Defendants

1619. Plaintiff MMO incorporates by reference all preceding paragraphs, as if fully set forth herein. For efficiency and to avoid repetition, for purposes of this claim, Plaintiff MMO specifically incorporates by reference the paragraphs of Plaintiff MMO's Third Claim for Relief concerning the Consumer Pull-Through Marketing Enterprise, and further alleges as follows.

1620. Plaintiff MMO brings this Claim against the Manufacturer Defendants, because of the impact of this scheme on MMO described herein.

1621. The Manufacturer Defendants are "persons" within the meaning of Ohio Revised Code § 2923.31(G) who participated in the conduct of the affairs of the Consumer Pull-Through Marketing Enterprise through a pattern of "corrupt activity" in violation of Ohio Revised Code Chapter 2923.

1622. Plaintiff MMO is a "person," as that term is defined in Ohio Revised Code § 2923.31(G), who was injured as a result of each Manufacturer Defendant's wrongful conduct. Ohio Revised Code § 2923.34(A).

1623. The Consumer Pull-Through Marketing Enterprise is an association-in-fact enterprise within the meaning of Ohio Revised Code § 2923.31(C) consisting of: (i) the Manufacturer Defendants, including their employees and agents, (ii) advocacy groups and professional societies known herein as Front Groups, and (iii) physicians associated with Manufacturer Defendants (or their Front Groups) known herein as KOLs.

1624. The Consumer Pull-Through Marketing Enterprise is an ongoing organization that functions as a continuing unit. It was created and used by each Manufacturer Defendant as a tool to effectuate a pattern of "corrupt activity." The Manufacturer Defendant "persons" are distinct from the Consumer Pull-Through Marketing Enterprise. The Manufacturer Defendants were aware of the essential nature and scope of this Enterprise and intended to participate in it.

1625. The Consumer Pull-Through Marketing Enterprise falls within the meaning of Ohio Revised Code § 2923.31(C) and consists of groups of "persons" associated together for the common purpose of promoting Opioid Drugs for unsafe uses and earning profits therefrom.

1626. The Manufacturer Defendants conducted and participated in the conduct of the affairs of the Consumer Pull-Through Marketing Enterprise through a pattern of "corrupt activity." As defined in Ohio Revised Code § 2923.31(I), "corrupt activity" means "engaging in, attempting to engage in, conspiring to engage in, or soliciting, coercing, or intimidating another person to engage in" any conduct defined as "racketeering activity" under the Organized Crime Control Act of 1970, 84 Stat. 941, 18 U.S.C. 1961(1)(B), (1)(C), (1)(D), and (1)(E), as amended.

1627. As previously alleged, the Manufacturer Defendants engaged in a pattern of racketeering activity within the meaning of 18 U.S.C. § § 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as described herein. The false and misleading predicate acts of racketeering activity committed, or caused to be committed, by the Manufacturer Defendants number in the hundreds if not thousands. The Manufacturer Defendants committed, or caused to be committed, at least two of the predicate acts, within the requisite six (6) year period.

1628. The Consumer Pull-Through Marketing Enterprise affected commerce in this jurisdiction and other jurisdictions throughout the nation, because, it operated through websites and media campaigns with national reach, and disseminated pamphlets, "education guides" and other materials to thousands of entities and individuals throughout the United States, including in Ohio, which were used as part of the Consumer Pull-Through Marketing Enterprise, which, *inter alia*, marketed, sold or provided Opioid Drugs to thousands of entities and individuals throughout the United States, including in Ohio.

1629. The Manufacturer Defendants exerted control over the Consumer Pull-Through Marketing Enterprise, and the Manufacturer Defendants participated in its operation or

management of the affairs of the Consumer Pull-Through Marketing Enterprise, through a variety of actions including the following:

- the Manufacturer Defendants controlled the content of the Consumer Pull-Through Marketing Enterprise, and the marketing messages contained therein, promulgated by the Consumer Pull-Through Marketing Enterprise, including the misinformation and false statements described herein;
- the Manufacturer Defendants controlled the content of the messages being delivered by the Consumer Pull-Through Marketing Enterprise by pamphlets and other "educational" written materials that were provided directly to consumers at their physicians' offices;
- the Manufacturer Defendants controlled the content of the messages being delivered by the Consumer Pull-Through Marketing Enterprise on the Manufacturer Defendants' own Opioid Drug websites, which included information for consumers suffering from chronic pain (and/or their family members);
- the Manufacturer Defendants controlled the content of the messages being delivered by the Consumer Pull-Through Marketing Enterprise by exerting control over the content of "education guides" (or similar information material) provided to consumers suffering from chronic pain by various Front Groups (as identified above);
- the Manufacturer Defendants controlled the content of various media appearances and media campaigns—meant to reach a broad base of the population including consumers suffering from chronic pain—operated by their Front Groups;
- the Manufacturer Defendants funded the Front Groups for their participation in the Consumer Pull-Through Marketing Enterprise;
- the Manufacturer Defendants concealed their relationship and control of Front Groups disseminating information to consumers suffering from chronic pain, which made the Consumer Pull-Through Marketing Enterprise more effective;
- the Manufacturer Defendants controlled the content of KOLs who made media appearances meant to reach a broad base of the population including consumers suffering from chronic pain;
- the Manufacturer Defendants funded KOLs to make media appearances meant to reach a broad base of the population including consumers suffering from chronic pain;
- the Manufacturer Defendants concealed their relationship and control of KOLs making media appearances meant to reach a broad base of the population including consumers suffering from chronic pain, which made the Consumer Pull-Through Marketing Enterprise more effective;

- the Manufacturer Defendants funded and encouraged Front Groups to target elderly consumers with false and misleading statements regarding Opioid Drugs, through media campaigns, "educational" material available online, published "educational" pamphlets, and direct contact with the elderly and/or groups advocating on the elderly's behalf;
- the Manufacturer Defendants funded and encouraged Front Groups to target wounded veteran consumers with false and misleading statements regarding Opioid Drugs, through media campaigns, "educational" material available online, published "educational" pamphlets, and direct contact with the wounded veterans and/or groups advocating on the elderly's behalf;
- the Manufacturer Defendants—in furtherance of the Consumer Pull-Through Marketing Enterprise—created financial incentives to attract consumers to the use of Opioid Drugs, including co-payment assistance, coupons, and vouchers; and
- the Manufacturer Defendants placed their own employees and agents in positions of authority and control over the Consumer Pull-Through Marketing Enterprise.

