UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF WEST VIRGINIA

STATE OF WEST VIRGINIA *ex rel.*,
John B. McCuskey, Attorney General

Plaintiff,

v.

UNITEDHEALTH GROUP, INC.;
OPTUM, INC.;
OPTUMINSIGHT, INC. F/K/A INGENIX, INC.;
OPTUMINSIGHT LIFE SCIENCES, INC. F/K/A QUALITYMETRIC, INC.;
OPTUMRX, INC.;
OPTUMRX DISCOUNT CARD SERVICES, LLC;
OPTUM PERKS, LLC;
OPTUMHEALTH CARE SOLUTIONS, LLC;
OPTUMHEALTH HOLDINGS, LLC; and OPTUM HEALTH NETWORKS, INC.

Defendants.

COMPLAINT

Case No.: 5:25-cv-267 Bailey

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Plaintiff, the State of West Virginia ("Plaintiff" or "State"), by and through its Attorney General John B. McCuskey (the "Attorney General"), brings this action upon personal knowledge and upon information and belief from the investigation of counsel against UnitedHealth Group, Inc.; Optum, Inc.; OptumInsight, Inc. f/k/a Ingenix, Inc.; OptumInsight Life Sciences, Inc. f/k/a QualityMetric, Inc.; OptumRx, Inc.; OptumRx Discount Card Services, LLC; Optum Perks, LLC; OptumHealth Care Solutions, LLC; OptumHealth Holdings, LLC; and Optum Health Networks, Inc. (referred to collectively herein as "Optum").

In support of its claims, the State alleges as follows:

I. NATURE OF THE ACTION

1. The State brings this action against Optum—one of the nation's largest Pharmacy Benefit Managers ("PBM")—to hold it accountable for leveraging its market dominance to exacerbate the opioid epidemic, the worst man-made crisis in modern medical history.

2. By prioritizing profits over compliance and public safety, Optum violated its legal duties under West Virginia law, contributing directly to the oversupply of opioids and the deepening of opioid use disorder across the State.

3. The opioid crisis did not emerge in a vacuum—it was ignited and perpetuated by actors across the entire pharmaceutical supply chain. Manufacturers, distributors, pharmacies, and PBMs, including Optum, each played a pivotal role. While opioid manufacturers have drawn much of the public's scrutiny, Optum and other PBMs have worked to keep their own roles in the crisis obscured. That veil of secrecy is finally being lifted.

4. Optum has played a central, and concealed, role in enabling the widespread oversupply of opioids. Through a combination of intentional conduct, strategic partnerships, and calculated inaction, Optum helped facilitate the unchecked prescribing, dispensing, and sale of opioids in West Virginia. As a key intermediary between drug manufacturers, pharmacies, and

insurers, Optum inserted itself directly into the supply chain and, in doing so, assumed legal duties to act responsibly. It failed to do so.

5. As alleged in detail throughout this Complaint, Optum contracts with drug manufacturers, the pharmacies that dispense the drugs, and the payors who finance them. As a result, it occupies a uniquely powerful position at the center of the prescription drug ecosystem. Rather than using this influence to safeguard public health, Optum fueled the opioid crisis from behind the scenes while projecting an image of public concern.

6. Optum's misconduct was complex, far-reaching, and violated West Virginia law in multiple, distinct ways, including but not limited to:

- Conspiring with opioid manufacturers to deceptively market opioids and manipulate public perception regarding their safety and addictive potential;
- Securing preferred formulary placement for opioids in exchange for substantial rebates and fees—thereby incentivizing increased sales and undermining clinical judgment;
- Eliminating or weakening utilization management ("UM") protocols, such as prior authorization and quantity limits, which are designed to prevent excessive or inappropriate prescribing;
- Ignoring overwhelming internal and external data that signaled widespread abuse, overprescription, and patterns of diversion—choosing profit over public safety; and
- Dispensing opioids through mail-order pharmacies without adequate controls or oversight, in clear violation of West Virginia and federal controlled substances laws.

7. Optum's misconduct was enabled by its unmatched combination of access, influence, and insight into the West Virginia prescription drug system. Though originally created to handle administrative tasks, Optum has evolved into a powerful gatekeeper that dictates drug access, availability, and pricing.

