VIRGINIA: IN THE CIRCUIT COURT OF LEE COUNTY

LEE COUNTY, VIRGINIA

Plaintiff,

v.

PURDUE PHARMA, L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; RHODES PHARMACEUTICALS, L.P.; ABBOTT LABORATORIES; ABBOTT LABORATORIES, INC.; MALLINCKRODT PLC; MALLINCKRODT LLC; ENDO HEALTH SOLUTIONS, INC; ENDO PHARMACEUTICALS, INC.; PAR PHARMACEUTICAL COMPANIES, INC.; PAR PHARMACEUTICAL, INC.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; BARR LABORATORIES, INC.; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC.; WATSON LABORATORIES, INC.; ALLERGAN PLC; ACTAVIS PHARMA, INC.; ACTAVIS, LLC; INSYS THERAPEUTICS, INC.; KVK-TECH, INC.; AMNEAL PHARMACEUTICALS LLC; IMPAX LABORATORIES, LLC; AMNEAL PHARMACEUTICALS, INC.; AMNEAL PHARMACEUTICALS OF NEW YORK, LLC; MYLAN PHARMACEUTICALS, INC.; MCKESSON CORPORATION; MCKESSON MEDICAL-SURGICAL INC.; CARDINAL HEALTH, INC.; AMERISOURCEBERGEN DRUG CORPORATION; HENRY SCHEIN, INC.; GENERAL INJECTABLES & VACCINES, INC.; INSOURCE, INC.; CVS HEALTH CORPORATION; CVS PHARMACY, INC.; CVS TN DISTRIBUTION, L.L.C.; WALGREENS BOOTS ALLIANCE, INC.; WALGREEN CO.; EXPRESS SCRIPTS HOLDING COMPANY; EXPRESS SCRIPTS, INC; CAREMARK RX, L.L.C.; CAREMARKPCS HEALTH, L.L.C.; CAREMARK, L.L.C.; UNITEDHEALTH GROUP INCORPORATED; OPTUM, INC.; OPTUMRX, INC.; and DOES 1-100,

Defendants.

Case No. CL18 - _____

Jury Trial Demanded

PLAINTIFF'S ORIGINAL COMPLAINT

Plaintiff, Lee County, Virginia, by and through the undersigned attorneys, (hereinafter "Plaintiff," "Lee County," or "County") against Defendants: Purdue Pharma, L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Rhodes Pharmaceuticals, L.P.; Abbott Laboratories; Abbott Laboratories, Inc.; Mallinckrodt PLC; Mallinckrodt LLC; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Par Pharmaceutical Companies, Inc.; Par Pharmaceuticals, Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Barr Laboratories, Inc.; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc.; Watson Laboratories, Inc.; Allergan PLC; Actavis Pharma, Inc.; Actavis, LLC; Insys Therapeutics, Inc.; KVK-Tech, Inc.; Amneal Pharmaceuticals LLC; Impax Laboratories, LLC; Amneal Pharmaceuticals, Inc.; Amneal Pharmaceuticals of New York, LLC; Mylan Pharmaceuticals, Inc.; McKesson Corporation; McKesson Medical-Surgical Inc.; Cardinal Health, Inc.; AmerisourceBergen Drug Corporation; Henry Schein, Inc.; General Injectables & Vaccines, Inc.; Insource, Inc.; CVS Health Corporation; CVS Pharmacy, Inc.; CVS TN Distribution, L.L.C.; Walgreens Boots Alliance, Inc.; Walgreen Co.; (collectively, "Distributor Defendants"); Express Scripts Holding Company; 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.; (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 tens of thousands of Americans throughout virtually every community in the United States. It is indiscriminate and ruthless. It has impacted across demographic lines, harming every economic class, race, gender and age group. It is killing Americans, more than 134

people 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 accidents[2] or guns.[3] In 2016 more than one hundred seventy-five (175) people died every day from drug overdoses, comparable to an airplane crashing, killing everyone on board, every day.[4] In 2017, the number rose to over one hundred ninety-seven (197), the increase largely due to synthetic opioids.[5]

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.[6]

3. Prescription drug manufacturers, wholesalers/distributors, and pharmacy benefit managers ("PBMs") 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. And the PBMs control, through their pharmacy plan design and formulary management, which drugs go where and how they are paid for.

4. Each defendant group profits enormously from the movement of opioid products. Each has incentives to move certain drugs over others. Defendants themselves create the incentives

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[1] *See* NIH, *Overdose Death Rates*, NATIONAL INSTITUTE ON DRUG ABUSE, Rev. Aug. 2018, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (estimating more than 49,000 opioid related deaths in 2017).

[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/

[5] NIH, *Overdose Death Rates, supra* note 1.

[6] NIH, *Opioid Overdose Crisis*, NATIONAL INSTITUTE ON DRUG ABUSE, Rev. March 2018, https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis#two

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 was roughly equal the number of Americans who died in the Vietnam, Iraq, and Afghanistan wars combined.[7]

7. Lee County has been hit particularly hard by the opioid epidemic. The rate of neonatal abstinence syndrome (NAS) in Lee County has been higher than the statewide rate in Virginia during the entire course of the opioid epidemic.[8] The NAS rate peaked in 2014 at 71.8 per 1,000 births.[9] That rate is more than thirteen times higher than the statewide rate, and indicates that more than 7% of all babies born in Lee County in 2014 were born addicted to opioids.[10] The most recently available data reveals the NAS rate to have been more than six times higher than the statewide rate in 2016, when more than 4% of Lee County newborns were born addicted to

[7] 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

[8] VIRGINIA DEPARTMENT OF HEALTH, VIRGINIA OPIOID ADDICTION INDICATORS (2016), https://public.tableau.com/views/VirginiaOpioidAddictionIndicators/VAOpioidAddictionIndicators?:embed=y&:display_count=yes&:showVizHome=no

[9] *Id.*

[10] *Id.*

opioids.[11] The reported rate of Hepatitis C cases in Lee County has also been consistently high since at least 2011, with the rate peaking in 2012 at more than sixteen times higher than the statewide rate.[12] That year, 43 new cases of Hepatitis C were reported among 18 to 30-year-olds in Lee County, where just over 3,000 people in that age range live.[13] Although the reported rate of Hepatitis C has fallen somewhat, it is still exceedingly high, with 30 new cases reported among 18 to 30-year-olds in Lee County in 2016 alone.[14] Perhaps most disturbingly, the rate of overdose deaths in Lee County has steadily risen from 8 to 9.9 deaths per 100,000 people in 1999 to 28 to 29.9 deaths per 100,000 people in 2016.[15] Simply put, Lee County has been one of the unfortunate epicenters of the harm inflicted by the opioid epidemic.

8. The acute opioid problem in Lee County reflects the overwhelming epidemic affecting the entire Commonwealth. In 2016, Virginia's state health commissioner declared the state's opioid addiction problem a public health emergency. On average, three Virginians die of a drug overdose and over two dozen are treated in emergency departments for drug overdoses each day.[16] Fatal drug overdoses in the first half of 2016 increased by 35% compared to the same period in 2015.[17] More Virginians die each year from drug overdoses than motor vehicle accidents.[18]

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[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] *Id.*

[15] Centers for Disease Control and Prevention Drug Poisoning Mortality Rates in the United States, 1999-2016, https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality/.

[16] Dr. Melissa Levine, State Health Commissioner Telebriefing on Opioid Addiction Public Health Emergency (Nov. 21, 2016) (transcript available at http://www.vdh.virginia.gov/commissioner/opioid-addiction-in-virginia/).

[17] *Id.*

[18] Andrew Barnes and Katherine Neuhausen, Virginia Commonwealth University School of Medicine, "The Opioid Crisis Among Virginia Medicaid Beneficiaries," https://hbp.vcu.edu/media/hbp/policybriefs/pdfs/Senate_OpioidCrisisPolicyBrief_Final.pdf

9. Defendants' opioid-related misconduct drives heroin abuse. A 2015 study found that four out of five heroin users reported that their addiction started with opioid pain relievers.[19] In this way, prescription opioids – now, thanks to Defendants, provided to patients for everyday conditions such as knee pain, headaches, and dental pain – can operate as a "gateway" drug to heroin use and involvement with the illegal drug market.

10. In addition, Lee County 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. The County's costs for incarceration and correction services have increased in recent years due to an increasing crime rate attributable to the opioid epidemic. The costs that the County has borne for foster care and other child placement services have similarly increased due to the increasing number of children who need such services because opioid addiction has destroyed the structure of their families. Fire and emergency medical services are over-utilized because of an increased number of opioid-related overdoses. The burden on law enforcement is substantially increased by opioid-related crimes related to prescription opioid theft, diversion, and sales on the black market. Courts, social workers, nurses, schools, intervention programs, and clinics have all been harmed. Nearly every aspect of Lee County's budget has been significantly and negatively impacted by this Defendant-made epidemic.

11. 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

[19] 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

percent (5%) of the world's population, they consume eighty percent (80%) of the world production of prescription opioids.[20]

12. The side effects of opioid use have provided even more profits for drug manufacturers. For example, television airwaves are now flooded with advertisements for remedies for the most common opioid-related side effect, opioid-induced constipation, which increases a long-term opioid user's healthcare costs by over $10,000.[21]

13. 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.

14. The scheme began with Manufacturer Defendants, who deliberately polluted the national marketplace, including in Lee County, with lies and misinformation about the efficacy of opioids to treat chronic pain and the risks of addiction. Using hired guns, advertising and marketing materials, the Manufacturers promoted the fictitious concept of "pseudoaddiction," advocated that signs of 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.

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[20] 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

[21] Yin Wan, Shelby Corman, Xin Gao, Sizhu Liu, Haridarshan Patel, Reema Mody , *Economic Burden of Opioid-Induced Constipation Among Long-Term Opioid Users with Noncancer Pain*, AM HEALTH DRUG BENEFITS. 2015 Apr; 8(2): 93–102, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4437482/

15. Wholesale distributors, such as the Distributor Defendants, could have and should have been able to stem the excess flow of opioids into Virginia and Lee County, but they did not. 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 deliberately ignored these responsibilities, lobbied for higher reporting thresholds and pocketed profits at the expense of Lee County.

16. The Manufacturer and Distributer Defendants' efforts to promote their scheme to distribute unnecessary opioids were purposefully facilitated by pharmacy benefit managers ("PBMs) who ensured that opioids were paid for, reimbursed, or covered by public and private payors through their pharmacy benefit plans.

17. PBMs are the gatekeepers to the vast majority of opioid prescriptions filled in the United States. Caremark, Express Scripts, and OptumRx (all named defendants here) manage the drug benefits for approximately eighty-nine percent of the market, or 238 million lives.[22] PBMs design prescription drug benefit programs and create formularies which set the criteria and terms under which pharmaceutical drugs are reimbursed. They also determine numbers of refills permitted, number of pills per prescription, pre-authorization requirements, generic and branded drug co-pay amounts, and other criteria. PBMs thereafter commit to monitor their customers' utilization, manage drug plans and overall employee wellbeing. In these ways, PBMs tout their ability to control and manage overall prescription drug utilization.

[22] NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, *PBM Resources*, http://www.ncpanet.org/advocacy/the-tools/pbm-resources (last visited Sept. 8, 2018).

18. Because PBMs are the intermediary between drug manufacturers, pharmacies, and ultimately patients, these companies control everything from pharmacy reimbursements to what drugs are covered under formularies.[23] 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.

19. Virginia and Lee County have experienced a significant spike in opioid-related abuse and deaths in recent years. The CDC found that Virginia was one of the states with a statistically significant increase in drug overdose death rates from 2015 to 2016.[24] The CDC estimated that 1,405 people died from drug overdoses in Virginia in 2016.[25]

20. Accordingly, Plaintiff brings this action to recover damages and costs it has incurred as a result of the prescription drug abuse problem in Lee County. Plaintiff seeks to recover those costs and damages from the Defendants because they are the entities that have substantially contributed to and profited from the scourge of opioid abuse in Lee County.

21. Plaintiff also seeks an order compelling the abatement and removal of the public nuisance the Defendants have created, knew their misconduct would likely create and from which they profited, by ceasing their unlawful promotion, distribution, reimbursement and sale of opioids, as well as treble damages, punitive damages and attorneys' fees and costs in addition to granting any other equitable relief authorized by law.

II. VENUE AND JURISDICTION

[23] 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

[24] *Drug Overdose Death Data*, CENTERS FOR DISEASE CONTROL AND PREVENTION, last updated Dec. 19, 2017, https://www.cdc.gov/drugoverdose/data/statedeaths.html

[25] *Id.*

22. This Court has subject matter jurisdiction over this matter pursuant to Virginia Code § 17.1-513.

23. This Court has personal jurisdiction over Defendants pursuant to Virginia Code § 8.01-328.1 because they conduct business in Virginia, purposefully direct or directed their actions toward Virginia, caused tortious injury in Virginia, consented to be sued in Virginia by registering an agent for service of process, and/or consensually submitted to the jurisdiction of Virginia when obtaining a manufacturer or distributor license and have the requisite minimum contacts with Virginia necessary to constitutionally permit the Court to exercise jurisdiction.

24. Venue is proper in this Court pursuant to Virginia Code § 8.01-262 in that the Defendants regularly conduct substantial business activity in Lee County, Virginia and the causes of action alleged herein arose in Lee County, Virginia.

25. Defendants are regularly engaged in the business of manufacturing, marketing, distributing, dispensing and reimbursing prescription opioids in Virginia and, specifically, in Lee County, including to Lee County's own current and former employees. Defendants' activities in Lee County in connection with the manufacture, marketing, distribution, dispensation and reimbursement of prescription opioids was, and is, continuous and systematic, and gives rise to the causes of action alleged herein.

III. PARTIES

A. PLAINTIFF

26. Lee County is a political subdivision of the Commonwealth of Virginia.

27. Lee County derives its governmental powers from the laws of the Commonwealth of Virginia.

B. MANUFACTURER DEFENDANTS

28. Defendant, PURDUE PHARMA, L.P., is a limited partnership organized under the laws of Delaware. Defendant, PURDUE PHARMA, INC., is a New York corporation with its principal place of business in Stamford, Connecticut, and Defendant, THE PURDUE FREDERICK COMPANY, INC., is a Delaware corporation with its principal place of business in Stamford, Connecticut.

29. PURDUE PHARMA, L.P. may be served through its registered agent: The Prentice-Hall Corporation System, Inc., 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808. PURDUE PHARMA INC. may be served through its registered agent: The Prentice-Hall Corporation System, Inc., 80 State Street, Albany, New York 12207. THE PURDUE FREDERICK COMPANY may be served through its registered agent: The Prentice-Hall Corporation System, Inc., 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

30. PURDUE PHARMA, L.P., PURDUE PHARMA, INC., and THE PURDUE FREDERICK COMPANY, INC. are referred to collectively as "Purdue."

31. In Virginia and nationally, Purdue is 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."

32. 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).

33. 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.

34. Purdue transacts business in Virginia, targeting the Virginia market for its products, including the opioids at issue in this lawsuit. Purdue hires employees to service the Virginia market. For example, Purdue recently advertised online that it was seeking a Territory Business Manager to operate out of Bristol, Virginia, and another Territory Business Manager to operate out of Richmond South, Virginia.[26] On information and belief, Purdue also directs advertising and informational materials to impact Virginia physicians and potential users of Purdue products. Purdue possesses a Virginia out-of-state manufacturer license.

35. Purdue also benefits from reimbursements by the Virginia Medicaid program. Between 2006 and 2017, Virginia Medicaid spent over $23.8 million on Purdue's opioids. This represents approximately 18% of total Virginia Medicaid reimbursements for opioids during that time period.[27] These reimbursements represent only a fraction of the total earned by Purdue from its opioid distribution in Virginia. Plaintiff does not yet have access to the DEA ARCOS data that

[26] https://www.google.com/search?q=purdue+pharma+job+virginia&oq=purdue+pharma+job+virginia&aqs=chrome..69i57.7359j0j9&sourceid=chrome&ie=UTF-8&safe=active&ibp=htl;jobs&sa=X&ved=0ahUKEwjhv_fM_9_ZAhVDtFMKHUq2CakQiYsCCCkoAA#fpstate=tldetail&htidocid=7crc6THcWHB7I7Y_AAAAAA%3D%3D&htivrt=jobs

[27] State Medicaid Drug Utilization Data, Centers for Medicaid and CHIP Services (CMS), https://www.medicaid.gov/medicaid/ prescription-drugs/state-drug-utilization-data/index.html

will provide substantially greater transparency into Purdue's ill-gotten gains and the harm caused in Virginia through improper public and commercial opioid reimbursements.

36. Defendant, RHODES PHARMACEUTICALS, L.P. ("Rhodes") is a Delaware limited partnership owned by the Sackler family, who also own Purdue Pharma LP. The Sacklers created Rhodes in 2007, four months after Purdue pleaded guilty to federal criminal charges that it had mis-marketed OxyContin.

37. Rhodes has its principal place of business in Coventry, Rhode Island. Rhodes may be served through its registered agent: Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808.

38. Rhodes is presently among the largest producers of off-patent generic opioids in the U.S.[28] Together with Purdue, Rhodes accounted for 14.4 million opioid prescriptions in 2016, or 6% of the US Opioid market.[29]

39. Upon information and belief, Rhodes manufactures, promotes, distributes and/or sells opioids nationally, in Virginia, and in Lee County, including many controlled substances such as oxycodone, morphine sulfate, hydrocodone and hydromorphone.

40. Rhodes benefits from reimbursements by the Virginia Medicaid program. Between 2006 and 2017, Virginia Medicaid spent over $3.6 million on Rhodes' opioids. This represents approximately 3.68% of total Virginia Medicaid reimbursements for opioids during that time period.[30] These reimbursements represent only a fraction of the total earned by Rhodes from its opioid distribution in Virginia. Plaintiff does not yet have access to the DEA ARCOS data that

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

[29] *Id.*

[30] State Medicaid Drug Utilization Data, *supra* note 27.

will provide substantially greater transparency into Rhodes' ill-gotten gains and the harm caused in Virginia through improper public and commercial opioid reimbursements.

41. Defendant, ABBOTT LABORATORIES, is an Illinois corporation with its principal place of business in Abbott Park, Illinois. Defendant, ABBOTT LABORATORIES, INC., is an Illinois corporation with its principal place of business in Abbott Park, Illinois.

42. ABBOTT LABORATORIES and ABBOTT LABORATORIES, INC. are both registered to do business in Virginia and have been since at least October 4, 2013. Both may be served in Virginia through their registered agent: The Corporation Service Company, 4701 Cox Road, Suite 285, Glen Allen, Virginia.

43. Defendants ABBOTT LABORATORIES and ABBOTT LABORATORIES, INC. are referred to collectively as "Abbott."

44. Abbott was primarily engaged in the promotion and distribution of opioids nationally due to a co-promotional agreement with Defendant Purdue. Pursuant to that agreement, between 1996 and 2006, Abbott actively promoted, marketed, and distributed Purdue's opioid products as set forth above.

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

46. With Abbott's help, sales of OxyContin went from a mere $49 million in its first full year on the market to $1.6 billion in 2002. Over the life of the co-promotional agreement, Purdue paid Abbott nearly half a billion dollars.

47. Abbott transacts business in Virginia, targeting the Virginia market for its products, including the opioids at issue in this lawsuit. Abbott hires employees to service the Virginia market. For example, Abbott recently advertised online that it was seeking a Laboratory Technician for Richmond, Virginia, a Coronary Account Manager for Charlottesville, Virginia, and a Territory Representative for Alexandria, Virginia.[31] On information and belief, Abbott also directs advertising and informational materials to impact Virginia physicians and potential users of Abbott products.

