UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster
This document relates to: ALLEGIANCE SPECIALTY HOSPITAL OF GREENVILLE, LLC, CLHG-LEESVILLE, LLC d/b/a BYRD REGIONAL HOSPITAL, CLHG-AVOYELLES, LLC d/b/a AVOYELLES HOSPITAL, BIENVILLE MEDICAL CENTER, INC., CLHG-VILLE PLATTE, LLC d/b/a MERCY REGIONAL MEDICAL CENTER, CLHG-OAKDALE, LLC d/b/a OAKDALE COMMUNITY HOSPITAL, ALLEGIANCE HOSPITAL OF MANY, LLC d/b/a SABINE MEDICAL CENTER, CLHG-WINN, LLC d/b/a WINN PARISH MEDICAL CENTER, CLHG-DEQUINCY, LLC d/b/a DEQUINCY MEMORIAL HOSPITAL, CLHG-MINDEN, LLC d/b/a MINDEN MEDICAL CENTER, CLHG-ACADIAN, LLC d/b/a ACADIAN MEDICAL CENTER, ALLEGIANCE HEALTH CENTER OF RUSTON, LLC d/b/a FREEDOM BEHAVIORAL HOSPITAL OF MONROE, FREEDOM BEHAVIORAL HOSPITAL OF MAGNOLIA, ALLEGIANCE BEHAVIORAL HEALTH CENTER OF PLAINVIEW, L.L.C. d/b/a FREEDOM BEHAVIORAL HOSPITAL OF PLAINVIEW, THOMAS W. WALDREP JR., TRUSTEE OF THE LITIGATION TRUST OF CAH ACQUISITION COMPANY 1, LLC d/b/a WASHINGTON COUNTY HOSPITAL, THOMAS W. WALDREP JR., TRUSTEE OF THE LITIGATION TRUST OF CAH ACQUISITION COMPANY 2, LLC d/b/a OSWEGO COMMUNITY HOSPITAL, THOMAS W. WALDREP JR., TRUSTEE OF THE LITIGATION TRUST OF CAH ACQUISITION COMPANY 3, LLC d/b/a HORTON COMMUNITY HOSPITAL, THOMAS W. WALDREP JR., CHAPTER 7	Case No. _____ **COMPLAINT** **JURY TRIAL DEMANDED**

TRUSTEE FOR CAH ACQUISITION COMPANY 6, LLC d/b/a I70 COMMUNITY HOSPITAL, THOMAS W. WALDREP JR., TRUSTEE OF THE LITIGATION TRUST OF CAH ACQUISITION COMPANY 7, LLC d/b/a PRAGUE COMMUNITY HOSPITAL, THOMAS W. WALDREP JR., TRUSTEE OF THE LITIGATION TRUST OF CAH ACQUISITION COMPANY 12, LLC d/b/a FAIRFAX COMMUNITY HOSPITAL, and THOMAS W. WALDREP JR., TRUSTEE OF THE LITIGATION TRUST OF CAH ACQUISITION COMPANY 16, LLC d/b/a HASKELL COUNTY COMMUNITY HOSPITAL,

Plaintiffs,

v.

ABBVIE, INC., ANDA, INC., CARDINAL HEALTH, INC., CENCORA, INC., CEPHALON, INC., CVS INDIANA, L.L.C., CVS PHARMACY, INC., JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, MCKESSON CORPORATION, TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., WALGREEN CO., WALGREEN EASTERN CO., INC., WALMART INC. f/k/a WAL-MART STORES, INC., WAL-MART STORES EAST, LP, and XCENDA L.L.C.,

Defendants.

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COMPLAINT

1. Allegiance Specialty Hospital of Greenville, LLC, CLHG-Leesville, LLC d/b/a Byrd Regional Hospital, CLHG-Avoyelles, LLC d/b/a Avoyelles Hospital, Bienville Medical Center, Inc., CLHG-Ville Platte, LLC d/b/a Mercy Regional Medical Center, CLHG-Oakdale, LLC d/b/a Oakdale Community Hospital, Allegiance Hospital of Many, LLC d/b/a Sabine Medical Center, CLHG-Winn, LLC d/b/a Winn Parish Medical Center, CLHG-DeQuincy, LLC d/b/a DeQuincy Memorial Hospital, CLHG-Minden, LLC d/b/a Minden Medical Center, CLHG-Acadian, LLC d/b/a Acadian Medical Center, Allegiance Health Center of Ruston, LLC d/b/a Freedom Behavioral Hospital of Monroe, Freedom Behavioral Hospital of Magnolia, Allegiance Behavioral Health Center of Plainview L.L.C. d/b/a Freedom Behavioral Hospital of Plainview, Thomas W. Waldrep Jr., as Trustee of the Litigation Trust of CAH Acquisition Company 1, LLC d/b/a Washington County Hospital, Thomas W. Waldrep Jr., as Trustee of the Litigation Trust of CAH Acquisition Company 2, LLC d/b/a Oswego Community Hospital, Thomas W. Waldrep Jr., as Trustee of the Litigation Trust of CAH Acquisition Company 3, LLC d/b/a Horton Community Hospital, Thomas W. Waldrep Jr., as Chapter 7 Trustee for CAH Acquisition Company 6, LLC d/b/a I70 Community Hospital, Thomas W. Waldrep Jr., as Trustee of the Litigation Trust of CAH Acquisition Company 7, LLC d/b/a Prague Community Hospital, Thomas W. Waldrep Jr., as Trustee of the Litigation Trust of CAH Acquisition Company 12, LLC d/b/a Fairfax Community Hospital, and Thomas W. Waldrep Jr., as Trustee of the Litigation Trust of CAH Acquisition Company 16, LLC d/b/a Haskell Community Hospital (collectively, "Plaintiffs") bring this Complaint against Defendants AbbVie, Inc., Anda, Inc., Cardinal Health, Inc., Cencora, Inc., Cephalon, Inc., CVS Indiana, L.L.C., CVS Pharmacy, Inc., Janssen Pharmaceuticals, Inc., Johnson & Johnson, McKesson Corporation, Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals

USA, Inc., Walgreen Co., Walgreen Eastern Co., Inc., Walmart Inc. f/k/a Wal-Mart Stores, Inc., Wal-Mart Stores East, LP, and Xcenda L.L.C. (collectively "Defendants") under the Racketeering Influenced and Corrupt Organizations Act (18 U.S.C. §§ 1961–1968) ("RICO"); Nuisance; Fraud; Civil Conspiracy and Unjust Enrichment seeking judgment against Defendants and in favor of Plaintiffs; compensatory damages; treble damages; pre-judgment and post-judgment interest; cost of suit; and equitable relief, including injunctive relief and allege as follows:

I. JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction based on the federal claims asserted under the Racketeering Influenced Corrupt Organizations Act, 18 U.S.C. §§ 1961–1968. This Court has supplemental jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. § 1367 because those are so related to Plaintiffs' federal claims that they form part of the same case or controversy.

3. This Court has personal jurisdiction over Defendants because at all relevant times Defendants engaged in substantial business activities in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma and purposefully directed their actions toward these States, consensually submitted to the jurisdiction of these States when obtaining licenses or permits to manufacturer, distribute, and/or dispense prescription opioids, and have the requisite minimum contacts with these States necessary to constitutionally permit this Court to exercise jurisdiction.

4. Venue is proper in this District and all districts in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma under 28 U.S.C. § 1391 and 18 U.S.C. § 1965 because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in these Districts and each Defendant transacted affairs and conducted activity that gives rise to the claims for relief in these Districts.

5. This case is being direct filed in this district pursuant to Paragraph 6.a. of the *In re: National Prescription Opiate Litigation*, Case No. 1:17-CV-2804, "Case Management Order One"

(Doc. # 232, filed 4/11/18).

II. PARTIES

A. Plaintiffs

1. Allegiance Health Management, Inc. Hospitals

6. The following Plaintiffs are private, for-profit entities operating as part of Allegiance Health Management, Inc. (hereinafter, "Allegiance Health"): Allegiance Specialty Hospital of Greenville, LLC, CLHG-Leesville, LLC d/b/a Byrd Regional Hospital, CLHG-Avoyelles, LLC d/b/a Avoyelles Hospital, Bienville Medical Center, Inc., CLHG-Ville Platte, LLC d/b/a Mercy Regional Medical Center, CLHG-Oakdale, LLC d/b/a Oakdale Community Hospital, Allegiance Hospital of Many, LLC d/b/a Sabine Medical Center, CLHG-Winn, LLC d/b/a Winn Parish Medical Center, CLHG-DeQuincy, LLC d/b/a DeQuincy Memorial Hospital, CLHG-Minden, LLC d/b/a Minden Medical Center, CLHG-Acadian, LLC d/b/a Acadian Medical Center, Allegiance Health Center of Ruston, LLC d/b/a Freedom Behavioral Hospital of Monroe, Freedom Behavioral Hospital of Magnolia, Allegiance Behavioral Health Center of Plainview L.L.C. d/b/a Freedom Behavioral Hospital of Plainview.

7. Allegiance Health is a corporation organized under the laws of the State of Louisiana, with its headquarters and principal place of business located in Bossier City, Louisiana. Allegiance Health is largely comprised of companies that serve individuals within communities and geographic areas located in Louisiana and Mississippi.

8. Allegiance Health endeavors to provide optimal patient care seamlessly across service lines to ensure spiritual, emotional, and physical healing wherever possible while always respecting life, fostering dignity, and preserving quality of life.

9. Services provided by Plaintiff include, but are not limited to, companion care, day neuro care, home health hospice, in-home primary care, inpatient hospice, inpatient rehabilitation

hospital, long-term acute care, long-term care, medical house calls, occupational therapy, outpatient therapy, palliative physical therapy, private duty respiratory therapy, skilled nursing, and speech therapy.

10. Plaintiff Allegiance Specialty Hospital of Greenville, LLC is a private, for-profit Mississippi limited liability company with its principal office located in Greenville, Mississippi.

11. Plaintiff CLHG-Leesville, LLC is a private, for-profit Louisiana limited liability company with its principal office located in Bossier City, Louisiana and operates Byrd Regional Hospital in Leesville, Louisiana.

12. Plaintiff CLHG-Avoyelles, LLC is a private, for-profit Louisiana limited liability company with its principal office located in Bossier City, Louisiana, and operates Avoyelles Hospital in Marksville, Louisiana.

13. Plaintiff Bienville Medical Center, Inc. is a private, for-profit corporation organized under the laws of the State of Louisiana, with its headquarters located in Bossier City, Louisiana and principal place of business in Arcadia, Louisiana. Bienville Medical Center is part of the Bienville Parish Hospital Service District No. 2.

14. Plaintiff CLHG-Ville Platte, LLC is a private, for-profit Louisiana limited liability company with its principal office located in Bossier City, Louisiana and operates Mercy Regional Medical Center in Ville Platte, Louisiana.

15. Plaintiff CLHG-Oakdale, LLC is a private, for-profit Louisiana limited liability company with its principal office located in Bossier City, Louisiana and operates Oakdale Community Hospital in Oakdale, Louisiana.

16. Plaintiff Allegiance Hospital of Many, LLC is a private, for-profit Louisiana limited liability company with its principal office located in Bossier City, Louisiana and operates Sabine

Medical Center in Many, Louisiana.

17. Plaintiff CLHG-Winn, LLC is a private, for-profit Louisiana limited liability company with its principal office located in Bossier City, Louisiana and operates Winn Parish Medical Center in Winnfield, Louisiana.

18. Plaintiff CLHG-DeQuincy, LLC is a private, for-profit Louisiana limited liability company with its principal office located in Bossier City, Louisiana and operates DeQuincy Memorial Hospital in DeQuincy, Louisiana.

19. Plaintiff CLHG-Minden, LLC is a private, for-profit Louisiana limited liability company with its principal office located in Bossier City, Louisiana and operates Minden Medical Center in Minden, Louisiana.

20. Plaintiff CLHG-Acadian, LLC is a private, for-profit Louisiana limited liability company with its principal office located in Bossier City, Louisiana and operates Acadian Medical Center in Eunice, Louisiana.

21. Plaintiff Allegiance Health Center of Ruston, LLC d/b/a Freedom Behavioral Hospital of Monroe is a Louisiana limited liability company with its principal office located in Bossier City, Louisiana and operates Freedom Behavioral Hospital of Monroe in Monroe, Louisiana.

22. Plaintiff Freedom Behavioral Hospital of Magnolia is a distinct part unit of Beacham Memorial Hospital operating in Magnolia, Mississippi.

23. Allegiance Behavioral Health Center of Plainview L.L.C. d/b/a Freedom Behavioral Hospital of Plainview is a Louisiana limited liability company with its principal office located in Bossier City, Louisiana and operates Freedom Behavioral Hospital of Plainview in Plainview, Texas.

2. Critical Access Hospitals

24. Plaintiff Thomas W. Waldrep Jr. is the Trustee of the Litigation Trusts of CAH Acquisition Company 1, LLC d/b/a Washington County Hospital, CAH Acquisition Company 2, LLC d/b/a Oswego Community Hospital, CAH Acquisition Company 3, LLC d/b/a Horton Community Hospital, CAH Acquisition Company 7, LLC d/b/a Prague Community Hospital, CAH Acquisition Company 12, LLC d/b/a Fairfax Community Hospital, and CAH Acquisition Company 16, LLC d/b/a Haskell Community Hospital, and the Chapter 7 Trustee of CAH Acquisition Company 6, LLC d/b/a I70 Community Hospital (collectively, the "CAH Hospitals" or "Debtors") in the jointly administered cases proceeding before the United States Bankruptcy Court for the Eastern District of North Carolina (the "Trustee").

25. The Debtors owned and operated a number of for-profit, critical access hospitals ("CAH")[1] that provided acute care, swing bed, emergency medicine, imaging, rehabilitation, laboratory, and related outpatient ancillary services in small rural areas in North Carolina, Kansas, Missouri, and Oklahoma. Each of the Hospitals is classified as a CAH or was classified as a CAH before it ceased operations.

26. The CAH Hospitals have common ownership and integrated management. Each of the CAH Hospitals is owned by Health Acquisition Company, LLC (80% interest) and HMC/CAH Consolidated, Inc. (20% interest).

[1] The Balanced Budget Act of 1997, Pub. Law. 105-33, created a new category of hospitals, known as critical access hospitals ("CAH"). Hospitals qualify for the CAH program by meeting certain regulatory requirements promulgated by the Centers for Medicare & Medicaid Services ("CMS"), including that the hospital: (1) is located in a rural area; (2) provides 24-hour emergency services seven days a week; (3) has 25 or fewer inpatient beds also used for swing bed services; and (4) has an annual average acute inpatient stay length of 96 hours or less. Congress created the CAH program to address a string of rural hospital closures and a concern about the ongoing financial viability of rural hospitals. The program is designed to ensure the continued viability of rural hospitals, which provide life-saving medical treatment and needed jobs to underserved communities. To further that goal, CAHs are reimbursed by insurance companies at much higher rates than other hospitals—typically 101 percent of reasonable costs—for most inpatient and outpatient services, including certain laboratory testing procedures.

27. An involuntary Chapter 7 bankruptcy petition was filed against Debtor CAH Acquisition Company 1, LLC d/b/a Washington County Hospital on February 19, 2019. The case was converted to Chapter 11 on March 15, 2019. The Debtor owned and operated a critical access hospital in Plymouth, North Carolina. Thomas W. Waldrep Jr. is the Litigation Trustee of CAH Acquisition Company #1, LLC ("CAH 1") and together with its affiliates in cases proceeding before the United States Bankruptcy Court for the Eastern District of North Carolina. The hospital was sold by the Trustee with Court approval.

28. Debtor CAH Acquisition Company 2, LLC d/b/a Oswego Community Hospital filed its voluntary Chapter 11 petition on March 17, 2019. The Debtor owned and operated a critical access hospital in Oswego, Kansas. Thomas W. Waldrep Jr. is the Litigation Trustee of CAH Acquisition Company #2, LLC ("CAH 2") and together with its affiliates in cases proceeding before the United States Bankruptcy Court for the Eastern District of North Carolina. The hospital was sold by the Trustee with Court approval.

29. Debtor CAH Acquisition Company 3, LLC d/b/a Horton Community Hospital filed its voluntary Chapter 11 petition on March 17, 2019. The Debtor owned and operated a critical access hospital in Horton, Kansas. Thomas W. Waldrep Jr. is the Litigation Trustee of CAH Acquisition Company #3, LLC ("CAH 3") and together with its affiliates in cases proceeding before the United States Bankruptcy Court for the Eastern District of North Carolina. The hospital was sold by the Trustee with Court approval.

30. Debtor CAH Acquisition Company 6, LLC d/b/a I-170 Community Hospital filed its voluntary Chapter 11 petition on March 21, 2019. The Debtor owned and operated a critical access hospital in Sweet Springs, Missouri. On March 3, 2019, Thomas W. Waldrep Jr. was appointed as Chapter 11 Trustee. On October 19, 2022, the case was converted to Chapter 7, and

Thomas W. Waldrep Jr. was appointed as Chapter 7 Trustee. The hospital was sold by the Trustee with Court approval.

31. Debtor CAH Acquisition Company 7, LLC d/b/a Prague Community Hospital filed its voluntary Chapter 11 petition on March 21, 2019. The Debtor owned and operated a critical access hospital in Prague, Oklahoma. Thomas W. Waldrep Jr. is the Litigation Trustee of CAH Acquisition Company #7, LLC ("CAH 7") and together with its affiliates in cases proceeding before the United States Bankruptcy Court for the Eastern District of North Carolina. The hospital was sold by the Trustee with Court approval.

32. Debtor CAH Acquisition Company 12, LLC d/b/a Fairfax Community Hospital filed its voluntary Chapter 11 petition on April 1, 2019. The Debtor is a Delaware limited liability company. The Debtor's business was the operation of a 15-bed critical care access hospital in Fairfax, Oklahoma. Thomas W. Waldrep Jr. is the Litigation Trustee of CAH Acquisition Company #12, LLC ("CAH 12") and together with its affiliates in cases proceeding before the United States Bankruptcy Court for the Eastern District of North Carolina. The hospital was sold by the Trustee with Court approval.

33. Debtor CAH Acquisition Company 16, LLC d/b/a Haskell County Community Hospital filed its voluntary Chapter 11 petition on March 17, 2019. The Debtor owned and operated a critical access hospital in Stigler, Oklahoma. Thomas W. Waldrep Jr. is the Litigation Trustee of CAH Acquisition Company #16, LLC ("CAH 16") and together with its affiliates in cases proceeding before the United States Bankruptcy Court for the Eastern District of North Carolina. The hospital was sold by the Trustee with Court approval.

B. Defendants and Nonparty Associates

1. Marketing Defendants and Associates

a. Teva and Associated Companies

34. Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petach Tikva, Israel.

35. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in Pennsylvania and is a wholly owned subsidiary of Teva Ltd.

36. Defendant Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In October 2011, Teva Ltd. acquired Cephalon, which became a wholly owned subsidiary of Teva Ltd.

37. Teva USA and Cephalon worked together to manufacture, promote, sell, and distribute the branded opioids Actiq (fentanyl citrate) and Fentora (fentanyl buccal) in the United States. Since Teva Ltd.'s acquisition of Cephalon in October 2011, Teva USA has conducted all sales and marketing activities for Cephalon in the United States through its "specialty medicines" division.[2] Teva USA holds out Actiq and Fentora as Teva products to the public. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA and directs physicians to contact Teva USA to report adverse events.[3] Until as recently as 2019, Cephalon's promotion websites for

[2] *Teva Completes Acquisition of Cephalon*, Fierce Pharma (Oct. 14, 2011), https://www.fiercepharma.com/pharma/teva-completes-acquisition-of-cephalon; *Cephalon – Overview*, LinkedIn, https://www.linkedin.com/company/cephalon/about/ (last visited July 12, 2021).

[3] *Actiq Package Insert*, U.S. Food & Drug Admin. (Apr. 5, 2021), https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/020747s053lbl.pdf; *Fentora Package Insert*, U.S. Food & Drug Admin. (Apr. 4, 2021), https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/021947s034lbl.pdf.

Actiq and Fentora displayed Teva Ltd.'s logo.[4] Teva USA's parent company, Teva Ltd., lists Cephalon and Teva USA's sales as its own on its financial reports, and its year-end report for 2012—the year immediately following the Cephalon acquisition—attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including *inter alia* sales of Fentora.[5]

38. Teva Ltd. acquired Defendants Watson Laboratories, Inc.; Actavis LLC; and Actavis Pharma, Inc. from Allergan plc on August 2, 2016, as part of an acquisition of Allergan's global generic pharmaceutical business, which included manufacturing and selling generic opioids.

39. Teva also sold generic opioids prior to the acquisition of Watson Laboratories, Inc.; Actavis LLC; and Actavis Pharma, Inc. Teva was the Abbreviated New Drug Application ("ANDA") holder for generic hydrocodone bitartrate and ibuprofen tablets (generic Vicoprofen and approved by the FDA in 2003) and the ANDA holder (through its subsidiary Barr Pharmaceuticals ("Barr"), which Teva acquired in 2008) for generic meperidine hydrochloride tablets (generic Demerol and approved by the FDA in 1984). An ANDA allows the sale of a generic version of a branded drug. On September 5, 2006 (prior to the acquisition of Barr), Teva granted Barr a license to manufacture and sell generic Actiq.

40. Teva Ltd., Teva USA, and Cephalon are referred to herein as "Teva."

41. On August 28, 2020, Teva was indicted for three separate conspiracies in the early- to mid-2010s to fix the prices of generic drugs:

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[4] *See*, *e.g.*, *Actiq*, Actiq.com, https://web.archive.org/web/20180313214430/http://www.actiq.com/ (last accessed Jan. 20, 2024 as of Mar. 23, 2018) (displaying logo at bottom-left); *Fentora*, Fentora.com, https://web.archive.org/web/20190402193423/http://www.fentora.com/ (last accessed Jan. 20, 2024 as of Apr. 2, 2019) (displayed logo at bottom-right).

[5] Teva Pharm. Indus. Ltd., *Form 20-F* (Feb. 12, 2013), https://www.annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2013.pdf.

a. Conspiracy with Glenmark and Apotex to fix the price of pravastatin and other generics. Apotex admitted its participation in this conspiracy as part of a deferred prosecution agreement and agreed to pay a $24.1 million fine.

b. Conspiracy with Taro Pharmaceuticals and its vice president, Ara Aprahamian to fix the price of carbamazepine, clotrimazole topical solution, etodolac, fluocinonide cream, and warfarin, among other generics. Taro admitted its participation in this conspiracy as part of a deferred prosecution agreement and agreed to pay a $205 million fine.

c. Conspiracy with Sandoz to fix the price of, among other generics, etodolac, nadolol, temozolomide, and tobramycin. Sandoz admitted its participation in this conspiracy as part of a deferred prosecution agreement and agreed to pay a $195 million fine.[6]

Teva's willingness to conspire with other drugmakers to artificially raise the price of valuable and, in some cases, lifesaving drugs demonstrates Teva's attitude toward its legal and regulatory responsibilities regarding the drugs it manufactures, markets, and sells.

b. Janssen and Associated Companies

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

43. 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 J&J. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which was formerly known as Janssen Pharmaceutica, Inc.

44. J&J is the only company that owns over 10% of Janssen Pharmaceuticals, Inc.'s stock. Janssen Pharmaceuticals, Inc.'s profits inure to J&J's benefit. J&J controls the development, sale, and marketing of Janssen Pharmaceuticals, Inc.'s drugs. For example, according to its

[6] *Seventh Generic Drug Manufacturer is Charged in Ongoing Criminal Antitrust Investigation*, U.S. Dept. Just. (Aug. 25, 2020), https://www.justice.gov/opa/pr/seventh-generic-drug-manufacturer-charged-ongoing-criminal-antitrust-investigation.

website, J&J's policies "govern[]" the "sales and marketing practices" for the "Johnson & Johnson family of companies," which includes Janssen Pharmaceuticals, Inc. J&J also "provides sales representatives with ongoing scientific training and product knowledge," as well as training on J&J policies.[7] J&J employees monitor and enforce Janssen Pharmaceuticals, Inc.'s compliance with J&J's policies. Janssen Pharmaceuticals Inc.'s website provides links to J&J's policies.[8] J&J corresponded with the U.S. Food and Drug Administration (the "FDA") regarding Janssen's opioids and marketing practices.

45. Janssen, like many other companies, has a corporate code of conduct, which sets forth the organization's mission, values, and principles. Janssen's employees are required to read, understand, and follow its Code of Conduct for Health Care Compliance. J&J imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website, *Ethical Code of Conduct of Research and Development*, names only J&J and does not name Janssen anywhere within the document. The *Ethical Code of Conduct of Research and Development* posted on Janssen's website is J&J's company-wide ethical code, which J&J requires all subsidiaries to follow.[9]

46. The *Every Day Health Care Compliance Code of Conduct* is a J&J company-wide document that describes Janssen as one of the "Pharmaceutical Companies of Johnson & Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees

[7] *Position on Ethical Sales and Marketing*, Johnson & Johnson, https://www.jnj.com/about-jnj/policies-and-positions/our-position-on-ethical-sales-and-marketing (last visited Jan. 20, 2024).

[8] *See, e.g.*, *Transparency*, Janssen, https://www.janssen.com/transparency (last updated July 12, 2021) (linking to J&J's Ethical Code of Conduct).

[9] *See id.*; *Ethical Code for the Conduct of Research and Development*, Johnson & Johnson, https://www.jnj.com/about-jnj/policies-and-positions/ethical-code-for-the-conduct-of-research-and-development (last visited Jan. 20, 2024).

of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, and sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case.[10]

47. J&J, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. (collectively, "Janssen") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

c. Allergan and Associated Companies

48. Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Allergan plc does business in the United States through its U.S. Specialized Therapeutics and U.S. General Medicine segments, which together generated nearly 80% of the company's $15.8 billion in net revenue in 2018.

49. Defendant Allergan Finance, LLC is a Nevada limited liability company headquartered in Madison, New Jersey. Allergan Finance, LLC is a wholly owned subsidiary of Allergan plc.

50. Defendant Allergan Sales, LLC is incorporated in Delaware and headquartered in Irvine, California.

51. Defendant Allergan USA, Inc. is incorporated in Delaware and headquartered in Madison, New Jersey. Allergan USA, Inc. is a wholly owned subsidiary of Allergan plc.

52. Allergan plc; Allergan Finance, LLC; Allergan Sales, LLC; and Allergan USA, Inc.

[10] Janssen: Pharmaceutical Companies of Johnson & Johnson, *Every Day Health Care Compliance Code of Conduct* (n.d.).

are collectively referred to as "Allergan."

53. Defendant Watson Laboratories, Inc. ("Watson") is a Nevada corporation with its principal place of business in Corona, California.

54. Defendant Actavis Pharma, Inc. (f/k/a Watson Pharma Inc.) ("Actavis Pharma") is a Delaware corporation with its principal place of business in New Jersey.

55. Defendant Actavis LLC (f/k/a Actavis Inc.) ("Actavis LLC") is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

56. Watson, Actavis Pharma, and Actavis LLC are collectively referred to as "Actavis."

57. Allergan and Actavis have manufactured, promoted, marketed, advertised, and sold branded opioids nationwide and in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma, including Kadian (extended-release morphine sulfate) and Norco (hydrocodone bitartrate and acetaminophen). They have also marketed and sold generic opioids including oxymorphone, extended-release morphine sulfate, fentanyl, oxymorphone hydrochloride, and an extended-release version of the same.

58. Watson received approval of the New Drug Application ("NDA") for branded Norco in February 1997 and sold and marketed this opioid.

59. In 2008, Actavis, Inc. (n/k/a Allergan Finance, LLC) acquired the opioid Kadian through its subsidiary, Actavis Elizabeth LLC, which had been the contract manufacturer of Kadian since 2005. Since 2008, Kadian's label has identified the following entities as the manufacturer or distributor of Kadian: Actavis Elizabeth LLC; Actavis Kadian LLC; Actavis Pharma, Inc.; and Allergan USA, Inc. Allergan Sales, LLC is the current holder of the Kadian NDA. Currently, Allergan USA, Inc. is contracted with UPS SCS, Inc. to distribute Kadian on its behalf.

60. In 2012, Watson acquired Actavis, Inc., and the combined company took the Actavis name. Prior to its 2012 acquisition by Watson, Actavis produced twelve different generic opioids, including some of the most abused and diverted opioids such as generic OxyContin, generic Opana ER, and generic Duragesic.

61. In 2013, Actavis acquired Warner Chilcott plc, another pharmaceutical company; these two companies were combined and incorporated in Ireland as Actavis plc. In March 2015, Actavis plc purchased Allergan, Inc. and adopted the name Allergan plc.

62. In 2016, Allergan Sales, LLC held an ANDA for Norco. The Norco ANDA is currently held by Allergan Pharmaceuticals International Limited.

63. In 2016, Teva Ltd. acquired Actavis (i.e., Watson, Actavis LLC, and Actavis Pharma) from Allergan plc. Following the sale of Actavis to Teva, Allergan continued to sell branded Kadian and Norco, and Actavis continued to sell generic opioids as well as certain dosages of branded Kadian.

d. Abbott Laboratories and AbbVie

64. Defendant Abbott Laboratories, Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business in Chicago, Illinois. Defendant Abbott Laboratories, Inc. is a subsidiary of Abbott Laboratories, whose principal place of business is also in Abbott Park, Illinois. Defendants Abbott Laboratories and Abbott Laboratories, Inc. are referred to collectively as "Abbott."

65. Defendant AbbVie, Inc. ("AbbVie"), is a corporation organized under the laws of Delaware, with its principal place of business in North Chicago, Illinois.

66. Abbott and Abbvie have stated in periodic reports filed with the Securities and Exchange Commission that Abbvie was formed in 2012 with the stated purpose of effecting a separation or "spinoff" (the "AbbVie Spinoff" or the "Spinoff") of certain of Abbott's business

operations, principally what Abbott described as its "research-based proprietary pharmaceuticals business." Many of the terms of the separation between Abbott and AbbVie were set forth in a "Separation Agreement"[11] entered between Abbott and AbbVie in late 2012, which took effect on January 1, 2013.

67. The Separation Agreement was made public in 2012. The Separation Agreement defines the sectors allocated to AbbVie, defined as the "Business of AbbVie," in the definitions section (Article I, Section 1.01 of the Separation Agreement) as the following:

> "AbbVie Business" means:
>
> (i) *Exclusive AbbVie Products*. The business, operations and activities conducted at any time prior to the Effective Time by either Party or any of its Subsidiaries relating to, arising out of or resulting from the Exclusive AbbVie Products (including the discovery, research, development, importation, exportation, manufacture, marketing, distribution, promotion and sale of such Exclusive AbbVie Products worldwide); provided that the AbbVie Business shall not include the business, operations and activities relating to, arising out of or resulting from Sevoflurane or Isoflurane within the Veterinary Field-of-Use;
>
> (ii) *Special Products.* The business, operations and activities with respect to the Special Products, solely to the extent that the rights to such business, operations and activities are allocated to AbbVie or an AbbVie Subsidiary under the Special Products Master Agreement;
>
> (iii) *Research and Development*. The business, operations and activities conducted at any time prior to the Effective Time by or on behalf of either Party or any of its Subsidiaries of discovery and research and development projects (a) with respect to pharmaceutical products (except vaccines) for purposes of obtaining a first regulatory approval of a biological or a chemical entity; (b) by GPRD; or (c) by GPO, except, in each of cases (a), (b) and (c), for the discovery and research and development projects set forth on Schedule 1.01(d);
>
> (iv) *Contract Manufacturing*. Subject to Section 5.01, the business, operations and activities conducted at any time prior to the Effective Time by either

[11] Separation and Distribution Agreement by and between Abbott Laboratories and AbbVie Inc. (Nov. 28, 2012).

> Party or any of its Subsidiaries of manufacturing for any Third Party products at the manufacturing plants listed on Schedule 1.01(b); and
>
> (v) *AbbVie Former Businesses, AbbVie Discontinued Products, AbbVie Discontinued Projects and AbbVie Discontinued Facilities.* The business, operations and activities conducted at any time prior to the Effective Time by either Party or any of its Subsidiaries to the extent such business, operations and activities relate to, arise out of or result from an AbbVie Former Business, an AbbVie Discontinued Product, an AbbVie Discontinued Project or an AbbVie Discontinued Facility.

As per subsection (iii), above, the principal document indicates that what Abbott described as its research-based proprietary pharmaceutical business was allocated to AbbVie. While Abbott and Abbvie made the main document of the Separation Agreement publicly available, they have kept the details of the Spin-off, detailed in schedules and/or exhibits to the main document confidential and out of public purview. These include: (1) Schedule 1.01(m), which defines the "Exclusive AbbVie Products" allocated to AbbVie; (2) Schedule 1.01(s), which defines "Special Products," (3) the Special Products Master Agreement; (4) Schedule 1.01(d), which lists certain "discovery and research and development projects" allocated to AbbVie, (5) Schedule 1.01(b) which defines those manufacturing plants at which manufacturing of third party products is allocated to AbbVie; (6) Schedule 1.01(h) – a list of the "AbbVie Former Businesses"; (7) Schedule 1.01(f) – a list of the "AbbVie Discontinued Products, and (8) Schedule 1.01(e) – a list of the "AbbVie Discontinued Facilities." Because the details as to which business segments, assets and liabilities were allocated to AbbVie are contained in non-public documents, it cannot be known precisely which pre-Spinoff liabilities were allocated to AbbVie.

68. Ironically, in a footnote on Page 2 of Abbott's Notice of Claim filing in the Purdue bankruptcy matter, Abbott claimed that it would make the Separation Agreement "and other supporting" documents for its claim available in the bankruptcy proceeding. Certain Plaintiffs' counsel have expressly requested these documents from defense counsel but were rebuffed.

Abbott simply refuses to release these documents.

69. Plaintiffs allege, as a first alternative, that AbbVie is contractually liable under the Separation Agreement and as a matter of law for all pre-Spinoff liabilities of Abbott relating to its research-based proprietary pharmaceutical business, and the other sectors allocated to AbbVie in the non-public exhibits to the Separation Agreement, because AbbVie assumed those liabilities. AbbVie's contractual liability for pre-Spinoff conduct of Abbott does not absolve Abbott of liability, although it may grant Abbott rights of indemnification. AbbVie's contractual liability is joint and several with that of Abbott, which is also alleged to be liable for these liabilities.

70. The portion of the Separation Agreement made public indicates that AbbVie expressly assumed, *inter alia*, those liabilities that "relate to, arise out of or result from" AbbVie's Business. Indeed, AbbVie has repeatedly represented that it has assumed those liabilities:

> Subject to certain exceptions specified in the separation agreement by and between Abbott and AbbVie, AbbVie assumed the liability for, and control of, all pending and threatened legal matters related to its business, including liabilities for any claims or legal proceedings related to products that had been part of its business, but were discontinued prior to the distribution, as well as assumed or retained liabilities, and will indemnify Abbott for any liability arising out of or resulting from such assumed legal matters.[12]

71. As a second alternative basis for liability, AbbVie is liable as a matter of law, as a legal successor, for all pre-Spinoff liabilities of Abbott relating to its research-based proprietary pharmaceutical business and other business sectors allocated to AbbVie, including, but not necessarily limited to: liabilities relating to the manufacture and sale of branded Vicodin. AbbVie expressly took title to all Abbott assets relating to its research-based proprietary pharmaceutical business, and to the extent it did not expressly assume all liabilities relating thereto, it impliedly assumed those liabilities. AbbVie's common law liability for pre-Spinoff conduct of Abbott is

[12] AbbVie Report on Form 10-Q for the period ending March 31, 2018 (the same language appears in many other AbbVie SEC filings in the years following the Spinoff).

joint and several with that of Abbott, which is also alleged to be liable for these liabilities.

72. On May 23, 2020, AbbVie acquired Allergan plc, including Allergan Finance, LLC; Allergan Sales, LLC; and Allergan USA, Inc.

e. Endo (unnamed associate)

73. Endo Pharmaceuticals Inc., Endo Health Solutions, Inc., Par Pharmaceutical, Inc., Par Pharmaceuticals Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. are collectively referred to herein as "Endo." Endo is not named as a Defendant in this action due to Endo seeking reorganization pursuant to Bankruptcy Code, Chapter 11.

74. Endo manufactures the branded opioids Percocet (oxycodone and acetaminophen), Opana (oxymorphone hydrochloride), and Percodan (oxycodone and aspirin). Through Par Pharmaceutical, Endo also manufactures and sells generic opioids, including oxycodone, oxymorphone, hydromorphone, and hydrocodone.

75. Endo previously manufactured Opana ER (extended release oxymorphone hydrochloride). On June 8, 2017, the FDA requested that Endo remove Opana ER from the market because of a "serious outbreak" of HIV and hepatitis C among opioid users after its reformulation from a nasal spray to an injectable.[13] This was the first time the agency had ever moved to pull an opioid medication from sale. Endo removed Opana ER from the market in July 2017.[14]

76. Endo has promoted, marketed, advertised, and sold its opioid products (including Percocet, Opana, and Opana ER) in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma.

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[13] *FDA Requests Removal of Opana ER for Risks Related to Abuse*, U.S. Food & Drug Admin. (June 8, 2017), https://www.fda.gov/news-events/press-announcements/fda-requests-removal-opana-er-risks-related-abuse (hereinafter "FDA Requests Removal of Opana ER").

[14] *Endo Provides Update on Opana ER*, Endo (July 6, 2017), https://investor.endo.com/news-releases/news-release-details/endo-provides-update-opanar-er (hereinafter "Endo Provides Update").

f. Mallinckrodt (unnamed associate)

77. Mallinckrodt LLC, Mallinckrodt plc, and SpecGx LLC (collectively, "Mallinckrodt") manufactured, promoted, advertised, distributed, and sold branded and generic opioids in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma. Mallinckrodt is not named as a defendant in this action due to Mallinckrodt seeking reorganization pursuant to Bankruptcy Code, Chapter 11.

78. Mallinckrodt manufactures four branded opioids: Exalgo (extended-release hydromorphone), Roxicodone (oxycodone), Xartemis XR (extended-release oxycodone and acetaminophen), and Methadose (methadone hydrochloride). Mallinckrodt is also one of the largest manufacturers of generic opioids, manufacturing extended-release morphine sulfate, oral solution of morphine sulfate, fentanyl transdermal system, oral transmucosal fentanyl citrate, oxycodone and acetaminophen, hydrocodone bitartrate and acetaminophen, hydromorphone hydrochloride and an extended-release version of the same, oxymorphone hydrochloride, methadone hydrochloride, oxycodone hydrochloride, buprenorphine, and naloxone.

79. Mallinckrodt described itself as a "manufacturer *and distributor* of oxycodone and hydrocodone products" in a 2017 settlement with the DEA.[15]

g. Purdue (unnamed associate)

80. Although not named as a defendant in this matter, Purdue Pharma, L.P.; Purdue Pharma, Inc.; and The Purdue Frederick Company (collectively, "Purdue") participated with Defendants in the misconduct alleged in this action. Purdue is not presently named as a Defendant in this action due to Purdue seeking reorganization pursuant to Bankruptcy Code, Chapter 11.

81. Purdue manufactures the opioids OxyContin (extended-release oxycodone

[15] Administrative Memorandum of Agreement (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download (emphasis added) (hereinafter "2017 Mallinckrodt MOA").

hydrochloride), MS Contin (extended-release morphine sulfate), Butrans (buprenorphine), Hysingla ER (hydrocodone bitartrate), Dilaudid (hydromorphone hydrochloride), Dilaudid-HP (same), and Targiniq ER (extended-release oxycodone hydrochloride and naloxone hydrochloride). Purdue has promoted and sold these opioids in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma.

82. Collectively, Actavis, Teva, Cephalon, Janssen, and Allergan are referred to as "Marketing Defendants." Throughout this Complaint, Purdue, Endo and Mallinckrodt, although not named as defendants in this action, are included as participants in any conduct alleged of the "Marketing Defendants" as a collective entity and in any conduct alleged of "Defendants" as a collective entity.

2. Distributor Defendants

83. Although the Marketing Defendants held licenses to distribute prescription drugs into Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma, the Distributor Defendants also held such licenses. Cencora, Cardinal, and Anda distributed opioids to doctors, pharmacies, hospitals (including Plaintiffs), and other health care settings in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma. Walgreens, WalMart and CVS distributed opioids to their own retail stores. All of these opioids were then purchased by consumers in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma.

84. The Distributor Defendants are among the largest and most profitable companies in the United States. For instance, in 2023, CVS ranked sixth on the list of Fortune 500 companies, McKesson ranked ninth, Cencora ranked eleventh, Cardinal ranked fourteenth, and Walgreens ranked twenty-seventh.[16]

[16] *Fortune 500*, Fortune, https://fortune.com/ranking/fortune500/2023/search/ (last visited Aug. 18, 2023).

85. The Distributor Defendants also marketed opioids. The Distributor Defendants marketed and promoted both branded and generic opioids to pharmacies and, in some cases, hospitals, health care providers, and patients. The Distributor Defendants provided discount cards to induce consumers to purchase the Manufacturer Defendants' opioids. The Distributor Defendants also invested in overcoming resistance on the part of insurance and health plans to pay for opioids prescribed for chronic, noncancer conditions. Strategies to overcome insurers' refusal to cover opioids included call centers to help patients navigate the insurance and insurance appeals process, as well as working with doctors on the same issues.

86. These Distributor marketing activities were an integral part of the Marketing Defendants' deceptive scheme to spread misrepresentations about opioids and increase opioid prescribing. The Marketing Defendants worked with the Distributor Defendants to develop marketing activities and paid the Distributor Defendants for their efforts. As these marketing activities drove dramatic increases in opioid prescriptions, the Distributor Defendants continued to market opioids and continued to distribute unconscionable quantities of opioids, ignoring their obligations to monitor, report, and stop suspicious orders.

87. The Distributor Defendants engaged in marketing efforts designed to inflate demand for opioids despite knowing about high order histories and widespread diversion of these same opioids by their customers in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma and elsewhere. Additional details concerning each Distributor Defendant's marketing activities are described in the sections detailing particular actions by each Defendant.

88. In addition to distributing opioids to their pharmacies in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma, Walgreens and CVS also dispensed and

continue to dispense opioids to consumers in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma. These entities also marketed opioids and served as a conduit between the manufacturers of opioids and customers.

a. Cencora

89. Defendant Cencora, Inc. ("Cencora") is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. Cencora was known as Amerisource Bergen Drug Corporation at all pertinent times until approximately August 30, 2023.

90. Cencora operates many distribution centers around the country.

91. In addition to distributing opioids, Cencora has marketed and promoted opioids, including through its subsidiary, Defendant Xcenda L.L.C. ("Xcenda"). Defendant Xcenda is a Florida limited liability company with its principal place of business in Palm Harbor, Florida.

b. Anda

92. Defendant Anda, Inc. ("Anda") is a Florida corporation with its principal place of business in Weston, Florida.

93. In October 2016, Defendant Teva Ltd. acquired Anda from Allergan plc.

c. Cardinal

94. Defendant Cardinal Health, Inc. ("Cardinal") is an Ohio corporation with its principal place of business in Dublin, Ohio.

95. In addition to distributing opioids, Cardinal has marketed opioids during the relevant times.

d. McKesson

96. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business in Irving, Texas.

97. In addition to distributing opioids, McKesson has marketed opioids during the

relevant times.

e. Walgreens

98. Defendant Walgreen Co. is an Illinois corporation with its principal place of business in Deerfield, Illinois.

99. Defendant Walgreen Eastern Co., Inc. ("WEC") is a New York corporation with its principal place of business in Deerfield, Illinois.

100. Walgreen Co. and WEC are collectively referred to herein as "Walgreens."

101. At all times relevant to this Complaint, Walgreens distributed and dispensed prescription opioids throughout the United States, including in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma.

102. In addition to distributing and dispensing opioids, Walgreens also marketed opioids.

f. CVS

103. Defendant CVS Pharmacy, Inc. is a Rhode Island corporation with its principal place of business in Rhode Island.

104. Defendant, CVS Indiana, L.L.C. is an Indiana limited liability company with its principal place of business in Rhode Island.

105. CVS Pharmacy, Inc. and CVS Indiana, L.L.C. are collectively referred to as "CVS." CVS distributed and dispensed prescription opioids throughout the United States, including in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma.

106. In addition to distributing and dispensing opioids, CVS also marketed opioids.

g. Walmart

107. Defendant Walmart Inc. f/k/a Wal-Mart Stores, Inc. is a Delaware corporation with its principal place of business in Arkansas.

108. Defendant, Wal-Mart Stores East, LP is a Delaware limited partnership with its principal place of business in Arkansas.

109. Walmart Inc. and Wal-Mart Stores East, LP are collectively referred to as "Walmart."

110. Walmart has dispensed prescription opioids from its pharmacies in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma.

111. In addition to distributing and dispensing opioids, Walmart also marketed opioids.

112. Defendants Cencora, Cardinal, Anda, H.D. Smith, McKesson, Walgreens, CVS, and Walmart are collectively referred to herein as the "Distributor Defendants." Walgreens, CVS, and Walmart are collectively referred to herein as the "National Retail Pharmacies."

3. Defendants' Agents and Affiliated Persons

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

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

III. MARKETING DEFENDANTS' AND CVS' FALSE, DECEPTIVE, AND UNFAIR MARKETING OF OPIOIDS

115. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. As a result, doctors generally did not prescribe opioids

for chronic pain.

116. Each Marketing Defendant has conducted, and continues to conduct, a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Marketing Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny, trivialize, or materially understate the risks of opioids while overstating the benefits of using them for chronic pain.

117. Marketing Defendants have disseminated these common messages to reverse the generally accepted medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians that Marketing Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded Front Groups.

118. Marketing Defendants' efforts have been effective. Opioids became, and still were at least as of 2016, "the most commonly prescribed class of any medication."[17]

119. Marketing Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

120. As alleged throughout this Complaint, Defendants' conduct created a public health crisis and a public nuisance. The harm and endangerment to the public health, safety, and the environment created by this public nuisance is ongoing and has not been abated.

[17] Dr. Stephen Ross, "An Addiction Specialist Explains the Deadly Link between Prescription Opioids & Heroin Abuse," NYU Langone Health NewsHub (May/June 2016), https://nyulangone.org/news/addiction-specialist-explains-deadly-link-between-prescription-opioids-heroin-abuse.

121. Marketing Defendants spread their false and deceptive statements by marketing their branded opioids directly to health care providers throughout the United States. Marketing Defendants also deployed seemingly unbiased and independent third parties that they actually controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma.

A. Marketing Defendants' False and Deceptive Statements About Opioids.

122. Marketing Defendants' misrepresentations fall into the following nine categories:

a. The risk of addiction from chronic opioid therapy is low;

b. To the extent there is a risk of addiction, it can be easily identified and managed;

c. Signs of addictive behavior are "pseudoaddiction," requiring more opioids;

d. Blaming addicts as "abusers" of opioids;

e. Opioid withdrawal can be avoided by tapering;

f. Opioid doses can be increased without limit or greater risks;

g. Long-term opioid use improves functioning;

h. Alternative forms of pain relief pose greater risks than opioids; and

i. New formulations of certain opioids successfully deter abuse.

123. Each of these propositions was false. Marketing Defendants knew this, but they nonetheless set out to convince health care professionals, legislatures, and the public at-large of the truth of each of these propositions in order to expand the market for their opioids.

1. Falsehood #1: The Risk of Addiction from Chronic Opioid Therapy is Low.

124. Each of the Marketing Defendants claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to

support those claims. None have acknowledged, retracted, or corrected their false statements.