8. But Optum is not only a PBM. It is also a pharmacy in West Virginia operating a mail-order pharmacy platform and functioning as a vertically integrated drug company under the ownership of UnitedHealth. Optum possesses vast data assets, including real-time prescription and claims information, which it uses for analytics, consulting, and targeted marketing. This data gave the company detailed insight into opioid prescribing trends in West Virginia.

9. With this data, Optum could identify red flags—including prescribers writing high volumes of opioid prescriptions, patients filling prescriptions from multiple providers or pharmacies, and the use of dangerous drug combinations. It also had access to refill patterns and overdose data. Despite this visibility, Optum failed to act and continued to prioritize revenue over public safety.

10. Through its control over formularies and UM programs, Optum had the power to limit access to high-risk opioids. Instead, it granted favorable formulary status to opioids, removed safety checks, and facilitated broader distribution—all while collecting substantial rebates and fees from manufacturers.

11. Optum's default formularies and UM protocols were widely adopted by plan sponsors, many of whom lacked the expertise or leverage to modify them. In practice, this meant that Optum dictated which opioids were available and how easily they could be obtained.

12. Rather than use its influence and data to reduce harm, Optum actively supported opioid manufacturers by helping plan marketing strategies, analyzing sales, and shaping formularies to maximize opioid utilization. These actions were taken in exchange for financial incentives.

13. Optum and opioid manufacturers formed an association-in-fact enterprise, the "Formulary & UM Enterprise" with the shared objective of maximizing opioid sales regardless of

the public health consequences. Optum participated in this enterprise by coordinating formulary and UM actions to increase prescribing, supporting misleading promotional efforts, and failing to comply with state and federal controlled substance laws. This conduct deceived the State and undermined the public assurances Optum made to its clients and the healthcare system.

14. Although Optum now points to remedial measures adopted under public scrutiny, its prior conduct reveals a clear pattern: it prioritized profit over compliance, safety, and the health interests of the State. Rather than using its data analytics capabilities to identify and mitigate the harms of excessive opioid distribution, Optum sold these services to opioid manufacturers, enabling manufacturers to refine their false, deceptive, and misleading marketing strategies to increase opioid sales within the State.

15. The consequences were devastating. Prescription opioid use exploded. Sales soared. The State was flooded with unnecessary, dangerous medications. Optum profited at every point in the chain—from rebates and fees, to pricing spreads, to the sale of healthcare data, to consulting arrangements with opioid manufacturers. Optum was not a passive actor. It was an architect of the crisis.

16. Optum helped build and sustain the opioid firestorm that has devastated the State. It must be held accountable.

II. PARTIES

A. Plaintiff

17. Plaintiff, the State of West Virginia, by and through its Attorney General, John B. McCuskey, appears to protect the interests of the State. The Attorney General is authorized by the West Virginia Constitution, West Virginia common law and by statute to bring this action.

18. John B. McCuskey is the duly elected Attorney General of West Virginia, an independent constitutional officer of the State of West Virginia and its chief law officer, with full authority to institute and prosecute all civil actions in which the State has an interest.

19. The Attorney General is charged with enforcing the West Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-1-101, *et seq*. ("WVCCPA"). Pursuant to W. Va. Code § 46A-7-108, the Attorney General is authorized to bring a civil action for violations of the WVCCPA and for other appropriate relief. *See State ex rel. McGraw v. Imperial Mktg.*, 506 S.E.2d 799, 811-12, 203 W. Va. 203 (1998). The Attorney General has all common law powers except those restricted by statute. *State ex rel. Discover Financial Services, Inc. v. Nibert*, 744 S.E.2d 625, 231 W. Va. 227 (2013).

20. To protect the quasi-sovereign interests in the public health and general welfare of the State, recover relief for past, ongoing, and future harms to these interests, and to address the opioid epidemic caused, in part, by Optum's conduct, the Attorney General, on behalf of the State, has standing as *parens patriae* to bring this action.

