

MEMORANDUM

To: Selectboard

From: Robert M. Fisher, Esq.

Date: October 10, 2019

Re: Multi-District Municipal Litigation against Opioid Manufacturers, Distributors, Pharmacy Benefit Managers, and Pharmacies

The VLCT hosted an Opioid Action Forum at which the attorneys for the multiple district litigation provided a background of the lawsuits against the opioid manufacturers, distributors, pharmacies, and benefit managers. These lawsuits seek to hold accountable those entities who have created and fostered this epidemic by seeking injunctive relief designed to halt the flow of opioids, to recover money damages which will be used toward treatment and prevention efforts at the local level, and to direct reimbursement of the costs that local governments have incurred in fighting this epidemic. These lawsuits, unlike some state level lawsuits, sue not only the manufacturers, but also the pharmacies, the distributors and those companies that manage the flow of these drugs. This last group of defendants are companies are called pharmacy benefit managers and they provide reimbursement/payment to the pharmacies from the health insurance companies based on formulas that they create and negotiate with the insurers and the drug companies. Rather than attack just certain manufacturers, such as Purdue Pharma, these municipal suits cast a wide net in terms of the defendants.

The Town of Bennington was the first Vermont municipality to institute a lawsuit against these defendants. The counts, as set forth in the Complaint in which the Town of Bennington is the plaintiff, include public nuisance, unjust enrichment, fraud, negligence, conspiracy, and racketeering, among others. I have attached a copy of the voluminous complaint filed by the Town of Bennington because it is this lawsuit to which the Town of Bennington and the attorneys bringing the case would like to add other municipalities.

This case is brought in federal court in Ohio as part of a multi-district litigation and is under the management of Judge Polster. In the event of a trial, the trial would be here in Vermont Federal District Court. The case is on a contingent fee basis, meaning that the attorneys do not get paid unless there is a settlement or court verdict in favor of the plaintiffs. The attorneys are fronting all of the costs associated with bringing the litigation. The initial burden on the Town is minimal in terms of filing and it is likely that the case will not proceed to the "discovery" (document production and depositions) for at least a year or two.

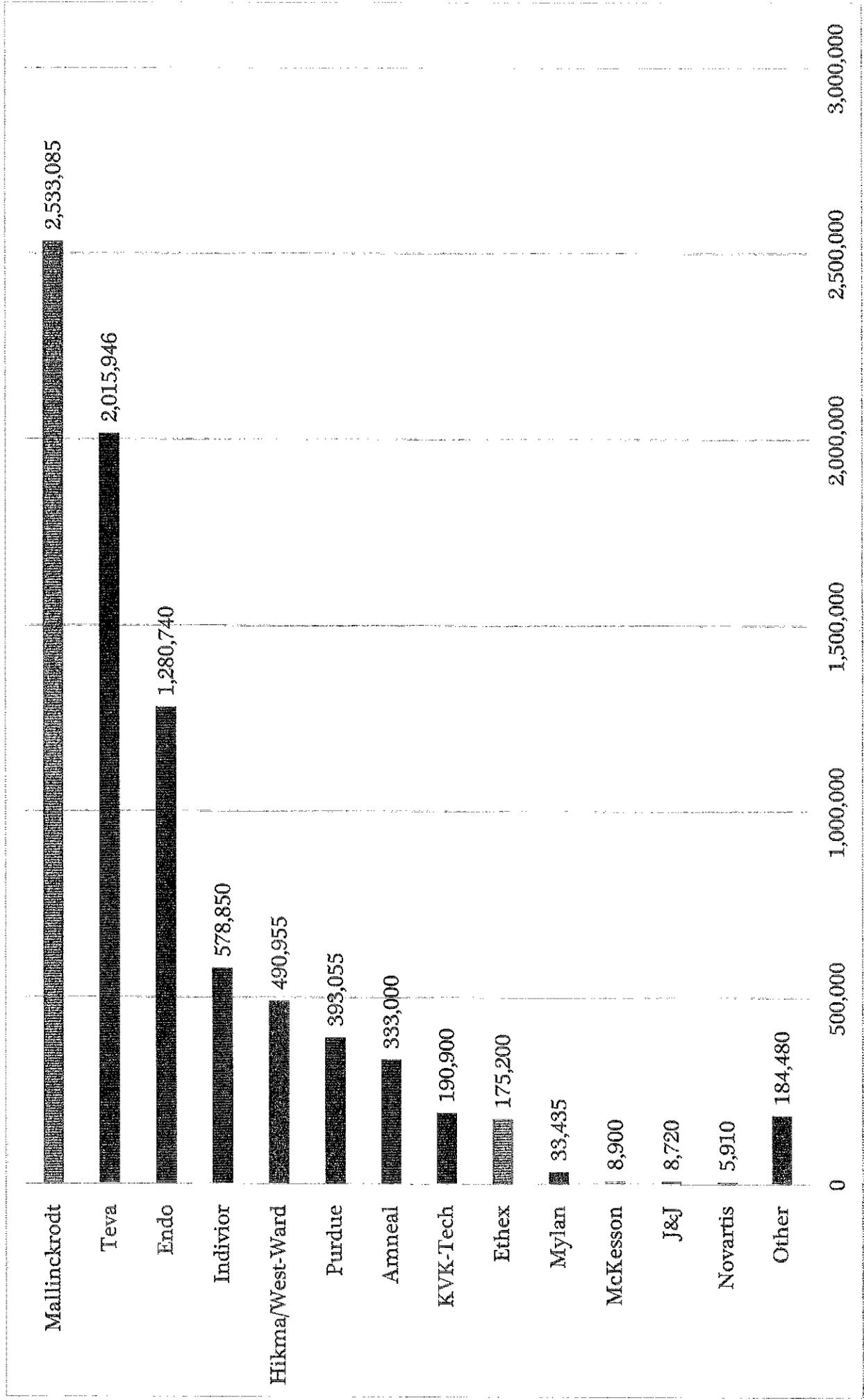
The forum hosted by the VLCT was an introduction to this type of litigation and broadly defined the litigation. Further factual inquiry into the statistics in Brattleboro have shown that the

number of opioid related deaths has dramatically increased over the last five years. The opioid epidemic has been front and center for emergency first responders and the local health system. Based on the information presented at the forum, review of the Bennington case filing, and review of the particular data regarding opioid distribution in Brattleboro, the Board is asked to approve the Town's joinder into the Bennington litigation.

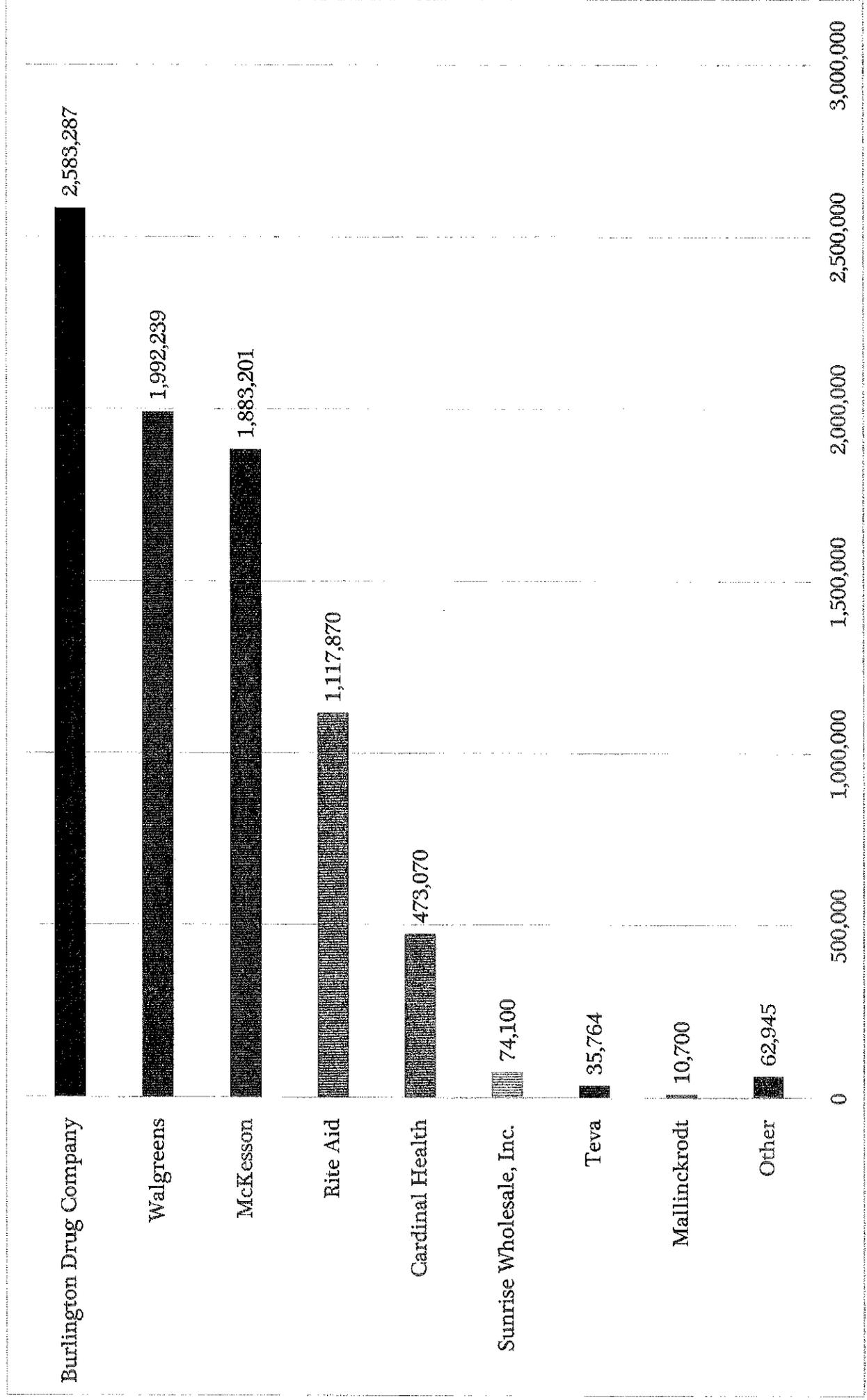
Of course, there are many questions that will need to be answered as the case progresses, such as: What are the measure of damages? How to prove damages that Brattleboro has incurred? How do the settlement proceeds (assuming a settlement) get allocated among municipalities? What will be the administrative burden on the Town? How much of any verdict actually goes to prevention and treatment? What are the elements of proof as to each claim? What happens if a defendant company goes into bankruptcy, like Purdue Pharma? How does the Town link its damages to each of the defendants? Are there local pharmacies which the Board would want to exclude from this litigation? How does the State litigation affect these municipality suits? Town Counsel is in contact with the litigation attorneys on this case regarding these questions. However, given the long period of time it will take for the case to mature toward a trial, these are questions that can be answered while the case is pending.

The following are attachments to this summary:

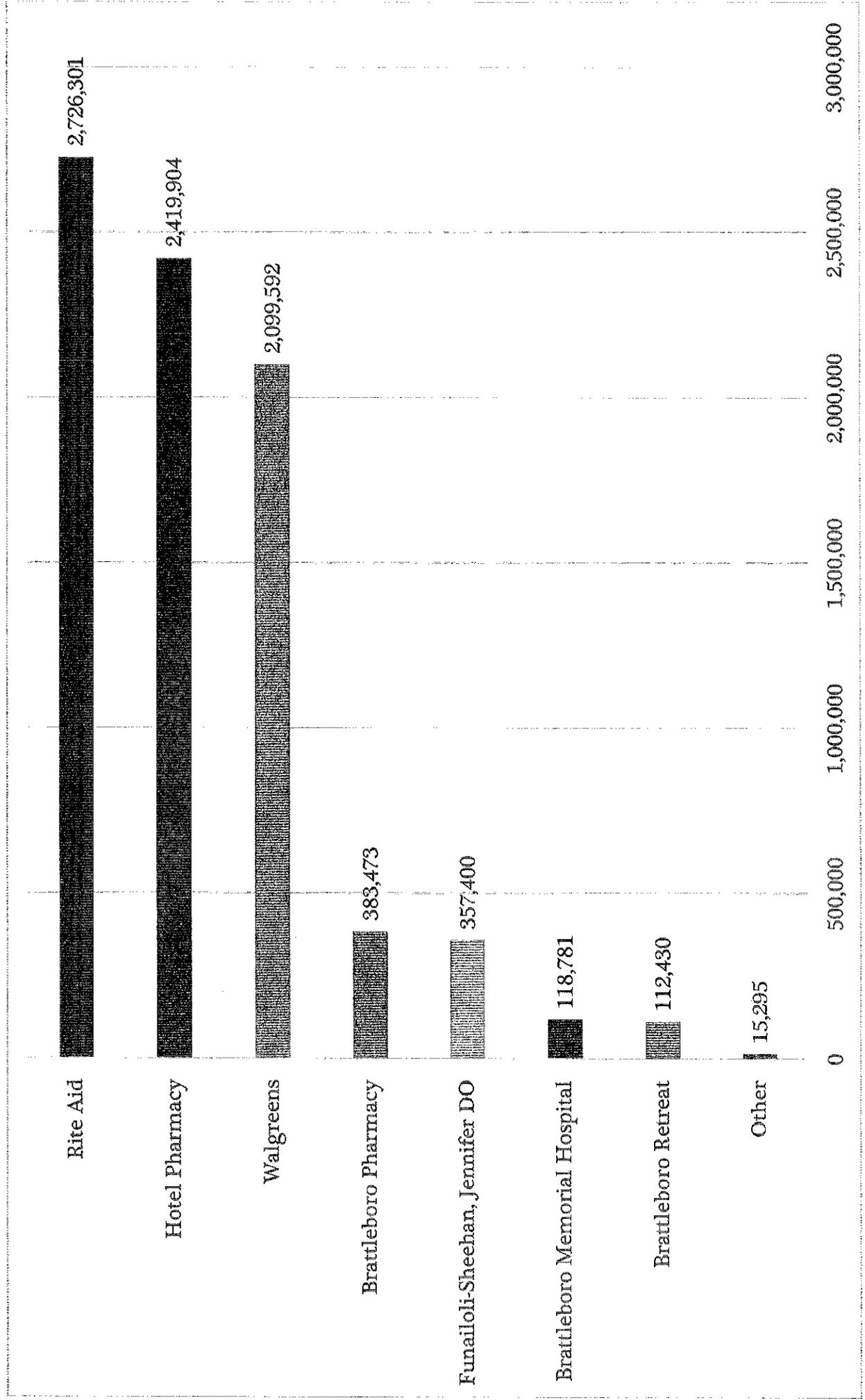
- 1) ARCOS reports for the Town of Brattleboro from 2006-2012
- 2) Bennington's Complaint as filed recently



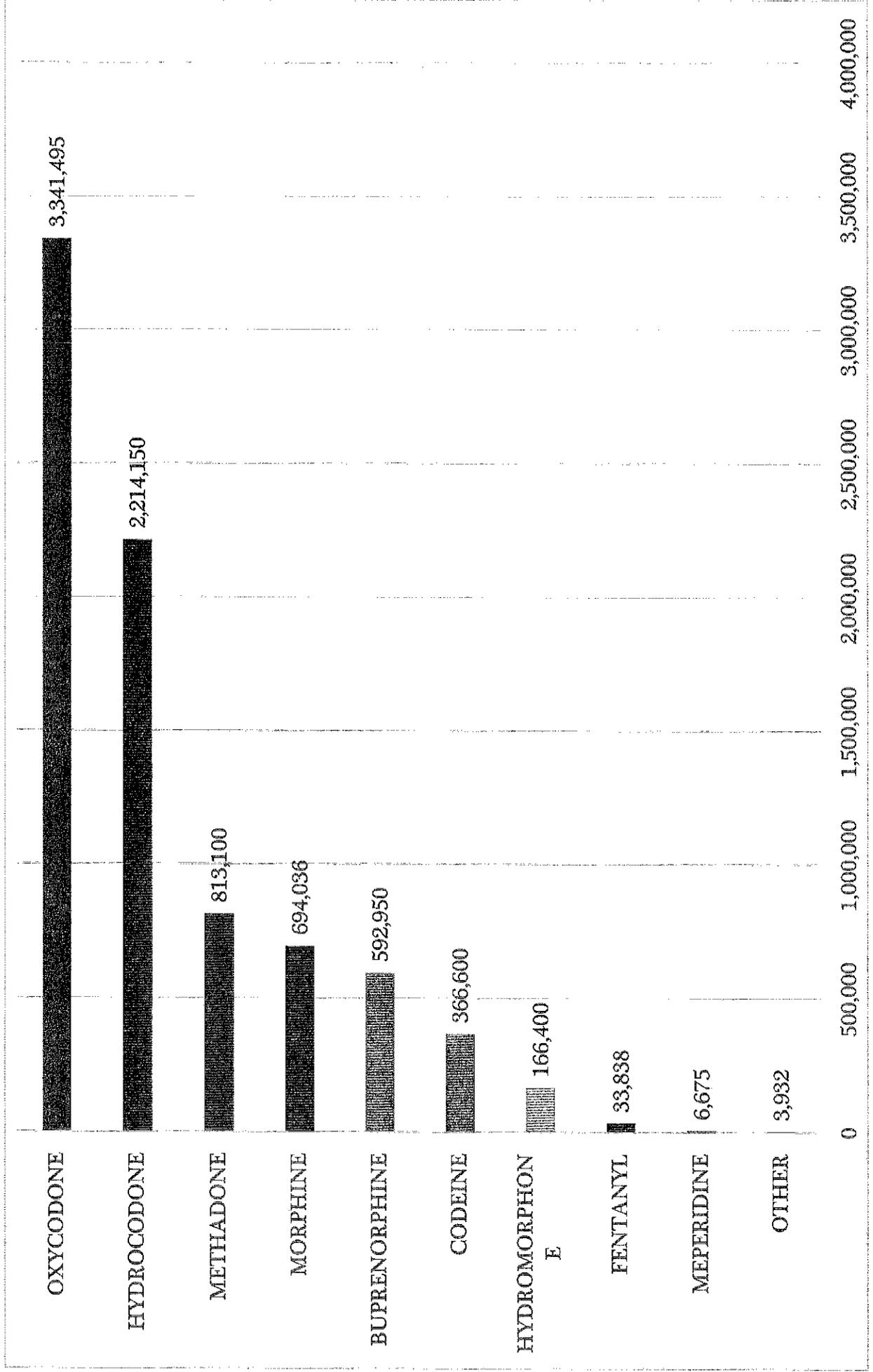
Town of Brattleboro, Vermont
ARCOS 2006-2012
DISTRIBUTORS
Dosage Units



Town of Brattleboro, Vermont
ARCOS 2006-2012
RETAILERS
Dosage Units



OPIOIDS
Dosage Units



UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

THE TOWN OF BENNINGTON, VERMONT

Plaintiff,

v.