1630. As detailed above, the Manufacturer Defendants' Consumer Pull-Through Marketing Enterprise and related publications were aimed at increasing patient demand and securing formulary placement for Opioid Drugs. The "targets" of the misrepresentations and omissions contained in the Consumer Pull-Through Marketing Enterprise publications included both patients and individuals responsible for making formulary and coverage decisions on behalf of TPPs (including Plaintiff MMO and its contracted PBM).

1631. As detailed above, the Manufacturer Defendants' Consumer Pull-Through Marketing Enterprise, in an effort to increase patient demand for Opioid Drugs, made various misrepresentations and omissions to potential customers suffering from chronic pain as to: (1) the existence of a "pain epidemic" and urgency with which it must be addressed; (2) that living with pain is a "choice"; (3) the efficacy with which long-term Opioid Drug therapy treats or manages long-term chronic pain; (4) downplaying the serious risk of addiction; (5) suggesting patients "advocate" for themselves with their HCPs, should not "take no for an answer," and

threaten to leave prescribers who did not provide Opioid Drugs; and (6) actively concealing, and causing others to conceal, information about the safety (including addiction risk), efficacy, and usefulness of Opioid Drugs to treat long-term chronic pain.

1632. The illegal activities of the Consumer Pull-Through Marketing Enterprise required extensive use of the wires and mails by each of the Manufacturer Defendants, Front Groups, and KOLs including, *inter alia*: (1) making travel arrangements for KOLs to make media appearances (booking of hotels, airplane tickets, arranging meals, etc.); (2) e-mailing communications between Manufacturer Defendants and Front Groups regarding the substance of various media campaigns and/or media appearances; (3) e-mailing communications between Manufacturer Defendants and KOLs regarding the substance of various media appearances; (4) disseminating consumer marketing materials (including pamphlets and videos) to sales representatives who provided them for consumers at various physician offices; (5) mailing of consumer marketing materials (including pamphlets and videos) to physicians who provided them to consumers at various physician offices; (6) mailing of consumer marketing materials by Front Groups to various advocacy groups representing the interests of the elderly or wounded veterans; (7) mailing of consumer rebates, co-pay assistance vouchers, or coupons to physicians who provided them to consumers suffering from chronic pain; (8) developing Opioid Drug websites that included marketing materials aimed at consumers suffering from chronic pain; (9) developing Front Group websites that included marketing materials aimed at consumers suffering from chronic pain; and (10) television broadcasting of various KOL interviews aimed at disseminating marketing material to consumers suffering from chronic pain.

1633. Many of the precise dates of the fraudulent uses of the wires and mails by each Manufacturer Defendant are concealed from Plaintiff MMO and cannot be alleged with more

particularity without discovery and access to the Manufacturers' books, records and other documents. However, Plaintiff MMO has described the types of predicate acts of mail and wire fraud that occurred. The secretive nature of the Consumer Pull-Through Marketing Enterprise's activities make the unlawful tactics alleged herein even more deceptive and harmful.

1634. The Manufacturer Defendants' schemes and the above-described racketeering activities amounted to common courses of conduct intended to cause Plaintiff MMO to pay for excessive amounts of Opioid Drugs. Within the Consumer Pull-Through Marketing Enterprise, each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff MMO. The Manufacturer Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to Plaintiff MMO.

1635. The Manufacturer Defendants and the other members of the Consumer Pull-Through Marketing Enterprise created and maintained systematic links for the common purpose of gaining revenue from marketing Opioid Drugs for the long-term treatment of chronic pain (including revenue from Plaintiff MMO). Each of the members of the Consumer Pull-Through Marketing Enterprise received substantial revenue (including from Plaintiff MMO) from misleadingly marketing Opioid Drugs in this manner. Such revenue was exponentially greater than it would have been if Opioid Drugs had been marketed appropriately.

1636. The Consumer Pull-Through Marketing Enterprise has a hub and spoke organizational, decision-making structure, with the Manufacturer Defendants serving as the hub.

1637. All members of the Consumer Pull-Through Marketing Enterprise were aware of the Manufacturer Defendants' control over its activities. Furthermore, each member of the

Consumer Pull-Through Marketing Enterprise benefited from the existence of the other members.

1638. The pattern of "corrupt activity" alleged herein and the Consumer Pull-Through Marketing Enterprise are separate and distinct from each other. The Manufacturer Defendants engaged in a pattern of "corrupt activity" alleged herein for the purpose of conducting the affairs of the Consumer Pull-Through Marketing Enterprise.

1639. Plaintiff MMO has been injured in its property by reason of these violations. Through the Consumer Pull-Through Marketing Enterprise, the Manufacturer Defendants - by increasing not only patient demand but aggressive lobbying by patients of their physicians - caused prescribing HCPs to write far more prescriptions for Opioid Drugs than they would otherwise have written absent the Consumer Pull-Through Marketing Enterprise's racketeering activities. Thus, through the Consumer Pull-Through Marketing Enterprise, Manufacturer Defendants caused TPPs (including Plaintiff MMO) to make coverage and formulary decisions that they would not have otherwise made absent the Consumer Pull-Through Marketing Enterprise's racketeering activities. This led Plaintiff MMO to make millions of dollars in payments for Opioid Drugs—as well as payments for Opioid Drug-related addiction treatment services—that it would not have made otherwise.

1640. Plaintiff MMO thus suffered direct, consequential, and concrete financial loss flowing from the injury to its property by expending these funds, and thereby suffered out-of-pocket losses. And but for the predicate acts committed or caused to be committed by the Manufacturer Defendants, Plaintiff MMO would not have suffered its OCPA injuries.

1641. Plaintiff MMO's injuries were directly and proximately caused by the Manufacturer Defendants' racketeering activity, as described above. Plaintiff MMO's injuries

were directly caused by the predicate acts and are not attributable to any independent or intervening factors; its injuries were a foreseeable and natural consequence of the Manufacturer Defendants' scheme; and there are no others, more directly injured, that could vindicate Plaintiff MMO's claims.

1642. By virtue of these violations of Ohio Revised Code §§ 2923.31, et seq., the Manufacturer Defendants are jointly and severally liable to Plaintiff MMO for triple the actual damages Plaintiff MMO has sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

TENTH CLAIM FOR RELIEF

Violation of the Ohio Corrupt Practices Act
Ohio Revised Code §§ 2923.31, et seq.
(Formulary Access and Coverage Enterprises)
Against All Defendants

1643. Plaintiff MMO incorporates by reference all preceding paragraphs, as if fully set forth herein. For efficiency and to avoid repetition, for purposes of this claim, Plaintiff MMO specifically incorporates by reference the paragraphs of Plaintiff MMO's Fourth Claim for Relief concerning the Formulary Access and Coverage Enterprise, and further alleges as follows.