21. The State is entitled to the protections of sovereign immunity. Pursuant to Article VI, Section 35 of the West Virginia Constitution and West Virginia Code §55-17-4(3), the filing of this action shall not be construed as a waiver of that immunity and no counterclaim, set-off, recoupment, cross-claim, or other form of avoidance may be asserted in this action against the State of West Virginia.

B. The Optum Defendants

22. **Defendant UnitedHealth Group, Inc.** ("UnitedHealth Group" or "UHG") is a corporation organized under the laws of Delaware with its principal place of business at 9900 Bren Road East, Minnetonka, MN, 55343.

23. UnitedHealth Group may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

24. UnitedHealth Group is a Fortune 500 diversified managed healthcare company. In 2024, UnitedHealth Group listed revenue of roughly $400 billion. UnitedHealth Group offers a spectrum of products and services including health insurance plans and pharmacy benefits through its wholly owned subsidiaries.

25. UnitedHealth Group operates through two connected divisions—Optum and UnitedHealthcare ("UHC"). As discussed in greater detail herein, Optum provides PBM services, mail order pharmacy services, and data, analytics, consulting, and research services. UHC provides health insurance and health benefit services.

26. UnitedHealth Group, through its executives and employees, controls the enterprise-wide policies that govern both UHC's and Optum's lines of business in order to maximize profits across the corporate family.

27. Over two-thirds of the overall revenues of UnitedHealth Group come from Optum, which operates a network of more than 67,000 pharmacies.

28. UnitedHealth Group had declared in its annual Sustainability Report that "OptumRx works directly with pharmaceutical manufacturers to secure discounts that lower the

overall cost of medications and create tailored formularies — or drug lists — to ensure people get the right medications. We then negotiate with pharmacies to lower costs at the point of sale."[1]

29. In addition to being a PBM and a mail-order pharmacy, UnitedHealth Group owns and controls a major health insurance company, UnitedHealthcare. As a result, UnitedHealth Group controls the health plan/insurer, the PBM and the mail-order pharmacies utilized by tens of millions UnitedHealthcare members in the United States, including in West Virginia. UnitedHealth Group controls the entire drug pricing chain for these Americans.

30. At all times material herein, UnitedHealth Group transacted business in West Virginia and its conduct had a direct effect in West Virginia and damaged Plaintiff.

31. UnitedHealth Group has declared in prior annual reports that UnitedHealth Group utilizes Optum's capabilities to help coordinate patient care, improve affordability of medical care, analyze cost trends, manage pharmacy benefits, work with care providers more effectively and create a simpler consumer experience. In annual reports, it has represented that it is involved in establishing the prices charged by retail pharmacies, determining which drugs will be included in formulary listings and selecting which retail pharmacies will be included in the network offered to plan sponsors' members. As of December 31, 2021, "total pharmaceutical manufacturer rebates receivable included in other receivables in the Consolidated Balance Sheets amounted to $7.2 billion [2021] and $6.3 billion [2020]."[2]

32. **Defendant Optum, Inc.** ("Optum, Inc.") is a corporation organized under the laws of Delaware with its principal place of business located at 11000 Optum Circle, Eden Prairie,

[1]https://www.unitedhealthgroup.com/content/dam/UHG/PDF/2024/sustainability/2020-sustainability-report.pdf.

[2] *See generally* UnitedHealth Group Annual Report (Form 10-K) (FYE Dec. 31, 2018); UnitedHealth Group Annual Report (Form 10-K, Exhibit 21) (FYE Dec. 31, 2021).

Minnesota and may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801 and/or CT Corporation System, 600 N. 2nd Street, Suite 401, Harrisburg, Pennsylvania 17101.

33. Optum, Inc. is a health services company managing the subsidiaries that administer UnitedHealth Group's pharmacy benefits, including OptumRx, Inc.

34. Since 2005, Optum, Inc. has been a part of the UnitedHealth Group. As alleged above, UnitedHealth Group has two major segments of its business: UHC, which is its medical insurance arm, and Defendant Optum, Inc., which includes UnitedHealth Group's PBM and research, data, and consulting arms.

35. Optum, Inc. is engaged in five types of business activities relevant to this Complaint: (1) data analytics; (2) pharmacy benefit management; (3) healthcare services; and (4) mail-order pharmacy dispensing; and (5) medical discount card services.