MALLINCKRODT PLC; MALLINCKRODT
LLC; SPECGX LLC; RICHARD SACKLER;
BEVERLY SACKLER; DAVID SACKLER;
ILENE SACKLER LEFCOURT; JONATHAN
SACKLER; KATHE SACKLER;
MORTIMER D.A. SACKLER; THERESA
SACKLER; JOHN STEWART; MARK
TIMNEY; CRAIG LANDAU; RUSSELL
GASDIA; INDIVIOR; RECKITT
BENCKISER PHARMACEUTICALS INC.;
ENDO PHARMACEUTICALS, INC.; PAR
PHARMACEUTICAL COMPANIES, INC.;
PAR PHARMACEUTICAL, INC.; HIKMA
PHARMACEUTICALS; TEVA
PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; BARR
LABORATORIES, INC.; WATSON
LABORATORIES, INC.; ACTAVIS
PHARMA, INC.; JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC.; JANSSEN
PHARMACEUTICA, INC.; NORAMCO,
INC.; TASMANIAN ALKALOIDS
LIMITED;KVK-TECH, INC.; AMNEAL
PHARMACEUTICALS LLC; AMNEAL
PHARMACEUTICALS, INC.; AMNEAL
PHARMACEUTICALS OF NEW YORK,
LLC; MYLAN PHARMACEUTICALS, INC.;
MYLAN INSTITUTIONAL, INC.; MYLAN
TECHNOLOGIES, INC.; BURLINGTON
DRUG COMPANY; MCKESSON
CORPORATION; CARDINAL HEALTH,
INC.; AMERISOURCEBERGEN DRUG
CORPORATION; BELLCO DRUG
CORPORATION; H.D. SMITH; WALMART
INC.; WALMART PHARMACY
WAREHOUSE #45; WALMART

MDL 2804

Case No. 1:17-md-2804-DAP

Member Case No. _____

Judge Dan Aaron Polster

**COMPLAINT
AND JURY DEMAND**

PHARMACY WAREHOUSE #46;
WALMART PHARMACY 10-2289; CVS
HEALTH CORPORATION; CVS
PHARMACY, INC.; CVS RX SERVICES,
INC.; VERMONT CVS PHARMACY, LLC;
RITE AID MID-ATLANTIC; RITE AID OF
VERMONT, INC.; MAXI GREEN, INC.;
RITE AID DAYVILLE DISTRIBUTION
CENTER; ECKERD CORPORATION; THE
PHARMACY, INC.; PRICE CHOPPER
OPERATING CO. OF VERMONT, INC.;
GOLUB CORPORATION; EXPRESS SCRIPTS
HOLDING COMPANY; EXPRESS
SCRIPTS, INC; EXPRESS SCRIPTS
PHARMACY, INC.; CAREMARK RX,
L.L.C.; CAREMARKPCS HEALTH, L.L.C.;
CAREMARK, L.L.C.; CAREMARKPCS,
L.L.C.; UNITEDHEALTH GROUP
INCORPORATED; OPTUM, INC.;
OPTUMRX, INC.; WALGREEN BOOTS
ALLIANCE, INC.; WALGREEN CO.;
WALGREEN EASTERN CO.; and DOES 1-
100,

Defendants.

PLAINTIFF'S ORIGINAL COMPLAINT

Plaintiff, the Town of Bennington, Vermont, by and through the undersigned attorneys, (hereinafter "Plaintiff," "Town of Bennington," or "Bennington") against Defendants: Mallinckrodt PLC; Mallinckrodt LLC; SpecGx LLC; Richard Sackler; Beverly Sackler; David Sackler; Ilene Sackler Lefcourt; Jonathan Sackler; Kathe Sackler; Mortimer D.A. Sackler; Theresa Sackler; John Stewart; Mark Timney; Craig Landau; Russell Gasdia; Indivior; Reckitt Benckiser Pharmaceuticals, Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceutical Companies, Inc.; Par Pharmaceuticals, Inc.; Hikma Pharmaceuticals; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Barr Laboratories, Inc.; Watson Laboratories, Inc.; Watson Pharma, Inc.; Actavis Pharma, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc.; Noramco, Inc.; Tasmanian Alkaloids Limited; KVK-Tech, Inc.; Amneal Pharmaceuticals LLC; Amneal Pharmaceuticals, Inc.; Amneal Pharmaceuticals of New York, LLC; Mylan Pharmaceuticals, Inc.; Mylan Institutional Inc.; Mylan Technologies, Inc. (collectively, "Manufacturer Defendants"); Burlington Drug Company; McKesson Corporation; Cardinal Health, Inc.; AmerisourceBergen Drug Corporation; Bellco Drug Corporation; H.D. Smith, LLC; CVS Health Corporation (in its distributor capacity); CVS Pharmacy, Inc. (in its distributor capacity); CVS Rx Services, Inc.; Rite Aid Corp. (in its distributor capacity); Rite Aid Mid-Atlantic; Rite Aid Dayville Distribution Center; Eckerd Corporation; Walmart Inc.; Walmart Pharmacy Warehouse #45; Walmart Pharmacy Warehouse #46 (collectively, "Distributor Defendants"); The Pharmacy, Inc.; Vermont CVS Pharmacy, L.L.C; Walmart, Inc. (in its retail and mail order pharmacy capacity); Walmart Pharmacy 10-2289; Rite Aid of Vermont, Inc.; Maxi Green, Inc.; Price Chopper Operating Co. of Vermont, Inc.; Golub Corporation; Walgreen Boots Alliance, Inc.; Walgreen Co.; Walgreen Eastern Co. (collectively, "Pharmacy Defendants"); Express Scripts Holding Company (in its pharmacy benefit management capacity); Express

Scripts, Inc.; CVS Health Corporation (in its pharmacy benefit management capacity); Caremark Rx, L.L.C.; CaremarkPCS Health, L.L.C. d/b/a CVS/Caremark; Caremark, L.L.C.; UnitedHealth Group Incorporated; Optum, Inc.; OptumRx Inc. (in its pharmacy benefit management capacity); (collectively, "PBM Defendants"); and DOES 1 through 100 inclusive (collectively, "Defendants") alleges as follows:

I. INTRODUCTION

1. Defendants have caused an opioid epidemic that has resulted in economic, social and emotional damage to virtually every community in the United States and tens of thousands of Americans. It is indiscriminate and ruthless. It has impacted across demographic lines, harming every economic class, race, gender and age group. It is killing more than one hundred fifteen (115) Americans every day.¹ Prescription and illegal opioids account for more than sixty percent (60%) of overdose deaths in the United States, a toll that has quadrupled over the past two decades, according to the United States Centers for Disease Control and Prevention ("CDC"). More people died from opioid-related causes in 2016 than from car accidents² or guns.³ More than one hundred seventy-five (175) people die every day from drug overdoses, as if an airplane crashes killing everyone on board, every day.⁴

¹ *Opioid Overdose Crisis*, NATIONAL INSTITUTE ON DRUG ABUSE, revised March 2018, , CTRS FOR DISEASE CONTROL & PREVENTION, <https://www.cdcdrugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis>.

² *Deaths from Opioid Overdoses Now Higher Than Car Accident Fatalities*, HEALTHLINE, March 30, 2018, <https://www.healthline.com/health-news/deaths-from-opioid-overdoses-higher-than-car-accident-fatalities#1>

³ Ethan Siegal, *Opioid Epidemic So Dangerous, Says CDC, It's Finally Killing As Many Americans As Guns*, FORBES, March 20, 2018, <https://www.forbes.com/sites/startswithabang/2018/03/20/opioid-epidemic-so-dangerous-says-cdc-its-finally-killing-as-many-americans-as-guns/#32f5256f6c21>

⁴ Jerry Mitchell, *With 175 Americans dying a day, what are the solutions to the opioid epidemic?* USA TODAY NETWORK, Jan. 29, 2018, <https://www.usatoday.com/story/news/nation-now/2018/01/29/175-americans-dying-day-what-solutions-opioid-epidemic/1074336001/>

2. According to the CDC, the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement due to opioid misuse *alone* is \$78.5 billion a year.⁵

3. Prescription drug manufacturers, wholesalers/distributors, pharmacy benefit managers (“PBMs”), and pharmacies have created this epidemic. The manufacturers make the opioids and lie about their efficacy and addictive properties. The wholesalers distribute the opioids from the point of manufacture to the point of delivery to the patient. The PBMs control, through their pharmacy plan design and formulary management, which drugs go where and how they are paid for. And the retail pharmacies serve as the final link in the chain by releasing the opioids into the public.

4. Each defendant group profits enormously from the movement of the opioid products. Each has incentives to move certain drugs over others. Defendants themselves create the incentives and share in their perversity—usually without disclosure to those who reasonably rely on Defendants to abide by their federal, state and common law duties. They do so at the expense of Plaintiff and communities like it nationwide.

5. Each defendant group bears culpability in the crisis and is a necessary party to addressing the damage it has wreaked, including the costs of abatement.

6. The devastating impact of opioid abuse cannot be overstated. After years of decreasing death rates in the United States, they are now on the rise fueled by an increase in opioid-related drug overdose deaths. Drug overdoses are now the leading cause of death for Americans under the age of fifty (50). The number of Americans who died of drug overdose deaths in 2017

⁵ *Supra*, note 1.

was roughly equal the number of Americans who died in the Vietnam, Iraq, and Afghanistan wars combined.⁶

7. The Town of Bennington has been hit hard by the opioid epidemic. For example, the rate of overdose deaths in Bennington County has sharply risen from 6.78 deaths per 100,000 people in 2003 to 14.5 deaths per 100,000 people in 2017.⁷ That startling increase in recorded overdose deaths is likely not inclusive of all opioid overdose deaths in Bennington, as local information reflects the fact that the Town of Bennington averages about ten fatal opioid overdoses per year.⁸ Perhaps not surprisingly, the body count in Bennington has increased over the last two decades as the amount of opioids distributed in Bennington has increased.⁹

8. The increase in the volume of opioids in Bennington is a microcosm of the statewide pattern in Vermont. In 2010, 482,572 opioid prescriptions were dispensed in Vermont, a state with a population of just over 625,000.¹⁰ That number continued to rise. In 2015, the number of opioid prescriptions increased to 498,973¹¹, the equivalent of giving a prescription to every 1.3 people living in Vermont, including infants.

9. There is no question that this volume of opioids leads to increased incidence of dependence and addiction. In a 2014 survey by the U.S. Department of Health and Human

⁶ Nicholas Kristof, *Opioids, a Mass Killer We're Meeting With a Shrug*, NEW YORK TIMES, Jun. 22, 2017, <https://www.nytimes.com/2017/06/22/opinion/opioid-epidemic-health-care-bill.html>

⁷ Centers for Disease Control and Prevention Drug Poisoning Mortality Rates in the United States, 2003-2017, <https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality/>.

⁸ Christie Wisniewski, *Testimony Supports Call For Opioid Recovery Housing*, BENNINGTON BANNER, <https://www.benningtonbanner.com/stories/testimony-supports-call-for-opioid-recovery-housing.557014>

⁹ ARCOS Data

¹⁰ Anne VanDorisel, Shayla Livingston, and John Searles (Vermont Department of Health), *Opioids in Vermont: Prevalence, Risk, and Impact* (October 27, 2016), http://www.healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioids_Prevalence_Risk_Impact.pdf, at 30 ("Number of Prescriptions by Drug Type and Year"); Vermont Department of Health, *Special Report: Opioid Prescriptions and Benzodiazepines, 2014* (February 2016), http://www.healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioids_Benzodiazepines_Report.pdf, at 3.

¹¹ Id.

Services, more than three percent of Vermonters – approximately 18,000 people – reported a dependence on a controlled substance.¹² Vermont ranks as the 8th-highest state for drug dependence nationwide¹³, despite other favorable health indicators like better access to health care and insurance coverage as compared to other states.¹⁴

10. Opioids are killing Vermont citizens at a skyrocketing rate, and a common origin is prescription opioids. Drug-related fatalities involving opioids nearly doubled between 2012 and 2016.¹⁵ While the national average of opioid-related overdose deaths in 2016 was 13.3 per 100,000 persons, the rate in Vermont was 18.4.¹⁶ These overdose deaths have a broad impact. In a state like Vermont, there are no anonymous deaths.

11. Defendants' opioid-related misconduct causes heroin abuse. A 2015 study found that four out of five heroin users reported that their addiction started with opioid pain relievers.¹⁷ In this way, prescription opioids—now, thanks to Defendants, provided to patients for everyday conditions such as chronic knee pain and dental pain—can operate as a “gateway” drug to heroin use and involvement with the illegal drug market.

12. The Town of Bennington is now having to allocate substantial taxpayer dollars, resources, staff, energy and time to address the damage the opioid scourge has left in its wake and to address its many casualties. Fire and emergency medical services are over-utilized because of an increased number of opioid-related overdoses. The burden on law enforcement is substantially

¹² amfAR Opioid & Health Indicators Database, *Percent of People 12+ Reporting Drug Dependence*, <https://opioid.amfar.org/indicator/drugdep>

¹³ *Id.*

¹⁴ State Health Assessment Plan—Healthy Vermonters 2020 (December 2012), <https://www.healthvermont.gov/sites/default/files/documents/2016/11/Healthy%20Vermonters%202020%20Report.pdf>

¹⁵ Vermont Department of Health, *Opioid-Related Fatalities Among Vermonters (updated August 2018)* https://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Data_Brief_Opioid_Related_Fatalities.pdf

¹⁶ National Institute on Drug Abuse, *Vermont Opioid Summary* (March 2018), <https://www.drugabuse.gov/opioid-summaries-by-state/vermont-opioid-summary>

¹⁷ NAT'L SAFETY COUNCIL, *PRESCRIPTION NATION 2016: ADDRESSING AMERICA'S DRUG EPIDEMIC* 9 (2016), <http://www.nsc.org/RxDrugOverdoseDocuments/Prescription-Nation-2016-American-Drug-Epidemic.pdf>

increased by opioid-related crimes related to prescription opioid theft, diversion, and sales on the black market. Courts, social workers, schools' treatment centers, intervention programs, clinics, employee benefit plans, and others directly spending on opioids and opioid antagonists have all been harmed. Nearly every aspect of the Town of Bennington's services and budget has been significantly and negatively impacted by this Defendant-made epidemic.

13. Defendants' efforts to deceive and make opioids widely accessible have also resulted in a windfall of profits. Opioids are now the most prescribed class of drugs; they generated \$11 billion in revenue for drug companies in 2014 alone. While Americans represent only five percent (5%) of the world's population, they consume eighty percent (80%) of the world production of prescription opioids.¹⁸

14. The recipe for generating sky-high revenues is clear: patients who are prescribed opioids become physically and psychologically dependent on the drugs. When these opioid-addicted patients can no longer legally obtain opioids, they seek the drugs on the black market or turn to heroin which provides a similar high to prescription opioids. Defendants have generated a loyal customer base: hundreds of thousands of patients whose addiction guarantees an insatiable demand for the drugs and consistently high profits.

15. The scheme begins with Manufacturer Defendants who deliberately polluted the national marketplace, including in the Town of Bennington, with lies and misinformation about the efficacy of opioids to treat chronic pain, safety and abuse deterrent properties of their particular opioid products, and the risks of addiction. Using hired guns, advertising, and marketing materials, the Manufacturers promoted the fictitious concept of "pseudoaddiction," advocated that signs of

¹⁸ Dina Gusovsky, *Americans Consume Vast Majority of the World's Opioids*, CNBC, Apr. 27, 2016 9:13 AM, <http://www.cnbc.com/2016/04/27/americans-consume-almost-all-of-the-global-opioid-supply.html>

addiction should be treated with more opioids, falsely claimed that opioid dependence and withdrawal could be easily managed, and denied the risks of higher and protracted opioid dosages.

16. Even those Opioid manufacturers who may not have affirmatively polluted the national marketplace with false information about the dangers of opioids substantially contributed to the epidemic by purposefully and knowingly riding the coattails of the false narrative that had been intentionally developed by others. The generic opioid manufacturers identified in this complaint recognized the profits to be made from the lies that had been spun regarding opioid addiction and offered “spread pricing¹⁹” to motivate the purchase, dispensing, utilization, and reimbursement of their products by distributors, retailers, mail order pharmacies, and pharmacy benefit managers.

17. The Distributor Defendants did nothing to stem the excess flow of opioids into Vermont and the Town of Bennington. Wholesale drug distributors receive prescription opioids from drug manufacturers and transfer the opioids to hospitals, pharmacies, doctors, and other healthcare providers who then dispense the drugs to patients. Distributors are required by federal and state law to control and report unlawful drug diversions. The Distributor Defendants purposefully ignored these responsibilities, lobbied for higher reporting thresholds and pocketed profits on every opioid they moved – all at the expense of the Town of Bennington.

18. The Pharmacy Defendants (retail and mail order) likewise did nothing to stem the flow of excess opioids into The Town of Bennington. To the contrary, each of the Pharmacy Defendants dispensed opioids—and profited therefrom—through both their brick and mortar

¹⁹ “Spread pricing” is a phrase used to describe the practice of purposefully causing a reimbursement price (such as Average Wholesale Price “AWP” or Maximum Allowable Cost “MAC”) to be higher than the actual acquisition cost of a drug. In a commodity marketplace, such as the retail and mail order pharmacy market for generic drugs, pharmacies generally will stock their shelves with whichever commodity generates the most profit. That profit is largely influenced by the “spread” between the price the pharmacy is reimbursed for the drug (based on AWP or MAC, for example) and the pharmacy’s acquisition cost. Generic drug manufacturers compete based on spreads and intentionally set prices to maximize spread.

stores, and mail order pharmacies.

19. The Pharmacy Defendants made money on every opioid prescription they filled; even more so when filled through their mail order facilities or shipped by their own distribution centers. Much of the money Pharmacy Defendants made came from opioid manufacturers themselves (either directly or as a result of favorable “spread pricing”, *see* FN 19 above) or distributors—both of whom were likewise incentivized to maximize opioid use.

20. The Pharmacy Defendants ignored their responsibilities under federal and state law to monitor, detect, investigate, refuse to fill, and report suspicious orders which the Pharmacy Defendants knew or should have known were likely to be diverted in and around the Town of Bennington.

21. The Manufacturer, Distributor, and Pharmacy Defendants’ efforts to promote their scheme to distribute unnecessary opioids were purposefully facilitated by pharmacy benefit managers (“PBMs”) who—in addition to operating mail order pharmacies and, at times, acting as distributors—ensured that opioids were available, paid for, reimbursed, and at all times covered by public and private pharmacy benefit plans.

22. PBMs are the gatekeepers to the vast majority of opioid prescriptions filled in the United States. For most of the relevant time period, Caremark, Express Scripts, and OptumRx (all named defendants here) managed the drug benefits for approximately ninety-five percent (95%) of the United States’ population, or 253 million Americans.²⁰ Today, they manage approximately 75%.