1644. Plaintiff MMO brings this Claim against the following Defendants, defined above: the Manufacturer Defendants, the Distributor Defendants, and the Retail Pharmacy Defendants (collectively, for purpose of this Claim, the "Defendants"), because of the impact of this scheme on MMO described herein.

1645. The Defendants are "persons" within the meaning of Ohio Revised Code § 2923.31(G) who participated in the conduct of the affairs of the Formulary Access and Coverage Enterprise through a pattern of "corrupt activity" in violation of Ohio Revised Code Chapter 2923.

1646. Plaintiff MMO is a "person," as that term is defined in Ohio Revised Code § 2923.31(G), who was injured as a result of each of the Defendant's wrongful conduct. Ohio Revised Code § 2923.34(A).

1647. The Formulary Access and Coverage Enterprise is an association-in-fact enterprise within the meaning of Ohio Revised Code § 2923.31(C) consisting of: (i) Defendants, including their employees and agents, (ii) advocacy groups and professional societies known herein as Front Groups, and (iii) physicians associated with Manufacturer Defendants (or their Front Groups) known herein as KOLs.

1648. The Formulary Access and Coverage Enterprise is an ongoing organization that functions as a continuing unit. It was created and used by each Defendant as a tool to effectuate a pattern of "corrupt activity." The Defendant "persons" are distinct from the Formulary Access and Coverage Enterprise. The Defendants, however, were aware of the essential nature and scope of this Enterprise and intended to participate in it and/or conduct it.

1649. The Formulary Access and Coverage Enterprise falls within the meaning of Ohio Revised Code § 2923.31(C) and consists of groups of "persons" associated together for the common purpose of promoting Opioid Drugs for unsafe uses, securing formulary access and preferred formulary placement for Opioid Drugs, and earning profits therefrom.

1650. The Defendants have conducted and participated in the conduct of the affairs of the Formulary Access and Coverage Enterprise through "corrupt activity" as defined in Ohio Revised Code § 2923.31(I) to mean "engaging in, attempting to engage in, conspiring to engage in, or soliciting, coercing, or intimidating another person to engage in" any conduct defined as "racketeering activity" under the Organized Crime Control Act of 1970, 84 Stat. 941, 18 U.S.C. 1961(1)(B), (1)(C), (1)(D), and (1)(E), as amended.

1651. As previously alleged, the Defendants engaged in a pattern of racketeering activity within the meaning of 18 U.S.C. § § 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, described herein. The false and misleading predicate acts of racketeering activity committed, or caused to be committed, by the Defendants number in the hundreds if not thousands. The Defendants committed, or caused to be committed, at least two of the predicate acts, within the requisite six (6) year period.

1652. The Formulary Access and Coverage Enterprise engaged in and affected commerce in this jurisdiction and other jurisdictions throughout the nation, because, *inter alia*, it marketed, sold, or provided Opioid Drugs to thousands of entities and individuals throughout the United States, including in Ohio, and engaged in the prohibited conduct alleged herein throughout the United States, including in Ohio.

1653. The Defendants exerted control over the Formulary Access and Coverage Enterprise, and the Defendants participated in its operation or management of the affairs of the Formulary Access and Coverage Enterprise, through a variety of actions including the following:

- the Defendants controlled the content of the Formulary Access and Coverage Enterprise, and the messages contained therein, promulgated by the Formulary Access and Coverage Enterprise, including the misinformation, concealments, and false statements described herein;
- the Defendants controlled the content of the messages being delivered by the Formulary Access and Coverage Enterprise at MMO and PQM committee meetings and at P&T committee meetings with its contracted PBM;
- certain Defendants controlled the stream of information disseminated by the Formulary Access and Coverage Enterprise concerning Opioid Drugs by exerting control over the communications concerning Opioid Drugs by managed care sales groups, KOLs, and/or Front Groups that were made to MMO or its contracted PBM;

- certain Defendants funded the KOLs and/or Front Groups responsible for communications concerning Opioid Drugs made to MMO or its contracted PBM;
- the Defendants controlled the content of misleading messages aimed at MMO that were published in periodicals to which TPPs (including MMO) subscribed, including, inter alia: 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;
- the Defendants controlled the content (or lack thereof) of information regarding drug diversion reported to the appropriate federal agencies, as required under the CSA;
- the Defendants utilized the Formulary Access and Coverage Enterprise to target Plaintiff MMO, its PQM committees and P&T meetings of its contracted PBM, by concealing the significant evidence of drug diversion, which deceived them into placing Opioid Drugs on their formularies and giving them preferred status; and
- the Defendants placed their own employees and agents in positions of authority and control over the Formulary Access and Coverage Enterprise.

1654. As detailed above, Defendants' Formulary Access and Coverage Enterprise, in an effort to secure and protect formulary access and status for Opioid Drugs, made various misrepresentations and omissions to MMO, its PQM committees, to MMO's contracted PBM and its P&T committees and relevant decision-makers as to: (1) the efficacy with which long-term Opioid Drug therapy treats or manages long-term chronic pain; (2) the ability of Opioid Drugs to improve life functions (such as psychological health, health-related quality of life, and quality of life itself), which in turn would save expenditures by TPPs including MMO; (3) downplaying the serious risk of addiction; (4) exaggerating the effectiveness of screening tools to prevent drug diversion; and (5) actively concealing information relating to the rampant drug diversion affecting Opioid Drugs.

1655. The illegal activities of the Formulary Access and Coverage Enterprise required extensive use of the wires and mails by each of the Defendants, Front Groups, and KOLs including, *inter alia*: (1) making travel arrangements for Defendants and/or KOLs to attend conferences which were attended by TPPs including MMO (booking of hotels, airplane tickets, arranging meals, etc.); (2) engaging in telephonic meetings whereby certain Defendants provided MMO misleading information regarding Opioid Drugs; (3) e-mailing communications wherein certain Defendants provided MMO misleading information regarding Opioid Drugs; (4) providing false and misleading content regarding Opioid Drugs to numerous journals or similar publications, which were in turn mailed to TPPs including MMO; and (5) providing false and misleading content regarding Opioid Drugs to various e-mail newsletters, which were in turn transmitted to TPPs including MMO.

1656. Many of the precise dates of the fraudulent uses of the wires and mails by each of the Defendants are concealed from Plaintiff MMO and cannot be alleged with more particularity without discovery and access to the Defendants' books, records and other documents. However, Plaintiff MMO has described the types of predicate acts of mail and wire fraud that occurred. The secretive nature of the Formulary Access and Coverage Enterprise's activities make the unlawful tactics alleged herein even more deceptive and harmful.