125. In fact, studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, "even at recommended dose,"[18] and the risk substantially increases with more than three months of use.[19] As the CDC Guideline states, "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder," the latter being a diagnostic term for addiction.[20]

126. For example, Janssen ran (at least until 2018) an unbranded website, *www.PrescribeResponsibly.com*, that stated that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients."[21]

2. Falsehood #2: To the Extent There is a Risk of Addiction, It Can Be Easily Identified and Managed

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

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[18] FDA announces safety labeling changes and post market study requirements for extended-release and long-acting opioid analgesics, FDA (Sept. 10, 2013), https://www.fda.gov/drugs/information-drug-class/new-safety-measures-announced-extended-release-and-long-acting-opioids; *see also* FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death, FDA (Mar. 22, 2016), https://www.fda.gov/drugs/information-drug-class/new-safety-measures-announced-immediate-release-ir-opioids.

[19] Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain*, at 21 (March 15, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm, (hereinafter "2016 CDC Guideline").

[20] *Id.* at 2.

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

say, identify those with higher addiction risks so that doctors can then more closely monitor those patients.

128. Janssen, for example, on its website www.PrescribeResponsibly.com, stated that the risk of opioid addiction "can usually be managed" through tools such as opioid agreements between patients and doctors.[22]

129. There are three fundamental flaws in Marketing Defendants' representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Second, there is no reliable scientific evidence that enhanced monitoring of high-risk patients identified through screening allows those patients to take opioids long-term without triggering addiction. Third, there is no reliable scientific evidence that patients who are not identified through such screening can take opioids long-term without significant danger of addiction.

3. Falsehood #3: Signs of Addictive Behavior are "Pseudoaddiction" Requiring More Opioids

130. Marketing Defendants instructed patients and prescribers that signs of addiction are actually indications of untreated pain, such that the appropriate response is to prescribe even more opioids. Dr. David Haddox, later a Senior Medical Director for Purdue, co-authored and published a 1989 study coining the term "pseudoaddiction," which he characterized as "the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain

[22] Howard A. Heit, MD, FACP, FASAM and Douglas L. Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/before-prescribing-opioids#pseudoaddiction, (last modified July 2, 2015) (hereinafter "What a Prescriber Should Know Before Writing the First Prescription Prescribing Opioids.").

management."[23] In other words, people on prescription opioids who exhibited classic signs of addiction—for example, asking for more and higher doses of opioids, self-escalating their doses, or claiming to have lost prescriptions in order to get more opioids—were not addicted, but rather suffering from under-treatment of their pain.

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

132. For example, Janssen sponsored, funded, and edited a website called *Let's Talk Pain*, which in 2009 stated "pseudoaddiction . . . refers to patient behaviors that may occur when pain is undertreated . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

4. Falsehood #4: Blaming Addicted Patients as "Untrustworthy" "Abusers"

133. A recurring strategy employed by Purdue was to blame any negative consequences from opioid use on moral failings of a minority of users, who were labeled "abusers" or "untrustworthy." In 2001, Purdue's Richard Sackler explained his "solution" to the overwhelming evidence of overdose and death: blame and stigmatize people who become addicted to opioids. He wrote in a confidential email: "we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals."

5. Falsehood #5: Opioid Withdrawal Can Be Avoided by Tapering

134. In an effort to underplay the risk and impact of addiction, Marketing Defendants falsely claimed that, while patients become physically dependent on opioids, physical dependence

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

is not the same as addiction. They further claimed that dependence can be easily addressed, if and when pain relief is no longer desired, by gradually tapering a patient's dose to avoid withdrawal. Defendants failed to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—effects that also make it less likely that patients will be able to stop using the drugs. Defendants also failed to disclose how difficult it is for patients to stop using opioids after prolonged use.

135. Marketing Defendants have not corrected or retracted their misrepresentations regarding tapering as a solution to opioid withdrawal.

6. Falsehood #6: Opioid Doses Can Be Increased Without Limit or Greater Risk

136. In materials they produced, sponsored, or controlled, Marketing Defendants instructed prescribers that they could safely increase a patient's dose to achieve pain relief. Each of Marketing Defendants' claims was deceptive in that failed to warn of increased adverse effects that occur at higher doses (as confirmed by scientific evidence).

137. These misrepresentations were integral to Marketing Defendants' promotion of prescription opioids. As discussed above, patients develop a tolerance to opioids' analgesic effects, so that achieving long-term pain relief requires constantly increasing the dose. Patients who take larger doses, and who escalate to larger doses faster, are much more likely to remain on opioids for a longer period of time, resulting in increased revenue.

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

overdose deaths is directly related to maximum daily dose.

7. Falsehood #7: Long-term Opioid Use Improves Functioning

139. Despite evidence to the contrary, Marketing Defendants consistently promoted long-term use of opioids to improve patients' function and quality of life because they viewed these claims as a critical part of their marketing strategies. Increasing the perceived benefits of opioid treatment was necessary to counterbalance its risks.

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

141. These claims are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long term. FDA warning letters to manufacturers have pointed out this lack of evidence.[24] After reviewing the scientific evidence, the CDC Guideline similarly concluded that "there is no good evidence that opioids improve pain or function with long-term use."[25]

8. Falsehood #8: Alternative Forms of Pain Relief Pose Greater Risks Than Opioids

142. In materials they produced, sponsored, or controlled, Marketing Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing

[24] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

[25] 2016 CDC Guideline, *supra* n. 19, at 20.

products so that prescribers and patients would favor opioids over other therapies such as over-the-counter medication.

143. For example, in addition to failing to disclose the risks of addiction, overdose, and death in promotional materials, Marketing Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"[26] hormonal dysfunction;[27] decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;[28] NAS (when an infant exposed to opioids prenatally suffers withdrawal after birth); and potentially fatal interactions with alcohol.[29]

144. A guide published by Janssen styled *Finding Relief: Pain Management for Older Adults* listed dose limitations as "disadvantages" of other pain medicines but omitted any discussion of risks from increased doses of opioids. *Finding Relief* described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "can increase the risk of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or sleepiness," which the brochure claims will go away, and constipation.

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[26] 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).

[27] H.W. Daniell, Hypogonadism in men consuming sustained-action oral opioids, 3(5) J. Pain 377-84 (2001), https://www.ncbi.nlm.nih.gov/pubmed/14622741.

[28] *See* Bernhard M. Kuschel, et al., *The risk of fall injury in relation to commonly prescribed medications among older people – a Swedish case-control study*, 25 Eur. J. Pub. H. 527-32 (July 31, 2014), doi:10.1093/eurpub/cku120, https://www.ncbi.nlm.nih.gov/pubmed/25085470.

[29] Karen H. Seal, et al., *Association of Mental Health Disorders With Prescription Opioids and High- Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940-47, (March 7, 2012) doi:10.1001/jama.2012.234, https://jamanetwork.com/journals/jama/fullarticle/1105046.

145. As a result of Marketing Defendants' deceptive promotion of opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as prescriptions for acetaminophen and nonsteroidal anti-inflammatory drugs fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.[30]

9. Falsehood #9: New Formulations of Certain Opioids Successfully Deter Abuse

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

147. The CDC Guideline confirms that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of

[30] M. Daubresse, et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Med. Care, 870-878 (2013). "For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady." *See also* J. Mafi, et al., *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. Am Med. Ass'n Internal Med. 1573, 1573 (2013).

opioid abuse, and can still be abused by non-oral routes." Tom Frieden, the former Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death."

B. Marketing Defendants Directly Targeted Hospitals.

148. From the beginning, hospitals were directly targeted by Marketing Defendants. Internal documents from the 1995 "OxyContin Launch" orchestrated by Purdue and Abbott (1) identified "hospital pharmacists" as among their "audience," (2) identified "hospitals" among their "institutional targets," (3) identified an objective of "[f]ormulary acceptance in 75% of hospitals for first twelve months," and (4) identified an objective of developing a "successful distribution program" to "hospitals." In 1996, Purdue made a deal with Abbott under which Abbott's sales force would promote Purdue's lead opioid, OxyContin, in hospitals.

C. Marketing Defendants Disseminated Their Misleading Messages About Opioids Through Multiple Direct and Indirect Channels.

149. Marketing Defendants utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids: (1) direct, targeted communications with prescribers by sales representatives or "detailers;" (2) "Front Groups" with the appearance of independence from Marketing Defendants; (3) so-called KOLs, that is, doctors who were paid by Marketing Defendants to promote their pro-opioid message; (4) disseminating their misleading messages through reputable organizations; (5) Continuing Medical Education (or "CME") programs controlled and/or funded by Marketing Defendants; (6) branded advertising; (7) unbranded advertising; (8) publications; and (9) speakers bureaus and programs.

1. Marketing Defendants Used "Detailers" To Directly Disseminate Their Misrepresentations to Prescribers

150. Marketing Defendants' sales representatives executed carefully crafted marketing

tactics to reach targeted health care professionals with centrally orchestrated messages. Marketing Defendants' sales representatives also distributed deceptive third-party marketing material. Marketing Defendants' direct contact with prescribers was, by far, their most important means of disseminating the False Narrative and increasing opioid prescriptions and thus their sales.

2. Marketing Defendants Deceptively Directed Front Groups to Promote Opioid Use

151. Patient advocacy groups and professional associations also became vehicles to reach prescribers, patients, and policymakers. Marketing Defendants exerted influence and effective control over the messaging by these groups by providing major funding directly to them, as well as through KOLs who served on their boards. These "Front Groups" put out patient education materials, treatment guidelines, and CMEs that supported the use of opioids for chronic pain, overstated the benefits of opioids, and understated their risks.[31] Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of the Front Groups own constituencies.

152. Front Groups utilized by the Marketing Defendants included, but are not necessarily limited to:

a. American Pain Foundation ("APF"): The most prominent of the Front Groups, funded by Teva and others, which presented itself as a patient advocacy organization, but functioned largely as an advocate for the interests of the Marketing Defendants, not patients. APF developed the National Initiative on Pain Control ("NIPC") and its website www.*Painknowledge.com*, which claimed that "[p]eople who take opioids as prescribed usually do not become addicted."

[31] U.S. Senate Homeland Sec. & Governmental Affairs Comm., Ranking Members' Office, *Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, at p. 3 (Feb. 12, 2018), https://www.hsdl.org/?abstract&did=808171 (hereinafter "Fueling an Epidemic").

b. American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS"), professional medical societies, each of which received substantial funding from Teva and other Defendants. AAPM and APS issued their own guidelines, which promoted the prescription of opioids. AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and continued to recommend the use of opioids to treat chronic pain.

c. Federation of State Medicine Boards ("FSMB") which has been developing treatment guidelines for the use of opioids for the treatment of pain, and which promote the broad use of opioids.

d. The Alliance for Patient Access, purportedly a patient advocacy and health professional organization that styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care," but in practice a front group for the industry that has promoted the prescription of opioids.

e. The U.S. Pain Foundation ("USPF") was another Front Group with systematic connections and interpersonal relationships with the Marketing Defendants, one of the largest recipients of contributions from the Marketing Defendants, and a critical component of the Marketing Defendants' lobbying efforts to reduce the limits on over-prescription.

f. American Geriatrics Society, a large recipient of contributions from the Marketing Defendants, including Endo, Purdue and Janssen, which contracted with Purdue, Endo, and Janssen to disseminate guidelines regarding the use of opioids for chronic pain.

g. American Chronic Pain Association.

h. National Pharmaceutical Council: an organization of pharmaceutical companies, styled as a "policy research organization." Its functions include "information dissemination" to benefit its members, including Allergen, Johnson & Johnson, Abbott Laboratories ("Abbott") and Teva.

153. Marketing Defendants took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups. By funding, directing, editing, approving, and distributing these materials, Defendants exercised control over and adopted their false and deceptive messages and acted in concert with and through the Front Groups to deceptively promote the use of opioids for the treatment of chronic pain.

154. In addition, as set forth in other places in the Complaint, Janssen funded front groups by so doing, creating an echo chamber that amplified Janssen's message, but doing so in a way that concealed Janssen's involvement. In total, from 1997 to 2012, Janssen made the following payments:

The American Pain Foundation	$633,300
The American Academy of Pain Medicine	$562,674
The American Pain Society	$1,793,906
The American Geriatrics Society	$565,626
The Center for Practical Bioethics	$8,000
Joint Commission Resources	$515,244
(SUB TOTAL)	$4,078,750.00
Payments to KOLs	$327,546
TOTAL	$4,406,296

155. Janssen's payments to the American Geriatrics Society are notable. In 2002 and 2009, the AGS came out with pro-opioid Guidelines. AGS did not want money up front from the manufacturers. Janssen made payments to AGS in the years following the promulgation of the Guidelines. Treatment guidelines, like the AAPM/APS Guidelines, were particularly important to Janssen and the other opioid manufacturers in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Nine of the twenty-one panel members who drafted the AAPM/APS Guidelines received support from Janssen, and many of the other panel members received support from other opioid manufacturers.

156. As described elsewhere, the AAPM and the APS are entities that were funded by the Marketing Defendants and run in substantial part by some of the KOLs who were paid by the manufacturers in other contexts. In 1996, AAPM and APS issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. In the next four years, Janssen paid about $1.4 million to those

organizations.

157. Janssen also made payments to the "Joint Commission" – the hospital standard setting organization.

158. Because J&J, through Janssen was not only a seller of an opioid product – Duragesic – but, through Noramco, was supplying APIs to the opioid manufacturing industry, it had profound financial incentives to expand the market for opioid products.

159. As a supplier (through Noramco) of raw materials to other opioid manufacturers, including Purdue, J&J played a unique role in keeping the conspiracy together, as the conspirators included its customers.

160. As described in various places in the Complaint, the conspiracy functioned in part through the numerous actions of the various Defendants working together to fund or establish front-groups and/or to use common KOLs. As but one example, in 2001 the NEW YORK TIMES published an article about the opioid industry. An internal email from Purdue reflects that a Purdue executive had a conversation with "Russ" [Portenoy], one of the KOLs used by Janssen and Purdue. "Russ said that Janssen called and has called others to try to help deal with this media blitz and protect the pain movement." This is the Conspiracy in action.

161. When issues began to arise about abuse and diversion of Purdue's OxyContin, an internal Janssen email reflected that "[i]t was not [Janssen's] policy to advance language that would attack a competitor's product." The email stresses the "need to have enough foresight to look towards the future of pain management." In other words, what is bad for Purdue is bad for Janssen. This is, of course, in addition to Johnson & Johnson's interest in Purdue as a customer for Noramco APIs.

162. At about the same time, Purdue sent a memorandum to its "Entire Field Force"

instructing them about the agreement that Purdue and Janssen reached to not disparage the other's products or to raise competitor's drug diversion problems:

> This past week, we received a complaint from Janssen's president indicating that our representatives are discussing various ways in which the Duragesic patch is abused and diverted. . . . While abuse and diversion reports for OxyContin, Duragesic, and other pharmaceutical preparations may be part of the printed and electronic press, this knowledge or information should not be discussed or used as part of the promotion of OxyContin. . . . Janssen Pharmaceuticals and Purdue have agreed that should either company have representatives who promote product out of label ***or out of policy***, the name of the representative will be provided to the other company for investigation and disciplinary action if necessary. . . . I trust that this memo is clear." (emphasis supplied).

3. Marketing Defendants Deceptively Paid KOLs to Promote Opioid Use.

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

164. Despite being funded by Marketing Defendants, the KOLs could present the false appearance that independent medical professionals were reporting unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain.

165. In addition, the following KOLs were funded in whole or in part by the following companies (including Janssen). The boxes marked with an X indicate that the given company paid the given KOL:

	Janssen	Purdue	Teva	Endo	Mallinckrodt	Teva/ Cephalon
Foley	x	x				x
Portenoy	x	x		x		
Joransson	x					
Dahl		x				
Webster		x	x	x	x	x
Fine	x	x		x		
Fishman	x	x				
Haddox		x				

166. Notably, the 1997 APS/AAPM Consensus statement was drafted by Drs. Haddox, and Portenoy, and Mr. Joransson, among others.

167. A Purdue email from 2004 noted that the National Pain Education Council ("NPEC"), an organization supported by Janssen, used "the same speakers [who] spoke for us at regional and national meetings." Dr. Portenoy was cochair of the NPEC, which was a continuing medical education platform. An internal Janssen document referenced using the NPEC to assist in marketing Duragesic.

168. Dr. Russell Portenoy in particular received payments from both Purdue and Janssen.

169. At no point after Purdue pleaded guilty in 2007 to a federal felony related to marketing OxyContin did Janssen ever inform Dr. Portenoy that it wanted to cease involvement with him so long as remained involved with Purdue.

170. Janssen formed a "Independent Steering Committee" ("ISC") associated with the so-called Scientific Advisory Board of the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS) System, whose members describe it as "an independent nonprofit post-marketing surveillance system that is supported by subscription fees from pharmaceutical manufacturers."

171. The ISC was ostensibly formed to monitor abuse of tramadol products. But the real

objective of the ISC was to placate the FDA into approving tramadol as a Schedule IV drug (rather than a Schedule II controlled substance). When it was formed, J&J executives even referred to the project as forming a sort of "SWAT Team," which made presentations across the country, to attempt to persuade various states not to put tramadol products in a more restrictive regulatory category.

172. ISC members compensated by J&J included physicians Dr. Theodore J. ("Ted") Cicero of the Washington University Department of Psychiatry, and Dr. Sidney Schnoll, now with a private consultancy.

4. Marketing Defendants Also Spread Their Misleading Messages to the Joint Commission and Other Reputable Organizations

173. The Marketing Defendants also manipulated reputable organizations like the Joint Commission on Accreditation of Healthcare Organizations (the "Joint Commission") in order to further advance their unlawful marketing of opioids. The Joint Commission certifies over 21,000 health care organizations and is the nation's oldest and largest standards-setting and accrediting body in health care.[32]

174. At all relevant times, Marketing Defendants, especially Purdue Pharma, Janssen/J & J, Teva and Endo, acted in concert with a number of entities, including the NPC (co-author of the Joint Commission's 1999/2001 Pain Guidelines); the Robert Wood Johnson Foundation (RWJF); the FSMB (author of the 1998 Pain Guidelines), aided directly by the American Academy of Pain Medicine and the American Pain Society led by Dr. David Haddox, then President of the American Pain Foundation; and the University of Wisconsin Pain Policy and Study Group, whose efforts to advocate for the assessment and treatment of pain and to minimize the risks of addiction

[32]Joint Commission, *FAQ Page*, available at https://www.jointcommission.org/about/jointcommissionfaqs.aspx?CategoryId=10#2274 (last visited Jan. 20, 2024).

from opioids were financed primarily by the RWJF. These coordinated efforts and those of key opinion leaders such as Scott Fishman led to guidelines and to the creation of a demand for narcotic painkillers to treat chronic pain. For hospitals and the doctors who practice there, the primary vehicle through which Marketing Defendants collectively accomplished this result was through the creation and enforcement of the Joint Commission's guidelines for the treatment of pain.

175. Following the issuance of the Joint Commission's revised standards relating to pain assessment and management in 2001, the prescription of opioids continued to increase substantially. Finally, in 2016, the Joint Commission began a project to both revise its pain assessment and management standards and to develop standards related to safe and judicious prescribing of opioids have been revised to lessen emphasis on pain. However, the damage caused by Marketing Defendants' marketing campaigns could not be undone. Dr. David W. Baker, Executive Vice President for Healthcare Quality Evaluation and Improvement at The **Joint Commission**, explains that "the concept that iatrogenic addiction was rare and that long acting opioids were less addictive had been greatly reinforced and widely repeated, and studies refuting these claims were not published until several years later."[33]

5. Marketing Defendants Disseminated Their Misrepresentations Through CME Programs.

176. Now that Marketing Defendants had both a group of physician promoters and had built a false and/or fictional body of "literature," Defendants needed to make sure their false marketing message was widely distributed. One way Marketing Defendants aggressively distributed their false message was through countless CME programs.

177. Doctors are required to attend a CME program each year as a condition of their

[33] David W. Baker, "The Joint Commission's Pain Standards: Origins and Evolution," JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, 317(11):1117-1118 (Mar. 21, 2017), available at https://pubmed.ncbi.nlm.nih.gov/28241189/.

licensure. These programs are generally delivered in person (often in connection with professional organizations' conferences), online, or through written publications.

178. Marketing Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

6. Marketing Defendants Used "Branded" Advertising to Promote Their Products to Doctors and Consumers.

179. Marketing Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. Marketing Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the *Journal of Pain* and *Clinical Journal of Pain*, to journals with wider medical audiences, such as the *Journal of the American Medical Association*. Marketing Defendants collectively spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

180. Janssen, for example, made numerous representations that vastly overstated the efficacy of Janssen's opioids, minimized their risks, and otherwise falsely and misleadingly stressed that opioids were appropriate for all types of "chronic pain," rather than only for treatment of pain in the limited circumstances authorized by the FDA. Janssen's marketing of its own drugs mirrored the claims it was making about opioids generally. Even in the face of numerous FDA warnings, Janssen stubbornly marketed its products as having "less abuse potential" and consistently tried to expand the market for its own opioids by getting prescribers to prescribe them for chronic pain. Janssen viewed chronic pain as the real untapped market.

a. Janssen and J&J's Promotion of Duragesic

181. Starting in the mid-1990s, at around the same time that Purdue introduced OxyContin CR, Janssen's promotion of Duragesic shifted from a focus on cancer pain to chronic pain generally and introduced comparisons to oral opioids. The "Duragesic Ad Campaign Overview" timeline noted that as of May 1994 there was a "[s]hift away from limiting consideration to only malignant patients" to "[p]romotion of around-the-clock control highlights benefits of 72 hour efficacy in limiting breakthrough pain associated with oral medications." The Duragesic "Journal Advertising Overview" shows that, from April 1995 to July 1997, Janssen's "Core Campaign Journal Ad" for Duragesic used the headline: "Why Interrupt These Moments With Oral Opioid Dosing?" and the tagline "Chronic Pain Control That Goes On."

182. A Duragesic Business Plan for 2001, dated 2000, stated that Duragesic's "vision" was to be the "first choice of chronic pain patients for around-the clock-therapy." The Plan noted that "Non-malignant market is the growth opportunity," but stated just below this point that "DURAGESIC data is non-existent." Another analysis in the same document stated that "opioid acceptance for non-malignant pain" was an opportunity for Duragesic, but that "limited clinical data" was a weakness. Elsewhere in the same plan is the statement "need non-malignant pain data (lower back, OA [osteoarthritis]/RA [rheumatoid arthritis])."

183. A 2003 "Duragesic Public Relations Activities" PowerPoint identified "Expand in non-malignant pain categories (back pain)" as a "Core Duragesic Brand Strategy" and "Target non-malignant severe chronic pain states (primarily lower back)" as a "2003 PR Objective."

184. Under "Direct-to-Patient Awareness," the presentation advocated that Janssen "[u]se broad, unbranded messages and stories about serious chronic back pain to attract potential patients," and "[d]raw potential patients to 'opt-in' to branded Duragesic information on Internet." It further suggested creating a website called www.chronicbackpain.com to "utilize Internet to

engage, capture chronic back pain patients." The PR plan explained that the "primary emphasis on lower back pain" was because "[a]long with osteoarthritis" lower back pain was "identified as key growth opportunity," but "[u]nlike OA, chronic back pain is not 'owned' by any medication or pharmaceutical company."

185. Janssen sent its sales force bulletins and training materials alerting them to studies of Duragesic for chronic non-cancer pain and used professional file cards and similar materials in marketing that touted these studies.

186. One of the studies was by Milligan et al. entitled "Evaluation of Long-term Efficacy and Safety of Transdermal Fentanyl in the Treatment of Chronic Noncancer Pain." Janssen advised the Sales Force that the study's authors stated that Duragesic provided "stable, sustained, long-term pain control," although the study had found that 1/3 of its subjects did not respond to Duragesic. Janssen explained this fact by stating that it "coincided with Perry Fine's comments (see editorial) that a process of trial and error is often needed to achieve adequate pain management." With regards to the study's reported global efficacy rate of 42%, Janssen advised its Sales Force that "[a] possible explanation for the low rate of global efficacy is that . . . the results for the global efficacy measurement did not include a "moderate" rating," an explanation not offered by the study itself. As to the study's reported withdrawal (drop-out) rate of 43%, Janssen's advised its Sales Force that the study's authors found "the incidence of AEs [adverse events] and the rate of withdrawal from the trial are relatively high but neither unusual nor unexpected considering the baseline clinical status of the study population." The Bulletin further advised the Sales Force that the fact that withdrawals due to adverse events or insufficient response diminished after 6 months "may indicate that most of the withdrawals [were] secondary to insufficient response or AEs may be related to improper titration and lack of tolerability to the

transient side effects of TDF [transdermal fentanyl, i.e., Duragesic]," again an explanation not found in the study.

187. Canadian health authorities had previously commented to Janssen that the studies it submitted in support of the use of Duragesic for chronic pain, including the Milligan study, involved only patients who were already taking potent opioids before entering the studies. The Canadian authorities further noted that "the treatment of opioid naive patients with transdermal fentanyl for postoperative pain has resulted in deaths due to respiratory depression in the past." In its reply to the Canadian comments, Janssen stated, "We acknowledge that the experience in opioid naive non-cancer patients is limited." No such acknowledgement was made in Janssen's Bulletin to its Sales Force about the Milligan study. Janssen also did not advise its Sales Force in the Bulletin that the stability of pain control achieved in the study came at the cost of a near doubling of the mean dose of Duragesic over 12 months. A Janssen scientist raised concerns with the Milligan study, sending an email stating she wanted "reiterate" concerns that had been raised regarding using the Milligan study "to make an argument for efficacy." She noted that "these studies not [sic] the appropriate design neither the end points to make a case for efficacy." Janssen did not disclose these concerns in its Bulletin to its Sales Force. Nor did Janssen disclose in the Bulletin that the Milligan study was supported by a grant from the Janssen Research Foundation and that the lead author had received financial support from Janssen.

188. Janssen also provided its sales force with a 1997 study by Simpson et al entitled "Transdermal Fentanyl as Treatment for Chronic Low Back Pain." Janssen advised its sales force that the study results suggested "that patients on DURAGESIC treated for chronic low back pain report greater improvement in pain relief and disability than those who received oral opioids" and that "use of Duragesic may be associated with less disability caused by chronic lower back pain."

In professional file cards and other materials used by sales representatives, Janssen likewise cited the Simpson study for its claims that Duragesic "[de]monstrated effectiveness in chronic back pain with additional patient benefits" and that "[a]ll patients who experienced overall benefit from DURAGESIC would recommend it to others with chronic low back pain."

189. In its September 2004 warning letter to Janssen, the FDA found that the Simpson study was "inadequate to support th[ese] claim[s], because it was an open-label, single-arm trial with no control group," and further stated, "[w]e are not aware of substantial evidence or substantial clinical experience to support th[ese] claim[s]." The FDA found these claims to be "unsubstantiated effectiveness claims," that they and other misleading claims on the file card were "serious" violations and constituted misbranding, and requested that Janssen "immediately cease dissemination" of these claims and come up with a plan for corrective action.

190. Janssen knew and intended to promote its opioids for the sort of chronic pain relief that was not permitted by the FDA, and the 2004 FDA letter was the third of three letters that the FDA sent Janssen about its marketing claims. As an example, in the FDA's 2000 letter to Janssen, the FDA described Janssen's poster as recommending use in chronic pain patients. The FDA characterized this ad as the "promotion of unapproved use," noting that the qualifying limitation that use is approved "in the management of chronic pain in patients who required continuous opioid analgesia for pain that cannot be managed by lesser means" "was placed near the bottom of the poser in small, inconspicuous type size, misleading and overwhelmed by the more prominent claim of chronic pain at the top of the poster."

191. In that same letter, the FDA termed as "false and misleading" Janssen's claim that Duragesic "stops the pain. Not the patient." The FDA stated: "Janssen's statement implies that the use of Duragesic is not associated with any impairment of mental or physical abilities. Janssen has

not submitted data to substantiate such a claim."

192. But Janssen continued to market Duragesic in materially the same way.

193. In or about 2002, Janssen developed another ad campaign for Duragesic. Photos on the four ads depicted the following:

a. a man (presumably the father of the bride) laughing with the bride (presumably his daughter, wearing a wedding dress) with the caption in quotes: This day will be a lifelong memory. I'm glad chronic pain won't be a part of it."

b. two hands kneading a loaf of bread, with the caption "1,360 loaves … and counting. Work, uninterrupted."

c. the torso of a "blue-collar" man (jeans and work gloves) holding a bowling ball, with the caption "506 strikes … and counting. Game, uninterrupted."

d. a man holding a packing box, with the caption, "Work. Plan. Stand. Sit. Bend. Stretch. Move. Carry."

In 2004, in the same warning letter discussed above relating to the Simpson study, the FDA found the above ad campaign to be "misleading." Referencing the text on these ads, the FDA stated: "These outcome claims are misleading because they imply that patients will experience improved social or physical functioning or improved work productivity when using Duragesic. Janssen has not provided references to support these outcome claims." The FDA requested that Janssen "immediately cease the dissemination of promotional materials for Duragesic the same as or similar to those described above. . . . Because the violations described above are serious, we request, further, that your submission include a plan of action to disseminate truthful, nonmisleading, and complete information to the audience(s) that received the violative promotional materials."

194. Janssen, for example, promoted Duragesic as improving patients' functioning and work productivity through an ad campaign that included the following statements: "[w]orc,

uninterrupted," "[l]ife, uninterrupted," "[g]ame, uninterrupted," "[c]hronic pain relief that supports functionality," and "[i]mprove[s] . . . physical and social functioning."

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

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

> Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained release morphine . . . We do not have such data to support OxyContin promotion. . . . In addition, Janssen has been using the "life uninterrupted" message in promotion of Duragesic for non-cancer pain, stressing that Duragesic "helps patients think less about their pain." This is a competitive advantage based on our inability to make any quality of life claims. [34]

197. In short, Janssen marketed Duragesic in a way to broaden its indications beyond the label. By so doing, it lent its powerful voice to the chorus of those advocating for the expanded use of powerful opioids (in this case Fentanyl) for chronic pain, minimizing the risks, and overstating the benefits. This conduct expanded the use of prescription opioids in general and the use of long-lasting opioids in particular.

b. FDA Warnings to Janssen Failed to Deter Janssen's Misleading Promotion of Duragesic

198. On February 15, 2000, the FDA sent Janssen a letter concerning the dissemination of "homemade" promotional pieces that promoted the Janssen drug Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA explained that the "homemade" promotional pieces were "false or misleading because they contain

[34] Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* 47 (2003), at 281.

misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance." The March 30, 2000 letter detailed numerous ways in which Janssen's marketing was misleading.

199. The letter did not stop Janssen. On September 2, 2004, the U.S. Department of Health and Human Services ("HHS") sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic," including, specifically, "suggesting that Duragesic has a lower potential for abuse compared to other opioid products." The September 2, 2004 letter detailed a series of unsubstantiated, false or misleading claims.

200. One year later, Janssen was still at it. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been "examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch" and noted the possibility "that patients and physicians might be unaware of the risks" of using the fentanyl transdermal patch, which is a potent opioid analgesic approved only for chronic pain in opioid-tolerant patients that could not be treated by other drugs.

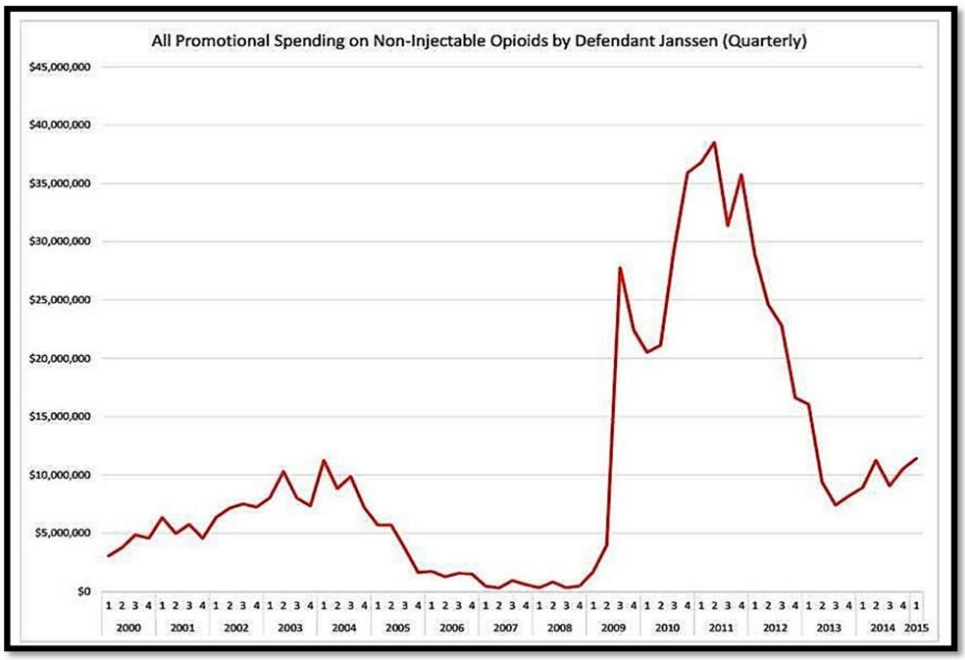
c. Janssen and J&J's Promotion of Nucynta

201. This same sort of approach to defining the market and the uses for its product was in Janssen's DNA. In connection with Janssen's 2011 Nucynta Business Plan, among the "Strategies & Executional Drivers" was "Strengthen differentiation through new & compelling Evidence (the "Value Proposition"), which included demonstrating: "Superior Efficacy vs. Oxy;" "Real World outcomes vs. Oxy;" and "Reduced abuse potential."

202. In connection with Janssen's 2012 Nucynta and Nucynta ER 2012 Business Plan, again, as aspect of the Marketing Strategies associated with "differentiation" was to "Generate

data to support . . . Lower abuse potential." The conduct and goal – to legitimize and expand the market for opioids to the "lower back pain" sufferer – was unchanged.

203. Janssen's quarterly spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011), as shown below:



204. Marketing Defendants also targeted consumers in their advertising. They knew that physicians are more likely to prescribe a drug if a patient specifically requests it.[35] They also knew that this willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved.[36]

d. Janssen and J&J's Deceptive Promotion of Its Tramadol Products

205. J&J schemed to have its versions of the opioid Tramadol (styled Ultracet and

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

[36] *Id.*

Ultram) approved by the FDA as an unscheduled drug. J&J promised to the FDA to have a so-called "Independent Steering Committee," discussed in Section III(C)(4), *supra*, to monitor for abuse problems and notify FDA if a problem was detected.

206. As part of its marketing efforts for Ultram, J&J disseminated a 7-minute video that downplayed the risks of tramadol (Ultram) and overstating benefits.

207. Shortly after the drug was approved, problems with abuse and dependence began increasing rapidly. Instead of alerting the FDA of the need to schedule tramadol, J&J used the ISC to lobby regulators against scheduling the drug.

208. In 2009, the FDA sent J&J a warning letter for disseminating the promotional video. The letter indicated that a failure to present any risk information during the first six minutes of a seven minute video was insufficient. Further, presenting risk information in a rapidly scrolling telescript "lacks comparable prominence to the benefit claims contained in the testimonial portion of the webcast" and failed to include certain contraindications. The FDA found that J&J violated the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 352(a) & (n); 321(n).

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

209. Marketing Defendants also aggressively promoted opioids through "unbranded advertising" that touted the benefits of opioids without naming any particular brand-name drug. Instead, unbranded advertising encourages consumers to "talk to your doctor" about a certain health condition without promoting a specific product and, therefore, without providing balanced disclosures about the product's limits and risks. In contrast, a pharmaceutical company's "branded" advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications. Branded advertising is also subject to FDA review for consistency with the drug's FDA-approved

label. Through unbranded materials, Marketing Defendants expanded the overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising.

210. Many of the Marketing Defendants utilized unbranded websites to promote opioid use without promoting a specific branded drug.

211. Janssen made numerous representations that minimized addiction risks and made numerous other related representations (such as advocating the concept of "pseudo-addiction"). These representations pertained to opioid use generally and were not limited solely to Janssen products (Duragesic, Nucynta, and Nucynta ER). Though these messages were useful for expanding the market for Duragesic, for example, they were also useful for expanding the market for opioids generally, thus increasing the demand for the oxycodone supplied by Tasmanian Alkaloids and Noramco. Some of these unbranded marketing efforts were undertaken unilaterally, others in concert with its competitors.

212. Janssen sponsored, funded, and edited a website called *Let's Talk Pain*, which, as noted above, stated, in 2009, 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 online until at least May 2012.

213. *Let's Talk Pain*, stated, among other things, that "the stigma of drug addiction and abuse" associated with the use of opioids stemmed from a "lack of understanding addiction."

214. The *Let's Talk Pain* website also associated patient behaviors such as "drug seeking," "clock watching," and "even illicit drug use or deception" with undertreated pain which can be resolved with "effective pain management."

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

216. Janssen also ran (at least until 2018) an unbranded website, *www.PrescribeResponsibly.com*, that stated that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients."[37] Janssen, on its website *www.PrescribeResponsibly.com*, states that the risk of opioid addiction "can usually be managed" through tools such as opioid agreements between patients and doctors.[38] The website, which directly provided screening tools to prescribers for risk assessments, [39] included a "[f]our question screener" to purportedly help physicians identify and address possible opioid misuse. [40]

217. *www.Prescriberesponsibly.com*, claimed that concerns about opioid addiction are "overestimated," and describes pseudoaddiction as "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." [41]

218. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults*, discussed above, which described as "myth" that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain" (emphasis in original). Until recently, this guide was still available online.

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[37] *Use of Opioid Analgesics in Pain Management*, *supra* n. 21.

[38] What a Prescriber Should Know Before Writing the First Prescription Prescribing Opioids, *supra* n. 22.

[39] Risk Assessment Resources, PRESCRIBE RESPONSIBLY, http://www.prescriberesponsibly.com/risk-assessment-resources (last visited Aug. 1, 2018).

[40] *Id.*

[41] What a Prescriber Should Know Before Writing the First Prescription Prescribing Opioids, *supra* n. 22.

219. *Finding Relief: Pain Management for Older Adults* further stated as "a fact" that "opioids may make it easier for people to live normally." This guide featured a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. It assures patients that, "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

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

221. Similarly, *Responsible Opioid Prescribing* (2007), sponsored and distributed jointly by Teva, Endo, and Purdue, taught that relief of pain by opioids, by itself, improved

patients' function. The book remains for sale online.

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

222. Marketing Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was calculated to shape the perceptions of prescribers, patients, and payors. This literature served marketing goals rather than scientific advancement and was intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

223. To accomplish their goal, Marketing Defendants—sometimes through third- party consultants and/or Front Groups—commissioned, edited, and arranged for the placement of favorable articles in academic journals.

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

224. In addition to making sales calls, Marketing Defendants' detailers also identified doctors to serve, for payment, on speakers' bureaus or to attend programs featuring those speakers with meals paid for by Marketing Defendants. These speaker programs and associated speaker trainings provided 1) an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; 2) an opportunity for doctors to be selected to attend forum at which the drug companies could further market to the speaker himself or herself; and 3) an opportunity for the doctors to market to their peers. Marketing Defendants graded their speakers, and future opportunities were based on speaking performance, post-program sales, and product usage. Purdue, Janssen, Endo, Cephalon, and Mallinckrodt each made thousands of payments to physicians nationwide, for activities including participating on speakers' bureaus, providing consulting services, and other services.

D. Marketing Defendants' Goal Was for More Patients to Take More Opioids at Higher Doses for Longer Periods of Time

1. Increasing the Patient Population

a. Marketing Defendants Focused on Vulnerable Populations

225. Marketing Defendants targeted their marketing at vulnerable populations—like the elderly and veterans—who tend to suffer from chronic pain.

226. Marketing Defendants targeted vulnerable patients even though the risks of long-term opioid use are significantly greater for them. For example, a 2016 CDC Guideline observes that existing evidence confirms that elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance, and a smaller window between safe and unsafe dosages.[42] Elderly patients taking opioids have also been found to have a greater risk for hospitalizations and increased vulnerability to adverse drug effects and interactions. The Guideline concludes that there must be "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients.[43]

b. Marketing Defendants Focused on Having Opioids Perceived as a "First Line" of Medication for "Opioid-Naïve" Patients, Rather Than as a Last Resort for Cancer Patients and the Terminally Ill

227. Purdue, particularly after its overall OxyContin sales began to slow after 2010, instructed its sales representatives to focus on expanding the patient base by promoting its drugs specifically for patients who had not previously taken opioids. A particularly insidious aspect of Purdue's focus on "naïve" patients, and on keeping patients on opioids longer, was its savings card program. The cards provided a discount on a patient's first five prescriptions. In 2012, Purdue's internal 10-year plan highlighted its discovery that opioid savings cards kept patients

[42] 2016 CDC Guideline, *supra* n. 19.
[43] *Id*. at 27.

on opioids longer. The savings card program was incredibly lucrative -- the return on investment for Purdue was 4.28, so that every $1,000,000 Purdue gave away in savings came back to Purdue as $4,280,000 in revenue because patients stayed on dangerous opioids longer. Purdue sales representatives did not disclose to doctors that "opioid naïve" patients faced greater risks of overdose and death. Purdue focused on less sophisticated prescribers, such as its "core" prolific prescribers, and certain nurses and PAs who might be more vulnerable to persuasion by its sales representatives.

2. Increasing Dosages and Increasing Them Quickly to Keep Patients on Longer

228. In order to promote long-term sales, Marketing Defendants promoted the prescription of higher dosages of opioids. Importantly, patients who took higher dosages would stay on opioids longer. For example, at Purdue, staff, from sales representatives to senior management, regularly and candidly discussed internally the imperative of increasing prescribed dosages. Accordingly, Purdue's second most important sales tactic (after frequent sales representative visits, the most important strategy employed by Purdue) was to cause prescribers to prescribe higher doses. This was manifested in Purdue's Individualize the Dose campaign and was communicated to prescribers in sales representatives' visits, including by the sales representatives in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma. Sales representatives were relentlessly pressured to increase the average doses prescribed by the prescribers in their territories. An aspect of this strategy was to encourage faster upward titration, that is moving quickly from smaller to larger doses. The lowest dosage of Purdue's Butrans product, for example, was described to prescribers as an "introductory" dose that would presumptively be increased for most if not all patients. Purdue secretly determined that pushing patients to higher doses would keep them on opioids longer. Purdue developed

tactics specifically to keep patients hooked on opioids longer, which it called by the euphemism: "*Improving the Length of Therapy*" — sometimes abbreviated as "LOT" or "LoT." Purdue taught its employees that there is "a direct relationship" between getting patients on higher doses and keeping them on Purdue's opioids longer. Marketing Defendants' focus on increasing the dose and duration of opioid usage had devastating consequences for patients. Patients exposed to higher dosages, and for longer periods of time, are many times more likely to become addicted and to overdose.

E. Marketing Defendants' Scheme Succeeded, Creating A Public Health Epidemic

1. Dramatically Expanded Opioid Prescribing and Use

229. Marketing Defendants necessarily expected a return on the enormous investment they made in their deceptive marketing scheme. Their own documents show that they knew they were influencing prescribers and increasing prescriptions. Studies also show that, in doing so, they fueled an epidemic of addiction and abuse.

230. This success should have come as no surprise. Drug Company marketing materially impacts prescribing behavior.[44] The effects of sales calls is well documented in the literature. One study examined four practices (visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing) and found that sales representatives

[44] *See*, *e.g.*, P. Manchanda & P. Chintagunta, Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis, 15 (2-3) Mktg. Letters 129 (2004) *See*, *e.g.*, P. Manchanda & P. Chintagunta, Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); I. Larkin, Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children, 33(6) Health Affairs 1014 (2014)) (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* A. Van Zee, The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy, 99(2) Am J. Pub. Health 221 (2009)) (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). (hereinafter "Commercial Triumph").

have the strongest effect on drug utilization. Another study found that doctor meetings with sales representatives are related to changes in both prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

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

231. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes." The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[45]

F. Each of the Marketing Defendants Made Materially Deceptive Statements and Concealed Material Facts.

232. As alleged herein, Marketing Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts in the course of manufacturing, marketing, and selling prescription opioids. Marketing Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint**.**

1. Purdue (non-party)

233. Purdue made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning

[45] *See* Robert M. Califf, et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. End. J. Med. 1480 (Apr. 14, 2016), doi:10.1056/NEJMsr1601307, https://www.nejm.org/doi/full/10.1056/NEJMsr1601307.

the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;

d. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for

long-term efficacy;

n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;

q. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing; and

r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

2. Endo (non-party)

234. Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high-risk patients;

d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations – including over $5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Directly distributing and assisting in the dissemination of literature written by pro- opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

3. Abbott and AbbVie

a. Abbott's Collaboration with Purdue

235. As discussed *supra*, AbbVie is liable for the pre-Spinoff liabilities of Abbott related to its manufacturing, marketing, sale, and distribution of prescription opioids.

236. Between 1996 and 2006, Abbott actively promoted, marketed, and distributed Purdue's opioid products, thereby supporting Purdue's activities described above.

237. Abbott, as part of the co-promotional agreement, helped turn OxyContin into the largest selling opioid in the nation. Under the co-promotional agreement with Purdue, the more Abbott generated in sales, the higher the reward. Specifically, Abbott received 25% to 30% of all net sales for prescriptions written by doctors its sales force called on. This agreement was in operation from 1996 to 2002, following which Abbott continued to receive a residual payment of 6% of net sales up through at least 2006.

238. With Abbott's help, sales of OxyContin went from a mere $49 million in its first full year on the market to $1.2 billion in 2002. Over the life of the co-promotional agreement, Purdue paid Abbott nearly half a billion dollars.

239. Abbott and Purdue's conspiring with Pharmacy Benefit Managers (PBMs) to drive opioid use is well established. As described in a *Psychology Today* article:

> Abbott and Purdue actively misled prescribers about the strength and safety of the painkiller [OxyContin]. To undermine the policy of requiring prior authorization, they offered lucrative rebates to middlemen such as Merck Medco [now Express Scripts] and other pharmacy benefits managers on condition that they eased availability of the drug and lowered co-pays. The records were part of a case brought by the state of West Virginia against both drug makers alleging inappropriate and illegal marketing of the drug as a cause of widespread addiction…. One reason the documents are so troubling is that, in public at least, the drug maker was carefully assuring authorities that it was working with state authorities to curb abuse of OxyContin. Behind the scene, however, as one Purdue official openly acknowledged, the drug maker was "working with Medco (PBM) [now

> Express Scripts] to try and make parameters [for prescribing] less stringent."[46]

240. Abbott sales staff were instructed about the euphoria patients were receiving on the shorter-acting painkiller Vicodin, they should tell the physician that "OxyContin has fewer such effects." Abbott's "King of Pain" taught his staff of "Royal Crusaders" that OxyContin would "minimize[e] the risk of dependence" and "lower[] euphoria," when, in fact, he had little knowledge of pharmacology and no basis for these statements.

241. Internal documents from the 1995 "OxyContin Launch" orchestrated by Purdue and Abbott (1) identified "hospital pharmacists" as among their "audience," (2) identified "hospitals" among their "institutional targets," (3) identified an objective of "[f]ormulary acceptance in 75% of hospitals for first twelve months," and (4) identified an objective of developing a "successful distribution program" to "hospitals." In 1996, Purdue made a deal with Defendant Abbott under which Abbott's sales force would promote Purdue's lead opioid, OxyContin, in hospitals. Abbott's co-promotion of OxyContin was, in the words of Abbott's counsel, by terms of its contract, dedicated to "hospitals, surgical centers and hospital-based surgeons." Promoting the use of OxyContin for "postoperative pain" and "support[ing] the Abbott agreement" were paramount objectives identified in Purdue's internal documents. "Abbott and Purdue consciously targeted hospitals. [Purdue] representatives will work with their Abbott counterparts to make calls on all Pharmacy and Therapeutic (P&T) communities." "[S]ales force will provide the *appropriate* clinical data necessary to continue to add OxyContin Tablets to hospital formularies."[47] Initial plans called for marketing to "[a]ll 1,200 cancer centers," "[a]ll 1,200 major teaching institutions,"

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[46] American Society of Addiction Medicine, *America's Opioid Epidemic – Court released documents show drug makers blocked efforts to curb prescribing*, PSYCHOLOGY TODAY (Oct. 28, 2016), https://www.psychologytoday.com/blog/side-effects/201610/america-s-opioid-epidemic.