²⁰ Brittany Hoffman-Eubanks, *The Role of Pharmacy Benefit Managers in American Health Care: Pharmacy Concerns and Perspectives: Part 1*, PHARMACY TIMES, Nov. 14, 2017, <http://www.pharmacytimes.com/news/the-role-of-pharmacy-benefit-mangers-in-american-health-care-pharmacy-concerns-and-perspectives-part-1>

23. PBMs design plans and create formularies which set the criteria and terms under which pharmaceutical drugs are reimbursed, numbers of refills permitted, number of pills per prescriptions, pre-authorization requirements, generic co-pay amount, branded drug co-pay amounts and other criteria. PBMs thereafter commit to monitor their customers' utilization and to manage drug plans and overall employee wellbeing. In these ways, PBMs influence prescription drug utilization overall.

24. Because PBMs are the intermediary between drug manufacturers, pharmacies (including their own captive mail-order pharmacies and, in CVS's case, their additional brick and mortar retail stores), and ultimately patients, these companies impact everything from pharmacy reimbursements to what drugs are covered under formularies and pursuant to what terms.²¹ In these ways, the PBMs influence which drugs enter the marketplace. Their fingerprints are on nearly every opioid prescription filled and they profit in myriad ways on every pill.

25. Accordingly, Plaintiff seeks an order compelling Defendants to halt their unlawful dangerous practices and to abate and remove the foreseeable public nuisance they knowingly caused and from which they have profited mightily.

26. Plaintiff also seeks to recover damages for the costs it has and will incur as a result of Defendants' unlawful conduct, which conduct will have multi-generational consequences for the Town. Plaintiff seeks treble damages, punitive damages and disgorgement of all ill-gotten gains, together with attorneys' fees and costs in addition to any other equitable relief authorized by law.

II. VENUE AND JURISDICTION

²¹ Matthew Kandrach, *PBM stranglehold on prescription drug market demands reform*, THE HILL, May 2, 2017, <http://thehill.com/blogs/pundits-blog/healthcare/331601-pbm-stranglehold-on-prescription-drug-market-demands-reform>

27. This Court has original jurisdiction over this action for purposes of pretrial proceedings pursuant to 28 U.S.C. § 1407, and Case Management Order One entered on April 11, 2018 as ECF Doc. No. 232 in *In re: National Prescription Opiate Litigation*, Case No. 1:17-cv-2804 (N.D. Ohio).

28. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations ACT, 18 U.S.C. §§ 1961, *et seq.* (“RICO”). This Court has supplemental jurisdiction over Plaintiff’s state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff’s federal claims that they form part of the same case or controversy.

29. Defendants are subject to the Court’s jurisdiction because Defendants conduct business in Vermont, purposefully direct or directed their actions toward Vermont, consented to be sued in Vermont by registering an agent for service of process, consensually submitted to the jurisdiction of Vermont when obtaining a manufacturer, distributor or pharmacy license, and have the requisite minimum contacts with Vermont necessary to permit the Court to exercise jurisdiction over Defendants.

30. Venue is proper within this District pursuant to 28 U.S.C. § 1391, as this District is a judicial district where Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. §§ 1391(a) and (c).

31. Certain Defendants are non-domiciliaries of Vermont who regularly engage in business within Vermont. These defendants have committed tortious acts outside and within Vermont that have caused injury within Vermont and to the Town of Bennington. Defendants expect or should reasonably have expected those acts to have consequences in Vermont. Defendants, moreover, solicited business within Vermont, engaged in persistent courses of conduct in Vermont, and derived substantial revenue from goods used and services rendered in

Vermont through interstate commerce, including through the Vermont Medicaid program.

32. Defendants are regularly engaged in the business of manufacturing, distributing, dispensing and reimbursing prescription opioids in Vermont and, specifically, in the Town of Bennington. Defendants' activities in the Town of Bennington in connection with the manufacture, distribution, dispensation and reimbursement of prescription opioids was, and is, continuous and systematic, and give rise to the causes of action alleged herein.

III. PARTIES

A. PLAINTIFF

33. The Town of Bennington is a municipal corporation duly chartered and existing under the laws of Vermont with its governing body being the Bennington Select Board. The Plaintiff has standing to bring this suit. 24 App. V.S.A. c. 103 § 101.

B. MANUFACTURER DEFENDANTS

34. Defendant, MALLINCKRODT PLC, is an Irish public limited company with its corporate headquarters in Staines-upon-Thames, United Kingdom. MALLINCKRODT PLC may be served through its registered agent in the United States: CT Corporation System, 120 South Central Avenue, Suite 400, Clayton, Missouri 63105.

35. Defendant, MALLINCKRODT LLC, is a wholly owned subsidiary of MALLINCKRODT PLC and is a Delaware limited liability company with its principal place of business in St. Louis, Missouri. MALLINCKRODT LLC is registered to do business in Vermont and has been since at least October 4, 2013.

36. Defendant, SPECGX LLC is a Delaware limited liability company with its principal place of business in Clayton, Missouri and is a wholly-owned subsidiary of MALLINCKRODT PLC. SPECGX LLC may be served in Vermont through its registered agent:

C T Corporation System, 17 G W Tatro Dr, Jeffersonville, VT, 05464. SPECGX LLC is licensed as a Wholesale Drug Outlet with the Vermont Department of Health Professionals.

37. MALLINCKRODT PLC, MALLINCKRODT LLC and SPECGX LLC are referred to collectively as “Mallinckrodt.”

38. Mallinckrodt manufactures, markets, sells and distributes pharmaceutical drugs throughout the United States. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

39. In Vermont and nationally, Mallinckrodt is engaged in the manufacture, promotion, and distribution of Roxicodone, oxycodone, and hydrocodone, among other drugs. Mallinckrodt transacts business in Vermont, targeting the Vermont market for its products, including the opioids at issue in this lawsuit, which Mallinckrodt has sold in Vermont.

40. According to the DEA ARCOS database, drugs manufactured by Mallinckrodt represented approximately 15.1% of the opioid market share in the Town of Bennington from 2006 through 2012. Through this period, opioids in the Town of Bennington manufactured by Mallinckrodt totaled over 41.6 million MME, or more than 4.3 million dosage units.

41. On information and belief, Mallinckrodt hires employees to service the Vermont market, including a Medical Science Liaison for Nephrology,²² and also directs advertising and informational materials to impact Vermont physicians and potential users of Mallinckrodt products.

42. At all times relevant hereto, the PBM Defendants listed the brand drug Roxicodone or its generic alternative oxycodone as approved reimbursable drugs on their formularies. They

²² <https://www.linkedin.com/jobs/view/medical-science-liaison-nephrology-connecticut-rhode-island-massachusetts-new-hampshire-vermont-at-mallinckrodt-pharmaceuticals-29984951/>

imposed no pre-authorization requirements or quantity limits on prescriptions until 2014 at the earliest and even there, the limitations did not extend to the PBM commercial plans. The PBM Defendants listed other generic opioids manufactured by Mallinckrodt as approved reimbursable drugs on their formularies, often without any quantity limits or pre-authorization requirements; often in preferred tiers.

43. Defendant, RICHARD SACKLER, a resident of Riviera Beach, Florida, has served on the board of directors for Purdue at all relevant times and until 2018.

44. Defendant, BEVERLY SACKLER, a resident of Connecticut, has served on the board of directors for Purdue at all relevant times and until 2017.

45. Defendant, DAVID SACKLER, a resident of New York, has served on the board of directors for Purdue from 2012 to 2018.

46. Defendant, ILENE SACKLER LEFCOURT, a resident of New York, has served on the board of directors for Purdue at all relevant times.

47. Defendant, JONATHAN SACKLER, a resident of Connecticut, has served on the board of directors for Purdue at all relevant times.

48. Defendant, KATHE SACKLER, a resident of Connecticut, has served on the board of directors for Purdue at all relevant times.

49. Defendant, MORTIMER D.A. SACKLER, a resident of New York, has served on the board of directors for Purdue at all relevant times.

50. Defendant, THERESA SACKLER, a resident of the United Kingdom, has served on the board of directors for Purdue at all relevant times and until 2018.

51. At all relevant times, the aforementioned Defendants (collectively, the “Sackler Defendants”) comprised a majority of the board of directors for Purdue, enabling the Sackler Defendants to exert control over Purdue’s business decisions, including the implementation of

deceptive sales and marketing practices associated with opioids.

52. Defendant, JOHN STEWART, a resident of Florida, served as Purdue's CEO from 2007 to 2013.

53. Defendant, MARK TIMNEY, a resident of Connecticut, served as Purdue's CEO from 2014 to 2017.

54. Defendant, CRAIG LANDAU, a resident of Connecticut, served as Purdue's CEO from 2017 to the present.

55. Defendants, JOHN STEWART, MARK TIMNEY, and CRAIG LANDAU, in their capacities as CEO of Purdue Pharma L.P. and Purdue Pharma, Inc., each directed Purdue's misconduct.

56. Defendant RUSSELL GASDIA, a resident of Massachusetts, carried out the misconduct in his capacity as Vice President of Sales and Marketing for Purdue at all relevant times until 2014.

57. Defendants, John Stewart, Mark Timney, Craig Landau, and Russell Gasdia are collectively referred to as the "Purdue Officer Defendants". The Sackler Defendants and the Purdue Officer Defendants are collectively referred to as the "Purdue Individual Defendants."

58. Substantially all of the Sackler Defendants (except David Sackler) were heavily involved in the conduct that led to the fines and criminal convictions in 2007. From the 1990s until 2007, they directed a decade of misconduct, which led to criminal convictions and commitments that Purdue would not deceive doctors and patients again. That background confirms that their misconduct since 2007 was knowing, purposeful, reckless, and intentional.

59. While the Sackler Defendants relinquished their officer titles in or around 2003 to try to shield themselves from future criminal and civil liability, they remained Purdue's owners, in control of its Board of Directors, and thus in control of the firm.

60. At all relevant times, at least through the end of 2018, the Sackler Defendants controlled Purdue's deceptive sales campaign. They directed the company to hire hundreds more sales representatives to visit doctors thousands more times. They insisted that sales representatives repeatedly visit the most prolific prescribers. They directed representatives to encourage doctors to prescribe more of the highest doses of opioids. They studied unlawful tactics to keep patients on opioids longer and then ordered staff to use them. They asked for detailed reports about doctors suspected of misconduct, how much money Purdue made from them, and how few of them Purdue had reported to the authorities. They sometimes demanded more detail than anyone else in the entire company, so staff had to create special reports just for them. Richard Sackler even went into the field to promote opioids to doctors and supervise representatives face-to-face. In connection with a single meeting in 2011, for example, sales and marketing staff scrambled to prepare responses to questions from the Sackler Defendants, Defendant Mortimer Sackler asked about launching a generic version of OxyContin to "capture more cost sensitive patients," Defendant Kathe Sackler recommended looking at the characteristics of patients who had switched to OxyContin to see if Purdue could identify more patients to convert, and Defendant Jonathan Sackler wanted to study changes in market share for opioids, focusing on dose strength.

61. On information and belief, the Sackler Defendants' micromanagement was so intrusive that staff begged for relief. Defendant Gasdia wrote to the CEO: "Anything you can do to reduce the direct contact of Richard into the organization is appreciated." To convince the Sackler Defendants to make him CEO, Defendant Landau wrote a plan that he titled: "SACKLER PHARMA ENTERPRISE." He started by admitting that the Sackler Defendants in fact controlled the company like chief executive officers. The family ran "the global Sackler pharmaceutical enterprise ... with the Board of Directors serving as the 'de-facto' CEO." The Sackler Defendants concealed their ongoing, extensive involvement with Purdue and its sales and marketing practices.

62. From the money that Purdue collected as a result of its wrongful conduct, the Sackler Defendants paid themselves and their family billions of dollars. From the 2007 convictions (of certain Purdue officers) until 2018, the Sackler Defendants voted dozens of times to pay out Purdue's opioid profits to their family - in total **more than four billion dollars**.

63. The Purdue Individual Defendants all actively participated in the common law torts and federal and state statutory violations of Purdue and benefited therefrom. The tortious conduct of the Purdue Individual Defendants was not, and could not have been through the exercise of due diligence, known to the public until their conduct was detailed in recent court filings by the Attorney General of Massachusetts.

64. Under the Purdue Individual Defendants, Purdue has engaged in the manufacture, promotion, and distribution of opioids, including: (a) OxyContin (oxycodone hydrochloride extended release), a Schedule II opioid agonist tablet first approved in 1995 and marketed by Purdue for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." OxyContin was indicated, or legally approved, for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time"; and (b) MS Contin (morphine sulfate extended release), a Schedule II opioid agonist tablet first approved in 1987 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

65. Both OxyContin and MS Contin are brand drugs. The original OxyContin formulation first faced generic competition in 2004. MS Contin has faced generic competition since 1998.

66. Purdue secured a new patent for an abuse-deterrent formulation of OxyContin in 2010.

67. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up almost four-fold from 2006 sales of \$800 million. OxyContin constitutes roughly thirty percent (30%) of the entire market for analgesic drugs (painkillers).

68. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States \$635 million. At the time, this was one of the largest settlements with a drug company for marketing misconduct. Purdue's misconduct has continued, as alleged herein, settlement notwithstanding.

69. Purdue transacts business in Vermont, targeting the Vermont market for its products, including the opioids at issue in this lawsuit. On information and belief, Purdue hires and/or has hired employees to service the Vermont market. On information and belief, Purdue also directs advertising and informational materials to impact Vermont physicians and potential users of Purdue products.

70. According to the DEA ARCOS database, drugs manufactured by Purdue represented approximately 6.1% of the opioid market share in the Town of Bennington from 2006 through 2012. Through this period, opioids in the Town of Bennington manufactured by Purdue totaled approximately 16,793,125 Milligram Morphine Equivalent ("MME") which translates to over 303,000 dosage units of opioids.²³

²³ MME is a value assigned to opioids to represent their relative potencies by comparing a given opioids strength to an equivalently strong dose of morphine. While a 100 mg of hydrocodone dose would equate to a 100 MME dose due to its being comparably potent to morphine, it would take only a 769 *microgram* dose of a fentanyl tablet to reflect a 100 MME dose due to its relatively high potency compared to morphine.

71. Rhodes Pharmaceuticals, also under the guidance of many of the Purdue Individual Defendants, is presently among the largest producers of generic opioids in the U.S.²⁴ Together with Purdue, Rhodes accounted for 14.4 million opioid prescriptions in 2016, or 6% of the US Opioid market.²⁵

72. Rhodes also owns, together with Purdue, the '919 Patent entitled "Oxycodone Compositions" and is involved in the manufacture of the active pharmaceutical ingredient used in Purdue's OxyContin.

73. Rhodes is also now the registered holder of approved New Drug Application No. 19-891, which covers the manufacturer and sale of Dilaudid.

74. Upon information and belief, Rhodes manufactures, promotes, distributes and/or sells generic opioids nationally, in Vermont, and in the Town of Bennington, including but not limited to oxycodone, morphine sulfate, hydrocodone and hydromorphone.

75. According to the DEA ARCOS database, drugs manufactured by Rhodes represented approximately .3%% of the opioid market share in the Town of Bennington from 2006 through 2012. Through this period, opioids in the Town of Bennington manufactured by Rhodes totaled approximately 755,924 Milligram Morphine Equivalent ("MME"), which translates to more than 42,000 dosage units of opioids.

76. Defendant, ENDO PHARMACEUTICALS, INC., is a wholly owned subsidiary of Endo Health Solutions, Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

²⁴ David Crow, *Billionaire Sackler family owns second opioid drugmaker*, FINANCIAL TIMES, Sept. 9, 2018, <https://www.ft.com/content/2d21cf1a-b2bc-11e8-99ca-68cf89602132>

²⁵ *Id.*

77. ENDO PHARMACEUTICALS, INC. may be served through its registered agent, The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

78. Defendant PAR PHARMACEUTICAL COMPANIES, INC. (“Par Pharmaceutical Cos.”) is a Delaware corporation, having a principal place of business in Chestnut Ridge, New York. On information and belief, Par Pharmaceutical Cos. is a holding company and is a wholly-owned subsidiary, directly or indirectly, of Endo International plc.

79. Defendant, PAR PHARMACEUTICAL, INC. (“Par Pharmaceutical”) is a New York corporation, having a principal place of business located in Chestnut Ridge, New York. On information and belief, Par Pharmaceutical is a wholly-owned subsidiary of Par Pharmaceutical Cos. and holds itself out as “an Endo International Company.” Par Pharmaceutical is and has been licensed as a Wholesale Drug Outlet with the Vermont Department of Health Professionals since 1992.

80. Par Pharmaceutical Cos. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. Par Pharmaceutical may be served through its registered agent: CT Corporation System, 28 Liberty Street, New York, New York 10005.

81. Par Pharmaceutical and Par Pharmaceutical Cos. are referred to collectively as “Par.”

82. ENDO PHARMACEUTICALS, INC., and Par are, at times, referred to collectively as “Endo.”

83. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, throughout the United States, including Vermont. Opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion in 2012.

Opana ER yielded \$1.15 billion in revenue from 2010 to 2013, and it accounted for ten percent (10%) of Endo's total revenue in 2012. Endo, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc., also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, meperidine and hydrocodone products across the United States, including Vermont.

84. Par develops, markets, and sells prescription drugs including the brand opioid Endocet and generic opioids consisting of oxycodone, oxymorphone, hydrocodone, morphine sulfate, and fentanyl citrate, throughout the United States, including Vermont.

85. According to the DEA ARCOS database, drugs manufactured by Endo Pharmaceuticals represented approximately .3% of the opioid market share in the Town of Bennington from 2006 through 2012. Through this period, opioids in the Town of Bennington manufactured by Endo totaled nearly 800,000 MME, or more than 35,000 dosage units.

86. According to the DEA ARCOS database, drugs manufactured by Par Pharmaceutical represented approximately 3.9% of the opioid market share in Bennington from 2006 through 2012. Through this period, opioids in Bennington manufactured by Par totaled nearly 10.8 million MME, or more than 1 million dosage units.

87. At all times relevant hereto, the PBM Defendants listed generic opioids manufactured by Endo as approved reimbursable drugs on their formularies, often without any quantity limits or pre-authorization requirements; often in preferred tiers.

88. On information and belief, Endo transacts business in Vermont, targeting the Vermont market for its products, including the opioids at issue in this lawsuit. On information and belief, Endo hires employees to service the Vermont market. On information and belief, Endo also directs advertising and informational materials to impact Vermont physicians and potential users of Endo products.

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

90. Defendant, CEPHALON, INC. (“Cephalon”), is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

91. Defendant, BARR LABORATORIES, INC. (“Barr”), is a Delaware corporation with its principal place of business in Horsham, Pennsylvania. In 2008, Teva Ltd. acquired Barr.

92. Defendant, WATSON LABORATORIES, INC., is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

93. Defendant, ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc.

94. WATSON LABORATORIES, INC., WATSON PHARMA, INC. and ACTAVIS PHARMA, INC. are wholly-owned indirect subsidiaries of Teva, Ltd., which acquired the companies in 2016. Prior to 2016, each of these companies were subsidiaries of Allergan plc.