36. At all times material herein, Optum, Inc. transacted business in West Virginia and its conduct had a direct effect in West Virginia.

37. Optum, Inc. is directly involved, through its executives and employees, in the company policies that inform its PBM services and formulary construction.

38. **Defendant OptumRx, Inc.** ("OptumRx") is a California corporation with its principal place of business at 2300 Main Street, Irvine, California, 92614. OptumRx is the arm of Optum that provides PBM and pharmacy dispensing services.

39. OptumRx is registered to do business in West Virginia (operating until 2011 under the name RxSolutions, Inc.). OptumRx, Inc. may be served through its registered agent: CT Corporation System, 5098 Washington St. W., STE 407, Charleston, WV 25313-1561.

40. OptumRx applied for and currently holds, and throughout the Relevant Period held, at least one active license with the West Virginia Insurance Commissioner to operate as a pharmacy benefits manager in the State of West Virginia and is registered with the DEA to dispense controlled substances, including opioids.

41. During the relevant time period, OptumRx provided PBM services in West Virginia, including in this Judicial District.

42. Prior to 2011, OptumRx was known as Prescription Solutions and grew as a result of numerous mergers and acquisitions. For example, in 2012, a large PBM, SXC Health Solutions, bought one of its largest rivals, Catalyst Health Solutions Inc., in a roughly $4.14 billion deal. Shortly thereafter, SXC Health Solutions Corp. renamed the company Catamaran Corp. Following this, UHG bought Catamaran Corp. in a deal worth $12.8 billion and merged Catamaran with OptumRx.

43. Prior to merging with OptumRx (or being renamed), Prescription Health Solutions, Catalyst Health Solutions, Inc., and Catamaran Corp. engaged in the at-issue PBM and mail order activities alleged more fully herein.

44. OptumRx now provides both PBM and mail-order dispensing services. At all relevant times, OptumRx provided PBM services for entities in West Virginia.

45. At all relevant times, OptumRx has sold and continues to sell prescription opioids in West Virginia through its mail order pharmacies (the "Optum Mail Order Pharmacy"). OptumRx is, and at all relevant times has been, registered with the DEA as a dispenser.

46. OptumRx and all of its predecessors, including but not limited to Prescription Health Solutions, Catalyst Health Solutions, Inc., and Catamaran Corp., are referred to herein as "OptumRx."

47. **Defendant OptumInsight, Inc.** (f/k/a Ingenix, Inc.) is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. OptumInsight was formerly known as Ingenix. The name change came after the State of New York investigated Ingenix related to a scheme to defraud consumers by manipulating reimbursement rates, resulting in a $50 million settlement with New York, a $350 million payout to settle a class action suit with providers, and giving rise to U.S. Congressional hearings.

48. OptumInsight, Inc. is registered to do business in West Virginia and may be served through its registered agent: United Agent Group Inc., 126 East Burke Street, Martinsburg, WV 25401 and/or CT Corporation System, 5098 Washington St. W., Ste. 407, Charleston, WV 25313-1561.

49. At all times material herein, OptumInsight, Inc. transacted business in West Virginia and its conduct had a direct effect in West Virginia.

50. As a result of numerous interlocking directorships and shared executives, UnitedHealth Group, OptumRx Holdings, LLC and Optum, Inc. are directly involved in the conduct of and control OptumInsight's and OptumRx's operations, management and business decisions related to the at-issue formulary construction, negotiations, and mail-order pharmacy services to the ultimate detriment of Plaintiff. For example:

a. These parent and subsidiaries have common officers and directors, including:

> Andrew Witty previously served as the Chief Executive Officer of Optum, Inc., UnitedHealth Group's health services subsidiary. In March 2018, UnitedHealth elevated Witty from Optum, Inc. to the parent company's senior leadership, and in February 2021 he was appointed Chief Executive Officer of UnitedHealth Group. Witty simultaneously served on UnitedHealth Group's Board of Directors during his tenure as CEO. He remained in both roles until May 2025, when he stepped down as Chief Executive Officer and subsequently resigned from the Board of Directors on May 22, 2025.