[47] 2002 Purdue Budget Plan, https://khn.org/news/purdue-and-the-oxycontin-files/ (last visited Aug. 20, 2018) (emphasis added).

and "[a]ll 2,500 community hospitals with >= 100 beds." The hospital marketing plan further entailed the following actions:

a. The Purdue Frederick sales force should call on all hospital P&T committees to gain hospital formulary acceptance during the first three months of launch. This effort would entail contacting directors of pharmacies in an effort to gain formulary acceptance of OxyContin.

b. Educate MD's/RN's/RPH's regarding the advantages of OxyContin over other Step 2 opioids for cancer patients. The promotional effort should focus on the ease of use and the reduced administration time. If available, clinical outcomes studies, showing improved quality of life and cost effectiveness, should be used to convince the house staff to use OxyContin as their opioid of choice.

c. Educational lectures should be held through the Speakers' Bureau program during grand rounds, tumor boards, etc. The Purdue Frederick Speakers' Bureau should educate the house staff about the benefits of OxyContin, while presenting clinical study data.

d. Educational symposia should be conducted through the use of satellite teleconferencing to various cancer centers and major teaching institutions across the country, offering CME credits to MD's/RN's/RPH's and focus on the implementation of the AHCPR Clinical Practice Guideline for the Management of Cancer Pain and the results of clinical trials with OxyContin.

e. Target the top 100 MS CONTIN/Duragesic hospitals and offer them a special pain management day where our OxyContin clinical investigators will train the staff on the use of OxyContin.

242. Defendant Abbott, in a 1997 document, indicated that prescriptions written by "Abbott MD's" comprised 25% of all OxyContin prescriptions. In addition, Purdue's budget records reveal details of the payments to Abbott for its OxyContin work, which were termed "commissions." From 1996 through 2002, Abbott was paid $374 million in commissions, according to those documents. Total sales of the drug during that time were nearly $5 billion. From 2003 to 2006, OxyContin sales were nearly $6 billion. From 1996 to 2005, inclusive, Abbott's "commissions" exceeded $500 million. The importance of targeting hospital emergency rooms was illustrated by a study that demonstrated that patients who receive an opiate

prescription within 7 days of surgery are 44% more likely to still be using the medication one year after surgery than patients who do not receive an opioid prescription."[48]

243. Abbott, which was tasked with marketing Purdue's products to hospitals, heavily incentivized its staff to push OxyContin, offering $20,000 cash prizes and luxury vacations to top performers. Abbott's almost religious zeal to sell the drug is evident in the wide use of terminology from the Middle Ages Crusades: Sales reps were called "royal crusaders" and "knights" in internal documents, and they were supervised by the "Royal Court of OxyContin" – executives referred to in memos as the "Wizard of OxyContin," "Supreme Sovereign of Pain Management," and the "Empress of Analgesia." The head of pain care sales, Jerry Eichhorn, was the "King of Pain," and signed memos simply as "King."

244. From the very beginning, Purdue and Abbott intended to position OxyContin as

[48] Cheryl Genord, et al., *Opioid exit plan: A pharmacist's role in managing acute postoperative pain*, Journal of the American Pharmacists Association (Jan. 2017), at 593, available at https://www.japha.org/article/S1544-3191(17)30016-X/fulltext (hereinafter "Opioid Exit Plan").

useful for more than just cancer pain. Internal documents from the 1995 "OxyContin Launch" indicate that they also intended it for a "secondary market . . . for non-malignant pain (musculoskeletal, injury and trauma)" and that it must be "reinforced that we do not want to niche OxyContin just for cancer pain." In 1996, Purdue envisioned OxyContin being prescribed for a long laundry list of conditions, and literally generated a "wish list" of clinical studies to support its prescription in a variety of contexts, including: (1) postoperative pain, with specific objectives of supporting the "Abbott agreement" to market to hospitals, removing "the prohibition of giving the product during the 12-24 hour immediate postop period," and removing "the qualification limiting the indication to pain for more than a few days;" (2) "nonmalignant pain" (including low back pain, osteoarthritis); and (3) HIV/AIDS treatment.

245. On or about October 20, 2020, Abbott's marketing partner, Purdue, pleaded guilty to federal criminal charges relating to the marketing of OxyContin and other opioid products. Purdue faces penalties of approximately $8.2 billion. This is the second time that Purdue has pleaded guilty to federal criminal charges.

246. Working closely with Purdue, Abbott played a central role in establishing the market for opioids, without which there would be no epidemic in Florida. In 1995, Abbott conducted a "commercial review" of the viability of the promotion of OxyContin for acute postoperative pain and concluded that such use of OxyContin would be inappropriate. Despite these concerns Abbott recognized that a commercial relationship with Purdue to promote the purchase of vast amounts of OxyContin could be very profitable for Abbott.

247. On January 1, 1996, Abbott entered into a "Co-Promotion Agreement" with Purdue to market OxyContin using a dedicated sales force focused on hospitals and their doctors. Under the Agreement, Abbott's hospital products division would expand the market for OxyContin well

beyond the existing market, which was then limited to cancer patients and patients facing end-of-life pain.

248. Abbott requested to review Purdue's sales aids used to promote all forms of OxyContin in order to make sure each aid met with Abbott's approval prior to being distributed.

249. Abbott regularly sent sales records and sales call records regarding OxyContin, OxyContin IR, and Oxyfast to Purdue for Purdue's use in its sale and distribution of OxyContin, OxyContin IR, and Oxyfast.

250. Instead of being forthcoming with information regarding the addictive nature of OxyContin after newspaper and electronic media reports regarding OxyContin and addiction began to be released, Abbott instructed its sales force representatives to avoid any discussion of abuse or diversion unless the called-upon physician specifically brought the subject up first.

251. Abbott sales representatives would also plan and host events for targeted physicians and staff such as outings to professional sporting events.

252. Abbott sales representatives gave other incentives such as flashlights to target physician in order to promote OxyContin's sale.

253. Abbott used fifteen-minute and thirty-minute phone cards as incentives in order "to gain access" to physicians so that Abbott's sales representatives could promote the use of OxyContin products.

254. Abbott and Purdue required intense efforts from Abbott sales representatives in order to promote the use of OxyContin including devoting fifty percent (50%) of sales representatives' daily time to marketing the use of OxyContin products and keeping up an average of six (6) sales physician and/or clinic meetings a day.

255. In order to allay physician concerns regarding OxyContin and addiction, Abbott

requested, received, and used training materials in the form of presentations from Purdue entitled, "Handling Abuse, Addiction and Diversion Issues – Manager Meeting Workshop".

256. Abbott agreed to market OxyContin to hospitals and to specifically target anesthesiologists, surgeons and orthopedists. To accomplish this, Abbott agreed to dedicate a group of three hundred detailers and twenty "hospital integrated systems executives" to call on hospitals and doctors across the country, including in Florida. In detailing hospitals and their doctors, Abbott supplied its representatives with IMS Health data reflecting the prescribing data for the targeted doctors, including opioids.

257. Abbott performed its part of the Agreement well and succeeded in expanding the market for OxyContin and other opioids. Abbott's detailers called on hospitals and doctors in Florida, targeting anesthesiologists, surgeons and emergency room doctors to convince these doctors to begin to prescribe OxyContin for long-term, chronic pain.

258. Abbott was not a passive partner. Abbott described its efforts as a promotional "blitz." Abbott's sales representatives worked closely with Purdue sales representatives to aggressively promote OxyContin. The marketing campaigns included utilizing promotional items such as gifts, free phone cards, and other incentives. Abbott funded dinners for surgeons, selling them on OxyContin while they waited for the food. Representatives would also purchase and send lunch and/or snacks to potential prescribers' offices.

259. These efforts were so effective that when bad press ultimately started to be received by Abbott about OxyContin abuses, Abbott sales representatives worked with Purdue representatives to counter negative press and ensure that these criticisms would not impact the prescription-writing habits of OxyContin prescribers.

260. Abbott sales directors and managers and Purdue management met quarterly

throughout the contract term to discuss future sales materials in development, how to benefit from market research, and how to develop unmet needs to increase the purchase of OxyContin.

261. Over the life of the contract with Purdue, Abbott did not rely solely upon the training materials from Purdue. Abbott and Purdue examined market research and data in order to fine tune the promotional materials. Abbott worked with a third party to create and use an adult learning module-type program to make its sales calls more effective. Abbott received sales and profit information from Purdue which reflected that its sales calls were very effective in expanding the market for OxyContin. Sales continued to remain strong in both hospital and retail markets during and after the Co-Promotional Agreement.

262. Part of Abbott's duties under the contract was to build "good will" regarding OxyContin so that even after the contract between Abbott and Purdue expired Purdue could maintain a relationship with physicians and entities whom Abbott and Purdue intended to keep purchasing OxyContin. This was accomplished, in part, by Abbott's providing Purdue with Abbott's sales call records and notes in both electronic and paper formats.

263. For its efforts to build good will so that Purdue could continue to profit from OxyContin sales after the Co-Promotional Agreement expired, including sales in Florida, Abbott received for three years following termination of the Co-Promotional Agreement a commission of six percent (6%) of net sales.

264. Abbott's efforts to expand the market for and influence the standard of care for prescription of OxyContin and solidify Purdue's future sales of OxyContin were successful. Abbott's efforts substantially contributed to the maintenance of the expanded market for OxyContin for treatment of chronic pain until 2018 when Purdue stopped marketing OxyContin to prescribers.

265. Many remain dependent on opioids, thereby continuing the damage caused by Abbott and Purdue's actions herein, in part, described.

266. Abbott assisted Purdue in expanding the market for OxyContin by recruiting doctors to participate in studies regarding new uses for OxyContin. These studies were used to convince other doctors to prescribe OxyContin. For instance, in November 1997, Abbott distributed an "OxyContin post PCA" study to promote OxyContin use following surgery. Abbott also recruited doctors to promote OxyContin through CME seminars.

267. Abbott made deceptive statements regarding the risks of Oxycontin in order to expand the market for OxyContin into chronic care.

268. Abbott instructed its sales representatives to detail doctors with the message and charts that OxyContin provided a slower peak in oxycodone blood concentration, "a lower peak concentration" and slower concentration decrease than a comparable dose of immediate-release (IR) oxycodone.

269. Abbott used "sage" advice to address concerns that doctors who were concerned with euphonia of competing products to OxyContin by instructing its representatives to "Tell your doctor that with its longer half life Oxycontin has fewer such [euphoric] effects" than its competitors such as Vicodin.

270. Abbott's training manuals highlighted the "delayed absorption" language from the OxyContin label and noted, "slower absorption may lessen abuse risk." Abbott's training materials described the statement regarding "iatrogenic addiction" (addiction arising out of a legitimate prescription) not as a warning about risk, but simply a "reminder to the physician that addiction as a result of legitimate medical use is very uncommon, and not to mistake tolerance, physical dependence, or attempt by the patient to obtain adequate analgesia as signs of addiction."

271. Abbott trained its sales representatives to deliver the message that OxyContin's formulation diminished side effects and lowered oxycodone's abuse or addiction potential. For instance, in a 1999 handout Abbott noted that short-acting Schedule III opioids had a higher abuse potential.

272. Abbott trained its sales representatives to tell doctors that the lack of a high peak also lowered the incidence of side effects associated with OxyContin and lowered its abuse potential.

273. Abbott provided its sales representatives with an OxyContin visual aid entitled "24 hours of pain relief THE HARD WAY," which included a log graph depicting blood plasma concentrations of OxyContin over time as flatter than they actually were. The piece also asserted that "100% of all clinical patients were dosed Q 12 H in clinical trials," something which was not true.

274. Abbott trained its sales representatives to describe a slower elimination half-life for OxyContin compared to other immediate-release opioids, and claim that such would decrease its abuse potential. At the time of those representations, however, no studies or scientific data supported this claim.

275. Abbott further instructed sales representatives to tell doctors that the "sustained analgesia that OxyContin provides helps minimize the risk of patient dependence because patients don't have to keep dodging themselves to achieve and maintain pain relief more than twice daily."

276. Abbott trained its sales representatives to state that OxyContin was "less habit-forming" than other opioids and that "less than 1% [of patients] become addicted."

277. Abbott, along with Purdue, pursued postoperative studies to support a "supplemental new drug application" that would remove the restriction on postoperative use of

OxyContin for pain immediately following surgery. Abbott and Purdue pursued this change in spite of growing reports of OxyContin addiction.

278. Abbott provided its sales representatives with reprints to give to doctors, one of which was a piece written by Purdue KOL Dawn Marcus. The Marcus article advocated using long-action opioids for the treatment of chronic pain and stated, without citation, "While studies report drug abuse/dependence/addiction is 3 to 19 percent of chronic pain patients, true addiction (psychologic dependency) is uncommon with the use of long-acting opioids for chronic pain."

279. Abbott continued to aggressively market OxyContin even when doctors began to raise concerns about addiction. In response, Abbott instructed its sales force to not raise the topic of abuse or diversion unless the prescriber did so. If doctors did raise concerns about addiction, Abbott instructed its representatives to downplay concerns about addiction, and to describe such instances as "abuse," which was not happening in "true pain patients." Abbott made these statements despite the lack of any scientific support.

280. Abbott's website touted that OxyContin was "co-promoted by Purdue Pharma LP and Abbott Laboratories" and that Abbott's "pain management therapies are safe, effective and easy to use." Abbott recommended that OxyContin Tablets were "for patients with moderate to severe pain requiring opioid therapy for more than a few days."

281. Beginning in 2000, Abbott continued to aggressively market OxyContin, but in addition to the above measures, it also utilized recently adopted pain care standards issued by the Joint Commission. Abbott instructed its sales force to leverage the new pain guidelines, which had been made part of the accreditation requirements for hospitals, by reminding doctors and hospitals that if did not treat pain they could risk the hospital's accreditation.

282. These efforts were so effective that when bad press ultimately started to be received

by Abbott about OxyContin abuses, Abbott sales representatives worked with Purdue representatives religiously to take on the abuse problem head-on and found that negative press was not changing the prescribing habits of OxyContin prescribers.

283. Abbott knew as early as 1999 that OxyContin was being improperly shared between patients but when confronted with this knowledge, Abbott chose to adjust its selling points to insist that doctors should really weigh the high value of patient's pain relief with OxyContin against the chance of pills being shared.

284. Abbott's efforts to expand and establish the market for OxyContin in Florida resulted in a flood of OxyContin. The market that Purdue and Abbott created persists to this day, substantially contributing to the opioid epidemic.

b. Abbott's Other Pre-Spinoff Promotion of Opioids

285. Abbott was, at least at all times pre-Spinoff, an active member of the National Pharmaceutical Council (NPC).

286. Between approximately 1999 and 2003, Abbott was a leader in Front Groups and a leading supporter of the JCAHO/Joint Commission Guideline creation, discussed *supra*, used against hospitals in the late 1990s and early 2000s. Abbott was one of six organizations that provided support for the Joint Commission's pain management program, which culminated in the promulgation, implementation, and enforcement of its 2001 Pain Guidelines against hospitals that it accredited.

287. In 2000, Abbott continued to aggressively market OxyContin, but in addition to the above measures, it also utilized the recently adopted pain care standards issued by the Joint Commission. Abbott instructed its sales force to leverage the new pain guidelines, which had been made part of the accreditation requirements for hospitals, by reminding doctors and hospitals that if they did not treat pain they could risk the hospital's accreditation.

288. According to records of the Joint Commission, Abbott contributed to the Joint Commission in March 2003 for "honoraria and related expenses" concerning "Topic: JCAHO Standards Related to Sedation, Pain Management and Restraint issues" and additional funds in October 2010 for "honoraria and related expenses" concerning "Topic: How Quality Measures are Developed and Used by Providers/Payer."

289. Abbott was an original member of the Pain Care Forum ("PCF"), formed in 2006, and Abbott expanded the number of its representatives participating in PCF by 2010. Abbott was listed as a participating organization on a membership directory in February 2010, listing four Abbott employees as participants.

290. In 2007, Abbott funded prominent KOL Scott Fishman, who published his notorious book, *Responsible Opioid Prescribing, a Physician's Guide*.

291. Abbott funded leading KOL Russell Portenoy. A 2007 fundraising prospectus from Dr. Portenoy's program shows that his program received millions of dollars over the preceding decade in funding from opioid makers including Endo, Abbott, Cephalon, Purdue, and J&J.

292. Abbott funded a medical writer to assist authors with a manuscript preparation for a CME designed to promote the broader use of opioids: *Opioids May be Useful for Chronic Noncancer Pain Management in Primary Care* by L. Barclay & P. Murata.

293. Abbott also utilized APS's *Journal of Pain* to disseminate marketing materials directed at physicians. For example, Abbott conducted a survey entitled "Unmet needs: among patients experiencing acute and chronic pain: Results from a survey of 606 pain patients and 491 physicians," published in APS's *Journal of Pain* in April 2008. The authors claimed the survey showed that "end-of-dose pain" occurred in over 90% of the paint patients and further "highlights

some unmet needs experienced by pain patients taking IR medications."[49]

c. Abbott's Sales of Vicodin and Other Opioids

294. On June 30, 2002, Abbott completed its acquisition of the pharmaceutical assets of BASF SE (a German conglomerate). These assets included the business entity then known as Knoll Pharmaceuticals (Knoll Pharmaceuticals and its successor entities are referred to as "Knoll").

295. Knoll is the creator of at least two opioid products, and has held, at all pertinent times, the patents for these products. The first is Dilaudid, the brand name for hydromorphone, a legacy opioid invented in the 1920s. The second is Vicodin, the brand name for a composite product containing hydrocodone and acetaminophen, first approved in the early 1980s.

296. Knoll was an Abbott subsidiary at all times from June 30, 2002 to January 1, 2013. Abbott directed and controlled all of Knoll's conduct and operations relating to Knoll's pharmaceutical business, including all operations relating to opioids.

297. At all times between June 30, 2002, and January 1, 2013, Abbott manufactured and sold Dilaudid and Vicodin.

298. At all times (at the very least) between 2003 and late-2008, Abbott was planning to sell a controlled-release version of Vicodin, which it referred to internally as "Vicodin CR," and had a large staff of sales representative prepared to market the product—but the FDA denied approval for the product in late 2008.

299. The hydrocodone/acetaminophen composite originally developed by Knoll (which includes Vicodin, and now its generic versions) is the dominant form of opioid. At most (if not all) pertinent times in the past 30 years, it has been the most prescribed painkiller of any kind. In 2012,

[49] P. Vo, et al., Unmet Needs: Among Patients Experiencing Acute and Chronic Pain: Results from a Survey of 606 Pain Patients and 491 Physicians, 9 Suppl. 2 J. Pain. 69 (2008), https://www.jpain.org/article/S1526-5900(08)00298-8/fulltext.

hydrocodone/acetaminophen was prescribed approximately 135 million times. In 2017, hydrocodone/acetaminophen represented approximately half of the U.S. painkiller market. In at least some years, hydrocodone/acetaminophen has been the most prescribed medication of any kind in the United States.

300. One reason for the brisk sales was that, until 2014, hydrocodone/acetaminophen was a Schedule III drug (rather than Schedule II, as it is today). As such, prescriptions could be refilled by patients without additional prescriptions. In fact, Knoll made this part of the basis for its promotion of Vicodin in the 1980s and 1990s. Knoll marketed Vicodin as "The Highest Potency Pain Relief You Can Still Phone In." Knoll used such advertising on trinkets and toys, such as fanny packs and water bottles bearing the name "Vicodin," to promote increased sales.

301. Abbott's sales of Vicodin generated $166 million in revenues in 2010 and $168 million in 2011. Upon information and belief, revenues were of a similar dimension in other time periods.

d. AbbVie's Continued Sale of Opioids and Support of Front Groups

302. In addition to being liable for certain of Abbott's pre-Spinoff conduct as a matter of contract and successorship law, AbbVie itself engaged in actionable conduct and immediately joined the conspiracy described herein. AbbVie continued certain of Abbott's pharmaceutical operations, including the manufacture and sale of branded Vicodin, picking up right where Abbott left off.

303. Jerry Eichhorn, the notorious "King of Pain" and head of sales at Abbott in the 1990s, never left the business. Eichhorn became the senior marketing executive at AbbVie.[50]

[50] David Armstrong, *Secret Trove Reveals 'Crusade' to Make OxyContin a Blockbuster* (Sept. 22, 2016), https://www.statnews.com/2016/09/22/abbott-oxycontin-crusade/.

304. At all times between January 1, 2013, and at least November 17, 2018 (at which time AbbVie's website indicated it was still manufacturing and selling Vicodin), AbbVie manufactured and sold Vicodin.

305. AbbVie participated in many collaborative efforts to promote opioid use.

306. AbbVie contributed a total of $705,000 to AfPA spread out between 2014 ($175,000); 2015 ($125,000); and 2016 ($405,000). "Since 2012, the AfPA has received at least $2.1 million in payments for opioid manufacturers including AbbVie, Endo, Grunenthal, Mallinckrodt, Pfizer, Purdue and Teva. Open Payments data further shows that . . . doctors who sat on the organization's board of directors have received more than $5 million in payments from pharmaceutical manufacturers and device manufacturers, of which $1.9 million came from opioid makers." AbbVie paid Robin Dore, one of the directors, $145,000.

307. AbbVie contributed a total of $919,500 to USPF starting in 2014; most of the contributions occurred in 2016 ($310,000); 2017 ($300,000); and 2018 ($300,000).

308. Between 2013 and 2015, AbbVie also contributed to AAPM and ACPA.

309. As of 2016, both AbbVie and Abbott were members of the Pain Care Forum, the most notorious of the "Front Groups," and which was the principal entity coordinating strategy for Defendants to mislead regulators and the public about opioids. In 2016, the Associated Press and the Center for Public Integrity published an extensive report on front groups and lobbying efforts by the Marketing Defendants. In connection with that report, a list of Pain Care Forum members was published. The first two members listed, in alphabetical order, were Abbott and AbbVie, who were members of the organization *at the same time.*

310. A 2020 U.S. Senate report specifically identifies AbbVie as a major funder of the ten Front Groups that it looked at during the period from 2012 to 2019. "Based upon payment data

collected for this investigation, between 2012 and 2019, drug manufacturers that marketed opioids or opioid-related therapies paid almost $30 million to these organizations . . . major funders included . . . AbbVie, which made payments of more than $1.6 million."[51]

311. On May 8, 2020, AbbVie completed its acquisition of Defendant Allergan for $63 billion. Through that acquisition it acquired, at the very least, Allergan's branded opioid product lines, including Kadian. AbbVie has disclosed on its most recent Form 10-K filed with the SEC that Allergan faces over 3,000 lawsuits relating to opioids.[52]

312. AbbVie never took any affirmative act to leave, or even distance itself from, the conspiracy alleged herein.

e. Abbott's Post-Spinoff Conduct: Abbott Never Left the Pharmaceutical Business or Withdrew from the Conspiracy Alleged Herein

313. Abbott never left the pharmaceutical business. Pharmaceutical sales were the significant sector of Abbott's gross revenues for each year since the Spinoff. Abbott's pharmaceutical business consists principally (if not necessarily entirely) of the sale of "Established Pharmaceutical Products" outside the United States. Abbott's pharmaceutical sales were between $2.9 billion and $4.7 billion in each year since the Spinoff:

Year	Pharmaceuticals Net Sales ($ bln)	Pharma Sales as a Percentage of Total Net Sales	Total Net Sales ($ bln)
2013	2.862	14.56%	19.657

[51] Sen. Chuck Grassley & Sen. Ron Wyden, Senate Fin. Comm., Findings from the Investigation of Opioid Manufacturers' Financial Relationships with Patient Advocacy Groups and Other Tax-Exempt Entities 9 (Dec. 16, 2020).

[52] AbbVie, Inc., *Form 10-K* (Feb. 19, 2021), https://investors.abbvie.com/static-files/b1ca3ffe-226e-499d-992e-344f42d470d1.

2014	3.118	15.40%	20.247
2015	3.720	18.23%	20.405
2016	3.859	18.51%	20.853
2017	4.287	15.65%	27.390
2018	4.422	14.46%	30.578
2019	4.486	14.06%	31.904
2020	4.303	12.43%	34.608
2021	4.718	10.95%	43.075

314. As of 2016, Abbott and AbbVie were both members of the Pain Care Forum, the most notorious of the "Front Groups," and which was the principal entity coordinating strategy for Defendants to mislead regulators and the public about opioids. As of 2019, Abbott remained a member of the Pain Care Form. Upon information and belief, Abbott remained in the Pain Care Forum to continue its support of the worldwide opioid market it helped to create.

315. On July 29, 2020, Abbott filed a claim, signed under pains and penalties of perjury by an in-house attorney and corporate officer, in the Purdue Bankruptcy, *In re Purdue Pharma, L.P.*, Case No. 19-23649, Claim No. 146149 (Bankr. S.D.N.Y.), seeking indemnity and contribution relating to Abbott's liabilities for conduct relating to Purdue. As such, upon information and belief, Abbott at least asserts that it continues to have liability for the marketing of Oxycontin in 2020. On July 29, 2020, Abbott filed a claim in the Purdue Bankruptcy, *In re Purdue Pharma, L.P.*, Case No. 19-23649, Claim No. 146149 (Bankr. S.D.N.Y.), seeking indemnity and contribution relating to Abbott's liabilities for conduct relating to Purdue. Abbott is certainly acting as if it (and not AbbVie) assumed liabilities relating to Abbott's collaboration with Purdue, and that the agreement with Purdue is alive and well at least for some purposes. To

be clear, while Plaintiffs have alleged that AbbVie, too, shares this liability, Plaintiffs do not allege that Abbott is not also liable.

316. Abbott never took any affirmative act to leave, or even distance itself from, the conspiracy alleged herein.

4. Janssen and J&J

317. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials,

concerning the use of opioids to treat chronic non-cancer pain;

h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

318. Janssen's branded, and unbranded, promotion of opioids, and support of Front Groups and KOLs are described in some detail in Section III(C), *supra*.

319. Sometime in the 1980s, Janssen acquired Tasmanian Alkaloids PTY, LDT ("Tasmanian Alkaloids"). According to a presentation created by Janssen sometime prior to its sale of Noramco, Inc., and Tasmanian Alkaloids, the purpose of Janssen's acquisition was to

"secure another piece of the value chain."

320. In the early 1990s, J&J, through Noramco, began discussions with Purdue Pharmaceuticals regarding the anticipated future demand of opioid painkillers, including those opioid painkillers with oxycodone as the primary active ingredient.

321. In or around 1994, Tasmanian Alkaloids began a research project with the purpose of creating a poppy plant with enhanced thebaine content. Thebaine is the active ingredient in oxycodone. The purpose of the project was to meet the foregoing "anticipated demand" for oxycodone based opioids, including, but not limited to, Purdue Pharmaceutical's then soon to be released Oxycontin.

322. The foregoing research project was successful, and in or around 1996 Tasmanian Alkaloids began a program to entice Tasmanian farmers to grow the new "thebaine poppy" (also known as the "Norman Poppy"). Eventually, the thebaine poppy constituted the majority of the Tasmanian poppy crop.

323. These Tasmanian poppies were noted for containing a significant quantity of a substance called thebaine from which oxycodone and hydrocodone could be readily manufactured. In addition, unlike traditional opioids poppies, the Tasmanian poppies had no morphine, meaning that the purification process was simpler.

324. The individual credited with the discovery or development of the "Tasmanian poppy," Anthony J. Fist, an agricultural scientist, was given the "Johnson & Johnson Medal," J&J's highest award for scientific research and innovation, in 2000.

325. Tasmanian Alkaloids bought the poppies from farmers and then shipped concentrated poppy products to the United States where Noramco processed the raw materials into oxycodone, hydrocodone, and other opioid products.

326. The development of the Tasmanian poppy in the mid-1990s generally coincided with the introduction of OxyContin, the oxycodone-based pill made by Purdue. An affiliate of Purdue, PF Laboratories, was one of the first major customers of the product from Noramco.

327. By 1998, Defendant Noramco had begun receiving the highly concentrated thebaine poppy straw from Tasmanian Alkaloids and engaged in discussions and/or business transactions with Purdue Pharmaceuticals to supply oxycodone.

328. As a condition of supplying oxycodone, Defendant Noramco requested assurances from Purdue Pharmaceuticals that the latter would be able to manufacture and sell significant oxycodone based opioid products.

329. Over the next two decades, Noramco provided active pharmaceutical ingredients, including oxycodone and other thebaine based products to several of the manufacturer defendants. J&J and Noramco created genetically mutated poppies. In 1998, scientists at Johnson & Johnson commercialized "Norman," a variety that produced a much higher concentration of thebaine. They followed in 2009 with "Ted," a variety that made mostly thebaine.

330. A Noramco official would later boast that the "patented, high-thebaine poppy was a transformational technology that enabled the grown of oxycodone." As described below, Tasmanian Alkaloids and Noramco, together, became world leaders in the supply of oxycodone, and J&J through those entities financially benefitted from the epidemic in addition to the profits from its subsidiary Janssen's sales of opioid products.

331. Noramco became a supplier to Purdue. A Noramco executive wrote to PF Laboratories (Purdue) in October 1998: "Noramco will work with PF Laboratories to secure its entire worldwide requirements. This is not a minor point. As we have discussed, access to raw materials is going to be critical to obtaining security of supply." The letter is replete with references

to the intent of Noramco to expand its production to meet the needs of Purdue, explaining that "[t]he capacity expansions are . . . still on track;" "[t]he Wilmington facility to produce the penultimate and final steps of oxycodone will be completed by year-end[;]" "[t]he engineering for the expansion of our hydrogenation capacity is well underway,[;]" and "[t]he facility in Athens [Georgia] will be completed by year-end."

332. The letter contemplates a "long-term commitment" by Noramco: "With a long term commitment, Noramco can work to provide even more capacity than in this proposal that will give PF Laboratories the maximum security of supply for its franchise . . . ." In return: "Of course, we need long term commitment from PF Laboratories to be able to provide the support this proposal envisions." The precise date when Noramco began to supply Purdue and the precise terms of their supply agreement are not currently known.

333. In 2011, the Johnson & Johnson Family of Companies in Australia submitted a document titled "Submission to the Transparency Review of the Therapeutic Goods Administration." (The Therapeutic Goods Administration is the part of the Australian Government Department of Health responsible for regulating therapeutic goods such as medicines, vaccines, medical devices and similar products.). In that submission, Johnson & Johnson represented:

> In 1995, Tasmanian Alkaloids initiated a project to develop a high-thebaine poppy. In sampling the alkaloid content of thousands of plants, one plant was found to have a high content of thebaine and no morphine, and the first commercial crop of these unique poppies was harvested in 1998. The new plant revolutionised thebaine production and today it has up to 80% of the worldwide market for Oxycodone raw materials. Tasmanian Alkaloids is presently the largest manufacturer of active pharmaceutical ingredients in Australia and the largest exporter of codeine and thebaine in the world.

334. It is unknown precisely how much oxycodone was produced by Noramco, or the quantities sold to various customers (including Purdue). In 2015, at the time when Johnson & Johnson was attempting to sell off Noramco and Tasmanian Alkaloids, Johnson & Johnson

prepared a marketing brochure for those companies. That brochure represented:

a. that the purchaser had the opportunity to "[a]cquire the #1 supplier of Narcotic AOSs in the United States;" and "[b]ecome a key supplier to the world's largest multi-source generics[.]"

b. that the Noramco portfolio of products (with net trade sales in 2014) included Oxycodone ($94 million); hydrocodone ($52 million); buprenorphine ($20 million), morphine ($20 million); codeine ($18 million); and other products for global 2014 sales of $258 million.

c. that Noramco's US market share of these products in 2014 was as follows: oxycodone – 65%; hydrocodone – 54%; codeine – 60%; and morphine – 60%.

d. that "Tasmanian Alkaloids produces over 40% of the world's supply of Narcotic Raw Materials" and that "Tasmanian Alkaloids has the highest content poppies for key alkaloids."

e. that Noramco and Tasmanian Alkaloids, located in four locations around the world (Wilmington, Delaware; Athens, Georgia; Tasmania, Australia; and Schaffhausen, Switzerland) had 483 full-time equivalent employees, including 28 employees shared with Johnson & Johnson;

That brochure also represented that "Noramco has long-term agreements and/or majority controlled substance share with all 7 of the top US generic companies." The marketing materials represented, as to "typical supply terms:"

a. Covers multiple controlled substance products (4 or more)

b. Agreements are for more than 80% of customer's volume

c. Terms are for 3 to 5 years minimum with rolling renewals

335. The thebaine poppy allowed a dramatic increase in the production of oxycodone, which in turn allowed a dramatic increase in the production, marketing, and sales, of oxycodone based opioid products. As of 2015, roughly sixty-five percent of all oxycodone consumed in the United States was distributed by Noramco.

336. Upon information and belief, J&J, through its subsidiaries, Noramco and Tasmanian Alkaloids, incentivized Tasmanian farmers to grow the best crop of the mutant poppies

awarding them with "prizes" like a Mercedes, a Jaguar, a BMW. The poppy was farmed in abundance.

337. At all relevant times, J&J and Noramco had reason to know that their stockpiles of the Tasmanian poppy were dangerous and subject to diversion. The International Narcotics Control Board specifically discouraged J&J and Noramco from holding big stockpiles of the poppy due diversion into the production of heroin, whose market was (as of 2014) more than four times the size of the opiate painkillers market. Until its sale, J&J and Noramco continued to create excess stockpiles for shipment to the United States, without sufficient regard for the heroin market and with sole focus on the lucrative opioid market in the United States.

338. J&J sold Noramco and Tasmanian Alkaloids for $650 million to a private equity firm in or about 2016.

5. Teva

339. Defendant Teva made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Teva's potent rapid-onset opioids;

e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Teva's rapid-onset opioids;

h. Directing its marketing of Teva's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

i. Making deceptive statements concerning the use of Teva's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

j. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

a. Unbranded Marketing and Promotion

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

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

> [C]hronic pain is often undertreated, particularly in the 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 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.[53]

342. Purdue and Cephalon sponsored the APF's *Treatment Options: A Guide for People Living with Pain* (2007), which also falsely reassured patients that opioid agreements between doctors and patients can "ensure that you take the opioid as prescribed" and counseled patients that opioids "give [pain patients] a quality of life we deserve."

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

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

345. At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Dr. Webster and others titled, "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results." The presentation's agenda description states: "Most patients with chronic pain experience episodes of breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment." The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the "[i]nterim results of

[53] Michael J. Brennan, et al., Pharmacologic Management of Breakthrough or Incident Pain, Medscape, https://www.medscape.org/viewarticle/449803.

this study suggest that [fentanyl buccal] is safe and well-tolerated in patients with chronic pain and [breakthrough pain]." This CME effectively amounted to off-label promotion of Cephalon's opioids, even though they were approved only for cancer pain.

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

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

348. Another Cephalon-sponsored CME presentation titled Breakthrough Pain: Treatment Rationale with Opioids was available on Medscape starting September 16, 2003, and was given by a self-professed pain management doctor who "previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis." He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using "targeted pharmaco therapeutics to affect multiple points in the pain-signaling pathway."[54] The doctor lists fentanyl as one of the most effective opioids available for treating breakthrough pain, describing its use as an expected and normal part of the pain management process.[55] Nowhere in the CME is cancer or cancer-related pain even mentioned, despite FDA restrictions that fentanyl use be limited to cancer-related pain.

[54] Daniel S. Bennett, Breakthrough Pain: Treatment Rationale With Opioids, Medscape, http://www.medscape.org/viewarticle/461612 (last accessed Jan. 20, 2024).

[55] *Id.*

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

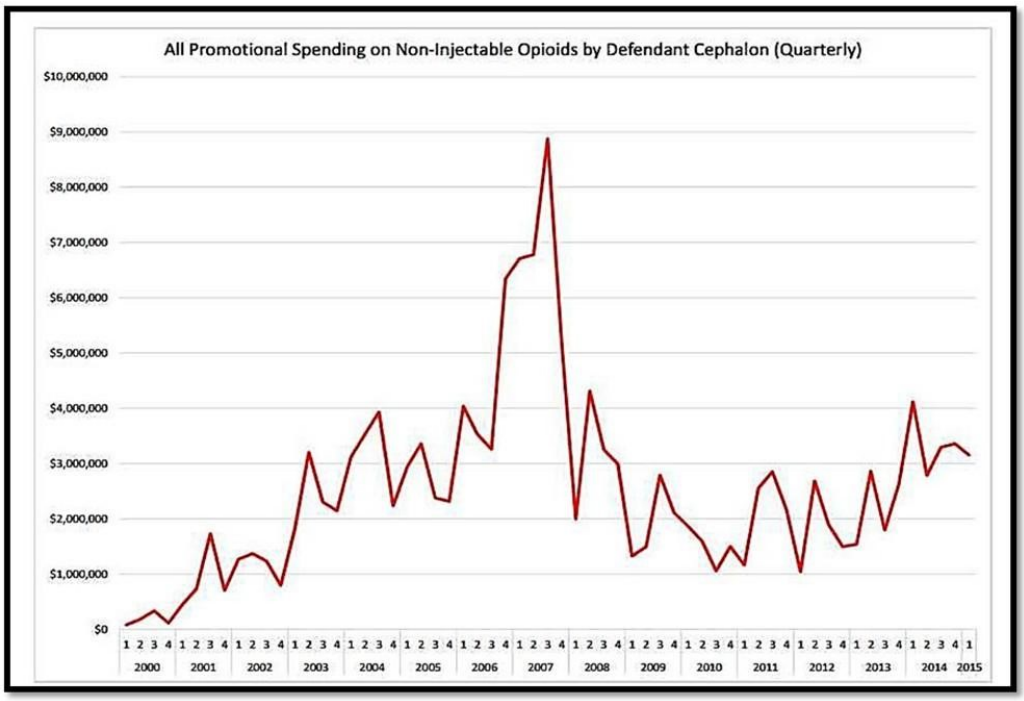
350. Responsible Opioid Prescribing was sponsored by Purdue, Endo and Teva. The FSMB website described it as the "leading continuing medical education (CME) activity for prescribers of opioid medications." Endo sales representatives distributed copies of Responsible Opioid Prescribing with a special introductory letter from Dr. Fishman. In all, more than 163,000 copies of Responsible Opioid Prescribing were distributed nationally. In 2007, Cephalon sponsored the publication of an article titled "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,"[56]published in the nationally circulated Journal of Pain Medicine, to support its effort to expand the use of its branded fentanyl products. The article's authors (including Dr. Webster, discussed above) stated that the "OTFC [fentanyl] has been shown to relieve BTP [breakthrough pain] more rapidly than conventional oral, normal-release, or 'short acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of non-cancer pain patients." The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

[56] Donald R. Taylor, 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), 8(3) Pain Med. 281-88 (Mar. 2007).

> In summary, BTP appears to be a clinically important condition in patients with chronic non-cancer pain and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP and the potential benefits of BTP-specific therapy suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.[57]

b. Branded Marketing

351. Cephalon's quarterly spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of more than $27 million in 2007, as shown below:



352. Cephalon and Teva made over 500,000 sales visits to healthcare providers from 1999 to 2017 for Actiq and Fentora. Most of these providers were not treating cancer patients; they were providers in specialties like primary care, family medicine, physical medicine, and neurology. Most of the prescriptions these providers wrote were not for cancer treatment.

[57] *Id.*

i. Actiq

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

354. Cephalon also recognized the return of its efforts to market Actiq and Fentora off-label for chronic pain. In 2000, Actiq generated $15 million in sales. By 2002, Actiq sales had increased by 92%, which Cephalon attributed 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."[58] Actiq became Cephalon's second best-selling drug. By the end of 2006, Actiq's sales had exceeded $500 million.[59] Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. One measure suggested that "more than 80 percent of patients who use[d] the drug don't have cancer."[60]

355. The FDA granted a restricted approval for Actiq pursuant to 21 C.F.R. § 314.20, which allows the FDA to approve drugs with restrictions on use and marketing "as are needed to assure safe use of the drug product." The Risk Management Plan developed in conjunction with FDA approval for Actiq required ensuring that it was used "solely" to treat breakthrough pain in opioid-tolerant cancer patients. The Risk Management Plan also required working to produce educational materials for providers that reinforced key safety messages and promoted proper patient selection messages. The RMA also suggested there would be a salesforce of "Oncology

[58] Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003), https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm.

[59] John Carreyrou, "Narcotic 'lollipop' is big seller despite FDA curbs." THE WALL STREET JOURNAL (Nov. 3, 2006).

[60] *Id.*

Sales Specialists" to implement the RMA, including limiting Actiq's promotion to the approved indication of cancer use, discouraging off-label use, and spreading the message of the serious consequences of violating the policy. The RMA also included a commitment to catching and stopping improper use through surveillance and monitoring for improper prescriptions and intervention when problems were discovered.

356. With these restrictions, the FDA thought it could control and contain use of Actiq, limiting its marketing and use to providers treating metastatic cancer patients. The FDA did so to protect public health.

357. Actiq's manufacturer knew, however, that even if it was subject to the FDA's restrictions, physicians were not limited to the approved indication. Teva exploited that loophole and subverted the RMA commitment in three ways: (1) by wooing physicians prescribing off-label; (2) by sending its sales force to visit physicians who were prescribing off-label; and (3) by providing physicians and patients with misleading information on Actiq's risks and benefits, often through channels that circumvented FDA scrutiny.

358. The result was that Cephalon ran a massive uncontrolled experiment to see what happened when non-cancer patients used rapid-release fentanyl. The experiment was conducted on thousands of the very patients it had pledged to protect, patients for whom the FDA had determined that Actiq was too risky. Public health and individual patients suffered the consequences.

359. Teva paid for many of the top opioid prescribers in the U.S. to travel to conferences at top hotels. Teva tracked which of its well-paid speakers helped them sell Actiq. For example, in 2003, Teva paid Dr. Steven Simon from Kansas an honorarium of $1,500 per conference, plus travel expenses, to present at 20 of its 21 conferences. He frequently presented slides on use of

opioids including Actiq for chronic back pain and for arthritis. After his presentation to 48 physicians at the Four Seasons in Carlsbad, California, Cephalon's agents circulated a glowing review to Teva's top managers for Actiq, including touting Dr. Simon's post-lecture efforts to pitch Actiq to other doctors through "peer-to-peer" detailing (selling):

> Steve Simon is fantastic. He is very good with the attendees at dinner, during free time and in the meeting room. He really takes time to "peer-to-peer detail" the attendees. He is a real jewel. During his presentation, he does spend quite as bit of time on the non-pharmacological treatments for OA/RA which on the surface may seem off-strategy. My feeling, is that the time he spends on "other" treatments actually "sets" up his strong ACTIQ endorsement by building credibility. Unlike Andrea Cheville who tends to over-endorse ACTIQ, he builds credibility as a "well-rounded" pain doc who has found a place for ACTIQ in his everyday practice and I think this message resonates. He does want to change a few things - but I am trying to discourage this if you are OK with that. I would like to see him "not to change a single thing".

360. Teva's regional sales managers and senior managers, including those responsible for insuring compliance with the Actiq RMA, attended these conferences. However, rather than monitoring for off-label use, contraindicated uses, or doctors prescribing off-label, these sales managers identified those doctors so that they could provide them with more reasons to prescribe off label. Materials prepared for conferences and meetings, which promoted Actiq for migraines, back pain, and arthritis, were withheld from the FDA under the theory that they were not promotional. The fact that attendees were selected by sales staff and that Cephalon's agents thought the purpose was to sell some Actiq shows otherwise. The meetings were, in fact, promotional and were a key part of the sales strategy for Actiq.

361. Doctors attending conferences returned to their states where they prescribed Actiq

for off-label uses. For example, a Virginia Beach rheumatologist attended the August 2003 MidAtlantic Conference at the Ritz-Carlton Reynolds Plantation, in Greensboro, Georgia. There, he listened to presentations from Dr. Simon on Actiq's use for chronic back pain and from another doctor on Actiq's use for migraine headaches. He also attended a roundtable where doctors discussed Actiq's use for fibromyalgia, migraines, and chronic pain. After the conference, the doctor continued to aggressively prescribe Actiq (and other opioids) to patients suffering from fibromyalgia, chronic pain, and headaches. From December 2003 to August 2008, five of his patients died of narcotics overdoses. Others were hospitalized for drug-related conditions, including two of his Actiq patients, both of whom were sent to psychiatric treatment and drug detoxification in February 2004. During this time, Teva rated the doctor a top prescriber of Actiq (8 out of a possible 10, with 10 being the top), conducted scores of sales visits to him, and only ceased sales visits when the Virginia Board of Medicine summarily suspended the doctor's license in August 2008. Teva also circulated at least four internal lists flagging the doctor as a "repeat off-label Actiq prescriber." Despite these internal flags, Cephalon's sales staff continued to regularly visit the doctor to push Actiq and Fentora sales up until the date the Board of Medicine suspended his license.

362. The following chart illustrates sales calls for Actiq during the first seven months of 2004:

Actiq Physician Universe Call Activity
2004 YTD

Specialty	Total Number of Physicians Targeted		Physicians Called On During 2004		Total Number of Actiq Calls During 2004 *	
	N	%	N	%	N	%
Family Practice (FP)	8943	29%	2247	25%	7534	15%
Internal Medicine (IM)	7840	26%	1824	23%	6209	12%
Oncology-Medical (ON)	1696	6%	691	41%	1970	4%
Anesthesiology (AN)	1656	5%	1279	77%	9329	18%
Physical Medicine (PM)	1593	5%	1111	70%	7309	14%
Neurology (N)	1060	3%	706	67%	3809	7%
General Practice (GP)	931	3%	281	30%	1046	2%
Hematology/Oncology (HO)	799	3%	292	37%	888	2%
Anesthesiology-Pain Management (APM)	786	3%	634	81%	5148	10%
All Other Oncology	781	3%	298	38%	969	2%
Rheumatology (RHU)	659	2%	333	51%	1504	3%
All Other Specialties	3765	12%	1085	29%	5832	11%
Total	30509	100%	10781	30%	51547	100%

* The total number of calls may be higher than the number physicians called upon because a physician may be called on multiple times.

363. Sales strategies for Actiq focused on top prescribers to drive sales up. For example, a 2002 email from a salesperson in the southeast said that 14 physicians deemed "product champions" accounted for 30% of Actiq sales in the region, prescribing 162,527 lozenges in just 6 months. A high-performing salesperson described her interactions with a high prescribing doctor, "[i]f I knew that this physician was in town and practicing medicine, I would've been in there three times a week pushing him to write more Actiq." It was later determined that doctor should be removed from the Actiq prescriber target list after he fled the country in the face of a DEA

investigation.

364. Teva targeted new non-cancer patients by distributing coupons good for six free Actiq lozenges through doctors treating non-cancer patients. The coupons worked. The Actiq business plan for 2000 described coupons as "a remarkably effective promotional tool that fuels prescription growth." The use of coupons was expanded. By 2005 and 2006, 6,000 to 9,000 coupons per month for Actiq were being distributed nationwide, including coupons for Actiq's highest doses, 1200 mcg and 1600 mcg. As a result of Actiq marketing efforts, the numbers of Actiq prescriptions rose from 10,000 in the first quarter of 2001 to 90,000 in the last quarter of 2003. Revenue soared too, rising from $15 million in 2000 to $600 million a year in 2006.