1657. The Defendants' schemes and the above-described racketeering activities amounted to common courses of conduct intended to cause Plaintiff MMO to pay for excessive amounts of Opioid Drugs. Within the Formulary Access and Coverage Enterprise, each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff

MMO. The Defendants' fraudulent activities are part of their ongoing business and constitute a continuing threat to Plaintiff MMO.

1658. The Defendants and the other members of the Formulary Access and Coverage Enterprise created and maintained systematic links for the common purpose of securing Opioid Drug access and preferred status on MMO's formulary. This allowed each of the members of the Formulary Access and Coverage Enterprise to receive substantial revenue (including from Plaintiff MMO). Such revenue was exponentially greater than it would have been if Opioid Drugs had been marketed appropriately, or if Defendants had complied with their obligations to identify, monitor and report evidence of drug diversion.

1659. The Formulary Access and Coverage Enterprise has a hub and spoke organizational, decision-making structure, with the Defendants serving as the hub.

1660. All members of the Formulary Access and Coverage Enterprise were aware of the Defendants' control over its activities. Furthermore, each member of the Formulary Access and Coverage Enterprise benefited from the existence of the other members.

1661. The pattern of "corrupt activity" alleged herein and the Formulary Access and Coverage Enterprise are separate and distinct from each other. The Defendants engaged in a pattern of "corrupt activity" alleged herein for the purpose of conducting the affairs of the Formulary Access and Coverage Enterprise.

1662. Plaintiff MMO has been injured in its property by reason of these violations. Through the Formulary Access and Coverage Enterprise, the Defendants secured and protected access and status with respect to Plaintiff MMO's formulary, which increased both prescriber and patient demand for Opioid Drugs. Defendants' illegal conduct through the Formulary Access and Coverage Enterprise led TPPs (including Plaintiff MMO) to make coverage and

formulary decisions that they would not have otherwise made absent the Formulary Access and Coverage Enterprise racketeering activities. This led Plaintiff MMO to make millions of dollars in payments for Opioid Drugs – as well as payments for Opioid Drug-related addiction treatment services-that it would not have made otherwise.

1663. Plaintiff MMO thus suffered direct, consequential, and concrete financial loss flowing from the injury to its property by expending these funds, and thereby suffered out-of-pocket losses. And but for the predicate acts committed or caused to be committed by the Defendants, Plaintiff MMO would not have suffered its OCPA injuries.

1664. Plaintiff MMO's injuries were directly and proximately caused by the Defendants' racketeering activity, as described above. Plaintiff MMO's injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; its injuries were a foreseeable and natural consequence of the Defendants' scheme; and there are no others, more directly injured, that could vindicate Plaintiff MMO's claims.

1665. By virtue of these violations of Ohio Revised Code §§ 2923.31, et seq., the Manufacturer Defendants are jointly and severally liable to Plaintiff MMO for triple the actual damages Plaintiff MMO has sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

ELEVENTH CLAIM FOR RELIEF

Violation of the Ohio Corrupt Practices Act
Ohio Revised Code §§ 2923.31, et seq.
(The Drug Diversion Concealment Enterprises)
Against All Defendants

1666. Plaintiff MMO incorporates by reference all preceding paragraphs, as if fully set forth herein. For efficiency and to avoid repetition, for purposes of this claim, Plaintiff MMO

specifically incorporates by reference the paragraphs of Plaintiff MMO's Fifth Claim for Relief concerning the Drug Diversion Concealment Enterprise, and further alleges as follows.

1667. Plaintiff MMO brings this Claim against the following Defendants, defined above: the Manufacturer Defendants, the Distributor Defendants, and the Retail Pharmacy Defendants (collectively for purpose of this Claim, the "Defendants"), because of the impact of this scheme on MMO described herein.

1668. The Defendants are "persons" within the meaning of Ohio Revised Code § 2923.31(G) who participated in the conduct of the affairs of the Drug Diversion Concealment Enterprise through a pattern of "corrupt activity" in violation of Ohio Revised Code Chapter 2923. Specifically, Defendants engaged in a conspiracy to expand the market for Opioid Drugs – thus inflating their own profits-by intentionally violating their legal requirements to identify, detect, monitor, and report evidence of Opioid Drug diversion.

1669. Plaintiff MMO is a "person," as that term is defined in Ohio Revised Code § 2923.31(G), who was injured as a result of each of the Defendant's wrongful conduct. Ohio Revised Code § 2923.34(A).

1670. The Drug Diversion Concealment Enterprise is a legal association and/or association-in-fact enterprise within the meaning of Ohio Revised Code § 2923.31(C), consisting of at a minimum, a Manufacturer Defendant, a Distributor Defendants, and a Pharmacy Defendant (or a smaller and/or local pharmacy not named as a defendant in the instant case). These legal associations and/or associations in fact are, for purposes of the OCPA, an enterprise (hereinafter, for purpose of this count, an "Enterprise," a "Drug Diversion Concealment Enterprise," or collectively, the "Enterprises").

1671. Under the present facts, each Defendant either (a) agreed to operate or manage the Enterprise that did and does feloniously deal in controlled substances, an offense punishable under federal and state laws, or (b) if a co-conspirator did not agree to operate or manage the Enterprise, each co-conspirator knowingly agreed to facilitate others who did and do operate or manage the Enterprise of felonious dealing in controlled substances, an offense punishable under federal and state laws.

1672. To illustrate of the concept of an Enterprise, consider the following example. A Manufacturer Defendant manufactures Opioid Drugs. The Manufacturer Defendant then sells the same Opioid Drugs to a Distributor Defendant. The Distributor Defendant then distributes, or sells, the same Opioid Drugs to a Pharmacy Defendant. Finally, the Pharmacy Defendant sells the same Opioid Drugs to the Pharmacy Defendant's customers who have been provided a prescription for the Opioid Drugs.

1673. To the Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants, what the customer does with the Opioid Drugs once the final sale has been made is irrelevant. He may ingest the Opioid Drugs for legitimate medical purposes, such as to treat severe acute or chronic pain; he may abuse the Opioid Drugs personally by ingesting them for recreational purposes or to support a drug habit; or he may give or sell them to a third-party abuser who ingests them recreationally or out of habit to support an addiction, thus supporting the black market for Opioid Drugs.

1674. Members of the Drug Diversion Concealment Enterprise systematically violated their statutory duties to maintain effective controls against diversion of their Opioid Drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders. Consequently, Defendants

allowed hundreds of millions of pills to enter the illicit market, which allowed the Defendants to derive and be unjustly enriched by obscene profits.