i. Dirk McMahon served as President & Chief Operating Officer of UnitedHealth Group from February 2021 until his retirement effective April 1, 2024, after more than two decades with the company. Prior to that, he was President & COO of Optum from April 2017 to June 2019, and before that he served as Chief Executive Officer of OptumRx from November 2011 to November 2014;

ii. John F. Rex joined Optum, Inc. in 2012 as Executive Vice President and Chief Financial Officer. He was appointed Executive Vice President and Chief Financial Officer of UnitedHealth Group in 2016 and was later elevated to President of UnitedHealth Group in 2024;

iii. Dan Schumacher is Chief Strategy & Growth Officer at UnitedHealth Group (since April 2021) and simultaneously CEO of OptumInsight. Before that, he served as President & Chief Operating Officer of Optum, Inc.;

iv. Terry M. Clark is Senior Vice President & Chief Marketing Officer of UnitedHealth Group (a role he's held since 2014) and, in 2022, added the title of Chief Marketing & Customer Officer for Optum;

v. Heather Cianfrocco joined UnitedHealth Group in 2008 and has held a succession of leadership roles across its businesses. She most recently served as CEO of Optum Rx and then CEO of Optum, Inc., and in May 2025 she was appointed Executive Vice President of Governance, Compliance & Information Security at UnitedHealth Group.;

vi. Peter M. Gill serves as Senior Vice President and Treasurer of UnitedHealth Group, Inc., and also holds the Treasurer role for its subsidiary OptumRx, Inc.;

vii. John Santelli joined UnitedHealth Group in 1986, has served as Chief Information Officer of UnitedHealth Group and as Executive Vice President of Optum Technology (the technology de-livery division of Optum, Inc.);

b. UnitedHealth Group is a diversified healthcare holding company. Optum, Inc. is a wholly owned subsidiary of UnitedHealth Group and serves as the parent company for UnitedHealth Group's health-services businesses. OptumRx, Inc. and OptumInsight, Inc. are each wholly owned—directly or

through one or more intermediate subsidiaries—by UnitedHealth Group. Accordingly, UnitedHealth Group directly or indirectly owns 100% of the stock of Optum, OptumRx, and OptumInsight, and exercises ultimate control over their management, operations, and policies.

c. The UnitedHealth Group corporate family does not operate as separate entities. The public filings, documents, and statements of UnitedHealth Group present its subsidiaries, including Optum, Inc., OptumRx, Inc., and OptumInsight as divisions, departments or "segments" of a single company that is "a diversified family of businesses" that "leverages core competencies" to "help[] people live healthier lives and helping make the health system work better for everyone." The day-to-day operations of this corporate family reflect these public statements. These entities are a single business enterprise and should be treated as such as to all legal obligations detailed in this Complaint.[3]

d. All the executives of Optum, Inc., OptumRx, Inc., and OptumInsight ultimately report to the executives, including the CEO, of UnitedHealth Group.

51. **Defendant OptumInsight Life Sciences, Inc.** (f/k/a QualityMetric, Inc.) is a Delaware corporation with its principal place of business located at 11000 Optum Circle Eden Prairie, MN 55344. OptumInsight Life Sciences, Inc. is a wholly-owned subsidiary of UHG. Prior to 2011, OptumInsight Life Sciences, Inc. was known as QualityMetric.

[3] UnitedHealth Group, Quarterly Report (Form 10-Q) (FQE Mar. 31, 2017).

52. OptumInsight Life Sciences, Inc. may be served through its registered agent: CT Corporation System, 40600 Ann Arbor Road East, Suite 201, Plymouth, Michigan 48170 and/or 640 George Washington Highway, Lincoln, Rhode Island 02865.

53. OptumInsight, Inc. and OptumInsight Life Sciences, Inc., as well as their predecessors, successors, affiliates, including but not limited to Innovus, Innovus Research, i3, QualityMetric, HTAnalytics, ChinaGate, and CanReg, are referred to herein as "OptumInsight." OptumInsight is the Optum group that engages in data analytics.

54. OptumInsight emerged from a collection of entities acquired by the UnitedHealth Group over the years. Those legacy entities include Innovus, QualityMetric, HTAnalytics, ChinaGate, CanReg, Ingenix, and the Lewin Group.