95. TEVA USA, has a may be served through its registered agent: 1233 Shelburne Road, Suite 400, South Burlington, VT, 05403. TEVA USA is licensed and has been licensed as a Wholesale Drug Outlet with the Vermont Department of Health Professionals since 1992. CEPHALON may be served at 41 Moores Road, Frazer, Pennsylvania 19355.

96. WATSON LABORATORIES, INC. may be served through its registered agent: Corporate Creations Network Inc., 8275 South Eastern Avenue, #200, Las Vegas, Nevada 89123. ACTAVIS PHARMA, INC. may be served through its registered agent: Corporate Creations Network Inc. 3411 Silverside Road, Tatnall Building STE 104, Wilmington, DE 19810.

CEPHALON, INC. and BARR LABORATORIES may be served through their registered agent: Corporate Creations Network Inc. 3411 Silverside Road, Tatnall Building STE 104, Wilmington, DE 19810.

97. TEVA USA, CEPHALON, BARR, WATSON LABORATORIES, INC., Watson pharma, Inc., and ACTAVIS PHARMA, INC. are referred to collectively as “Teva.”

98. Teva manufactures, promotes, distributes and sells both brand name and generic versions of opioids nationally, and in The Town of Bennington, including the following: (a) Actiq, and (b) Fentora. Teva also was in the business of selling generic opioids, including morphine, hydromorphone, tramadol, codeine, and meperidine from at least 2000, and a generic form of OxyContin from 2005 to 2009, among others.

99. Teva transacts business in Vermont, targeting the Vermont market for its products, including the opioids at issue in this lawsuit. Teva hires employees to service the Vermont market, including a Clinical Nurse Educator CNS in Burlington, Vermont.²⁶ On information and belief, Teva also directs advertising and informational materials to impact Vermont physicians and potential users of its products.

100. According to the DEA ARCOS database, drugs manufactured by Teva represented approximately 10.7% of the opioid market share in the Town of Bennington from 2006 through 2012. Through this period, opioids in the Town of Bennington manufactured by Teva totaled over 29.3 million MME, or nearly 1.8 million dosage units.

101. At all times relevant hereto, the PBM Defendants listed the generic opioids manufactured by Teva as approved reimbursable drugs on their formularies, often without any quantity limits or pre-authorization requirements; often in preferred tiers.

²⁶ <https://www.linkedin.com/jobs/view/clinical-nurse-educator-cns-albany-ny-burlington-vt-western-ma-at-teva-pharmaceuticals-138500477/>

102. At all times relevant hereto, PBM Defendant OptumRx listed both Actiq and Fentora as approved reimbursable brand drugs on its formularies. In many years, the products had preferred brand status.

103. OptumRx did not impose any quantity limits or pre-authorization requirements for the generic Teva OxyContin.

104. Defendant, JOHNSON & JOHNSON, is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Johnson & Johnson Health Care Systems Inc. is a wholly owned subsidiary of JOHNSON & JOHNSON, has been registered to do business in Vermont since at least 2019 and may be served through their registered agent: CT Corporation System, 17 GW Tatro Dr, Jeffersonville, VT 05464.

105. Defendant, JANSSEN PHARMACEUTICALS, INC. (formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.) is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON.

106. Upon information and belief, JOHNSON & JOHNSON controls the sale and development of JANSSEN PHARMACEUTICALS, INC.'s drugs and JANSSEN PHARMACEUTICALS, INC.'s profits inure to JOHNSON & JOHNSON's benefit.

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

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

109. JANSSEN PHARMACEUTICALS, INC. may be served at 1125 Trenton-

Harbourton Road, Titusville, New Jersey 08560.

110. Defendant NORAMCO, INC. is a Georgia corporation with its principal place of business in Wilmington, Delaware. NORAMCO, INC. is an active pharmaceutical ingredient (“API”) developer and manufacturer of pharmaceutical products including opioids. NORAMCO, INC. is and has been registered to do business in Vermont since at least 2016 and may be served through its registered agent: CT Corporation System, 17 GW Tatro Dr, Jeffersonville, VT 05464.

111. TASMANIAN ALKALOIDS PTY. LTD. is an Australian company that cultivates and processes opium poppy plants to manufacture narcotic raw materials that are imported into the U.S.

112. NORAMCO, INC. and TASMANIAN ALKALOIDS PTY. LTD. were wholly owned subsidiaries of JOHNSON & JOHNSON at all relevant times until July 2016 when JOHNSON & JOHNSON sold its interest in both companies to private equity firm SK Capital.

113. NORAMCO, INC. and TASMANIAN ALKALOIDS PTY. LTD. worked together to shepherd the production of opioids through the pharmaceutical supply chain from cultivation and development to the processing of ingredient APIs. These ingredient APIs were then sold to other pharmaceutical companies who in turn developed and manufactured their own opioid drugs that they ultimately unleashed onto the U.S. and Vermont markets, including Bennington.

114. Upon information and belief, JOHNSON & JOHNSON controlled the sale and development of NORAMCO, INC.’s drugs during all relevant times until July 2016, and in that time NORAMCO, INC.’s profits inured to JOHNSON & JOHNSON’s benefit.

115. JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC, JANSSEN PHARMACEUTICA, INC., JOHNSON & JOHNSON, NORAMCO, INC., and TASMANIAN ALKALOIDS LTD. are collectively referred to as “Janssen.”

116. Up until 2016, when Janssen sold its Noramco/Tasmanian Alkaloids businesses, Tasmanian Alkaloids and Noramco were sister companies, as both of them were members of Janssen's family of companies. Janssen, Noramco, and Tasmanian Alkaloids shared employees and resources that were required to operate the business. Noramco employees physically worked at Janssen facilities in New Jersey at various times, and employees simultaneously held positions at multiple companies within the Janssen family of companies at times. During this time, Noramco and Tasmanian Alkaloids were key parts of Janssen's pain management franchise, which included all of Janssen's pain products and was an important part of Janssen's business from the mid-1990s to after 2010.

117. Dr. Paul Janssen originally invented fentanyl in the 1950s, and since at least the mid-1990s, Janssen has been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in Bennington, including the following: (i) Duragesic, a transdermal patch made out of the active pharmaceutical ingredient ("API"), fentanyl; (ii) Ultram and Ultram Extended Release ("ER") tablets made out of the API, tramadol; (iii) Ultracet-tablets made out of the APIs, tramadol and acetaminophen; (iv) Nucynta and Nucynta ER, tablets made out of the API, tapentadol; (v) Tylenol with Codeine, tablets made out of the APIs, acetaminophen and codeine; (vi) Tyloxcapsules made out of the APIs, acetaminophen and oxycodone. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least \$1 billion in annual sales.

118. According to the DEA ARCOS database, drugs manufactured by Janssen Pharmaceuticals represented approximately 3.4% of the opioid market share in the Town of Bennington from 2006 through 2012. Through this period, opioids in the Town of Bennington manufactured by Janssen totaled over 9.4 million MME, or more than 12,900 dosage units.

119. Janssen transacts business in Vermont, targeting the Vermont market for its

products, including the opioids at issue in this lawsuit. Janssen hires employees to service the Vermont market. For example, Janssen recently advertised online that it was seeking a District Manager to operate out of Montpelier, Vermont.²⁷ On information and belief, Janssen also directs advertising and informational materials to impact Vermont physicians and potential users of its products.

120. At all times relevant hereto, Janssen promoted to physicians and teaching hospitals the sale and use of its opioid products throughout the U.S., including in Vermont and Bennington. Between 2013 and 2016, Janssen made 25,606 payments totaling \$2.04 million to promote the sale and use of Nucynta (tapentadol).

121. At all times relevant hereto, the PBM Defendants have ensured access to and reimbursement of Janssen's opioids.

122. PBM Defendant OptumRx has routinely listed Janssen's Duragesic as an approved reimbursable brand drug on its formularies, often with preferred brand status and without pre-authorization requirements. It has also reimbursed for the Nucynta products, again without pre-authorization requirements and with preferred brand status.

123. PBM Defendant Express Scripts has listed Janssen's Nucynta and Nucynta ER as approved reimbursable brands on its formulary without quantity limits or preauthorization requirements.

124. PBM Defendant Caremark also has listed Duragesic and Nucynta products as approved brands on its formularies without prior authorization requirements. The publicly available DEA ARCOS data reveals that Janssen's opioids were widely purchased in the mail order pharmacy environment. From 2006-2012, Janssen sold over 1.24 billion MME to mail order

²⁷ <https://find.jobs/jobs/johnson-johnson/district-manager-oncology-new-england-so/1566214097568320161>

pharmacies. This translates to over 8 million dosage units of opioids- all purchased for dispensing by mail nationwide.

125. The publicly available ARCOS data reveals that the PBM Mail Order Pharmacies named herein each purchased Janssen opioids for dispensing by mail nationwide. During the 2006-2012 time period, Express Scripts Mail Order Pharmacy purchased over 702 million MME in Endo's opioids, Caremark's Mail Order Pharmacy purchased over 416 million MME and Optum's Mail Order Pharmacy purchased over 25 million MME.

126. Defendant, KVK-TECH, INC. ("KVK-Tech") is a Pennsylvania corporation with its principle place of business in Newton, Pennsylvania. KVK-Tech may be served through its registered agent: Frank Ripp, Jr., 110 Terry Drive, Newton, Pennsylvania 18940.

127. KVK-Tech is currently licensed as Wholesale Drug Outlet with the Vermont Department of Health Professionals. Upon information and belief, KVK-Tech manufactures, promotes, distributes and/or sells generic opioids nationally, in Vermont, and in the Town of Bennington, including but not limited to oxymorphone and oxycodone.

128. According to the DEA ARCOS database, drugs manufactured by KVK-Tech represented approximately .3% of the opioid market share in the Town of Bennington from 2006 through 2012. Through this period, opioids in the Town of Bennington manufactured by KVK-Tech totaled over 907,000 MME, or more than 79,000 dosage units.

129. At all times relevant hereto, the PBM Defendants listed generic opioids manufactured by KVK-Tech as approved reimbursable drugs on their formularies, often without any quantity limits or pre-authorization requirements; often in preferred tiers.

130. Defendant, AMNEAL PHARMACEUTICALS LLC, is a Delaware limited liability company with its principal place of business in Bridgewater, New Jersey. AMNEAL PHARMACEUTICALS LLC has been registered to do business in Vermont since at least 2015

and is currently licensed as a Wholesale Drug Outlet with the Vermont Department of Health Professionals. AMNEAL PHARMACEUTICALS LLC may be served through its registered agent: The CT Corporation System, 17 G W Tatro DR, Jeffersonville, VT, 05464 .

131. Upon information and belief, in May of 2018 Impax Laboratories, Inc. merged with and into AMNEAL PHARMACEUTICALS LLC to form Defendant, AMNEAL PHARMACEUTICALS, INC., a Delaware corporation with its principal place of business in Bridgewater, New Jersey. AMNEAL PHARMACEUTICALS, INC. may be served through its registered agent: Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808.

132. Defendant, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, is a Delaware limited liability company with its principal place of business in Hauppauge, New York. Upon information and belief, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC is a subsidiary of AMNEAL PHARMACEUTICALS, INC. AMNEAL PHARMACEUTICALS OF NEW YORK, LLC is currently licensed as a wholesale drug outlet with the Vermont Department of Health Professionals. AMNEAL PHARMACEUTICALS OF NEW YORK, LLC may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

133. AMNEAL PHARMACEUTICALS, INC., AMNEAL PHARMACEUTICALS LLC, and AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, are collectively referred to as "Amneal."

134. Upon information and belief, Amneal manufactures, promotes, distributes and/or sells generic opioids nationally, in Vermont, and in the Town of Bennington, including but not limited to oxycodone, oxymorphone, hydrocodone and codeine.

135. According to the DEA ARCOS database, drugs manufactured by Amneal represented approximately .6% of the opioid market share in the town of Bennington from 2006 through 2012. Through this period, opioids in the town of Bennington manufactured by Amneal totaled over 1.7 million MME, or more than 327,000 dosage units.

136. At all times relevant hereto, the PBM Defendants listed generic opioids manufactured by Amneal as approved reimbursable drugs on their formularies, often without any quantity limits or pre-authorization requirements; often in preferred tiers.

137. Defendant, MYLAN PHARMACEUTICALS, INC., is a West Virginia corporation with its principal place of business in Canonsburg, Pennsylvania. Mylan Pharmaceuticals, Inc. is and has been registered to do business in Vermont since 2019 and may be served in Vermont through its registered agent: CT Corporation System, 17 G W Tatro DR, Jeffersonville, VT, 05464.

138. Defendant, MYLAN INSTITUTIONAL, INC. is an Illinois corporation with its principal place of business in Rockford, Illinois. Mylan Institutional, Inc. is and has been registered to do business in Vermont since 1991 and may be served through its registered agent: CT Corporation System, 17 GW Tatro Drive, Jeffersonville, Vermont 05464.

139. Defendant, MYLAN TECHNOLOGIES, INC. is a West Virginia corporation with its principal place of business in St. Albans, Vermont. Mylan Technologies, Inc. is and has been registered to do business in Vermont since 1993 and may be served through its registered agent: CT Corporation System, 17 GW Tatro Drive, Jeffersonville, Vermont 05464. Mylan Technologies, Inc. is currently licensed as an In-State Manufacturing Drug Outlet with the Vermont Department of Health Professionals.

140. MYLAN PHARMACEUTICALS, INC., MYLAN INSTITUTIONAL, INC., and MYLAN TECHNOLOGIES, INC. are collectively referred to as "Mylan."

141. Upon information and belief, Mylan manufactures, promotes, distributes and/or sells generic opioids nationally, in Vermont, and in the Town of Bennington, including but not limited to oxycodone, hydrocodone, and morphine sulfate.

142. According to the DEA ARCOS database, drugs manufactured by Mylan represented approximately 6.4% of the opioid market share in the Town of Bennington from 2006 through 2012. Through this period, opioids in the Town of Bennington manufactured by Mylan totaled over 17.6 million MME, or more than 51,900 dosage units.

143. At all times relevant hereto, the PBM Defendants listed generic opioids manufactured by Mylan as approved reimbursable drugs on their formularies, often without any quantity limits or pre-authorization requirements; often in preferred tiers.

144. Defendant, RECKITT BENCKISER PHARMACEUTICALS, INC. is a Delaware corporation with its principal place of business in Parsippany, New Jersey. Reckitt Benckiser Pharmaceuticals, Inc. may be served through its registered agent: The Corporation Service Company, 251 Little Falls Drive, Wilmington DE 19808.

145. Defendant, INDIVIOR, is a Delaware corporation with its principal place of business in Richmond, Virginia. Indivior is and has been registered to do business in Vermont since 2007 and may be served through its registered agent: Corporation Service Company, 100 North Main Street, Suite 2, Barre, Vermont 05641. Indivior, Inc. is currently licensed as a Wholesale Drug Outlet with the Vermont Department of Health Professionals.

146. According to the DEA ARCOS database, drugs manufactured by Indivior represented approximately 42.4% of the opioid market share in the Town of Bennington from 2006 through 2012. Through this period, opioids in the Town of Bennington manufactured by Indivior totaled nearly 116.8 million MME, or more than 550,700 dosage units.

147. Defendant, HIKMA PHARMACEUTICALS USA, INC., is a Delaware corporation with its principal place of business in Eatontown, New Jersey. Hikma Pharmaceuticals is and has been registered to do business in Vermont since 2017 and may be served through its registered agent: CT Corporation System, 17 GW Tatro Drive, Jeffersonville, Vermont 05464. Hikma Pharmaceuticals USA, Inc. is currently licensed as a Wholesale Drug Outlet with the Vermont Department of Health Professionals.

148. According to the DEA ARCOS database, drugs manufactured by Hikma Pharmaceuticals USA, Inc. represented approximately 6.3% of the opioid market share in the Town of Bennington from 2006 through 2012. Through this period, opioids in the Town of Bennington manufactured by Hikma Pharmaceuticals USA, Inc. totaled over 17.3 million MME, or more than 574,000 dosage units.

149. The corporate defendants listed above are all engaged in the manufacturing of opioids. Together with the Purdue Individual Defendants, they are collectively referred to herein as the “Manufacturer Defendants.”

150. The failure of all Manufacturer Defendants to effectively monitor and report suspicious orders of prescription opioids, their aggressive misinformation campaign aimed at increasing public consumption of highly addictive opioids nationally, in Vermont, and in the Town of Bennington, their failure to forthrightly provide accurate information to the United States Food and Drug Administration (“FDA”), their failure to adhere to FDA regulations regarding misbranding, their failure to implement measures to prevent the filling of suspicious orders, and their perverse utilization of so-called “patient advocacy” groups to evade FDA regulations concerning consumer drug-marketing greatly contributed to a vast increase in opioid overuse and addiction. Manufacturer Defendants’ conduct thus directly caused a public-health and law-enforcement crisis across this country, including in the Town of Bennington.

C. DISTRIBUTOR DEFENDANTS

151. Defendant McKESSON CORPORATION (“McKesson”) is a Delaware corporation with its principal place of business in San Francisco, California.

152. McKesson is currently licensed as a Wholesale Drug Outlet with the Vermont Department of Health Professionals. McKesson has been registered to do business in Vermont since at least August 24, 1994 and does substantial business in Vermont. McKesson has a Vermont taxpayer number and may be served in Vermont through its registered agent: Corporation Service Company, 100 North Main Street, Suite 2, Barre, VT, 05641.

153. McKesson is the largest pharmaceutical distributor in North America. It distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states, including Vermont.

154. Upon information and belief, McKesson is one of the largest distributors of opioid pain medications in the country, including Vermont. In 2015, McKesson had a net income in excess of \$1.5 billion.

155. In its 2017 Annual Report, McKesson states that it “partner[s] with pharmaceutical manufacturers, providers, pharmacies, governments and other organizations in healthcare to help provide the right medicines, medical products and healthcare services to the right patients at the right time, safely and cost-effectively.”²⁸

156. According to the 2017 Annual Report, McKesson “pharmaceutical distribution business operates and serves thousands of customer locations through a network of 27 distribution centers, as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities, serving all 50 states and Puerto Rico.”²⁹

²⁸ McKesson 2017 Annual Report found at investor.mckesson.com/sites/mckesson.investorhq.businesswire.com/files/report/file/2017_McKesson_Annual_Report_0.pdf

²⁹ *Id.*

157. McKesson hires employees to service the Vermont market. For example, McKesson recently advertised online that it was seeking an EnterpriseRx Implementation Consultant to operate out of Vermont and a Technical Solutions Sales Representative to operate out of Vermont.³⁰

158. The DEA ARCOS database reveals that between 2006-2012, McKesson distributed over 32.5 million MME into the Town of Bennington, across over 1.2 million dosage units.

159. Defendant CARDINAL HEALTH, INC. (“Cardinal”) is an Ohio corporation with its principal place of business in Dublin, Ohio. Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including Vermont.

160. Cardinal may be served in through its registered agent: CT Corporation System, 4400 Easton Commons Way Suite 125, Columbus, Ohio 43219.