48. Abbott and Purdue's conspiring with PBMs to drive opioid use is documented. As described in an October 28, 2016 article from Psychology Today entitled *America's Opioid Epidemic*:

> Abbott and Purdue actively misled prescribers about the strength and safety of the painkiller [OxyContin]. To undermine the policy of requiring prior authorization, they offered lucrative rebates to middlemen such as Merck Medco [now Express Scripts, a defendant herein] and other pharmacy benefits managers, on condition that they eased availability of the drug and lowered co-pays. The records were part of a case brought by the state of West Virginia against both drug makers alleging inappropriate and illegal marketing of the drug as a cause of widespread addiction. … One reason the documents are so troubling is that, in public at least, the drug maker was carefully assuring authorities that it was working with state authorities to curb abuse of OxyContin. Behind the scenes, however, as one Purdue official openly acknowledged, the drug maker was "working with Medco (PBM) [now defendant Express Scripts] to try to make parameters [for prescribing] less stringent.[32]

[31] https://www.google.com/search?safe=active&ei=wuSiWqjaEo3azwLA-6_oCw&q=ABBOTT+LABORATORIES+jobs+virginia&oq=ABBOTT+LABORATORIES+jobs+virginia&gs_l=psy-ab.3...64303.67196.0.67351.15.10.0.0.0.0.584.1084.5-2.2.0....0...1.1.64.psy-ab..13.2.1083...0j0i22i30k1.0.VtU5QZ7lGP0&ibp=htl;jobs&sa=X&ved=0ahUKEwj3o4W_geDZAhWFvlMKHX5GDLwQiYsCCCkoAA#fpstate=tldetail&htidocid=7MBAw2y9JNZKVNMnAAAAAA%3D%3D&htivrt=jobs

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

49. Upon information and belief, Abbott's and Purdue's practices with Medco (now Defendant Express Scripts (as defined below)), were not confined to West Virginia and has caused injury nationwide, including in Lee County.

50. Indeed, PBM giant Express Scripts appears to have played a particularly critical role in facilitating and preserving market growth for OxyContin. From at least 2003, it has maintained the brand drug OxyContin as an approved reimbursable drug on Express Scripts' formularies. Express Scripts imposed no pre-authorization requirements or quantity limits on OxyContin prescriptions until 2013 at the earliest.

51. Express Scripts also facilitated reimbursement of MS-Contin, which similarly appears not to have had pre-authorization requirements before those imposed by Medicare in 2013 and often had preferred tier placement.

52. All of the foregoing was pursuant to agreements between Purdue and Express Scripts that set forth the terms of Express Scripts services to Purdue and how it would be paid by Purdue.

53. PBM Defendant Caremark (as defined below) also facilitated OxyContin's market position throughout the relevant time period. For most, if not all, of the relevant times hereto, on information and belief, Caremark maintained OxyContin as a reimbursable drug on its formulary. Caremark imposed no pre-authorization requirements or quantity limits on OxyContin prescriptions until 2014 at the earliest. Caremark also facilitated reimbursement of MS-Contin, which similarly appears not to have had pre-authorization requirements or quantity limits on prescriptions before those imposed by Medicare in 2013.

54. The foregoing treatment of OxyContin reimbursement was pursuant to agreements between Purdue and Caremark that set forth the terms of Caremark services to Purdue and how it would be paid by Purdue.

55. PBM Defendant OptumRx (as defined below) also facilitated OxyContin and MS-Contin's market growth. At all times relevant hereto, on information and belief, both were approved drugs on OptumRx's formulary.

56. 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.

57. 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 Virginia and has been since at least October 4, 2013. Mallinckrodt LLC may be served in Virginia through its registered agent: CT Corporation System, 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060.

58. MALLINCKRODT PLC and MALLINCKRODT LLC are referred to collectively as "Mallinckrodt."

59. In Virginia and nationally, Mallinckrodt is engaged in the manufacture, promotion, and distribution of Roxicodone, oxycodone, and hydrocodone, among other drugs. Mallinckrodt transacts business in Virginia, targeting the Virginia market for its products, including the opioids at issue in this lawsuit, which Mallinckrodt has sold in Virginia. On information and belief, Mallinckrodt hires employees to service the Virginia market and also directs advertising and informational materials to impact Virginia physicians and potential users of Mallinckrodt products.

60. Mallinckrodt also benefits from reimbursements by the Virginia Medicaid program. Between 2006 and 2017, Virginia Medicaid spent over $36.1 million on Mallinckrodt's opioids. This represents approximately 32.23% of total Virginia Medicaid reimbursements for opioids

during that time period.[33] These reimbursements represent only a fraction of the total earned by Mallinckrodt from its opioid distribution in Virginia. Plaintiff does not yet have access to the DEA ARCOS data that will provide substantially greater transparency into Mallinckrodt's ill-gotten gains and the harm caused in Virginia through improper public and commercial opioid reimbursements.

61. 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 imposed no pre-authorization requirements or quantity limits on prescriptions until 2014 at the earliest.

62. Defendant, ENDO HEALTH SOLUTIONS, INC., is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. 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.

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

64. 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.

[33] State Medicaid Drug Utilization Data, *supra* note 27.

65. 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 licensed and has been licensed as a non-resident distributor with the Virginia Department of Health Professions since 2005.

66. 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, 111 Eight Avenue, 13th Floor, New York, New York 10011.

67. Par Pharmaceutical and Par Pharmaceutical Cos. are referred to collectively as "Par".

68. ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC. and Par are, at times, referred to collectively as "Endo".

69. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, throughout the United States, including Virginia. 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 Virginia.

70. 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 Virginia.

71. Endo transacts business in Virginia, targeting the Virginia market for its products, including the opioids at issue in this lawsuit. Endo hires employees to service the Virginia market. For example, Endo recently posted online that it was seeking a Specialty Sales Consultant to work out of its Richmond, Virginia location.[34] On information and belief, Endo also directs advertising and informational materials to impact Virginia physicians and potential users of Endo products.

72. Endo also benefits from reimbursements by the Virginia Medicaid program. Between 2006 and 2017, Virginia Medicaid spent over $25.5 million on Endo's opioids. This represents approximately 18% of total Virginia Medicaid reimbursements for opioids during that time period.[35] These reimbursements represent only a fraction of the total earned by Endo from its opioid distribution in Virginia. Plaintiff does not yet have access to the DEA ARCOS data that will provide substantially greater transparency into Endo's ill-gotten gains and the harm caused in Virginia through improper public and commercial opioid reimbursements.

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

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[34] https://www.google.com/search?safe=active&ei=EumiWrqUHMjBzgKl65_ICg&q=ENDO+HEALTH+SOLUTIONS,+INC.+jobs+virginia&oq=ENDO+HEALTH+SOLUTIONS,+INC.+jobs+virginia&gs_l=psy-ab.3...155352.155352.0.155764.1.1.0.0.0.0.364.364.3-1.1.0....0...1.1.64.psy-ab..0.0.0....0.Mvfb-eZuOfE&ibp=htl;jobs&sa=X&ved=0ahUKEwjm3JmQhuDZAhUKXlMKHbpJCb0QiYsCCCkoAA#fpstate=tldetail&htidocid=J6XwduKDNlT-vHtgAAAAAA%3D%3D&htivrt=jobs

[35] State Medicaid Drug Utilization Data, *supra* note 27.

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

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

76. Teva USA has a Virginia taxpayer number and may be served through its registered agent: Corporate Creations Network Inc., 3411 Silverside Road Tatnall Building, Suite 104, Wilmington, Delaware 19810. Cephalon. may be served at 41 Moores Road, Frazer, Pennsylvania 19355. Barr is registered to do business and Virginia may be served in Virginia through its registered agent: Corporate Creations Network Inc., 6802 Paragon Place Suite 410, Richmond, Virginia 23230.

77. Teva USA, Cephalon and Barr are referred to collectively as "Teva"

78. Teva manufactures, promotes, distributes and sells both brand name and generic versions of opioids nationally, and in Lee County, 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.

79. Teva transacts business in Virginia, targeting the Virginia market for its products, including the opioids at issue in this lawsuit. Barr hires employees to service the Virginia market, and operates a manufacturing plant in Lynchburg, Virginia. On information and belief, Teva also directs advertising and informational materials to impact Virginia physicians and potential users of their products.

80. Teva also benefits from reimbursements by the Virginia Medicaid program. Between 2006 and 2017, Virginia Medicaid spent over $1.6 million on Teva's opioids. This represents approximately 1.3% of total Virginia Medicaid reimbursements for opioids during that

time period.[36] These reimbursements represent only a fraction of the total earned by Teva from its opioid distribution in Virginia. Plaintiff does not yet have access to the DEA ARCOS data that will provide substantially greater transparency into Teva's ill-gotten gains, and the harm caused in Virginia through improper public and commercial opioid reimbursements.

81. 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.

82. Each PBM defendant included Teva's generic opioids on their formularies as approved drugs. OptumRx did not impose any quantity limits or pre-authorization requirements for the generic Teva OxyContin.

83. Defendant, JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with is principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICALS, INC. was formerly known as ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., which in turn was formerly known as JANSSEN PHARMACEUTICA, INC.

84. 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.

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

[36] State Medicaid Drug Utilization Data, *supra* note 27.

86. JANSSEN PHARMACEUTICALS, INC. may be served at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

87. JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC, and JANSSEN PHARMACEUTICA, INC. are collectively referred to as "Janssen."

88. Janssen is or has been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in Lee County, including the following: (a) Duragesic, (b) Nucynta and (c) Nucynta ER. 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.

89. Janssen transacts business in Virginia, targeting the Virginia market for its products, including the opioids at issue in this lawsuit. Janssen hires employees to service the Virginia market. For example, Janssen recently advertised online that it was seeking a District Manager to operate out of Arlington, Virginia.[37] On information and belief, Janssen also direct advertising and informational materials to impact Virginia physicians and potential users of their products.

90. Janssen also benefits from reimbursements by the Virginia Medicaid program. Between 2006 and 2017, Virginia Medicaid spent over $5.1 million on Janssen's opioids. This represents approximately 3.8% of total Virginia Medicaid reimbursements for opioids during that time period.[38] These reimbursements represent only a fraction of the total earned by Janssen from its opioid distribution in Virginia. Plaintiff does not yet have access to the DEA ARCOS data that

[37] https://www.google.com/search?safe=active&ei=KeuiWtb-D4mxzwKTg6CoCw&q=janssen+jobs+virginia&oq=janssen+jobs+virginia&gs_l=psy-ab.3...23190.24380.0.25837.7.7.0.0.0.0.511.948.0j1j1j5-1.3.0....0...1.1.64.psy-ab..5.1.242...0i7i30k1j0i8i7i30k1.0.Z9oevDVYbek&ibp=htl;jobs&sa=X&ved=0ahUKEwjKo5GxieDZAhWOtlMKHbslD8wQiYsCCCkoAA#fpstate=tldetail&htidocid=kZ61d5_IbdmdWVOxAAAAAA%3D%3D&htivrt=jobs

[38] State Medicaid Drug Utilization Data, *supra* note 27.

will provide substantially greater transparency into Janssen's ill-gotten gains and the harm caused in Virginia through improper public and commercial opioid reimbursements.

91. 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.

92. 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.

93. PBM Defendant Caremark also has listed Duragesic and Nucynta products as approved brands on its formularies without prior authorization requirements.

94. Defendant, WATSON LABORATORIES, INC., is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of Defendant, ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.), a public limited company incorporated under the laws of the State of Ireland with its headquarters and principal place of business in Dublin, Ireland.

95. 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.

96. Defendant, ACTAVIS, LLC, is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

97. Each of these defendants is owned by Defendant, ALLERGAN PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, ALLERGAN

PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit.

98. WATSON LABORATORIES, INC. may be served through its registered agent: Corporate Creations Network Inc., 8275 South Eastern Avenue, #200, Las Vegas, Nevada 89123. ACTAVIS, LLC may be served through its registered agent: Corporate Creations Network Inc., 3411 Silverside Road Tatnall Building, Suite 104, Wilmington, Delaware 19810. ACTAVIS PHARMA, INC. is registered to do business in Virginia may be served in Virginia through its registered agent: Corporate Creations Network Inc., 6802 Paragon Place #410, Richmond, Virginia 23230.

99. ALLERGAN PLC, ACTAVIS LLC, ACTAVIS PHARMA, INC., and WATSON LABORATORIES, INC. are collectively referred to as "Actavis."

100. Actavis manufactures, promotes, sells and distributes opioids, including the branded drugs Kadian and Norco, and generic versions of Duragesic and Opana throughout the United States, including Virginia, and in Lee County. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008 and began marketing Kadian in 2009.

101. Actavis transacts business in Virginia, targeting the Virginia market for its products, including the opioids at issue in this lawsuit. Actavis hires employees to service the Virginia market. For example, Actavis recently advertised online that it was seeking a Pharmaceutical Sales Representative to operate out of Manassas, Virginia. Actavis also direct advertising and informational materials to impact Virginia physicians and potential users of their products.

102. Actavis also benefits from reimbursements by the Virginia Medicaid program. Between 2006 and 2017, Virginia Medicaid spent over $8.5 million on Actavis' opioids. This

represents 9.04% of total Virginia Medicaid reimbursements for opioids during that time period.[39] These reimbursements represent only a fraction of the total earned by Actavis from its opioid distribution in Virginia. Plaintiff does not yet have access to the DEA ARCOS data that will provide substantially greater transparency into Actavis' ill-gotten gains and the harm caused in Virginia through improper public and commercial opioid reimbursements.

103. At all times relevant hereto, the PBM Defendants listed Actavis's opioid products as approved reimbursable drugs on their formularies, often without any quantity limits or pre-authorization requirements; often in preferred tiers.

104. Defendant, INSYS THERAPEUTICS, INC. ("Insys"), is a Delaware corporation with its headquarters and principal place of business in Chandler, Arizona. Insys may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

105. Insys manufactures, promotes, distributes and sells prescription opioids such as Subsys. These opioids are manufactured in the United States and promoted, distributed, and sold across the United States— including in Virginia and Lee County.

106. Insys transacts business in Virginia, targeting the Virginia market for its products, including the opioids at issue in this lawsuit, which it has sold in Virginia. On information and belief, Insys hires employees to service the Virginia market, and also directs advertising and informational materials to impact Virginia physicians and potential users of their products.

107. 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.

[39] State Medicaid Drug Utilization Data, *supra* note 27.

108. KVK-Tech is currently licensed as an out-of-state manufacturer/distributor with the Virginia Department of Health Professions. Upon information and belief, KVK-Tech manufactures, promotes, distributes and/or sells opioids nationally, in Virginia, and in Lee County, including many controlled substances such as oxymorphone and oxycodone.

109. KVK-Tech also benefits from reimbursements by the Virginia Medicaid program. Between 2006 and 2017, Virginia Medicaid spent over $3.7 million on KVK-Tech's opioids. This represents approximately 3.84% of total Virginia reimbursements for opioids during that time period.[40] These reimbursements represent only a fraction of the total earned by KVK-Tech from its opioid distribution in Virginia. Plaintiff does not yet have access to the DEA ARCOS data that will provide substantially greater transparency into KVK Tech's ill-gotten gains and the harm caused in Virginia through improper public and commercial opioid reimbursements.

110. Defendant, AMNEAL PHARMACEUTICALS LLC, is a Delaware limited liability company with its principal place of business in Bridgewater, New Jersey. AMNEAL PHARMACEUTICALS LLC was registered to do business in Virginia until 2017 and is currently licensed as a non-resident wholesale distributor with the Virginia Department of Health Professions. AMNEAL PHARMACEUTICALS LLC may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

111. Defendant, IMPAX LABORATORIES, LLC., formerly known as Impax Laboratories, Inc., is a Delaware limited liability company with its principle place of business in Bridgewater, New Jersey. IMPAX LABORATORIES, LLC. may be served through its registered agent: Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808.

[40] State Medicaid Drug Utilization Data, *supra* note 27.

112. 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.

113. 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 was registered to do business in Virginia until 2017 and is currently licensed as a non-resident wholesale distributor with the Virginia Department of Health Professions. 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.

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

115. Upon information and belief, Amneal manufactures, promotes, distributes and/or sells opioids nationally, in Virginia, and in Lee County, including many controlled substances such as oxycodone, oxymorphone, hydrocodone, tramadol, morphine and codeine.

116. Amneal also benefits from reimbursements by the Virginia Medicaid program. Between 2006 and 2017, Virginia Medicaid spent over $7.9 million on Amneal's opioids. This represents approximately 1.36% of total Virginia reimbursements for opioids during that time

period.[41] These reimbursements represent only a fraction of the total earned by Amneal from its opioid distribution in Virginia. Plaintiff does not yet have access to the DEA ARCOS data that will provide substantially greater transparency into Amneal's ill-gotten gains and the harm caused in Virginia through improper public and commercial opioid reimbursements.

117. Defendant, MYLAN PHARMACEUTICALS, INC. ("Mylan"), is a West Virginia corporation with its principal place of business in Canonsburg, Pennsylvania. Mylan is and has been registered to do business in Virginia since 2010 and may be served in Virginia through its registered agent: Corporation Service Company, 100 Shockoe Slip, 2nd Floor, Richmond, Virginia 23219.

118. Mylan is currently licensed as an out-of-state manufacturer/distributor with the Virginia Department of Health Professions. Upon information and belief, Mylan manufactures, promotes, distributes and/or sells opioids nationally, in Virginia, and in Lee County, including many controlled substances such as fentanyl, methadone, oxycodone, hydrocodone, morphine and tramadol.

119. Mylan also benefits from reimbursements by the Virginia Medicaid program. Between 2006 and 2017, Virginia Medicaid spent over $4.5 million on Mylan's opioids. This represents approximately 3.4% of total Virginia reimbursements for opioids during that time period.[42] These reimbursements represent only a fraction of the total earned by Mylan from its opioid distribution in Virginia. Plaintiff does not yet have access to the DEA ARCOS data that will provide substantially greater transparency into Mylan's ill-gotten gains and the harm caused in Virginia through improper public and commercial opioid reimbursements.

[41] State Medicaid Drug Utilization Data, *supra* note 27.

[42] State Medicaid Drug Utilization Data, *supra* note 27.

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

121. 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 Virginia and in Lee County, 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 Lee County.

C. DISTRIBUTOR DEFENDANTS

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

123. McKesson has been registered to do business in Virginia since at least January 1, 2018 and does substantial business in Virginia. McKesson has a Virginia taxpayer number and may be served in Virginia through its registered agent: Corporation Service Company, 100 Shockoe Slip, 2nd Floor, Richmond, Virginia 23219.

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

125. Upon information and belief, McKesson is one of the largest distributors of opioid pain medications in the country, including Virginia. In 2015, McKesson had a net income in excess

of $1.5 billion. McKesson also has a local warehouse that it operates out of Ruther Glen, Virginia, which distributes pharmaceutical drugs including opioids in and around the Virginia.

126. 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."[43]

127. 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."[44]

128. McKesson hires employees to service the Virginia market. For example, McKesson recently advertised online that it was seeking a Delivery Driver to operate out of Chesapeake, Virginia, a Senior Accountant to operate out of Richmond, Virginia, and a Client Service Rep to operate out of Richmond, Virginia.