365. The risk of addiction to Actiq was downplayed. From 2000 to approximately 2003, Actiq salespeople told patients they would not get addicted to Actiq if they followed their physician's instructions.

Will I get addicted to this medicine?
You will not get addicted to *Actiq*. A common misconception is that people with cancer who are taking strong pain-relieving medicines will become addicted. This is not true. If you follow the instructions that you received from your healthcare professional about taking your pain medicines, these medicines will not become addictive.
What does happen when you take pain-relieving medicines, like *Actiq*, is that your body becomes dependent on the medicine. This means that if you suddenly stopped taking the medicine, you would experience unpleasant side effects, often referred to as "withdrawal" effects. To prevent this from happening, if you no longer need to take *Actiq* your doctor or nurse will gradually decrease your dose so that you don't have these side effects of withdrawal.

366. From 2002 to 2006, Actiq salespeople were trained to tell physicians asking about drug abuse that a "comprehensive evaluation of the abuse potential of ACTIQ was performed prior to FDA approval" and that Cephalon's risk management program could reduce Actiq's risk of abuse and diversion. Of course, this message was not supported by clinical trials – there had been no clinical study of Actiq's abuse potential.

ii. Fentora

367. Cephalon was undeterred from changing its aggressive sales techniques. Instead, these tactics shifted to a new rapid release product for cancer pain treatment: Fentora.

368. On a 2007 earnings call for Cephalon, its marketing director described the primary target audience for Fentora sales visits were 2,000 "high prescribing opioid physicians who were responsible for 80% of Actiq prescriptions." The next tier of targets was "high prescribers of opioids but who have not historically prescribed Actiq." There was no mention of limiting sales to prescribers treating cancer patients.

369. A February 2008 internal audit showed no process to "monitor call universes for appropriate prescribers."

370. It should come as no surprise that the targeting practices for Fentora were also successful. Prescriptions increased from 14,600 in 2006 to nearly 91,000 in 2007. Only a small percentage of these were properly written to cancer patients: 14% in 2006; 16-19% in 2007; 17-21% in 2008.

371. By September 2007, the FDA realized that Cephalon's risk mitigation plan for Fentora would not actually reduce risks associated with Fentora and issued a Public Health Advisory FDA's warnings continued, but so did Cephalon's off-label marketing. 2006 to 2015, Cephalon paid speakers, many of whom were top prescribers, $9 million to speak about Fentora. Speaking engagements occurred not only at medical offices, but also at bars and restaurants (frequently steakhouses). Attendees received free meals and drinks, and speakers were paid honoraria and travel expenses. Hundreds of doctors repeatedly attended the same presentations – some going to the same presentation more than 30 times – suggesting an interest more in the substance of the meal than the substance of the presentation. Medical office "practice managers" who could help get prescribers in their offices to write Fentora prescriptions or get insurance

companies to pay for Fentora were also invited to steakhouse presentations around the country.

372. Honoraria were paid to speakers even if nobody other than sales representatives attended, which occurred on 276 occasions where speakers were paid a total of $395,600 in honoraria.

c. FDA Warnings Did Not Prevent Cephalon from Continuing False Marketing of Fentora

373. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: "Fentora should not be used to treat any type of short-term pain." Indeed, the FDA specifically denied Cephalon's application, in 2008, to broaden the indication of Fentora to include treatment of non-cancer breakthrough pain and use in patients who were not already opioid-tolerant.

374. Flagrantly disregarding the FDA's refusal to broaden the indication for Fentora, Cephalon nonetheless marketed Fentora beyond its approved indications. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case." It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

375. Despite this warning, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq. For example, on January 13, 2012, Cephalon published an insert in Pharmacy Times titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite

the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."

6. Actavis

376. Defendant Actavis made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

a. Marketing of Kadian and Brand Name Products

377. The Actavis parent company bought the brand-name opioid Kadian in 2008 and actively promoted it through early 2013. A Kadian prescriber guide deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. Although full of disclaimers that Actavis has not done any studies on the topic and that the guide is "only intended to assist you in forming your own conclusion," the guide includes the following misleading statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users;" and 2) "KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action;" "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine;"

"Long duration of action;" and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state."

378. Actavis received a warning letter from the FDA for circulating a brochure to patients for Kadian representing that pain "can keep you from enjoying life" and "[i]f left untreated, pain can place stress on your body and your mental health. . . ." The FDA found that these representations constituted unsubstantiated claims of effectiveness, as it was "not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect the drug has in alleviated pain, taken together with any drug-related side effects patients may experience . . . results in an overall positive impact on a patient's work, physical and mental functioning, daily activities, or the enjoyment of life."

379. Allergan told patients whose bodies became "tolerant" at their current dose that "[t]his is not addiction," but rather indicated that a "dose adjustment" was required.

380. In 2010, FDA observed that Actavis promotional materials for its Kadian were misleading and "particularly concerning considering the serious and potentially fatal risks associated with the drug."

381. Nathalie Leitch, head of Actavis's brand name marketing, in an email to CEO Douglas Boothe on August 26, 2011, stated that an upcoming direct mail and email marketing campaign's "[m]ain messages . . . are long history of safe and efficicacious [sic] use, favorable formulary position and co-pay program." In the very same email, Leitch concedes that:

> We have looked at speakers programs and every derivative thereof and have made the decision not to pursue. Legal and regulatory have been strongly opposed plus the cost-benefit very uncertain *given the complete lack of clinical data for Kadian*." (emphasis added).

b. Marketing of Generic Opioids

382. Before its acquisition by Watson in 2012, Actavis produced twelve different

generic opioids including some of the most abused and diverted opioids such as generic OxyContin (Oxycodone I hydrochloride tablet), generic Opana ER (Oxymorphone tablet), and generic Duragesic (a fentanyltransdermal patch).

383. Allergan had a sophisticated and well-developed generic marketing program headed by Jinping McCormick, "Director of Generic Marketing." When she was director, Actavis marketed oxycodone immediate-release tablets, oxycodone extended-release tablets (generic OxyContin), fentanyl patches, oxymorphone extended-release (generic Opana ER), and morphine sulfate extended release (generic Kadian). Indeed, Ms. McCormick was tasked with growing generic sales from $477 million to $535 million from 2010 to 2011. Her compensation was directly tied to maximizing generic drug sales including generic opioids.

384. Allergan sold both brand-name and generic opioids and the generic marketing team led by McCormick worked closely with the brand-name marketing team and its sales force. That sales force was provided with specific targets for the drugs it promoted, i.e., "1306 Kadian prescriptions per day" with "the main messages [being] long history of safe and efficacious use, favorable formulary position and co-pay program." This target was set despite a reference in the same email by Allergan's head of marketing for brand drugs, Natalie Leitch, to the CEO Douglas Boothe, that there was "complete lack of clinical data for Kadian."

385. Allergan's sales force reached out to physicians regarding generic opioids for the sole purpose of maximizing sales. A sales force of about 48 representatives promoted generic Kadian and oxymorphone across most of U.S. through 2012.

386. Allergan used the same sales representatives that marketed its brand-name drugs, including Kadian, to market its generic opioids, including generic Kadian, directly to physicians. These were the same sales representatives that had already been trained with false messaging

regarding branded Kadian and opioids generally. McCormick even suggested a "contest" and "bonus plan" for those sales representatives that sold the most oxymorphone ER. The sales representatives' compensation was directly tied to their ability to maximize sales of generic opioids.

387. Actavis trained its sales representatives with false messaging about branded Kadian and opioids generally and then had those very same sales representatives market generic Kadian and other generic opioids, with their compensation based on maximizing those generic drugs.

388. In addition to using their Kadian sales representatives to promote generic opioids, Allergan employed a wide variety of other marketing tools that contributed to its flooding of the market with generic opioids. For example, Allergan engaged placed advertisements that omitted the full extent of the risks of the generic opioids in a various medical publications. Allergan also misleadingly marketed fentanyl at high doses by saying nothing about risk of addiction or overdose with such doses. Allergan worked with physician-based telemarketing companies to target high-prescribing physicians with its Kadian messaging.

389. Allergan also marketed its generic opioid drugs through joint marketing plans with distributors like McKesson, for example, on oxymorphone. While the oxymorphone "sell sheet" stated that the drug could only be used for "continuous around-the-clock opioid treatment *for an extended period of time*" and could not be used short-term or "as needed," the sell sheet was false and misleading because it stated nothing about the dangers of addiction associated with taking opioids long-term. Indeed, in one email discussing the advertisement, Ms. McCormick asked McKesson whether the requirement to include safety information in a fax blast would be different if they omitted the Actavis logo, suggesting that including the safety information was not a high priority for the generics marketing department.

390. Allergan also promoted its generic opioid drugs by implementing strategic points /rebate plans whereby their customers received points and rebates as high as 15% for selling their generic drugs under what was called a "Choice program;" opioid products were associated with higher amounts of points. It implemented pricing and incentive programs with customers and offered store discounts through its suppliers.

391. Mallinckrodt made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating and promoting publications that misrepresented and trivialized the risks of addiction;

b. Creating and promoting publications that overstated the benefits of opioids for chronic pain; and

c. Making deceptive statements about pseudoaddiction.

G. Fraudulent Marketing Conduct by CVS

1. CVS's Work with Purdue

392. As early as 2001, CVS worked with Purdue and its unbranded marketing arm, Partners Against Pain ("PAP") to "fight back" against allegations (later proved to be true) that Purdue's OxyContin was being abused at alarming rates. Purdue and its partners, including CVS, used the PAP website to claim that Oxycontin carried only a very small risk of addiction.

393. Purdue worked with CVS to ensure that Purdue trained CVS's pharmacists on many of the misleading marketing messages that would form the basis for a 2007 guilty plea and fine for misleading regulators, doctors, and patients about OxyContin's risk of addiction and its potential for abuse. CVS's ties to PAP were so deep that CVS included the logo from its "partner" in its own communications to CVS pharmacists.

2. CVS's Work with Endo

394. CVS worked with Endo to increase patient adherence to continued use of opioids. CVS had a crucial role in carrying out one of the key sales tactics in Endo's 2012 business plan.

395. Through a company called Catalina Health ("Catalina"), Endo helped target OxyContin patients in areas where Opana ER, a highly abused opioid manufactured by Endo, had preferred formulary status. Catalina in turn worked to create a brand loyalty program that kept new patients on their opioids. CVS, through its pharmacy retention programs, sent letters to the patients' homes to encourage them to stay on Opana – even though prolonged use of opioids increases the risk of addiction and even though patients in pain presumably need no reminder to continue to take their pain medications.

396. The agreement between CVS and Endo was formalized in an agreement to promote, market, and advertise Endo's opioid products via its "CVS Carecheck Plus Patient Education Service." CVS contractually agreed to promote Opana ER to its customers (patients) at the point of sale, and it even insisted upon reviewing and ***approving*** the specific messaging used.

397. CVS contracted with Endo to prepare and disseminate materials promoting Opana ER nationwide.

3. CVS's Work with Actavis

398. CVS helped Actavis promote its opioids by participating with Cardinal's Marketing and Business Development team in programs designed to offer rebates and off-invoice discounts on products, with the aim being to "move [] product."

IV. DEFENDANTS THROUGHOUT THE SUPPLY CHAIN DELIBERATELY DISREGARDED THEIR DUTIES TO MAINTAIN EFFECTIVE CONTROLS AND TO IDENTIFY, REPORT, AND TAKE STEPS TO HALT SUSPICIOUS ORDERS.

399. Marketing Defendants created a vastly and dangerously larger market for opioids. All of the Defendants compounded this harm by facilitating the supply of far more opioids than

could have been justified to serve that market. Defendants' failure to maintain effective controls and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious breached both their statutory and common law duties.

A. All Defendants Have, and Breached, Duties to Guard Against, and Report, Unlawful Diversion and to Report and Prevent Suspicious Orders.

400. Multiple sources impose duties on Defendants with respect to the supply of opioids, including the common law duty to exercise reasonable care.

401. Each Defendant was required to register with the DEA, pursuant to the CSA. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each Defendant is a "registrant" of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Each Defendant has an affirmative duty under federal law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that "requirements" of Schedule II drugs, including opioids, must 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).

402. Under federal law, distributors, opioid manufacturers are required to "design and operate a system to disclose . . . suspicious orders of controlled substances" and to maintain "effective controls against diversion." 21 C.F.R. § 1301.74; 21 USCA § 823(a)(1). Federal requirements impose a non-delegable duty upon registrants to design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b). "Suspicious orders" include orders of an unusual size, orders of unusual frequency or orders deviating substantially

from a normal pattern. *See* 21 C.F.R. § 1301.74(b). 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, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry.

403. All of the above federal requirements have been adopted and incorporated into Louisiana,[61] Mississippi,[62] Texas,[63] North Carolina,[64] Kansas,[65] Missouri,[66] and Oklahoma[67] state laws.

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[61] *See* La. Rev. Stat. Ann. §§ 40:973(A), 40:974(A)(1)–(4), 40:975; 40:967(A); 46 La. Admin. Code Pt XCI, § 313.

[62] *See* Miss. Code Ann. § 41-29-127.

[63] *See* Tex. Health & Safety Code Ann. § 481.071(a) (imposing, like federal law, a non-delegable duty upon drug distributors not to "prescribe, dispense, deliver, or administer a controlled substance or cause a controlled substance to be administered under the practitioner's direction and supervision for a valid medical purpose and in the course of medical practice.").

[64] *See* N.C. Gen. Stat. § 90-102 (mandating "maintenance of effective controls against diversion of any controlled substances"); N.C. Gen. Stat. § 106-145.7 (for wholesale distributors, mandating use of a security system to provide "protection against . . . diversion that is facilitated or hidden by tampering with computers or electronic records"). *See also* N.C. Gen. Stat. § 90-104; N.C. Gen. Stat. § 106-145.10; 10A NCAC 26E.0129(a); N.C. Gen. Stat. § 90-102 (a)(2) (incorporating the federal law non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b)).

[65] *See* Kan. Admin. Regs. 68-14-7(i).

[66] *See* Mo. Rev. Stat. § 343; Missouri Code of State Regulations, 20 CSR 2220-5.030(3)(M)(5), (7), 20 CSR 2220-5.060 (requiring all manufacturers, wholesalers, and retailers of controlled substances to maintain effective controls against opioid diversion); 19 CSR 30-1.032 (2) (requiring registrants to "design and operate a system to disclose to the registrant suspicious orders of controlled substances.").

[67] *See* Okla. Stat. Ann. tit. 63, § 2-101, *et seq*. (Oklahoma Controlled Substances Act).

404. The Defendants also had legal duties under Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma common law, statutes, and regulations to maintain adequate records, and prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids. Defendants violated state laws prohibiting false advertising or other false statements relating to drugs. This includes the common law of fraud, statutes designed to generally prohibit unfair and deceptive acts in commerce, as well as statutes specifically prohibiting deceptive practice relating to drugs.

405. Under Louisiana law, Defendants were required to be licensed by the Louisiana Board of Pharmacy. La. Rev. Stat. Ann. § 40:973(A). To receive and maintain this license, each Defendant assumed a duty to comply with "applicable state and local laws and regulations." La. Rev. Stat. Ann. § 40:974(A)(2). To receive a license under the Louisiana Drug and Device Distributors Act, Defendant Wholesale Distributors had to meet "all applicable requirements under federal law and regulation." La. Rev. Stat. Ann. § 37:3469. *See also* La. Rev. Stat. Ann. §§ 37:3467, 37:3472 ("Failure to comply with state and federal laws or the board's regulations shall be prima facie evidence of a violation of this Chapter and shall subject the applicant or licensee either to disciplinary action ... or forfeiture of the license."); La. Admin. Code Pt XCI, § 711.

406. The Louisiana State Board of Pharmacy has the authority to suspend or revoke a license for violations of the Louisiana Controlled Dangerous Substance Law or any "state or federal laws pertaining to the manufacture, distribution or dispensing of controlled dangerous substances." La. Rev. Stat. Ann. § 40:975. Except as authorized, it is unlawful to knowingly or intentionally "manufacture, distribute, or dispense" Schedule II drugs. La. Rev. Stat. Ann. § 40:967(A).

407. The Louisiana Board of Drug and Device Distributors also can "deny, revoke or

suspend a license" for "violation of any federal, state or local law or regulation relating to drugs." 46 La. Admin. Code Pt XCI, § 711.

408. Louisiana law further requires that drug distributors shall "adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs or devices, including policies and procedures for identifying, recording, and reporting losses or thefts," including, procedures to review suspicious purchases and to notify the board in writing after discovering any theft or diversion of a drug. 46 La. Admin. Code Pt XCI, § 313. *See also* La. Rev. Stat. Ann. § 40:974(A)(1), (4).

409. Under Mississippi law, Defendants were required to register with the Mississippi Board of Pharmacy. *See* Miss. Code Ann. § 41-29-127. Before allowing a pharmaceutical distributor to register, the Board of Pharmacy must determine that granting a registration is consistent with the public interest and, to be consistent with the public interest, a registrant must, among other things, demonstrate its ability to maintain effective controls against the diversion of opioids under Mississippi law. *See* Miss. Code Ann. § 41-29-127(a)(1) and (4).

410. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 U.S.C. §§ 823 and 824 and Miss. Code Ann. § 41-29-127 and may result in the revocation of the registrant's DEA Certificate of Registration or registration with the State of Mississippi.

411. As such, Defendants owe, and owed, the following duties under Mississippi law: (1) to monitor and detect suspicious orders of prescription opioids; (2) to investigate and refuse suspicious orders of prescription opioids; (3) to report suspicious orders of prescription opioids; and (4) to prevent diversion of prescription opioids into illicit markets in the State of Mississippi. *See* Miss. Code Ann. § 41-29-127.

412. Defendants also violated provisions of the Texas Controlled Substances Act, Tex. Health & Safety Code §§ 481.001 through 481.354, which describes prohibited acts under the law and penalties for those acts. The statute makes it unlawful, for example, for any registrant or dispenser to knowingly "distribute[], deliver[], or dispense[] a controlled substance in violation of Sections 481.070-481.075." Tex. Health & Safety Code Ann. § 481.128 (a)(1).

413. Under North Carolina law, Defendants were required to register with the North Carolina Department of Health and Human Services and obtain a license as a wholesaler of controlled substances from the North Carolina Commissioner of Agriculture. N.C. Gen. Stat. §§ 90-102-(a)(2), 90-101(a), 106-145.3. Each Distributor Defendant is licensed by the North Carolina Commissioner of Agriculture and is a "registrant" with the North Carolina Department of Health and Human Services as a wholesale distributor in the chain of distribution of Schedule II controlled substances and assumed a duty to comply with all requirements imposed under the regulations adopted by these agencies, all state law, and all requirements imposed under federal law. *See* N.C. Gen. Stat. § 106-145.10 ("A wholesale drug distributor . . . shall comply with applicable federal, State, and local laws and regulations."); 10A NCAC 26E.0129(a) ("Any person who manufactures, distributes, dispenses, or conducts research with any controlled substance shall comply with Part 1301 of Title 21 of the Code of Federal Regulations . . . ."); N.C. Gen. Stat. § 90-104 ("Each registrant or practitioner manufacturing, distributing, or dispensing controlled substances under this Article shall keep records and maintain inventories in conformance with the record-keeping and the inventory requirements of the federal law . . ."); N.C. Gen. Stat. § 90-102 (a)(2) (a factor considered for registration to manufacture or distribute controlled substances in North Carolina is "[c]ompliance with applicable federal, State and local law").

414. North Carolina law makes it "unlawful . . . [t]o furnish false or fraudulent material

information in, or omit any material information from, any application, report, or other document required to be kept or filed under this Article, or any record required to be kept by this Article," including suspicious order reports, since North Carolina law requires compliance with federal law on this issue. *See* N.C. Gen. Stat. § 90-108.

415. Under Kansas law, Defendants were required to be licensed by the Kansas State Board of Pharmacy. *See* Kan. Admin. Regs. 68-14-3. To receive and maintain these licenses, each of the Defendants assumed a duty to comply with applicable local, state, and federal laws and regulations. *See* Kan. Admin. Regs. 68-14-7(i).

416. The Kansas Board of Pharmacy prohibits fraud or intentional misrepresentation in securing the issuance or renewal of a license. K.S.A. § 65-1627(a)(1), (11). Defendants violated K.S.A. § 65-1627 by knowingly making or causing to be made any false or fraudulent statement or misrepresentation in securing issuance or renewal of a permit and by engaging in fraud in connection with the wholesale distribution or manufacturing of drugs, as alleged herein.

417. The Missouri Comprehensive Drug Control Act, including Mo. Rev. Statutes §§ 195.030, 050, and 195.017, and numerous related Missouri registration laws and regulations, are public laws, imposing numerous requirements on Defendants.

418. Missouri Revised Statutes, Section 195.030, provides that manufacturers, distributors and prescribers of controlled substances are required to obtain a registration by the Department of Health and Senior Citizens. The registration issued by Missouri Department of Health to conduct procedures with controlled substances may be suspended or revoked if it "[h]as violated any federal controlled substances statute or regulation, or any provision of this chapter." Mo. Rev. Statutes §§ 195.040(7)(4).

419. Under Mo. Rev. Statutes § 338.220(1), it is "unlawful for any person,

copartnership, association, corporation or any other business entity to open, establish, operate, or maintain any pharmacy as defined by statute without first obtaining a permit or license to do so from the Missouri board of pharmacy." Mo. Rev. Statutes § 388.250 states:

> No permit shall be issued or renewed for the operation of a pharmacy unless the pharmacy shall be operated in a manner and according to the rules and regulations prescribed by law and by the Missouri board of pharmacy with respect to obtaining and maintaining such a permit. Any pharmacy that receives or possesses drugs or devices shall be held responsible for compliance with all laws within this chapter as well as state and federal drug laws on all drugs received or possessed, including but not limited to drugs and devices received or possessed pursuant to a consignment arrangement.

Mo. Rev. Statutes § 388.333(1) further states:

> No license shall be issued or renewed for a wholesale drug distributor, pharmacy distributor, drug outsourcer, or third-party logistics provider to operate unless the same shall be operated in a manner prescribed by law and according to the rules and regulations promulgated by the board of pharmacy with respect thereto.

420. Mo. Rev. Statutes § 195.050(6) states:

> Every person registered to manufacture, distribute or dispense controlled substances under this chapter shall keep records and inventories of all such drugs in conformance with the record keeping and inventory requirements of federal law, and in accordance with any additional regulations of the department of health and senior services.

Mo. Rev. Statutes § 195.050(7) further states:

> Manufacturers and wholesalers shall keep records of all narcotic and controlled substances compounded, mixed, cultivated, grown, or by any other process produced or prepared, and of all controlled substances received and disposed of by them, in accordance with this section.

Similarly, Mo. Rev. Statutes § 343 further states:

> Any licensee licensed under the provisions of sections 338.330 to 338.340 must maintain required records to guarantee security, storage and accountability. These records shall be available for inspection by the board.

Similarly, 19 CSR 30-1.032 (2) states:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Department of Health and Senior Services of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency.

421. Thus, in addition to having common law duties, Defendants are governed by the statutory requirements of the Missouri Comprehensive Drug Control Act, Mo. Rev. Statutes §§ 195.005, *et seq*., Missouri Regulations on Pharmacies, Mo. Rev. Statutes §§ 338.210, *et seq*., and regulations promulgated by Missouri Department of Health and Missouri Board of Pharmacy thereunder, Missouri Code of State Regulations §§ 19 CSR 30-1.002., Missouri Code of State Regulations 20 CSR 2220-5, *et seq*.

422. In addition to filing distribution and transactional reports on controlled substances, Missouri law requires each registrant to maintain on a current basis a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. It is a violation of Missouri law for any person to negligently fail to abide by the recordkeeping and reporting requirements. *See* Missouri Code of State Regulations, 20 CSR 2220-5.030(3)(I), (M).

423. Missouri's minimum requirements for wholesale drug distribution mandate that "every person registered to manufacture, distribute or dispense controlled substances under this chapter shall keep records and inventories of all such drugs in conformance with the record keeping and inventory requirements of federal law, and in accordance with any additional regulations of the department of health and senior services." Mo. Rev. Stat. § 195.050.

424. Missouri Code of State Regulations, 19 CSR § 30-1.032 provides: "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Department of Health and Senior Services of suspicious

orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency."

425. Missouri Code of State Regulations, 20 CSR 2220-5, *et seq*., governs the State Board of Pharmacy and statutory requirements for dispensing medication. Missouri Code of State Regulations, 20 CSR 2220-5.030(3)(I) requires wholesale drug distributors to establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs.

426. Missouri Code of State Regulations, 20 CSR 2220-5.030(3)(M) requires wholesale drug distributors to establish written policies and procedures for identifying, recording, and reporting losses or thefts and for correcting errors and inaccuracies in inventory. Missouri Code of State Regulations, 20 CSR 2220-5.030(3)(M)(5) requires wholesale drug distributors to report suspicions of diversion or theft. Missouri Code of State Regulations, 20 CSR 2220-5.030(3)(M)(5), (7) requires that any suspected criminal activity or diversion be reported. Missouri Code of State Regulations, 20 CSR 2220-5.060 requires wholesale drug and pharmacy distributors to report the distribution of opioid controlled substances.

427. In addition to reporting all suspicious orders, the Distributor Defendants must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the recipient can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc*., 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F. 3d 206 (D.C. 2017). Regardless, all flagged orders must be reported. *Id*.

428. These prescription drugs are regulated for the purpose of providing a "closed"

system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[68] "Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and responsibilities."[69] The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction, with costs and damages necessarily inflicted on and incurred by Plaintiffs and others. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality, along with the costs imposed upon Plaintiffs and others associated with the treatment of these conditions and related health consequences caused by opioid abuse. Finding it impossible to legally achieve their ever-increasing sales ambitions, Defendants engaged in the common purpose of increasing the supply of opioids and fraudulently increasing the quotas that governed the manufacture and distribution of their prescription opioids.

429. Wholesale distributors such as Distributor Defendants have close financial relationships with both Marketing Defendants and customers, to whom they provide a broad range of value-added services that render them uniquely positioned to control against diversion. For

[68] *See* 1970 U.S.C.C.A.N. 4566, 4571-–72.

[69] Brief for Healthcare Distribution Mgmt. Association and National Ass'n of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 (hereinafter "Brief for HDMA and NACDS"). The Healthcare Distribution Mgmt. Ass'n (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)— is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation and Cardinal Health, Inc. *See generally* HDA, *About*, https://www.healthcaredistribution.org/about (last accessed Aug. 1, 2018). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, https://www.nacds.org/%20about/mission/ (last accessed Jan. 20, 2024).

example, "[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock."[70] Through their generic source programs, wholesalers are also able "to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers." Wholesalers typically also offer marketing programs, patient services, and other software to assist their dispensing customers.

430. Distributor Defendants had financial incentives from Marketing Defendants to distribute higher volumes and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Higher volumes were encouraged by discounts and rebates based on market share and volume. These allowed wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

431. Marketing Defendants engaged in the practice of paying rebates and/or chargebacks to Distributor Defendants for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts. The practice was industry-wide, and the Healthcare Distribution Alliance ("HDA") maintained a "Contracts and Chargebacks Working Group," suggesting an industry-wide standard. Further, in a recent settlement with the DEA, Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors)." The transaction information contains data relating to the direct customer sales of controlled substances to "downstream registrants", such as pharmacies or hospitals. Marketing Defendants buy data from

[70] Fed. Trade Comm'n v. Cardinal Health, Inc., 12 Supp. 2d 34, 41 (D.D.C. 1998).

pharmacies as well. This exchange of information, upon information and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well.

432. An example of the use of prescription information provided by IMS Health was described in Congressional testimony:

> Mr. Greenwood: Well, why do you want that [IMS Health] information then?
>
> Mr. Friedman: Well, we use that information to understand what is happening in terms of the development of use of our product in any area.
>
> Mr. Greenwood: And so the use of it--and I assume that part of it--a large part of it you want is to see how successful your marketing techniques are so that you can expend money in a particular region or among a particular group of physicians-- you look to see if your marketing practices are increased in sales. And, if not, you go back to the drawing board with your marketers and say, how come we spent "X" number of dollars, according to these physicians, and sales haven't responded. You do that kind of thing. Right?
>
> Mr. Friedman: Sure.[71]

433. Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. Defendants negotiated agreements whereby Marketing Defendants installed security vaults for Distributor Defendants in exchange for agreements to maintain minimum sales performance thresholds. Defendants violated their reporting and diversion duties in order to reach the required sales requirements.

1. Defendants' Use of Trade and Other Organizations

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

[71] Oxycontin: Its Use and Abuse: Hearing Before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce House of Representatives, 107th Cong. 54 (2001) (statements of James C. Greenwood, Member, Committee on Energy and Commerce and Michael Friedman, Executive Vice President and COO of Purdue Pharma, L.P.), available at https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm.

a. Pain Care Forum

435. PCF has been described as a coalition of drug makers, trade groups, and dozens of non-profit organizations supported by industry funding, including the Front Groups described in this Complaint. PCF members spent over $740 million lobbying on an array of issues, including opioid-related measures.[72] Membership and participating organizations included Endo, Purdue, Actavis and Cephalon. Each of the Marketing Defendants worked together through the PCF, and the Distributor Defendants actively participated, and continue to participate, in the PCF through, at a minimum, their trade organization, the HDA.[73] The Distributor Defendants participated directly in the PCF as well.

b. Healthcare Distribution Alliance (HDA)

436. The HDA led to the formation of interpersonal relationships and an organization among the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Marketing Defendants, were members of the HDA.[74] Additionally, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Marketing Defendants by advocating for the many benefits of members, including "strengthening . . . alliances."[75] 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

[72] *Id*.

[73] *Id*. The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc. and the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation. *Executive Committee*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/executive-committee%20 (last visited on Aug. 1, 2018).

[74] *Manufacturer Membership*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/membership/manufacturer (last accessed Aug. 1, 2018).

[75] *Manufacturer Membership Benefits*, Healthcare Distribution Alliance, https://www.hda.org/join-hda/manufacturer-membership/ (last accessed Sept. 14, 2017).

Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[76] The HDA and the Distributor Defendants used membership in the HDA as an opportunity to create interpersonal and ongoing organizational relationships and "alliances" between the Marketing and Distributor Defendants.

437. The closed meetings of the HDA's councils, committees, task forces and working groups provided the Marketing and Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Marketing Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[77] The conferences also gave the Marketing and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[78] The HDA and its conferences were significant opportunities for the Marketing and Distributor Defendants to interact at a high-level of leadership. The Marketing Defendants embraced this opportunity by attending and sponsoring these events.[79]

438. After becoming members of the HDA, Defendants were eligible to participate on

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[76] *Id.*

[77] *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 Sept. 14, 2017, and no longer available).

[78] *Id.*

[79] *2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-distribution-management-conference (last accessed Aug. 1, 2018, and no longer available).

councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributor and manufacturer members.

c. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributor and manufacturer members.

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

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

439. The Distributor Defendants and Marketing Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.[80] For example, on April 27, 2011, the HDA offered a Webinar to "accurately and effectively exchange business transactions between distributors and manufacturers…" The

[80] *Webinars*, Healthcare Distribution Alliance, (last accessed Sept. 14, 2017), https://www.healthcaredistribution.org/resources/webinar-leveraging-edi.

Marketing Defendants used this information to gather high-level data regarding overall distribution and to direct the Distributor Defendants on how to most effectively sell opioids.

440. Taken together, the interaction and length of the relationships between and among the Marketing and Distributor Defendants reflect a deep level of interaction and cooperation between two groups in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the Pain Care Forum are but two examples of the overlapping relationships and concerted efforts to accomplish goals and demonstrates that the leaders of each of the Defendants were in communication and cooperation.

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

442. This statement by the HDA and the Industry Compliance Guidelines support the allegation that Defendants utilized the HDA to form agreements about their approach to their legal duties with respect to the distribution of controlled substances. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce Subcommittee on Health in April 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Here, it is apparent that

all of the Defendants found the same balance – an overwhelming pattern and practice of failing to identify, report or halt suspicious orders, and failure to prevent diversion.

443. The Defendants worked together to control the flow of information and to influence governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Marketing and Distributor Defendants did this through their participation in the PCF and HDA. The Defendants also had obligations to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible for each other's compliance with their reporting obligations. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be revealed. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency. The desired consistency was achieved. As described below, none of the Defendants reported suspicious orders and the flow of opioids continued unimpeded.

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

444. The reason for the reporting rules is to create a "closed" system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Based on their knowledge of their customers and orders, distributors are the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market. When distributors fail to fulfill their

obligations, the closed system of distribution, designed to prevent diversion, collapses.[81] Defendants were well aware they had an important role to play in this system and knew or should have known that their failure to comply with their obligations would have serious consequences.

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

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

446. Publicly available information confirms that Distributor and Marketing Defendants ignored red flags of suspicious orders and funneled far more opioids into communities across the United States than could have been expected to serve legitimate medical use. The conclusion that Defendants were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids—even in the wider market for chronic pain.

447. Information, including information known only to Distributor and Marketing Defendants, that would have alerted them to potentially suspicious orders of opioids includes the following facts:

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

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

[81] *See* Rannazzisi Decl. ¶ 10, *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW ECF No. 14-2 (D.D.C. Feb. 10, 2012).

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

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

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

448. At all relevant times, Defendants possessed national, regional, state, and local prescriber-and patient-level data that allowed them to track prescribing patterns over time. They obtained this information from data companies. 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 Defendants identify suspicious orders or customers who were likely to divert prescription opioids.[82] The "know your customer" questionnaires informed Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy purchased opioids from other distributors, and the types of medical providers in the area. These questionnaires put the recipients on notice of suspicious orders.

[82] *Suggested Questions a Distributor should ask prior to shipping controlled substances*, DEA, https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf; Richard Widup, Jr. & Kathleen H. Dooley, Esq. *Pharmaceutical Product Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC, https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

4. Defendants Failed to Report Suspicious Orders or Otherwise Act to Prevent Diversion

449. Defendants failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into communities across America. Despite the notice described above, Defendants continued to pump massive quantities of opioids into communities in disregard of their legal duties to control the supply, prevent diversion, and report and take steps to halt suspicious orders.

450. Governmental agencies and regulators have confirmed (and in some cases Defendants have admitted) that Defendants did not meet their obligations and have uncovered especially blatant wrongdoing.

451. For example, in December 2022, the United States Department of Justice filed a nationwide lawsuit against Cencora, alleging that it engaged in years of repeated violations of the CSA and that it contributed to the opioid epidemic. This proceeding is discussed in more detail in Section IV(D)(2)(d), *infra*.

452. When a manufacturer or distributor does not report or stop suspicious orders, controlled substances may be dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action - or may not know to take action at all. After being caught failing to comply with their obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens.

453. Public statements by Defendants and their associates gave regulators, prescribers, and the public the false and misleading impression that Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent

diversion of these dangerous drugs, and further created the false impression that Defendants worked voluntarily to prevent diversion as a matter of corporate responsibility.

5. Marketing Defendants' Unlawful Failure to Prevent Diversion and Monitor, Report, And Prevent Suspicious Orders

454. The same legal duties to prevent diversion and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon Distributor Defendants were also required of Marketing Defendants under federal and state law. Defendants violated federal and state law in failing to maintain effective controls against the diversion of opioids into other than legitimate medical channels. Defendants also violated federal law in failing to operate a system to stop orders which is flagged or should have been flagged as suspicious. Like Distributor Defendants, Marketing Defendants breached these duties.

455. Marketing Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. Marketing Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, Marketing Defendants knew – just as Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. Marketing Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

456. Marketing Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful

diversion of opioids throughout the United States.

457. At least as early as 2010, Par Pharmaceutical was selling opioid products, but, according to an outside audit, it had no SOM program. Par Pharmaceutical notified the DEA of no suspicious orders between 2010 and 2015.

458. After Endo acquired Par Pharmaceutical in 2015, internal documents confirmed that Par's order review process still had major deficiencies, including: SOM decisions made by sales or customer service rather than regulatory employees; no customer due diligence other than confirming a DEA license; no reliable review for size, pattern, or frequency; and an SOP that only required reporting "criminal" activities to the DEA, which "misse[d] the point of the regulations," which is, "suspicious orders should be reported as soon as they are identified." Furthermore, there was no SOM staff, and the SOM function was limited to a manual review conducted by sales personnel, which was "viewed as a conflict of interest by the DEA." After the Par-Endo merger, the former elements of the Qualitest DEA compliance unit took responsibility for SOMs for both businesses.

459. Endo and Par Pharmaceutical did not maintain effective controls against diversion, implement a reasonable SOM program, or take reasonable steps to prevent their products from being diverted. Endo employed a rigid "excessive orders" system operated by sales and commercial personnel, never looked to available data on its customers' customers, and failed to conduct any meaningful due diligence of its customers. Until at least the spring of 2013, Qualitest applied SOM review only to "retail" customers; used a rigid formula that did not examine orders for unusual size, frequency, or pattern, or account for class of trade; ignored available data on its customers' customers; and failed to conduct any meaningful due diligence. After the spring of 2013, Qualitest's SOM program lacked real rigor, independence, and consistency. Par

Pharmaceutical had no effective, independent SOM program prior to 2015 and, thereafter, operated under the deficient program Qualitest used. None of these entities employed an SOM or order review program that was an effective control against diversion.

B. Distributor Defendants' Unlawful Distribution of Opioids

460. Distributor Defendants owe a duty under, *inter alia*, federal and state common law and statutory law, to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids as well as those orders which Distributor Defendants knew or should have known were likely to be diverted.

461. The foreseeable harm from a breach of these duties was the medical, social, and financial consequences rippling through society, arising from the abuse of diverted opioids for nonmedical purposes.

462. Each Distributor Defendant repeatedly and purposefully breached its duties under federal and state law. Such breaches are a direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes, with the resultant medical and financial damages.

463. For over a decade, Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully increasing the volume of opioids they sold. Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

464. The unlawful diversion of prescription opioids is a direct and proximate cause of the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality, with social and financial costs borne by, among others, individuals, families and hospitals.

465. Distributor Defendants intentionally continued their conduct, as alleged herein,

with knowledge that such conduct was creating the opioid epidemic and causing the damages alleged herein.

C. Distributor Defendants Breached Their Duties

466. Opioids are controlled substances. These "Schedule II" drugs are controlled substances with a high potential for abuse.

467. Each Distributor Defendant was required to comply with the registration requirements of Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma state laws.

468. Each Distributor Defendant has an affirmative duty to act as a gatekeeper against the diversion of highly addictive and dangerous opioid drugs.

469. Regulations impose a non-delegable duty upon wholesale drug distributors to design and operate a system to disclose to the registrant suspicious orders of controlled substances.

470. "Suspicious orders" include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. 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 wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

471. In addition to reporting all orders flagged as suspicious, distributors must also stop shipment on any order flagged as suspicious and only ship flagged orders if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels.[83]

472. As the DEA advised Distributor Defendants in a letter dated September 27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly … distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as … the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[84]

473. Distributor Defendants have admitted that they are responsible for reporting suspicious orders.[85]

474. The DEA's letter also warned Distributor Defendants that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate

[83] *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017).

[84] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug Enf't Admin., U.S. Dept. of Justice, to Cardinal Health (Sept. 27, 2006) (hereinafter "Rannazzisi Letter") ("This letter is being sent to every commercial entity in the United States registered with the Drug Enf't Admin. (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, ECF No. 14-51 (D.D.C. Feb. 10, 2012) (hereinafter "Letter from Joseph T. Rannazzisi to Cardinal Health").

[85] *See* Brief for HDMA and NACDS, *supra* n. 69, 2016 WL 1321983, at *4 ("[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").

medical, scientific, and industrial channels."[86] The letter also instructs that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes."[87] The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

475. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007. [88] This letter reminds Distributor Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[89] The letter further explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders.
>
> The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive.
>
> Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.[90]

476. Finally, the DEA letter references the Revocation of Registration issued in Southwood Pharmaceuticals, Inc., 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the

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[86] Rannazzisi Letter, *supra* n. 84, at 2.
[87] *Id.* at 1.
[88] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dept. of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.
[89] *See* Letter from Joseph T. Rannazzisi to Cardinal Health, *supra* n. 84.
[90] *Id.*

obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[91]

477. Distributor Defendants admit that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."[92]

478. Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association (now known as the HDA, a front group of Defendants, discussed below), the trade association of pharmaceutical distributors, explain that distributors 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." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.[93]

479. Distributor Defendants have acquired businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual

[91] *Id.*

[92] *See* Amicus Curiae Brief of Healthcare Distribution Mgmt. Ass'n in Support of App. Cardinal Health, Inc., Cardinal Health, Inc. v. U.S. Dept. of Justice, No. 12- 5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 (hereinafter "Brief of HDMA in Support of Cardinal").

[93] Healthcare Distribution Mgmt. Ass'n (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in *Cardinal Health, Inc. v. Holder*, Doc. No. 1362415 (Appx. B), No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (Appx. B).

distribution of pharmaceuticals, as wholesalers, Distributor Defendants also offer their pharmacy, or dispensing, customers a broad range of added services. For example, Distributor Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Distributor Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support.[94] As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, Distributor Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

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

481. Each of the Distributor Defendants sold prescription opioids, including

[94] *See Fed. Trade Comm'n v. Cardinal Health, Inc*., 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal, Inc. and Bergen Brunswig Corp).

hydrocodone and/or oxycodone, to retailers from which Distributor Defendants knew prescription opioids were likely to be diverted.

482. Each Distributor Defendant owes a duty to monitor, detect and refuse suspicious orders of prescription opioids, to report suspicious orders of prescription opioids and to prevent the diversion of prescription opioids into illicit markets.

483. The laws at issue here concerning the sale and distribution of controlled substances are also the public safety statutes and regulations of states in which Plaintiffs' hospitals operate.

484. The unlawful conduct by Distributor Defendants is purposeful and intentional. Distributor Defendants refuse to abide by the duties imposed by state law which are required to legally acquire and maintain a license to distribute prescription opiates.

485. Distributor Defendants acted with actual malice in breaching their duties, i.e., they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

1. Inadequate Compliance Staffing and Training

486. First, Distributor Defendants routinely failed to staff their compliance functions with qualified personnel and failed to appropriately train employees performing these functions. Compliance functions, such as approving threshold increases, detecting, blocking, and reporting suspicious orders, and terminating and/or suspending customers, were often assigned to operations, sales, and administrative employees with no regulatory compliance experience.

2. Inadequate Scrutiny of Customers

487. None of the Distributor Defendants had a consistent practice of conducting appropriate due diligence of either prospective or existing customers. New customers were routinely on-boarded despite the acknowledged presence of unresolved red flags, and none of the Distributor Defendants ensured that additional investigations were conducted when existing

customers made suspicious orders, even when compliance staff flagged those orders as suspicious, blocked them, and reported them.

488. Indeed, Distributor Defendants routinely allowed their customers to make multiple suspicious orders within the same year, month, or even week without conducting any additional due diligence. In fact, salespeople would warn customers when they were approaching their monthly threshold limits for ordering certain categories of controlled substances, enabling customers to manipulate the timing and volume of their orders to evade the compliance reviews that would have otherwise occurred.

489. Even where customers had to be blocked multiple times within a month from ordering opioids in excess of their threshold allowance, Distributor Defendants would allow those customers to resume ordering opioids the next month, at the same volume levels as before, without requiring any follow up investigation.

490. And none of the Distributor Defendants conducted periodic, unexpected due diligence audits of their customers, even among the easily identifiable and relatively small groups of pharmacies that consistently ordered the highest volumes of opioids. Instead, these pharmacies could go for years without Distributor Defendants updating their knowledge of those customers' prescriber base, customer traffic patterns, and other relevant store conditions. Even when those pharmacies were scrutinized, they were often warned in advance.

3. Failure to Detect, Block and Report Suspicious Orders

491. Distributor Defendants failed to report "suspicious orders," which Distributor Defendants knew were likely to be diverted, to the relevant governmental authorities.

492. Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, and/or orders of unusual frequency, and/or in areas from which Distributor Defendants knew opioids were likely to be diverted.

493. Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates, and/or in areas from which Distributor Defendants knew opioids were likely to be diverted.

494. Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

495. Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities, including the DEA, of suspicious orders when discovered in violation of their duties under state law.

496. Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific, and industrial channels.[95] While Distributor Defendants' policies nominally allowed for compliance staff to identify any order as suspicious, as a matter of practice, only orders that exceeded a customer's monthly threshold limit for a particular category of controlled substances would actually trigger a compliance review. As a result, untold numbers of opioid orders that should have been reviewed were never even checked to determine whether they were suspicious. Because Distributor Defendants routinely allowed their customers to obtain information about the monthly threshold limits governing their orders of opioid products, orders customers made within the limits after being enabled to "game" them were improperly excluded from compliance review.

497. Even as to orders that exceeded customers' monthly thresholds, Distributor Defendants, over varying time periods, routinely failed to accurately identify those orders as

[95] *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

suspicious. Instead, they released those orders for delivery based on perfunctory and unverified information provided by the customer or for no documented reason at all. Moreover, even when Distributor Defendants did identify orders as suspicious and did block them, they routinely failed to report those suspicious orders to the State, sometimes going months or years without reporting any at all. When they did make suspicious-order reports, the reports were routinely incomplete, for example, by failing to identify all of the relevant suspicious orders for a customer.

498. The sheer volume of prescription opioids distributed to pharmacies in various areas, and/or to pharmacies from which Distributor Defendants knew the opioids were likely to be diverted, was excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.[96]

4. Distributor Defendants Failed to Suspend Suspicious Customers.

499. Distributor Defendants failed to act to suspend customers from ordering controlled substances, let alone terminate their accounts, even after compliance staff had blocked and reported dozens, or even hundreds, of suspicious orders from those customers. In the relatively rare instances where a customer had been terminated or suspended, Distributor Defendants allowed them to reinstate their accounts or to open accounts under new business names, without investigating and resolving the issues that had led to the initial termination or suspension.

[96] *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy*, Nos. 219 and 5195, 77 Fed. Reg. 62,316, 62,322 (2012)).

5. Distributor Defendants Failed to Adequately Maintain Accessible Data Concerning Customers and Prescribers.

500. None of the Distributor Defendants systematically stored, organized, and made accessible for reference information about their customers or their owners, pharmacists, and top prescribers in order to allow for meaningful compliance efforts.

501. Distributor Defendants did not require compliance staff to obtain customers' prescriber information, and some actually changed their policies to forbid such inquiries, willfully blinding themselves to one of the most important indicators of diversion. While compliance staff and/or third-party investigators retained by Distributor Defendants would sometimes flag prescribers as suspicious in the course of conducting due diligence of a pharmacy, that information was not stored or shared in any useable format. As a result, when the same suspicious prescriber appeared among another pharmacy's top prescribers, the compliance staff handling that subsequent due diligence investigation would have no way of knowing about this risk that had already been identified, unless they had personally handled the earlier investigation, and happened to remember the prescriber's name. Similarly, they made no effort to collect and compare information about pharmacies that made high-volume orders of opioids, had been flagged for making suspicious orders, or had been suspended or terminated for suspicious or illegal practices. As a result, compliance staff had no way of knowing that a pharmacy they were investigating shared ordering patterns or top prescribers with another risky, suspicious, and/or previously disciplined customer.

6. Distributor Defendants Failed to Report Violations to Government Authorities.

502. Distributor Defendants failed to promptly report compliance violations to the federal government, the States of Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma, and other governments. Indeed, even when they actually detected failures in their

compliance systems, they made no effort to report those known incidents. More broadly, due to the combination of systematic failures riddling their compliance systems described above, none of the Distributor Defendants had the competence to effectively detect their own violations.