55. OptumInsight partnered with various opioid manufacturers to create studies, marketing, educational programs, and even identifying algorithms to simultaneously downplay opioids' addictive properties and expand their use and availability throughout the country, including in West Virginia.

56. Defendant OptumRx Discount Card Services, LLC is a Delaware limited liability company with its principal place of business at 1101 Red Ventures Drive, Fort Mill, South Carolina 29707.

57. OptumRx Discount Card Services, LLC is registered to do business in West Virginia and may be served through its registered agent: CT Corporation, 5098 Washington St. W, Ste. 407, Charleston, WV 25313.

58. OptumRx Discount Card Services, LLC (formerly HealthTran, Inc.; Catamaran PBM of Colora-do, LLC; and Catamaran Discount Card Services, LLC) contracts with third-party businesses to administer their prescription discount card programs. For example, the American

Association of Retired Persons ("AARP") prescription discount card is merely endorsed by AARP, but the pro-gram itself is administered by OptumRx Discount Card Services, which pays AARP a royalty fee for the use of its intellectual property.

59. At all times material herein, OptumRx Discount Card Services, LLC transacted business in West Virginia and its conduct had a direct effect in West Virginia.

60. Defendant Optum Perks, LLC is a Delaware limited liability company with its principal place of business in Livonia, Michigan.

61. Optum Perks, LLC may be served through its registered agent for process: The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801.

62. Optum Perks, LLC (f/k/a Script Relief, LLC) is a discount card program that originally started as a joint venture between Loeb Enterprises, LLC, and Catalyst, where by 2012 Catalyst had a 47% ownership interest. Per Catamaran's 2012 10-K, "Script Relief is a variable interest entity with Catamaran being the primary beneficiary, as the Company's underlying PBM and pharmacy contracts represent Script Relief's key business operations and the Company has the power to direct these activities."

63. By 2019, OptumRx, Inc. had fully acquired Script Relief and renamed the program Optum Perks.

64. At all times material herein, Optum Perks, LLC transacted business in West Virginia and its conduct had a direct effect in West Virginia.

65. **Defendant OptumHealth Care Solutions, LLC** is a Delaware limited liability company with its principal place of business at 11000 Optum Cir., Eden Prairie, Minnesota 55344.

66. OptumHealth Care Solutions, LLC is registered to do business in West Virginia and may be served through its registered agent: United Agent Group Inc., 126 East Burke Street,

Martinsburg, WV 25401 and/or CT Corporation System, 5098 Washington St. W., Ste. 407, Charleston, WV 25313-1561.

67. OptumHealth partnered with Purdue to "educate" many case managers, nurse practitioners, and medical directors throughout UnitedHealth Group's various enterprises. These programs were specifically endorsed and coordinated through one of OptumHealth's national medical directors. The content of these programs targeted pain as an undertreated disease, among other issues, and contained the similar dangerous messaging regarding the use of OxyContin that Purdue plead guilty to in 2007.

68. At all times material herein, OptumHealth transacted business in West Virginia and its conduct had a direct effect in West Virginia.

69. **Defendant OptumHealth Holdings, LLC** is a Delaware limited liability company with its principal place of business at 11000 Optum Cir., Eden Prairie, Minnesota 55344 and may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

70. At all times material herein, OptumHealth Holdings transacted business in West Virginia and its conduct had a direct effect in West Virginia.

71. **Defendant Optum Health Networks, Inc.** is a Delaware corporation with its principal place of business at 9900 Bren Road East, Minnetonka, Minnesota 55343. Optum Health Networks, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

72. At all times material herein, Optum Health Networks, Inc. transacted business in West Virginia and its conduct had a direct effect in West Virginia.

73. Optum Health Networks, Inc. provides care services to enrolled members of its subsidiaries and parents that include care management services, arranging for delivery of services, and managing client relationships and contracts for access to said services.

74. Together, OptumHealth Care Solutions, LLC, Optum Health Holdings, LLC, and OptumHealth Networks, Inc. are referred to herein as "OptumHealth."