129. Defendant MCKESSON MEDICAL-SURGICAL INC. ("McKesson Medical-Surgical") is a Virginia corporation with its principal place of business in Richmond, Virginia.

130. McKesson Medical-Surgical has been registered to do business in Virginia since at least January 1, 2018 and does substantial business in Virginia. McKesson Medical-Surgical may be served in Virginia through its registered agent: Corporation Service Company, 100 Shockoe Slip, 2nd Floor, Richmond, Virginia 23219.

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[43] McKesson 2017 Annual Report found at https://investor.mckesson.com/sites/mckesson.investorhq.businesswire.com/files/report/file/2017_McKesson_Annual_Report_0.pdf

[44] *Id.*

131. McKesson Medical-Surgical engages in business in Virginia as a wholesale distributor of pharmaceuticals, including opioids.

132. 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 Virginia.

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

134. Cardinal, through its many subsidiaries, including Cardinal Health Care Services, Inc., possesses out-of-state pharmaceutical distribution licenses in Virginia, has been registered to do business in Virginia since at least October 4, 2013 and may be served in Virginia through its registered agent: CT Corporation System, 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060.

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

136. Defendant AMERISOURCEBERGEN DRUG CORPORATION ("Amerisource") is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. Amerisource distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including Virginia.

137. Amerisource has been registered to do business in Virginia since at least October 4, 2013 and may be served in Virginia through its registered agent: CT Corporation System, 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060. Amerisource also has a local warehouse that it operates out of Glen Allen, Virginia, which distributes pharmaceutical drugs including opioids in and around the Virginia.

138. 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."[45]

139. Amerisource hires employees to service the Virginia market. For example, Amerisource recently advertised online that it was seeking a Warehouse Associate I for the Night Shift to operate out of Glen Allen, Virginia, a Warehouse Associate II for the Day Shift to operate out of Glen Allen, Virginia, and a Dispatcher/Operations to operate out of Herndon, Virginia.

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

141. Defendant HENRY SCHEIN, INC. is a Delaware corporation with its principal place of business in Melville, New York. HENRY SCHEIN, INC. has been registered to do business in Virginia since 1997, and at all relevant times, it conducted business as a licensed prescription drug distributor in Virginia. HENRY SCHEIN, INC. may be served in Virginia through its registered agent: Corporation Service Company, 100 Shockoe Slip, 2nd Floor, Richmond, Virginia 23219.

142. Defendant GENERAL INJECTABLES & VACCINES, INC. ("GIV") is a Virginia corporation with its principal place of business in Bastian, Virginia. In 1998, HENRY SCHEIN, INC. acquired GIV for an estimated $65 million dollars.[46] At all relevant times, GIV conducted business as a licensed prescription drug distributor in Virginia. GIV may be served in Virginia through its registered agent: Corporation Service Company, 100 Shockoe Slip, 2nd Floor, Richmond, Virginia 23219.

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

[46] HENRY SCHEIN, *Henry Schein, Inc. Acquires Leading Independent U.S. Vaccine Supplier - 1998 Sales of $118 Million,* Dec. 29, 1998, http://investor.henryschein.com/phoenix.zhtml?c=74322&p=irol-newsArticle&ID=53636

143. Defendant INSOURCE, INC. ("Insource") is a Virginia corporation with its principal place of business at the same location as GIV in Bastian, Virginia. HENRY SCHEIN, INC. is the direct parent company of Insource, and, according to the Virginia State Corporation Commission, Insource, Inc. is also an assumed name used by GIV. At all relevant times, Insource conducted business as a licensed prescription drug distributor in Virginia. Insource may be served in Virginia through its registered agent: Corporation Service Company, 100 Shockoe Slip, 2nd Floor, Richmond, Virginia 23219.

144. HENRY SCHEIN, INC., GIV, AND INSOURCE are collectively referred to as "Henry Schein."

145. Henry Schein distributes, among other things, branded and generic pharmaceuticals to customers that include dental practitioners, dental laboratories, animal health practices and clinics, and office-based medical practitioners, ambulatory surgery centers, and other institutions. At all relevant times, Henry Schein was in the business of distributing, and redistributing, pharmaceutical products, including opioids, to consumers within Virginia.

146. In November of 2014, Henry Schein and Cardinal Health entered into a strategic partnership, which consolidated Cardinal Health's physician office-sales organization into Henry Schein's subsidiary Henry Schein Medical. Henry Schein took responsibility for serving physician offices, and through its contract with Cardinal Health, gained access to over 25,000 physical offices as customer locations.[47] As a result of this agreement, Henry Schein Medical added more than $300 million in annual sales.

147. In 2015, Henry Schein reported that its sales reached a record $10.4 billion and that it had grown at a compound annual rate of approximately sixteen percent (16%) since becoming a

[47] Raymond Davis, *Henry Schein and Cardinal*, THE J. OF HEALTHCARE CONTRACTING, Feb. 12, 2018, http://www.jhconline.com/henry-schein-and-cardinal.html

public company in 1995. Overall, it is the world's largest provider of health care products and services to office-based dental, animal health, and medical practitioners.

148. 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.

149. 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 Virginia since at least 1996 and may be served in Virginia through its registered agent: CT Corporation System, 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060.

150. Defendant CVS TN DISTRIBUTION, L.L.C. ("CVS TN") is Tennessee limited liability company whose principal place of business is at the same location as CVS Health and CVS Pharmacy. On information and belief, CVS Pharmacy is the sole member of CVS TN. CVS TN may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919.

151. Upon information and belief, CVS Health, CVS Pharmacy and CVS TN distribute pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including Virginia. At all relevant times, CVS TN conducted business as a licensed prescription drug distributor in Virginia.

152. 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.

153. 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. has been registered to do business in Virginia since 1995 and may be served in Virginia through its registered agent: Corporation Service Company, 100 Shockoe Slip, 2nd Floor, Richmond, Virginia 23219. Walgreens Boots and WALGREEN CO. are collectively referred to as "Walgreens."

154. Upon information and belief, Walgreens distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including Virginia. Walgreens is currently licensed as a non-resident distributor with the Virginia Department of Health Professions.

155. 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."

156. The Distributor Defendants purchased opioids from manufacturers, such as the Manufacturer Defendants herein, and sold them to pharmacies throughout Virginia, including in Lee County. The Distributor Defendants played an integral role in opioids being distributed across Virginia, including Lee County.

157. 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 Lee County.

D. PHARMACY BENEFIT MANAGER DEFENDANTS

158. 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 morphine milligram equivalents ("MMEs") 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 administrative fees and volume bonuses, and fees from maintaining pharmacy networks.[48]

159. 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.

160. 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. 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

[48] 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/do/10.1377/hpb20171409.000178/full/

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 RX, L.L.C. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange, Street, Wilmington, Delaware 19801.

161. 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 Virginia and may be served in Virginia through its registered agent: CT Corporation System, 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060.

162. 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, CAREMARK RX, L.L.C. is the sole member of CAREMARK, L.L.C. CAREMARK, L.L.C. is registered to do business in Virginia and may be served by its registered agent: CT Corporation System, 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060.

163. Defendants CAREMARK RX, L.L.C., CAREMARKPCS HEALTH, L.L.C., and CAREMARK, L.L.C. are collectively referred to as "Caremark."

164. 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.

165. 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.

166. 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.[49]

167. 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.[50]

168. At all times relevant hereto, CVS Health, through Caremark, derives substantial revenue providing pharmacy benefits in Virginia through several different means including, but

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[49] *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

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

not limited to, providing services and its formulary to the Piedmont Community Health Plan[51], the Fairfax County Public Schools,[52] and the University of Virginia Health Plan.[53]

169. 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 nationwide, including in Lee County. 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 Virginia, including in Lee County.

170. Defendant, EXPRESS SCRIPTS HOLDING COMPANY ("ESHC"), is a Delaware corporation with its principal place of business in St. Louis, Missouri. ESHC may be served through its registered agent: Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808.

171. 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 Virginia since at least 1987 and has an active license with the Virginia Department of Health Professions (the original of which was applied for in 1991). ESI may be served in Virginia through its registered agent: The Corporation Service Company, 100 Shockoe Slip, 2nd Floor, Richmond, Virginia 23219.

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[51] Piedmont Community Health Plan, Prescription Drugs, https://www.pchp.net/index.php/group-coverage-providers/provider-prescription-drugs.html

[52] Fairfax County Public Schools, Prescription Benefits, https://www.fcps.edu/node/32873

[53] University of Virginia Health Plan, Important Guidelines, 2010, http://www.hr.virginia.edu/uploads/documents/media/UVA_Health_ImportantGuidelines2010.pdf

172. ESHC and ESI are collectively referred to as "Express Scripts".

173. 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, filing a combined 1.4 billion prescriptions for employers and insurers.[54] 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.

174. 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.[55]

175. 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."[56]

176. 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."[57] 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*."[58] Express Scripts "re-

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[54] 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

[55] *Cigna-Express Scripts: Vertical Integration and PBMs' Medical-Pharmacy Future*, *supra* note 49.

[56] 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-formular y-2018/, at 1.

[57] Express Scripts, *Express Scripts 2017 Annual Report*, https://expressscriptsholdingco.gcs-web.com/static-files/76a9c03e-2e6b-4f6b-80de-fe80d 4ebc826, at 11.

[58] *Id.*

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."[59]

177. Express Scripts derives substantial revenue managing pharmacy benefits in Virginia through several different means, including, but not limited to, providing services and its formulary to (i) the Express Scripts Medicare for the Commonwealth of Virginia Retiree Health Benefits Program[60], (ii) the Virginia Private Colleges Benefits Consortium, which covers as many as 7,000 lives[61], and (iii) workers' compensation insurance programs in Virginia such as the Virginia Association of Counties Group Self-Insurance Risk Pool ("VACORP").[62] Upon information and belief, these are some of the many ways in which Express Scripts reimburses for claims in Lee County, including opioids.

178. Express Scripts publishes employment vacancies related to its Virginia PBM business activities on its website.[63]

179. 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 Lee County.

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

[60] The Virginia Private Colleges Benefits Consortium, http://www.cicv.org/Benefits-Consortium.aspx

[61] State Retiree Health Benefits Program—Fact Sheet #8A, Prescription Drugs—Medicare—Eligible Participants. https://www.dhrm.virginia.gov/docs/default-source/benefitsdocuments/ohb/factsheets/sheet-8aA894A6CA3857.pdf?sfvrsn=0

[62] VACORP, Understanding the Virginia Workers' Compensation Claims Process, 2016, http://www.vacorp.org/wp-content/uploads/2016/02/Workers-Compensation-VACORP.pdf

[63] Express Scripts employment listings in Virginia, e.g., (i) Infusion Nurse RN – Accredo, Richmond, Virginia (https://www.indeed.com/viewjob?jk=f5ccf1a9c43b2c03&tk=1c85ulcckafthav0&from=serp&vjs=3); (ii) Infusion Nurse RN Per Diem - Accredo. Roanoke, Virginia (https://www.indeed.com/viewjob?jk=7d1b16bc59d5d0d0&tk=1c85ulcckafthav0&from=serp&vjs=3); and (iii) Infusion Nurse RN – Accredo, Ashburn, Virginia (https://www.glassdoor.com/job-listing/infusion-nurse-rn-accredo-express-scripts-JV_IC1130338_KO0,25_KE26,41.htm?jl=2627435077&ctt=1520618868067)

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 Virginia, including in Lee County.

180. 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.

181. On information and belief, UnitedHealth is the parent company of UnitedHealthcare of the Mid-Atlantic, Inc., UnitedHealthcare of Wisconsin, Inc. and UnitedHealthcare Plan of the River Valley, Inc. (collectively "UHC Subs"). All of the UHC Subs are registered to do business in Virginia, are licensed with the Virginia State Corporation Commission's Bureau of Insurance and may be served in Virginia through their registered agent: CT Corporation System, 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060.

182. 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.

183. Defendant, OPTUMRX, INC. ("OptumRx"), is a California 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 operates as the PBM for UnitedHealth.

184. UnitedHealth and OPTUM, INC. may be served through their registered agent: CT Corporation System, Inc., 1010 Dale Street North, St. Paul, Minnesota 5517.

185. OptumRx has been registered to do business in Virginia since at least 2008 and may be served in Virginia through its registered agent: CT Corporation System, 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060.

186. 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.[64]

187. 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."[65]

188. "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."[66]

189. At all times relevant hereto, OptumRx derived substantial revenue providing pharmacy benefits in Virginia through several different means, including, but not limited to, providing services and formulary management for (i) the Eastern Virginia Medical School,[67] and

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[64] *Cigna-Express Scripts: Vertical Integration and PBMs' Medical-Pharmacy Future*, *supra* note 49.

[65] 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

[66] *Id.*

[67] Eastern Virginia Medical School, Student Wellness Program, 2017, http://www.evms.edu/about_evms/administrative_offices/human_resources/student_health_insurance/; Eastern Virginia Medical School,

(ii) the Washington Metropolitan Area Transit Authority (WMATA) Employee Health and Welfare Plan[68] and Prescription Drug Benefits.[69]

190. 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 Lee County. 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 Virginia, including in Lee County.

191. 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.

E. DOE DEFENDANTS

192. 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

Student Injury and Sickness Insurance Plan, 2014-2015, https://www.uhcsr.com/uhcsrBrochures/Public/ClientBrochures/2014-193-1_Brochure.pdf

[68] Washington Metropolitan Area Transit Authority ("WMATA") Transit Employees' Health and Welfare Plan, Plan Benefit Overview, http://www.tehw.org/plan-benefits/plan-benefit-overview.aspx

[69] Washington Metropolitan Area Transit Authority ("WMATA") Transit Employees' Health and Welfare Plan, Prescription Drug Benefits, http://www.tehw.org/plan-benefits/health-and-welfare-benefits/prescription-drug-benefits.aspx

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

193. 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.[70]

194. Prior to the 1990's, doctors prescribed opioid pain relievers sparingly, and only for short term use, for cases of acute injury or illness, during surgery or end-of-life ("palliative") care.[71] Doctors' reluctance to use opioids for an extended period of time was due to the legitimate fear of causing addiction.[72]

195. 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 and

[70] 21 U.S.C. § 812 Schedule II (2012).

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

[72] *Id.*

regularly prescribed and reimbursed, while failing in their obligation to monitor inappropriate drug utilization.

196. 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 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 VIRGINIA AND LEE COUNTY

197. While the Defendants have profited from the alarming rate of opioids used in the United States, communities across the country, especially those in lower-income areas, 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.[73] Aggregate costs for prescription opioid overdose, abuse, and dependence were estimated at over $78.5 billion (in 2013 dollars).[74]

198. 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 Lee County and deal with its fallout.

199. 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, first responders such as emergency medical services, detention

[73] Wolters Kluwer Health, *Costs of US prescription opioid epidemic estimated at $78.5 billion*, SCIENCE DAILY, Sept. 14, 2016, https://www.sciencedaily.com/releases/2016/09/160914105756.htm

[74] *Id.*

centers and jails, courts, prevention and treatment centers, community outreach programs, equipment and supplies, victim services supports, drug abuse prevention programs, inmate services including housing, health and support staff, intervention programs, foster care and child placement services, together with general societal costs, and lost productivity costs.

200. According to the CDC, in Virginia there were 1,405 drug overdose deaths in 2016, with opioids being the main driver, a 34.7 percent increase over drug overdose deaths in 2015.[75]

201. The CDC in 2012 reported that there were between 72 and 82.1 painkiller prescriptions per 100 people in Virginia.[76]

202. The CDC reports that Lee County's mortality rates due to drug poisoning rose drastically in the seventeen-year period between 1999 and 2016.[77] These drug-related deaths grew steadily from an 8-9.9 death per 100,000 population in 1999 to 28-29.9 in 2016.[78] During the same period (1999-2016) the population increased slightly, from 23,662 in 1999 to 24,179 in 2016.

203. Data reveals a dramatic increase in opioid abuse and deaths in recent years. The Virginia Department of Health numbers estimates the 1,136 overdose deaths from prescription painkillers, heroin, and heroin synthetics statewide in 2016 was 40 percent higher than the 811 deaths from the same cause in 2015.[79] In just the first nine months of 2016, the state recorded 822

[75] CDC Drug Overdose Data, https://www.cdc.gov/drugoverdose/data/statedeaths.html

[76] German Lopez, *The growing number of lawsuits against opioid companies, explained*, VOX, Feb. 27, 2018, https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-companies-epidemic-lawsuits

[77] Centers for Disease Control and Prevention Drug Poisoning Mortality Rates in the United States, 1999-2016, https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality/

[78] *Id.*

[79] AG Mark Herring announces policy proposals on heroin and opioid abuse, *DAILY PRESS*, September 18, 2017, http://www.dailypress.com/health/dp-nws-herring-heroin-20170918-story.html

opioid overdose deaths compared to 811 in all of 2015.[80] There was a 77% increase in fatal opioid overdoses in the five years from 2011-2016.[81] "[T]he [statewide] numbers are so big they almost don't seem real," declared Attorney General Mark Herring in 2017, "[w]e have too many empty bedrooms, too many empty chairs at kitchen tables."[82]

204. There are several factors that point to the severity of the opioid crisis in Virginia. A recent Virginia Commonwealth University study found that "[a]t least two Virginians die from prescription opioid and heroin overdoses every day."[83] The state estimates that its Medicaid program spent $26 million on opioid use and misuse in 2013.[84] The number of babies in Virginia born with neonatal abstinence syndrome (NAS), resulting from opioids being used during pregnancy, has continued to rise with the NAS birth rate doubling from 2.9 per 1,000 live births in 2011 to 6.1 per 1,000 live births in 2015.[85] In 2016, state health officials found that more than 770 Virginia newborns, out of nearly 96,000 live births, were diagnosed with NAS.[86] The number

[80] Katie Demeria, Va. board creates new opioid prescription guidelines, RICHMOND TIMES-DISPATCH, Feb. 20, 2017, http://www.richmond.com/life/health/va-board-creates-new-opioid-prescription-guidelines/article_34ceace4-24f7-5125-9445-680f6f7bede4.html

[81] Dr. Melissa Levine, State Health Commissioner Telebriefing on Opioid Addiction Public Health Emergency (Nov. 21, 2016) (transcript available at http://www.vdh.virginia.gov/commissioner/opioid-addiction-in-virginia/).

[82] Patricia Sullivan, *Va. attorney general urges collaboration in battling opioid crisis*, THE WASHINGTON POST, May 26, 2017, https://www.washingtonpost.com/local/virginia-news/va-attorney-general-urges-collaboration-in-battling-opioid-crisis/2017/05/24/2c1ca6b2-3fcc-11e7-9869-bac8b446820a_story.html?utm_term=.a760b4a4fa85

[83] Andrew Barnes and Katherine Neuhausen, *The Opioid Crisis Among Virginia Medicaid Beneficiaries*, VIRGINIA COMMONWEALTH UNIVERSITY SCHOOL OF MEDICINE, https://hbp.vcu.edu/media/hbp/policybriefs/pdfs/Senate_OpioidCrisisPolicyBrief_Final.pdf

[84] *Id.*

[85] Virginia Neonatal Perinatal Collaborative Receives State Support For Pregnant Women With Substance Use Disorders, Infants With Neonatal Abstinence Syndrome, June 28, 2017, http://www.alexandrianews.org/2017/06/new-virginia-neonatal-perinatal-collaborative-committed-to-improving-birth-outcomes-receives-state-support-to-enhance-care-for-pregnant-women-with-substance-use-disorders-and-infants-with-neonatal-ab/

[86] *Id.*

of infants diagnosed with NAS quadrupled from 2012-2016.[87] In Lee County, the problem is even more severe, with the NAS rate far exceeding the statewide rate every year since at least 2011.[88]

205. Like other Virginia localities, Lee County has also had to allocate resources to preventing and addressing opioid abuse by children and teenagers. A study of child overdose deaths in Virginia between 2009 and 2013 found that "[n]early two-thirds of child overdose victims were teenagers between the ages of 13 and 17."[89] Prescription medications, specifically methadone and oxycodone, "caused or contributed to more child deaths than any other substance (68%)."