161. Cardinal, through its many subsidiaries, including Cardinal Health 100, Inc., is currently licensed as a Third-Party Logistics Provider with the Vermont Department of Health Professionals. Cardinal has been registered to do business in Vermont since at least June 29, 1992 and may be served in Vermont through its registered agent: CT Corporation System, 17 GW Tatro Dr, Jeffersonville, VT, 05464.

162. Upon information and belief, Cardinal is one of the largest distributors of opioid pain medications in the country, including Vermont.

163. The DEA ARCOS database reveals that between 2006-2012, Cardinal distributed over 72.4 million MME into the Town of Bennington, across over 2.3 million dosage units.

164. Defendant AMERISOURCEBERGEN DRUG CORPORATION (“Amerisource”) is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania.

³⁰ https://mckesson.wd3.myworkdayjobs.com/en-US/External_Careers/job/Atlanta-Metro/Technical-Solutions-Sales-Representative_JR0013922

Amerisource distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states, including Vermont.

165. Amerisource is currently licensed as a Wholesale Drug Outlet with the Vermont Department of Health Professionals. Amerisource has been registered to do business in Vermont since at least September 27, 1994 and may be served in Vermont through its registered agent: CT Corporation System, 17 GW Tatro Dr, Jeffersonville, VT, 05464.

166. Defendant, BELCO DRUG CORPORATION, is a New York corporation with its principal place of business in Amityville, New York. Bellco Drug Corporation is a subsidiary of Amerisource. Bellco Drug Corporation is currently licensed as a Wholesale Drug Outlet with the Vermont Department of Health Professionals and may be served through its registered agent: CT Corporation System, 28 Liberty Street, New York, New York, 10005.

167. Defendant, H.D. SMITH LLC, is a Delaware corporation with its principal place of business in Springfield, Illinois. H.D. Smith is a subsidiary of Amerisource. H.D. Smith is and has been registered to do business in Vermont since 2018 and may be served through its registered agent: CT Corporation System, 17 GW Tatro Drive, Jeffersonville, Vermont 05464. H.D. Smith is currently licensed as a Wholesale Drug Outlet with the Vermont Department of Health Professionals.

168. According to its 2016 Annual Report, Amerisource is “one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care.”³¹

³¹ Amerisource 2016 Annual Report found at <http://www.amerisourcebergen.com/investor/phoenix.zhtml?c=61181&p=irol-irhome>

169. Amerisource hires employees to service the Vermont market. For example, Amerisource recently advertised online that it was seeking a Client Service Manager in Vermont.³²

170. Upon information and belief, Amerisource is one of the largest distributors of opioid pain medications in the country, including Vermont.

171. The DEA ARCOS database reveals that between 2006-2012, Amerisource distributed over 22.5 million MME into the Town of Bennington, across over 592 thousand dosage units.

172. Defendant CVS HEALTH CORPORATION (“CVS Health”), formerly known as CVS Caremark Corporation, is a Delaware corporation with its principal place of business located in Woonsocket, Rhode Island. CVS Health may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange, Street, Wilmington, Delaware 19801. CVS Health is named as a defendant in its capacities as a distributor, retail and mail order pharmacy, and PBM (*see* Sections D and E, *infra*).

173. Defendant CVS PHARMACY, INC. (“CVS Pharmacy”) is a Rhode Island corporation whose principal place of business is at the same location as CVS Health. On information and belief, CVS Health is the direct parent company of CVS Pharmacy. CVS Pharmacy has been registered to do business in Vermont since at least 1996 and may be served in Vermont through its registered agent: CT Corporation System, 17 GW Tatro Dr, Jeffersonville, VT, 05464 - 9919. CVS Pharmacy is currently licensed as a Wholesale Drug Outlet with the Vermont Department of Health Professionals. CVS Pharmacy is named as a defendant in its capacities as a distributor and retail and mail order pharmacy (*see* Section D, *infra*).

³² https://abccareers.taleo.net/careersection/2/jobdetail.ftl?job=00001VRE&tz=GMT-04%3A00&tzname=America%2FNew_York

174. Defendant CVS RX SERVICES, INC. (“CVS Rx”) is a New York company whose principal place of business is at the same location as CVS Health and CVS Pharmacy. CVS Rx is and has been registered to do business in Vermont since at least 1999 and may be served through its registered agent: CT Corporation System, 17 GW Tatro Drive, Jeffersonville, Vermont 05464.

175. Upon information and belief, CVS Health, CVS Pharmacy, and CVS Rx distribute pharmaceuticals to retail pharmacies and institutional providers in all 50 states, including Vermont.

176. The DEA ARCOS database reveals that between 2006-2012, CVS Health distributed over 16.6 million MME into the Town of Bennington, across over 1 million dosage units.

177. Defendant WALMART INC., formerly known as Wal-Mart Stores, Inc. (“Walmart”), is a Delaware corporation with its principal place of business in Bentonville, Arkansas. Walmart has been registered to do business in Vermont since at least 1990 and may be served in Vermont through its registered agent: CT Corporation System, 17 GW Tatro Dr, Jeffersonville, Vermont 05464.

178. Upon information and belief, Walmart distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states, including Vermont.

179. The DEA ARCOS database reveals that between 2006-2012, Walmart distributed over 13.2 million MME into the Town of Bennington, across over 965 thousand dosage units.

180. Defendant RITE AID CORP. is a Delaware corporation with its principal place of business in Camp Hill, Pennsylvania. RITE AID CORP. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center 1209 Orange St., Wilmington, Delaware 19801. RITE AID CORP. is named as a defendant in its capacities as a distributor and retail and mail order pharmacy (*see* Section D, *infra*).

181. Defendant RITE AID of Maryland is a Maryland corporation whose principal place

of business is in Perryman, Maryland. RITE AID MID-ATLANTIC may be served through its registered agent: The Corporation Trust, Incorporated, 2405 York Road, Suite 201, Lutherville Timonium, Maryland 21093-2264. Rite Aid of Maryland is currently licensed as a Wholesale Drug Outlet with the Vermont Department of Health Professionals.

182. Defendant ECKERD CORPORATION is a Delaware corporation whose principal place of business is in Camp Hill, Pennsylvania. Eckerd Corporation may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange, Street, Wilmington, Delaware 19801.

183. RITE AID CORP., in its distribution capacity, RITE AID MID-ATLANTIC, RITE AID DAYVILLE DISTRIBUTION CENTER, and ECKERD CORPORATION are collectively referred to as "Rite Aid Distribution."

184. Upon information and belief, Rite Aid Distribution distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states, including Vermont.

185. The DEA ARCOS database reveals that between 2006-2012, Rite Aid distributed over 31.8 million MME into the Town of Bennington, across over 923 thousand dosage units.

186. Defendant, BURLINGTON DRUG COMPANY, is a Vermont corporation with its principal place of business in Milton, Vermont. Burlington Drug Company is and has been registered to do business in the state of Vermont since at least 1998 and may be served through its registered agent: CT Corporation System, 17 GW Tatro Drive, Jeffersonville, Vermont 05464.

187. The DEA ARCOS database reveals that between 2006-2012, Burlington Drug Company distributed over 85.4 million MME into the Town of Bennington, across over 2.3 million dosage units.

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

may be served through its registered agent: Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808. Walgreens Boots is named as a defendant in its capacities as a distributor and retail pharmacy (*see* Section D, *infra*).

189. Defendant WALGREEN CO. is an Illinois corporation whose principal place of business is at the same location as Walgreens Boots. On information and belief, Walgreens Boots is the parent company of WALGREEN CO. WALGREEN CO. may be served through its registered agent: Illinois Corporation Services Co., 801 Adlai Stevenson Drive, Springfield, IL 62703.

190. Defendant, WALGREEN EASTERN CO. (“Walgreen Eastern”) is an Illinois corporation whose principal place of business is at the same location as Walgreens Boots. On information and belief, Walgreens Boots is the parent company of Walgreen Eastern. Walgreen Eastern has been registered to do business in Vermont since at least 2003 and may be served through its registered agent: Corporation Service Company, 100 North Main Street, Suite 2, Barre, VT 05641.

191. Defendants Walgreens Boots, WALGREEN CO. and Walgreen Eastern, in their distributor capacities, are collectively referred to as “Walgreens Distribution.”

192. Walgreens Distribution distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states, including Vermont. Walgreens Distribution is currently licensed as a Wholesale Drug Outlet with the Vermont Office of Professional Regulation.

193. The DEA ARCOS database reveals that between 2006-2012 Walgreens distributed over 73.2 million MME into Vermont, across over 3 million dosage units.

194. The distributor defendants listed above are all engaged in the wholesale distribution of opioids. The distributor defendants listed above are collectively referred to herein as the “Distributor Defendants.”

195. The Distributor Defendants purchased opioids from manufacturers, such as the Manufacturer Defendants herein, and sold them to pharmacies throughout Vermont, including in the Town of Bennington. The Distributor Defendants played an integral role in opioids being distributed across Vermont, including the Town of Bennington.

196. The failure of all Distributor Defendants to effectively monitor and report suspicious orders of prescription opioids and to implement measures to prevent the filling of invalid and medically unnecessary prescriptions greatly contributed to the vast increase in opioid overuse and addiction. Distributor Defendants' conduct thus directly caused a public-health and law-enforcement crisis across this country, including in the Town of Bennington.

D. PHARMACY DEFENDANTS

197. Defendant, VERMONT CVS PHARMACY, L.L.C. ("Vermont CVS"), is a Vermont limited liability company whose principal place of business is at the same location as CVS Health. Vermont CVS Pharmacy, LLC has been registered to do business in Vermont since at least February 8, 2008 and may be served in Vermont through its registered agent: CT Corporation System, 17 GW Tatro Drive, Jeffersonville, Vermont 05464.

198. Defendant, CAREMARK RX, L.L.C., is a Delaware limited liability company whose principal place of business is at the same location as CVS Health. CAREMARK RX, L.L.C. is a wholly owned subsidiary of CVS Pharmacy. According to CVS Health's 2016 Annual Report, Defendant CAREMARK RX, L.L.C. is "the parent of [CVS Health]'s pharmacy services subsidiaries, is the immediate or indirect parent of many mail order, pharmacy benefit management, infusion, Medicare Part D, insurance, specialty mail and retail specialty pharmacy subsidiaries, all of which operate in the U.S. and its territories." CAREMARK RX, L.L.C. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center,

1209 Orange, Street, Wilmington, Delaware 19801. CAREMARK RX, L.L.C. is named as a defendant in its capacities as a retail and mail order pharmacy and PBM (*see* Section E, *infra*).

199. Defendant CAREMARK, L.L.C., is a California limited liability company whose principal place of business is at the same location as CVS Health. CAREMARK, L.L.C. is registered to do business in Vermont and may be served by its registered agent: CT Corporation System, 17 GW Tatro Drive, Jeffersonville, VT 05464. CAREMARK, L.L.C. is a wholly owned subsidiary of CAREMARK RX, L.L.C.

200. CAREMARK, L.L.C. is the direct or indirect parent of dozens of limited liability companies all over the U.S. that provide mail-order pharmacy services in the U.S. and in Vermont.³³ Many of these CAREMARK, L.L.C. entities are registered with the DEA to dispense controlled substances, including opioids. CAREMARK, L.L.C. is named as a defendant in its capacities as a retail and mail order pharmacy and PBM (*see* Section E, *infra*).

201. CVS Health, CVS Pharmacy, Vermont CVS, CAREMARK RX, L.L.C. and CAREMARK L.L.C., in their capacities as retail and mail order pharmacies, are collectively referred to as “CVS”.

202. In 2018, CVS was the largest U.S. pharmacy by total prescription revenue.³⁴

203. CVS operates dozens of retail pharmacies in Vermont. At all relevant times, CVS has sold and continues to sell prescription opioids at its retail pharmacies in the Town of Bennington, or through its mail order pharmacies. In 2018, CVS was the largest U.S. pharmacy by total prescription revenue.³⁵

³³ CVS Health Corporation, *Annual Report (Form 10-K)* (Feb. 14, 2018).

³⁴ Drug Channels Institute, *Largest 15 U.S. Pharmacies, by Total Prescription Revenues, 2018*, (last visited Mar. 12, 2018), <https://www.drugchannels.net/2019/02/the-top-15-us-pharmacies-of-2018-m.html>.

³⁵ Drug Channels Institute, *Largest 15 U.S. Pharmacies, by Total Prescription Revenues, 2018*, (last visited Mar. 12, 2018), <https://www.drugchannels.net/2019/02/the-top-15-us-pharmacies-of-2018-m.html>.

204. CVS describes itself “a market leader in mail order pharmacy, retail pharmacy, specialty pharmacy, and retail clinics....**that provide unparalleled service and capabilities.**”³⁶

205. According to the DEA ARCOS Database, between 2006-2012, CVS pharmacies in the Town of Bennington purchased nearly 65.7 million MME across over 2.5 million dosage units.

206. Defendant, EXPRESS SCRIPTS HOLDING COMPANY, is a Delaware corporation with its principal place of business in St. Louis, Missouri. EXPRESS SCRIPTS HOLDING COMPANY is named as a defendant in its capacities as a retail and mail order pharmacy and PBM (*see* Section E, *infra*).

207. Defendant ESI MAIL PHARMACY SERVICE, INC., doing business as Express Scripts or ESI Distribution Services, is a Delaware corporation with its principal place of business in St. Louis, Missouri.

208. Defendant EXPRESS SCRIPTS PHARMACY, INC., doing business as Catamaran Home Delivery or Express Scripts, is a Delaware corporation with its principal place of business in St. Louis, Missouri.

209. Both ESI MAIL PHARMACY SERVICE, INC. and EXPRESS SCRIPTS PHARMACY, INC. are subsidiaries of defendant EXPRESS SCRIPTS HOLDING COMPANY.

210. EXPRESS SCRIPTS HOLDING COMPANY, in its capacity as a retail and mail order pharmacy, ESI MAIL PHARMACY SERVICE, INC., and EXPRESS SCRIPTS PHARMACY, INC. are collectively referred to as “Express Scripts Pharmacy.”

211. At all relevant times, Express Scripts Pharmacy has sold and continues to sell prescription opioids through its mail order pharmacies nationwide, serving patients nationally and

³⁶ CVS Health, *CVS Caremark Announces PBM Succession Plan* (Mar. 30, 2012), <https://cvshhealth.com/newsroom/press-releases/cvs-caremark-announces-pbm-succession-plan-1> (emphasis added)

in Amherst. Even though it operates no brick and mortar stores, in 2018, Express Scripts Pharmacy was the third largest pharmacy in the U.S. by total prescription revenue.³⁷

212. Defendant, OPTUMRX, INC. (“OptumRx”), is a Delaware corporation with its principal place of business located in Irvine, California. OptumRx operates as a subsidiary of OptumRx Holdings, LLC, which in turn operates as a subsidiary of OPTUM, INC. OptumRx has been registered to do business in Vermont since at least 2008 and may be served in Vermont through its registered agent: CT Corporation System, 17 GW Tatro Drive, Jeffersonville, VT 05464. OptumRx is named as a defendant in its capacities as a retail and mail order pharmacy and PBM (*see* Section E, *infra*).

213. OptumRx is registered with the DEA to dispense controlled substances, including opioids. At all relevant times, OptumRx has sold and continues to sell prescription opioids through its mail order pharmacies in Vermont, including in Bennington. In 2018, OptumRx was the fourth largest pharmacy in the U.S. by total prescription revenue.³⁸

214. Defendants Walgreens Boots, WALGREEN CO. and Walgreen Eastern are named as Distributor Defendants in Section C and, in their capacities as retail and mail order pharmacies, are collectively referred to as “Walgreens.”

215. In 2018, Walgreens was the second largest U.S. pharmacy by total prescription revenues.³⁹

216. Walgreens operates over a dozen retail pharmacies in Vermont. At all relevant times, Walgreens has sold and continues to sell prescription opioids at its retail pharmacies in Vermont, including in Bennington. According to the DEA ARCOS database, between 2006-2012,

³⁷ Drug Channels Institute, *Largest 15 U.S. Pharmacies*, *supra* note 35.

³⁸ *Id.*

³⁹ Drug Channels Institute, *Largest 15 U.S. Pharmacies*, *supra* note 35.

Walgreens' pharmacies in Vermont purchased over 95.6 million MME across over 3.2 million dosage units.

217. Defendant RITE AID CORP., identified above in Section C regarding distributors, is also a pharmacy defendant.

218. Defendant, RITE AID OF VERMONT, INC., is a Vermont limited liability company whose principal place of business is at the same location as RITE AID CORP. RITE AID OF VERMONT, INC. has been registered to do business in Vermont since at least 1974 and may be served in Vermont through its registered agent: CT Corporation System, 17 GW Tatro Drive, Jeffersonville, Vermont 05464. Upon information and belief, RITE AID OF VERMONT, INC. is a wholly owned subsidiary of RITE AID CORP.

219. RITE AID CORP., in its capacity as a retail and mail order pharmacy, and RITE AID OF VERMONT, INC. are collectively referred to as "Rite Aid Pharmacy".

220. Rite Aid Pharmacy operates dozens of retail pharmacies in Vermont. At all relevant times, Rite Aid Pharmacy has sold and continues to sell prescription opioids at its retail pharmacies in the Town of Bennington, or through its mail order pharmacies. According to the DEA ARCOS Database, between 2006-2012, Rite Aid pharmacies in the Town of Bennington purchased nearly 47.6 million MME across over 1.5 million dosage units.

221. Defendant, THE PHARMACY, INC. is a Vermont corporation with its principal place of business in Bennington, Vermont. The Pharmacy, Inc. is and has been registered to do business in Vermont since at least 1968 and may be served through its registered agent: Philip J. O'Neill, 205 North Street, Bennington, Vermont 05201. The Pharmacy, Inc. is currently licensed as an Instate Pharmacy with the Vermont Department of Health Professionals.

222. According to the DEA ARCOS Database, between 2006-2012, The Pharmacy, Inc. in the Town of Bennington purchased more than 119.2 million MME across over 3.1 million dosage units.

223. Defendant GOLUB CORPORATION (d/b/a Price Chopper Supermarkets) is a Delaware Corporation with its principal place of business in Schenectady, New York. GOLUB CORPORATION may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. Price Chopper is currently licensed as Wholesale Drug Outlet with the Vermont Department of Health Professionals.

224. Defendant, PRICE CHOPPER OPERATING CO. OF VERMONT, INC, (“Price Chopper”) is a Vermont Corporation with its principal place of business in Schenectady, New York. Price Chopper is and has been registered to do business in Vermont since at least 1975 and may be served through its registered agent: CT Corporation System, 17 GW Tatro Drive, Jeffersonville, Vermont 05464. Upon information and belief, Price Chopper is a wholly-owned subsidiary of Defendant GOLUB CORPORATION. Price Chopper is currently licensed as Wholesale Drug Outlet with the Vermont Department of Health Professionals. Price Chopper and GOLUB CORPORATION are collectively referred to as “Golub.” According to the DEA ARCOS Database, between 2006-2012, Golub pharmacies in the Town of Bennington purchased more than 10.9 million MME across over 625 thousand dosage units.