503. For example, if any of the Distributor Defendants had conducted periodic audits of their own records of customers' orders, those customers' patterns of ordering in excess of their monthly threshold allowance for opioid products, the number of times those orders were released without justification, and the number of times those orders were blocked as suspicious without being reported to government agencies and/or triggering additional investigations, suspensions, or terminations, they would have each been obliged to report hundreds, if not thousands, of violations.

504. In short, Distributor Defendants deliberately lied to the federal government, and to Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, Oklahoma, and other state governments, both expressly and by omission, year in and year out, about the effectiveness of their compliance systems and the incidence of violations, so that they could fraudulently maintain their licenses to continue doing business in the Region and elsewhere.

505. Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of damages.

D. Each of the Distributor Defendants Engaged in Wrongful Conduct

1. Cardinal

a. Cardinal's Flawed Written Policies Enabled Opioid Diversion

506. Cardinal's written policies for compliance were and are contained in Standard Operating Procedures ("SOPs") that apply to its various operating and sales departments. These SOPs were first implemented in 2008 and have since undergone several revisions.

507. These policies were not coordinated within the context of a consistent, unified umbrella policy to prevent the diversion of controlled substances, resulting in employees governed by one of the SOPs being unaware of the obligations imposed by other SOPs on other employees, even when effective anti-diversion measures required that understanding and coordination. Furthermore, these documents are not readily available even to the employees charged with implementing them.

508. In addition, Cardinal's SOPs and policies contained numerous gaps that would have prevented them from effectively preventing diversion, even if enforced. For example, these policies:

a. Allowed new accounts with no formal mechanism to ensure review and approval by a supervisor;

b. Allowed onboarding of new accounts even where customers failed to provide requested information about other suppliers, dispensing data, and top prescriber information;

c. Allowed compliance staff to release a customer's first order in excess of its monthly threshold, regardless of whether the customer made other orders in excess of the same drug threshold at the same time; and

d. Allowed compliance staff to approve on boarding Cardinal's Failure to Effectively Prevent Diversion in Practice.

509. At all relevant times, Cardinal failed to employ qualified compliance staff to implement these policies, failed to adequately train those compliance staff or its sales representatives concerning Cardinal's anti-diversion duties, and failed to enforce even the defective policies it had in place.

510. Cardinal failed to install qualified personnel in key compliance positions. For example, Cardinal's front-line "New Account Specialists" and "Analysts," responsible for onboarding new customers and monitoring existing customers, respectively, were routinely recruited from the ranks of the company's existing pool of administrative assistants. These

employees, who had no experience in regulatory compliance, were generally supervised by pharmacists or other professionals with no prior experience in supervising investigative functions.

511. Moreover, Cardinal failed to provide meaningful training to either these unqualified compliance personnel or sales representatives. Instead, Cardinal expected the compliance staff to "learn on the job" through informal in-person "team meetings." Due to the lack of proper training and clear guidelines, compliance staff did not fully understand critical components of their jobs and often developed their own procedures and benchmarks for reviewing customers.

512. Unsurprisingly, these unqualified and untrained staff routinely failed to follow even the most basic procedures required under the company's various SOPs. In addition, Cardinal allowed customers to reinstate their accounts through the new account onboarding process despite having compliance red flags.

513. Even to staff charged with investigations and anti-diversion, the message was clear: without sales, there is no Cardinal. Indeed, many of Cardinal's policies and practices have prioritized sales over regulatory obligations.

514. In 2012 and 2013, Cardinal took significant steps to renew focus on increased sales at the cost of a robust and responsible compliance structure, thereby keeping as customers pharmacies that it knew or should have known were high risk for diversion of opioids. For example, Cardinal:

a. Continuously reduced the due diligence information collected from prospective and existing customers, diluting the customer questionnaire, removing the requirements to collect photos of the pharmacies, and ceasing to ask about top prescribers;

b. Expanded the geographic scope of investigators with essential regional knowledge of, for example, top prescribers and their locations relative to the pharmacies where their prescriptions were being filled, thus reducing the investigators' efficacy;

c. Restricted the information reviewed from site visits by first removing the investigator comment section and for a time eliminating written reports entirely; and

d. Demoted, moved to non-compliance functions, or let go several staff members who articulated an interest in expanding the company's compliance functions, aggressively scrutinizing pharmacy customers, and/or terminating problematic customers.

515. As to existing customers, Cardinal routinely failed to follow the SOPs for detecting, monitoring, and reporting suspicious orders. Cardinal's compliance staff routinely released orders in excess of a customer's threshold without conducting the follow-up investigation and providing the detailed written justification called for by the SOPs.

516. Even where Cardinal did block customers' orders and report them as suspicious, it routinely took no steps to suspend or terminate those customers and instead allowed them to continue receiving their threshold amount of opioids month after month thereafter, regardless of whether the customer continued to make additional suspicious orders.

517. Between 2012 and 2017, for example, Cardinal reported twelve or more opioid related suspicious orders for at least one year-the equivalent of one per month-for hundreds of pharmacies nationwide. Those pharmacies had several known red flags in their shipment orders and prescription data. More than half of these pharmacies: (a) exceeded the 90th percentile in their states in terms of opioid volume shipped; (b) exceeded the 90th percentile in their states in terms of oxycodone volume shipped; and (c) exceeded the 90th percentile in their states in terms of median strength of opioids prescribed per day. Nonetheless, even after reporting twelve or more opioid-related suspicious orders for one of these pharmacies, Cardinal continued to ship opioids, on average, for more than three years. Within this group of suspect pharmacies that Cardinal did nothing to control, these included particularly egregious cases in which Cardinal reported more than 50 opioid-related suspicious orders per year-the equivalent of one suspicious order per ·week

to the authorities for three or more consecutive years.

518. In still other instances, neither Cardinal nor other distributors reported numerous suspicious orders, but almost certainly should have, given that a handful of prescribers were responsible for writing an unusually high percentage of the pharmacy's opioid prescriptions. By itself, having a high concentration of opioid prescriptions written by a small number of providers is a known red flag for opioid diversion. Subsequently, these pharmacies had among the highest percentage of prescriptions written by providers who were indicted or convicted on opioid-related prescribing and distribution charges.

519. Examples of egregious cases identified in an investigation by a state attorney general included:

a. A pharmacy in the 99th percentile in the state, to which Cardinal reported an average of 85 suspicious orders per year for five years, the equivalent of more than once a week, yet as of 2018, as of 2018, this pharmacy continued to receive opioids from Cardinal.

b. A pharmacy in the 95th percentile in the state, to which Cardinal, from 2012 to 2018, shipped more than 20,000 grams of opioids, the equivalent of about thirteen 30mg oxycodone pills for every person in the county.

c. A pharmacy in the 90th percentile where more than 20% of its customers have received opioid prescriptions by three or more doctors in a six-year period, and to which Cardinal continued to ship opioids after other distributors had issued 223 SORs.

d. A pharmacy in the 99th percentile where approximately 60% of prescriptions were written by prescribers who were later indicted or convicted, and to which Cardinal has failed to issue a single SOR as of December 2017.

520. Finally, even if Cardinal had conducted due diligence to investigate its high-volume opioids customers, Cardinal's failure to implement any system to store and share information about their suspicious customers and/or suspicious prescribers would have compromised the effectiveness of any such investigation.

521. Due to these flaws, Cardinal routinely continued to supply pharmacies that filled prescriptions for prescribers that had been flagged in its own (infrequent) investigations of other pharmacies as likely sources of diversion.

b. Cardinal Was Put on Notice of its Wrongful Conduct.

522. In addition to numerous instances in which Cardinal's own employees acknowledged failures in its compliance systems, the company was explicitly put on notice on multiple occasions by government agencies that it was not fulfilling its duties.

523. To date, Cardinal has paid at least $98 million in fines in multiple DEA and various state actions relating to its improper management and distribution of opioids to pharmacies across the United States.

524. In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven warehouses around the United States (the "2008 Cardinal Settlement Agreement").[97] These allegations included failing to report to the DEA thousands of suspicious orders of hydrocodone that Cardinal then distributed to pharmacies that filled illegitimate prescriptions originating from rogue Internet pharmacy websites.[98]

525. In connection with the 2008 Cardinal Settlement Agreement, the DEA stated that "[d]espite [its] repeated attempts to educate Cardinal on diversion awareness and prevention, Cardinal engaged in a pattern of failing to report blatantly suspicious orders for controlled

[97] Settlement and Release Agreement and Administrative Memorandum of Agreement (Sept. 30, 2008), https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html (last visited Jan. 20, 2024); Press Release, U.S. Atty. Office, Dist. of Colo., Cardinal Health Inc., Agrees to Pay $34 Million to Settle Claims that it Failed to Report Suspicious Sales of Widely-Abused Controlled Substances (Oct. 2, 2008), https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

[98] *Id.*

substances filled by its distribution facilities located throughout the United States."[99] The DEA concluded that "Cardinal's conduct allowed the 'diversion' of millions of dosage units of hydrocodone from legitimate to non-legitimate channels."[100]

526. As part of the 2008 Cardinal Settlement Agreement, Cardinal agreed to "maintain a compliance program designed to detect and prevent diversion of controlled substances as required by the CSA and applicable DEA regulations."[101] However, in 2012, the DEA issued an "immediate suspension order," suspending Cardinal's registration for its distribution facility in Lakeland, Florida. That order stated that "[d]espite the [2008 Cardinal Settlement Agreement], the specific guidance provided to Cardinal by DEA, and despite the public information readily available regarding the oxycodone epidemic, Cardinal has failed to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of [the CSA]."[102]

527. In 2012, Cardinal reached another settlement with the DEA relating to its failure to "conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels" resulting in systemic opioid diversion in its Florida distribution center (the "2012 Cardinal Settlement Agreement").[103] Cardinal's Florida center received a two-year license suspension for supplying more than 12 million dosage units to only four area

[99] U.S. Attorney Office, Dist. of Colo., Cardinal Health Inc. Agrees to Pay $34 Million to Settle Claims that It Failed to Report Suspicious Sales of Widely-Abused Controlled Substances (Oct. 2, 2008), https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

[100] *Id.*

[101] *Cardinal Health, Inc. v. Eric Holder, Jr., Atty. Gen.*, D.D.C. Case No. 12-185, ECF No. 3-4, at ¶ 2 (Feb. 3, 2012).

[102] *Id.* at ¶ 3.

[103] Administrative Memorandum of Agreement (May 14, 2012), https://www.dea.gov/divisions/hq/2012/cardinal_agreement.pdf (last accessed Aug1, 2018); Press Release, Drug Enf't Admin., DEA Suspends for Two Years Pharmaceutical Wholesale Distributor's Ability to Sell Controlled Substances from Lakeland, Florida Facility (May 15, 2012), https://www.dea.gov/pubs/pressrel/pr051512.html hereinafter "Administrative Memorandum of Agreement (May 14, 2012)").

pharmacies, nearly fifty times as much oxycodone as it shipped to the rest of Florida and an increase of 241% in only two years.[104] The DEA found that Cardinal's own investigator warned Cardinal against selling opioids to these pharmacies, but that Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacies.[105] Instead, Cardinal's opioid shipments to the pharmacies increased.[106]

528. In the 2012 Cardinal Settlement Agreement, Cardinal agreed that it had (i) failed to maintain effective controls against the diversion of controlled substances, including failing to conduct meaningful due diligence to ensure that controlled substances were not diverted; (ii) failed to detect and report suspicious orders of controlled substances as required by the CSA, on or before May 14, 2012; and (iii) failed to adhere to the provisions of the 2008 Cardinal Settlement Agreement.[107]

529. In December 2016, Cardinal again settled charges that it had violated the CSA by failing to prevent diversion of oxycodone for illegal purposes by failing to report suspicious orders, this time for $44 million (the "2016 Cardinal Settlement Agreement").[108]

c. Cardinal Actively Marketed Prescription Opioids.

530. Cardinal worked to increase sales of opioids through a range of in-house marketing platforms directed at prescribers, pharmacists, and consumers.

531. Cardinal incentivizes and encourages drug manufacturers to use its marketing services to build their business and increase their sales of prescription opioids.

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[104] *Id.*
[105] *Id.*
[106] *Id.*
[107] Administrative Memorandum of Agreement, *supra* n. 103.
[108] U.S. Atty. Office, Dist. of Md., *Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act* (Dec. 23, 2016) https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.

532. Cardinal utilized a variety of marketing programs to promote sales of prescription opioids, including direct consumer marketing, direct mail marketing, email marketing, marketing in customer newsletters, telemarketing, advertisement on ordering platform, pharmacy rebates, and auto-shipments.

533. Purdue and other manufacturers worked hand-in-glove with Cardinal to promote their products through the distributors to pharmacies and pharmacists.

534. Cardinal profited in two ways from its marketing activities: (1) it was paid by the drug manufacturers to promote their prescription opioids; and (2) it was paid from increases in pharmacy drug sales that resulted from these marketing efforts.

535. Through marketing activities, Cardinal built upon, reinforced, and profited from the drug manufacturers' campaign to deceive healthcare providers about the risks and benefits of prescription opioid use—a campaign that encouraged and normalized over-prescribing and over-dispensing of prescription opioids.

536. Cardinal made false statements that it had no role in influencing the prescribing or dispensing of prescription opioids and did not promote and market any pharmaceuticals-including opioids-directly to consumers.

2. Cencora

a. Cencora's Flawed Written Policies Enabled Opioid Diversion

537. Cencora's written compliance policies were and are contained within its Diversion Control Program and its Order Monitoring Program ("COMP"). From 2007 to 2015, the program's specifics were scattered through a series of documents, which were not uniform for Cencora and its subsidiary, Bellco Health (acquired in 2007).

538. Cencora's compliance policies are flawed from the point of initial new customer onboarding. Since 2007, Cencora has generally required a customer questionnaire, a site visit,

license verification, and online investigation as part of its new customer due diligence process. Cencora asks for information about other distributors, disciplinary history, customer payment methods, percentages of controlled substances, usage numbers for specific high-risk drugs, and top prescribers of opioids, among other questions. Though Cencora requests information about prescribing physicians, it is not Cencora's policy to perform news searches on those prescribers as part of the new customer procedure. As a result, controlled substances could account for an excessive portion of the prescriptions dispensed before triggering additional investigation.

539. Cencora does not require new customers to provide usage reports or dispensing data as part of the on boarding process. By relying on these customers to self-report without verification, Cencora does not fulfill its obligation of truly knowing its customers' business practices.

540. Both prior to and after program revision, Cencora's policies have allowed for frequent threshold manipulation to avoid orders being held for review, rejected from shipment, or reported as suspicious. Staff reviewing orders have high benchmarks for these numbers before considering them red flags.

541. Cencora's policies are not sufficient to comply with the requirements of federal and state law requiring it to establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions. Under its deficient policies, Cencora does not hold for review orders that only meet one of these qualifications. In doing so, Cencora's policy does not fulfill its obligation to identify even orders of interest, much less suspicious orders.

542. Examples of egregious cases identified recently in a complaint filed by a state attorney general included:

a. A pharmacy at or above both the 99th percentile in terms of both number of opioid orders and total opioid weight, at which, between 2014 and 2016, more

than 10% of its prescriptions were written by prescribers who were later indicted or convicted of opioid-related prescribing and distribution charges, concerning which Cencora reported nearly 200 SORs in 2013-14, and to which as of 2018, Cencora was still serving as this pharmacy's primary opioid distributor;

b. A pharmacy where, between 2013 and 2017, 77% of its prescriptions, on average, were written by prescribers who were later indicted or convicted, including 90% in 2014, and to which Amerisource appears to have only stopped shipping in 2017; and

c. A pharmacy that exceeded the 95th percentile for the percentage of oxycodone volume shipped for five years straight (2012 to 2016), where on average 58% of its opioid prescriptions were paid in cash (99th percentile), where for three consecutive years (2013 to 2015) approximately half of all opioid scripts were filled by prescribers who were later convicted, and which, as of 2018, was still a customer of Cencora.

b. Cencora's Failure to Effectively Prevent Diversion in Practice

543. At all relevant times, Cencora failed to employ sufficient numbers of qualified compliance staff to implement these policies, failed to ensure those compliance staff were meeting Cencora's anti-diversion duties, and failed to enforce even the defective policies it had in place.

544. Since the integration of Bellco into Cencora and the revamp of its Diversion Control Program in 2015, the company has increased anti-diversion staffing, but has not significantly increased the number of fully trained ground level employees. Since that time, Cencora has maintained only five to seven front-line employees on its Diversion Control Team, responsible for reviewing new customers and monitoring its existing customers.

545. Many of Cencora's compliance violations begin with its new customer policy. The process relies heavily on the company's 590 Form, given that Cencora only requests dispensing information from new customers when it already knows of potential issues.

546. Despite the 590 Form being so critical to understanding its customers and ensuring it can fulfill its regulatory obligations, and despite numerous other Cencora procedures relying on reviewing or updating this form, Cencora has had significant issues related to failing to perform

even this baseline screening. Bellco Generics customers, for example, regularly completed the 590 Form independently, submitted it to Bellco, and were onboarded thereafter without receiving a site visit.

547. Disjunction between Cencora and Bellco has led to many compliance failures. Until system integration in or around November 2015, staff had no systematic way of identifying dual customers. The lack of an integrated system also meant that thresholds were not coordinated between Cencora and Bellco. As a result, a dual customer could have high thresholds set with both, could be exceeding both thresholds, or even having its threshold periodically increased with both, without detection. In or around April 2013, Cencora implemented a policy for dual customers that prevented both Cencora and Bellco from supplying controlled substances to the same customer, but implementation was spotty. In practice, only a small percentage of orders flagged for review are cancelled, and even fewer are deemed suspicious.

548. Cencora has a high tolerance for compliance issues before it will terminate a customer. It still lacks an internal rule or policy that requires investigation of a customer based on a specific number of suspicious order reports. Even when customers were restricted, blocked, or terminated, Cencora's system failed to ensure their accounts were de-activated.

549. Cencora displays an unwillingness to identify suspicious orders, even among customers that regularly exceeded their thresholds and presented multiple red flags of diversion. These flags included:

a. Scoring above the 90th percentile in the county for opioid order volume;

b. Scoring above the 90th percentile in the county for total opioid orders;

c. Scoring above the 90th percentile in the county for oxycodone order volume;

d. Scoring above the 90th percentile in the county for total oxycodone orders;

e. Scoring above the 90th percentile in the state for the percentage of oxycodone volume shipped out of all controlled substances shipped;

f. Filling prescriptions by prescribers who were later indicted or convicted on opioid-related prescribing and distribution charges;

g. Scoring above the 90th percentile in terms of percentage of patient doctor-shoppers;

h. Scoring above the 90th percentile in terms of percentage of cash payments; and

i. Scoring above the 90th percentile in terms of the median MME prescribed per day.

c. Cencora Was Put on Notice of its Wrongful Conduct.

550. Cencora's deficiencies and failures did not go undetected. The company was explicitly put on notice on multiple occasions by government agencies that it was not fulfilling its duties.

551. Cencora has paid $16 million in settlements and had certain licenses revoked as a result of allegations related to the diversion of prescription opioids.

552. In 2007, Cencora lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies.[109] Over the course of one year, Cencora had distributed 3.8 million dosage units of hydrocodone to "rogue pharmacies."[110] The DEA suspended Cencora's registration after determining that "the continued registration of this company constitutes an imminent danger to public health and safety."[111]

[109] Press Release, Drug Enf't Admin., *DEA Suspends Orlando Branch of Drug Company from Distributing Controlled Substances* (Apr. 24, 2007), https://www.dea.gov/divisions/mia/2007/mia042407p.html.

[110] *Id.*

[111] *Id.*

553. Again in 2012, Cencora was implicated for failing to protect against diversion of particular controlled substances into non-medically necessary channels.[112]

d. Cencora Is Sued by the Justice Department.

554. In December 2022, the United States Department of Justice filed a nationwide lawsuit against Cencora, alleging that it engaged in years of repeated violations of the CSA and that it contributed to the opioid epidemic. The Department of Justice seeks civil penalties and injunctive relief for what it describes as "thousands" of violations of the CSA. [113]

555. The complaint, which covers the period from 2014 to the date of filing in late 2022, alleges that Cencora violated the CSA by failing to report at least hundreds of thousands of suspicious orders of controlled substances to the DEA as required by law. The alleged unlawful conduct includes filling and failing to report numerous orders from pharmacies that Cencora knew were likely facilitating diversion of prescription opioids. The filing was "the result of a multi-year investigation by the DEA, the Civil Division's Consumer Protection Branch and several U.S. Attorneys' Offices."

556. The government's complaint alleges that there were several specific pharmacies for which Cencora was aware of significant "red flags" suggesting the existence of diversion of prescription drugs to illicit markets. The complaint asserts that Cencora nevertheless continued to distribute drugs to the pharmacies for years and reported few suspicious orders to the DEA. The five examples include: two pharmacies, one in Florida and one in West Virginia, for which

[112] Jeff Overley, *AmerisourceBergen Subpoenaed by DEA Over Drug Diversion,* Law360.com (Aug. 9, 2012), available at https://www.law360.com/articles/368498/amerisourcebergen-subpoenaed-by-dea-over-drug-diversion.

[113] *See* Complaint, *United States v. Amerisource Bergen Corp.*, No. 2:22-cv-05209 (E.D. Pa. filed Dec. 29, 2022), https://www.justice.gov/opa/press-release/file/1559811/download; *see also Justice Department Files Nationwide Lawsuit Against AmerisourceBergen Corp. and Subsidiaries for Controlled Substances Act Violations*, U.S. Dept. of Just. (Dec. 29, 2022), https://www.justice.gov/opa/pr/justice-department-files-nationwide-lawsuit-against-amerisourcebergen-corp-and-subsidiaries.

Cencora knew the drugs it distributed were likely being sold in parking lots for cash; a New Jersey pharmacy that has pleaded guilty to unlawfully selling controlled substances; another New Jersey pharmacy whose pharmacist-in-charge has been indicted for drug diversion; and a Colorado pharmacy that Cencora knew was its largest purchaser of oxycodone 30mg tablets in all of Colorado. The government further alleges that for this Colorado pharmacy, Cencora specifically identified eleven patients as potential "drug addicts" whose prescriptions likely were illegitimate. Two of those patients subsequently died of overdoses.

557. The complaint further alleges that Cencora not only ignored red flags of diversion, but also relied on internal systems to monitor and identify suspicious orders that were deeply inadequate, both in design and implementation. These systems allegedly flagged only a tiny fraction of suspicious orders, thereby enabling diversion and Cencora's failure to report orders it was legally obligated to identify to the DEA. In fact, the complaint asserts that in the midst of the opioid epidemic, Cencora intentionally altered its internal systems in a way that reduced the number of controlled substances reported as suspicious. Even for the small percentage of orders that Cencora did identify as suspicious, the company routinely failed to report them to the DEA.

3. McKesson

558. Despite being a giant distributor with purportedly comprehensive systems for tracking the movement of drugs, McKesson failed to take adequate steps to prevent diversion of opioids in California.

559. McKesson sold and shipped unreasonable quantities of opioids into California, including many red-flag pharmacies in California, and continued to do so despite extensive and blatant evidence of diversion at many facilities in California. McKesson has been investigated and fined for some of its many failures to secure its supply chain but continues to allow inappropriate and harmful distribution of opioids.

560. This distribution has generated enormous profits. For the fiscal year ending on March 31, 2021, McKesson generated revenues of $232 billion.[114]

561. The volume of opioids McKesson shipped into California was so high as to put it on notice that not all of the drugs being ordered would be used to fill prescriptions for legitimate medical uses.

562. McKesson has acknowledged these failures. Speaking about certain pharmacies in West Virginia that McKesson belatedly terminated after supplying them with excessive quantities of opioids for years, McKesson's CEO admitted, "[i]n hindsight, I would have liked to have seen us move much more quickly to identify the issues with these pharmacies."[115]

563. The opioid crisis described herein is a direct and foreseeable result of McKesson's actions.

a. McKesson's Flawed Written Policies Enabled Opioid Diversion

564. While McKesson's first written policy aimed at preventing diversion dates back to at least 1997, the company has shown an unwillingness to comply with that policy and those that followed it.

565. Before 2008, McKesson utilized a SOMS that only retrospectively reported sales of controlled substances that exceeded certain thresholds. The SOMS did not flag truly suspicious orders, and McKesson performed no due diligence and did not block the shipment of suspicious orders. McKesson's only system utilized for identifying and reporting suspicious orders was found in Section 55 of the McKesson Drug Operations Manual. Under this system, McKesson produced

[114] McKesson Corp., *Form-10K*, May 12, 2021, https://s24.q4cdn.com/128197368/files/doc_financials/2021/ar/MCK-Q4FY21-10-K.pdf.

[115] *Combatting the Opioid Epidemic: Examining Concerns about Distribution and Diversion*, Hearing before the Subcomm. on Oversight & Investigations of the Comm. On Energy & Commerce, No. 115-124 (May 8, 2018), https://www.govinfo.gov/content/pkg/CHRG-115hhrg31601/html/CHRG-115hhrg31601.htm (hereinafter "Combatting the Opioid Epidemic")

daily and monthly reports—known as DU-45 reports—that documented retrospective sales of controlled substances when those sales exceeded three times that customer's twelve-month purchase average for that drug base code.[116] Orders listed on this report were not held or halted but were shipped without review.

566. McKesson's own regulatory employees have conceded that these reports did not satisfy McKesson's obligation to report suspicious orders. According to McKesson's Regulatory Affairs Director, David Gustin, "the previous reports [DU-45] were not the exclusive and proper response to this regulation. We have an obligation to report 'suspicious orders.' . . . Simply reporting larger than usual orders does not when there are so many plausible and routine reasons for orders to be 'larger than normal.'"[117] Similarly, another Director of Regulatory Affairs for McKesson, Gary Hilliard, has testified that McKesson's suspicious-order monitoring system prior to 2007 was not designed to detect true suspicious orders.[118] Instead, this system was focused solely on reporting excessive orders, which is not consistent with the requirements of the CSA. Of equal importance, Section 55 included no requirement to block orders that were deemed excessive and ultimately reported to DEA. In fact, McKesson made no effort to block suspicious opioid orders until it began utilizing a new SOM system in May 2008.[119] Similarly, outside of confirming erroneous "fat fingered" orders, McKesson undertook no investigation of the legitimacy of excessive orders under the Section 55 program.[120]

567. The massive shortcomings of Section 55 led to the DEA's investigation into large shipments of opioids provided by McKesson to rogue internet pharmacies in 2005 and 2006. In

[116] McKesson, Drug Operations Manual: Section 55 DEA Compliance 39–40 (1997).
[117] Email from Dave Gustin to Tyra Williams, et al. (Feb. 4, 2011, 3:08 PM).
[118] MDL 1091-1 at 80 Ex. 238 (1/10/19 Gary Hilliard Depo. at 176:8-176:22).
[119] MDL 1091-1 at 80 Ex. 238 (1/10/19, Gary Hilliard Depo. at 52:21-53:3).
[120] MDL 1091-1 at 80 Ex. 241 (11/8/18, Blaine Snider Depo. at 77:3-78:4).

response to this investigation, in May 2007, McKesson launched the Lifestyle Drug Monitoring Program (hereinafter "LDMP").[121]

568. The LDMP was limited to four drugs (oxycodone, hydrocodone, alprazolam, and phentermine).[122] For these four drugs, an 8,000 monthly dosage unit threshold was set for every McKesson customer nationwide.[123] Once the 8,000 dosage unit threshold was met in a given month, a three-level review process was to be triggered.[124] McKesson represented to the DOJ that under the LDMP "customers will not be allowed to exceed the 8,000 monthly dosage limit until a due diligence review has been completed."[125] But this is not how the program actually operated. Testimony from McKesson's regulatory employees has confirmed the LDMP had no mechanism to block orders once the 8,000 unit threshold was met and while an investigation was ongoing. In fact, pharmacy customers were routinely permitted to exceed the 8,000 monthly dosage thresholds prior to a due-diligence review being completed by McKesson.

569. McKesson's LDMP did not fare any better when it came to identifying suspicious orders. To the extent any orders were reported to DEA under the LDMP, it was only excessive orders meeting the parameters of the Section 55 protocols discussed above.

570. Additional problems with the LDMP were uncovered during routine auditing of the program. First, it was noted that "it is possible not all of the products containing one of the generic ingredients are included" in the reports generated as part of the LDMP. Additionally, the Daily Dosage Summary Report generated under the LDMP was organized by distribution center, and therefore a customer could exceed the monthly 8,000 dosage unit threshold and avoid detection by

[121] Keith McIntrye, *Lifestyle Drug Monitoring Program* (May 16, 2007).
[122] *Id.*
[123] *Id.*
[124] *Id.*
[125] Letter from Hyman, Phelps, & McNamara, P.C., Counsel for McKesson, to Linden Barber, Associate Chief Counsel, Diversion & Regulatory Litigation Section, Drug Enf't Admin. (Apr. 25, 2007).

simply spreading its purchases across multiple distribution centers.

571. In May 2008, McKesson launched the Controlled Substances Monitoring Program ("CSMP"). The CSMP continued to apply monthly thresholds, but, unlike the LDMP thresholds, the CSMP's monthly thresholds applied to all opioid products. Thresholds were initially set under the CSMP by reviewing the customer's twelve-month purchase history for each drug base code, reviewing the highest month of purchases in that twelve-month period, and adding a 10% buffer to that purchase amount. Thresholds could then be adjusted through a process referred to as a threshold change request. The CSMP also retained the LDMP's tiered three-level review process, which was triggered once a customer met their monthly threshold. However, in many cases, including in Ohio's Summit and Cuyahoga Counties, McKesson's files reveal that Level 2 or 3 reviews were never conducted.

572. Under the CSMP, McKesson also included a "Know Your Customer" process. Again, however, McKesson's due diligence files produced in the federal opioid MDL show that for years this process was very rudimentary in nature and that there were very few substantive investigations being performed. Thus, McKesson's due diligence files make clear that McKesson was completely failing to comply with its duty to investigate its customers and their orders.

573. At the outset of the program, McKesson notified all of its customers they should not expect any change in their ability to order controlled substances. When introducing the CSMP to its customers, McKesson stated, "[t]his program addresses the DEA's requirements to ensure controlled substances are used in the way they were intended, but it also ensures that you as a McKesson customer can continue with business as usual." But it was precisely this "business as usual" that had already led McKesson into a $13.25 million dollar settlement with the DOJ for failing to have effective controls against diversion as it pertained to opioid distribution.

574. The CSMP did belatedly allow McKesson to block opioid orders that were identified as suspicious. However, the CSMP contained multiple loopholes to ensure that as few orders as possible were blocked.

575. First, although McKesson established thresholds under the CSMP, those thresholds were frequently set far too high to ever be triggered. In fact, in August 2014, the DOJ pointed out this flaw and noted that McKesson's review process under the CSMP was not even triggered until a customer had purchased 10% more than its monthly average. In addition, the monthly average was calculated based on purchases from the 2007-2008 time period, which the DOJ noted was a "year in which McKesson had settled claims because diversion was flourishing in McKesson-supplied pharmacies." The extremely high thresholds set by McKesson for controlled substances did not go unnoticed within the company. On August 31, 2011, Director of Regulatory Affairs, David Gustin, stated, "I have thought of an area that needs to be tightened up in CSMP and it is the number of accounts we have that have large gaps between the amount of Oxy or Hydro they are allowed to buy (their threshold) and the amount they really need. (Their current purchases) This increases the 'opportunity' for diversion by exposing more product for introduction into the pipeline than may be being used for legitimate purchases."[126] Despite Gustin's concerns, no serious efforts were undertaken to systematically reduce thresholds until 2015, a full four years later.[127]

576. Second, McKesson routinely increased thresholds without obtaining adequate justification for the increase. A customer was supposed to provide documentation supporting a legitimate change in business that warranted the threshold increase. Despite this requirement, McKesson would increase thresholds for the flimsiest of reasons or for no reason at all. For

[126] Email from Dave Gustin to Dave Fagerskog, et al. (Aug. 31, 2011, 3:15 PM).

[127] *See* Email from Nate Hartle to Krista Peck (May 1, 2015, 5:05 PM) (hereinafter "Hartle Email"); Nate Hartle, *McKesson's Controlled Substance Monitoring Program: Oxycodone Threshold Reduction Report* (Feb. 9, 2015) (hereinafter "Threshold Reduction Report").

example, in November 2008, McKesson employees permanently increased opioid thresholds for 200 customers by 30% for no reason other than it was around the Thanksgiving holiday. In April 2011, David Gustin explained that McKesson needed to tighten up the process regarding threshold increases because threshold increases were "almost automatic" and being granted for insufficient reasons, like "business increase." Regulatory Affairs Director Tom McDonald reiterated these concerns in July 2012, noting that the company was too liberally granting threshold increases without proper documentation and often based only on a claim of business growth by the customer. Mr. Gustin became so concerned about the lack of due diligence being conducted by McKesson that he even noted to other colleagues in regulatory affairs that "[w]e as DRAs need to get out visiting more customers and away from our laptops or the company is going to end up paying the price . . . big time." Another Regulatory Affairs Director, Michael Oriente, responded, "I am overwhelmed. I feel that I am going down a river without a paddle and fighting the rapids. Sooner or later, hopefully later I feel we will be burned by a customer that did not get enough due diligence. I feel it is more of when than if we have a problem rise up."

577. McKesson ultimately acknowledged the problem of deficient due diligence, especially as to threshold increase requests. A November 2013 training deck noted a desire to make threshold change increases "the exception, not the rule" going forward in order to address the lack of due diligence that had become commonplace at McKesson.[128] The lack of due diligence for threshold increases was also readily apparent to DOJ. In August 2014, DOJ noted that McKesson appeared to be willing to approve threshold increases for opioids for the flimsiest of reasons.

578. Third, McKesson has a long history of absolute deference to retail national account customers when it comes to threshold increases. McKesson's Senior Director of Distribution

[128] McKesson, Controlled Substance Compliance Program (Nov. 1, 2013).

Operations, Donald Walker, testified that McKesson did not ask for dispensing data in order to verify the legitimacy of threshold increases for retail national account customers and generally deferred to those customers to decide when it was appropriate for them to get threshold increases for controlled substances. These lax practices resulted in McKesson routinely granting threshold increases to retail national account customers without any apparent due diligence. Retail national accounts received even more leeway on their thresholds, generally being given a 20-25% buffer, rather than 10%. McKesson also deferred completely to retail national account customers to dictate when their thresholds would be increased. McKesson's Senior Director of Distribution Operations, Donald Walker, readily acknowledged that McKesson did not ask for dispensing data in order to verify the legitimacy of threshold increases for retail national account customers and generally deferred to those customers to decide when it was appropriate for them to get threshold increases for controlled substances. For example, as seen in a January 2009 presentation, McKesson outlined its plan for automatic threshold increases for CVS stores when they approached their threshold and to seek a justification for thresholds increases from CVS only if the increases were "extraordinary" and without "further CVS explanation." McKesson's erroneous reasoning for such automatic threshold increases was to "minimize disruption of business" and to ignore reviewing "routine" threshold increases. McKesson adopted this "hands-off" approach to its largest customers for one reason only—fear of losing the large chains' business.

579. Fourth, McKesson took affirmative steps to reduce the number of blocked orders by warning customers that they were approaching a threshold. This process ensured that customers could seek an increase before McKesson would be forced to block their orders. In discussing the creation of these warning reports in October 2006, Sharon Mackarness of McKesson noted, "[w]e are in the business to sell product. If we could produce a report … that warned a customers

approach to the threshold, say at 85% of their 10,000 dosages, work could begin on justifying an increase in threshold prior to any lost sales." These threshold warning reports were utilized for years thereafter to great effect as a preemptive tool to increase thresholds before orders had to be blocked.

580. Acknowledging the impropriety of providing these warning reports to customers, in November 2013 McKesson announced to its employees a new policy pertaining to threshold warning reports. The presentation states "[w]e are not communicating specific thresholds or providing threshold warning reports. We believe this is a better practice. Thresholds are not intended to allow customers to manage against a number. We strongly believe that customers should exercise their corresponding responsibility one prescription at a time."[129] However, in the following months, McKesson was already making exceptions to this newly established policy.[130] The shift to not providing these warning reports was appropriate, and McKesson should have abided by this policy without exception.

581. The above measures individually and collectively rendered McKesson's CSMP ineffective as an anti-diversion tool. Thus, while the CSMP could have been used as a tool to identify suspicious orders and properly investigate them, significant efforts were undertaken by McKesson to thwart the effectiveness of the system as a whole.

582. McKesson's CSMP also could have been used as a tool to report suspicious orders, but it was not used to meet that regulatory requirement until five years after the program was initially launched. For instance, of the 1.6 million orders for controlled substances processed between 2008 and 2013 by its Aurora, Colorado Distribution Center, McKesson reported only

[129] McKesson, Suggested Talking Points and FAQs Regarding Decision to Significantly Reduce Thresholds (n.d.).

[130] *See* Email from David Graziano to Melenie Petropoulos (Dec. 23, 2013, 2:03 PM); Email from Stephen Schmidt to Melenie Petropoulos (Jan. 27, 2014).

sixteen as suspicious.[131] The DEA and DOJ began investigating McKesson again in 2013 and quickly discovered that McKesson had developed a policy of not reporting suspicious orders. As a result, there was a "nationwide" and "systemic" failure of McKesson to report suspicious orders and otherwise maintain effective controls against diversion.

583. The egregiousness of McKesson's failure to report suspicious orders is shown supported by the quantity of orders McKesson did report as suspicious once it finally decided to start fulfilling its reporting obligation. McKesson reported almost no suspicious orders of opioids from 2008 to 2013, but in 2015, McKesson reported a total of 230,000 suspicious controlled substance orders nationally.[132] Hundreds of thousands of orders did not suddenly become suspicious overnight. They had always been suspicious and simply were not reported.

584. In fact, the term "suspicious" when it came to controlled substances was taboo within the company. When McKesson's CSMP was created in 2008, it advised employees to "[r]efrain from using the word 'suspicious' in communications"' because "[o]nce McKesson deems an order and/or customer suspicious, McKesson is required to act. This means that all controlled substances sales to that customer must cease and the DEA must be notified." This passage demonstrates that McKesson was both fully aware of its regulatory responsibilities and was determined to avoid them at all costs.

585. McKesson's CSMP was riddled with flaws and loopholes that rendered them substantially ineffective. Specifically, the CSMP at various points:

a. Directed that customers' monthly threshold limits be set by reference to customers' prior ordering volumes, without requiring investigation of those volumes' appropriateness, effectively building all prior diversion

[131] *McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs*, U.S. Dept. Just. (Jan. 17, 2017), https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders (hereinafter "McKesson Agrees to Pay").

[132] McKesson Board of Directors' Response to International Brotherhood of Teamsters 24 (n.d.).

activity into the company's future shipments of opioids to those customers;

b. Allowed customers to resolve investigations into orders in excess of their monthly threshold and into requests to increase monthly thresholds by self-reporting the answers to three yes or no questions, without requiring validation of those answers;

c. Failed to require key indicators of diversion as part of the company's due diligence of pharmacies, including but not limited to obtaining prescriber-level information;

d. Exempted some customers from scrutiny who consistently placed orders in excess of their threshold;

e. Alerted customers when they were nearing their monthly threshold limit for opioid products;

f. Failed to adequately design and operate a system to disclose suspicious orders to the DEA; and

g. Required little to no diligence on chain-pharmacy orders, so as to maintain these large customer accounts regardless of the consequences.

586. McKesson never required pharmacies to provide prescriber-level dispensing data when granting threshold increases or investigating suspicious orders. Moreover, when compliance staff did receive prescriber-level data and identified suspicions about particular pharmacies based on doctors for whom they filled prescriptions, the company lacked any system by which it could identify other pharmacies that filled prescriptions for the same physicians. McKesson deliberately blinded itself to that key data—resulting in continued shipments of opioids to many pharmacies that the company should have scrutinized due to the prevalence of suspicious prescribers whose prescriptions were being filled in those locations.

587. McKesson's lack of attention to its compliance and anti-diversion obligations is evidenced by the *de minimis* resources the company invested in regulatory staff. From 2008 to 2012, implementation of the CSMP for all McKesson pharmacy customers across the country was left to four regional Directors of Regulatory Affairs ("DRAs"). Each of these four DRAs—a

number that grew to six in 2012—was responsible for onboarding new pharmacy customers, reviewing and increasing thresholds, and conducting all due diligence for all of the pharmacies across their region, with no other dedicated regulatory staff.

588. Upon learning in 2008 that a competing distributor had increased its regulatory department to at least 30 employees, a DRA suggested that McKesson do that same, but no such position was created until five years later. The DRAs did not receive any designated regulatory staff to assist them until 2014, and the training eventually provided to that staff was inadequate to allow them to perform their jobs effectively.

589. In the absence of dedicated regulatory staff, McKesson assigned virtually all of its front-line compliance functions to operations and sales staff and administrative assistants with no experience with controlled-substance regulations, or indeed any corporate compliance experience at all. Though the operations and administrative staff reported to the DRA, these employees also often lacked prior experience in regulatory compliance. And sales staff reported to sales management and rarely interacted with compliance personnel at all.

590. McKesson provided minimal training to these operations, administrative, and sales personnel with respect to their roles in ensuring the company's compliance with state and federal controlled substances laws and regulations. Senior regulatory staff also did not do audits or even ask for feedback on the CSMP from these front-line sales personnel.

591. McKesson failed to provide any mechanism to ensure that these employees' responsibility and incentive to promote sales did not compromise their ability and/or willingness to perform their compliance-related functions when doing so could result in the loss of those sales. Even McKesson management recognized this inherent problem.

592. McKesson's under-resourced, under-qualified, and untrained staff routinely

bypassed critical procedures set forth in the CSMP and frequently failed to obtain and maintain the records called for by its CSMPs in the due-diligence files of its customers. For example, McKesson employees regularly failed to ensure completion of even the minimal, three-question form used to resolve inquiries into orders in excess of the customer's threshold.

593. When customers requested increases in their threshold allowance for opioid orders, McKesson routinely approved those increases within days, hours, or even minutes, before any independent, diligent investigation could possibly have been conducted, and without being provided any reasonable justification. On many occasions, McKesson uncritically and immediately accepted the most perfunctory explanations from its customers.

594. Even though McKesson's CSMP required it to keep records of each request for a threshold change, McKesson routinely failed to complete and maintain those records.

595. In the cases where McKesson's compliance staff did identify issues with a particular pharmacy, the company lacked any mechanism to ensure the retention and sharing of information to identify other customers with related red flags. For example, when McKesson identified suspicions about particular pharmacies based on doctors for whom they filled prescriptions, the company lacked any system by which it could identify other pharmacies that filled prescriptions for the same physician. McKesson's head of compliance had explicitly recognized this problem—but the company did nothing to remedy this key failure in its compliance system.

596. Even when McKesson actually did identify customers' obvious red flags, it frequently failed to implement suspensions or terminations.

597. In those few cases in which McKesson did block customers' orders and report them as suspicious to the DEA, McKesson routinely took no steps to suspend or terminate those

customers pending further investigation and instead simply allowed them to continue receiving their threshold amount of opioids month after month thereafter, regardless of whether the customer continued to make additional suspicious orders.

598. For example, in New York between 2011 and 2017, McKesson submitted twelve or more opioid-related suspicious order reports ("SORs") for at least one year for 245 distinct pharmacies, representing one opioid-related SOR every month for more than ten percent of its pharmacies in the state. For 133 of these pharmacies, McKesson submitted opioid-related SORs roughly twice a month for a full year. During the first year in which McKesson sent at least two opioid-related SORs per month, those pharmacies exhibited several telltale red flags.

599. Specifically, more than half of those pharmacies: (a) exceeded the 90th percentile in the (entire) state in terms of volume of oxycodone shipped; (b) exceeded the 90th percentile in the (entire) state in terms of number of oxycodone orders; and (c) filled over one hundred opioid prescriptions in a year by one or more prescribers later indicted or convicted by law enforcement of medically unnecessary prescribing, opioid diversion, or related crimes.

600. Following the first year in which McKesson submitted 24 or more opioid-related SORs for a year, McKesson continued to ship to these pharmacies, on average, for nearly three years. In fact, as of 2018, it appeared that McKesson was still shipping to 116 of these pharmacies, or 77% of the group.

601. Moreover, as of 2018, 67% of these pharmacies had filled prescriptions by one or more prescribers later indicted or convicted of opioid-related crimes. Indeed, some of these pharmacies had a majority of their opioid prescriptions written by prescribers who were later indicted or convicted.

602. Even worse than its record in dealing with pharmacies that McKesson did identify

as placing suspicious orders is its pattern of failing to even identify and block as suspicious any orders at all for pharmacies that persistently displayed red flags of diversion.

603. These failures extended to the highest levels of the company. As revealed in an action on behalf of McKesson's shareholders, the company's records show that the Company's Audit Committee failed to monitor McKesson's information reporting system to assess the state of the Company's compliance with the CSA and McKesson's 2008 Settlements. The records show that in October 2008, the Audit Committee had an initial discussion of the 2008 Settlements and results of internal auditing, which revealed glaring omissions, specifically:

a. some customers had "not yet been assigned thresholds in the system to flag large shipments of controlled substances for review";

b. "[d]ocumentation evidencing new customer due diligence was incomplete";

c. "documentation supporting the company's decision to change thresholds for existing customers was also incomplete"; and

d. Internal Audit "identified opportunities to enhance the Standard Operating Procedures."

604. Yet, instead of correcting these deficiencies, for a period of more than four years, the Audit Committee failed to address the CSMP or perform any more audits of McKesson's compliance with the CSA or the 2008 Settlements, the shareholder action's description of McKesson's internal documents reveals. During that period of time, McKesson's Audit Committee failed to inquire whether the Company was in compliance with obligations set forth in those agreements and with the controlled substances regulations more generally. It was only in January 2013 that the Audit Committee received an Internal Audit report touching on these issues.

605. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement]," as a DEA official working on the case noted. Quite the opposite, "their bad acts

continued and escalated to a level of egregiousness not seen before."[133]

606. After renewed investigations by the DEA and DOJ beginning in late 2013, McKesson began to try and tighten up its SOM policies. Included within those efforts was the threshold-reduction initiative wherein McKesson reduced the oxycodone thresholds for most customers, which ultimately resulted in a total threshold reduction for oxycodone of 42 million doses per month.[134]

607. Then in 2013, McKesson began to report every order placed in excess of a customer's threshold as a suspicious order. In 2015, for example, McKesson provided the DEA with over 230,000 suspicious order reports, or over 630 per day. McKesson's automatic submission of every order in excess of a threshold without any review thereby shifted the burden to the DEA to determine whether the order was in fact suspicious. Indeed, McKesson was well aware that this was not an adequate system to disclose suspicious orders to the DEA, as McKesson had been previously told that "inundating local DEA office[s]" was not useful.

608. McKesson also began working with a consulting company named Analysis Group (AGI) in 2014 to create a new SOM policy. AGI and McKesson tinkered around with some advanced analytics over the next couple of years until finally settling into a new analytics-based program in 2017. Under this new system, McKesson established two separate thresholds: the benchmark threshold and the same-customer threshold. The lower of these two thresholds was binding on the customer as their operative threshold. The same-customer threshold is simply a threshold created based on the customer order history for the product in question. That threshold changes monthly as a new average is established for the customer. The benchmark threshold is

[133] Hijacked, *supra*.
[134] Hartle Email, *supra*. Threshold Reduction Report, *supra*.

established by weighing factors such as the size of the pharmacy and typical usage for the geographic region whether the pharmacy is located. Orders exceeding these thresholds are blocked and reported to DEA.

b. McKesson Was Put on Notice of its Wrongful Conduct.