206. With the increase in prescription opioid abuse, Virginia localities such as Lee County have seen a rise in illegal drug use, including the use of heroin and illegally obtained fentanyl, as well as an increase in drug-related arrests.

207. As a result of the increase in opioid-related criminal activity, Lee County's correctional and incarceration costs have been exceedingly high over the last five years. The opioid epidemic has not only impacted Lee County's law enforcement and correctional costs. It has also had a startling impact on other costs. For example, the influx of opioids into Lee County has led to a startling rise in the need for foster care and other child placement services in the County. Between 2013 and 2016, the annual cost of providing foster care and related child-placement services in Lee County increased 84% and has remained nearly constant through 2018.[90]

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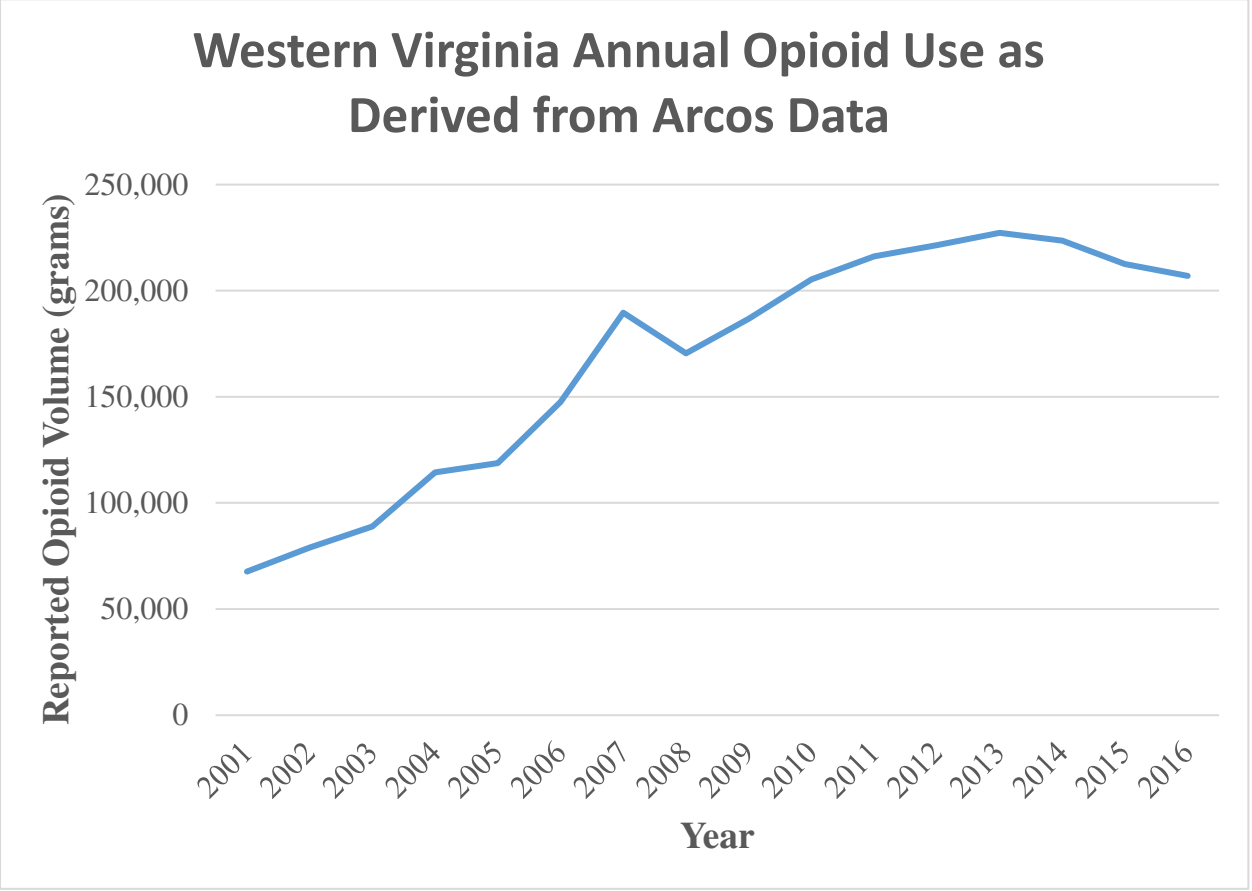
[87] *Id.*

[88] VIRGINIA DEPARTMENT OF HEALTH, VIRGINIA OPIOID ADDICTION INDICATORS (2016), https://public.tableau.com/views/VirginiaOpioidAddictionIndicators/VAOpioidAddictionIndicators?:embed=y&:display_count=yes&:showVizHome=no

[89] *Id.*

[90] Virginia Office of Children's Services, *CSA Utilization Reports*, available at: http://csa.virginia.gov/OCSReports/Reports/DatasetReports.aspx

208. Retail drug summary reports publicly available through the DEA's Automation of Reports and Consolidated Orders System ("ARCOS") confirm that the western edge of Virginia, which includes Lee County, has experienced the same startling trend of soaring opioid use as is seen nationwide. The ARCOS Data table below reflects transactional data for selected opioid drugs submitted by the drug manufacturers and distributors doing business in Virginia. The volume of selected opioid drugs distributed in the western edge of Virginia between 2001 and 2016 reflects a startling increase of over 300% in annual opioid consumption during that period.[91]



[91] The ARCOS transactional data reflected in this chart includes the following drugs categorized as opioids: codeine, buprenorphine, dihydrocodeine, oxycodone, hydromorphone, hydrocodone, levorphanol, meperidine (pethidine), methadone, morphine, opium (powdered), oxymorphone, alfentanil, remifentanil, sufentanil base, tapentadol, and fentanyl base. The ARCOS transaction data reflected in this chart includes the following regions of Virginia: Washington County, Dickenson County, City of Bristol, Lee County, City of Norton, Russell County, Scott County, Buchanan County, Scott County, Grayson County, and Wise County.

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

i. THE MANUFACTURER DEFENDANTS' CAMPAIGN OF DECEPTION

a. THE MANUFACTURER DEFENDANTS' CAMPAIGN TO NORMALIZE WIDESPREAD OPIOID USE

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

210. 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); Endo's Opana and Opana ER (2006); and Insys' Subsys (2012).

211. 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.

212. 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.

213. 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 Actavis. These amount to twice as much as Defendants spent on detailing in 2000.

214. 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.

215. The Manufacturer Defendants' misinformation campaign worked as intended. Across the country, demand for prescription opioids exploded, including in Lee County. 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

(1) DR. PORTENOY AND WEBSTER

216. 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.[92]

217. 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, salutary and more humane alternative … in those patients with intractable non-malignant pain and no history of drug abuse."[93] Portenoy's study also cited Jick's one-paragraph letter to the New England Journal of Medicine.

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[92] *Addiction rare in patients treated with narcotics*, 302(2) NEW ENG. J. MED. 123 (Jan. 10, 1980).

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

218. 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."[94]

219. 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.

220. 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.

221. 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.

222. 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.

223. 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 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 related 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.

[94] Meier B., Pain Killer: A Wonder Drug's Trail of Addiction and Death, New York, NY: St. Martin's Press; 2003.

224. 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).

225. 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.

226. 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."[95]

> 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 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

[95] Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, THE WALL STREET JOURNAL (Dec. 17, 2012).

> to think about how the growth in that prescribing driven by people like me led, in part, to that occurring.[96]

227. 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."[97]

228. 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."[98] "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."[99]

(2) DEFENDANT-FUNDED ORGANIZATIONS

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

(A) THE AMERICAN PAIN FOUNDATION

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

[97] 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

[98] 376 New Eng. J. Med. 2194, 2194–95 (2017).

[99] *Id.*

230. 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.

231. 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 Virginia consumers, physicians, patients, and third-party payers.

232. 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.

233. 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.

234. 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."

235. 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."[100]

(B) THE AMERICAN ACADEMY OF PAIN MEDICINE

236. The American Academy of Pain Medicine ("AAPM"), with the assistance, prompting, involvement, and funding of the Manufacturer Defendants, issued treatment guidelines and sponsored and hosted CME programs for doctors essential to the Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

[100] 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

237. 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 Actavis were members of the council.

238. 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.

239. 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."[101]

240. 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.

(C) THE PAIN CARE FORUM

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

[101] 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

242. 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.

243. 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.

244. 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 Lee County.

c. THE MANUFACTURER DEFENDANTS' FALSE AND MISLEADING DIRECT ADVERTISING AND MARKETING OF OPIOIDS

245. The Manufacturer Defendants have intentionally made false and misleading statements regarding opioids in their advertising and marketing materials disseminated

nationwide, including in Lee County. 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 are tamper- or crush-resistant and harder to abuse or misuse.

246. 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.

247. 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.

248. 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.

249. Actavis 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."[102]

250. 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

251. For example:

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

(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.[103]

(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 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

[102] 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

[103] Available at https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf

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."[104]

(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.[105]

(h) Consistent with the Manufacturer Defendants' published marketing materials, upon information and belief, detailers for the Manufacturer Defendants in Virginia have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in Virginia 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.

(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,[106] and concluded that Purdue's

[104] Available at, http://www.prescriberesponsibly.com/articles/opioid-pain-management

[105] Available at, http://s3.documentcloud.org/documents/277603/apf-policymakers- guide.pdf

[106] *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

failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.[107]

252. 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.[108]

253. 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.[109]

(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."

(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

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20, 2015), https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent (last accessed December 20, 2017)

[107] 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.

[108] Lynn Webster & Beth Dove, Avoiding Opioid Abuse While Managing Pain (2007).

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

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.

254. 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."[110.]

255. 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."[111]

256. 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.

[110] John Fauber, *Painkiller Boom Fueled by Networking*, MILWAUKEE WISC. J. SENTINEL, Feb. 18, 2012

[111] *CDC Guidelines for Prescribing Opioids for Chronic Pain,* available at https://www.cdc.gov/drugoverdose/prescribing/guideline.html

257. 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.

258. For example,

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

(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.[112]

(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."[113]

(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.

(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

[112] Available at, https://assets.documentcloud.org/documents/277605/apf- treatmentoptions.pdf

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

unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.[114]

(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.[115]

259. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guidelines, "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."[116]

260. 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 Lee County, 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.[117]

261. 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

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[114] Available at, http://s3.documentcloud.org/documents/277603/apf-policymakers- guide.pdf

[115] 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

[116] 2016 CDC Guidelines *supra* note 111.

[117] *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), https://painmedicinenews.com/download/BtoB_Opana_WM.pdf (last accessed December 19, 2017).

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.

262. 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 Lee County.

263. 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.[118]

d. MANUFACTURER DEFENDANTS' MISUSE OF TREATMENT GUIDELINES

264. 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

[118] 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

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, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits including visits throughout Virginia and Lee County.

(1) FEDERATION OF STATE MEDICAL BOARDS (FSMB)

265. 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.

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

267. 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 Lee County.

268. 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."[119]

269. 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.

(2) AAPM/APS GUIDELINES

270. American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement, *The Use of Opioids for the Treatment of Chronic Pain*, that endorsed opioids to treat chronic pain and claimed that the there was little risk of addiction or overdose in pain patients. [120] 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 and was taken down only after a doctor complained, though it lingers on the internet elsewhere.

271. 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

[119] Scott M. Fishman, *Responsible Opioid Prescribing*, WATERFORD LIFE SERVICES (2007)

[120] The Use of Opioids for the Treatment of Chronic Pain, APS & AAPM (1997), http://opi.areastematicas.com/generalidades/OPIOIDES.DOLORCRONICO.pdf (as viewed 3/31/2016).

who drafted the 2009 Guidelines, including Dr. Portenoy and Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue.

272. 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 Lee County during the relevant time period, were reprinted in the *Journal of Pain* and are still available online.

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

274. 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.

275. 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."[121]

276. Similarly, the 2011 Guidelines for the Chronic Use of Opioids, issued by the American College of Occupational and Environmental Medicine, recommend against the "routine use of opioids in the management of patients with chronic pain," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence."[122]

277. 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.[123]

ii. MANUFACTURER AND DISTRIBUTOR DEFENDANTS VIOLATED THEIR REQUIREMENTS TO PREVENT DIVERSION AND REPORT SUSPICIOUS ORDERS UNDER VIRGINIA AND FEDERAL LAW.

[121] 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).

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

[123] Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, May 2010, http://www.healthquality.va.gov/_guidelines/Pain/cot/COT_312_Full- er.pdf

278. In addition to their common law duties, Manufacturer and Distributor Defendants are subject to statutory and regulatory requirements under Virginia law. Virginia 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 Virginia Board of Pharmacy. Virginia 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. Virginia, 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.

279. The opioid epidemic was further fueled by Defendants' failure to follow the specific mandates in Virginia 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 Lee County, paid the price.

280. Recognizing that highly addictive drugs like opioids can be easily abused and diverted to the black market, Virginia, in the Virginia Drug Control Act, and Congress, in the CSA, sought to combat diversion of prescription narcotics by providing for a closed system of drug distribution in which manufacturers, wholesalers/distributors, and retail and mail-order pharmacies must register with the Virginia Board of Pharmacy and the DEA.

281. 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. *See*, *e.g.* Va. Code Ann. § 54.1-3435; Va. Code Ann. § 54.1-3303; 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).

282. 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). Registrants must further report to the Virginia Board of Pharmacy any time they cease distribution of a suspicious order pursuant to CSA requirements. Va. Code Ann. § 54.1-3435.

283. 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). Virginia regulations require that registrants "provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of prescription drugs." 18 VAC 110-50-90.

284. On information and belief, Defendants knowingly, recklessly, and/or negligently supplied suspicious quantities of prescription opioids to obviously suspicious physicians and pharmacies in and around Lee County, without disclosing suspicious orders as required by regulations and otherwise circumventing their statutory obligations under Virginia and Federal law.

285. 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.

286. 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 Lee County.

a. MANUFACTURER DEFENDANTS

287. 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.

288. 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.

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

290. 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.

291. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion, but instead they utilized the data to understand which regions and which doctors to target through their sales force.

292. With the knowledge of improper diversion, the Manufacturer Defendants could have but failed to report each instance of diversion to the DEA, as they were required to do, instead rolling out marketing campaigns to churn its prescription opioid sales.

293. Indeed, upon information and belief, the Manufacturer Defendants withheld from the DEA information about suspicious orders – and induced others to do the same – to obfuscate the extent of the opioid epidemic. Upon information and belief, the Manufacturer Defendants knew that if they or the other defendants disclosed suspicious orders, the DEA would become aware that many opioids were being diverted to illegal channels, and would refuse to increase the production quotas for opioids.

294. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by law, fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[124] Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report suspicious orders for controlled substances

[124] *See* U.S. Dep't of Justice, *Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations*, Jul. 11, 2017, https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders

– orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[125] Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007."[126]

295. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Through its extensive network of sales representatives, Purdue had and continues to have knowledge of the prescribing practices of thousands of doctors and could identify doctors who displayed red flags for diversion, such as those whose waiting rooms were overcrowded, whose parking lots had numerous out-of-state vehicles, and whose patients seemed young and healthy or homeless. Using this information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs.[127] Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*,[128] Purdue's senior compliance officer acknowledged that in five years of

[125] *Id.* (internal quotation omitted).

[126] 2017 Settlement Agreement between the United States of America and Mallinckrodt, plc, at p. 2-3, https://www.justice.gov/usao-edmi/press-release/file/986021/download

[127] *See* Scott Glover and Lisa Girion, *OxyContin maker closely guards its list of suspect doctors*, LOS ANGELES TIMES, Aug. 11, 2013, http://articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811

[128] *See* Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminal and addicts. What the drugmaker knew*, LOS ANGELES TIMES, Jul. 10, 2016, http://www.latimes.com/projects/la-me-oxycontin-part2/

investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring" until years after law enforcement shut it down. In doing so, Purdue protected its own profits at the expense of public health and safety.

296. In 2016, the New York Attorney General found that, between January 1, 2008 and March 7, 2015, Purdue's sales representatives, at various times, failed to timely report suspicious prescribing and continued to detail those prescribers even after they were placed on a "no-call" list.[129]

297. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services, said in a *Los Angeles Times* article, "Any drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people's lives has a responsibility to report it."[130] The New York Attorney General's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

298. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the New York Attorney General found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing

[129] *See* NY Purdue Settlement, at 6-7, available at https://ag.ny.gov/pdfs/Purdue- AOD-Executed.pdf

[130] Glover and Girion, *supra* note 127.

prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

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

300. On information and belief, the other Manufacturer Defendants have engaged in similar conduct in violation of their responsibilities to prevent diversion.

301. The Manufacturer Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into Lee County's community.

b. DISTRIBUTOR DEFENDANTS

302. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescriptions opioids that were incumbent upon the Manufacturer Defendants are also legally required of the Distributor Defendants under Virginia and federal law.

303. All opioid distributors are required to maintain effective controls against opioid diversion. They are required to create and use a system to identify and report to law enforcement downstream suspicious orders of controlled substances, such as orders of unusually large size, orders that are disproportionate, orders that deviate from a normal pattern, and/or orders of unusual frequency. To comply with these requirements, distributors must know their customers, must conduct due diligence, must report suspicious orders, and must terminate orders if there are indications of diversion.

304. Under Virginia law and the CSA, anyone authorized to handle controlled substances must track their shipments. The DEA's ARCOS is an automated drug reporting system that records and monitors the flow of Schedule II controlled substances from the point of manufacture through distribution to the point of sale. ARCOS accumulates data on distributors'-controlled substances and transactions, which are then used to identify diversion. Each person or entity that is registered to distribute controlled substances such as opioids must report each acquisition and distribution transaction to the DEA. *See* 21 U.S.C. § 827; 21 C.F.R. § 1304.33. Each registrant must also maintain a complete, accurate and current record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of.

305. Each registrant must also comply with the security requirements to prevent diversion set forth in 18 VAC 110-50-90 and 21 C.F.R. § 1301.71.

306. The DEA has provided guidance to distributors on how to combat opioid diversion. On information and belief, since 2006 the DEA has conducted one-on-one briefings with distributors regarding downstream customer sales, due diligence, and regulatory responsibilities. On information and belief, the DEA also provides distributors with data on controlled substance distribution patterns and trends, including data on the volume and frequency of orders and the percentage of controlled versus non-controlled purchases. On information and belief, the DEA has also hosted conferences for opioid distributors and has participated in numerous meetings and events with trade associations.

307. On September 27, 2006 and December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors providing guidance on suspicious order monitoring and the responsibilities and obligations of registrants to prevent diversion.

308. As part of the legal obligation to maintain effective controls against diversion, the distributor is required to exercise due care in confirming the legitimacy of each and every order

prior to filling. Circumstances that could be indicative of diversion include ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; ordering a disproportionate amount of controlled substances versus non-controlled prescription drugs; ordering excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs; and ordering the same controlled substance from multiple distributors.