1675. In addition to their statutory duties, the Pharmacy Defendants violated their contractual duty to MMO (and/or its PBM) to refrain from knowingly submitting claims to ESI that were false, were not accurate, or otherwise complete.

1676. The Drug Diversion Concealment Enterprise is an ongoing organization that functions as a continuing unit. It was created and used by each Defendant as a tool to effectuate a pattern of "corrupt activity." The Defendant "persons" are distinct from the Drug Diversion Concealment Enterprise. The Defendants, however, were aware of the essential nature and scope of this Enterprise and intended to participate in it and/or conduct it.

1677. The Drug Diversion Concealment Enterprise falls within the meaning of Ohio Revised Code § 2923.31(C) and consists of groups of "persons" associated together for the common purpose of promoting Opioid Drugs for unsafe uses, nurturing a diversion-based market for Opioid Drugs (to increase their profits), and secure formulary access and preferred formulary placement for Opioid Drugs by denying TPPs, such as Plaintiff MMO, of the knowledge needed to make informed formulary decisions, and earning profits therefrom.

1678. The Defendants have conducted and participated in the affairs of the Drug Diversion Concealment Enterprise through "corrupt activity" as defined in Ohio Revised Code § 2923.31(I) to mean "engaging in, attempting to engage in, conspiring to engage in, or soliciting, coercing, or intimidating another person to engage in" any conduct defined as "racketeering activity" under the Organized Crime Control Act of 1970, 84 Stat. 941, 18 U.S.C. 1961(1)(B), (1)(C), (1)(D), and (1)(E), as amended.

1679. As previously alleged, the Defendants engaged in a pattern of racketeering activity within the meaning of 18 U.S.C. § § 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, described herein. The false and misleading predicate acts of racketeering activity committed, or caused to be committed, by the Defendants number in the hundreds if not thousands. The Defendants committed, or caused to be committed, at least two of the predicate acts, within the requisite six (6) year period.

1680. The Drug Diversion Concealment Enterprise engaged in and affected commerce in this jurisdiction and other jurisdictions throughout the nation, because, *inter alia*, it marketed, sold, or provided Opioid Drugs to thousands of entities and individuals throughout the United States, including in Ohio, and engaged in the prohibited conduct alleged herein throughout the United States, including in Ohio.

1681. The Defendants exerted control over the Drug Diversion Concealment Enterprise, and the Defendants participated in its operation or management of the affairs of the Drug Diversion Concealment Enterprise, through a variety of actions including the following:

- through their memberships in various industry groups, such as the PCF and the HDA;
- through their own contractual relationships;
- without regard to their obligations under the CSA and other state and federal laws and regulations, such as the obligation to report suspicious orders;
- without regard to whether the prescriptions presented by purchasers are for legitimate purposes;
- without regard to whether the size of individual doses or collective volume of doses in individual prescriptions is appropriate, or extremely inappropriate, given the conditions for the Opioid Drug prescriptions;
- without regard to whether the purchasers did in the past or continue to exhibit drug seeking behavior;

- without regard to whether the purchasers have a known history of criminal activity inside the Pharmacy Defendants' stores, or on or near their property;
- without regard to whether an individual customer presents multiple prescriptions from different doctors, who are unaware of each other, during a single month; and
- without regard to whether prescriptions were written by doctors who have a known history of, or presently continue, engaging in suspicious or downright fraudulent over-prescribing.

1682. It was further part of said scheme and artifice that Defendants' communications directed toward government officials and courts would be and were designed to preserve and increase the market for prescription opioids while concealing Defendants' role in supporting an illegal market for Opioid Drugs, which in turn protected formulary access and preferred placement for the Opioid Drugs.

1683. Throughout the existence of the Drug Diversion Concealment Enterprise, the Defendants purposefully failed to comply with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription Opioid Drugs—all the while espousing to the general public, to Congress, federal and state agencies, and TPPs (including MMO) their commitment to preventing diversion of prescription Opioid Drugs.

1684. The felonious dealings described herein were made in furtherance of the Defendants' unified scheme to increase and maintain profits from unlawful sales of Opioid Drugs while thwarting the ability of federal and state regulators, as well as TPPs (including MMO) to prevent diversion. This unified scheme was furthered by: (1) habitual noncompliance with federal and state law; (2) intensive lobbying of federal and state officials to evade further regulation; and (3) increasing and/or maintaining high production quotas for their prescription Opioid Drugs from which Defendants could profit for as long as possible.

1685. The Defendants unlawfully, knowingly and intentionally combined, conspired, confederated, and agreed together with each other, and with others whose names are both known and unknown, to conduct and participate, directly and indirectly, in the overall objective of their unified scheme, and participated in the common course of conduct to fail to prevent the overprescribing and diversion of prescription opioids.

1686. Upon information and belief, each of the Defendants had to agree to implement similar tactics regarding marketing prescription Opioid Drugs and refuse to report suspicious orders. If any of the Defendants had properly disclosed and/or withheld suspicious orders, the conspiracy would be endangered.

1687. The illegal activities of the Drug Diversion Concealment Enterprise required extensive use of the wires and mails by each of the Defendants including, *inter alia*: (1) Defendants' practice of asserting their commitment to preventing Opioid Drug diversion by various representations and statements in national publications; (2) providing false information by mail and/or wires (including the electronic submission of information) to federal agencies such as the DEA; (3) using webinars hosted by the HDA designed for Defendants to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices; (4) using wires to transmit false acquisition and distribution transaction reports (as required by the CSA); (5) using wires to transmit false information to the DEA's ARCOS; and (6) mailing and/or electronically transmitting orders of Opioid Drugs that Defendants knew would promote the Drug Diversion Concealment Enterprise.

1688. Many of the precise dates of the fraudulent uses of the wires and mails by each of the Defendants are concealed from Plaintiff MMO and cannot be alleged with more particularity without discovery and access to the Defendants' books, records and other documents. However,

Plaintiff MMO has described the types of predicate acts of mail and wire fraud that occurred. The secretive nature of the Drug Diversion Concealment Enterprise's activities make the unlawful tactics alleged herein even more deceptive and harmful.

1689. The Defendants' schemes and the above-described racketeering activities amounted to common courses of conduct intended to cause Plaintiff MMO to pay for excessive amounts of Opioid Drugs. Within the Drug Diversion Concealment Enterprise, each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff MMO. The Defendants' illegal activities, aimed at the concerted concealment of drug diversion data, are part of their ongoing business and constitute a continuing threat to Plaintiff MMO.