225. The pharmacy defendants listed above are all engaged in the business of retail selling opioids and other drugs. The pharmacy defendants are collectively referred to herein as the “Pharmacy Defendants.”

226. The failure of all Pharmacy Defendants to effectively monitor and report suspicious orders of prescription opioids and to implement measures to prevent filling of improper

prescriptions greatly contributed to the vast increase in opioid overuse and addiction.

227. Pharmacy Defendants' conduct thus directly caused a public-health and law-enforcement crisis across this country, including in the Town of Bennington.

228. As discussed further below, each of the Pharmacy Defendants has consistently failed to comply with its legal obligations concerning opioid diversion, and almost all have paid civil penalties to resolve government allegations regarding opioid diversion.

E. PHARMACY BENEFIT MANAGER DEFENDANTS

229. The Pharmacy Benefit Manager Defendants ("PBM Defendants") are defined below. At all relevant times the PBM Defendants acted as the gatekeepers of prescription drugs including opioids. Pharmacy benefit managers ("PBMs") establish formularies which govern which drugs are reimbursed and how. They determine MME quantity limits and pre-authorization requirements. They negotiate with drug manufacturers to offer preferred drug formulary placement for drugs. They establish reimbursement rates for the drugs dispensed. PBMs earn revenue from at least the following sources: fees from health plans and employers, rebates and other incentives from drug manufacturers, including but not limited to administrative fees and volume bonuses, and fees from maintaining pharmacy networks.⁴⁰

230. At all times relevant hereto, the reimbursement of the Manufacturer Defendants' opioids was guaranteed and facilitated by the PBM defendants who constructed formularies and designed plans that made such opioids easily accessible. In many cases, the PBMs made it easier to obtain these highly-addictive products than a less-addictive pain alternative or OUD treatment medicine. In many cases, the PBMs failed to install reasonable quantity or refill limits on these

⁴⁰ Health Policy Brief, *On behalf of payers, pharmacy benefit managers negotiate rebates from drug makers in exchange for preferred formulary placement*, HEALTH AFFAIRS, Sep. 14, 2017, <https://www.healthaffairs.org/doi/10.1377/hpb20171409.000178/full/>

highly addictive drugs. Often the PBMs imposed no pre-authorization requirements on the controlled substances at issue in this proceeding.

231. On information and belief, the PBMs constructed their national offerings in this fashion because of their contractual arrangements with the Manufacturer Defendants. In all events, the PBMs failed to install reasonable and necessary controls on the reimbursement of opioids, consistent with medical literature and the PBMs' own expressed commitment to public health and safety. In so doing, the PBMs provided necessary and dangerous fuel for the opioid epidemic as described herein.

232. Only recently, and more than three years after the March 2016 CDC Guidelines were issued, have the PBM defendants prepared national offerings that make contact with the national health crisis the PBMs themselves helped to create.

233. Defendants CVS Health, CAREMARK RX, L.L.C., and CAREMARK, L.L.C. identified above in Section D regarding retail and mail order pharmacies, are also PBM defendants.

234. Defendant, CVS HEALTH CORPORATION ("CVS Health"), formerly known as CVS Caremark Corporation, is a Delaware corporation with its principal place of business located in Woonsocket, Rhode Island. CVS Health is registered to do business in Vermont and may be served through its registered agent: 17 G W Tatro Dr, Jeffersonville, VT, 05464.

235. Defendant, CAREMARK, L.L.C., is a California limited liability company whose principal place of business is at the same location as CVS Health. On information and belief, CVS Health is the direct parent company of CAREMARK RX, L.L.C. According to CVS Health's 2016 Annual Report, Defendant CAREMARK RX, L.L.C. is "the parent of [CVS Health]'s pharmacy services subsidiaries, is the immediate or indirect parent of many retail pharmacies, mail-order pharmacies, a pharmacy benefit management division, infusion services, services to Medicaid and Medicare Part D beneficiaries, insurance, specialty mail and retail specialty pharmacy subsidiaries,

all of which operate in the United States and its territories.” CAREMARK, L.L.C. is registered to do business in Vermont and may be served through its registered agent: CT Corporation System, 17 GW Tatro Drive, Jeffersonville, Vermont 05464.

236. Defendant, CAREMARKPCS HEALTH, L.L.C., is a Delaware limited liability company whose principal place of business is at the same location as CVS Health. On information and belief, CVS Health is the direct or indirect parent company of CAREMARKPCS HEALTH, L.L.C. CAREMARKPCS HEALTH, L.L.C. is registered to do business in Vermont and may be served through its registered agent: CT Corporation System, 17 GW Tatro Drive, Jeffersonville, Vermont 05464. Defendants CAREMARK RX, L.L.C., CAREMARK, L.L.C., and CAREMARKPCS HEALTH, L.L.C. are collectively referred to as “Caremark.”

237. CVS Health describes itself in a September 3, 2014 press release as a “pharmacy innovation company helping people on their path to better health. Through our 7,700 retail pharmacies, 900 walk-in medical clinics, a leading pharmacy benefits manager with nearly 65 million plan members, and expanding specialty pharmacy services, we enable people business and communities to manage health in more affordable, effective ways. This unique integrated model increases access to care, delivers better health outcomes and lowers overall health care costs.” In 2016, CVS Health reported an operating income of \$10 billion.

238. In the above-referenced September 3, 2014 press release CVS Health announced its change of name from CVS Caremark Corporation to CVS Health. CVS Health explained that it was changing its name “to reflect its broader health care commitment and its expertise in driving the innovations needed to shape the future of health.” CVS Health explained that the newly-named company included “its pharmacy benefit management business, which is known as CVS/Caremark.” In that same press release, CVS Health touted, “[f]or our patients and customers, *health is everything* and...we are advising on prescriptions [and] helping manage chronic and

specialty conditions.” [emphasis supplied]. In December 2017, CVS made a \$69 billion bid to purchase Aetna. If the companies merge, the clout of CVS will grow even more.

239. According to the Drug Channels Institute, CVS Health (Caremark) was the highest ranking PBM in 2017 with over twenty-five percent (25%) of the industry market share.⁴¹

240. Caremark says the following about its “Formulary Development and Management”:

Development and management of drug formularies is an integral component in the pharmacy benefit management (PBM) services CVS Caremark provides to health plans and plan sponsors. Formularies have two primary functions: 1) to help the PBM provide pharmacy care that is clinically sound and affordable for plans and their plan members; and 2) to help manage drug spend through the appropriate selection and use of drug therapy.⁴²

241. At all times relevant hereto, CVS Health, through Caremark, derives substantial revenue providing pharmacy benefits in Vermont through several different means including, but not limited to, providing services and its formulary to plans on Vermont Health Connect, the state’s ACA exchange, including MVP Secure (Catastrophic) 2019⁴³, MVP VT Standard Bronze⁴⁴, and MVP VT Standard Gold⁴⁵ 46.

242. At all times relevant hereto, CVS Health and Caremark offered pharmacy benefit management services nationwide and maintained a national formulary or formularies that are used

⁴¹ *Cigna-Express Scripts: Vertical Integration and PBMs’ Medical-Pharmacy Future*, DRUG CHANNELS INSTITUTE, Mar. 9, 2018, <https://www.drugchannels.net/2018/03/cigna-express-scripts-vertical.html>

⁴² CVS Caremark, *Formulary Development and Management at CVS Caremark*, Mar. 25, 2018, <https://www.caremark.com/portal/asset/FormDev Mgmt.pdf>, at 1

⁴³ Summary of Benefits and Coverage, MVP Secure VT, 2019 <https://vt.checkbookhealth.org/hie/vt/2019/assets/pdfs/77566VT0040013-01.pdf>

⁴⁴ Summary of Benefits and Coverage MVP VT Bronze 1 HMO Plus, 2019 <https://vt.checkbookhealth.org/hie/vt/2019/assets/pdfs/77566VT0040011-01.pdf>

⁴⁵ Summary of Benefits and Coverage MVP VT Gold 1 HMO, 2019 <https://vt.checkbookhealth.org/hie/vt/2019/assets/pdfs/77566VT0040002-01.pdf>

⁴⁶ Prescription Benefits, MVP and CVS Caremark “MVP’s prescription drug coverage is provided through CVS Caremark®, MVP’s Pharmacy Benefit Manager” <https://www.mvphealthcare.com/members/prescription-benefits/>

nationwide, including in the Town of Bennington. At all times relevant hereto, those formularies included opioids, including those at issue in this case. At all times relevant hereto, those formularies allowed for the dispensing and reimbursement of such opioids in Vermont, including in the Town of Bennington.

243. Defendant, EXPRESS SCRIPTS HOLDING COMPANY (“ESHC”), identified above in Section D regarding retail and mail order pharmacies, is also a PBM defendant.

244. Defendant, EXPRESS SCRIPTS, INC. (“ESI”), is incorporated in the State of Delaware with its principal place of business located in St. Louis, Missouri, is a pharmacy benefit management company, and is a wholly-owned subsidiary of ESHC. ESI has been registered to do business in Vermont since at least 2015 and is currently licensed as a Non-Resident Pharmacy with the Vermont Department of Health Professionals. ESI may be served in Vermont through its registered agent: Corporation Service Company, 100 North Main Street, Suite 2, Barre, VT, 05641.

245. ESHC, in its capacity as a PBM, and ESI are collectively referred to as “Express Scripts”.

246. In 2012, ESI acquired its rival, Medco Health Solutions Inc., in a \$29.1 billion deal. As a result of the merger, ESHC was formed and became the largest PBM in the nation, filling a combined 1.4 billion prescriptions for employers and insurers.⁴⁷ In March of 2018, ESI made a \$67 billion bid to purchase Cigna. If the companies merge, the clout of ESI will grow even more.

247. According to the Drug Channels Institute, Express Scripts was the second highest ranking PBM in 2017 with twenty-four (24%) of the industry market share.⁴⁸

⁴⁷ Peter Frost, *Express Scripts closes \$29.1-billion purchase of Medco*, LOS ANGELES TIMES (Apr. 3, 2012), <http://articles.latimes.com/2012/apr/03/business/la-fi-medco-20120403>

⁴⁸ *Cigna-Express Scripts: Vertical Integration and PBMs' Medical-Pharmacy Future*, *supra* note 41.

248. Express Scripts “provides pharmacy benefits to 83 million members. Of these, more than 27 million obtain their pharmacy benefit coverage through one of Express Scripts’ standard formularies and more people use the [Express Scripts’] National Preferred Formulary than any other formulary in the U.S.”⁴⁹

249. Express Scripts standard formularies are “governed by [its] National Pharmacy & Therapeutics Committee (the ‘P&T Committee’), a panel of independent physicians and pharmacists in active clinical practice, representing a variety of specialties and practice settings and typically with major academic affiliations.”⁵⁰ Express Scripts touts that the “the P&T Committee considers the drug’s *safety and efficacy*,” and the company “fully compl[ies] with the P&T Committee’s clinical recommendations regarding drugs that must be included or excluded from the formulary based on their assessment of *safety and efficacy*.”⁵¹ Express Scripts “re-evaluate[s] [its] National Preferred Formulary on an annual basis. [It] looks at the formulary first from a clinical perspective to ensure that it provides access to *safe and effective* medications in all therapy classes.”⁵²

250. Express Scripts derives substantial revenue managing pharmacy benefits in Vermont through several different means, including, but not limited to, providing services and its formulary to The Vermont State Employees’ Retirement System (VSERS)⁵³, and the Burlington

⁴⁹ Express Scripts, *The Value of Active Pharmacy Management: Express Scripts 2018 National Preferred Formulary*, 2018, <https://www.multivu.com/players/English/81495241-express-scripts-national-preferred-formulary-2018/>, at 1.

⁵⁰ Express Scripts, *Express Scripts 2017 Annual Report*, <https://expressscriptsholdingco.gcs-web.com/static-files/76a9c03e-2e6b-4f6b-80de-fe80d4ebc826>, at 11.

⁵¹ *Id.*

⁵² Express Scripts, *Smart Formulary Management*, Jan. 2, 2014, <http://lab.express-scripts.com/lab/insights/drug-options/smart-formulary-management>, at 2 (emphasis added).

⁵³ State of Vermont Office of the State Treasurer, VSERS Health Insurance Information <https://www.vermonttreasurer.gov/content/retirement/state/health-insurance>

Vermont School District⁵⁴. Upon information and belief, these are some of the many ways in which Express Scripts reimburses for claims in the Town of Bennington, including opioids.

251. On information and belief, Express Scripts publishes employment vacancies related to its Vermont PBM business activities on its website.⁵⁵

252. At all times relevant hereto, Express Scripts offered pharmacy benefit management services, including mail-order pharmacy services, a nationwide retail pharmacy network, and maintained a national formulary or formularies that are used nationwide, including in the Town of Bennington. At all times relevant hereto, those formularies included opioids, including those at issue in this case. At all times relevant hereto, those formularies allowed for the dispensing and reimbursement of such opioids in Vermont, including in the Town of Bennington.

253. Defendant, UNITEDHEALTH GROUP INCORPORATED (“UnitedHealth”), a Delaware corporation with its principal place of business located in Minnetonka, Minnesota, is a diversified managed health care company with two business platforms. UnitedHealth serves approximately 115 million individuals throughout the United States. For 2016, UnitedHealth reported an operating income of \$12.9 billion.

254. Defendant, OPTUM, INC., is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. OPTUM, INC. is a health services company managing the subsidiaries that administer UnitedHealth’s pharmacy benefits, including OPTUMRX, INC. On information and belief, OPTUM, INC. is a subsidiary of UnitedHealth.

255. UnitedHealth and OPTUM, INC. may be served through their registered agent: CT

⁵⁴ Burlington School District, Health Benefits 2019: <https://www.bsdt.org/employee-benefits/> “Bluecross Blueshield of Vermont has contracted with ESI for Pharmacy Benefits” <http://www.bcbsvt.com/pharmacy/mail-order-pharmacy/express-scripts>

⁵⁵ Express Scripts employment listings in Vermont, e.g., (i) Infusion Nurse RN – ExpressScripts, Montpelier, Vermont, (https://vermontnursingjobs.blogspot.com/2018/04/infusion-nurse-rn-position-at-express.html?utm_campaign=google_jobs_apply&utm_source=google_jobs_apply&utm_medium=organic);

Corporation System, Inc., 1010 Dale Street North, St. Paul, Minnesota 55117.

256. Defendant OptumRx, identified above in Section D regarding retail and mail order pharmacies, is also a PBM defendant. OptumRx operates as the PBM for UnitedHealth. OptumRx is and has been registered to do business in Vermont since at least 2008 and may be served through its registered agent: CT Corporation System, 17 GW Tatro Dr, Jeffersonville, VT 05464.

257. According to the Drug Channels Institute, OptumRx was the third highest ranking PBM in 2017 with twenty-two percent (22%) of the industry market share.⁵⁶

258. In one case, OptumRx, which is owned by UnitedHealth, suggested that a member taking Butrans consider switching to a “lower cost alternative,” such as OxyContin or extended-release morphine, according to a letter provided by the member. Mr. Wiggin, the UnitedHealthcare spokesman, said the company’s rules and preferred drug list “are designed to ensure members have access to drugs they need for acute situations, such as post-surgical care or serious injury, or ongoing cancer treatment and end of life care, as well as for long-term use after alternatives are tried.”⁵⁷

259. “UnitedHealthcare places morphine on its lowest-cost drug coverage tier with no prior permission required, while in many cases excluding Butrans. And it places Lyrica, a non-opioid, brand-name drug that treats nerve pain, on its most expensive tier, requiring patients to try other drugs first.”⁵⁸

260. At all times relevant hereto, OptumRx derived substantial revenue providing pharmacy benefits in Vermont through several different means, including, but not limited to,

⁵⁶*Cigna-Express Scripts: Vertical Integration and PBMs’ Medical-Pharmacy Future*, *supra* note 41.

⁵⁷ Katie Thomas and Charles Ornstein, *Amid Opioid Crisis, Insurers Restrict Pricey, Less Addictive Painkillers*, THE NEW YORK TIMES, Sep. 17, 2017, <https://www.nytimes.com/2017/09/17/health/opioid-painkillers-insurance-companies.html?mwrsm=Email>

⁵⁸ *Id.*

providing services and formulary management for various private and public health insurance providers that operate in Vermont.

261. At all times relevant hereto, OptumRx offered pharmacy benefit management services nationwide and maintained a national formulary or formularies that are used nationwide, including in the Town of Bennington. At all times relevant hereto, those formularies included opioids, including those at issue in this case. At all times relevant hereto, those formularies allowed for the dispensing and reimbursement of such opioids in Vermont, including in the Town of Bennington.

262. The PBM Defendants managed the reimbursement for the vast majority of opioids at issue in this case. Without the PBM Defendants' reimbursement for the opioids at issue herein, the opioids likely would not have entered the marketplace and the entire scheme would have failed.

F. DOE DEFENDANTS

263. Doe DEFENDANTS 1 to 100 are sued herein under fictitious names because after diligent and good faith efforts their names, identities, and capacities, whether individual, corporate, associate, or otherwise, are presently unknown to Plaintiff. Plaintiff will make the names or identities of said Defendants known to the Court after the information has been ascertained. Plaintiff is informed and believes, and based thereupon alleges, that each of the Defendants designated herein as a DOE DEFENDANT has taken part in and participated with, and/or aided and abetted, some or all of the other Defendants in some or all of the matters referred to herein and the Plaintiff is informed and believes, and on such information and belief alleges, that each of the Defendants named as a DOE is responsible in some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein.

IV. FACTUAL ALLEGATIONS

A. BACKGROUND ON PRESCRIPTION OPIOIDS

264. The term opioid includes (a) all drugs derived in whole or in part from the morphine-containing opium poppy plant such as morphine, laudanum, codeine, thebaine, hydrocodone, oxycodone, and oxymorphone, and (b) synthetic opioids like fentanyl or methadone.⁵⁹

265. Prior to the 1990's, doctors prescribed opioid pain relievers sparingly, and only in the short term, for cases of acute injury or illness, during surgery or end-of-life ("palliative") care.⁶⁰ Doctors' reluctance to use opioids for an extended period of time was due to the legitimate fear of causing addiction.⁶¹

266. Beginning in the late 20th century, however, and continuing through today, the pharmaceutical industry acted to dramatically expand the marketplace for opioids. As set forth below, pharmaceutical actors facilitated this expansion in three ways. *First*, pharmaceutical manufacturers engaged in a misinformation campaign which altered public perception of opioids, and deceived doctors, federal regulators, and the general public about their addictive qualities. *Second*, opioid manufacturers and wholesalers/distributors flouted their federally imposed requirements to report suspicious opioid orders to the United States Drug Enforcement Administration ("DEA") and state agencies. These facilitated an explosion in the illegitimate marketplace for prescription opioids. *Third*, PBMs ensured that opioids were widely available, regularly prescribed and reimbursed, while failing in their obligation to monitor inappropriate drug utilization.

267. As a result of Defendants' wrongful conduct, the number of prescriptions for opioids increased sharply, reaching nearly 250 million prescriptions in 2013, almost enough for

⁵⁹ 21 U.S.C. § 812 Schedule II (2012).