309. Reporting an order as suspicious will not absolve a distributor of responsibility if the distributor knew, or should have known, that the prescription opioids were being diverted. Indeed, reporting a suspicious order and then filling said order with knowledge it may be suspicious constitutes a failure to maintain effective controls against diversion under 18 VAC 110-50-90 and 21 U.S.C. §§ 823 and 824.

310. On information and belief, the Distributor Defendants' own industry group, the Healthcare Distribution Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," emphasizing the critical role of each member of the supply chain in distributing controlled substances. These industry guidelines stated: "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

311. Opioid distributors have admitted to the magnitude of the problem and, at least superficially, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

312. On their face, these assurances – of identifying and eliminating criminal activity and curbing the opioid epidemic – create a duty for the Distributor Defendants to take reasonable measures to do just that.

313. Despite their duties to prevent diversion, the Distributor Defendants have knowingly or negligently allowed diversion.[131] The DEA has repeatedly taken action to attempt to force compliance, including 178 registrant actions between 2008 and 2012, 76 orders to show cause issued by the Office of Administrative Law Judges, and 41 actions involving immediate suspension orders.[132] The Distributor Defendants' wrongful conduct and inaction have resulted in numerous civil fines and other penalties, including:

(a) In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the Country, resulting in millions of doses of controlled substances being diverted. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer.

(b) In a 2017 Administrative Memorandum of Agreement between McKesson and the DEA, McKesson admitted that it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." McKesson was fined $150,000,000.

(c) On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Auburn, Washington, for failure to maintain effective controls against diversion.

(d) On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion.

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[131] Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, WASH. POST, Oct. 15, 2017, https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industrycongress/?utm_term=.75e86f3574d3; Lenny Bernstein, David S. Fallis, and Scott Higham, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* WASH. POST, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.3076e67a1a28

[132] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, The Drug Enforcement Administration's Adjudication of Registrant Actions 6 (2014), available at https://oig.justice.gov/reports/2014/e1403.pdf (last accessed January 8, 2018)

(e) On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Swedesboro, New Jersey, for failure to maintain effective controls against diversion.

(f) On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Stafford, Texas, for failure to maintain effective controls against diversion.

(g) In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States.[133]

(h) On February 2, 2012, the DEA issued another Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion.

(i) In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states.

(j) In December 2016, the Department of Justice announced a multi-million-dollar settlement with Cardinal for violations of the Controlled Substances Act.[134] On information and belief, in connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Wisconsin that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000 doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year.

(k) In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center in Florida amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies.[135]

(l) In 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels.

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[133] Lenny Bernstein and Scott Higham, *Cardinal Health fined $44 million for opioid reporting violations*, WASH. POST, Jan. 11, 2017, https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.0c8e17245e66

[134] Press Release, United States Dep't of Justice, *Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act*, Dec. 23, 2016, https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act

[135] *AmerisourceBergen Plant license pulled*, BOSTON NEWS, Apr. 25, 2007, http://archive.boston.com/news/education/higher/articles/2007/04/25/amerisourcebergen_plant_license_pulled/

314. Although distributors have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit.

315. Once the DEA started to enforce suspensions of registrations to distribute controlled substances, rather than comply, manufacturers and defendants spent at least $102 million to undermine the DEA's ability to do so.

316. On February 19, 2014, acting at the behest of industry lobbyists, U.S. Representative Tom Marino introduced the "Ensuring Patient Access and Effective Drug Enforcement Act" as a supposed effort to define "imminent danger" in the 1970 act. A DEA memo noted that this bill would essentially destroy the agency's power to file an immediate suspension order of any suspicious drug shipments.

317. This bill required that the DEA show the company's actions had demonstrated a "substantial likelihood of an immediate threat," whether in death, serious bodily harm or drug abuse, before a suspension order can be sought. It also gave drug companies the ability to submit "corrective action" plans before any penalties could be issued. The law essentially makes it impossible for the DEA to halt any suspicious narcotic shipments before opioids are diverted to the illegal black market.

318. The Distributor Defendants' failure to prevent the foreseeable injuries from opioid diversion created an enormous black market for prescription opioids, which extended to Lee County. Each Distributor Defendant knew or should have known that the opioids reaching Lee County were not being consumed for medical purposes alone and that the number of opioids flowing to Lee County was far in excess of what could be consumed for medically necessary purposes.

319. The Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably prudent distributor of Schedule II controlled substances would have anticipated the danger of opioid diversion and protected against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in and around Lee County; providing information to pharmacies and retailers about opioid diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies and using a little bit of common sense.

320. It was reasonably foreseeable that the Distributor Defendants' conduct in flooding the market in and around Lee County with highly addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

321. It is reasonably foreseeable that when unintended users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses, and death.

322. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the opioid epidemic faced by Lee County, and would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of addiction, demand, illegal transactions, economic ruin, and human tragedy.

323. The Distributor Defendants were aware of widespread prescription opioid abuse in and around Lee County, but, on information and belief, they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in geographic areas and in such quantities, and

with such frequency that they knew, or should have known, these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

324. The use of opioids by Lee County's citizens who were addicted or who did not have a medically necessary purpose could not occur without the knowing cooperation and assistance of the Distributor Defendants. If the Distributor Defendants adhered to effective controls to guard against diversion, Lee County and its citizens would have avoided significant injury.

325. The Distributor Defendants made enormous profits over the years based on the diversion of opioids into Lee County.

326. The Distributor Defendants' intentional distribution of excessive amounts of prescription opioids to Lee County showed an intentional or reckless disregard for the safety of Lee County and its citizens. Their conduct poses a continuing threat to the health, safety, and welfare of Lee County.

iii. PBMS ENSURED THAT OPIOIDS WERE REGULARLY PRESCRIBED AND FLOODED THE MARKET.

327. PBMs are the middlemen between the defendant drug manufacturers and the availability of opioids. The PBM plan designs determine what drugs (a) will be available (or not available) to patients; (b) for what diagnosis, efficacious or otherwise; (c) in what quantities; (d) at what co-pay; (e) what level of authorization will be required; and (f) what beneficial drugs or treatments will not be available.

328. PBMs hold themselves out as "provid[ing] pharmacy care that is clinically sound,"[136] "ensur[ing] that [they] provide[] access to safe and effective medications"[137] and helping their customers "achieve better health outcomes"[138]

329. Notwithstanding this, PBMs collude with manufacturers who pay fees in the form of rebates, administrative fees and other incentives in order to maximize utilization to the financial benefit of the PBMs and manufacturers. This leads to more prescriptions and more pills available to the general public, many of which find their way to the black market.

330. PBMs have the ability to limit the number of pills available. PBMs were well aware that benefit plan design, formulary placement, and drug utilization management would result in more addictive opioids entering the marketplace and more addicts being created. Yet, notwithstanding their contractually bound commitment to their customers, whose public and private plans cover the vast majority of Americans, they chose to place profits over their professional and ethical duties.

331. PBMs not only control the majority of this country's prescriptions through their benefit plan design and formulary management, they generate massive profits from that work. PBMs are paid by drug companies to move product. "[N]early one third of all expenditures on branded drugs in 2015 were eventually rebated back. And, most of these rebates directly benefited the PBM."[139] In addition to rebates, PBMs negotiate the payment of administrative fees, volume bonuses and other forms of consideration from manufacturers. The PBMs' ability to negotiate

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[136] CVS Caremark, *Formulary Development and Management at CVS Caremark*, *supra* note 50 at 1.

[137] Express Scripts, *Smart Formulary Management*, *supra* note 59 at 2.

[138] OptumRx, *OptumRx Opioid Risk Management*, 2018, https://www.accesskent.com/Benefits/pdf/Opioid-Brochure.pdf, at 4.

[139] Wayne Winegarden, *To Improve Pharmaceutical Pricing, Reform PBMs And Fix Health Care's Systemic Problem*s, FORBES, Apr. 4, 2017, https://www.forbes.com/sites/econostats/2017/04/04/to-improve-pharmaceutical-pricing-reform-pbms-and-fix-health-cares-systemic-problems/#4da58c5a3322

these incentives from drug manufacturers derives from their control of the factors driving usage, including formulary development, plan design and utilization management programs.

332. The power of the PBMs has evolved over time. Originally mere claims processors, PBMs now play a major role in managing pharmaceutical spending. They also tout their ability to enhance the health benefits for end-users. Drug manufacturers recognize the power of the PBMs to drive utilization.

333. PBMs quietly became an integral part of the pharmaceutical supply chain – that is, the path a drug takes from the manufacturing facility to a bathroom medicine cabinet – following the passage of the Medicare Modernization Act in 2003.

334. Today, the big three PBMs manage drug benefits for approximately eighty-nine percent of the market, or 238 million lives.[140] They drive what drugs are covered by virtually all health insurance providers for over 266 million people. PBMs made almost $260 billion last year.[141] In 2015 they covered most of the 4 billion retail prescriptions that were covered in the United States.[142] They are key participants and play a crucial role in the administration and reimbursement of prescription drugs.[143]

335. PBM influence results from the lack of competition in the PBM space. Market concentration is an important indicator of a company's ability to earn extraordinary returns, and

[140] NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, *PBM Resources*, *supra* note 22.

[141] John Breslin, *Health care experts call for more transparency into PBMs*, PATIENTDAILY, Dec. 20, 2017, https://patientdaily.com/stories/511298841-health-care-experts-call-for-more-transparency-into-pbms

[142] Lydia Ramsey and Skye Gould, *A huge pharma middleman just lost its biggest customer — and it shows how drug pricing really works*, BUSINESS INSIDER, Apr. 25, 2017, http://www.businessinsider.com/express-scripts-esrx-anthem-not-renewing-pbm-2017-4

[143] Health Policy Brief, *supra* note 48.

several segments in the United States pharmaceutical distribution system are highly concentrated.[144]

336. In this environment, the big three PBMs have substantial if not exclusive control over the dissemination of opioids. In concert with drug manufacturers who provide them with assorted complicated payments as incentives,[145] PBMs design benefit plans determining which drugs will be paid for, reimbursed, or covered by public and private pharmacy benefit plans, allowing the drugs to enter the marketplace to be abused. For example, notwithstanding its express assurance to its customers that it "agrees to act as a fiduciary in good faith, with candor and due diligence in connection with the performance of [its PBM contract] and any negotiations related thereto,"[146] OptumRx proceeds to define its formulary as follows:

> A list of prescription drugs administered by PBM that has been evaluated by the PBM for inclusion on its formulary ('Formulary')… [T]he drugs included on the PBM's Formulary may be modified by PBM, with prior approval by [client], from time-to-time as a result of factors including, but not limited to, medical appropriateness, *manufacturer rebate arrangements* and patent expirations.[147] [emphasis added]

337. Notably, OptumRx does not explain how "manufacturer rebate arrangements" impact its formulary design.

338. Express Scripts likewise is paid by drug manufacturers based on formulary design:

> Express Scripts contracts for its own account with pharmaceutical manufacturers to obtain rebates attributable to the utilization of certain prescription products by individuals who receive benefits from clients for

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[144] Neeraj Sood, Tiffany Shih, Karen Van Nuys, Dana Goldman, *Follow the Money: The Flow of Funds In the Pharmaceutical Distribution System*, HEALTH AFFAIRS, Jun. 13, 2017, https://www.healthaffairs.org/do/10.1377/hblog20170613.060557/full/

[145] Health Policy Brief, *supra* note 48.

[146] United Healthcare Services, Inc. and Employees Retirement System of Texas, *Pharmacy Benefit Management Services Executed Contract*, Section 2.3 (2016), https://ers.texas.gov/Doing-Business-with-ERS/PDFs/Contract-for-Pharmacy-Benefit-Management-Services-for-the-HealthSelect-Prescription-Drug-Program.pdf

[147] *Id.* at Section 4.1(h)(i).

> whom we provide PBM services. *Rebate amounts vary based on the volume of utilization as well as the benefit design and formulary position applicable to utilization of a product*. Express Scripts often pays all or a portion of the rebates it receives to a client based on the client's PBM services agreement. Express Scripts retains the financial benefit of the use of any funds held until payment is made to a client. In connection with our maintenance and operation of the systems and other infrastructure necessary for managing and administering the rebate process, *Express Scripts also receives administrative fees* from pharmaceutical manufacturers participating in the rebate program discussed above. *The services provided to participating manufacturers include* making certain drug utilization data available, as allowed by law, for purposes of verifying and evaluating the rebate payments. The administrative fees paid to Express Scripts by manufacturers for participation in the rebate program do not exceed 3.5% of the AWP of the rebated products.[148]

339. It is notable that Express Scripts does not commit to share all of the rebates it receives from drug manufacturers with its clients, nor does it commit to share any of the administrative fees. Nor does it explain all of the services for which it receives the administrative fees. Nor does it explain how any of these payments actually influence its formulary design. Also noteworthy is that Express Scripts pegs its administrative fees to Average Wholesale Price (AWP), which is a reported price higher than any Express Scripts customer pays for any drug.

340. Express Scripts' standard contract language contemplates that it will derive even further revenue from drug manufacturers in other vaguely described arrangements, none of which are shared with its customers:

> [I]f any, ESI and ESI's wholly-owned subsidiaries derive margin from fees and revenue in one or more of the ways as further described [herein] ESI and ESI's wholly-owned subsidiaries act on their own behalf, and not for the benefit of or as agents for [its customers]. *ESI and ESI's wholly-owned subsidiaries retain all proprietary rights and beneficial interest in such fees*

[148] Express Scripts, Inc. and Oklahoma City Municipal Facility Authority, Pharmacy Benefit Management Agreement, pg. 30, Exhibit E (2008), http://nationalprescriptioncoveragecoalition.com/wp-content/uploads/2017/ 07/WebPage-2.pdf

> *and revenues* described in the Financial Disclosure and, accordingly, *[customer] acknowledges that neither it, any Member, nor the Plan, has a right to receive, or possesses any beneficial interest in, any such fees or revenues.*[149]

341. A standard Caremark PBM Contract reflects similar perverse incentives. It explains that "Manufacturer' means a pharmaceutical company that has contracted with Caremark (or its affiliate or agent) *to offer discounts for pharmaceutical products in connection with Caremark's Formulary Service*s."[150] [emphasis added]

342. And, "Manufacturer Payments" include revenues received by Caremark,

> [F]rom each of the following sources: 1) payments received in accordance with agreements with pharmaceutical manufacturers for formulary placement and, if applicable, drug utilization; 2) rebates, regardless of how categorized; 3) market share incentives; 4) commissions; 5) any fees received for the sale of utilization data to a pharmaceutical manufacturer; 6) educational grants; 7) administrative management fees; and 8) all compensation from manufacturers including rebates paid by a manufacturer as a result of product inflation caps and/or guarantees negotiated by the Service Provider.[151]

343. Caremark's standard PBM contract further explains:

> [T]hat, in lieu of billing Member County a 'per Claim' fee for Services, Caremark shall retain 100% of the Rebates as reasonable compensation for the Services. Customer and Member County understand and agree that neither they nor any Participant will share in the Rebate monies collected from Manufacturers by Caremark.[152]

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[149] *Id*. at pp. 8-9, Section 6.4.

[150] CaremarkPCS Health, L.P. and the National Association of Counties, Managed Pharmacy Benefit Service Agreement, pg. 10, Section 10(f) (2006), http://www.nassauclerk.com/agendaindex/Ordinances/other/CS-08-125.pdf

[151] CaremarkPCS Health, L.L.C. and Florida Department of Management Services, *Pharmacy Benefit Management Services contract,* pg. 7, Section 1.1 (2015), https://www.dms.myflorida.com/content/download/107930/607791/2015_PBM_Contract_REDACTED_FINAL.pdf

[152] CaremarkPCS Health, L.P. and the National Association of Counties, Managed Pharmacy Benefit Service Agreement, pg. 4, Section 2.1 (2006), http://www.nassauclerk.com/agendaindex/Ordinances/other/CS-08-125.pdf

344. Caremark also explains that it will encourage the use of its "Preferred Drugs" (those where it has the most lucrative arrangement with a drug manufacturer) over "non-Preferred" drugs. Its standard contract language states that Caremark will encourage the use of "Preferred Drugs" by:

> (i) identifying appropriate opportunities for converting a prescription from a non-Preferred Drug to a Preferred Drug, and (ii) contacting the Participant and the prescriber to request that the prescription be changed to the Preferred Drug. A Preferred Drug is one on the Performance Drug List, which has been developed by Caremark as a clinically appropriate *and economically advantageous subset of the Caremark Formulary*, as revised by Caremark from time to time.[153] [emphasis added]

345. The harm caused by the PBMs is not just monetary: "[t]he PBMs and insurers are harming the health of patients with chronic and rare diseases by limiting access and charging them retail for drugs they buy at deep discounts."[154] PBMs also fail to control quantities, or numbers of refills for highly addictive drugs and ignore or neglect their assorted contractual undertakings to ensure patient wellness.

346. PBMs also provide discount drug cards so individuals can directly purchase medications without going through insurance companies. This allows individuals to fill multiple prescriptions while avoiding the oversight that insurance coverage brings, thus fueling the epidemic. PBMs allow this loophole because they are paid for every prescription filled in this manner.

347. MedPageToday, a source for clinical and policy coverage that directly affects the lives and practices of health care professionals, describes the PBMs' complicity in the opioid crisis this way:

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[153] *Id.* at p. 3, Section 1.11.

[154] Jonathan Wilcox, *PBMs Must Put Patients First*, HUFFINGTON POST, Feb. 28, 2017, https://www.huffingtonpost.com/entry/pbms-must-put-patients-first_us_58b60bd8e4b02f3f81e44dcc

> We live in a world where payers -- not physicians -- determine what drugs and treatments patients receive. If patients have a life-threatening condition, it is not unusual for a payer to demand that a physician first prescribe a cheaper and less effective alternative. Physicians know that the drugs they are allowed to use may not work very well, but frequently, payers demand that they be tried first anyway.
>
> What happens if the patient doesn't respond to the cheap drug? Often, the physician continues to prescribe it, because -- to gain access to the more effective drug -- physicians need to go through a painful process of preauthorization. For many practitioners, it isn't worth it.
>
> So we spend more for healthcare than any other country in the world, but Americans do not get the care they need. There is a simple reason. Treatment decisions are not being driven based on a physician's knowledge or judgment. They are being driven by what payers are willing to pay for.[155]

348. Thus, people with pain are at the mercy of PBMs, yet PBMs make it easier to get opioids than to get other pain medication that is less addictive, because opioids are generally cheaper than non-opioid alternatives and opioid manufacturers have provided rich incentives, as described above. According to a study by the New York Times and ProPublica of 35.7 million people on Medicare prescription drug plans, in the second quarter of 2017 only one-third of them had access to pain medication less addictive than opioids.[156]

349. Even when they were asked to limit accessibility to opioids, PBMs refused. The seeds of the opioid epidemic were sown with early over prescription of OxyContin. In 2001, when officials in the West Virginia state employee health plan tried to get Purdue, which manufactured OxyContin, to require pre-authorization, Purdue refused.[157] Using the financial *quid pro quo* it had

[155] Milton Packer MD, *Are Payers the Leading Cause of Death in the United States?,* MEDPAGETODAY, Nov. 1, 2017, https://www.medpagetoday.com/blogs/revolutionandrevelation/68935

[156] Thomas and Ornstein, *supra* note 65.