609. In late 2005, DEA began investigating McKesson for filling large quantities of hydrocodone and oxycodone orders for rogue internet pharmacies. In January 2006, DEA notified McKesson that it had identified more than 2 million doses of hydrocodone delivered by McKesson to several rogue internet pharmacies during a three-week period. Importantly, during discussions with DEA, McKesson conceded that these extremely large orders were not flagged, in part, because McKesson did not track the sale of generic drugs for suspicious order monitoring purposes under that system.[135]

610. The violations at issue were as egregious as they were widespread. For example, from January 2005 to October 2006 McKesson delivered over 3 million doses of hydrocodone to a single small pharmacy in Baltimore, Maryland while also failing to report any of the orders from that pharmacy as suspicious. In a single month, McKesson delivered more than 2 million doses of hydrocodone to seven pharmacies in the Tampa area and failed to report any orders from those pharmacies as suspicious. Over a several-month period in 2007, McKesson delivered 2.6 million doses of hydrocodone to two Texas pharmacies while failing to report any orders from those pharmacies as suspicious.[136]

611. These excessive and suspicious purchases ultimately led to DEA seeking a show cause order against the distribution center supplying these pills. McKesson ultimately resolved

[135] Memorandum from Michael Mapes to Joseph Rannazzisi (Jan 23, 2006).

[136] Settlement and Administrative Memorandum of Agreement (May 2, 2008) (hereinafter, "McKesson 2008 Settlement").

these violations as part of a 2008 settlement.[137]

612. On May 2, 2008, McKesson agreed to pay more than $13 million in civil penalties for filling hundreds of suspicious opioid orders. McKesson also entered into an Administrative Memorandum of Agreement with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program."[138]

613. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the future," including specific measures delineated in a "Compliance Addendum" to the Settlement.[139]

614. Despite this promise, McKesson paid $150 million in 2017 to resolve another investigation into its violations of the CSA in California, Colorado, Florida, Illinois, Massachusetts, Michigan, Missouri, Kentucky, Nebraska, New Jersey, Ohio, Washington, West Virginia, and Wisconsin. In this investigation, the DEA and DOJ concluded that McKesson's desire for increased sales and retaining its customers overrode its obligations to report suspicious orders and jeopardized the health and safety of people around the country. Among other things, the investigation revealed that McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that, in a five-year period, it filled more than 1.6 million orders, but reported just 16 orders as suspicious - all from a single consumer.[140] Even more troublingly, the investigators found that McKesson's distribution centers "were supplying

[137] *Id.*
[138] *Id.*
[139] *Id.*
[140] *McKesson Agrees to Pay*, *supra* n. 131.

pharmacies that sold to criminal drug rings."[141]

615. In this settlement, McKesson admitted that, between January 1, 2009 and January 17, 2017, it "did not identify or report to 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." Despite its obligations under the 2008 settlement agreement, McKesson "failed to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations under the 2008 Agreements, the CSA, and 21 C.F.R. § 1301.74(b)."[142]

616. McKesson further admitted that it had "distributed controlled substances to pharmacies even though those [McKesson] Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R. § 1306.04(a)." McKesson admitted that it had "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations."[143]

617. As part of the 2017 McKesson Settlement Agreement, McKesson agreed that its authority to distribute controlled substances from 12 distribution centers would be partially

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[141] Lenny Bernstein & Scott Higham, *'We Feel Like Our System Was Hijacked': DEA Agents Say Huge Opioid Case Ended with a Whimper*, Wash. Post (Dec. 17, 2017), https://www.washingtonpost.com/investigations/mckesson-dea-opioids-fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8-62589434a581_story.html (hereinafter "Hijacked").

[142] Settlement Agreement and Release (Jan. 5, 2017), https://www.justice.gov/opa/press-release/file/928471/download.

[143] *Id.* at 3, 4.

suspended for several years.[144] The overall sanctions to which McKesson submitted were the most severe ever imposed on a DEA-registered distributor.

618. As the *Washington Post* reported in 2017, DEA staff recommended a much larger penalty than the $150 million ultimately agreed to for McKesson's continued and renewed breach of its duties, as much as a billion dollars, and delicensing of certain facilities.[145] A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."

619. On December 17, 2017, CBS aired an episode of *60 Minutes* featuring Assistant Special Agent David Schiller, who described McKesson as a company that killed people for its own financial gain and blatantly ignored the CSA requirement to report suspicious orders:

> DAVID SCHILLER: If they would have stayed in compliance with their authority and held those that they're supplying the pills to, the epidemic would be nowhere near where it is right now. Nowhere near.
>
> * * *
>
> They had hundreds of thousands of suspicious orders they should have reported, and they didn't report any. There's not a day that goes by in the pharmaceutical world, in the McKesson world, in the distribution world, where there's not something suspicious. It happens every day.
>
> [INTERVIEWER:] And they had none.

[144] *Id.* at 3.
[145] Hijacked, *supra*.

> DAVID SCHILLER: They weren't reporting any. I mean, you have to understand that, nothing was suspicious?[146]

c. McKesson's Public Statements of Compliance

620. McKesson's public representations created the appearance that McKesson would secure its supply chain. These representations were false because McKesson failed to take reasonable steps to prevent opioid diversion in California.

621. McKesson publicly claims that its "customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process," creating the impression that McKesson uses this tracking to help prevent diversion.

622. McKesson has also publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[147]

623. As part of its 2008 settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the future"[148]

624. McKesson's public statements misled the public, including Plaintiffs, into believing that McKesson was taking effective steps to fight the opioid epidemic.

d. McKesson Actively Marketed Prescription Opioids.

625. McKesson and Cardinal promoted opioids for Allergan.

626. McKesson, Cardinal, and Cencora all helped market Janssen's opioids.

627. Purdue's savings program for OxyContin was administered by McKesson:

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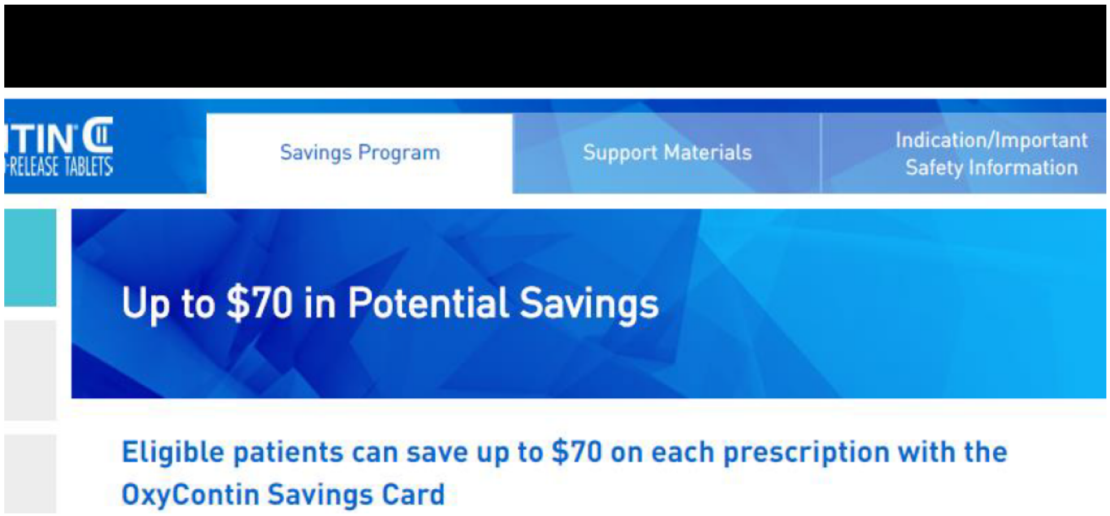
[146] Bill Whitaker, Interview with David Schiller, *60 Minutes* (aired Dec. 17, 2017).

[147] Scott Higham, et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post (Dec. 22, 2016), https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

[148] McKesson 2008 Settlement, *supra*.



4. Anda

628. Anda recklessly distributed opioids, as its SOMs program was deficiently designed and implemented in numerous ways.

629. Anda routinely shipped orders in excess of the monthly threshold it assigned customers, for which it was cited by the DEA.

630. Customer thresholds were routinely increased when a customer placed an order that exceeded the threshold. Examples include (a) obtaining a 3900% increase to 200,000 pills per opioid family per month; (b) approving an increase of 99,999% allowing a Nevada customer to "purchase up to unlimited dosage units per month;" and (c) approving a request from a Virginia customer to "make this location unlimited" and removing all thresholds and allowing unlimited purchases. Once adjusted upwards, the new limits would become permanent, even if the reason for the increase was temporary.

631. Anda repeatedly ignored red flags. When Walgreens' Jupiter, Florida distribution center of was shut down, Anda became Walgreens' exclusive secondary distributor of Schedule II Controlled Substances. Anda agreed to do so despite the fact that Anda had conducted an audit showing that many Walgreens stores had red flags of diversion.

632. Anda shipped suspicious orders without reporting them to the DEA. In fact, between 2007 and 2012, Anda did not reported a single suspicious order to the DEA.

633. Anda's policy was to clear suspicious orders for a number of standard reasons that did not actually involve investigation. The list of acceptable reasons suspicious orders could be cleared was vague, allowing clearance for just about any reason. When the DEA told Anda in 2011 that it should start an onsite inspection program, Anda never did. At that time, the DEA told Anda that its distributions were a "mess," citing a problem sales representative and many problem pharmacies.

634. Anda's compliance department was severely understaffed. Anda's compliance program had just 6 employees as compared to the 216 employees in the Sales Department. This means that each compliance officer would have to review 722 suspicious orders per month to keep up with the workload. Anda's own documents evidence its failed SOM program –in 2011 Anda had 9,624 customers without appropriate due diligence materials to whom Anda was still shipping opioids.

635. Anda's failures with respect to its SOM program are all the more egregious because it knew of the propensity for opioids to be abused and knew that it had an obligation to take "reasonable measures" to identify suspicious orders and implement procedures to ensure that its opioids were not diverted for illicit use. Instead of focusing on preventing diversion, Anda focused on sales. Anda promoted various opioids to increase its sales numbers while failing to implement an effective SOM program.

5. CVS

a. CVS' Deficient Internal Controls and SOM Systems

636. CVS's public statements indicate that it was aware of its responsibilities to monitor and report suspicious orders of controlled substances. The systems CVS uses for business purposes

could have easily been used to identify suspicious orders and practices.

637. The DEA explained red flags that CVS should be familiar with to carry outs its controlled substance responsibilities in a December 2010 meeting with CVS representatives and counsel. In order to ensure that controlled substances were dispensed for legitimate medical purposes, CVS would want to look out for red flags such as: many customers receiving the same combination of prescriptions (i.e., oxycodone and alprazolam); many customers receiving the same strength of controlled substances (i.e., 30 milligrams of oxycodone with 15 milligrams of oxycodone and 2 milligrams of alprazolam); many customers paying cash for their prescriptions; many customers with the same diagnosis codes written on their prescriptions (i.e., back pain, lower lumbar, neck pain, or knee pain); and individuals driving long distances to visit physicians and/or to fill prescriptions.[149]

638. For years after this meeting, the DEA repeatedly advised CVS of the need for a monitoring system and operating procedures to track, investigate, and report suspicious orders. The systems CVS put into place remained deficient. CVS did not report its first suspicious opioid order until February 29, 2012. Nearly two years later, on November 21, 2013, CVS had reported only 7 orders to the DEA across all of its distribution centers and pharmacies in the United States.

b. CVS Works with Other Defendants to Increase Profits and Disseminate False Information

639. As noted elsewhere, CVS worked with opioid manufacturers and trade groups to ensure false messaging surrounding the treatment of pain and the true addictive nature of opioids was consistent and geared to increase profits for all stakeholders.

[149] *See* Declaration of Joe Rannazzisi, *Holiday CVS, L.L.C. v. Holder*, 839 F. Supp. 2d 145 (D.D.C. 2012).

c. CVS's Partnership with Cardinal

640. In 2014, CVS entered into a 50/50 joint venture with Cardinal to create Red Oak Sourcing, LLC ("Red Oak"). Red Oak uses the combined generic purchasing power of CVS and Cardinal to negotiate with generic drug manufacturers, and its website touts its management of a "multi billion dollar pharmaceutical portfolio." To fund the venture, Cardinal would make quarterly payments of $25.6 *million* to CVS, and also would contribute additional funds if the joint venture reached certain milestones.

i. CVS Conspired with Cardinal and McKesson to Prevent SOM in CVS Retail Pharmacies.

641. CVS understood that in order for Cardinal and McKesson to meet their due diligence obligations under the CSA to monitor sales of controlled substances, they would need access to CVS's dispensing information. CVS refused to provide dispensing information about doctors or patients unless it was requested by the DEA.

642. Prior to 2013, Cardinal and McKesson performed due diligence differently for CVS pharmacies and stores than for other pharmacies. Instead of distributors contacting or visiting CVS stores, as with other pharmacies, they contacted CVS's loss prevention offices at corporate headquarters. This meant that CVS controlled all "due diligence investigations" of its opioid orders. CVS prevented distributors from independently determining appropriate order thresholds for opioids at CVS stores, reserving the right to adjust threshold quantities and percentages to values CVS deemed appropriate.

d. CVS Acquires Omnicare

643. Omnicare provides pharmacy-related services to long-term care facilities and other health care facilities throughout the United States. The DEA investigated Omnicare in 2007 for countrywide violations of the CSA that led to a $50 million settlement with the DEA in 2012 to

resolve allegations that it had dispensed controlled substances without prescriptions, failed to comply with emergency oral prescription requirements, and failed to maintain records of prescriptions for controlled substances.

644. In 2015, CVS Health Corp. acquired Omnicare knowing of these allegations.

645. Omnicare continued to violate the CSA after the acquisition. In May 2020, Omnicare paid $15.3 million to settle DEA charges that it violated the CSA in its handling of emergency prescriptions, controls over emergency kits, and processing of written prescriptions.

e. Multiple Enforcement Actions Against CVS Confirm Its Compliance Failures

646. CVS is a repeat offender; the company has paid fines totaling over $40 million as the result of a series of investigations by the DEA and the DOJ. It nonetheless treated these fines as the cost of doing business and allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require and violating their recordkeeping and dispensing obligations under the law.

647. As recently as March 2019, CVS entered into a $535,000 settlement with the U.S. Attorney's Office for the District of Rhode Island regarding allegations that its pharmacies in Rhode Island violated federal law "including by . . . in 39 instances between September 9, 2015 and June 18, 2017, filling a prescription for a Schedule II drug under circumstances . . . that the CVS pharmacist filling the prescription knew or had reason to know that the prescription in question was invalid or unauthorized . . . ."

648. In July 2017, CVS entered into a $5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep

and maintain accurate records of Schedule II, III, IV, and V controlled substances.[150]

649. In February 2016, CVS paid $8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA by filling prescriptions with no legitimate medical purpose.[151]

650. In October 2016, CVS paid $600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.[152]

651. In September 2016, CVS entered into a $795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.[153]

652. In June 2016, CVS agreed to pay the DOJ $3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances— mostly addictive painkillers—more than 500 times between 2011 and 2014.[154]

653. In August 2015, CVS entered into a $450,000 settlement with the U.S. Attorney's

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[150] Press Release, U.S. Attorney's Office E. Dist. of Cal., *CVS Pharmacy Inc. Pays $5M to Settle Alleged Violations of the Controlled Substance Act*, U.S. Dept. of Just. (July 11, 2017), https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violationscontrolled-substance-act.

[151] Press Release, U.S. Attorney's Office Dist. of Md., *United States Reaches $8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances*, U.S. Dept. of Just. (Feb. 12, 2016), https://www.justice.gov/usao-md/pr/united-states-reaches-8-millionsettlement-agreement-cvs-unlawful-distribution-controlled.

[152] Press Release, U.S. Attorney's Office Dist. of Conn., *CVS Pharmacy Pays $600,000 to Settle Controlled Substances Act Allegations*, U.S. Dept. of Just. (Oct. 20, 2016), https://www.justice.gov/usao-ct/pr/cvs-pharmacy-pays-600000-settle-controlled-substances-actallegations.

[153] Dialynn Dwyer, *CVS will pay $795,000, strengthen policies around dispensing opioids in agreement with state*, Boston.com (Sept. 1, 2016), https://www.boston.com/news/localnews/2016/09/01/cvs-will-pay-795000-strengthen-policies-around-dispensing-opioids-inagreement-with-state.

[154] Press Release, U.S. Attorney's Office Dist. of Mass., *CVS to Pay $3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions*, U.S. Dept. of Just. (June 30, 2016), https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filledfake-prescriptions.

Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.[155]

654. In May 2015, CVS agreed to pay a $22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."[156]

655. In September 2014, CVS agreed to pay $1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.[157]

656. In August 2013, CVS was fined $350,000 by the Oklahoma Pharmacy Board for

[155] Press Release, U.S. Attorney's Office Dist. of R.I., Drug Diversion Claims Against CVS Health Corp. Resolved With $450,000 Civil Settlement, U.S. Dept. of Just. (Aug. 10, 2015), https://www.justice.gov/usao-ri/pr/drug-diversion-claims-against-cvs-health-corp-resolved-450000-civil-settlement.

[156] Press Release, U.S. Attorney's Office M. Dist. of Fla., United States Reaches $22 Million Settlement Agreement with CVS For Unlawful Distribution of Controlled Substances, U.S. Dept. of Just. (May 13, 2015), https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-agreement-cvs-unlawful-distribution.

[157] Patrick Danner, H-E-B, CVS Fined Over Prescriptions, San Antonio Express-News (Sept. 5, 2014), http://www.expressnews.com/business/local/article/H-E-BCVSfined-over-prescriptions-5736554.php.

improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.[158]

657. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.[159]

6. Walgreens

a. Walgreens designed and implemented an entirely inadequate SOM System.

i. Walgreens Dragged Its Feet on Developing a SOMS Program, Instead Relying on After-the-Fact Reports of "Excessive" Orders While Ignoring Red Flags.

658. At least as early as 1998, and perhaps as early as 1988, Walgreens began to utilize a series of formulas to identify orders that Walgreens deemed to be suspicious based on the orders' extraordinary size. These orders were listed on a report called the Suspicious Control Drug Order report.

659. Walgreens used two different formulas: one formula from (at least) 1998 to 2007 and another from March 2007 through 2012. These formulas were alike in that they each utilized an average number based on historical orders, applied a three times multiplier to that base number, and then deemed certain orders which were greater than that number to be suspicious. Under the later formula, orders were only listed on the report as being suspicious if the orders exceeded the three times multiplier for two consecutive months in a given time period. Walgreens based this

[158] Andrew Knittle, *Oklahoma pharmacy board stays busy, hands out massive fines at times*, NewsOK (May 3, 2015), http://newsok.com/article/5415840.

[159] Press Release, U.S. Attorney's Office W. Dist. of Okla., CVS to Pay $11 Million To Settle Civil Penalty Claims Involving Violations of Controlled Substances Act, U.S. Dept. of Just. (Apr. 3, 2013), https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penaltyclaims-involving-violations-controlled.

second formula on the DEA's Chemical Handler's Manual's order monitoring system for listed chemicals.

660. The first variation on this formula was in place until March 2007, even though the DEA warned Walgreens that the "formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient," via a Letter of Admonition in May 2006. The letter cited Walgreens for controlled substances violations at its Perrysburg, Ohio Distribution Center, but highlighted problems that went far beyond that particular facility.

661. The DEA also reminded Walgreens that its suspicious ordering "formula should be based on (size, pattern, frequency)" though Walgreens failed to ever examine anything other than the size of an order. When Walgreens did update its program some ten months later, however, it still did not perform the size, pattern, and frequency analysis prescribed by the DEA, continuing to use a "three times" formula.

662. Even with its ample threshold, each Walgreens Suspicious Control Drug Order report could be thousands of pages or more in length.

663. Walgreens failed to perform any reasonable due diligence on the thousands of orders identified as "suspicious" on the Suspicious Control Drug Order reports, but instead shipped the orders without meaningful review.

664. Walgreens did not report the suspicious orders listed on the Suspicious Control Drug Order report until *after* the orders were already filled and shipped. The report was generated on a monthly, nationwide basis, directly contravening the regulatory requirement that suspicious orders be reported *when discovered.*[160] In some instances, months may have elapsed between an order's shipment and its subsequent reporting to the DEA, given that reporting was triggered only

[160] 21 C.F.R. § 1301.74(b).

after two consecutive months of exceeding the three times multiplier.

665. In September 2012, the DEA issued an immediate suspension order ("ISO") for Walgreens's Schedule II distribution center in Jupiter, Florida, finding Walgreens's distribution practices constituted an "imminent danger to the public health and safety" and were "inconsistent with the public interest." The DEA further found that the center failed to report suspicious drug orders from Walgreens's retail pharmacies, resulting in at least tens of thousands of violations. According to the DEA, "Notwithstanding the ample guidance available, Walgreens has failed to maintain an adequate suspicious order reporting system and as a result, has ignored readily identifiable orders and ordering patterns that, based on the information available throughout the Walgreens Corporation, should have been obvious signs of diversion occurring at [its] customer pharmacies."

666. In the ISO, the DEA also specifically considered the Suspicious Control Drug Order reports and made the following further findings of fact and conclusions of law regarding the reports and Walgreens's suspicious order monitoring system—applicable across Walgreens's operations:

> "[Walgreens's] practice with regard to suspicious order reporting was to send to the local DEA field office a monthly report labeled 'Suspicious Control Drug Orders.'"
>
> "[The Suspicious Control Drug] reports, consisting of nothing more than an aggregate of completed transactions, did not comply with the requirement to report suspicious orders as discovered, despite the title [Walgreens] attached to these reports."
>
> Upon review of an example of the Suspicious Control Drug Order report for December 2011, "[Walgreens's] suspicious order report for December 2011 appears to include suspicious orders placed by its customers for the past 6 months. The report for just suspicious orders of Schedule II drugs is 1712 pages and includes reports on approximately 836 pharmacies in more than a dozen states and Puerto Rico."
>
> Finding that the reports failed to appropriately consider the population and area being served by the pharmacy: "This report from the Jupiter [Florida] Distribution Center covers pharmacies in multiple states and Puerto Rico,

yet the average order and trigger amount is the same for a particular drug regardless of the pharmacy's location, the population it serves, or the number of other pharmacies in the area."

"As made clear in 21 CFR§ 1301.74(b), *Southwood,* and the December 27, 2007 letter to distributors from the Deputy Assistant Administrator for the Office of Diversion Control, suspicious orders are to be reported *as discovered,* not in a collection of monthly completed transactions. Moreover, commensurate with the obligation to identify and report suspicious orders as they are discovered is the obligation to conduct meaningful due diligence in an investigation of the customer and the particular order to resolve the suspicion and verify that the order is actually being used to fulfill legitimate medical needs. This analysis must take place *before* the order is shipped. No order identified as suspicious should be fulfilled until an assessment of the order's legitimacy is concluded."

"DEA's investigation of [Walgreens] ... revealed that Walgreens failed to detect and report suspicious orders by its pharmacy customers, in violation of 21 C.F.R. §1301.74(b). 21 C.F.R. § 1301.74(b)."

". . . DEA investigation of [Walgreens's] distribution practices and policies ... demonstrates that [Walgreens] has failed to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of 21 U.S.C. 823(b)(l and (e)(l). [Walgreens] failed to conduct adequate due diligence of its retail stores, including but not limited to, the six stores identified above, and continued to distribute large amounts of controlled substances to pharmacies that it knew or should have known were dispensing those controlled substances pursuant to prescriptions written for other than a legitimate medical purpose by practitioners acting outside the usual course of their professional practice. . . . [Walgreens has not] recognized and adequately reformed the systemic shortcomings discussed herein."

"[DEA's] concerns with [Walgreens'] distribution practices are not limited to the six Walgreens pharmacies [for which DEA suspended Walgreens' dispensing registration]."

b. Walgreens Knew Its After-the-Fact Excessive Purchase Reports Failed to Satisfy Its Obligations to Identify, Report, and Halt Suspicious Orders.

667. Walgreens knew its procedures were inadequate well before the 2012 ISO issued. In addition to the guidance described above, in 1988, the DEA specifically advised Walgreens that "[t]he submission of a monthly printout of after-the-fact sales does *not* relieve the registrant of the

responsibility of reporting excessive or suspicious orders." The DEA further advised Walgreens that, while "[a]n electronic data system may provide the means and mechanism for complying with the regulations . . . the system is not complete until the data is carefully reviewed and monitored by the registrant."

668. Despite this instruction, there is no evidence that Walgreens ever took any action related to the Suspicious Control Drug Order report besides generating it and mailing it out. Walgreens did not perform due diligence reviews on any of the orders listed on the Suspicious Control Drug Order report before shipment.

c. Walgreens Lacked Meaningful Additional Systems to Address the Failures in Its System of After-the-Fact Reporting of Certain Orders.

669. Walgreens nominally employed additional procedures within its distribution centers; however, these systems did not address the failings of the Suspicious Control Drug Order reports. These distribution center systems were not designed to detect suspicious orders of controlled substances, but rather were designed to detect typos or errors in order entry by the stores. Walgreens' Distribution Centers are akin to supply warehouses, were not designed to be a backstop to pharmacists or to assist in combatting controlled substance abuse, were not well equipped to ensure compliance, and did not have the ability to detect trends in local markets.

670. The only review of the orders identified by the DC-level procedures was calling the pharmacy to make sure the order had not been entered in error. This procedure was not intended to detect suspicious orders.

671. There is no evidence that any orders were ever reported as suspicious or halted as a result of Walgreens's DC-level policies. There is no evidence these procedures resulted in timely reporting of, due diligence on, or non-shipment of any order, including those listed as being "suspicious" on the Suspicious Control Drug Order reports.

672. In March 2008, Walgreens finally formed a five department "team" to "begin creating" a SOM program. The new SOM program was not piloted until more than a year later, in August 2009, and, even then, the pilot included orders from just seven stores. Not until September 2010 would the program, implemented in pieces and phases, be rolled out chain-wide. From that point it took several more years to fully implement.

673. Through 2012, Walgreens continued to populate the Suspicious Control Drug Order report with thousands of orders that exceeded Walgreens's "three times" test, showing that Walgreens's post-2009 SOM program did little to mitigate the extraordinary volume of controlled substances being shipped by Walgreens to its pharmacies.

d. Even as it Rolled Out its New SOM Program, Walgreens Left Significant Gaps and Loopholes in Place and Failed to Report and Perform Due Diligence on Orders It Flagged.

674. Walgreens did not prioritize compliance when instituting its SOM system. Walgreens generally viewed the SOM system as an inventory control mechanism rather than as a compliance control mechanism.

675. The SOM program Walgreens slowly developed had significant gaps or loopholes. For example, for the first few years, the program did not include orders that Walgreens stores placed to outside distributors, effectively permitting double dipping. It also did not prevent stores from placing an order to an outside vendor if the store attempted to place the order to a Walgreens DC, but was rejected by the new SOM system.

676. The new SOM system also allowed Walgreens stores to transfer controlled substances between stores and did not review these transfers (known as "interstores") within the SOM program, so that these transfers were not factored into SOM analytics. Additionally, stores could also place ad hoc orders for controlled substances outside of their normal order days and outside of the SOM analysis and limits. Walgreens could even remove a store entirely from SOM

review.

677. Further, although the new SOM algorithm identified more than 389 pages of suspicious orders per week as of August 2010, it failed to identify all the orders that Walgreens had marked as suspicious under its "three times" formulas and previously listed on its Suspicious Control Drug Order reports and submitted to the DEA "on a monthly basis." This "discrepancy" prompted an internal email from an employee in Walgreens's Loss Prevention Department, to Walgreens's Vice President, Distribution Centers and Logistics, suggesting that "the new system should be tested further and enhanced to provide broader coverage of controlled substance activity." The same e-mail stated that "we are not equipped to handle the 389+ pages of ADR4 [suspicious order monitoring] data which are compiled nationwide each week" and asked if his department had "a resource available" to assist. An email in response "recall[ed] the old paper report as being inches thick" and an instruction "in 1985 not to review or contact anyone on the data," and inquired, among other things, "[w]ho from your group has been reviewing the data collected for the past twenty-five years?" and "[a]t present is anyone doing any review on what would be considered suspicious quantities that are physically ordered and are releasing to stores?"

678. Starting in 2010, certain orders that exceeded store-based limits imposed by Walgreens's new SOM system were reduced to the store limit and shipped out. These orders were not reported to the DEA as suspicious, nor were they halted for review. The DEA found that Walgreens's policy of reducing and then filling and shipping suspicious orders without reporting them violated the law:

> This policy ignores the fact that the reporting requirement of 21 CFR § 1301.74(b) applies to *orders,* not shipments. A suspicious order placed by a customer pharmacy is made no less suspicious by application of a system designed to reduce or eliminate such orders prior to shipping. Construing the regulation this way defeats the essential purpose of the suspicious order requirement, which, as I stated in *Southwood,* is "to provide investigators in

> the field with information regarding potential illegal activity in an expeditious manner."

679. Walgreens's post-2009 SOM system flagged thousands of items per month as being suspicious. In July 2011 alone, as many as 20,699 orders for controlled substances were "marked suspicious" by the new algorithm. However, very few of these orders received anything more than nominal review. Meanwhile, Walgreens failed to adequately staff the program and to train its employees regarding its requirements.

680. Barbara Martin, one of the two employees primarily responsible for performing due diligence on suspicious orders in the 2009-2012 time period under the new SOM system, estimated that she spent somewhere between one and three hours per week reviewing suspicious orders, reviewing only between ten to one hundred of the thousands of orders that were deemed suspicious under the new algorithm. Walgreens did not provide her access to information about the area the store was serving, the order history for comparable stores, or any other data beyond the sales and order history for that store. If an order did not "make sense" to her based on those limited resources, she testified that she would call the store or district manager or pharmacy supervisor. She lacked authority to take "direct action" on an order.

681. One example of the sorts of information that was available and considered, but not acted upon, is found in emails from January 10-11, 2011 between Ms. Martin and a Walgreens Distribution Center ("DC") employee. The DC employee notes that "several stores that are ordering huge quantities of 682971 [30 mg oxycodone] on a regular basis." The DC employee continued, with respect to a single store, "we have shipped them 3271 bottles [of 30 mg oxycodone] between 12/1/10 and 1/10/11. I don't know how they can even house this many bottles to be honest. How do we go about checking the validity of these orders?" Ms. Martin noted that the store had average weekly sales of 36,200 dosage units, which was equal to 362 bottles per

week, stating, "I have no idea where these stores are getting this type of volume. The last pharmacy I was manager at did about 525 rxs/day and we sold about 500 tabs a month (5 bottles)." Ms. Martin then told the DC employee that she could call the district pharmacy supervisor to see if he "may be able to shed some light on the subject." Despite the fact that questions had been raised about this store ordering volume in January 2011, the very next month, Walgreens filled and shipped orders totaling another 285,800 dosage units of 30 milligram oxycodone to the same pharmacy, which was located in a town of less than 3,000 people. Approximately 18 months after this email exchange, Walgreens agreed to surrender its DEA registration for this same store that Ms. Martin ostensibly reviewed.

682. In the ISO regarding the Distribution Center, the DEA found that "none of these orders were reported to DEA as suspicious and all appear to have been shipped, without any further due diligence to verify their legitimacy." The DEA further found that Walgreens "failed to conduct any meaningful investigation or analysis to ensure that the massive amounts of commonly abused, highly addictive controlled substances being ordered by these pharmacies were not being diverted into other than legitimate channels." The DEA noted that "[Walgreens] has been unable to provide any files related to any effort to adequately verify the legitimacy of any particular order it shipped to its customer stores."

683. In February 2013, the DEA issued similar Subpoenas and Warrant of Inspection on the Perrysburg DC in Ohio. Walgreens employees made plans in preparation for the Perrysburg DC being "shut down" by the DEA, like the Jupiter DC. Within weeks of receiving the six subpoenas and warrant, Walgreens decided to "discontinue distribution of controlled substances from the Perrysburg facility" in order to "eliminate any immediate need for further DEA administrative action" regarding the Perrysburg facility.

684. Further, after the DEA began its investigation, Walgreens held meetings with and informed the DEA that it was implementing "new changes" to "enhance" its SOM program.

685. Even so, by November 2012, the program still did not halt the orders for due diligence evaluation or report the orders as suspicious. Further, at that time, the program began to automatically reduce orders that violated ceiling thresholds, but there is no evidence that these flagged or cut orders were reported as suspicious to the regulatory authorities.

686. As a result of the DEA investigation, Walgreens formed the Pharmaceutical Integrity ("Rx Integrity") Team in 2012, purportedly to make sure that those types of failures did not continue. However, the group's true role was protecting Walgreens's Distribution Centers and stores from losing their DEA licenses. The effort was only for show. Walgreens never provided the Rx Integrity group the resources needed to achieve due diligence on the large number of orders identified by Walgreen's SOM program.

687. In December 2012, the further enhanced SOM system flagged "14,000 items that the stores ordered across the chain that would have to be investigated" before they could be shipped. Walgreens did not have sufficient resources to timely review these orders. Walgreens noted that "[t]he DEA would view this as further failures of our internal processes, which could potentially result in additional pharmacies and distribution centers being subjected to regulatory actions and ultimately prohibited from handling controlled substances." At the time these 14,000 orders were flagged Walgreens Rx Integrity Team was comprised of fewer than five people. Even at its height, Rx Integrity had only eleven employees.

688. Walgreens admits to failures in its suspicious order monitoring prior to 2012. Comparing the 2013 SOM system to the previous system, one of Walgreens's Pharmaceutical Integrity Managers in August 2013 explained:

> The Controlled Substances Order Monitoring system now in place sets limits for each item based on the chain average for that item for stores of similar size. If a particular store fills more of this item than normal and needs additional product we would need to document the reason and increase via a CSO Override . . . . The purpose for this is to ensure we have performed adequate review before sending in additional inventory.
>
> The previous system would continue to send additional product to the store without limit or review which made possible the runaway growth of dispensing of products like Oxycodone, that played a roll [sic] in the DEAs investigation of Walgreens.

689. Yet, even in 2013, orders being flagged as suspicious for review before shipment were "a week old" before they made it to the review team, often "ha[d] already been shipped," and were not being reported.

690. Walgreens never equipped its distribution operations to properly monitor, report, and halt suspicious orders or otherwise effectively prevent diversion. When it became clear Walgreens would need to devote significant resources to achieve compliance, Walgreens chose instead to cease controlled substance distribution all together.

e. Walgreens Failed to Put in Place Adequate Policies to Guard Against Diversion at the Pharmacy Level.

691. Although Walgreens purported to have in place "Good Faith Dispensing" ("GFD") Policies for many years, these policies were insufficient to prevent diversion.

692. Despite knowing that prescribers could contribute to diversion, and having a separate and corresponding duty with respect to filling prescriptions, from at least 2006 through 2012, Walgreens's dispensing policies explicitly instructed pharmacists who "receive[] a questionable prescription" or otherwise were "unable to dispense a prescription in good faith" to "contact the prescriber" and, if "confirm[ed]" as "valid" by the prescriber, to then "process the prescription as normal." Further, though Walgreens's policies listed a handful of "questionable circumstances," such as "increased frequency of prescriptions for the same or similar controlled

drugs by one prescriber[,] for large numbers of patients [,] for quantities beyond those normally prescribed," it is unclear what, if any, resources Walgreens made available to its pharmacists for checking these vague criteria, which, in any event, became meaningless if a prescriber "confirm[ed]" the prescription as "valid" by calling the prescriber.

693. In 2012, Walgreens finally removed the "process the prescription as normal" language from its formal GFD policies, admitting that under the law "it is not enough to get confirmation that the prescriber wrote the prescription." However, Walgreens still failed to ensure it complied with its duties.

694. Upon information and belief, Walgreens failed to adequately train its pharmacists and pharmacy technicians on how to prevent diversion, including what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when other suspicious circumstances are present.

695. Indeed, during the course of a 2009 DEA investigation into dispensing noncompliance, Walgreens noted that it had "no training" for employees dispensing controlled substances. Meanwhile, Walgreens corporate officers turned a blind eye to these abuses. In fact, a Walgreens corporate attorney suggested, in reviewing the legitimacy of prescriptions coming from Florida, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens's attitude that profit outweighed compliance with the law or protecting public health.

696. Ultimately, in 2011, Walgreens and the DEA entered a Memorandum of Agreement regarding all "Walgreens . . . pharmacy locations registered with the DEA to dispense controlled substances," requiring Walgreens to implement significant nationwide controls lacking in its operations. Walgreens was required to create a nationwide "compliance program to detect and

prevent diversion of controlled substances ***as required by the … (CSA) and applicable DEA regulations***." Pursuant to the MOA, the "program shall include procedures to identify the common signs associated with the diversion of controlled substances including but not limited to, doctor-shopping and requests for early refills" as well as "routine and periodic training of all Walgreens walk-in, retail pharmacy employees responsible for dispensing controlled substances on the elements of the compliance program and their responsibilities under the CSA." Further, Walgreens was required to "implement and maintain policies and procedures to ensure that prescriptions for controlled substances are only dispensed to authorized individuals pursuant to federal and state law and regulations."

697. Walgreens would also make more promises in a 2013 Memorandum with the DEA related to failures that lead to the ISOs described above.

698. As with distribution, Walgreens failed to allocate anywhere near the necessary resources to dispensing compliance and supervision. Walgreens has approximately 26,000 pharmacists, each of whom may receive as many as 400-500 prescriptions a day. In 2013, however, Walgreens internally reported that its District Managers and Pharmacy Supervisors were "challenged to get into the stores" and in a 90-day period, more than a thousand stores did not receive a visit from the managers or supervisors. These supervisory personnel were assigned a "high number of stores" and their time was consumed with "people processes, business planning, market and district meetings," such that supervision in store was being handled informally by "community leaders" who have "limited formal authority."

699. A Walgreens internal audit performed after the 2013 DEA settlement confirms Walgreens's continued supervision and compliance failures. Among other failings, the audit team noted no formal monitoring program existed to confirm that pharmacies across the chain are

complying with controlled substance documentation and retention requirements, no monitoring outside of the deficient "store walk program" existed to monitor target drug good faith dispensing requirements, and employees were failing to timely complete Good Faith Dispensing training.

700. In 2015, Walgreens performed a "business continuity" audit of a random sample of approximately 2,400 pharmacies to determine whether Walgreens was "compliant with the policies/procedures put in place" regarding dispensing pursuant to Walgreens's agreement with the DEA. In Walgreens's own words, "Results were unfavorable." Fewer than 60% of stores were complying with TD GFD with respect to filled prescriptions, 1,160 stores did not have a single refused prescription, and an additional 1,182 stores had refused fewer than 25 prescriptions total in a nine-month period. Only 63 out of 2,400 pharmacies had refused 26 or more prescriptions during that same nine months in 2015.

f. Walgreens Assumed Greater Responsibility for Controlling Against Diversion by Discouraging Outside Vendors from Exercising Their Own Oversight.

701. The "Big Three" wholesalers, Cardinal, McKesson, and Cencora gave deferential treatment to chain pharmacies, such as Walgreens.

702. For example, in 2008, Cardinal prepared talking points for a NACDS Conference about its planned retail chain SOM program, making it clear that the program would "minimize the disruption" to retail chains. Cardinal also provided warnings to chain pharmacies, including Walgreens, that they were approaching thresholds so that the chains could avoid triggering SOM reporting by adjusting their ordering patterns. Such "early warnings" were so helpful to Walgreens that as of 2012 Walgreens adopted the concept for its own SOM system for self-distribution, noting internally that by "flagging the stores at 75%," it could "avoid cutting/reducing orders and subsequently not have to report a SOM to the DEA."

703. In 2013, Walgreens entered a ten-year agreement with Cencora.[161]

704. Cencora allowed Walgreens to "police their own orders and block any order to [Cencora] that would exceed [Cencora]'s threshold thus triggering a suspicious order being sent to DEA from [Cencora]." Additionally, when Cencora received orders from Walgreens "outside the expected usage," Walgreens and Cencora met to discuss adjusting thresholds or using "soft blocking." Contrary to DEA guidance and its own stated policy, Cencora also shared the threshold limits set by its "order monitoring program" with Walgreens and also provided Walgreens with weekly SOM statistics. Cencora generally would not take action on Walgreens orders that exceeded its thresholds without first talking to Walgreens.

g. Multiple Enforcement Actions Against Walgreens Confirm Its Compliance Failures

705. Walgreens has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to an $80 million settlement and admitted that it failed to uphold its obligations as a DEA registrant by negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black-market sales.[162]

706. Certain Walgreens' pharmacies allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.[163] They increased their orders over time, in some cases as much as 600% in the space of just two years. Yet Walgreens'

[161] As a part of its distribution agreement, Walgreens gained purchase rights to Cencora equity, allowing it to further participate in the prescription opioid shipment boom in America. Walgreens subsequently exercised these purchase rights, ultimately owning approximately 26% of Cencora. As part of the transaction, Walgreens has the ability to nominate up to two members of the Board of Directors of Cencora. Currently, Walgreen's Co-Chief Operating Officer sits on the Cencora Board of Directors.

[162] Press Release, U.S. Attorney's Office S. Dist. of Fla., *Walgreens Agrees* to *Pay* a *Record Settlement* pf *$80 Million* for *Civil Penalties Under* the *Controlled Substances Act*, U.S. Dept. of Just. (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-recordsettlement-80-million-civil-penalties-under-controlled.

[163] Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.*, Drug Enf't Admin. (Sept. 13, 2012).

corporate officers not only turned a blind eye, but provided pharmacists with incentives through a bonus program that compensated them based on the number of prescriptions filled at the pharmacy.

707. Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.[164]

708. The six retail pharmacies in Florida that received the suspicious drug shipments from the Jupiter Distribution Center, in turn, filled customer prescriptions that they knew or should have known were not for legitimate medical use.[165]

709. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).[166]

710. 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 patients' drug use patterns and didn't use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.[167]

7. Walmart

711. Walmart operated registered distribution centers to supply its own pharmacies with

[164] *Id.*
[165] *Id.*
[166] *Walgreens to pay $200,000 settlement for lapses with opioids*, APhA (Jan. 25, 2017), https://www.pharmacist.com/article/walgreens-pay-200000-settlement-lapses-opioids.
[167] *Id.*

controlled substances from the early 2000s until 2018, when it ceased self-distributing controlled substances.

712. Prior to 2011, Walmart had not designed any formal system to identify suspicious orders of controlled substances and, therefore, utterly failed to meet its statutory obligations.

713. Walmart has claimed that its hourly employees and associates monitored the orders they were filling at Walmart Distribution Centers for unusual size, pattern, and frequency. Typically, this "review" involved between 700 and 800 orders a day. Walmart has also claimed that these hourly associates were instructed to alert a supervisor if an order appeared unusual based on their experience and memory.

714. Walmart failed to provide any guidance to the associates as to what constitutes a "suspicious" order. Instead, Walmart has emphasized its associates' subjective judgment based on their "knowledge and experience" as distribution center employees. There is no evidence that any Walmart employee ever flagged an order as suspicious prior to 2011.

715. In 2011, Walmart purportedly implemented a "monitoring program" that would identify suspicious orders of controlled substances.

716. This monitoring program was insufficient because it flagged only very large orders. Specifically, it flagged weekly orders for controlled substances of 50 bottles (5,000 dosage units) or more and orders or more than 20 bottles (2,000 dosage units) that were 30% higher than a rolling four-week average for that item. Orders under 2,000 units per week were never flagged, and even if an order was more than 30% greater than the four-week average, it could not draw an alert unless it also was for more than 20 bottles.

717. Under this system, an alert did not mean Walmart would report the order or halt it pending necessary due diligence. To the contrary, upon information and belief, Walmart *never*

reported an order flagged by its monitoring program to the DEA as suspicious. In addition, rather than halting the order, Walmart would simply cut the order to the 50-bottle threshold and ship it.

718. This practice continued until mid-2012, when Walmart implemented "hard limits" on opioid orders. Under this approach, weekly orders of Oxycodone 30 mg were automatically reduced to 20 bottles. Still, Walmart failed to report orders over that threshold to the DEA.

719. During this time period, Walmart also monitored weekly orders of other controlled substances in quantities of more than 20 bottles. Specifically, an "Over 20 Report" was provided to the corporate office in the morning, and, if nothing was done by mid-afternoon, the orders were filled and shipped. Upon information and belief, there is no evidence of any order over 20 bottles was ever held or reviewed pursuant to this practice.

720. Cutting the order did not mean that the Walmart pharmacy would not receive the full supply. Walmart pharmacies also purchased opioids from outside suppliers.

721. Walmart knew that its monitoring program was insufficient to fulfill its obligation to prevent diversion. For example, in 2013, Walmart acknowledged in an internal presentation that it had not yet designed a compliant system for suspicious order identification, monitoring, and reporting. Walmart further acknowledged in 2014 that it had "no process in place" to comply with government regulations and that this created the "severe" risk of "financial or reputational impact to the company."

722. It was not until late 2014 that Walmart's written policies and procedures required orders of interest to be held and investigated.

723. In 2015, Walmart adjusted its suspicious order monitoring policy by implementing store-specific thresholds, which included minimum amounts, below which no orders were flagged under any circumstance, regardless of pattern or frequency. These minimums made the policy

deficient because it did not account for changes in ordering patterns. A pharmacy could, for example, go from ordering 10 dosage units of Oxycodone 10 mg per month to 7,999 per month without any order being flagged or reviewed.

724. When Walmart pharmacists suspected diversion based on an individual prescriber's prescribing practices, pharmacists could not refuse to fill all controlled-substance prescriptions from that provider. In fact, a 2011 document from Walmart Regulatory Affairs regarding the "Proper Prescriber-Patient Relationship" stated: "Blanket refusals of prescriptions are not allowed. A pharmacist must make an individual assessment of each prescription and determine that it was not issued based on a valid prescriber-patient relationship or a valid medical reason before refusing to fill."[168]

725. Until 2017, Walmart did not allow blanket refusals to fill. In addition, Walmart always had the ability to "centrally block" problematic prescribers across all Walmart and Sam's Club pharmacies, but did not establish a procedure to do so until 2017. In the "Practice Compliance" document describing this policy, Walmart admitted that it has information about prescribing practices that is not available to individual pharmacists:

> While pharmacists are in the best position to determine whether individual prescriptions are appropriate, *additional information may be obtained that is not available to our pharmacists*. Therefore, in certain situations, a prescriber may be identified whose prescribing practices raise concerns about prescribing controlled substances for legitimate medical purposes. After a thorough review, these additional insights may lead Walmart to place a block in Connexus on controlled substance prescriptions from these prescribers.

726. One internal email showed that in response to a question from a regional manager

[168] Jesse Eisinger & James Bandler, *Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment.*, ProPublica, (Mar. 25, 2020), https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment (hereinafter "Eisinger & Bandler").

in 2015 about documenting pharmacists' concerns about doctors believed to be operating pill mills, Walmart's director of Health and Wellness Practice Compliance, wrote, "We have not invested a great amount of effort in doing analysis on the data since the agreement [requiring such reporting] is virtually over. *Driving sales and patient awareness is a far better use of our Market Directors and Market manager's time*."[169]

727. Moreover, Walmart's pressure on pharmacists to fill more prescriptions quickly was at odds with a culture and practice of compliance. Incentive awards were tied to the number of prescriptions filled and amount of profit that the pharmacy generated. Upon information and belief, controlled substances were included in Walmart's pharmacy incentive program for most of the relevant time period. In addition, pharmacists were under constant pressure to increase the number of prescriptions they filled. As a result, upon information and belief, because of Walmart's drive for speed, pharmacists often did not have enough time to sufficiently review a prescription and conduct the appropriate due diligence. Because Wal-Mart also refused until 2017 to allow blanket refusals to fill or central blocks, Wal-Mart created a situation in which inappropriate dispensing of opioids was inevitable.