⁶⁰ Meldrum ML, *Progress in Pain Research and Management*, Vol. 25 Seattle, WA: IASP Press; 2003.

⁶¹ *Id.*

every person in the United States to have a bottle of pills. This represents an increase of three hundred percent (300%) since 1999.

B. IMPACT ON VERMONT AND THE TOWN OF BENNINGTON

268. While the Defendants have profited from the alarming rate of opioid use in the United States, communities across the country have suffered. According to the CDC, the nation is experiencing an opioid-induced “public health epidemic.” The CDC reports that prescription opioid use contributed to 16,651 overdose deaths nationally in 2010; 16,917 in 2011; and 16,007 in 2012. Based on the latest data, nearly two million Americans met criteria for prescription opioid abuse and dependence in 2013. Aggregate costs for prescription opioid overdose, abuse, and dependence were estimated at over \$78.5 billion (in 2013 dollars).

269. While Defendants were reaping billions of dollars in profits from their wrongful conduct, Plaintiff has been required to allocate substantial public monies and resources to combat the opioid crisis in Bennington and deal with its fallout.

270. Plaintiff has incurred and continues to incur substantial costs because of Defendants’ conduct as described herein, including, but not limited to, costs of increased services with respect to law enforcement and first responders, such as emergency medical services; detention centers and jails; courts, including drug courts; diversion programs; prevention and treatment centers; community outreach programs; equipment and supplies; victim services supports; drug abuse prevention programs in schools; inmate services including housing, health and support staff; intervention programs; and increased costs associated with its own employee benefits plan, together with general societal and lost productivity costs.

271. Between 2010 and 2018, opioid related fatalities nearly tripled in Vermont.⁶² In 2016, Vermont's opioid related overdose death rate was 38% higher than the national average (18.4 per 100,000 residents versus 13.3).⁶³ In 2010 and 2011, more than 5% of all Vermonters-roughly 30,000 people-had misused prescription opioids within the prior twelve months.

272. The relationship between the use of prescription opioids and the use of heroin and fentanyl is well documented. Opioids have become the most common gateway drug leading to the use and abuse of heroin, fentanyl and carfentanil, with often deadly consequences. Prescription opioid addicts are 40 times more likely to also be addicted to heroin and almost half (45%) of heroin users are also addicted to opioids.⁶⁴ As noted above, a 2015 study found that four out of five heroin users reported that their addiction started with opioid pain relievers.⁶⁵

273. Dangerous physical and mental comorbidities from heroin and fentanyl addiction have also become widespread in Vermont. Conditions such as bacterial infections of blood, heart valves and lungs are common among addicts. These conditions have placed additional strain on Vermont's health care system. Mental health conditions like depression, anxiety and PTSD are also tied to opiate addiction. Widespread opiate abuse also increases the risk of outbreaks of HIV and Hepatitis B and C. As a result of the opioid crisis, in 2016 the CDC placed Essex County and Windham County, Vermont in the top 5% of counties nationwide at greatest risk for HIV and Hepatitis C outbreaks.⁶⁶

⁶² Vermont Department of Health, Opioid-Related Fatalities Among Vermonters (updated 2019), http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Data_Brief_Opioid_Related_Fatalities.pdf.

⁶³ National Institute on Drug Abuse, Vermont Opioid Summary (March 2018), <https://www.drugabuse.gov/drug-facts/use/opioids/opioid-summaries-by-state/vermont-opioid-summary>.

⁶⁴ Centers for Disease Control and Prevention, *Today's Heroin Epidemic*, <https://www.cdc.gov/vitalsigns/heroin>.

⁶⁵ NAT'L SAFETY COUNCIL, PRESCRIPTION NATION 2016: ADDRESSING AMERICA'S DRUG EPIDEMIC 9 (2016), <http://www.nsc.org/RxDrugOverdoseDocuments/Prescription-Nation-2016-American-Drug-Epidemic.pdf>.

⁶⁶ Centers for Disease Control and Prevention, *Vulnerable Counties and Jurisdictions Experiencing or At-Risk of Outbreaks* <https://www.cdc.gov/pwids/vulnerable-counties-data.html>

274. Vermont's opioid crisis has had a ruinous effect on its mothers and children. The number of expectant mothers diagnosed with opioid use disorder prior to delivery has skyrocketed. In 2001, the occurrence rate was 0.5 per 1,000 deliveries. By 2014, the rate had increased to 48.6 per 1,000 deliveries. Vermont's 2014 rate was the highest amongst 30 other states who track this data and is over seven times higher than the national average.⁶⁷ Unsurprisingly, Vermont's rate of infants born with Neonatal Abstinence Syndrome—a medical condition that afflicts newborns who are born addicted to opioids—increased from 17 per 1,000 births in 2008 to 35.3 per 1,000 births in 2014.⁶⁸ Further, the Vermont Department of Health estimated the 2012 NAS rate was five times higher than the national average.⁶⁹

275. Sadly, the opioid crisis has disrupted or destroyed many of Vermont's families. In 2018, over 50% of children under five years of age that were removed from their homes were removed due to issues related to opioids.⁷⁰

C. PARTICULARS REGARDING EACH DEFENDANT GROUP'S ROLE IN THE OPIOID EPIDEMIC

1. The Manufacturer Defendants' Campaign of Deception

a. The Manufacturer Defendants' Campaign to Normalize Widespread Opioid Use

276. Unsatisfied with the market for opioid use in the context of acute and palliative care, the Manufacturer Defendants introduced new opioid drugs during the 1980s and 1990s and

⁶⁷ *Opioid Use Disorder Documented at Delivery Hospitalization-United States, 1999-2014*, CDC Morbidity and Mortality Weekly Report (August 10, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/mm6731a1.htm?s_cid=mm6731a1_e, at 847.

⁶⁸ *Opioid Use Disorder Documented at Delivery Hospitalization-United States, 1999-2014*. CDC Morbidity and Mortality Weekly Report (August 10, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/mm6731a1.htm?s_cid=mm6731a1_e, at 847.

⁶⁹ *Id.* at 845.

⁷⁰ Vermont Department of Health, *People Treated for Opiate Use in Vermont by Fiscal Year*, <http://www.healthvermont.gov/sites/default/files/documents/2016/12/adapTotalOpiatebyFY.pdf>.

began promoting their use for chronic pain therapy in an effort to increase the number of people taking opioids.

277. Those new drugs included, but were not limited to: Purdue's MS Contin (introduced 1987) and OxyContin (1995); Janssen's Duragesic (1990), Nucynta (2008), and Nucynta ER (2011); Cephalon's Actiq (1998) and Fentora (2006); and Endo's Opana and Opana ER (2006).

278. By 1994, certain manufacturers were able to anticipate the demand for oxycodone and other opioid APIs. That year, Janssen's scientists at Tasmanian Alkaloids began a project in order to develop a high thebaine poppy variety to meet the anticipated demand. The result of Janssen's research project was the creation of a high thebaine poppy, called the Norman Poppy, which Janssen internally described as a transformational technology that enabled the growth of oxycodone.

279. Through Noramco, Janssen met the anticipated opioid demand by selling API to other opioid manufacturers, including Purdue and Teva. Noramco sold the majority of its API via long-term agreements and had such agreements with all seven of the top U.S. generic opioid manufacturers.

280. Janssen, through its subsidiaries, supplied the following opioid APIs to other drug manufacturers in the U.S., including Purdue and Teva: oxycodone, hydrocodone, morphine, codeine, fentanyl, sufentanil, buprenorphine, hydromorphone, and naloxone.

281. Recognizing the enormous financial possibilities associated with expanding the opioid market, the Manufacturer Defendants rolled out a massive and concerted campaign to misrepresent the addictive qualities of their product, and to push opioids as safe, effective drugs for the treatment of pain associated with conditions such as everyday back pain, tooth aches, sprains, headaches and the like.

282. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or minimize the risks of opioids while overstating the benefit of using them for chronic non-cancer related pain. As just one example, on information and belief, the Manufacturer Defendants spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

283. Further, each Defendant promoted the use of opioids for pain through sales representatives who visited individual doctors and medical staff in their offices and through the implementation of small group speaker programs. Defendants devoted massive resources to direct such sales contacts with doctors. In 2014 alone, Defendants spent \$168 million on detailing branded opioids to doctors, including \$108 million by Purdue, \$34 million by Janssen, \$13 million by Cephalon, \$10 million by Endo, and \$2 million by Allergan. These amount to twice as much as Defendants spent on detailing in 2000.

284. The deceptive marketing schemes included, among others, (a) the hiring of certain physicians, “hired guns,” to pollute the marketplace with false information regarding the efficacy and risks of opioids for chronic pain treatment; (b) false or misleading materials, speaker programs, webinars, and brochures by purportedly neutral third parties that were really designed and distributed by the Manufacturer Defendants; (c) false or misleading direct, branded advertisements and marketing materials; and (d) the misuse of treatment guidelines.

285. The Manufacturer Defendants’ misinformation campaign worked as intended. Across the country, demand for prescription opioids exploded, including in The Town of Bennington. Doctors and medical professionals, swayed by the Manufacturer Defendants’ sophisticated propaganda machine, began prescribing prescription opioids for ailments ranging from headaches to neck pain to fibromyalgia. That unleashed a wave of addiction—further increasing the demand for opioids. The Manufacturer Defendants’ profits soared.

b. The Manufacturer Defendants' Hired Guns

i. Dr. Portenoy and Webster

286. The Manufacturer Defendants' campaign of deception to downplay the addictive nature of opioids was rooted in two pieces of purportedly "scientific" evidence. The first piece of evidence was a five-sentence letter to the editor published in 1980 in the *New England Journal of Medicine*. The letter was drafted by Hershel Jick, a doctor at Boston University Medical Center, with the help of a graduate student, Jane Porter. It noted, anecdotally, that a review of "current files" did not indicate high levels of addiction among hospitalized medical patients who received narcotic preparation treatment. In full, the letter reads:

Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well-documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients, Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.⁷¹

287. The second major piece of "evidence" used by Manufacturer Defendants was a 1986 study by Dr. Russell Portenoy in the medical journal *Pain*. The study, which had a patient cohort of merely 38 patients, claimed that opioids could be used for long periods of time to treat non-cancer related pain without any risk of addiction. The rationale behind the study was that patients in pain would not become addicted to opioids because their pain drowned out the euphoria associated with opioids. As such, the study concluded that opioids should be freely administered to patients with fibromyalgia, headaches, finicky backs, and a host of other issues. According to Portenoy and his co-author, Dr. Kathleen Foley, "opioid maintenance therapy can be a safe,

⁷¹ *Addiction rare in patients treated with narcotics*, 302(2) *New Eng. J. Med.* 123 (Jan. 10, 1980).

salutary and more humane alternative ... in those patients with intractable non-malignant pain and no history of drug abuse.”⁷² Portenoy’s study also cited Jick’s one-paragraph letter to the New England Journal of Medicine.

288. Dr. Portenoy’s study dovetailed perfectly with Manufacturer Defendants’ marketing strategy and, within a decade, Dr. Portenoy was financed by “at least a dozen companies, most of which produced prescription opioids.”⁷³

289. Dr. Portenoy went on to serve as one of the pharmaceutical industry’s most vocal advocates, regularly appearing at conferences and gatherings of medical professionals to promote the use of opioids for chronic, long-term pain.

290. The Manufacturer Defendants disseminated fraudulent and misleading messages to reverse the popular and medical understanding of opioids and their associated risks. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Manufacturer Defendants recruited for their support of their marketing messages, through unbranded marketing and through industry-funded front groups.

291. These statements were not only unsupported by or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that same evidence.

292. Hired guns like Dr. Portenoy promoted opioid analgesics and the myth that opioids could be liberally prescribed for non-cancer related pain, without any risk of addiction.

293. Others like Dr. Portenoy would speak at academic conferences to primary care physicians in an effort to destigmatize opioids and encouraged liberal prescription of narcotics for

⁷² Portenoy RK, Foley KM, *Chronic use of opioid analgesics in non-malignant pain: report of 38 cases*, 25 Pain 171 (1986).

⁷³ Meier B., *Pain Killer: A Wonder Drug’s Trail of Addiction and Death*, New York, NY: St. Martin’s Press; 2003.

the treatment of non-cancer related pain. They claimed that opioid analgesics have no “ceiling dosage” in that prescribing physicians should increase dosages for patients as high as necessary to treat non-cancer chronic pain. Invariably, the key piece of “data” cited in support of the proposition that opioids could be safely used to treat pain was the New England Journal of Medicine article.

294. The Manufacturer Defendants also paid Dr. Lynn Webster, the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah, to promote opioids. Dr. Webster was President of the American Academy of Pain Medicine (“AAPM”) in 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous continuing medical education programs (“CMEs”) sponsored by Cephalon, Endo and Purdue. At the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants (including nearly \$2 million from Cephalon).

295. In the years that have followed, both the New England Journal of Medicine letter and Dr. Portenoy’s 1986 study have been expressly disavowed. Neither article actually demonstrates that opioids can be safely prescribed for long-term, non-cancer related pain.

296. In a taped interview in 2011, Dr. Portenoy admitted that the information the Manufacturer Defendants were pushing was false. “I gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true,” Dr. Portenoy told a fellow doctor in 2010. “It was the wrong thing to do.”⁷⁴

I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite. I would cite 6 to 7 maybe 10 different avenues of thought or evidence, *none of which represents real evidence*. And yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in total and feel more comfortable about opioids in a way

⁷⁴ Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012).

they hadn't before ... Because the primary goal was to de-stigmatize, *we often left evidence behind.*

It was clearly the wrong thing to do and to the extent that some of the adverse outcomes now are as bad as they have become in terms of endemic occurrences of addiction and unintentional overdose death, it's quite scary to think about how the growth in that prescribing driven by people like me led, in part, to that occurring.⁷⁵

297. As to the New England Journal of Medicine letter, Dr. Jick, in an interview with Sam Quinones decades after the letter was published, stated: “[t]hat particular letter, for me, is very near the bottom of a long list of studies that I’ve done. It’s useful as it stands because there’s nothing else like it on hospitalized patients. But if you read it carefully, it does not speak to the level of addiction in outpatients who take these drugs for chronic pain.”⁷⁶

298. The New England Journal of Medicine itself has since disavowed the letter, stating, “[the letter] was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy.”⁷⁷ “We believe,” the journal provided, “that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers’ concerns about the risk of addiction associated with long-term opioid therapy.”⁷⁸

c. Defendant-Funded Organizations

299. Manufacturer Defendants also funded multiple organizations to advocate for the use of opioids to treat chronic pain. The names of the organizations suggest neutrality, but they were anything but. They included the American Pain Foundation (“APF”); the American Academy of Pain Management (which received funding from Manufacturer Defendants Endo, Janssens, and

⁷⁵ Live interview with Dr. Russell Portenoy. Physicians Responsible for Opioid Prescribing. <https://www.youtube.com/watch?v=DgyuBWN9D4w>. Accessed December 3, 2017 (emphases added).

⁷⁶ Harrison Jacobs, *This one-paragraph letter may have launched the opioid epidemic*, BUSINESS INSIDER, Mar. 26, 2016, <http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5>

⁷⁷ 376 New Eng. J. Med. 2194, 2194–95 (2017).

⁷⁸ *Id.*

Purdue); the American Pain Society (“APS”), the American Geriatrics Society (“AGS”), and the Pain Care Forum (“PCF”).

i. The American Pain Foundation

300. The most prominent nonparty advocate for opioids, funded by Defendants, was the American Pain Foundation (“APF”). APF received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next, at \$1.7 million.

301. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign — through radio, television, and the internet — to educate patients about their “right” to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach Vermont consumers, physicians, patients, and third-party payers.

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

303. In 2009 and 2010, more than eighty percent (80%) of APF’s operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of total income of about \$2.85 million in

2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of a total income of about \$3.5 million. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit.

304. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide “patient representatives” for Defendants’ promotional activities, including for Purdue’s “Partners Against Pain” and Janssen’s “Let’s Talk Pain.” But in reality, APF functioned as an advocate for the interests of the Manufacturer Defendants, not patients. Indeed, as early as 2011, Purdue told APF that the basis of a grant was Purdue’s desire to “strategically align its investments in nonprofit organizations that share [its] business interests.”

305. APF caught the attention of the United States Senate Finance Committee in May 2012 as the Committee sought to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation raised red flags as to APF’s credibility as an objective and neutral third party; the Manufacturer Defendants stopped funding it. Within days of being targeted by the Senate investigation, APF’s board voted to dissolve the organization “due to irreparable economic circumstances.” APF “cease[d] to exist, effective immediately.”⁷⁹

ii. The American Academy of Pain Medicine

306. The American Academy of Pain Medicine (“AAPM”), with the assistance, prompting, involvement, and funding of the Manufacturer Defendants, issued treatment guidelines

⁷⁹ Charles Ornstein and Tracy Weber, *Senate Panel Investigates Drug Companies’ Ties to Pain Groups*, WASH. POST, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html

and sponsored and hosted CME programs for doctors essential to the Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

307. AAPM has received over \$2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate in activities and conferences. Defendants Endo, Purdue, Cephalon, and Allergan were members of the council.

308. AAPM was viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its corporate events, and distributed its publications. The conferences sponsored by AAPM promoted opioids – 37 out of roughly 40 sessions at one conference alone were opioid-focused.

309. AAPM's presidents have included the same opioid advocates mentioned above, *i.e.* Drs. Fine, Portenoy, Webster and Fishman. Dr. Fishman, a past AAPM president, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are ... small and can be managed."⁸⁰

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

iii. The Pain Care Forum

311. On information and belief, the Manufacturer Defendants also combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and "promote and support taking collaborative action regarding federal pain policy issues." APF

⁸⁰ Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), available at <http://www.medscape.org/viewarticle/500829>

President Will Rowe described the forum as “a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations.”

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

313. PCF, for example, developed and disseminated “consensus recommendations” for a Risk Evaluation and Mitigation Strategy (“REMS”) for long-acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients. This was critical because a REMS that went too far in narrowing the uses or benefits or highlighting the risks of chronic opioid therapy would undermine the Manufacturer Defendants’ marketing efforts. On information and belief, the recommendations claimed that opioids were “essential” to the management of pain, and that the REMS “should acknowledge the importance of opioids in the management of pain and should not introduce new barriers.” The Manufacturer Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, not undermine, their deceptive marketing of opioids for chronic pain.