[157] David Armstrong, *Drug maker thwarted plan to limit OxyContin prescriptions at dawn of opioid epidemic*, STAT, Oct. 26, 2016, https://www.statnews.com/2016/10/26/oxycontin-maker-thwarted-limits/

with the West Virginia PBM, it paid Merck Medco (now Express Scripts) to prevent insurers from limiting access to the drug. This practice was consistent nationwide.

> The strategy to pay Merck Medco extended to other big pharmacy benefit managers and to many other states, according to a former Purdue official responsible for ensuring favorable treatment for OxyContin. The payments were in the form of "rebates" paid by Purdue to the companies. In return, the pharmacy benefit managers agreed to make the drug available without prior authorization and with low copayments.
>
> "That was a national contract," Bernadette Katsur, the former Purdue official, who negotiated contracts with pharmacy benefit managers, said in an interview. "We would negotiate a certain rebate percentage for keeping it on a certain tier related to copay or whether it has prior authorization. We like to keep prior authorization off of any drug."[158]

350. PBMs are "driving patients to opioids, away from abuse-deterrent form (ADF) and less addictive forms of opiates through formulary and pricing strategies."[159]

351. Not only do PBMs place roadblocks in the way of limiting excessive opioid prescriptions, they also make it more difficult to obtain ADF opioids. These pills are more difficult to physically alter (crushing to snort or dissolving to inject) and therefore are less prone to abuse.[160] The three major PBMs carry at most 3 of the 10 FDA approved ADF opioids, while CVS Caremark, which has nearly 90 million members, carries none.[161] A study by Tufts CSSD found that ninety-six percent (96%) of all prescription opioids were non-ADF in 2015.[162]

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[158] *Id.*

[159] Charles L. Bennett MD PhD MPP, *Do you have pain, cancer, or diabetes? Your PBM may now be your doctor for these illnesses,* COLLABRX, Dec. 27, 2017, http://www.collabrx.com/pain-cancer-diabetes-pbm-may-now-doctor-illnesses/

[160] Peter J. Pitts, *Pharmacy benefit managers are driving the opioid epidemic*, SW News Media, Nov. 21, 2017, http://www.swnewsmedia.com/shakopee_valley_news/news/opinion/guest_columns/pharmacy-benefit-managers-are-driving-the-opioid-epidemic/article_2f6be2a1-c7a3-5f8d-9f3e-, 61d29d25c84b.html

[161] Bennett, *supra* note 159.

[162] Pitts, *supra* note 160.

352. Making matters worse, in addition to making it easy to obtain generic highly addictive opioids, PBMs make it ***harder*** to obtain ***treatment***. The NY Times/ProPublica study found that insurers have erected more hurdles to approving addiction treatments than for the addictive substances themselves.[163] Only after being subject to much public pressure and congressional investigations did some insurers remove the barriers to addiction treatment.

353. A 2008 study by the Mayo Clinic[164] found that patients who were weaned off opioids and followed a non-drug treatment experienced less pain than when they were on opioids and had improved functioning. Some plans cover these costs but other do not.[165]

354. In addition to their role designing prescription drug benefit programs, one responsibility of all PBMs and their employed pharmacists is to properly monitor and control the distribution of prescription opioids. PBMs market their abilities to ensure that the medications they dispense are appropriately dosed, and monitored for drug interactions, therapeutic duplications, and possible misuse or abuse.

355. PBMs also market their ability to manage and oversee the quality of the retail pharmacies that are contracted to be in their network. At critical times, PBMs were – at best – asleep at the switch when it came to auditing pharmacies that were dispensing huge quantities of opioids. The fact that very few if any "pill-mill" pharmacies or over-prescribing physicians were reported by PBMs to the State Boards of Pharmacies or State Medical Boards is testament to the PBMs' lack of oversight of opioids.

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[163] Thomas and Ornstein, *supra* note 65.

[164] Available at https://www.ncbi.nlm.nih.gov/pubmed/18804915

[165] Barry Meier and Abby Goodnough, *New Ways To Treat Pain Meet Resistance*, THE NEW YORK TIMES, Jun. 22, 2016, https://www.nytimes.com/2016/06/23/business/new-ways-to-treat-pain-without-opioids-meet-resistance.html?mcubz=1,

356. In fact, OptumRx has recently been transparent with its knowledge that 45% of 'first fill' opioid prescriptions nationwide are not in compliance with CDC guidelines.[166]

357. There have always been steps the PBMs could take to abate the flow of opioids. They could make it easier to access other non-addictive forms of pain relief. They could require doctors to start treating pain first with non-opioid pain medications as recommended by the CDC and turn to opioids as a last resort. They could cover alternative, non-medication treatments for pain. They could make addiction treatment more accessible. They could monitor prescriptions. They could forbid 90-day supplies of opioids. They could audit pharmacies. They could require doctors and pharmacies in their networks to use PDMPs. They could make their pricing more transparent so everyone could see if they were being improperly influenced by manufacturers to make choices for financial, not medical reasons.

358. The PBM defendants expressly recognize that they have the ability to abate the opioid epidemic. OptumRx admits that PBMs are "uniquely positioned to help address the opioid epidemic."[167] Express Scripts admits that "we have the ability to make a significant impact."[168]

359. Yet PBMs are still not doing all they (easily) can to halt the improper dispensing of opioids and expand access to treatments for opioid overdose and addiction.

360. Each of the PBM Defendants recently have begun offering opioid management programs for certain customers that they claim (falsely) are consistent with the March 2016 U.S. Centers for Disease Control and Prevention, CDC Guideline for Prescribing Opioids for Chronic

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[166] OptumRx, *OptumRx Opioid Risk Management*, 2018, https://www.optum.com/resources/library/opioid-risk-management0.html, at 3.

[167] OptumRx, *Confronting the Opioid Epidemic*, 2018, https://www.optum.com/resources/library/opioid-e-book.html?s3=rxopioid, at 9.

[168] Express Scripts, *Express Scripts Significantly Reduces Inappropriate Selection and Excessive Dispensing of Opioids for New Patients,* Jan. 11, 2018, http://lab.express-scripts.com/lab/insights/drug-safety-and-abuse/reducing-inappropriate-selection-and-excessive-dispensing-of-opioids, at 2.

Pain – United States, 2016, 65 Morbidity and Mortality Weekly Report 1 (2016) ("CDC Guideline").

361. In truth, even these new opioid management programs do not apply across the board to all customers and still fall woefully short of the CDC Guideline and all current medical literature regarding the highly dangerous properties of opioids.

362. None of the big three PBMs' new opioid management programs are consistent with the CDC Guideline – they still permit the largely unchecked prescribing of opioids for chronic pain (the CDC says opioids are not proven effective for chronic pain); still provide seven-day quantity limits for acute pain (when the CDC says "three days or less will often be sufficient" and the PBMs themselves acknowledge that "a few days" can make a difference in whether one becomes addicted); still permit opioid prescriptions to be delivered through mail-order pharmacies for conditions outside of active cancer, end-of-life or palliative care (which typically supply maintenance drugs for chronic conditions; it is well-established that except for active cancer, end-of-life or palliative care, opioids should not be dispensed for chronic pain); do not adhere to CDC MME/day recommendations; do not cover high dosage nonopioid alternatives; do not require step therapies; and do not require prior authorizations for the most commonly prescribed immediate-release opioids.

363. At the same time, the PBMs also continue to impose unnecessary restrictions on access to treatments for opioid overdose and addiction.

364. These failures have contributed mightily to the roots of the opioid epidemic and its ongoing impact today.

365. The PBMs own documents confirm the important role PBMs play in implementing the CDC Guideline.

366. Nearly one year after the CDC Guideline was issued, Caremark publicly acknowledged that, "[p]harmacy benefit managers (PBMs) play an important role in implementing the CDC [G]uideline, and helping ensure access and patient safety" and assured its customers that it had "taken a thoughtful, evidence-based approach to implementing the CDC guideline into our utilization management (UM) criteria with consideration of the needs of those with chronic pain, as well as the potential for harm from these powerful medications."[169]

367. Caremark also assured the public that its, "UM criteria reinforce [the CDC] principles and encourage appropriate use of opioids by patients and prescribers. They provide coverage that fosters safe use of opioids, consistent with the … CDC [G]uideline, to support plans helping members on their path to better health."[170]

368. Express Scripts similarly boasts that its Advanced Opioid Management program "is based on CDC prescribing guidelines" and "promot[es] greater compliance with CDC guidelines."[171]

369. OptumRx likewise claims that its "utilization management edits are tightly aligned with Centers for Disease Control (CDC) prescribing guidelines."[172]

370. The foregoing assurances of fostering "safe use of opioids" consistent with the CDC Guideline are false. The PBM Defendants' utilization management criteria – to this day and despite all their talk – fall far short of meeting the CDC Guideline. As one news outlet described it, "[o]ne overlooked culprit worsening the epidemic, however, comes straight from our health care

[169] CVS Health, *The Balancing Act, Helping Ensure Appropriate Access to Opioids While Minimizing Risk*, INSIGHTS FEATURE, Feb. 28, 2017, https://payorsolutions.cvshealth.com/insights/balancing-act, at 1 (emphasis added).

[170] *Id.* at 5 (emphasis added).

[171] Express Scripts, *Express Scripts Significantly Reduces Inappropriate Selection and Excessive Dispensing of Opioids for New Patients, supra* note 168 at 1.

[172] *OptumRx Opioid Risk Management, supra* note 138.

system: pharmacy benefit managers, or PBMs. To improve their bottom line, they're blocking access to prescriptions that can help prevent overdoses."[173]

371. In sum, because PBMs are the intermediary between drug manufacturers, pharmacies, and ultimately patients, these companies influence everything from pharmacy reimbursements, to what drugs are covered under formularies. In these ways, the PBMs drive which drugs enter the marketplace. Their fingerprints are on nearly every opioid prescription filled and they profit in myriad ways on every pill.

372. PBMs' complicity in the overall fraudulent scheme is knowing and purposeful. Drug manufacturers compete for PBM formulary placement (preferred placement results in greater utilization and greater profits) and pay PBMs incentives to avoid pre-authorization requirements and other hurdles that would slow down flow. A review of the defendant PBM formularies confirms that they include all of the opioids at issue in this case, often in preferred tiers, without quantity limits or prior authorization requirements.

373. Caremark has three basic formularies: Standard Control, Advanced Control, and Value.[174]

374. A wholly owned Caremark subsidiary (SilverScript) also manages two basic formularies for Medicare Prescription Drug Plans ("PDPs"), Choice and Plus.[175] Each of Caremark's basic formularies include opioids.

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[173] Pitts, *supra* note 160.

[174] CVS Health, *Formulary Management*, https://payorsolutions.cvshealth.com/programs-and-services/cost-management/formulary-management (last visited Sept. 10, 2018)

[175] SilverScript, *Compare 2018 Plans – SilverScript,* https://www.silverscript.com/plan/compare-module.aspx (last visited Sept. 10, 2018)

375. Caremark's Standard Control formulary contains no step therapies, prior authorization requirements or quantity limits for opioids on its face.[176]

376. It imposes no three-day limitations for acute pain.[177]

377. It does not limit the use of opioids for chronic pain outside active cancer, end-of-life and palliative care.[178]

378. The prescribing guide for the Standard Control formulary refers clinicians to 2017 prescribing guidelines, but even those do not require nonopioid step therapies for treatment of chronic pain or three-day limits for acute pain.[179]

379. Although Caremark's Standard Control formulary covers methadone, and multiple buprenorphine and naloxone treatments, it does not cover any naltrexone treatments and it is unclear what utilization management or cost-sharing requirements may apply.[180]

380. Caremark's Standard Control formulary does not cover the higher strength prescription dosages of the following nonopioid pharmacological options, useful in many step therapies: ibuprofen, topical lidocaine, amitriptyline, doxepin, desipramine, diflunisal, choline magnesium trisalicylate, salsalate, etodolac, sulindac, indomethacin, celecoxib, meclofenamate, and nabumetone.[181]

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[176] *See* CVS Caremark, *Performance Drug List – Standard Control*, July 2018, https://www.caremark.com/portal/asset/caremark_recaprxclaimsdruglist.pdf (last visited Sept. 10, 2018) at 1;

[177] *Id.*

[178] *Id.*

[179] *See* CVS Caremark, *Prescribing Guide – Standard Control 2018,* https://www.caremark.com/portal/asset/Prescribing_Guide_Un-Authenticated.pdf (last visited Sept. 10, 2018) at 11.

[180] *See* CVS Caremark, *Performance Drug List – Standard Control, supra* note 176 at 1, 3.

[181] *Id.*

381. Caremark's Advanced Control formulary contains no step therapies, prior authorization requirements or quantity limits for opioids on its face.[182]

382. The Advanced Control formulary does not include many of the following prescription nonopioid pain treatment alternatives: capsaicin, diflunisal, choline magnesium trisalicylate, salsalate, etodolac, sulindac, indomethacin, meclofenamate, and nabumetone.[183]

383. Caremark's Value Formulary contains no step therapies for any immediate release opioids.[184]

384. It has prior authorization requirements for some opioids, but not the most widely used: hydrocodone-acetaminophen, oxycodone-acetaminophen and codeine-acetaminophen.[185]

385. The Value Formulary points to the same lax 2017 opioid prescribing guidelines.[186]

386. Caremark's Value Formulary imposes both prior authorization and/or quantity limits on the majority of pharmacologic treatments for opioid addiction and overdose.[187]

387. This Value formulary (like Caremark's other commercial offerings) excludes an array of nonopioid pain relief options including: topical lidocaine, choline magnesium trisalicylate, salsalate, indomethacin, celecoxib, and meclofenamate.[188]

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[182] *See* CVS Caremark, *Advanced Control Formulary*, July 2018, https://www.caremark.com/portal/asset/Advanced_Control_Formulary.pdf, at 1.

[183] *Id.*

[184] *See* CVS Caremark, *CVS Caremark® Value Formulary Effective as of 07/01/2018*, https://www.caremark.com/portal/asset/Value_Formulary.pdf, at 9-10.

[185] *Id.*

[186] *Id.* at 9.

[187] *Id.* at 10, 22-23.

[188] *Id.*

388. Caremark's Medicare PDP formularies have no prior authorization requirements for opioids except fentanyl-related products, and no step therapies for any opioids.[189] As with Caremark's other formularies, they impose dosage and quantity limits but these exceed the CDC Guideline's recommendations for MME per day. For example, Caremark sets a 360 tabs/30 day limit for all strengths of Hydrocodone-acetaminophen (5-325mg, 7.5-325mg, 10-325mg), one of the most widely overprescribed opioids. But even at the lowest dosage (5mg), this exceeds the CDC-recommended dosage limit of 50 MME/day. The following chart explains how Caremark's current hydrocodone Medicare quantity limits far exceed the CDC Guideline with respect to this highly abused drug:

Hydrocodone-acetaminophen, 360 tab per 30 days[190]	**Strength**	**MME [191]**	**Tabs/day**	**MME/day**
5-325mg	5mg	1.0	12	**60 MME**
7.5-325mg	7.5mg	1.0	12	**90 MME**
10-325mg	10mg	1.0	12	**120 MME**

389. Caremark is similarly lax when it comes to imposing limits on the other most commonly prescribed opioid – oxycodone-acetaminophen. Caremark's current Medicare quantity limits of 360 tablets/30 days for the 5-325mg, 7.5-325mg, and 10-325mg strengths of Oxycodone completely ignore the CDC Guideline.

Oxycodone-acetaminophen,	**Strength**	**MME[193]**	**Tabs/day**	**MME/day**

[189] *See* SilverScript, *2018 Formulary (List of Covered Drugs) [for SilverScript Choice],* https://www.silverscript.com/pdf/choice-comprehensive-formulary.pdf ("SilverScript Choice Formulary") (last visited Sept. 10, 2018) at 8-10; SilverScript, *2018 Formulary (List of Covered Drugs) [for SilverScript Plus]*, https://www.silverscript.com/pdf/plus-comprehensive-formulary.pdf ("SilverScript Plus Formulary") (last visited Sept. 10, 2018) at 8-10.

[190] *See Id.* (both formularies linked above) at 9.

[191] CMS Conversion Chart, *Opioid Oral Morphine Milligram Equivalent (MME) Conversion Factors,* CENTERS FOR MEDICARE & MEDICAID SERVICES, Aug. 2017, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Opioid-Morphine-EQ-Conversion-Factors-Aug-2017.pdf

[193] CMS Conversion Chart, *supra* note 193.

360 tab per 30 days[192]				
5-325mg	5mg	1.5	12	**90 MME**
7.5-325mg	7.5mg	1.5	12	**135 MME**
10-325mg	10mg	1.5	12	**180 MME**

390. Caremark applies the same limits to the widely used acetaminophen-codeine, again ignoring the CDC Guideline.

Acetaminophen-codeine, 400 tablets per 30 days[194]	**Strength**	**MME[195]**	**Tabs/day**	**MME/day**
300-30mg	30mg	0.15	13.33	**59.99 MME**
300-60mg	60mg	0.15	13.33	**119.97 MME**

391. Additionally, Caremark's Medicare PDP formularies impose quantity limits and/or prior authorization requirements on the majority of pharmacologic treatments for opioid addiction and overdose.[196] These treatments, including generics, are also all listed on Tier 3 or higher of the formulary.[197] This designation is associated with copays of at least $35 or coinsurance rates typically exceeding 33%.[198]

392. Even with its new Opioid Utilization Management Program, Caremark does not require step therapy as a pre-condition for coverage of immediate-release opioids.[199]

393. Caremark does not impose three-day limits on opioids prescribed for acute pain.[200]

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[192] *SilverScript Choice Formulary* and *SilverScript Plus Formulary, supra* note 189, both at 10.

[194] *SilverScript Choice Formulary* and *SilverScript Plus Formulary, supra* note 189, both at 8.

[195] CMS Conversion Chart, *supra* note 193.

[196] *SilverScript Choice Formulary, supra* note 189 at 9, 34-35; *SilverScript Plus Formulary, supra* note 189 at 9-10, 36.

[197] *Id.*

[198] *Id.* (both formularies) at 5-7.

[199] *See* CVS Caremark, *CVS Caremark Opioid Quantity Limits Pharmacy Reference Guide*, Jan. 2018, https://www.caremark.com/portal/asset/Opioid_Reference_Guide.pdf.

[200] *Id.*

394. Caremark does not require prior authorization when opioids are prescribed for chronic pain.[201]

395. Caremark limits the quantity of opioids prescribed per day, but only to 90 MME/day,[202] a quantity the CDC says should be avoided.[203]

396. Caremark does not require prior authorization prior to dispensing immediate-release opioids, *i.e.*, hydrocodone-acetaminophen, oxycodone-acetaminophen, codeine-acetaminophen.[204]

397. Caremark merely allows for an "emergency supply" of buprenorphine-naloxone products while it processes prior authorization, rather than broadly waiving such requirements.[205]

398. The standard commercial Express Scripts formulary contains no restrictions whatsoever on the majority of opioids covered – no quantity limits, no step therapies, no prior authorization requirements.

399. Express Scripts recently updated its National Preferred Formulary to exclude coverage for two long-acting opioid oral analgesics (Opana ER and Oxycodone ER) and two narcotic analgesics (Buprenorphine Patches and Butrans) but, even there, Express Scripts presents

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[201] *Id.*

[202] *Id.*

[203] *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 MORBIDITY AND MORTALITY WEEKLY REPORT 1 (2016) at 16, 22, 23.