728. These systemic issues are reflected in numerous enforcement actions and investigations that demonstrate that Walmart put profits and sales ahead of compliance, its customers and their communities, and public safety. In 2009, for example, the DEA issued a Show Cause order seeking to revoke the registration of a Walmart pharmacy in California. The order alleged that the pharmacy:

> (1) improperly dispensed controlled substances to individuals based on purported prescriptions issued by physicians who were not licensed to practice medicine in California; (2) dispensed controlled substances . . . based on Internet prescriptions issued by physicians for other than a legitimate medical purpose and/or outside the usual course of professional

[169] *Id.*

> practice . . . ; and (3) dispensed controlled substances to individuals that [the pharmacy] knew or should have known were diverting the controlled substances.

729. The 2011 Memorandum of Agreement ("2011 MOA") arising out of that investigation stated that the DEA also learned that the same pharmacy was allegedly dispensing controlled substances based on prescriptions that lacked valid DEA numbers and allegedly refilling controlled-substances prescriptions too early.

730. Upon information and belief, the failures described in the 2011 MOA were not limited to California but reflected systemic failures at the corporate level. Indeed, the 2011 MOA, which required Walmart to maintain a "compliance program," stated that it applied "all current and future Walmart Pharmacy locations."

731. Although Walmart was supposed to revamp its dispensing compliance program, systemic failures continued. Walmart's corporate office not only failed to insist that Walmart implement adequate controls against diversion, it ignored concerns raised by Walmart pharmacists.

732. One internal document from 2015, for example, notes concerns from a Walmart pharmacist that "his leadership would not support his refusing to fill any 'legitimate' (written by a Dr) prescriptions and he stated that his current volume/staffing structure doesn't allow time for individual evaluation of prescriptions[.]" When this pharmacist refused to fill a customer's controlled substance prescription because the customer was attempting to fill it too soon, the Market Health & Wellness Director for that store complained to management that the pharmacist "sent a customer to a competitor," "expressed significant concern about how 'sending customers away' would impact the sales figures for the store," and insisted that "the store needs to fill every available prescription."

733. In October 2018, the U.S. Department of Justice ("DOJ") had evidence that Walmart pharmacies in Texas dispensed opioids that killed customers who overdosed on the drugs.

The investigation reportedly revealed that between 2011 and 2017, "Walmart pharmacists repeatedly filled prescriptions that they worried were not for legitimate medical purposes, including large doses of opioids and mixtures of drugs the DEA considered red flags for abuse."[170] They did so even though Walmart pharmacists in Texas, Maine, North Carolina, Massachusetts, Kansas and Washington all "raised alarms to the company's national compliance department about doctors."[171] Regarding one Texas doctor who was later convicted of illegal distribution of opioids, a Walmart pharmacist wrote: "*We are all concerned about our jobs and about filling for a pill mill doctor. . . Please help us.*"[172] Another described the same doctor as a "problem," a "liability for us," and a "risk that keeps [him] up at night," cautioning "[t]his is a serious situation."[173] Similarly, in September 2016, a Walmart pharmacist in Pennsylvania advised that a doctor was "under investigation by the DEA for what we believe is a pill mill operation" and that Rite Aid had begun refusing to fill his prescriptions, prompting prescriptions from this prescriber, which were "*almost solely narcotic and controlled prescriptions*" to double.[174] Still, Walmart adhered to its policy of requiring a case-by-case analysis of each prescription from the suspected pill mill presented to any Walmart pharmacy; it would not block the prescriber in its system or allow a "blanket" refusal to fill. Walmart was more concerned with potential sales than it was with preventing diversion.

734. More recently, Walmart reportedly claimed to be cooperating with a federal investigation and "taking action to fix its opioid dispensing practices."[175] In fact, however, Walmart subsequently "acknowledged that it halted its cooperation in mid-2018."[176]

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[170] *Id.*
[171] *Id.*
[172] *Id.*
[173] *Id.*
[174] *Id.*
[175] Eisinger and Bandler, *supra* n. 162.
[176] *Id.*

735. Federal prosecutors have also taken action against five Walmart and Sam's Club Pharmacies in Texas, alleging that they failed to maintain records required by the CSA. Specifically, "accountability audits did not match the drugs on hand, revealing major overages and shortages in the accountability of controlled substances, and there were missing invoices for controlled substances all in violation of the CSA."[177] A U.S. Attorney further explained that "[b]ecause of the pharmacies' lack of proper record keeping, a variety of Schedule II, III, IV and V controlled substances were lost or stolen and possibly diverted."[178]

E. Distributor Defendants Have Sought to Avoid and Have Misrepresented Their Compliance with Their Legal Duties.

736. Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under state law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding Distributor Defendants' compliance with their legal duties.

737. Because of Distributor Defendants' refusals to abide by their legal obligations, the DEA has repeatedly taken administrative action in an attempt to force compliance.

738. Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

739. For example, a Cardinal executive claimed that it uses "advanced analytics" to monitor its supply chain and represented that it was being "as effective and efficient as possible in

[177] Associated Press, *Wal-Mart Settles Drug Records Accusation*, (Jan 7, 2009), http://prev.dailyherald.com/story/?id=262762.

[178] *Id.*

constantly monitoring, identifying, and eliminating any outside criminal activity."[179] Given the sales volumes and the company's history of violations, this executive was either not telling the truth, or, if Cardinal had such a system, it ignored the results.

740. By misleading the public about the effectiveness of their controlled substance monitoring programs, Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that Plaintiffs now assert.

741. Distributor Defendants pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

742. The wrongful actions and omissions of Distributor Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiffs' allegations of Defendants' unlawful acts below.

743. Distributor Defendants have abandoned their duties imposed under state law, taken advantage of a lack of adequate law enforcement, and abused the privilege of distributing controlled substances.

744. National retail pharmacy chains earned enormous profits by flooding the country with prescription opioids.[180] They were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and

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[179] Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* WASHINGTON POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.a5f051722a7a.

[180] Plaintiffs' allegations of wrongdoing are directed at the National Retail Pharmacies, not the pharmacy industry, which in general serves a vital healthcare function in the United States.

dispensaries. Yet, instead of taking any meaningful action to stem the flow of opioids into communities, they continued to participate in and profit from the oversupply.

745. Through their data, National Retail Pharmacies had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country (including in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma). On information and belief, the National Retail Pharmacies also provided Defendants with data regarding, *inter alia*, individual doctors in exchange for rebates or other forms of consideration. The National Retail Pharmacies' data is a valuable resource that they could have used to help stop diversion, but failed to do so.

746. Each participant in the supply chain of opioid distribution, including the National Retail Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring and reporting suspicious activity.

747. Despite their legal obligations, the National Retail Pharmacies allowed widespread diversion to occur—and they did so knowingly. They knew they made money by making it easy for doctors to refer patients to them to get their opioid prescriptions filled.

748. Throughout the country and in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma in particular, the National Retail Pharmacies were or should have been aware of numerous red flags of potential suspicious activity and diversion. The National Retail Pharmacies' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have contributed significantly to the opioid crisis by enabling, and failing to prevent, the diversion of opioids.

V. DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF LEGAL DUTIES CAUSED THE HARM AND SUBSTANTIAL DAMAGE ALLEGED HEREIN.

749. As Marketing Defendants' efforts to expand the market for opioids increased so

have the rates of prescription and sale of their products—and the rates of opioid-related substance abuse, hospitalization, and death among the people of the United States. Distributor Defendants have continued to unlawfully ship these massive quantities of opioids.

750. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[181]

751. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions. [182]

752. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[183]

753. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths. [184]

754. The opioid epidemic has escalated with devastating effects: substantial opiate-related substance abuse, hospitalization, and death that goes hand in hand with Defendants' increased distribution of opioids.

755. The economic distress occurring in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma triggered a sense of hopelessness, which exacerbated the opioid

[181] *See* Richard C. Dart, et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241-248 (2015), doi: 10.1056/NEJMsa1406143, http://www.nejm.org/doi/full/10.1056/NEJMsa1406143.

[182] *See* Nora D. Volkow, M.D. & A. Thomas McLellan, M.D., *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, 374 N Engl J Med 1253-1263 (2016), DOI: 10.1056/NEJMra1507771, https://www.nejm.org/doi/full/10.1056/NEJMra1507771 (hereinafter "Volkow & McLellan").

[183] *See* Califf, et al., *supra* n. 45.

[184] *See* Press Release, Centers for Disease Control and Prevention, Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

crisis.

756. "Drug overdose deaths have risen fivefold over the past 2 decades."[185] Opioids were involved in more than 80,000 overdose deaths in 2021, which was 10 times the number of opioid overdose deaths in 1999.[186]

757. In 2014, there were 777 overdose deaths in Louisiana, and opioids were involved at a rate of 5.7 deaths per 100,000 persons.[187] In 2015, there were 861 overdose deaths in Louisiana, and opioids were involved at a rate of 6.3 deaths per 100,000 persons.[188] In 2016, there were 996 overdose deaths in Louisiana, and opioids were involved at a rate of 7.7 deaths per 100,000 persons.[189] In 2017, there were 1,108 overdose deaths in Louisiana, and opioids were involved at a rate of 9.3 deaths per 100,000 persons.[190]

758. In 2014, there were 336 overdose deaths in Mississippi, and opioids were involved at a rate of 3.9 deaths per 100,000 persons.[191] In 2015, there were 351 overdose deaths in Mississippi, and opioids were involved at a rate of 5.3 deaths per 100,000 persons.[192] In 2016, there were 352 overdose deaths in Mississippi, and opioids were involved at a rate of 6.2 deaths

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[185] Centers for Disease Control and Prevention, *Drug Overdose Deaths in the United States*, 2001–2021, *available at* https://www.cdc.gov/nchs/products/databriefs/db457.htm (last accessed Feb. 16, 2024).

[186] *See* Centers for Disease Control and Prevention, *Wide-ranging online data for epidemiologic research* (WONDER) (2022), available at http://wonder.cdc.gov (last accessed Feb. 16, 2024).

[187] *See* Centers for Disease Control and Prevention, *Drug Overdose Mortality by State*, *available at* https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm (last accessed Feb. 16, 2024) (hereinafter, "Drug Overdose Mortality by State"); KFF, *Opioid Overdose Death Rates and All Drug Overdose Death Rates per 100,000 Population (Age-Adjusted)*, *available at* https://www.kff.org/other/state-indicator/opioid-overdose-death-rates/?currentTimeframe=7&selectedRows=%7B%22states%22:%7B%22louisiana%22:%7B%7D,%22kansas%22:%7B%7D,%22mississippi%22:%7B%7D,%22north-carolina%22:%7B%7D,%22missouri%22:%7B%7D,%22oklahoma%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last accessed Feb. 16, 2024) (hereinafter, "Opioid Overdose Death Rates").

[188] *See id.*

[189] *See id.*

[190] *See id.*

[191] *See id.*

[192] *See id.*

per 100,000 persons.[193] The number of reported deaths due to overdose reached a total of 256 in 2017, with naloxone being administered 2,085 times by Emergency Medical Services.

759. Between 1999 and 2015, Texas experienced a three-fold increase in the number of opioid-related deaths.[194] During that period alone, more than 14,171 opioid-related deaths were reported in the State.[195] And the number of opioid-related deaths in Texas has continued to grow. In 2016, there were 1,375 opioid-related deaths in Texas, and the number jumped to 1,458 in 2017.[196] This number is even more stark when one considers that fatal overdoses may be undercounted in Texas.[197] These statistics prompted the Texas Legislature in 2017 to find "that deaths resulting from the use of opioids and other controlled substances constitute a public health crisis."[198] The Office of the Texas Attorney General, the Texas Health and Human Services Commission, and the Texas Department of State all concur, having created an informational website that states: "Prescription opioid painkiller misuse is a big problem . . . in the great State of Texas."[199]

760. From 1999 to 2016, more than 12,000 North Carolinians died from opioid related overdoses.[200] In 2015, there were 1,567 North Carolina overdose deaths, up 14.5 percent from

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[193] *See id*.

[194] Tex. Dep't of St. Health Servs., Texas Health Data: Opioid-Related Deaths in Texas, Ctr. For Health Statistics, http://healthdata.dshs.texas.gov/Opioids/Deaths (last accessed April 15, 2019).

[195] *Id*.

[196] Scholl L, Seth P, Kariisa M, Wilson N, Baldwin G., Drug and Opioid-Involved Overdose Deaths — United States, 2013–2017, MMWR Morb Mortal Wkly Rep 2019; 67:1419–1427. DOI: http://dx.doi.org/10.15585/mmwr.mm675152e1 (last accessed April 15, 2019).

[197] *See* Huber, M., We are Not Immune: How the Opioid Crisis is hitting Central Texas, Austin-American Statesman, June 8, 2018, https://www.statesman.com/news/20180609/we-are-not-immune-howopioid-crisis-is-hitting-central-texas (last accessed April 15, 2019).

[198] Tex. Occ. Code § 168.003 (effective September 1, 2017).

[199] Office of the Tex. Att General, the Texas Health and Human Services Commission, and the Texas Department of State, Dose of Reality: Raising Awareness to Help Save Lives, http://doseofreality.texas.gov (last accessed April 15, 2019).

[200] North Carolina Department of Health and Human Resources, Opioid Overdose Fact Sheet, https://files.nc.gov/ncdhhs/Opioid_Overdose_Factsheet_FINAL_06_27_17.pdf.

1,358 North Carolina overdose deaths in 2014.[201] 1,110, or 82%, of these overdoses involved opioids.[202] Overdose deaths rose to 1,956 in 2016 and reached 2,414 in 2017.[203]

761. According to data collected by the Kansas Department of Health and Environment, pharmaceutical opioid pain relievers are the leading cause of specific drug poisoning deaths and account for almost one-half of drug poisoning deaths.[204] From 2013 to 2015, the pharmaceutical opioid-related death rate increased by 28 percent.[205] During this same timeframe, deaths in Kansas caused by heroin increased 71 percent.[206] Heroin deaths in Kansas from 2012 to 2016 were up 329 percent compared to data collected from 2005 to 2009.[207] In 2017, there were 333 overdose deaths in Kansas, and opioids were involved at a rate of 5.1 deaths per 100,000 persons.[208]

762. In 2017, there were 952 overdose deaths involving opioids in Missouri, a rate of 16.5 deaths per 100,000 persons, which is higher than the national rate of 14.6 deaths per 100,000 persons.[209]

763. From 1994 to 2006, prescription opioid sales increased fourfold and from 2011 to 2015, more than 2,100 Oklahomans died of an unintentional prescription opioid overdose. In 2016,

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[201] *See Drug Overdose Death Data* at https://www.cdc.gov/drugoverdose/data/statedeaths.html.

[202] *See County-by-County Figures: The Opioid Crisis in North Carolina*, at https://governor.nc.gov/news/county-county-figures-opioid-crisis-north-carolina, (last visited October 9, 2017).

[203] *See* Drug Overdose Mortality by State, *supra* n. 187.

[204] "Kansas Trends in Drug Poisoning Deaths," Kansas Department of Health and Environment, http://www.preventoverdoseks.org/download/2016_KS_SER_Drug_Poisoning.pdf (last visited November 22, 2017).

[205] *Id*.

[206] *Id*.

[207] "5 Year Cumulative Count of Drug Poisoning Deaths for Selected Drugs Among Kansas Poisoning Deaths by County, 2012-2016", Kansas Department of Health and Environment, http://www.preventoverdoseks.org/download/County_Level_Drug_Overdose_Deaths_2005-2009.pdf (last visited November 22, 2017).

[208] *See* Drug Overdose Mortality by State, *supra* n. 187; Opioid Overdose Death Rates, *supra* n. 187.

[209] Missouri Opioid Study, National Institute of Drug Abuse ("NIDA"), March 2019, available at https://www.drugabuse.gov.

there were 813 overdose deaths, and opioids were involved at a rate of 11.6 deaths per 100,000 persons.[210]

764. The high rate of overdoses is due at least in part to the extremely high rates at which opioids have been prescribed in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma. For example, in 2016, Louisiana had an opioid prescription rate of 98.1 per 100 persons, which ranked fifth in the country.[211] Louisiana's rate of opioid prescriptions has consistently been among the highest in the country and the equivalent to more than one prescription for each resident. For example, that rate was 100.4 prescriptions per 100 people in 2015[212] and 108.9 in 2014.[213] It was even higher in earlier years at 112.4 prescriptions per 100 persons in 2013,[214] 113 in 2021,[215] 111.7 in 2011,[216] 112.6 prescriptions per 100 people in 2010,[217] 113 in 2009,[218] and 113.7 in 2008.[219] The Louisiana Commission on Preventing Opioid Abuse estimates that 108 to 122 opioid prescriptions are written per 100 persons in Louisiana per year, among the

[210] *See* Drug Overdose Mortality by State, *supra* n. 187; Opioid Overdose Death Rates, *supra* n. 187.

[211] Centers for Disease Control and Prevention, *U.S. State Prescribing Rates*, 2016, available at https://www.cdc.gov/drugoverdose/maps/rxstate2016.html.

[212] Centers for Disease Control and Prevention, *U.S. State Prescribing Rates*, 2015, available at https://www.cdc.gov/drugoverdose/maps/rxstate2015.html.

[213] Centers for Disease Control and Prevention, *U.S. State Prescribing Rates*, 2014, available at https://www.cdc.gov/drugoverdose/maps/rxstate2014.html.

[214] Centers for Disease Control and Prevention, *U.S. State Prescribing Rates*, 2013, available at https://www.cdc.gov/drugoverdose/maps/rxstate2013.html.

[215] Centers for Disease Control and Prevention, *U.S. State Prescribing Rates*, 2012, available at https://www.cdc.gov/drugoverdose/maps/rxstate2012.html.

[216] Centers for Disease Control and Prevention, *U.S. State Prescribing Rates*, 2011, available at https://www.cdc.gov/drugoverdose/maps/rxstate2011.html.

[217] Centers for Disease Control and Prevention, *U.S. State Prescribing Rates*, 2010, available at https://www.cdc.gov/drugoverdose/maps/rxstate2010.html.

[218] Centers for Disease Control and Prevention, *U.S. State Prescribing Rates*, 2009, available at https://www.cdc.gov/drugoverdose/maps/rxstate2009.html.

[219] Centers for Disease Control and Prevention, *U.S. State Prescribing Rates*, 2008, available at https://www.cdc.gov/drugoverdose/maps/rxstate2008.html.

highest in the country.[220] The rate of 122 prescriptions per 100 people over the six years from 2010 to 2015 was 39 percent higher than the national average.[221]

765. Overdose deaths are just one devastating consequence of opioid abuse. Addicts who are not killed by drug addiction experience a variety of health consequences (including non-fatal overdoses) and engage in a variety of risky drug-seeking behaviors. Widespread drug addiction imposes costs on the community including health care and substance abuse treatment costs—a substantial portion of which were provided by Plaintiffs—as well as other costs borne by the community, increased costs and burdens imposed on the criminal justice system and the costs associated with the lost productivity of addicts.[222]

766. The Substance Abuse and Mental Health Services Administration (SAMHSA) estimated that 121,000 Mississippians were in need of substance use disorder treatment in 2018.

767. According to a 2016 report by Castlight Health, Inc., four cities in Texas rank among the country's twenty-five worst cities for opioid abuse rates.[223]

768. In 2014, North Carolina experienced 913 deaths, 2,698 hospitalizations and 3,515 emergency department visits related to opioids.[224] During that same year, approximately 349,000 North Carolina residents reported misusing prescription pain relievers.[225] Data maintained by the

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[220] Louisiana Commission on Preventing Opioid Abuse, *The Opioid Epidemic: Evidence Based Strategies Legislative Report*, April 2017, at 20 (citations omitted), available at http://dhh.louisiana.gov/assets/docs/BehavioralHealth/Opioids/LCPOAFinalReportPkg20170331.pdf.

[221] *Id*. at 21.

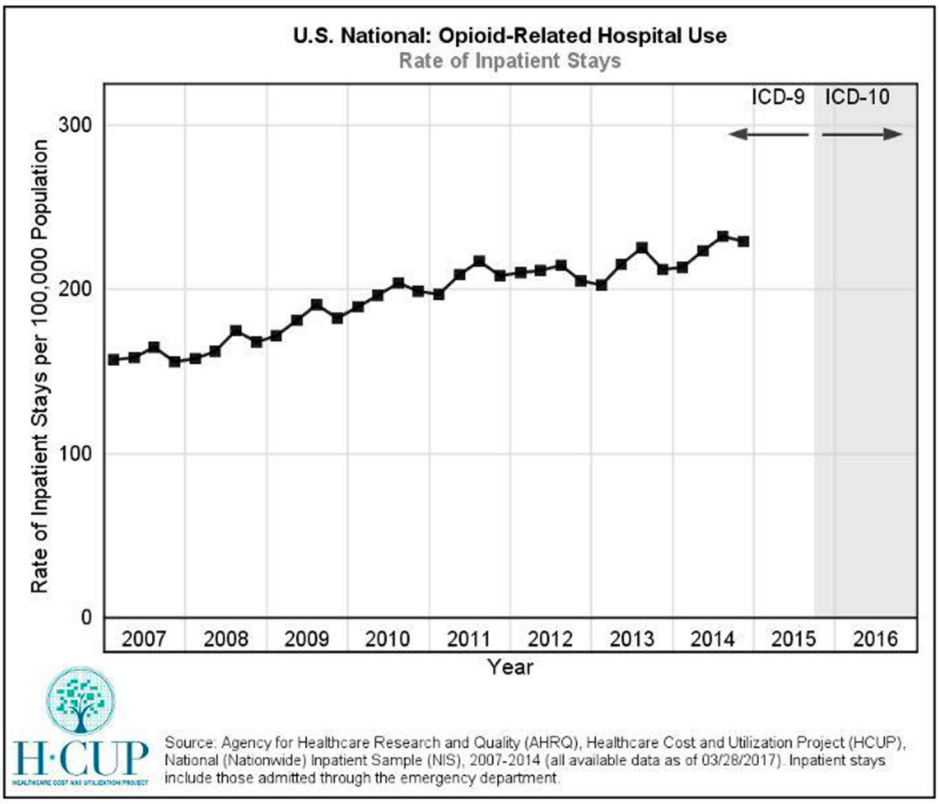
[222] Alex Brill & Scott Ganz, *The Geographic Variation in the Cost of the Opioid Crisis*, at 1-4, American Enter. Inst. (Mar. 20, 2018), *available at* https://www.aei.org/wp-content/uploads/2018/03/Geographic_Variation_in_Cost_of_Opioid_Crisis.pdf.

[223] Castlight Health, Inc., Research Report: The Opioid Crisis in America's Workforce, https://content.castlighthealth.com/rs/598-XVD-020/images/Castlight-Report-Opioid-Crisis-In-WorkforcewebC.PDF?aliId=eyJpIjoiOEtDZXhybHZNUzhaUUhYUCIsInQiOiJqejRucUdFdzNXcjJwYTY4cnVHQUxnPT0ifQ%253D%253D (last accessed May 1, 2019).

[224] *See* North Carolina's Opioid Action Plan 2017–2021, at https://files.nc.gov/ncdhhs/NC%20Opioid%20Action%20Plan%206-23-2017.pdf

[225] See *id*.

Agency for Healthcare Research and Quality for 2007 through 2016 document a sharp increase in opioid-related inpatient hospital stays in North Carolina. The annual rate of such stays per 100,000 population has risen substantially:



The rate of opioid-related Emergency Department visits increased 55% in North Carolina between 2009 and 2014.[226]

769. A study by the American Enterprise Institute concluded that, in 2015, Louisiana's total "cost per capita" resulting from the opioid crisis was $907, Mississippi's was $703, North Carolina's was $1,711, Kansas's was $745, Missouri's was $1,727, and Oklahoma's was

[226] *See* Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project, Statistical Brief #219, Opioid-Related Inpatient Stays and Emergency Department Visits by State, 2009–2014, https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.pdf, (last visited Oct. 25, 2017).

$1,330.[227]

770. From 2013 to 2015 there were 6,252 opioid-use-related treatment admissions in Louisiana.[228] The Louisiana Commission on Preventing Opioid Abuse has estimated that opioid abuse costs Louisiana $296 million a year in health care expenditures alone.[229]

771. Unintentional fatal drug overdoses cost North Carolinians $1.3 billion in 2015. North Carolina's Department of Health and Human Services estimates opioid related drug deaths cost $2.1 billion in 2016.[230] From 2011 to 2015, opioid overdose emergency department admissions increased 27%, and the administration of naloxone by EMS personnel increased 34%.[231]

772. In 2015, Missouri's total "cost per capita" resulting from the opioid crisis was $1,727, or approximately $10.3 billion total.[232] Missouri's state government estimates that the total cost of the opioid epidemic in Missouri for 2016 was $12.6 billion.[233]

773. Children have been especially vulnerable to the opioid epidemic. Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma have seen a substantial increase in opiate use, a significant increase in the number of babies born with neonatal abstinence syndrome (NAS), and an increase in blood-borne diseases from intravenous drug use, including

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[227] *See* Alex Brill & Scott Ganz, *The Geographic Variation in the Cost of the Opioid Crisis*, American Enter. Inst. (Mar. 20, 2018), *available at* https://www.aei.org/wp-content/uploads/2018/03/Geographic_Variation_in_Cost_of_Opioid_Crisis.pdf.

[228] Louisiana Department of Health, Opioid Abuse, Prevention, Treatment and Policy, Quick Facts (January 2017), available at http://ldh.la.gov/assets/opioid/OpioidAbsePrvntn_2017.pdf.

[229] Louisiana Commission on Preventing Opioid Abuse, The Opioid Epidemic: Evidence Based Strategies Legislative Report, April 2017, at 17, available at http://dhh.louisiana.gov/assets/docs/BehavioralHealth/Opioids/LCPOAFinalReportPkg20170331.pdf.

[230] *See* Seeking Community-Level Solutions to Opioid Epidemic, available at http://www.reflector.com/News/2017/09/26/Seeking-community-based-solutions-to-opioid-epidemic.html

[231] *See id*.

[232] *Id.* at 4, 5–6 (state data), 8–9 (county data).

[233] Missouri Opioid Data Factsheet, Missouri DHSS Bureau of Vital Statistics & Bureau of Health Care Analysis and Data Dissemination, 2017, available at https://health.mo.gov/data/opioids/.

hepatitis C and human immunodeficiency (HIV).

774. According to hospital data, from 2010 through 2015, there were 334 infants discharged from Mississippi hospitals with neonatal abstinence syndrome (NAS) related disorders.

775. In Texas, there were more than 1,300 cases of NAS/NOWS among Medicaid recipients in 2015 alone.[234] These infants will spend weeks in neonatal intensive care units while they painfully withdraw from the drugs—a process so painful that it traps many adults on opioids. Children are also injured by the removal from their homes due to opioid abuse and addiction. According to a report presented by the Texas House of Representatives' Select Committee on Opioids and Substance Abuse, the average hospital length of stay in Texas when NAS is involved is more than 20 days.[235]

776. From 2004 through 2015, the number of North Carolina hospitalizations associated with drug withdrawal in newborns increased by a staggering 902%.[236]

777. In Missouri, in 2016 alone, there were 2,112 reported cases of newborns diagnosed with NAS/NOWS.[237] This is a more than 4.5x increase from 461 NAS infants born in 2011 in Missouri.[238]

778. Statewide data from the DEA's Automation of Reports and Consolidated Orders

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[234] National Institute on Drug Abuse, Opioid-Related Overdose Deaths: Texas Opioid Summary, https://www.drugabuse.gov/opioid-summaries-by-state/texas-opioid-summary (last accessed Apr. 16, 2019).

[235] House Select Committee on Opioids and Substance Abuse, Interim Report to the 86th Texas Legislature, November 2018, at 38, https://house.texas.gov/_media/pdf/committees/reports/85interim/Interim-Report-Select-Committee-on-Opioids-Substance-Abuse-2018.pdf (last accessed May 21, 2019).

[236] *See* North Carolina's Opioid Action Plan 2017-2021, at https://files.nc.gov/ncdhhs/NC%20Opioid%20Action%20Plan%206-23-2017.pdf

[237] National Institute on Drug Abuse, Missouri Opioid Summary, (last updated March 2019), *available at* https://www.drugabuse.gov/opioid-summaries-by-state/missouri-opioid-summary.

[238] Missouri Department of Health and Senior Services, Bureau of Health Care Analysis and Data Dissemination, Neonatal Abstinence Syndrome (NAS) Infants Born in Missouri, available at https://health.mo.gov/data/opioids/pdf/nas-1.pdf.

System (ARCOS) database confirms that the Defendants distributed and dispensed substantial quantities of prescription opioids throughout Mississippi. Opioid distributors placed over 1.3 billion dosage units of these dangerous and addictive drugs into the State of Mississippi between 2006 and 2014. During 2017 alone, distributors flooded the State of Mississippi with 182,882,444 dosage units or nearly 61 opioid pills for every man, woman, and child in the State of Mississippi.

779. While Defendants have profited greatly from the increased sales of opioids, Mississippi citizens have borne the associated costs. As a single measure of that harm, opioids are by far the most commonly prescribed class of controlled substances in Mississippi. During 2017, over 3.3 million opioid prescriptions were dispensed in Mississippi, meaning over half of a million dosage units (e.g., pills) were dispensed every day. The rate of 110.5 opioid prescriptions per 100 persons is enough for each person in Mississippi to have an opioid prescription during 2017. In terms of dosage units, the rate was 6,119.1 opioid dosage units per 100 people - enough for each person in Mississippi to have a supply of 61 opioid dosage units during 2017 alone.

780. According to information made public from the DEA's ARCOS database through the Washington Post, 5,432,109,643 hydrocodone and oxycodone pills were funneled into Texas from 2006 to 2012.[239]

781. In 2012, North Carolina had an opioid prescription rate of 96.6 per 100 persons, which ranked thirteenth in the country (U.S. median rate: 82.5) and a benzodiazepine prescription rate of 45.3 per 100 persons which ranked fifteenth nationally (U.S. median rate: 37.6).[240] In 2014,

[239] Washington Post, *Drilling into the DEA's pain pill database, Texas*, https://www.washingtonpost.com/graphics/2019/investigations/dea-pain-pilldatabase/?utm_term=.b4847b9fff3b (last accessed July 25, 2019).

[240] *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.

7,717,711 prescriptions for opioids were dispensed in North Carolina.[241]

782. In 2012, Kansas had an opioid prescription rate of 93.8 per 100 persons, which ranked sixteenth in the country (U.S. median rate: 82.5) and a benzodiazepine prescription rate of 38.9 per 100 persons which ranked twenty-third nationally (U.S. median rate: 37.6).[242] From July to September 2017, 38,523,564 units of prescription opioids were dispensed to 274,260 Kansas patients, with approximately ten percent of these receiving more than 90 morphine milligram equivalent per day.[243] Hydrocodone, oxycodone, and tramadol were the most commonly dispensed prescription opioids.[244]

783. During the period from 2006 to 2014, opioid distributors shipped approximately 2,168,750,877 pills for distribution in Missouri.[245] That is enough pills for all 5,988,927 Missourian[246] to each have 362 opioid pills during this eight-year period. In 2017, enough opioid prescriptions were issued for every 71.8 persons out of 100 persons in Missouri, which is higher than the average rate in the U.S. of 58.7 prescriptions for every 100 persons.[247]

784. From 2006-2014, certain Defendants and their co-conspirators topped the supply chain lists for the number of oxycodone and hydrocodone opioid pills that were tracked entering

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[241] *See* North Carolina's Opioid Action Plan 2017-2021, at https://files.nc.gov/ncdhhs/NC%20Opioid%20Action%20Plan%206-23-2017.pdf

[242] *See* Paulozzi, M.D., et al., *supra* n. 240. 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.

[243] "Prescription Opioids in Kansas, July to September 2017 by Opioid and Year-Month", Kansas Department of Health and Environment, http://www.preventoverdoseks.org/download/KS_DDPI_Opioid_Trend_Data_Brief_1.pdf (last visited November 22, 2017).

[244] *Id*.

[245] Drilling into the DEA's pain pill database, Washington Post, Jan. 17, 2020, available at https://www.washingtonpost.com/graphics/2019/investigations/dea-pain-pill-database/.

[246] 2010 Demographic Profile Census, Missouri, U.S. Census Bureau, available at https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml?src=bkmk.

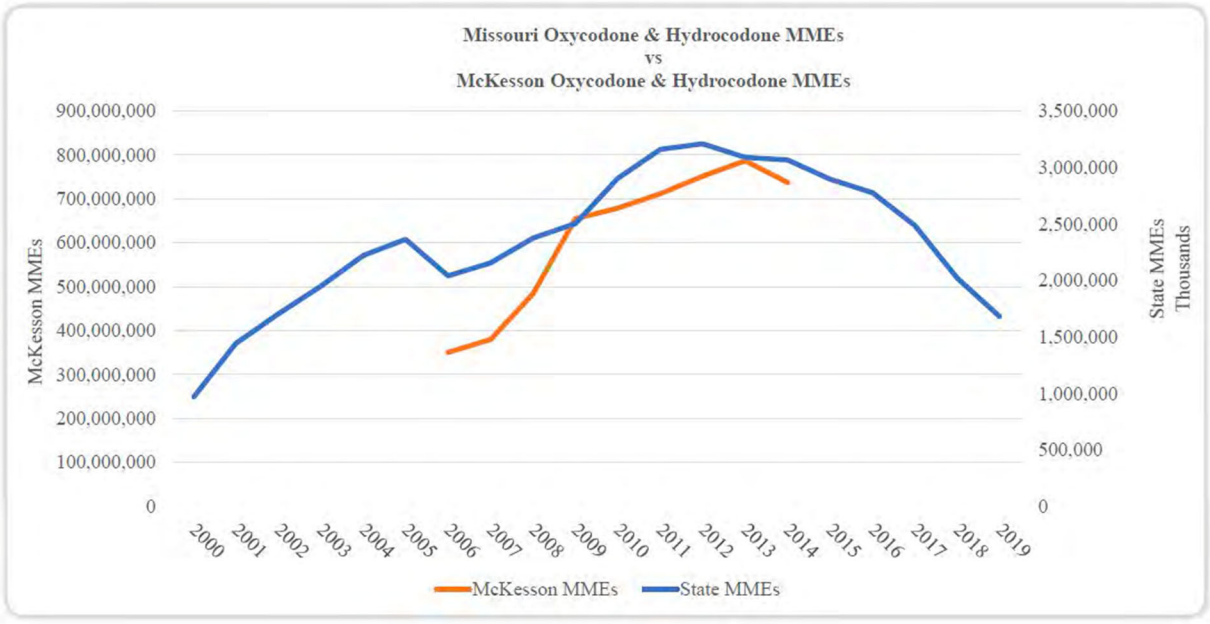
[247] Missouri Opioid Study, National Institute of Drug Abuse ("NIDA"), March 2019, available at https://www.drugabuse.gov.

Missouri: Walgreen Co. (434,751,920 pills), AmerisourceBergen Drug (326,552,585 pills), Wal-Mart (291,172,080 pills) and Cardinal Health (177,559,526 pills) SpecGx LLC (799,339,247 pills), Actavis Pharma, Inc. (714,339,247 pills), Par Pharmaceutical (324,154,474 pills) Amneal Pharmaceuticals LLC (123,437,600 pills), and Purdue Pharma LP (72,554,356 pills).[248] Three Walgreens locations each dispensed more than a million pills per year from 2006-2014, and were identified as three of the top five opioid pill distributors in Missouri: Walgreen Co., Festus (8,232,170 pills); Walgreen Co., Farmington (7,753,540 pills); and Walgreen Co., Springfield (7,644,860 pills).[249] During those same years, 2006 to 2014, Defendants supplied to Missourians, and correspondingly observed, increased availability of oxycodone and hydrocodone. *See* Figure No. 1, Missouri Oxycodone & Hydrocodone MMEs vs. McKesson Oxycodone & Hydrocodone MMEs:[250]

[248] Drilling into the DEA's pain pill database, Washington Post, Jan. 17, 2020, available at https://www.washingtonpost.com/graphics/2019/investigations/dea-pain-pill-database/.

[249] *Id*.

[250] Morphine Milligram Equivalents, or MMEs, means the amount of milligrams of morphine an opioid dose is equal to when prescribed. Calculating MME accounts for differences in opioid drug type and strength. U.S. Food & Drug Administration, Morphine Milligram Equivalents (MMEs): Current Applications and Knowledge Gaps, Research Opportunities, and Future Directions, June 7–8, 2021.



785. In 2015, over 326 million opioid pills were dispensed to Oklahoma residents, enough for every adult to have 110 pills.

786. Because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, like heroin, the massive distribution of opioids by Defendants has caused the opioid epidemic to include heroin addiction, abuse, and death.

787. Defendants repeatedly and purposefully breached their duties under federal and state law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes and the foreseeable, inevitable financial burdens imposed on and incurred by hospitals and other health care providers.

A. The Impact of Opioids on Plaintiffs' Hospitals

788. Hospitals—legally and morally—are compelled to act and treat patients with opioid-related conditions[251] and, as a result, are directly and monetarily damaged by the opioid

[251] "Opioid-related conditions" include but are not limited to opioid addiction and overdose; psychiatric and mental health treatment; NAS or other opioid-related conditions of newborns; illnesses associated with opioid use, such as endocarditis, hepatitis-C, and HIV; surgical procedures that are more

epidemic. Acute care hospitals have incurred and will continue to incur millions of dollars in losses for their treatment obligations in connection with opioid use disordered (OUD) patients.

789. Defendants' unlawful marketing, distribution, and sale of opioids (including to the Hospital Plaintiffs) has caused the Hospital Plaintiffs to expend more resources in the treatment of OUD patients, in comparison to non-OUD patients with similar diagnoses. When comparing the OUD patient cohort with the non-OUD patient cohort, with similar codes for diagnoses and treatments, the Hospitals post more charges with fewer payments realized (including from private payers) for the OUD cohort than the non-OUD cohort. These operational losses coincide with the increase of opioids circulating in the communities and increases in the OUD patient population.

790. Defendants' role in the opioid epidemic, as alleged herein, is placing an increasing strain on the hospitals in Louisiana's, Mississippi's, Texas's, North Carolina's, Kansas's, Missouri's, and Oklahoma's overburdened health care systems.

791. Nationally, adult hospitalizations due substantially to opioid-related medical conditions nearly doubled from 2000 to 2012.[252] From 2005 to 2014, also nationally, emergency department visits exhibited a 99.4% cumulative increase.[253]

792. The rates of opioid abuse during pregnancy have increased nationally and in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma. Indeed, in 2006, it was reported in the Journal of Opioid Management that "use of opioids may be safe for the

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complex and expensive due to opioid addiction; illnesses or conditions claimed by a person with opioid addiction in order to obtain an opioid prescription; and any other condition identified in Plaintiffs' records as related to opioid use and abuse.

[252] Owens PL, Barrett ML, Weiss AJ, Washington RE, Kronick R. Hospital Inpatient Utilization Related to Opioid Overuse Among Adults, 1993–2012. *HCUP Statistical Brief #177*. Agency for Healthcare Research and Quality, Rockville, MD 2014, https://hcup-us.ahrq.gov/reports/statbriefs/sb177-Hospitalizations-for-Opioid-Overuse.jsp.

[253] Weiss AJ, Elixhauser A, Barrett ML, Steiner CA, Bailey MK, O'Malley L. *Opioid-related inpatient stays and emergency department visits by state, 2009–2014. HCUP Statistical Brief #219.* Rockville, MD: Agency for Healthcare Research and Quality.

neonate if medically prescribed." Nationally, there has been an almost four-fold increase in admissions to NICUs for NAS from 2004 to 2012: from seven cases per 1,000 NICU admissions in 2004, to 27 cases per 1,000 NICU admissions in 2013.[254]

793. The misrepresentations of Marketing Defendants, Distributor Defendants, and others prompted health care providers in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through their marketing, Marketing and Distributor Defendants overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks, benefits, and sustainability of long-term opioid use. These harms were compounded by supplying opioids without regard for adequate controls, and beyond what the market could safely bear. Defendants disregard for the law, and for the residents of Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma, caused the surplus of opioids to be diverted and used illicitly. The excessive quantities of opioids that flooded into these States as a result of Defendants' wrongful conduct has devastated communities across Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma, including the communities served by Plaintiffs.

794. Hospitals are integral to the solution to the opioid epidemic, because they can "aid in the proper treatment of postoperative pain while also helping to combat a nationwide epidemic."[255] Defendants' wrongful conduct has increased the OUD patient encounters the Hospitals must accept, even to their own operational detriment. The Hospital Plaintiffs presently lack adequate resources to clean up the pill spill caused by Defendants. Indeed, by creating and fueling the opioid epidemic, Defendants have imposed a burden on the Hospitals' operations.

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[254] Veeral N. Tolier, et al., *Increasing incidence of the neonatal abstinence syndrome in U.S. neonatal ICUs*. N. ENGL. J. MED. 372(22):2118-26 (2015). https://pubmed.ncbi.nlm.nih.gov/25913111/.

[255] Opioid Exit Plan, *supra* n. 48.

795. During admission, hospital professionals routinely consult with the patient to assess which medications the patient is taking at home. But, due to Defendants' conduct, hospitals can no longer trust patients to self-report their prescriptions and often spend additional time eliciting a prescription and health history for an OUD patient.

796. Before discharge, hospital professionals "obtain the list of planned outpatient prescriptions and perform a counseling session on how to safely and effectively control postoperative pain."[256] The hospitals' efforts to provide meaningful counseling is subverted by Defendants' practices described in the Complaint, pursuant to which Defendants have disseminated misinformation throughout all levels of the marketplace and fostered increased demand for their products.

797. Defendants knew that federal and state law require hospitals to admit and treat opioid-addicted patients. Defendants relied on the Hospital Plaintiffs to provide a safety net to prevent overdose deaths and treat health consequences arising from opioid addictions and depended on Hospitals themselves to mitigate the health consequences of their illegal activities. In 2021, there were approximately 502,563 opioid-related ED visits (excluding visits related to fentanyl or heroin use).[257] Hospitals bear an enormous burden in providing care, as insurance covers only a portion of the cost.

798. Hospitals must treat opioid users who present in need of emergency care, a fact of which Defendants were well aware. This obligation arises under the Emergency Medical Treatment and Active Labor Act ("EMTALA"), 42 U.S.C. § 1395dd, which requires hospital emergency departments that accept payments from Medicare to provide care to anyone seeking

[256] *Id.*

[257] Substance Abuse and Mental Health Services Administration, "Findings from Drug-Related Emergency Department Visits, 2021" (Dec. 2022), available at https://store.samhsa.gov/sites/default/files/pep22-07-03-002.pdf.

treatment for a medical condition, regardless of citizenship, legal status, or ability to pay. Under EMTALA, participating hospitals may not transfer or discharge patients needing emergency treatment except with the informed consent or stabilization of the patient or when their condition requires transfer to a hospital better equipped to administer the treatment. EMTALA prevents the Hospitals from turning away the OUD patients.

799. This is no small burden. In 2021, there were approximately 502,563 opioid-related ED visits (excluding visits related to fentanyl or heroin use).[258]

800. Similarly, if a pregnant opioid-dependent person presents for treatment, under EMTALA the hospital must provide care for both the opioid-dependent parent and the opioid-dependent baby. Defendants relied on Plaintiffs to mitigate the health consequences of Defendants' illegal activities by providing a safety net to prevent overdose deaths and treat the health consequences arising from opioid addiction.[259]

801. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity, and mortality in the United States. This diversion and the epidemic are direct causes of foreseeable harm to Plaintiffs.

802. Defendants' unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiffs seek relief.

B. <u>Financial Impact of Defendants' Activities on Plaintiffs</u>

803. Plaintiffs have treated, and continue to treat, numerous patients for opioid-related conditions, including: (1) opioid overdose; (2) opioid addiction; (3) hepatitis C, HIV and other infections occurring as a result of intravenous drug use; (4) neonatal treatment in its NICU for

[258] *Id.*
[259] Opioid Exit Plan, *supra* n. 48.

babies born opioid-dependent, for which treatment is specialized, intensive, complex, lengthy and highly expensive; and (5) psychiatric and related treatment for patients with opioid addiction who present in need of mental health treatment programs.

804. Plaintiffs have incurred and continue to incur substantial losses associated with treatment of OUD patients. Patients with opioid-related conditions seek treatment from Plaintiffs for conditions associated with the opioid epidemic for which Defendants acts and omissions were a substantial cause. In connection with that treatment Plaintiffs are obligated to provide, Plaintiffs suffered monetary losses with respect to treatment of these patients. The conditions and the burgeoning OUD patient population were and are foreseeable to Defendants, and Defendants knew that the OUD patient population frequently and increasingly required treatment from the Hospitals, at a loss to the Hospitals. The losses were and are the proximate result of Defendants' acts and omissions specified herein. Hospitals obtain a lower rate of realization (receipt of revenues as a percentage of billings for services provided) relating to patients in the OUD patient cohort (patients who have historically and/or presently used prescription opioids) than with the similarly diagnosed non-OUD patient cohort (patients who do not have a history of prescription opioid use).

805. Additionally, individuals with opioid addiction have presented and continue to present themselves to Plaintiffs claiming to have illnesses and medical problems in an effort to obtain opioids. Plaintiffs have incurred and continue to incur operational losses related to the time and expenses in diagnosing, testing, and otherwise attempting to treat these individuals.

806. The losses sustained by Plaintiffs are the direct and proximate result of the False Narrative campaign described above and the opioid epidemic created and engineered by Defendants. Because opioids are very dangerous and highly addictive drugs, it was foreseeable to Defendants that the increase in the use of opioids would result in a corresponding epidemic of

patients with opioid-related conditions going to hospitals for treatment, including to Plaintiffs. It was foreseeable to Defendants that Plaintiffs would suffer substantial monetary losses because of the opioid epidemic, because hospitals are on the front line of treatment for these patients and must bear or otherwise absorb the additional resources that treatment of OUD patients necessitate.

807. Plaintiffs have purchased and continue to purchase and administer opioids marketed and sold by Defendants. Defendants have marketed and continue to market their opioid products directly to Plaintiffs. Defendants directly marketed their opioid products through the False Narrative campaign. Plaintiffs are direct customers and victims of Defendants' false, deceptive, and unfair marketing of opioids described hereafter. Plaintiffs and others have purchased opioids from Defendants, have used them as falsely and deceptively marketed by Defendants, and have suffered damages as a direct and proximate result of Defendants' acts and omissions as described in this Complaint. Plaintiffs would not have purchased the quantity of opioids they had from Defendants had they known the truth about Defendants' false marketing scheme, i.e. that Defendants' claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded, as described herein.

808. The increased financial burdens on hospitals include, but are not limited to the following:

a. Operational losses suffered in connection with providing treatment to patients suffering from opioid-related addiction or disease, including physical and mental disabilities, overdoses and deaths;

b. Operational losses associated with patient counseling with respect to pain management, necessitated by overprescription to the general population and dissemination of false and misleading information to prospective patients and others; as hospitals obtain their patients' self-reporting, it necessitates further steps to be taken in all phases of diagnosis, treatment and counseling;

c. The Hospitals' losses suffered as a result of opioids purchased by hospitals themselves, which were direct targets of Defendants' marketing campaigns;

d. Costs of training additional personnel in the proper treatment of drug overdoses;

e. Costs associated with obtaining and training staff in the application of naloxone—an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

f. Losses suffered in relation to providing treatment to infants born with opioid-related medical conditions, including Neonatal Abstinence Syndrome (NAS), due to exposure to opioids in the womb.

VI. COLLECTIVE CONDUCT ALLEGATIONS

A. CONSPIRACY ALLEGATIONS

809. Defendants conspired to engage in the wrongful conduct complained of herein and intended to benefit both independently and jointly from their wrongful conduct.