1690. The Defendants and other potential members of the Drug Diversion Concealment Enterprise created and maintained systematic links for the common purpose of securing Opioid Drug access on MMO's formulary. This allowed each of the members of the Drug Diversion Concealment Enterprise to receive substantial revenue (including from Plaintiff MMO). Such revenue was exponentially greater than it would have been if Defendants had complied with their obligations to identify, monitor, and report evidence of drug diversion.

1691. The Drug Diversion Concealment Enterprise has a hub and spoke organizational, decision-making structure, with the Defendants serving as the hub.

1692. All members of the Drug Diversion Concealment Enterprise were aware of the Defendants' control over its activities. Furthermore, each member of the Drug Diversion Concealment Enterprise benefited from the existence of the other members.

1693. The pattern of "corrupt activity" alleged herein and the Drug Diversion Concealment Enterprise are separate and distinct from each other. The Defendants engaged in a

pattern of "corrupt activity" alleged herein for the purpose of conducting the affairs of the Drug Diversion Concealment Enterprise.

1694. Plaintiff MMO has been injured in its property by reason of these violations. Through the Drug Diversion Concealment Enterprise, the Defendants secured and protected access and status with respect to MMO's formulary, which increased both prescriber and patient demand for Opioid Drugs. Defendants' illegal conduct through the Drug Diversion Concealment Enterprise led TPPs (including Plaintiff MMO) to make coverage and formulary decisions that they would not have otherwise made absent the Drug Diversion Concealment Enterprise racketeering activities. This led Plaintiff MMO to make millions of dollars in payments for Opioid Drugs – as well as payments for Opioid Drug-related addiction treatment services-that it would not have made otherwise.

1695. Plaintiff MMO thus suffered direct, consequential, and concrete financial loss flowing from the injury to its property by expending these funds, and thereby suffered out-of-pocket losses. And but for the predicate acts committed or caused to be committed by the Defendants, Plaintiff MMO would not have suffered its OCPA injuries.

1696. Plaintiff MMO's injuries were directly and proximately caused by the Defendants' racketeering activity, as described above. Plaintiff MMO's injuries were directly caused by the predicate acts and are not attributable to any independent or intervening factors; its injuries were a foreseeable and natural consequence of the Defendants' scheme; and there are no others, more directly injured, that could vindicate Plaintiff MMO's claims.

1697. By virtue of these violations of Ohio Revised Code §§ 2923.31, et seq., the Defendants are jointly and severally liable to Plaintiff MMO for triple the actual damages

Plaintiff MMO has sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

TWELFTH CLAIM FOR RELIEF

Violation of the Ohio Corrupt Practices Act
Ohio Revised Code §§ 2923.31, et seq.
(Conspiracy)
Against All Defendants

1698. Plaintiff MMO incorporates by reference all preceding paragraphs, as if fully set forth herein. For efficiency and to avoid repetition, for purposes of this claim, Plaintiff MMO specifically incorporates by reference the paragraphs of Plaintiff MMO's Sixth Claim for Relief concerning the Civil RICO Conspiracy to Violate 18 U.S.C. § 1962(c), and further alleges as follows.

1699. Plaintiff MMO brings this Claim against the following Defendants, defined above: the Manufacturer Defendants, the Distributor Defendants, and the Pharmacy Defendants (collectively, for purpose of this Claim, the "Defendants"), because of the impact of this scheme on MMO described herein.

1700. The Defendants are "persons" within the meaning of Ohio Revised Code § 2923.31(G), who conspired to violate Ohio Revised Code Chapter 2923, by conspiring to engage in a pattern of "corrupt activity," meaning any conduct defined as "racketeering activity" under the Organized Crime Control Act of 1970, 84 Stat. 941, 18 U.S.C. 1961(1)(B), (1)(C), (1)(D), and (1)(E), as amended.

1701. Plaintiff MMO is a "person," as that term is defined in Ohio Revised Code § 2923.31(G), who was injured as a result of each of the Defendant's wrongful conduct. Ohio Revised Code § 2923.34(A).

1702. The Manufacturer Defendants have violated Ohio Revised Code Chapter 2923, by conspiring to violate Ohio Revised Code § 2923.31(I). The object of the conspiracy has been and is to conduct or participate, directly or indirectly, in the affairs of the Physician Pull-Through Marketing Enterprise, the Scientific Literature Marketing Enterprise, and the Consumer Pull-Through Marketing Enterprise through a pattern of racketeering activity.

1703. Further, all Defendants (including the Manufacturer Defendants, the Distributor Defendants, and the Pharmacy Defendants) have violated Ohio Revised Code Chapter 2923, by conspiring to violate Ohio Revised Code § 2923.31(I). The object of the conspiracy has been and is to conduct or participate, directly or indirectly, in the affairs of the Formulary Access and Coverage Enterprise and Drug Diversion Concealment Enterprise through a pattern of racketeering activity.

1704. Defendants' co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including the numerous material misrepresentations and omissions, described in detail herein.

1705. The nature of the above-described Defendants' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an Ohio Revised Code Chapter 2923 violation, by conspiring to violate Ohio Revised Code § 2923.31(I), but they were aware that their ongoing fraudulent acts have been and are part of an overall pattern of racketeering activity.

1706. As a direct and proximate result of Defendants' overt acts and predicate acts in furtherance of violating Ohio Revised Code Chapter 2923, by conspiring to violate Ohio Revised Code § 2923.31(I), Plaintiff MMO has been and continues to be injured in its business or property as set forth more fully above.

1707. Defendants sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts:

- multiple instances of mail and wire fraud violations of 18 U.S.C. § 1341 and § 1342; and
- multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

1708. Defendants' violations of the above state and federal laws and the effects thereof detailed above are continuing and will continue into the future unless enjoined by this Court.

1709. Plaintiff MMO has been injured in its property by reason of these violations in that MMO has millions of dollars for Opioid Drugs and addiction-related costs that it would not have paid had Defendants not conspired to violate Ohio Revised Code § 2923.31(I).

1710. Injuries suffered by Plaintiff MMO were directly and proximately causes by Defendants' racketeering activity described above.

1711. By virtue of these violations of Ohio Revised Code §§ 2923.31, *et seq*., the Defendants are jointly and severally liable to Plaintiff MMO for triple the actual damages Plaintiff MMO has sustained, punitive damages, plus the cost of this lawsuit, including reasonable attorney fees.