[204] *See Performance Drug List – Standard Control*, *supra* note 176; *Prescribing Guide – Standard Control 2018*, *supra* note 179; *Advanced Control Formulary, supra* note 182; *CVS Caremark® Value Formulary Effective as of 07/01/2018, supra* note 184; *SilverScript Choice Formulary, supra* note 189; *SilverScript Choice Formulary, supra* note 189.

[205] *See* CVS Health, *The Balancing Act, Helping Ensure Appropriate Access to Opioids While Minimizing Risk*, INSIGHTS FEATURE, Feb. 28, 2017, https://payorsolutions.cvshealth.com/insights/balancing-act, at 6.

no fewer than six "preferred alternatives," each of which are highly addictive opioids available in extended-release forms.[206]

400. The National Preferred Formulary indicates that certain naloxone (Narcan nasal spray) and buprenorphine Suboxone Sublingual Film and Zubsolv sublingual tablets) treatments are available, but does not list any methadone or naltrexone treatments.[207]

401. The Express Scripts National Preferred formulary does not cover numerous highly effective prescription nonopioids including: doxepin, desipramine, diflunisal, choline magnesium trisalicylate, etodolac, sulindac, indomethacin, and meclofenamate.[208]

402. Express Scripts' Medicare PDP formularies impose prior authorization requirements for certain opioids but most immediate-release opioids are not subject to step therapy or prior authorization requirements.[209] There are also some quantity and dosage limits in place, but these limits exceed the CDC Guideline.[210]

403. The following charts explains how Express Scripts' current hydrocodone and oxycodone Medicare quantity limits far exceed CDC Guidance with respect to these highly abused drugs:

Hydrocodone-acetaminophen,	**Strength**	**MME[212]**	**Tabs/day**	**MME/day**

[206] *See* Express Scripts, *2018 National Preferred Formulary Exclusions*, https://www.express-scripts.com/art/pdf/Preferred_Drug_List_Exclusions2018.pdf (last viewed Sept. 10, 2018) at 1.

[207] *See* Express Scripts, *2018 Express Scripts National Preferred Formulary*, https://www.express-scripts.com/art/open_enrollment/INTEL_NPFList.pdf (last viewed Sept. 10, 2018).

[208] *Id.*

[209] *See* Express Scripts, *Saver Plan Express Scripts Medicare (PDP) 2018 Formulary*, https://www.express-scriptsmedicare.com/pdf/medicare/medicare-part-d-2018-formulary-saver.pdf (last viewed Sept. 10, 2018) ("Saver Plan Formulary); Express Scripts, *Value Plan Express Scripts Medicare (PDP) 2018 Formulary*, https://www.express-scriptsmedicare.com/pdf/medicare/medicare-part-d-2018-formulary-value.pdf (last viewed Sept. 10, 2018) ("Value Plan Formulary); Express Scripts, *Choice Plan Express Scripts Medicare (PDP) 2018 Formulary*, https://www.express-scriptsmedicare.com/pdf/medicare/medicare-part-d-2018-formulary-choice.pdf (last viewed Sept. 10, 2018) ("Choice Plan Formulary).

[210] *Id.* Saver Plan Formulary at 21-22; Value Plan Formulary at 20-22; and Choice Plan Formulary at 20-22.

[212] CMS Conversion Chart, *supra* note 193.

372 tablets per 31 days[211]				
5-325mg	5mg	1.0	12	**60 MME**
7.5-325mg	7.5mg	1.0	12	**90 MME**
10-325mg	10mg	1.0	12	**120 MME**

Oxycodone-acetaminophen, 372 tablets per 31 days[213]	**Strength**	**MME[214]**	**Tabs/day**	**MME/day**
5-325mg	5mg	1.5	12	**90 MME**
7.5-325mg	7.5mg	1.5	12	**135 MME**
10-325mg	10mg	1.5	12	**180 MME**

404. Express Script's Medicare PDP formularies impose prior authorization and/or quantity limits on the majority of covered pharmacologic treatments for opioid addiction and overdose.[215] These treatments are listed on Tiers 2 through 4 of the formularies, indicating that at least some non-nominal cost-sharing is required.[216]

405. As in the commercial contexts, the Express Scripts Medicare formulary does not include choline magnesium trisalicylate, indomethacin, meclofenamate, and nabumetone, all useful in a step therapy context.[217]

406. For an additional fee, Express Scripts now offers customers its Advanced Opioid Management Program.

407. Even in this program, Express Scripts does not impose a three-day limit for first-time users dealing with acute pain; does not require step therapy prior to dispensing immediate-release opioids; and does not require prior authorization for immediate-release opioids.[218]

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[211] *Id.*

[213] *See* Saver Plan Formulary, Value Plan Formulary and Choice Plan Formulary, *supra* note 209.

[214] CMS Conversion Chart, *supra* note 193.

[215] *See* Saver Plan Formulary, Value Plan Formulary and Choice Plan Formulary, *supra* note 209.

[216] *Id.* (all formularies) at vi ("[u]se Tier 1 drugs for the lowest copayments").

[217] *See* Saver Plan Formulary, Value Plan Formulary and Choice Plan Formulary, *supra* note 209.

[218] *See* Express Scripts, *Putting the brakes on the opioid epidemic*, https://my.express-scripts.com/opioids.html; Express Scripts, *A Comprehensive Solution to Reduce Opioid Abuse*, June 7, 2017, http://lab.express-

408. Express Scripts limits the dosage of opioids prescribed per day, but only to 200 MME/day, more than double the dosage which the CDC Guideline says should be avoided.[219]

409. Nowhere does any Express Scripts formulary advise that opioids are inappropriate for chronic pain treatment outside active cancer, end-of-life or palliative care.[220] To the contrary, virtually every opioid analgesic on every Express Scripts formulary (commercial or Medicare) is available through its mail order pharmacy.[221]

410. OptumRx offers five basic formularies, each of which includes opioids.[222]

411. OptumRx's 2018 Generic Centric Formulary appears to have no limits whatsoever surrounding the dispensing of opioids.[223]

412. OptumRx's other commercial formularies require prior authorization only on some opioids, not including the most popular immediate-release drugs.[224]

413. They do not appear to require step therapy for immediate-release opioids or a three-day limit for acute pain treatment.[225]

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scripts.com/lab/insights/industry-updates/a-comprehensive-solution-to-reduce-opioid-abuse; Nicholas Hamm, *Express Scripts Limits Opioid Prescriptions*, DRUG TOPICS, Aug. 17, 2017, http://www.drugtopics.com/clinical-news/express-scripts-limits-opioid-prescriptions; and Express Scripts, *Express Scripts Significantly Reduces Inappropriate Selection and Excessive Dispensing of Opioids for New Patients, supra* note 168.

[219] Nicholas Hamm, *Express Scripts Limits Opioid Prescriptions*, DRUG TOPICS, Aug. 17, 2017, http://www.drugtopics.com/clinical-news/express-scripts-limits-opioid-prescriptions, at 1.

[220] *See 2018 National Preferred Formulary Exclusions, supra* note 206; *2018 Express Scripts National Preferred Formulary*, *supra* note 207; Saver Plan Formulary, Value Plan Formulary and Choice Plan Formulary, *supra* note 209.

[221] *Id.*

[222] *See* OptumRx, *Formulary and drug lists*, https://professionals.optumrx.com/resources/formulary-drug-lists.html (last visited Sept. 10, 2018)

[223] OptumRx, *2018 Generic Centric Formulary*, July 1, 2018, https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/resources/forms/Generic-Centric%20Formulary.pdf, at 7-9.

[224] *See* OptumRx, *Formulary and drug lists, supra* note 222.

[225] *Id.*

414. They do not advise against the dispensing of opioids for chronic pain.[226]

415. OptumRx currently limits immediate-release opioids for patients new to opioid therapy to 49 MME a day. However, patients not new to opioid therapy may receive 90 MME per day, a limit the CDC Guideline recommends should avoided.

416. OptumRx's Medicare PDP formularies do not appear to have any prior authorization requirements for most long-acting opioids or widely used opioids such as hydrocodone/acetaminophen, oxycodone/acetaminophen and codeine/acetaminophen.[227]

417. These formularies have very few quantity limits, as well, including no apparent limits on the popular opioids identified above.[228]

418. OptumRx does not appear to limit Medicare reimbursement for acute pain treatment to three days.[229]

419. OptumRx offers its OptumRx Opioid Risk Management program for an additional fee. Only through enrollment in that program, for extra money, will its commercial customers receive services that OptumRx's falsely claims are compliant with the CDC Guideline. Even in its Opioid Risk Management Program, OptumRx does not appear to limit acute treatment to three-days and does not require step therapy for opioid treatment of chronic pain.[230]

420. As with the manufacturer and wholesaler defendants, PBMs must contribute to the damage their intentional and purposeful conduct has foreseeably caused plaintiff.

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[226] *Id.*

[227] *See, e.g.,* OptumRx, *Medicare Part D Prescription Drug Plan (PDP) 2018 Comprehensive Formulary*, https://chp.optumrx.com/rxsol/chp/ContentCalPERS/pdf/CalPERS_Anthem_2018_ComprehensiveMemberFormulary.pdf (last visited Sept. 10, 2018), at 10-15.

[228] *Id.*

[229] *Id.*

[230] *OptumRx Opioid Risk Management*, *supra* note 138.

V. CAUSES OF ACTION

COUNT I
PUBLIC NUISANCE
VIOLATION OF VA. CODE ANN. § 15.2-900
(AGAINST ALL DEFENDANTS)

421. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

422. This action is brought by Plaintiff pursuant to Va. Code Ann. § 15.2-900 to abate the public nuisance created by Defendants, and to recover costs Plaintiff has already incurred and future costs the Plaintiff expects to incur in its provision of emergency services that are reasonably required to abate the public nuisance created by Defendants.

423. Each Defendant, acting alone or with one or more co-defendants, created a condition that was and continues to be dangerous to the public and has injured those inhabitants of Lee County who have come within its influence. Each Defendant, acting alone or in concert, injured the property of Lee County.

424. The Manufacturer Defendants knew or should have known that their promotion of opioid use would create a public nuisance:

(a) The Manufacturer Defendants have engaged in massive production, promotion, and distribution of opioids for use by the residents of Lee County;

(b) The Manufacturer Defendants' actions created and expanded the market for opioids, promoting their wide use for pain management;

(a) The Manufacturer Defendants misrepresented the benefits of opioids for chronic pain and fraudulently concealed, misrepresented, and omitted the serious adverse effects of opioids, including the addictive nature of the drugs;

(b) The Manufacturer Defendants knew or should have known that their promotion would lead to addiction and other adverse consequences and that the larger community would suffer as a result.

425. The Manufacturer Defendants' actions were a substantial factor in making opioids widely available and widely used. The Manufacturer Defendants' actions were a substantial factor

in doctors and patients not accurately assessing and weighing the risks and benefits of opioids for chronic pain. Without the Manufacturer Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

426. The Manufacturer Defendants also knowingly, intentionally, recklessly, and/or negligently funneled massive quantities of prescription opioids to physicians and other prescribers who they knew or should have known wrote suspicious prescriptions and/or wrote prescriptions for known abusers of prescription opioids.

427. The Manufacturer Defendants knowingly, intentionally, recklessly, and/or negligently disseminated prescription opioids to distributors who they knew or should have known failed to implement effective controls and procedures to guard against theft, diversion, and abuse of prescription opioids.

428. The Manufacturer Defendants also knowingly enabled and/or failed to prevent the illegal diversion of prescription opioids into the black market, including "pill mills" known for providing opioids to known drug abusers, and known drug dealers, knowing that such opioids would be illegally trafficked and abused.

429. The Manufacturer Defendants knowingly and intentionally financially incentivized the PBM Defendants to place their opioids on the PBMs formularies irrespective of medical necessity, resulting in widespread and unnecessary overuse.

430. The Distributor Defendants' nuisance-causing activities include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of prescription opioids, and failing to adequately design and operate a system to detect, halt, and report suspicious orders of prescription opioids.

431. The Distributor Defendants also knowingly and intentionally enabled and/or failed to prevent the illegal diversion of prescription opioids into the black market, including "pill mills" known for providing opioids to known drug abusers, and known drug dealers, knowing that such opioids would be illegally trafficked and abused.

432. The PBM Defendants knowingly and intentionally designed benefit plans that would maximize the number of opioids in the marketplace.

433. The PBM Defendants knowingly and intentionally created their formularies to ensure that an excessive number of pills were made available to users for use and abuse.

434. The PBM Defendants knowingly and intentionally chose to include opioids on their formularies that were more addictive to users because they generated greater profits. This failure led directly to the increased likelihood of addiction.

435. The PBM Defendants knowingly and intentionally chose to include opioids that were easier to misuse (for example, by crushing them into powder and mixing them with liquid in order to inject them) instead of Abuse Deterrent Formulations ("ADFs") which tended to be more expensive. This choice directly led to the ease with which the pills could be misused.

436. The PBM Defendants knowingly and intentionally made it more expensive or more difficult to obtain knowingly efficacious non-opioid medications for pain. This led directly to the increased sale and use of opioids.

437. The PBM Defendants knowingly and intentionally chose not to include certain medications that would prevent overdoses or made them more difficult or expensive to obtain.

438. The PBM Defendants chose not to cover or provided less coverage for drug treatment.

439. The PBM Defendants knowingly, intentionally, recklessly and/or negligently failed to manage and/or monitor these plans to minimize the use and abuse of opioids.

440. The public nuisance created by the Defendants endangers the life, health and safety of Lee County's residents.

441. The public nuisance created by Defendants interferes with the reasonable and comfortable use of Lee County's property and resources.

442. The public nuisance created by Defendants' actions has caused and continues to cause significant harm to the community that includes but is not limited to:

(a) Opioid-related drug overdose deaths;

(b) The disease of opioid addiction and other diseases related to long-term opioid use;

(c) Infants born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts;

(d) Other child abuse and neglect resulting from opioid abuse;

(e) Crime associated with illegal drug use and opioid sales;

(f) Unemployment resulting from an inability to work while addicted to opioids;

(g) Blight, vagrancy, property damage, and property crime.

443. Defendants' controlled the creation and supply of a new secondary market for opioids—providing both the supply of narcotics to sell and the demand of addicts to buy them. The result of Defendants' actions is not only an explosion of prescription opioids on the black market, but also a marked increase in the availability of heroin and synthetic opioids.

444. The diversion of opioids into the secondary, criminal market by Defendants and the increase in the number of individuals who abuse or are addicted to opioids has placed unnecessary

and excessive demands on the medical, public health, law enforcement, and financial resources of Lee County.

445. Adults and children in Lee County who have never taken opioids have also suffered the costs of the Defendants' public nuisance. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

446. Public resources are being unreasonably consumed in efforts to address the opioid epidemic, thereby eliminating available resources which could be used to benefit the public at large in Lee County.

447. The public nuisance created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated.

448. Lee County has incurred significant costs to date in its efforts to provide services that were reasonably necessary to abate the public nuisance created, perpetuated, and maintained by Defendants. Lee County expects to incur significant costs going forward to ameliorate the harm caused by Defendants.

449. As a direct and proximate result of the public nuisance, Lee County has sustained (and continues to sustain) harm by spending a substantial amount of money trying to fix the societal harms caused by the Defendants' nuisance-causing activity, including, but not limited to, the costs of healthcare, emergency medical services, social services, prevention, treatment, intervention, law enforcement, lost tax revenues, direct spending on opioids and opioid antagonists, and lost communal benefits of Lee County's limited and diverted resources as set forth more fully above.

COUNT II
COMMON LAW PUBLIC NUISANCE

(AGAINST ALL DEFENDANTS)

450. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

451. This action is brought by Plaintiff to abate the public nuisance created by Defendants, and to recover costs Plaintiff has already incurred and future costs the Plaintiff expects to incur in its provision of emergency services that are reasonably required to abate the public nuisance created by Defendants.

452. Under common law, a public nuisance is a condition that is dangerous to the public. A public nuisance adversely impacts an entire community or significant portion of the public. Therefore, a cause of action for public nuisance exists where a defendant's conduct negatively affects the community at large. The public nuisance complained of herein includes the oversaturation, unlawful availability, and abuse of opioids in Lee County as well as the adverse social and environmental outcomes associated with widespread and/or illegal opioid use.

453. Each Defendant, acting alone or with one or more co-defendants, created a condition that was and continues to be dangerous to the public and has injured those inhabitants of Lee County who have come within its influence. Each Defendant, acting alone or in concert, injured the property of Lee County.

454. The Manufacturer Defendants knew or should have known that their promotion of opioid use would create a public nuisance:

(a) The Manufacturer Defendants have engaged in massive production, promotion, and distribution of opioids for use by the residents of Lee County;

(b) The Manufacturer Defendants' actions created and expanded the market for opioids, promoting their wide use for pain management;

(c) The Manufacturer Defendants misrepresented the benefits of opioids for chronic pain and fraudulently concealed, misrepresented, and omitted the serious adverse effects of opioids, including the addictive nature of the drugs;

(d) The Manufacturer Defendants knew or should have known that their promotion would lead to addiction and other adverse consequences and that the larger community would suffer as a result.

455. The Manufacturer Defendants' actions were a substantial factor in making opioids widely available and widely used. The Manufacturer Defendants' actions were a substantial factor in doctors and patients not accurately assessing and weighing the risks and benefits of opioids for chronic pain. Without the Manufacturer Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

456. The Manufacturer Defendants also knowingly, intentionally, recklessly, and/or negligently funneled massive quantities of prescription opioids to physicians and other prescribers who they knew or should have known wrote suspicious prescriptions and/or wrote prescriptions for known abusers of prescription opioids.

457. The Manufacturer Defendants knowingly, intentionally, recklessly, and/or negligently disseminated prescription opioids to distributors who they knew or should have known failed to implement effective controls and procedures to guard against theft, diversion, and abuse of prescription opioids.

458. The Manufacturer Defendants also knowingly enabled and/or failed to prevent the illegal diversion of prescription opioids into the black market, including "pill mills" known for providing opioids to known drug abusers, and known drug dealers, knowing that such opioids would be illegally trafficked and abused.

459. The Manufacturer Defendants knowingly and intentionally incentivized the PBM Defendants to place their opioids on the PBMs formularies irrespective of medical necessity, resulting in widespread and unnecessary overuse.

460. The Distributor Defendants' nuisance-causing activities include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of prescription opioids, and failing to adequately design and operate a system to detect, halt, and report suspicious orders of prescription opioids.

461. The Distributor Defendants also knowingly and intentionally enabled and/or failed to prevent the illegal diversion of prescription opioids into the black market, including "pill mills" known for providing opioids to known drug abusers, and known drug dealers, knowing that such opioids would be illegally trafficked and abused.

462. The PBM Defendants knowingly and intentionally designed benefit plans that would maximize the number of opioids in the marketplace.

463. The PBM Defendants knowingly and intentionally created their formularies to ensure that an excessive number of pills were made available to users for use and abuse.

464. The PBM Defendants knowingly and intentionally chose to include opioids on their formularies that were more addictive to users because they generated greater profits. This failure led directly to the increased likelihood of addiction.

465. The PBM Defendants knowingly and intentionally chose to include opioids that were easier to misuse (for example, by crushing them into powder and mixing them with liquid in order to inject them) instead of Abuse Deterrent Formulations ("ADFs") which tended to be more expensive. This choice directly led to the ease with which the pills could be misused.

466. The PBM Defendants knowingly and intentionally made it more expensive or more difficult to obtain knowingly efficacious non-opioid medications for pain. This led directly to the increased sale and use of opioids.