810. On December 16, 2020, the Senate Finance Committee issued the findings in its most recent report, which were summarized as follows:

> Our work reveals that opioid manufacturers have maintained extensive financial relationships with tax-exempt organizations, including pain advocacy groups, professional provider groups, and medical associations. In turn, these groups have sought to influence opioids prescribing practices and related Federal policy connected to opioid use and pain care that directly affects Medicare and Medicaid.[260]

1. Conspiracy Among Marketing Defendants

811. Marketing Defendants agreed among themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, health care providers such as hospitals, and health care payors through misrepresentations and omissions regarding the appropriate uses, risks, and safety of opioids in order to increase sales, revenue, and profit from their opioid products.

[260] December 2020 Senate Bipartisan Opioids Report, *supra*, at 2.

812. This interconnected and interrelated network relied on Marketing Defendants' collective use of unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups developed and funded collectively by Marketing Defendants and intended to mislead consumers and medical providers, such as hospitals, of the appropriate uses, risks, and safety of opioids.

813. Marketing Defendants' collective marketing scheme to increase opioid prescriptions, sales, revenues and profits centered around the development, dissemination, and reinforcement of nine false propositions: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition dubbed "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

814. Marketing Defendants knew that none of these propositions are true.

815. Each Marketing Defendant worked individually and collectively to develop and actively promulgate these nine false propositions in order to mislead physicians, patients, and health care providers such as hospitals and healthcare payors regarding the appropriate uses, risks, and safety of opioids.

816. Marketing Defendants' unbranded promotion and marketing network achieved marketing goals that would have been impossible to meet for a single or even a handful of the network's distinct members. For example, Marketing Defendants pooled their vast marketing

funds and dedicated them to expansive and normally cost-prohibitive marketing ventures, such as the creation of Front Groups. These collaborative networking tactics allowed each Marketing Defendant to diversify its marketing efforts, while sharing any financial or legal risk and exposure.

817. Marketing Defendants worked together to pervert the scientific method by citing not peer-reviewed articles that have been rigorously vetted by objective unbiased and disinterested experts in the field but rather opinion pieces, letters, and similar publications. Peer review ensures that an unfounded theory or proposition would, or should, never gain traction. But Marketing Defendants manufactured wide support for their unfounded theories and propositions involving opioids, for instance, by widely and repeatedly citing the Porter & Jick letter discussed above as proof of the low addiction risk connected to taking opioids. Marketing Defendants' egregious misrepresentations based on a letter with obvious shortcomings included claims that less than one percent of opioid users became addicted.

818. Marketing Defendants' collective misuse of the Porter & Jick Letter helped the opioid manufacturers convince patients and healthcare providers such as hospitals that opioids were not a concern. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, Marketing Defendants committed overt acts in furtherance of their conspiracy.

2. Conspiracy Among Marketing Defendants and Distributor Defendants

819. Marketing and Distributor Defendants agreed among themselves to increase the supply of opioids and fraudulently increase the quotas that governed the manufacture and supply of prescription opioids. Marketing and Distributor Defendants did so to increase sales, revenue, and profit from their opioid products.

820. The interaction and length of the relationships between and among Marketing and Distributor Defendants reflects a deep level of interaction and cooperation in a tightly knit industry.

Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Marketing and Distributor Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

821. Marketing and Distributor Defendants utilized their membership in the Healthcare Distribution Alliance and other forms of collaboration to agree to a common approach to their duties under the CSA to report suspicious orders. Marketing and Distributor Defendants overwhelmingly agreed on the same approach – to refuse to effectively identify, report, or halt suspicious opioid orders and so to fail to prevent diversion. Marketing and Distributor Defendants' agreement to restrict reporting insulated the entire industry from scrutiny. As such, Marketing and Distributor Defendants are thus collectively responsible for each other's compliance with their reporting obligations. Marketing and Distributor Defendants were aware, both individually and collectively, of the suspicious orders flowing from their facilities.

822. Marketing and Distributor Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the government's attention. As a result, Marketing and Distributor Defendants had an incentive to communicate with each other about the reporting or suspicious orders to ensure consistency in their dealings with the authorities.

823. The desired consistency and collective end goal were achieved. Marketing and Distributor Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

B. JOINT ENTERPRISE ALLEGATIONS

824. Defendants entered into an agreement with respect to opioids and/or distribution of opioids in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma and in

Plaintiffs' communities.

825. The agreement had a common purpose: to promote the sale and distribution of opioids through the marketing of opioids and/or distribution of opioids into Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma and into Plaintiffs' communities, in violation of state common law, statutes, and regulations.

826. Defendants had a community of pecuniary interest in that common purpose, as all of the Defendants profited from sales of opioids in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma.

827. Defendants had an equal right to a voice in the direction of the enterprise.

VII. TOLLING AND FRAUDULENT CONCEALMENT

828. Defendants, individually and acting through their employees and agents, knowingly and intentionally concealed material facts and knowledge from Plaintiffs and others to induce them to purchase and administer opioids as set forth in detail above.

829. Defendants invented the term "pseudoaddiction" and promoted it to the medical community, including to Plaintiffs. Defendants provided the medical community, including Plaintiffs, with false and misleading information about ineffectual medical strategies to avoid or control opioid addiction. Manufacturer Defendants recommended to the medical community that dosages be increased, while concealing the risks of doing so. Defendants spent millions on a misinformation campaign highlighting opioids' alleged benefits and disguising their risks.

830. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addition and death; in falsely promoting abuse-deterrent formulations as reducing abuse; in falsely claiming that OxyContin provides 12 hours of relief; in falsely portraying their efforts or commitment to rein in the supply and diversion of opioids; and doing all of this while knowing full well that their statements were

misrepresentations of facts material, Defendants have engaged in intentional, fraudulent misrepresentations and concealment of the material fact.

831. Defendants intended that Plaintiffs would rely on their misrepresentations, omissions, and concealment, knew that Plaintiffs would rely on their misrepresentations, and knew that such reliance would cause harm to Plaintiffs. The medical community, including Plaintiffs, were duped by Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing.

832. Plaintiffs reasonably relied on Defendants' misrepresentations in dispensing Defendants' opioids. The use of Defendants' opioid medicines became widespread and continuous as a result.

833. The continued tortious and unlawful conduct by Defendants has caused repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The harm is not complete nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants have not ceased. The nuisance created by Defendants remains unabated.

834. Plaintiffs' claims are equitably tolled because Defendants knowingly and fraudulently concealed the facts, their wrongful acts, and the material information needed to discover those acts. As a result of Defendants' conduct, Plaintiffs did not know and could not have known through the exercise of reasonable diligence, of their claims.

835. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result, Plaintiffs, without any fault or lack of diligence on their part, were unable to obtain

vital information bearing on their claims.

836. Plaintiffs seek economic losses (direct, incidental, or consequential pecuniary losses) resulting from the conduct of Defendants. They do not seek damages which may have been suffered by individual citizens for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of Defendants.

837. Plaintiffs suffered actual pecuniary damages proximately caused by Defendants concealment of material fact, which include but are not limited to an increase in OUD patient encounters which resulted in increased charges (for more treatment) with fewer payments recouped; increased resources directed toward emergency services, emergency response, additional training, additional security; and, physical and emotional fatigue and distress stemming from the relentless cycle of encounters with opioid use disordered patients.

838. Plaintiffs presently lack the operational resources necessary for implementing strategies to abate the consequences of Defendants' misconduct. To mitigate and reduce harm caused by the Defendants to the Hospital Plaintiffs, the nuisance of opioids experienced by the Hospitals must be addressed with specific tactics, equipment, staff and programming.

Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a hospital would reasonably expect to occur and is not part of the normal and expected operational expenditures for a hospital's existence. Plaintiffs allege wrongful acts which were neither discrete nor of the sort a hospital can reasonably expect.

VIII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Violation of Racketeering Influenced and Corrupt Organizations Act (18 U.S.C. §§ 1961–1968)

839. Plaintiffs repeat, reallege, and incorporate by Paragraphs 1 to 839 of this Complaint,

as if fully set forth herein.

840. This Claim for relief alleges violations of 18 U.S.C. §§ 1962(c)–(d).

841. At all relevant times, Plaintiffs were entities capable of holding legal or beneficial interest in property, which means that they were "person[s]" within the meaning of 18 U.S.C. §§ 1961(3), 1962(c).

1. Structure of the False Narrative Enterprise

842. At all relevant times, Defendants, in violation of RICO, conducted (managed) or participated, directly or indirectly, in the conduct (management) of the False Narrative Enterprise, through a pattern of unlawful or otherwise prohibited activity.

a. **Name:** At all relevant times, there existed an "enterprise," within the meaning of 18 U.S.C. §§ 1961(4), 1962(c) – to wit, an association-in-fact comprised of each of the Defendants – referred to herein as "The False Narrative Enterprise."

b. **Continuity**: The continuity of the False Narrative Enterprise was coterminous with the period of time necessary to defraud Plaintiffs, other hospitals, physicians, other healthcare providers, patients and their families, and the American public in general.

c. **Effect on Commerce**: The False Narrative Enterprise was engaged in, and its activities affected, interstate and foreign commerce.

d. **Membership and Roles of Each Class of Participant**: The False Narrative Enterprise reflected several types of participants, not all of which were complicit, and not all of which are named herein as Defendants:

i. **The Marketing Defendants and Associates**. The Marketing Defendants are Teva, Janssen, Allergan, and AbbVie. The Marketing Defendants along with unnamed co-conspirators Purdue, Endo and Mallinckrodt: (1) conceptualized and set in motion the falsehoods about opioids that created billions of dollars of artificial demand for these highly addictive and dangerous products, described in Section IV; (2) engaged in fraudulent and reckless conduct in the distribution of opioids, as described in Section V; and (3) conspired with other Defendants who were engaging in the same conduct.

ii. **The Front Groups**. The Marketing Defendants used the Front Groups, not named as defendants herein and not all of which were fully complicit, to stoke demand for opioids by falsely creating the impression of independent third-party authoritative validation of the false claims of the Marketing Defendants and Purdue and Mallinckrodt.

iii. **The KOLs.** The Marketing Defendants used KOLs, not named as defendants herein and who may not have been fully complicit, to provide ostensibly valid, third party, authoritative validation of the Marketing Defendants' false claims.

iv. **Distributor Defendants.** The Distributor Defendants are ABDC, Anda, Cardinal, H.D. Smith, McKesson, Walgreens, CVS, and Walmart; they joined the False Narrative Enterprise with full awareness and complicity and acted in concert with the Marketing Defendants to pool information about vulnerable targets and share the king size profits reaped from the sale of opioids to addicts, deliberately ignoring their obligations under the Controlled Substances Act. Distributor Defendants (1) engaged in their own predicate acts, described in section V; (2) conspired with other Defendants who were engaging in both fraudulent marketing conduct (Section IV) and wrongful distribution conduct (Section V).

v. **Corrupt Physicians and Pharmacies, a/k/a Pill Mills.** prescribed opioids illegally and with no basis in legitimate medicine; and dispensed opioids illegally and in direct violation of their legal obligations.

2. The Common Purpose and Scheme of the False Narrative Enterprise

843. The lawful purpose of the False Narrative Enterprise was the manufacture, marketing, distribution, and sale of pharmaceutical products in interstate and foreign commerce. The unlawful purpose of the False Narrative Enterprise was to engage in and carry out an intentional scheme to defraud purchasers and others, including doctors and hospitals, by propagating falsehoods about the safety and benefits of opioids.

844. In order to unlawfully increase the demand for opioids, Defendants formed an association-in-fact enterprise (the "False Narrative Enterprise") with the Front Groups and KOLs described above. Knowing that their products were highly addictive, ineffective and unsafe for the

treatment of long-term chronic pain, non-acute and non-cancer pain, Defendants formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales and grow their share of the prescription painkiller market through (1) repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain, and (2) ongoing disregard of their duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market.

3. Predicate Acts

845. At all relevant times, Defendants conducted (managed) or participated, directly or indirectly, in the conduct (management) of the False Narrative Enterprise, through a pattern of unlawful activity. In addition to participating in a RICO-violative enterprise, Defendants, with full knowledge and purpose, conspired, in violation of 18 U.S.C. § 1962(d), to violate § 1962(c). Defendants did so by engaging in multiple, repeated, and continuous violations of:

a. **Wire Fraud, 18 U.S.C. § 1343**. Defendants, in violation of § 1343, transmitted communications electronically to designated persons for ostensibly legitimate purposes, but with the actual, unlawful purpose of asserting false claims through fraud and to engage in an intentional scheme to defraud Plaintiff, other health care providers, patients and their families and, in general, the American public.

b. **Mail Fraud, 18 U.S.C. § 1341.** Defendants, in violation of § 1341, transmitted communications through the U.S. Mail to designated persons for ostensibly legitimate purposes, but with the actual, unlawful purpose of asserting false claims through fraud and to engage in an intentional scheme to defraud Plaintiff, other health care providers, patients and their families and, in general, the American public.

c. **The Controlled Substances Act, 21 U.S.C. § 801, *et seq.***

846. The Marketing Defendants' substantial financial contribution to the False Narrative Enterprise, and the advancement of opioid-friendly messaging, fueled the U.S. opioids epidemic. The Marketing Defendants' marketing conduct is set forth in more detail in Section IV.

847. The Marketing Defendants, through their participation in the False Narrative

Enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including Plaintiffs, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. These misrepresentations are identified in detail in Section IV above.

848. The Marketing Defendants, the Front Groups, and the KOLs acted together for a common purpose and perpetuated the False Narrative Enterprise's scheme, including through the unbranded promotion and marketing network described in Section IV.

849. There was regular communication between the Marketing Defendants, the Front Groups, and KOLs, in which information was shared, misrepresentations coordinated, and payments exchanged. Typically, the coordination, communication, and payment occurred, and continues to occur, through the repeated and continuing use of the wires and mail in which the Marketing Defendants, Front Groups, and KOLs shared information regarding overcoming objections and resistance to the use of opioids for chronic pain. The Marketing Defendants, Front Groups, and KOLs functioned as a continuing unit for the purpose of implementing the False Narrative Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

850. At all relevant times, the Front Groups were aware of the Marketing Defendants' conduct and were knowing and willing participants in and beneficiaries of that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and Plaintiffs. But for the False Narrative Enterprise's unlawful fraud, the Front Groups would have had incentive to disclose the deceit by the Marketing Defendants and the False Narrative Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the False Narrative Enterprise's

scheme and common purpose and reaped substantial benefits.

851. At all relevant times, the KOLs were aware of the Marketing Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. The Marketing Defendants selected the KOLs solely because they favored the aggressive treatment of chronic pain with opioids. The Marketing Defendants' support helped the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the benefits of using opioids to treat chronic pain, repaying the Marketing Defendants by advancing the latter's marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and Plaintiffs. But for the False Narrative Enterprise's unlawful conduct, the KOLs would have had incentive to disclose the deceit by the Marketing Defendants and the False Narrative Enterprise and to protect their patients and those of other physicians. By failing to disclose this information, the KOLs furthered the False Narrative Enterprise's scheme and common purpose and reaped substantial benefits.

852. As public scrutiny and media coverage revealed how opioids ravaged communities throughout the United States, the Front Groups and KOLs did not challenge the Marketing Defendants' misrepresentations, seek to correct their own previous misrepresentations, terminate their role in the False Narrative Enterprise, or disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence.

853. The Marketing Defendants, Front Groups, and KOLs engaged in certain discrete categories of activities in furtherance of the common purpose of the False Narrative Enterprise. As described herein, the False Narrative Enterprise's conduct in furtherance of the common purpose of the False Narrative Enterprise involved: (1) misrepresentations regarding the risk of addiction

and safe use of prescription opioids for long-term chronic pain (described in detail above); (2) lobbying to defeat measures to restrict over-prescription; (3) efforts to criticize or undermine CDC guidelines; and (4) efforts to limit prescriber accountability.

854. In addition to disseminating misrepresentations about the risks and benefits of opioids, the False Narrative Enterprise also furthered its common purpose by criticizing or undermining CDC guidelines. Members of the False Narrative Enterprise criticized or undermined the CDC Guidelines which represented "an important step - and perhaps the first major step from the federal government - toward limiting opioid prescriptions for chronic pain."[261]

855. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized the draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines."[262]

856. The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating "that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence."[263]

857. The Marketing Defendants alone could not have accomplished the purpose of the False Narrative Enterprise without the assistance of the Front Groups and the KOLs, who were perceived as "neutral" and more "scientific" than the Marketing Defendants themselves. Without the work of the Front Groups and the KOLs in spreading misrepresentations about opioids, the False Narrative Enterprise could not have achieved its common purpose.

858. The impact of the False Narrative Enterprise's scheme is still in place - i.e., the

[261] Fueling an Epidemic Part Two, *supra.*

[262] Pat Anson, *Chronic Pain Groups Blast CDC for Opioid Guidelines* (Sept. 22, 2015), https://www.painnewsnetwork.org/stories/2015/9/22/chronic-pain-groups-blast-cdc-for-opioid-guidelines.

[263] *CDC Guideline*, *supra* n. 19.

opioids continue to be prescribed and used for chronic pain, and the epidemic continues to injure Plaintiffs and consume Plaintiffs' resources.

859. As a result, it is clear that the Marketing Defendants, Front Groups, and KOLs were all willing participants in the False Narrative Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

860. Each of the Marketing Defendants exerted control over the False Narrative Enterprise and participated in the operation or management of the affairs of the False Narrative Enterprise, directly or indirectly, in the following ways:

a. Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

b. Creating and providing a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

c. Creating and providing a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

d. Creating and providing a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

e. Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute the Marketing Defendants' messages about the use of opioids for chronic pain;

f. Providing substantial opportunities for KOLs to participate in research studies on topics the Marketing Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

g. Paying KOLs to serve as consultants or on the Marketing Defendants' advisory boards, to serve on the advisory boards and in leadership positions of Front Groups, and to give talks or present CMEs, typically over meals or at conferences;

h. Selecting, cultivating, promoting, creating, and paying Front Groups based solely on their willingness to communicate and distribute the Marketing Defendants' messages about the use of opioids for chronic pain;

i. Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the Marketing Defendants suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

j. Paying significant amounts of money to the leaders and individuals associated with Front Groups;

k. Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;

l. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

m. Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

n. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;

o. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the Marketing Defendants, such as the elderly, and then funding that distribution;

p. Concealing their relationship to and control of Front Groups and KOLs from Plaintiffs and the public at large; and

q. Intending that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities promotional and other materials that claimed opioids could be safely used for chronic pain.

861. The False Narrative Enterprise had a hierarchical decision-making structure that was headed by Defendants and supported by the KOLs and Front Groups. The Marketing Defendants controlled representations made about their opioids and their drugs, doled out funds to PBMs and payments to KOLs, and ensured that representations made by KOLs, Front Groups, and the Marketing Defendants' sales detailers were consistent with the Marketing Defendants' messaging throughout the United States including in Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma. The Front Groups and KOLs in the False Narrative Enterprise were dependent on the Marketing Defendants for their financial structure and for career development and promotion opportunities.

862. The Front Groups also conducted and participated in the conduct of the False Narrative Enterprise, directly or indirectly, in the following ways:

a. The Front Groups promised to, and did, make representations regarding opioids and the Marketing Defendants' drugs that were consistent with the Marketing Defendants' messages;

b. The Front Groups distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the Marketing Defendants' financial interests;

d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The Front Groups strongly criticized the 2016 CDC that recommended limits on opioid prescriptions for chronic pain; and

f. The Front Groups concealed their connections to the KOLs and the Marketing Defendants.

863. The Marketing Defendants' Front Groups, "with their large numbers and credibility

with policymakers and the public—have 'extensive influence in specific disease areas.'" The larger Front Groups "likely have a substantial effect on policies relevant to their industry sponsors." "By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic."[264]

864. The KOLs also participated in the conduct of the affairs of the False Narrative Enterprise, directly or indirectly, in the following ways:

a. The KOLs promised to, and did, make representations regarding opioids and the Marketing Defendants' drugs that were consistent with the Marketing Defendants' messages themselves;

b. The KOLs distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction and misrepresented that the benefits of using opioids for chronic pain outweighed the risks;

c. The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the Marketing Defendants' financial interests;

d. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The KOLs strongly criticized the 2016 CDC guidelines that recommended limits on opioid prescriptions for chronic pain; and

f. The KOLs concealed their connections to the Front Groups and the Marketing Defendants and their sponsorship by the Marketing Defendants.

865. The scheme devised and implemented by the Marketing Defendants and members of the False Narrative Enterprise amounted to a common course of conduct intended to increase the Marketing Defendants' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many

[264] Fueling an Epidemic Part Two, *supra*.

aspects of it continue through to the present. As discussed in detail above, the Marketing Defendants funded and controlled the various Front Groups, which appeared to be independent, but were not, and which transmitted the Marketing Defendants' misrepresentations. The Marketing Defendants and the Front Groups thus worked together to promote the goals of the False Narrative Enterprise.

866. The Marketing Defendants worked together with each other through the Front Groups that they jointly funded and through which they collaborated on the joint promotional materials described above.

867. Similarly, as discussed in detail above, The Marketing Defendants paid KOLs to spread their misrepresentations and promote their products. The Marketing Defendants and the KOLs thus worked together to promote the goals of the False Narrative Enterprise.

868. To achieve the common goal and purpose of the False Narrative Enterprise, the Marketing Defendants and members of the False Narrative Enterprise hid from consumers, prescribers, regulators, and Plaintiffs: (a) the fraudulent nature of the Marketing Defendants' marketing scheme; (b) the fraudulent nature of statements made by the Marketing Defendants and by their KOLs, Front Groups and other third parties regarding the safety and efficacy of prescription opioids; and (c) the true nature of the relationship between the members of the False Narrative Enterprise.

869. The Marketing Defendants, and each member of the False Narrative Enterprise agreed, with knowledge and intent, to the overall objective of the Marketing Defendants' fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

870. Indeed, for the Marketing Defendants' fraudulent scheme to work, each of them

had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that the Marketing Defendants each financed, supported, and worked through the same KOLs and Front Groups and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines.

871. The Marketing Defendants' predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs' business and property, while simultaneously generating billion-dollar revenue and profits for the Marketing Defendants. The predicate acts were committed or caused to be committed by the Marketing Defendants through their participation in the False Narrative Enterprise and in furtherance of its fraudulent scheme.

872. Defendants' conduct in the distribution of opioids is set forth in more detail in Section V and summarized herein.

873. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort have categorically denied any criminal behavior or intent. But Defendants' actions went far beyond what could be considered ordinary business conduct. For more than a decade, Defendants worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

874. As "registrants" under state and federal law, Defendants are duty bound to identify and report suspicious orders of controlled substances. Critically, Defendants' responsibilities do not end with the products they manufacture or distribute—there is no such limitation in the law because their duties cut across company lines. Thus, when Defendants obtain information about the sales and distribution of other companies' opioid products, as they did through data mining

companies like IMS Health, they were legally obligated to report that activity.

875. If morality and the law did not suffice, competition dictates that Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a manufacturer or distributor could gain market share by reporting a competitor's illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so. Under RICO, this whistleblower or watchdog function is not only a protected choice, but a statutory mandate. Unfortunately, however, that is not what happened. Instead, knowing that investigations into potential diversion would only lead to shrinking markets, Defendants elected to operate in a conspiracy of silence, in violation of both federal and Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma state law concerning controlled substances and RICO.

876. Defendants' scheme required the participation of all. If any individual member broke rank, its compliance activities would highlight deficiencies of the others, and their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for the government authorities to go after any one of them. Accordingly, through the connections they made as a result of their participation in the HAD, Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances." But, privately, Defendants refused to act and through their lobbying efforts, they collectively sought to undermine the impact of government regulation and enforcement. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize Defendants' duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray,

President and CEO of the HDA said to Congress in 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Yet, Defendants apparently all found the same profit-maximizing balance - intentionally remaining silent to ensure the largest possible financial return.

877. As described above, at all relevant times, Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues, and profits. In support of this common purpose and fraudulent scheme, Defendants jointly agreed to disregard their duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market.

878. At all relevant times, as described above and so as to generate unlawful profits, Defendants exerted control over, conducted and/or participated in the False Narrative Enterprise by fraudulently claiming that they were complying with their duties to maintain effective controls against diversion, including duties to identify, investigate, and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market and to halt such unlawful sales

879. Defendants disseminated false and misleading statements to state and federal regulators claiming that:

a. they were complying with their obligation to maintain effective controls against diversion of their prescription opioids;

b. they were complying with their obligation to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;

c. they were complying with their obligation to report suspicious orders or diversion of their prescription opioids; and

d. they did not have the capability to identify suspicious orders of controlled substances.

880. Defendants applied political and other pressure to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied for less stringent regulation of their marketing and distribution of pharmaceutical products.

881. Defendants are required to make reports of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

882. Defendants knowingly and intentionally furnished false or fraudulent information in their reports about suspicious orders, and/or omitted material information from reports, records and other documents required to be filed. Specifically, Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to take responsive action. This failure included the failure to report this information to the government.

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

884. In devising and executing the illegal scheme, Defendants devised and knowingly carried out a scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

885. For the purpose of executing the illegal scheme, Defendants committed unlawful acts, which number in the thousands, intentionally and knowingly, with the specific intent to advance the illegal scheme. These unlawful acts, which included repeated acts of mail fraud and

wire fraud, constituted a pattern of unlawful activity.

886. Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce.

887. Each Defendant manufactured, shipped, paid for, and/or received payment for prescription opioids, throughout the United States.

888. Defendants used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, Defendants made misrepresentations about their compliance with the statutes, regulations, and other laws requiring them to identify, investigate, and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

889. At the same time, Defendants misrepresented the superior safety features of their order monitoring programs, their ability to detect suspicious orders, their commitment to preventing diversion of prescription opioids, and their compliance with federal and state laws regarding the identification and reporting of suspicious orders of prescription opioids. Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

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

891. The mail and wire transmissions described herein were made in furtherance of

Defendants' scheme and common course of conduct to deceive regulators, the public, and Plaintiffs that Defendants were complying with their legal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market.

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

893. Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for Defendants.

894. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

895. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs' business and property, while simultaneously generating billion-dollar revenue and profits for Defendants. The predicate acts were committed or caused to be

committed by Defendants through their participation in the False Narrative Enterprise and in furtherance of its fraudulent scheme.

896. As described above, Defendants were repeatedly warned, fined, and found to be in violation of applicable law and regulations, and yet they persisted. The sheer volume of enforcement actions against Defendants supports the conclusion that Defendants operated through a pattern and practice of willfully and intentionally omitting information from their mandatory reports.

897. Each instance of unlawful activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims. Defendants calculated and intentionally crafted their scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma, their citizens, or Plaintiffs. Defendants were aware that Plaintiffs and others rely on Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

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

4. Pattern of Unlawful Activity

899. Defendants' scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, and violations of statutes regulating the distribution of controlled substances, constituting a pattern of unlawful activity as described herein.

900. The pattern of unlawful activity used by the False Narrative Enterprise likely

involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful False Narrative Enterprise.

901. These communications included essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain, with the goal of profiting from increased sales of the Marketing Defendants' drugs induced by consumers', prescribers', regulators', and Plaintiffs' reliance on the Marketing Defendants' misrepresentations. Each of these fraudulent mailings and interstate wire transmissions constitutes an unlawful act, and, collectively, these violations constitute a pattern of unlawful activity, through which the Marketing Defendants, the Front Groups, and the KOLs defrauded and intended to defraud Plaintiffs. The Marketing Defendants devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive, and effective use of opioids for long-term chronic, non-acute, and non-cancer pain. The Marketing Defendants and members of the False Narrative Enterprise knew that these representations contradicted the FDA-approved use these drugs and were not supported by actual evidence. The Marketing Defendants intended that that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to advance and for the purpose of executing their illegal scheme. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain to prescribers, regulators, and the public, including Plaintiffs, the Marketing Defendants, the Front Groups, and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of unlawful activity. The Marketing Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids'

marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, *inter alia*:

a. Marketing materials about opioids, and their risks and benefits, which the Marketing Defendants sent to health care providers, such as hospitals transmitted through the internet and television, published, and transmitted to Front Groups and KOLs located across the country and the State;

b. Written representations and telephone calls between the Marketing Defendants and Front Groups regarding the misrepresentations, marketing statements, and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

c. Written representations and telephone calls between the Marketing Defendants and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

d. E-mails, telephone, and written communications between the Marketing Defendants and the Front Groups agreeing to or implementing the opioids marketing scheme;

e. E-mails, telephone, and written communications between the Marketing Defendants and the KOLs agreeing to or implementing the opioids marketing scheme;

f. Communications between the Marketing Defendants, Front Groups, and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the False Narrative Enterprise;

g. Communications between the Marketing Defendants, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the False Narrative Enterprise;

h. Written and oral communications directed to State agencies, federal and state courts, and private insurers throughout Louisiana, Mississippi, Texas, North Carolina, Kansas, Missouri, and Oklahoma that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and

i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities - the wrongful proceeds of the scheme.

902. In addition to the above-referenced predicate acts, it was intended by and foreseeable to the Marketing Defendants that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities and, in those publications, claim

that the benefits of using opioids for chronic pain outweighed the risks of doing so.

903. Defendants' use of U.S. Mail and interstate wires in conduct related to the distribution of opioids includes, but is not limited to, the transmission, delivery, or shipment of the following by Defendants, and/or third parties that were foreseeably caused to be sent as a result of Defendants' illegal scheme, of the following:

a. The prescription opioids themselves;

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

c. Defendants' government registrations;

d. Documents and communications that supported and/or facilitated Defendants' government registrations;

e. Defendants' records and reports that were required to be submitted to regulatory authorities;

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

g. Documents for processing and receiving payment for prescription opioids;

h. Payments from the Distributor Defendants to the Marketing Defendants;

i. Rebates and chargebacks from the Marketing Defendants to the Distributor Defendants;

j. Payments from the National Retail Pharmacies to the other Distributor Defendants;

k. Payments to Defendants' lobbyists through the PCF;

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

m. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and

n. Other documents and things, including electronic communications.

904. Defendants also participated in a pattern of violations of the federal Controlled

Substances Act and analogous state common and statutory law by refusing to comply with their obligations under the law to report suspicious orders and prescribers.

905. At all relevant times, Defendants, in violation of the above statutes, conducted (managed) or participated, directly or indirectly, in the conduct (management) of the False Narrative Enterprise, through a pattern of unlawful activity, by engaging in multiple, repeated, and continuous acts of mail fraud, wire fraud, and violations of the CSA. Defendants transmitted electronic communications to designated persons for ostensibly legitimate purposes, but with the actual, unlawful purpose of engaging in an intentional scheme to defraud Plaintiffs, other hospitals, health care providers, patients and their families, and, in general, the American public.

5. Consequences

906. By reason of the above-referenced violations of 18 U.S.C. § 1962(c)–(d), Plaintiffs were injured in their business or property within the meaning of 18 U.S.C. § 1964(c) and are entitled to assert this claim and to recover threefold the damages they sustained, as demonstrated at trial, and the cost of the suit, including reasonable attorneys' fees, as well as such other appropriate relief, as the Court may provide.

SECOND CLAIM FOR RELIEF

Nuisance

907. Plaintiffs repeat, reallege, and incorporate by reference Paragraphs 1 through 839 of this Complaint, as if fully set forth herein.

908. The nuisance is the over-saturation of opioids in the patient population of Plaintiffs and in the geographic areas served by Plaintiffs for illegitimate purposes, as well as the adverse social, economic, and human health outcomes associated with widespread illegal opioid use.

909. All Defendants substantially participated in nuisance-causing activities.

910. Marketing Defendants and CVS participated in nuisance-causing activities by, as described in Section III, through their marketing of opioids.

911. All Defendants participated in nuisance-causing activities by distributing and selling opioids, as described in Section IV, and/or otherwise exacerbating the flood of opioids into Plaintiffs' communities in ways that unreasonably interfere with the public health, welfare, and safety in Plaintiffs' communities.

912. Additionally, all Defendants are jointly liable for the conduct of their co-conspirators as per the collective conduct allegations in Section VI.

913. Defendants' nuisance-causing activities include selling or facilitating the sale of prescription opioids to the patients of Plaintiffs, as well as to unintended users, including children, people at risk of overdose or suicide, and criminals.

914. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of controlled substances, and their failure to adequately design and operate a system to detect, halt and report suspicious orders of controlled substances.

915. Defendants' activities unreasonably interfere with the economic rights of Plaintiffs.

916. Defendants' interference with Plaintiffs' rights is unreasonable because it:

a. Has harmed and will continue to harm the public health services of and public peace of Plaintiffs;

b. Has harmed and will continue to harm the communities and neighborhoods which Plaintiffs serve;

c. Is proscribed by statutes and regulation, including the CSA, pharmacy regulations, and the consumer protection statute;

d. Is of a continuing nature and it has produced long-lasting effects;

e. Defendants have reason to know their conduct has a significant effect upon Plaintiffs; and

f. Has inflicted substantial costs on Plaintiffs.

917. The nuisance undermines public health, quality of life, and safety. It has resulted in high rates of addiction, overdoses, dysfunction, and despair within families and entire communities. It has created a public health crisis.

918. The resources of Plaintiffs are being unreasonably consumed in efforts to address the prescription drug abuse epidemic, thereby eliminating available resources needed in other health care areas.

919. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in facilitating widespread opioid addiction and failing to identify, halt, and report suspicious opioid transactions.

920. At all times, all Defendants possessed the right and ability to control the nuisance causing outflow of opioids from pharmacy locations or other points of sale. Distributor Defendants had the power to shut off the supply of illicit opioids to Plaintiffs and in the geographic areas served by Plaintiffs.

921. As a direct and proximate result of the nuisance, Plaintiffs have sustained economic harm by spending a substantial amount of money trying to remedy the harms caused by Defendants' nuisance-causing activity, including, but not limited to, costs of hospital services and healthcare. In short, Defendants created a mess, leaving it to Plaintiffs and other hospitals the costs of cleaning it up. This is a classic nuisance.

922. As a result of Defendants' actions, Plaintiffs have suffered a special injury, different from that suffered by the public at large by individual users and by governmental entities, namely

that Plaintiffs have provided uncompensated care for patients suffering from opioid related conditions.

923. The effects of the nuisance can be abated, and the further occurrence of such harm and inconvenience can be prevented. All Defendants share in the responsibility for doing so.

924. Defendants should be required to pay the expenses Plaintiffs have incurred or will incur in the future to fully abate the nuisance.

THIRD CLAIM FOR RELIEF

Fraud and Deceit

925. Plaintiffs repeat, reallege, and incorporate by reference Paragraphs 1 through 839 of this Complaint, as if fully set forth herein.

926. Defendants' misconduct alleged in this case is ongoing and persistent.

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

928. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons and said actions had a great probability of causing substantial harm.

929. This claim is brought against all Defendants.

1. Defendants made false representations of material fact.

930. In the course of their business or other transactions in which they had a pecuniary interest, Defendants made false representations and otherwise failed to disclose material facts to the medical community, including to Plaintiffs' physicians.

931. Defendants' false representations and deceptions as to material facts during the relevant period include but are not limited to:

a. Misrepresentations overstating the benefits of and evidence supporting the use of opioids in chronic pain;

b. Misrepresentations that the risks of long-term opioid use, especially the risk of addiction, were overblown;

c. Misrepresentations that opioid doses can be safely and effectively increased until pain relief is achieved;

d. Misrepresentations that signs of addiction were "pseudoaddiction" and thus reflected undertreated pain, which should be responded to with more opioids;

e. Misrepresentations that screening tools effectively prevent addiction;

f. Misrepresentations concerning the comparative risks of NSAIDs and opioids;

g. Misrepresentations that opioids differ from NSAIDs in that opioids have no ceiling dose;

h. Misrepresentations that evidence supports the long-term use of opioids for chronic pain;

i. Misrepresentations that chronic opioid therapy would improve patients' function and quality of life;

j. False portrayals of their efforts and/or commitment to rein in the diversion and abuse of opioids;

k. Misrepresentations that withdrawal is easily managed;

l. Purdue's and Endo's misrepresentations that alleged abuse-deterrent opioids reduce tampering and abuse;

m. Teva's misrepresentations that Actiq and Fentora were appropriate for treatment of noncancer pain and its failure to disclose that Actiq and Fentora were not approved for such use;

n. Cephalon's unsubstantiated claims that Actiq and Fentora were appropriate for treatment of noncancer pain;

o. Defendants' use of Front Groups to misrepresent that the deceptive statements from the sources described in this Complaint came from objective, independent sources;

p. Defendants' creation of a body of deceptive, misleading, and unsupported medical and popular literature, advertisements, training materials, and speaker

presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) were thus more likely to be relied upon by physicians, patients, and payors; and,

q. Such other misrepresentations and deceptions outlined above.

932. By engaging in the acts and practices alleged herein, Defendants, in the relevant time period, omitted material facts that they had a duty to disclose by virtue of their other representations, including but not limited to the fact that:

a. Opioids are highly addictive and may result in overdose or death;

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

c. High dose opioids subject the user to greater risks of addiction, other injury, and/or death;

d. Opioids present the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, dizziness, increased falls and fractures in the elderly, NAS, and potentially fatal interactions with alcohol or benzodiazepines; these omissions were made while Defendants exaggerated the risks of competing products such as NSAIDs;

e. Claims regarding the benefits of chronic opioid therapy lack scientific support or are contrary to the scientific evidence;

f. Purdue's 12-hour OxyContin fails to provide a full twelve hours of pain relief in many patients;

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

h. The Marketing Defendants failed to consistently and accurately report suspicious prescribers and/or orders;

i. Cephalon's Actiq and Fentora were not approved for noncancer pain;

j. Defendants had substantial financial ties and other associations with Front Groups and KOLs that resulted in the production of deceptive literature and materials; and

k. Such other omissions and concealments as described above in this Complaint.

933. In each of the circumstances described in the foregoing paragraph, Defendants knew or should have known that their failure to disclose rendered their representations untrue or misleading.

934. The Distributor Defendants were also knowingly deceptive during the relevant period, and their deception was intended to induce reliance. These deceptions include but are not limited to:

a. Acknowledgment of the Distributor Defendants by and through their front group, the HDMA, that distributors are at 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;

b. Acknowledgment of the Distributor Defendants that because of their unique position within the "closed" system, they were to act as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market;

c. Cardinal claiming to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse";

d. ABDC taking the same position as its counterparts within the industry and stating that it was "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare to help find solutions that will support appropriate access while limiting misuse of controlled substances";

e. Misrepresentations by the Distributor Defendants that they were in compliance with their statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs and their obligation to undertake such efforts as responsible members of society;

f. Misrepresentations in publications and other materials produced or distributed by the Distributor Defendants that repeated the misrepresentations about the safety and efficacy of prescription opioids made by the Marketing Defendants;

g. ABDC assisting in marketing other Defendants' opioids (including Purdue's OxyContin) and disseminating false information about those opioids in order to created higher demand for the opioids;

h. ABDC's Xcenda subsidiary publishing scientific articles promoting the use of opioids and minimizing their risks;

i. Cardinal disseminating advertisements that contained deceptive statements regarding the risk of addiction, abuse, and diversion posed by opioids; and

j. Such other omissions or concealments as described above in this Complaint.

935. The Distributor Defendants, in the relevant time period and with the intent that others rely on their omissions or suppression of information, omitted material facts that the Distributor Defendants had a duty to disclose by virtue of their other representations, including but not limited to the fact that:

a. There was no legitimate medical purpose for the copious amounts of opioids shipped into and around Plaintiffs' communities;

b. They filled prescriptions for which there was no legitimate medical purpose;

c. They failed to report suspicious orders;

d. They 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;

e. They failed to prevent diversion from legitimate to non-legitimate channels;

f. They failed to conduct meaningful due diligence to ensure that controlled substances were not diverted into other than legitimate channels;

g. They failed to keep and maintain accurate records of Schedule II–V controlled substances; and

h. Such other omissions or concealments as alleged above in this Complaint.

936. Defendants had a duty not to deceive Plaintiffs, their agents, communities, and physicians, and the public because Defendants had in their possession unique material knowledge as to the risks and benefits of prescription opioids. This information was unknown and unknowable to Plaintiffs.

937. Defendants' false representations and omissions were material because they induced Plaintiffs to purchase and prescribe prescription opioids. The false representations and omissions were made intentionally and recklessly.

2. Defendants knew that these representations were false.

938. Defendants knew that the representations described above were false or, alternately, failed to exercise reasonable care or competence in obtaining or communicating the representations.

939. Defendants had knowledge of the falsity and materiality of the representations or made the representations in reckless disregard of whether the representations were true or false.

940. Defendants had knowledge of the materiality of the facts that they were intentionally or recklessly concealing.

3. Defendants intended that their statements would be relied upon.

941. Defendants made their false representations with the intent that the medical community, including physicians in hospitals like Plaintiffs, and others would rely on them.

942. Defendants made such false representations for the purposes of inducing the physicians to prescribe and administer, and consumers to purchase and consume, opioids.

943. Defendants intended that Plaintiffs, their agents, communities, and physicians, and persons on whom Plaintiffs and their agents relied would rely on Defendants' misrepresentations and omissions. These Defendants intended and knew or should have known that this reasonable and rightful reliance would induce Plaintiffs to purchase and prescribe opioids. Defendants intended and knew or should have known that such reliance would cause Plaintiffs to suffer loss.

4. Plaintiffs and others justifiably relied on Defendants' misrepresentations and omissions.

944. Plaintiffs and others rightfully, reasonably, and justifiably relied on Defendants' representations and/or concealments, both directly and indirectly regarding the safety and efficacy of opioids, and Defendants' compliance with the system that was designed to prevent diversion of dangerous drugs. Plaintiffs rely on Defendants to convey truthful, accurate, and complete

information about their products. Information about Defendants' compliance with suspicious order monitoring and similar anti-diversion efforts is peculiarly within Defendants' knowledge, necessitating Plaintiffs' reliance.

945. Defendants knew or should have known Plaintiffs were directly and proximately injured as a result of this reliance. Plaintiffs' injuries were directly and proximately caused by this reliance.

946. As a result of these representations and/or omissions, Plaintiffs proceeded under the misapprehension that the opioid crisis was simply a result of conduct by persons other than Defendants. As a consequence, these Defendants prevented Plaintiffs from making a more timely and effective response to the opioid epidemic.

5. Plaintiffs suffered injury as a result.

947. Because Defendants' fraudulent misrepresentations and omissions to Plaintiffs and others prevented an effective response to the opioid epidemic, Plaintiffs suffered a broad range of adverse operational impacts, including, but not necessarily limited to (1) the lower rate of realization from the provision of health care to patients with opioid-related conditions, (2) elevated operational expenses incurred to respond to the conditions created by the opioid epidemic, and (3) the cost of purchasing opioids Plaintiffs would not have otherwise purchased but for Defendants' misrepresentations and omissions.

948. Plaintiffs have suffered monetary damages as aforesaid. As such Plaintiffs seek all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants as well as attorney fees and costs, and pre- and post-judgment interest.

FOURTH CLAIM FOR RELIEF

Civil Conspiracy

949. Plaintiffs repeat, reallege, and incorporate by reference Paragraphs 1 through 839 of this Complaint, as if fully set forth herein, including, but not limited to, the concerted action allegations of Section VIII.

950. Plaintiffs bring this claim under the common law providing for the civil liability of persons who conspire to commit one or more unlawful or tortious acts.

951. Conspirators are liable for any tortious act, even unknown, committed in furtherance of the conspiracy, including acts not personally committed.

952. All named Defendants conspired with each other and with various entities and persons who are not named in this Complaint to commit the acts upon which each of the claims alleged in this action are based. At the core of the conspiracy was a meeting of the minds on an object to be accomplished. The goals of the conspiracy, that is, the gist of the conspiratorial meeting of the minds, was to expand the market for and supply of opioids, and to accomplish this, Defendants falsely marketed opioids and failed to control against diversion in the face of overwhelming evidence that diversion was taking place.

953. Even if some of the Distributor Defendants were competitors with each other in some spheres of business, or some of the Marketing Defendants were competitors with each other, or some of the National Retail Pharmacies were competitors with each other, it served all of their interests to promote opioid use, to sell as many opioids as possible, to create a marketplace where massive distribution and use of and addiction to opioids was the norm, and to look the other way and fail to report or control massive drug diversions against overwhelming evidence of the epidemic they were creating. They acted in concert and in tacit and explicit agreement to pursue these goals.

954. Each Defendant is liable for its co-conspirators' acts in furtherance of the

conspiracy.

955. Each of the Claims for Relief asserted in this Complaint arises from acts in furtherance of the conspiracy described in this Complaint and in this Count, and each Defendant is liable for the conduct of its co-conspirators in the commission of those torts and/or statutory violations.

956. Defendants' conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against its commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities when under a legal duty to do. Each Defendant acted against its commercial interests in this regard due to an actual or tacit agreement between Defendants that they would not report each other to the authorities so they could all continue to engage in their unlawful conduct.

957. Defendants had a meeting of the minds on the object of or course of action for this conspiracy. Defendants knew and agreed upon the unlawful object or course of action for this conspiracy. Defendants also knew that their wrongful actions would inflict injury upon the targets of the conspiracy, including Plaintiffs.

958. Defendants' conspiracy and their actions and omissions in furtherance thereof caused the direct and foreseeable losses alleged herein.

959. Defendants' misconduct alleged in this case is ongoing and persistent.

960. Because of Defendants' dissemination of false information and misleading information of opioid risks, benefits, and sustainability for chronic pain, and false and misleading statements regarding compliance with laws concerning the distribution of opioids, Defendants are responsible for the costs of addressing the public health crisis that they created.

961. Defendants conspired to create a public nuisance and to commit tortious conduct

and are therefore jointly and severally liable for the damages flowing from the conspiracy.

962. Plaintiffs have suffered monetary damages as aforesaid. As such Plaintiffs seek all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants as well as attorney fees and costs, and pre- and post-judgment interest.

FIFTH CLAIM FOR RELIEF

Unjust Enrichment

963. Plaintiffs repeat, reallege, and incorporate by reference Paragraphs 1 through 839 of this Complaint, as if fully set forth herein.

964. Plaintiffs provided unreimbursed healthcare treatment to patients with opioid conditions that Defendants are responsible for creating. Plaintiffs thereby conferred a benefit on Defendants because Defendants should bear the expense of treating these patients' opioid conditions. This is because Defendants created the opioid epidemic and the patients' opioid conditions, as described above.

965. Defendants appreciated and knew of this benefit because they knew their opioid promotional and marketing policies would cause, and in fact caused, hospitals throughout the United States to provide unreimbursed healthcare treatment to patients with opioid conditions that Defendants were responsible for creating.

966. The circumstances under which Defendants accepted or retained the benefit, described above, were such as to make it inequitable for Defendants to retain the benefit without payment of its value.

967. As described above, the benefit was received and retained under such circumstances that it would be inequitable and unconscionable to permit Defendants to avoid payment therefore Defendants have been unjustly enriched.

968. By reason of the foregoing, Defendants must disgorge their unjustly acquired profits and other monetary benefits resulting from its unlawful conduct and provide restitution to Plaintiffs.

IX. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask that the Court:

A. Enter judgment against Defendants, jointly and severely, and in favor of Plaintiffs;

B. Award compensatory damages in an amount sufficient to fairly and completely compensate Plaintiffs for all damages; treble damages pre-judgment and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate; and such equitable relief against Defendants as the Court should find appropriate, including disgorgement of illicit proceeds and other orders;

C. Award Plaintiffs their cost of suit, including reasonable attorneys' fees as provided by law; and

Award such further and additional relief as the Court may deem just and proper under the circumstances.

X. JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

Dated: February 26, 2024

Respectfully Submitted,

/s/ Don Barrett

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