314. All of these purportedly neutral, industry-funded organizations took aggressive stances to convince doctors and medical professionals that America was suffering from an epidemic of untreated pain — and that opioids were the solution. Their efforts were successful nationwide, including in The Town of Bennington.

d. The Manufacturer Defendants' False and Misleading Direct Advertising and Marketing of Opioids

315. The Manufacturer Defendants have intentionally made false and misleading statements regarding opioids in their advertising and marketing materials disseminated nationwide, including in The Town of Bennington. They have, among other things, (1) downplayed the serious risk of addiction; (2) created and promoted the imaginary concept of “pseudoaddiction,” advocating that when signs of actual addiction begin to appear, the patient should be treated with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher dosages; (6) described their opioid products as “steady state” – falsely implying that these products are less likely to produce the high and lows that fuel addiction – or as less likely to be abused or result in addiction; (7) touted the effectiveness of screening or monitoring patients as a strategy for managing opioid abuse and addiction; (8) stated that patients would not experience withdrawal if they stopped using their opioid products; (9) stated that their opioid products are effective for chronic pain without disclosing the lack of evidence for the effectiveness of long-term opioid use; and (10) stated that abuse-deterrent formulations were safer, tamper- or crush-resistant less divertible and less abusable than other opioids or treatment drugs.

316. The Manufacturer Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants' claims.

317. The Manufacturer Defendants engaged in deceptive direct-to-physician marketing, promoting the use of opioids for chronic pain through controlled and trained sales representatives who visited individual doctors and medical staff in their offices and small group speaker programs.

318. On information and belief, throughout the relevant time period these sales representatives have spread (and may continue to spread) misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors.

319. Allergan was notified by the FDA in 2010 that certain brochures were “false or misleading because they omit and minimize the serious risks associated with the drug, broaden and fail to present the limitations to the approved indication of the drug, and present unsubstantiated superiority and effectiveness claims.” The FDA also found that “[t]hese violations are a concern from a public health perspective because they suggest that the product is safer and more effective than has been demonstrated.”⁸¹

320. Through these means, and likely others still concealed, the Manufacturer Defendants collaborated to spread deceptive messages about the risks and benefits of long-term opioid use in patient education brochures and pamphlets, websites, ads and other marketing materials

321. For example:

(a) Allergan’s predecessor caused a patient education brochure, *Managing Chronic Back Pain*, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is “less likely if you have never had an addiction problem.” Based on Allergan’s acquisition of its predecessor’s marketing materials along with the rights to Kadian, it appears that Allergan continued to use this brochure in 2009 and beyond.

(b) Cephalon and Purdue sponsored *APF’s Treatment Options: A Guide for People Living with Pain* (2007), which suggests that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative prescriptions, or theft. This publication is available today.⁸²

(c) Endo sponsored a website, “*PainKnowledge*,” which, upon information and belief, claimed in 2009 that “[p]eople who take opioids as prescribed usually do not become

⁸¹ Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc’ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at <http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf>

⁸² Available at <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>

addicted.” Upon information and belief, another Endo website, PainAction.com, stated “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.” Endo also distributed an “Informed Consent” document on PainAction.com that misleadingly suggested that only people who “have problems with substance abuse and addiction” are likely to become addicted to opioid medications.

(d) Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that “[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem.”

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

(f) Janssen currently runs a website, *Prescriberesponsibly.com* (last updated July 2, 2015), which claims that concerns about opioid addiction are “overestimated.”⁸³

(g) Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to “misconceptions about opioid addiction[.]” This publication is still available online.⁸⁴

(h) Consistent with the Manufacturer Defendants’ published marketing materials, upon information and belief, detailers for the Manufacturer Defendants in Vermont have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in Vermont about the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

(i) Endo, on information and belief, has distributed and made available on its website *opana.com* a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement

(j) On information and belief, Purdue also ran a series of ads, called “Pain vignettes,” for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a “54-year-old writer with osteoarthritis of the hands” and implied that OxyContin would help the writer work more effectively.

⁸³ Available at, <http://www.prescriberesponsibly.com/articles/opioid-pain-management>

⁸⁴ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>

(k) The New York Attorney General found in its settlement with Purdue that through March 2015, the Purdue website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were paid by Purdue,⁸⁵ and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.⁸⁶

322. The Manufacturer Defendants falsely instructed doctors and patients that the signs of addiction should not be seen as warnings but are actually signs of undertreated pain and should be treated by prescribing more opioids. The Manufacturer Defendants called this phenomenon "pseudoaddiction" and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Dr. Webster was a leading proponent of this notion, stating that the only way to differentiate the two was to increase a patient's dose of opioids.⁸⁷

323. Other examples of the Manufacturer Defendants' advocacy for the fictional concept of "pseudoaddiction" include, but are not limited to:

(a) Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. The 2012 edition of *Responsible Opioid Prescribing* remains for sale online.⁸⁸

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

⁸⁵ See New York State Office of the Attorney General, *A.G. Schneiderman Announces Settlement with Purdue Pharma That Ensures Responsible and Transparent Marketing Of Prescription Opioid Drugs By The Manufacturer* (August 20, 2015), <https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent> (last accessed December 20, 2017)

⁸⁶ The New York Attorney General, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the New York Attorney General found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Upon information and belief, Endo continues to make these false statements elsewhere.

⁸⁷ Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

⁸⁸ See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2d ed. 2012).

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

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

(e) Upon information and belief, Purdue sponsored a CME program titled “*Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*.” In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or “overindulges in unapproved escalating doses.” The doctor treats this patient by prescribing a high-dose, long acting opioid.

324. However, Defendants’ own hired gun has now conceded that pseudoaddiction is fictional. Dr. Webster has acknowledged that “[pseudoaddiction] obviously became too much of an excuse to give patients more medication.”⁸⁹

325. The 2016 CDC Guidelines also reject the concept of pseudoaddiction. The Guidelines explain that “[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,” and that physicians should “reassess[] pain and function within 1 month” in order to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because the patient is “not receiving a clear benefit.”⁹⁰

⁸⁹ John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012

⁹⁰ *CDC Guidelines for Prescribing Opioids for Chronic Pain*, available at <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>

326. The Manufacturer Defendants also falsely claimed that there were addiction risk screening tools – such as patient contracts, urine drug screens, and other similar strategies – that allowed them to reliably identify and safely prescribe opioids to patients predisposed to addiction.

327. In addition, the Manufacturer Defendants widely spread misleading information about the risks of addiction associated with increasing dosages of opioids over time, and downplayed the risks created by the tolerance for opioids that patients would develop after consuming the drugs over a period of time.

328. For example,

(a) On information and belief, Allergan’s predecessor created a patient brochure for Kadian in 2007 that stated, “Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction.”

(b) Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients “need” a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have “no ceiling dose” and are therefore the most appropriate treatment for severe pain. This guide is still available online.⁹¹

(c) Endo sponsored a website, “*PainKnowledge*,” which, upon information and belief, claimed in 2009 that opioid dosages may be increased until “you are on the right dose of medication for your pain.”

(d) Endo distributed a pamphlet edited by an opioid advocate entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked “If I take the opioid now, will it work later when I really need it?” The response is, “The dose can be increased. . . . You won’t ‘run out’ of pain relief.”⁹²

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

⁹¹ Available at, <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf>

⁹² Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

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

(g) Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.⁹³

(h) In 2007, Purdue sponsored a CME entitled *Overview of Management Options* that was available for CME credit and available until at least 2012. It taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

(i) Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, APF and others argued to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.⁹⁴

329. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guidelines, "[t]here is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."⁹⁵

330. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients nationwide, and in The Town of Bennington, would look to opioids first for the treatment of chronic pain. The Manufacturer Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids.⁹⁶

331. The Manufacturer Defendants also promoted their products with a disregard for the truth about their safety and despite known risks of diversion and abuse. For example, Indivior developed Suboxone Film around 2007 as a patent-protected alternative to the tablet form of

⁹³ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf>

⁹⁴ Brief of the American Pain Foundation (APF), the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) at 9

⁹⁵ 2016 CDC Guidelines *supra* note 83.

⁹⁶ See, e.g., Case Challenges in Pain Management: Opioid Therapy for Chronic Pain (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids), http://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf (last accessed December 19, 2017).

Suboxone, which was then about to face generic drug competition. The primary ingredient in both Suboxone Film and tablets is buprenorphine, a highly potent opioid. According to the USDOJ indictment, Indivior promoted Suboxone Film as safer and less-divertible than its tablet form, even though the company lacked any scientific evidence to support those claims. In particular, Indivior aggressively marketed Suboxone Film, without an established basis, as having a “lower risk of child exposure” and “less divertible/abusable formulation”. The indictment alleges Indivior made these and other false and misleading claims in marketing materials and through representations throughout the country. The indictment also alleges that, to further its scheme, Indivior announced a “discontinuance” of its tablet form of Suboxone based on supposed “concerns regarding pediatric exposure to” tablets, when in fact Indivior executives knew the primary reason for the discontinuance was to delay the Food and Drug Administration’s approval of generic tablet forms of the drug.

332. Indivior’s scheme, as alleged in the indictment, was highly successful, converting thousands of opioid-addicted patients over to Suboxone Film and causing substantially increased utilization for the product. In addition, until earlier in 2019, when Suboxone Film became subject to generic competition, Indivior retained a high portion of the opioid- addiction treatment market.

333. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The Manufacturer Defendants and their PBM allies had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering

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

334. Notwithstanding their knowledge, in order to maximize profits, the Manufacturer Defendants continued to advocate in the false and deceptive manners described herein with the goal of increasing opioid use, purposefully ignoring the foreseeable consequences of their activity in terms of addiction and public health throughout the United States, and in The Town of Bennington.

335. The Manufacturer Defendants intentionally used these false and deceptive representations to maximize profits and utilization of opioids.

336. According to the US DOJ indictment, Defendant Indivior additionally used its "Here to Help" internet and telephone program as part of its scheme to induce physicians to write prescriptions for Suboxone Film. Touted as a resource for opioid- addicted patients, Indivior used the program in part to connect patients to doctors it knew were prescribing Suboxone and other opioids to more patients than allowed by federal law, at high doses, and in suspect circumstances. The indictment alleges that Indivior executives and employees knew from statistic and numerous firsthand reports that some doctors in the Here to Help referral system were issuing prescriptions in a careless and clinically unwarranted manner.

337. A very recent study in the Journal of the American Medical Association has further confirmed the falsity of defendants' representations. This study followed patients with chronic back, hip or knee pain who were treated with opioids and non-opioids over a 12-month period. The study concluded that there was no significant difference in pain control, but that pain intensity was significantly better for non-opioid users, while adverse medication-related side effects were

significantly more common for opioid users. The Study recommended against initiation of opioid therapy for moderate to severe chronic osteoarthritis pain.⁹⁷

e. Manufacturer Defendants' Misuse of Treatment Guidelines

338. In addition, treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by the Manufacturer Defendants, who are neither experts nor trained in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Allergan, and Purdue discussed treatment guidelines with doctors during individual sales visits including visits throughout Vermont and the Town of Bennington.

i. Federation of State Medical Boards (FSMB)

339. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

340. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with

⁹⁷ Erin E. Krebs, MD, MPH; Amy Gravely, MA; Sean Nugent, BA; et al, *Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain*, JAMA, March 6, 2018

pharmaceutical companies” and taught not that opioids could be appropriate in limited cases after other treatments had failed, but that opioids were “essential” for treatment of chronic pain, including as a first prescription option.

341. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in The Town of Bennington.

342. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as the “leading continuing medication (CME) activity for prescribers of opioid medications.”⁹⁸

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

ii. AAPM/APS Guidelines

344. American Academy of Pain Medicine (“AAPM”) and the American Pain Society (“APS”) are professional medical societies, each of which received substantial funding from

⁹⁸ Scott M. Fishman, *Responsible Opioid Prescribing*, Scott M. Fishman published by Waterford Life Services (2007)

Defendants from 2009 to 2013. In 1997, AAPM issued a “consensus” statement, *The Use of Opioids for the Treatment of Chronic Pain*, that endorsed opioids to treat chronic pain and claimed that there was little risk of addiction or overdose in pain patients.⁹⁹ The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Portenoy. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM’s website and remained until 2011; it was taken down only after a doctor complained, though it lingers on the internet elsewhere.

345. AAPM and APS issued their own guidelines in 2009 (“2009 Guidelines”) and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including Dr. Portenoy and Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue.

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

⁹⁹ *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997). Available at <http://opi.areastematicas.com/generalidades/OPIOIDES.DOLORCRONICO.pdf> (as viewed 3/31/2016).

347. The Manufacturer Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions.

348. The extent of the Manufacturer Defendants' influence on treatment guidelines is demonstrated by the fact that independent guidelines – the authors of which did not accept drug company funding – reached very different conclusions.

349. The 2012 Guidelines for *Responsible Opioid Prescribing* in Chronic Non- Cancer Pain, issued by the American Society of Interventional Pain Physicians (“ASIPP”), warned that “[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it.” ASIPP’s Guidelines further advise that “therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain.” ASIPP recommends long-acting opioids in high doses only “in specific circumstances with severe intractable pain” and only when coupled with “continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvements in physical and functional status and minimal adverse effects.”¹⁰⁰

350. Similarly, the 2011 Guidelines for the *Chronic Use of Opioids*, issued by the American College of Occupational and Environmental Medicine, recommend against the “routine

¹⁰⁰ Laxmaiah Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment*, 15 Pain Physician (Special Issue) S1-S66; *Part 2 – Guidance*, 15 Pain Physician (Special Issue) S67-S116 (2012).

use of opioids in the management of patients with chronic pain,” finding “at least moderate evidence that harms and costs exceed benefits based on limited evidence.”¹⁰¹

351. The Clinical Guidelines on Management of Opioid Therapy for Chronic Pain, issued by the United States Department of Veterans Affairs (“VA”) and Department of Defense (“DOD”) in 2010, notes that their review revealed a lack of solid evidence-based research on the efficacy of long-term opioid therapy.¹⁰²

2. Manufacturer, Distributor, and Pharmacy Defendants Violated their Requirements to Prevent Diversion and Report Suspicious Orders under Vermont and Federal Law.

352. In addition to their common law duties, Manufacturer, Distributor, and Pharmacy Defendants are subject to statutory and regulatory requirements under Vermont law. Vermont imposes numerous substantive requirements on parties involved in the distribution chain of opioids and other controlled substances. These requirements include providing adequate inventory control and security of opioids to prevent diversion, and reporting suspicious orders of opioids to the Vermont Board of Pharmacy. Vermont law also explicitly requires parties involved in the distribution chain of controlled substances such as opioids to comply with the requirements of the Controlled Substances Act, 21 U.S.C. § 801 et seq. (the “CSA”), and its implementing regulations. Vermont, in adopting the requirements of the CSA and its implementing regulations, indicated that it, like Congress when it passed the CSA, had concerns about “the widespread diversion of [controlled substances] out of legitimate channels into the illegal market.” H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572.

¹⁰¹ *American College of Occupational and Environmental Medicine's Guidelines for the Chronic Use of Opioids* (2011).

¹⁰² Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010). Available at http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full-er.pdf (accessed March 31, 2016).

353. The opioid epidemic was further fueled by Defendants' failure to follow the specific mandates in Vermont law and the CSA requiring them to help ensure that highly addictive drugs are not diverted to illegal use. The brunt of the opioid epidemic could have been, and should have been, prevented if Defendants had fulfilled their duties set by statute, regulation, and common law. Defendants, who operate at every level of the opioid supply chain, had an obligation and duty to act. They did not—and the country, including the Town of Bennington, paid the price.

354. Recognizing that highly addictive drugs like opioids can be easily abused and diverted to the black market, , and Congress enacted the CSA.

355. First, the DEA sets limits on the quantity of Schedule II controlled substances – such as opioids – that may be produced in the United States in any given year. *See* 21 U.S.C. § 826(a); 28 C.F.R. § 0.100. The DEA determines these quotas based on a variety of data including sales, production, inventories, and exports. The DEA can and does lower quotas as a means of addressing abuse and diversion.

356. Second, Congress anticipated that highly addictive prescription drugs like opioids could be abused and diverted to the black market. The CSA thus sought to combat diversion of prescription narcotics by providing for a closed system of drug distribution in which manufacturers, wholesalers/distributors, and retail pharmacies must register with the DEA. Every registrant, in turn, is charged with being vigilant in deciding whether a customer, be it a pharmacy, wholesaler, or end customer, can be trusted to deliver or use controlled prescription narcotics only for lawful purposes. 21 U.S.C. § 823(e). Specifically, every registrant is required to “maintain effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” 21 U.S.C. § 823(b)(1).

357. In particular, the CSA and its implementing regulations require all registrants to (1) report suspicious orders of prescription opioids to the DEA, and (2) perform required due diligence prior to filling any suspicious orders. See 21 U.S.C. § 823(b)(1); 21 C.F.R. § 1301.74(b).

358. In addition, the Code of Federal Regulations requires all registrants—including defendant manufacturers and wholesalers/distributors—to “design and operate a system to disclose to the registrant suspicious orders of controlled substances.” 21. C.F.R. § 1301.74(b).

359. On information and belief, Manufacturer and Distributor Defendants knowingly, recklessly, and/or negligently supplied suspicious quantities of prescription opioids to obviously suspicious physicians and pharmacies in and around the Town of Bennington, without disclosing suspicious orders as required by regulations and otherwise circumventing their statutory obligations under Vermont and Federal law.

360. Similarly, on information and belief, the Pharmacy Defendants knowingly, recklessly, and/or negligently dispensed suspicious prescriptions and suspicious quantities of prescriptions to customers who showed obvious indicators of opioid addiction and/or who received prescriptions that were manifestly not written pursuant to a bona fide patient-prescriber relationship.

361. Defendants’ refusal to report and investigate suspicious orders had far-reaching effects. The DEA is required to annually set production quotas for regulated drugs. In the context of opioids, however, the DEA has cited the difficulty of determining an appropriate production level to ensure that adequate quantities are available for legitimate medical use. That is because there are no direct measures available to establish legitimate medical need. The DEA’s difficulty in setting production quotas was compounded by the fact that the Manufacturer and Distributor Defendants failed to report suspicious orders of opioids and failed to maintain effective controls

against diversion. The Defendants' deliberate failures thus prevented the DEA from realizing the full extent of opioid diversion for years.

362. As a direct result of Defendants' failures, excess amounts of Defendants' opioids were shipped into Vermont, causing a public-health and law-enforcement crisis in the Town of Bennington.

363. The Defendants could have (and should have) reported and stopped the flow of prescription opioids into the black market. But Defendants intentionally, recklessly, and/or negligently failed to investigate, report, and halt suspicious orders. Accordingly, as a direct result of the Defendants' misconduct, substantial and dangerous quantities of prescription opioids were illegally diverted to and overprescribed in the Town of Bennington.

a. MANUFACTURER DEFENDANTS

364. The Manufacturer Defendants are required to design and operate a system to detect suspicious orders, and to report such orders to law enforcement. *See* 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823. They have not done so.

365. Upon information and belief, the Manufacturer Defendants collected, tracked, and monitored extensive data concerning suspicious physicians and pharmacies, obtained from the Distributor Defendants who supplied the Manufacturer Defendants with distribution data in exchange for rebates or other incentives so Manufacturer Defendants could better drive sales.

366. In return for these incentives, the distributor identified to the manufacturer the product, volume and the pharmacy to which it sold the product.

367. For example, IMS Health furnished Purdue and other Manufacturer Defendants with detailed information about the prescribing habits of individual doctors and the ordering habits of individual pharmacies.