467. The PBM Defendants knowingly and intentionally chose not to include certain medications that would prevent overdoses or made them more difficult or expensive to obtain.

468. The PBM Defendants chose not to cover or provided less coverage for drug treatment.

469. The PBM Defendants knowingly, intentionally, recklessly and/or negligently failed to manage and/or monitor these plans to minimize the use and abuse of opioids.

470. The public nuisance created by the Defendants endangers the life, health and safety of Lee County's residents.

471. The public nuisance created by Defendants interferes with the reasonable and comfortable use of Lee County's property and resources.

472. The public nuisance created by Defendants' actions has caused and continues to cause significant harm to the community that includes but is not limited to:

(a) Opioid-related drug overdose deaths;

(b) The disease of opioid addiction and other diseases related to long-term opioid use;

(c) Infants born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts;

(d) Other child abuse and neglect resulting from opioid abuse;

(e) Crime associated with illegal drug use and opioid sales;

(f) Unemployment resulting from an inability to work while addicted to opioids;

(g) Blight, vagrancy, property damage, and property crime.

473. Defendants' controlled the creation and supply of a new secondary market for opioids—providing both the supply of narcotics to sell and the demand of addicts to buy them.

The result of Defendants' actions is not only an explosion of prescription opioids on the black market, but also a marked increase in the availability of heroin and synthetic opioids.

474. The diversion of opioids into the secondary, criminal market by Defendants and the increase in the number of individuals who abuse or are addicted to opioids has placed unnecessary and excessive demands on the medical, public health, law enforcement, and financial resources of Lee County.

475. Adults and children in Lee County who have never taken opioids have also suffered the costs of the Defendants' public nuisance. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

476. Public resources are being unreasonably consumed in efforts to address the opioid epidemic, thereby eliminating available resources which could be used to benefit the public at large in Lee County.

477. The public nuisance created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated.

478. Lee County has incurred significant costs to date in its efforts to provide services that were reasonably necessary to abate the public nuisance created, perpetuated, and maintained by Defendants. Lee County expects to incur significant costs going forward to ameliorate the harm caused by Defendants.

479. As a direct and proximate result of the public nuisance, Lee County has sustained (and continues to sustain) harm by spending a substantial amount of money trying to fix the societal harms caused by the Defendants' nuisance-causing activity, including, but not limited to, the costs

of healthcare, emergency medical services, social services, prevention, treatment, intervention, law enforcement, lost tax revenues, direct spending on opioids and opioid antagonists, and lost communal benefits of Lee County's limited and diverted resources as set forth more fully above.

COUNT III
VIOLATION OF THE VIRGINIA CONSUMER PROTECTION ACT
VA. CODE ANN. § 59.1-196, *ET SEQ.*
(AGAINST MANUFACTURER DEFENDANTS)

480. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

481. The Virginia Consumer Protection Act ("CPA") seeks to provide a remedy to unfair and unethical standards of business interactions between suppliers and the consuming public. Va. Code Ann. § 59.1-197.

482. The CPA specifically prohibits sellers from "[m]isrepresenting that goods or services have certain quantities, characteristics, ingredients, uses, or benefits." Va. Code Ann. § 59.1-200(A)(5). As alleged herein, each Manufacturer Defendant violated the CPA by representing that opioids have uses or benefits in treating chronic that they do not have, and by representing that opioids do not have the characteristic of being dangerously addictive.

483. Defendants engaged in the above-described acts intentionally and with knowledge that harm might result, and thus willfully violated the CPA under Va. Code Ann. § 59.1-204.

484. Unless enjoined from doing so, Defendants will continue to violate the CPA.

485. Plaintiff seeks reimbursement of all monies paid for Defendants' products by Plaintiff and its residents.

486. Pursuant to the CPA, Plaintiff is entitled to three times the damages it sustained by the Defendants, as the Defendants' willfully and knowingly violated the CPA. Va. Code Ann. § 59.1-204(A).

487. As a proximate result of Defendants' deceptive acts, Defendants have caused Plaintiff to incur excessive costs related to responding to the opioid crisis. These costs include, but are not limited to, the costs of healthcare, emergency medical services, social services, prevention, treatment, intervention, law enforcement, lost tax revenues, direct spending on opioids and opioid antagonists, and lost communal benefits of Lee County's limited and diverted resources as set forth more fully above.

COUNT IV
FRAUD
(AGAINST MANUFACTURER DEFENDANTS)

488. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

489. Defendants, individually and acting through their employees and agents, and in concert with each other, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth herein.

490. Defendants' representations and assertions to Plaintiff, healthcare providers, and consumers contained intentional misrepresentations and material omissions as to the risks associated with opioids.

491. Defendants intentionally made inaccurate representations regarding the adverse medical conditions associated with the use of opioids and such false representations were made with the intent to mislead.

492. Defendants knew or reasonably should have known that the representations made to Plaintiff and the public-at large regarding the risks of opioids were false or incomplete and misrepresented material facts regarding the use of opioids for chronic pain.

493. Defendants had a duty to provide accurate information regarding the risks and side effects associated with opioids to consumers, including healthcare providers and the Plaintiff.

494. Defendants willfully, knowingly, and deceptively withheld material facts regarding the risks and side effects associated with opioids from Plaintiff, healthcare providers, and consumers.

495. Plaintiff and its residents reasonably relied on the representations made by Defendants, which caused Plaintiff, through its programs, departments, and agencies, to incur costs, including, but not limited to the costs of healthcare, emergency medical services, social services, prevention, treatment, intervention, law enforcement, lost tax revenues, direct spending on opioids and opioid antagonists, and lost communal benefits of Lee County's limited and diverted resources as set forth more fully above.

496. Plaintiff, healthcare providers, and consumers were justified in their reliance on Defendants to educate them as to the risks and dangerous and potentially life-threatening side effects associated with opioid use.

497. Defendants' conduct was willful, wanton, and malicious and was directed at Plaintiff and their residents.

498. The reprehensible nature of the Defendants' conduct further entitles Plaintiff to an award of punitive damages.

499. As a proximate and legal result of Defendants' fraudulent misrepresentations, Plaintiff has suffered and will continue to suffer damages and is therefore entitled to recover for those damages.

COUNT V
COMMON LAW CIVIL CONSPIRACY
(AGAINST ALL DEFENDANTS)

500. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

501. The Defendants acted in concert for the purpose of increasing the use of opioids and fraudulently selling and distributing as many opioids as possible, causing significant harm to Lee County.

502. The Manufacturer and Distributor Defendants violated Virginia law and the CSA by, *inter alia*:

(a) fraudulently making false or misleading statements, falsely marketing opioids as safe for treatment of chronic pain; suppressing evidence to the contrary, and improperly inducing physicians to prescribe opioids for chronic pain;

(b) evading controls on opioid diversion, increasing opioid quotas; and

(c) failing to design and operate a system to disclose suspicious orders of controlled substances, failing to provide and maintain appropriate inventory controls.

503. The conspiracy would not have succeeded absent the PBM's control of the flow of opioids from manufacturer to the end user. The PBM's plan design, including formulary placement, controlled which opioids were paid for, reimbursed, and covered by public and private pharmacy benefit plans. The PBMs exacerbated the opioid crisis by (a) intentionally designing benefit plans that would maximize the number of opioids in the marketplace, (b) failing to manage and/or monitor these plans to minimize the use and abuse of opioids, and (c) choosing drugs to put on their formularies that provided the largest profit to themselves, regardless of the addictive quality of the drug and whether there was an alternative available and limiting access to competing less-additive alternatives.

504. The PBM and Manufacturer Defendants coordinated to ensure that the maximum number of Manufacturers' opioids were prescribed and sold, and the PBM Defendants got the maximum profit at the expense of patients.

505. Each of the participants in the conspiracy received revenue, directly or indirectly, and/or otherwise benefitted from the scheme to promote opioids as safe and non-addictive.

506. At all relevant times, each Defendant was a knowing and willing participant in the conspiracy, and reaped profits from the conspiracy in the form of increased sales, distributions, rebates and kick-backs. Distributor Defendants received kick-backs from Manufacturer Defendants if they reached particular monthly goals. PBM Defendants received rebates, chargebacks, kickbacks, administrative fees, and other financial incentives to promote the Manufacturer Defendants' drugs.

507. All participants of the enterprise described herein were aware of Defendants' control over the activities of the conspiracy in promoting opioids for use in every situation in which a patient is in pain. Each part of the conspiracy benefited from the existence of the other parts.

508. The persons engaged in the conspiracy are systematically linked through contractual relationships, financial ties, and continuing coordination of activities.

509. Lee County has been injured by reason of these violations in that it has incurred costs, including, but not limited to the costs of healthcare, emergency medical services, social services, prevention, treatment, intervention, law enforcement, lost tax revenues, direct spending on opioids and opioid antagonists, and lost communal benefits of Lee County's limited and diverted resources as set forth more fully above. Lee County would not have incurred these costs had Defendants not conspired together. The injuries suffered by Lee County were directly and proximately caused by Defendants' actions and inactions.

510. Plaintiff was directly and proximately harmed by the Defendants' civil conspiracy.

COUNT VI
NEGLIGENCE PER SE
(AGAINST MANUFACTURER DEFENDANTS)

511. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

512. The Manufacturer Defendants failed to perform their statutory and regulatory obligations under the Virginia Drug Control Act, Va. Code Ann. § 54.1-3400 et seq., and the CSA, which were enacted to promote safety and to prevent exactly the type of harm that occurred as a result of Defendants' failures.

513. The Virginia Drug Control Act imposes certain specific responsibilities upon drug manufacturers, such as the Manufacturer Defendants, who manufacture and sell pharmaceutical drugs in Virginia. Va. Code Ann. § 54.1-3457. Among those responsibilities is the requirement that drug manufacturers refrain from the "dissemination of any false advertisement" in the promotion of their drugs. *Id.* "Advertisement" is defined as "all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs or devices." Va. Code Ann. § 54.1-3401.

514. The Manufacturer Defendants continually violated their duty to Plaintiff and its residents by making and/or disseminating false advertisements about opioids, including but not limited to:

(a) Making misleading statements about the true risk of addiction;

(b) Making deceptive statements concerning the ability of opioids to improve patient function long-term;

(c) Making deceptive statements about the efficacy of opioids for long-term treatment of chronic pain; and

(d) Promoting chronic opioid therapy as safe and effective for long term use for high-risk patients.

515. Manufacturer Defendants, by disseminating false and/or misleading advertisements, encouraged physicians to over-prescribe opioids to Plaintiff's residents, leading

to addiction. As a result, Plaintiff was saddled with the costs of harms arising from its residents' addictions.

516. The Manufacturer Defendants also failed to maintain effective controls against diversion, failed to report suspicious orders to law enforcement and perform due diligence prior to filling orders, and failed to design and operate a system to disclose suspicious orders of controlled substances, as required by the CSA.

517. Va. Code Ann.§ 54.1-3457 and the CSA were enacted, at least in part, to prevent the harms that can arise as a result of false advertisements and statements by drug manufacturers such as the Manufacturer Defendants and the other violations of the CSA as described herein.

518. Plaintiff is among the persons and entities intended to benefit from the protections of Va. Code Ann. § 54.1-3457 and the CSA, and the harm that has occurred as a result of the Manufacturer Defendants' violations are among the types of harm that the statutes were intended to prevent.

519. Therefore, as a proximate result of the false advertising and violations of the CSA, the Manufacturer Defendants have caused Plaintiff to incur excessive costs related to responding to the opioid crisis. These costs include, but are not limited to, the costs of healthcare, emergency medical services, social services, prevention, treatment, intervention, law enforcement, lost tax revenues, direct spending on opioids and opioid antagonists, and lost communal benefits of Lee County's limited and diverted resources as set forth more fully above.

COUNT VII
NEGLIGENCE PER SE
(AGAINST DISTRIBUTOR DEFENDANTS)

520. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

521. The Distributor Defendants failed to perform their statutory and regulatory obligations under the Virginia Drug Control Act, Va. Code Ann. § 54.1-3400 et seq., and the CSA,

which were enacted to promote safety and to prevent exactly the type of harm that occurred as a result of Defendants' failures.

522. Virginia and federal law impose certain specific responsibilities on Distributor Defendants, including the responsibility to design and operate a system to disclose suspicious orders of controlled substances. Va. Code Ann. § 54.1-3435.1(4); 21 C.F.R. § 1301.74(b). Furthermore, if Distributor Defendants cease distribution of opioids and certain other drugs "to a pharmacy, licensed physician dispenser, or licensed physician dispensing facility located in the Commonwealth due to suspicious orders of controlled substances" and inform the Virginia Board of Pharmacy within five days of the cessation. Va. Code Ann. § 54.1-3435. "'[S]uspicious orders of controlled substances' means, relative to the pharmacy's, licensed physician dispenser's, or licensed physician dispensing facility's order history and the order history of similarly situated pharmacies, licensed physician dispensers, or licensed physician dispensing facilities, (i) orders of unusual size, (ii) orders deviating substantially from a normal pattern, and (iii) orders of unusual frequency." *Id.*

523. Distributor Defendants are further required to "provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of prescription drugs." 18 VAC 110-50-90.

524. Distributor Defendants failed or refused to disclose suspicious orders to the DEA, the Board of Pharmacy, and boards whose licensees have prescribing authority, in violation of Virginia law and regulation and therefore failed to meet their duties as registered distributors of controlled substances.

525. The laws and regulations described above were enacted, at least in part, to prevent the harms that can arise as a result of an overabundance of opioids being made available in communities.

526. Plaintiff is among the persons and entities intended to benefit from the protections of these laws and regulations. The harm that has occurred is a proximate result of the Distributor Defendants' failure to abide by their legal obligations.

527. As a proximate result of failing to report and/or continuing to fill suspicious transactions, the Distributor Defendants have caused Plaintiff to incur excessive costs related to responding to the opioid crisis. These costs include, but are not limited to, the costs of healthcare, emergency medical services, social services, prevention, treatment, intervention, law enforcement, lost tax revenues, direct spending on opioids and opioid antagonists, and lost communal benefits of Lee County's limited and diverted resources as set forth more fully above.

COUNT VIII
NEGLIGENCE
(AGAINST ALL DEFENDANTS)

528. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

529. Defendants have a duty to Plaintiff to employ a reasonable standard of care in the sale, distribution, dispensing, reimbursement and promotion of prescription opioids. This includes a duty to not create a foreseeable risk of harm to others.

530. Defendants breached this duty by failing to take any action to prevent or reduce the unnecessary, non-medical or criminal use of opioids. Collectively, and individually, Defendants made prescription opioids available to the marketplace with the knowledge that they were likely being used for non-medical purposes and/or posed an inherent danger to patients who were using them for other than acute pain or palliative care.

531. Defendants were negligent in failing to monitor and guard against third-party misconduct and participated and enabled such misconduct.

532. Defendants placed their profit motives above their legal duty and enabled, encouraged and caused the over-prescribing and distribution of opioids.

533. All Defendants knew of the highly addictive nature of prescription opioids and knew of the high likelihood of foreseeable harm to patients and communities from prescription opioid addiction and diversion. Defendants breached their duties when they failed to act with reasonable care to prevent the diversion of prescription opioids.

534. A negligent and/or intentional violation of the Defendants' duties poses distinctive and significant dangers to the Plaintiff and its residents, including epidemic levels of addiction and the diversion of opioids for illegitimate purposes.

535. As a proximate result of the failure to prevent the over prescription and excessive distribution of opioids, the Defendants have caused the Plaintiff to incur excessive costs related to responding to the opioid crisis. These costs include but are not limited to, the costs of healthcare, emergency medical services, social services, prevention, treatment, intervention, law enforcement, lost tax revenues, direct spending on opioids and opioid antagonists, and lost communal benefits of Lee County's limited and diverted resources as set forth more fully above.

COUNT IX
GROSS NEGLIGENCE
(AGAINST ALL DEFENDANTS)

536. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

537. Defendants' scheme to optimize profits regardless of the effect on Lee County was undertaken and executed intentionally.

538. Defendants' failure to take any action to prevent or reduce the unnecessary, non-medical, or criminal use of opioids was grossly negligent in that it was done with indifference and an utter disregard of prudence that amounts to complete neglect of the safety of others and had a great probability of causing substantial harm.

539. Defendants' utter disregard of prudence was such that it is shocking to any fair-minded person.

540. As a proximate result of their grossly negligent conduct, the Defendants have caused the Plaintiff to incur excessive costs related to responding to the opioid crisis. These costs include but are not limited to, the costs of healthcare, emergency medical services, social services, prevention, treatment, intervention, law enforcement, lost tax revenues, direct spending on opioids and opioid antagonists, and lost communal benefits of Lee County's limited and diverted resources as set forth more fully above.

COUNT X
WILLFUL AND WANTON NEGLIGENCE
(AGAINST ALL DEFENDANTS)

541. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

542. Defendants' scheme to optimize profits regardless of the effect on Lee County was undertaken and executed intentionally.

543. Defendants' failure to take any action to prevent or reduce the unnecessary, non-medical, or criminal use of opioids was willfully and wantonly negligent in that it was done in conscious disregard of the rights of Lee County and its residents and/or with reckless indifference to the consequences of their actions.

544. At all relevant times, Defendants were aware, from their knowledge of existing circumstances and conditions, that their conduct would probably cause injury to Lee County and its residents.

545. As a proximate result of their willfully and wantonly negligent conduct, the Defendants have caused the Plaintiff to incur excessive costs related to responding to the opioid crisis. These costs include but are not limited to, the costs of healthcare, emergency medical services, social services, prevention, treatment, intervention, law enforcement, lost tax revenues, direct spending on opioids and opioid antagonists, and lost communal benefits of Lee County's limited and diverted resources as set forth more fully above.

546. Furthermore, Defendants should be held liable for punitive damages to Lee County because they had prior knowledge of the specific dangerous conditions their willful and wanton negligence created, they consciously disregarded that knowledge and continued to engage in their exceedingly dangerous course of conduct, and the harm inflicted on Lee County and its residents by Defendants' conduct was the natural and probable result of that conduct.

COUNT XI
UNJUST ENRICHMENT
(AGAINST ALL DEFENDANTS)

547. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

548. As an intended result of their intentional wrongful conduct as set forth in this Complaint, Defendants have knowingly profited and benefited from opioid purchases made by Plaintiff and its residents.

549. In exchange for opioid purchases, and at the time Plaintiff and its residents made these payments, Plaintiff and its residents expected that Defendants had not misrepresented any material facts regarding opioids, and had complied with their legal obligations in the manufacture, marketing, distribution, dispensation, and reimbursement of opioids.

550. Defendants have been unjustly enriched in the form of profits because of their wrongful conduct, and as a matter of equity, Defendants should be required to disgorge their unjustly obtained profits from purchases of opioids made by Lee County.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, Lee County, prays that the Court enter judgement against the Defendants, jointly and severally, as follows:

(1) awarding compensatory damages in an amount not less than $40,000,000, or as determined at trial;

(2) awarding punitive damages in the amount of $350,000 per defendant;

(3) awarding treble damages, as well as all costs and expenses of maintaining this action, including reasonable attorneys' fees, pursuant to statute where appropriate;

(4) awarding pre- and post-judgment interest;

(5) compelling the defendants to abate and remove the public nuisance they have caused by immediately ceasing the unlawful conduct described throughout this Complaint;

(6) such other and further relief as the Court deems just and proper.

[signature page follows]

Lee County

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