THIRTEENTH CLAIM FOR RELIEF

Negligence
Against All Defendants

1712. Plaintiff MMO incorporates by reference all preceding paragraphs, as if fully set forth herein.

1713. Plaintiff MMO brings this Claim against the following Defendants, defined above: the Manufacturer Defendants, the Distributor Defendants, and the Pharmacy Defendants

(collectively, for purpose of this Claim, the "Defendants"), because of the impact of this scheme on MMO as described herein.

1714. Separate and apart from the Defendants' statutory duties, each of the Defendants owed MMO common-law duties, including the duty to report to investigate and report plainly suspicious orders of highly addictive Opioid Drugs. Each of the Defendants breached these duties by failing to report such suspicious orders to the appropriate regulators, by failing adequately to investigate suspicious orders before filling them, and/or by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances. In so doing, Defendants acted unreasonably, recklessly and with actual malice.

1715. Separate and apart from the Manufacturer Defendants' statutory duties, each of the Manufacturer Defendants owed MMO common-law duties, including the duty to be forthright and honest regarding the necessity, efficacy, and risks associated with long-term Opioid Drug therapy for chronic pain; the duty to promote and market Opioid Drugs truthfully and pursuant to their federally approved indications for use; and the duty to disclose the true risk of addiction associated with the use of Opioid Drugs. Each of the Manufacturer Defendants breached those duties by, among other things, circulating false and misleading information concerning their safety and efficacy, and downplaying or failing to disclose the risk of addiction arising from their use. In so doing, Defendants acted unreasonably, recklessly and with actual malice.

1716. Separate and apart from the Distributor Defendants' statutory duties, each of the Distributor Defendants owed Plaintiff MMO common-law duties, including the duty to enact policies that would prevent and protect against the diversion of Opioid Drugs; and the duty to further enact policies to identify and report suspicious orders.

1717. The Distributor Defendants failed to enact policies that would prevent and protect against Opioid Drug diversion; and failed to identify and report suspicious Opioid Drug orders.

1718. In failing to take adequate measures to prevent substantial Opioid Drug-related injury to TPPs, including MMO, the Distributor Defendants have breached their duties imposed by law.

1719. The Distributor Defendants' conduct fell below the reasonable standard of care in the following ways:

- Using unsafe distribution practices;
- Disregarding the CSA and the DEA's suggestions for safe dispensing;
- Failing to properly review Opioid Drug orders for suspicious orders;
- Failing to report suspicious orders, and failing to investigate such orders before filling them;
- Failing to provide effective controls and procedures to guard against diversion of controlled substances; and
- Failing to determine whether the size of orders or collective volume of orders is appropriate, or extremely inappropriate, given the conditions for the Opioid Drugs.

1720. Separate and apart from the Pharmacy Defendants' statutory duties, each of the Pharmacy Defendants owed Plaintiff MMO common-law duties, including the duty to enact policies that would prevent the filling of Opioid Drug prescriptions that would be deemed questionable or suspicious by a reasonably prudent pharmacist; the duty to train and supervise their employees at the point of sale to investigate or report suspicious or invalid prescriptions; and the duty to protect against corruption or theft by its employees or agents.

1721. The Pharmacy Defendants failed to enact policies that would prevent pharmacists from filling questionable or suspicious Opioid Drug prescriptions; failed to train and supervise

their employees at the point of sale .to investigate and report suspicious or invalid prescriptions; and failed to protect against corruption or theft by its employees or agents.

1722. In failing to take adequate measures to prevent substantial Opioid Drug-related injury to TPPs, including MMO, the Pharmacy Defendants have breached their duties imposed by law.

1723. The Pharmacy Defendants' conduct fell below the reasonable standard of care in the following ways:

- Using unsafe dispensing practices;
- Disregarding the CSA and the DEA's suggestions for safe dispensing;
- Failing to properly review Opioid Drug prescription orders for suspicious orders;
- Failing to report suspicious orders, and failing to investigate such orders before filling them;
- Failing to provide effective controls and procedures to guard against diversion of controlled substances; and
- Promoting unsafe dispensing in the interest of speed.

1724. It was reasonably foreseeable that Defendants' breaches of the duties set forth in this Claim for Relief would cause harm to MMO in the form of higher payments for the reimbursement of Opioid Drugs and addiction-related costs that would not have been paid but for Defendants' wrongful conduct. Thus, Plaintiff MMO has suffered monetary losses proximately caused by Defendants' breaches of their duties set forth in this Claim for Relief.

1725. Each Defendant's breaches of the common-law duties they owed to MMO are the proximate cause of MMO's injuries, and Plaintiff MMO is entitled to all damages allowable by law, costs and attorney's fees, and any other relief the Court deems necessary and appropriate.

FOURTEENTH CLAIM FOR RELIEF

Common Law Fraud
Against All Defendants

1726. Plaintiff MMO incorporates by reference all preceding paragraphs, as if fully set forth herein, and further alleges as follows.

1727. Plaintiff MMO asserts common law fraud claims against the following Defendants, defined above: the Manufacturer Defendants, the Distributor Defendants, and the Pharmacy Defendants (collectively, for purpose of this Claim, the "Defendants").

1728. As described herein, Defendants violated their duty not to actively deceive by intentionally and unlawfully making knowingly false statements and intentionally and unlawfully concealing material information that made statements Defendants did make, knowingly false. Each Defendant made false representations and omissions of material fact with the intent to defraud in the course of Defendants' execution of their respective Physician Pull-Through Marketing, Scientific Literature Marketing, Consumer Pull-Through Marketing, Formulary Access and Coverage, and Drug Diversion Concealment Enterprises.

1729. The misrepresentations and omissions included in the Manufacturer Defendants' Scientific Literature Marketing Enterprise publications, on which prescribers and TPPs (including Plaintiff MMO) relied to that end, included: (1) the existence of a "pain epidemic" and urgency with which it must be addressed; (2) the efficacy with which long-term Opioid Drug therapy treats or manages long-term chronic pain; (3) the ability of Opioid Drugs to improve life functions (such as psychological health, health-related quality of life, and quality of life itself); (4) downplaying the serious risk of addiction; (5) creating and promoting the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (6) exaggerating the effectiveness of screening tools to prevent addiction; (7) claiming that opioid dependence and withdrawal are easily managed; (8) denying the risks of higher Opioid Drug dosages; (9) exaggerating the

effectiveness of "abuse-deterrent" Opioid Drug formulations to prevent abuse and addiction; and (10) actively concealing, and causing others to conceal, information about the safety (including addiction risk), efficacy, and usefulness of Opioid Drugs to treat long-term chronic pain.

1730. The Manufacturer Defendants' Physician Pull-Through Marketing Enterprise bombarded prescribers with various misrepresentations and omissions aimed at increasing prescriber demand for Opioid Drugs, including as to: (1) the existence of a "pain epidemic" and urgency with which it must be addressed; (2) the efficacy with which long-term Opioid Drug therapy treats or manages long-term chronic pain; (3) the ability of Opioid Drugs to improve life functions (such as psychological health, health-related quality of life, and quality of life itself); (4) downplaying the serious risk of addiction; (5) creating and promoting the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more Opioid Drugs; (6) exaggerating the effectiveness of screening tools to prevent addiction; (7) claiming that opioid dependence and withdrawal are easily managed; (8) denying the risks of higher Opioid Drug dosages; (9) exaggerating the effectiveness of "abuse-deterrent" Opioid Drug formulations to prevent abuse and addiction; and (10) actively concealing, and causing others to conceal, information about the safety (including addiction risk), efficacy, and usefulness of Opioid Drugs to treat long-term chronic pain.

1731. As detailed above, the Manufacturer Defendants' Consumer Pull-Through Marketing Enterprise, in an effort to increase patient demand for Opioid Drugs, made various misrepresentations and omissions to potential customers suffering from chronic pain as to: (1) the existence of a "pain epidemic" and urgency with which it must be addressed; (2) that living with pain is a "choice"; (3) the efficacy with which long-term Opioid Drug therapy treats or manages long-term chronic pain; (4) downplaying the serious risk of addiction; (5) suggesting

patients "advocate" for themselves with their HCPs, should not "take no for an answer," and threaten to leave prescribers who did not provide Opioid Drugs; and (6) actively concealing, and causing others to conceal, information about the safety (including addiction risk), efficacy, and usefulness of Opioid Drugs to treat long-term chronic pain.

1732. The Defendants' Formulary Access and Coverage Enterprise made false representations or omissions of material fact to MMO, its PQM committees, to MMO's contracted PBM and its P&T committees and relevant decision-makers concerning the safety, effectiveness and usefulness of Opioid Drugs. The various misrepresentations and omissions were made for the purpose of securing and protecting formulary access and status for Opioid Drugs, and inducing Plaintiff MMO to make payments for same, and include the following: (1) the efficacy with which long-term Opioid Drug therapy treats or manages long-term chronic pain; (2) the ability of Opioid Drugs to improve life functions (such as psychological health, health-related quality of life, and quality of life itself), which in turn would save expenditures by TPPs including MMO; (3) downplaying the serious risk of addiction; (4) exaggerating the effectiveness of screening tools to prevent drug diversion; and (5) actively concealing information relating to the rampant drug diversion affecting Opioid Drugs.

1733. Throughout the existence of the Drug Diversion Concealment Enterprise, the Defendants purposefully failed to comply with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids—all the while espousing to the general public, to Congress, federal and state agencies, and TPPs (including MMO) their commitment to preventing diversion of prescription Opioid Drugs.

1734. As described above and herein, Defendants' respective false representation and omissions of material fact were false and were known to be false or known to have been asserted without knowledge of their truth by each Defendant.

1735. Each Defendant intended that Plaintiff MMO rely on each Defendant's false representations or omissions of material fact in purchasing, paying for, reimbursing, and making formulary placements of Opioid Drugs, and MMO justifiably relied on each Defendant's misrepresentations, both directly and indirectly, to its detriment.

1736. Each Defendant intended to defraud and cause MMO's injuries.

1737. Plaintiff MMO was injured as a proximate result of each Defendant's fraud, as described herein, and Plaintiff MMO is entitled to all damages allowable by law, costs and attorney's fees, and any other relief the Court deems necessary and appropriate.

FIFTEENTH CLAIM FOR RELIEF

Unjust Enrichment
Against All Defendants

1738. Plaintiff MMO incorporates by reference all preceding paragraphs, as if fully set forth herein, and further alleges as follows.

1739. Defendants have been and continue to be enriched by their fraudulent acts and omissions described herein.

1740. Plaintiff MMO conferred a benefit directly and indirectly on each Manufacturer, Distributor, and Pharmacy Defendant by purchasing Opioid Drugs manufactured, distributed, and dispensed by each respective Defendant.

1741. In exchange for these payments, Plaintiff MMO expected that the Opioid Drugs were safe and effective as advertised, and not being knowingly diverted into the black market.

1742. Defendants each voluntarily accepted and retained these payments with full knowledge and awareness that, as a result of their wrongdoing, Plaintiff MMO paid for Opioid Drugs that it would not have paid for absent Defendants' wrongful conduct.

1743. These fraudulent acts and omissions allowed Defendants to gain billions of dollars in profits, and Defendants unjustly retained and continue to retain such benefits while Plaintiff MMO suffered damages as a result.

1744. As an expected and intended result of their own conscious wrongdoing, Defendants caused the unjustness of the benefit they knowingly received and have profited thereby. They benefited from Opioid Drug purchases that Plaintiff MMO and others made as a result of Defendant's wrongful conduct.

1745. It would be inequitable under these circumstances for the Defendants to retain this benefit without paying Plaintiff MMO for its value. Plaintiff MMO seeks recovery of the benefit they conferred upon Defendants and by which Defendants were enriched as a result of their inequitable conduct, and any other such relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

X. PRAYER FOR RELIEF

WHEREFORE, Plaintiff MMO demands judgment against Defendants, jointly and severally, as follows:

a) On Plaintiff MMO's First, Second, Third, Fourth, Fifth, Sixth, Seventh, Eighth, Ninth, Tenth, Eleventh, and Twelfth Claims for Relief, three times the damages Plaintiff MMO has sustained as a result of each Defendant's conduct, plus Plaintiff MMO's costs in this suit, including reasonable attorney fees;

b) On Plaintiff MMO's Thirteenth, Fourteenth, and Fifteenth Claims for Relief, an award to Plaintiff MMO of the maximum allowable damages under such statute(s) or laws;

c) An award of prejudgment interest in the maximum amount allowable by law;

d) An award to Plaintiff MMO of its costs and expenses in this litigation and reasonable attorney fees and expert fees and expenses; and

e) An award to Plaintiff MMO of such other and further relief as may be just and proper under the circumstances.

XI. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiff MMO demands a trial by jury on all issues so triable.

Dated: April 26, 2018

Respectfully submitted,

s/*Peter H. Weinberger*
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CERTIFICATE OF SERVICE

I hereby certify that on this 26th day of April, 2018, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF System. Copies will be served upon counsel of record by, and may be obtained through the Court CM/ECF Systems.

s/ Peter H. Weinberger
Peter H. Weinberger

One of the Attorneys for the Plaintiff
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