75. OptumHealth is a healthcare service provider that includes specialty health services, health banking services, ancillary care networks, and health education and information services to both individuals and health care professionals. It does this through four main lines of business: Care Solutions, Behavioral Solutions, Specialty Benefits, and Financial Services. In 2022, OptumHealth served 102 million individuals.[4]

76. Relevant to the opioid epidemic and Plaintiff's claims, OptumHealth partnered with opioid manufacturers throughout the 2000s to provide so-called "education" to health care providers, including medical directors, nurse practitioners, case managers, and care advisors throughout the country, including in West Virginia, regarding the so-called "undertreatment" of pain to expand the use of opioids.

77. Optum is named as a Defendant in its capacities as a: (1) PBM; (2) data, analytics, consulting, and research provider; (3) Mail Order Pharmacy and (4) discount card servicer and provider. During the relevant time period, Optum contracted directly with the opioid manufacturers in each of these capacities. At all relevant times, Optum performed these services and derived substantial revenue in West Virginia.

[4]https://www.sec.gov/ix?doc=/Archives/edgar/data/731766/000073176623000008/unh-20221231.htm.

78. At all times relevant hereto, Optum offered pharmacy benefit management services nationwide and in West Virginia and maintained various standard, national drug lists that were offered to and used by Optum's clients both across the country, in West Virginia, and this District. At all times relevant hereto, those formularies included opioids, including those at issue in this case. OptumRx national formularies include the Essential Health Benefits, Generic Centric, Core Standard, Core Choice, Select Standard, Select Choice, Premium Standard, and Premium Choice.

79. Optum (and/or its predecessors) processed claims for opioids dispensed pursuant to Optum's standard, national formularies and UM guidelines in West Virginia and this Judicial District throughout the opioid epidemic.

80. In addition to its pharmacy benefit services, Optum entities also provide services related to pharmaceutical reimbursement and dispensing that generate revenue and benefit from a lack of opioid controls.

81. At all times relevant hereto, Optum offered mail-order pharmacy services and dispensed opioids in West Virginia and in this District.

82. In 2021, Optum's Mail Order Pharmacy was the fourth largest dispensing pharmacy in the United States and made $34.2 billion in prescription revenues.

83. OptumInsight, Optum's data, research, and consulting arm, is one of the largest health information, technology, and consulting companies in the world. OptumInsight is an integral part of the conduct that gives rise to Plaintiff's causes of action. As alleged in detail herein, throughout the relevant time period, OptumInsight worked directly with opioid manufacturers to convince patients, prescribers, payors and the public, including in West Virginia, that long term opioid use was appropriate for the treatment of chronic pain and that opioids were not addictive.

84. Each opioid manufacturer had dedicated executives assigned to work with OptumInsight. The opioid manufacturers used their relationships with OptumInsight to deepen their ties to the overall Optum corporate family.

85. OptumInsight was paid tens of millions of dollars by the opioid manufacturers during the relevant time period for its work to expand the opioid market.

86. At all times material herein, Optum (and/or its predecessors) transacted business in West Virginia and its conduct had a direct effect in West Virginia. Upon information and belief, Optum derived and continues to derive substantial revenue as a result of managing pharmacy benefits throughout West Virginia.

87. At all times material herein, Optum's transaction of business in West Virginia involves trade or commerce within the meaning of the WVCCPA.

III. JURISDICTION AND VENUE

88. This Court has jurisdiction over the subject matter of this case pursuant to 28 U.S.C. § 1331 because the State's claims under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961, *et seq.*, raise a federal question. This Court has supplemental jurisdiction over the State's state-law claims under 28 U.S.C. § 1367 because those claims are so related to the RICO claim as to form part of the same case or controversy.

89. This Court has personal jurisdiction over Optum because it, through its authorized agents, servants and employees, regularly transacted business in West Virginia and further through its acts and omissions tortiously caused injuries in West Virginia by engaging in a persistent course of conduct in West Virginia that violated federal and West Virginia law. Moreover, Optum derived substantial revenue as the result of the controlled substances that were distributed to West Virginia entities and later consumed by persons then residing in West Virginia.

90. This Court also has personal jurisdiction over Optum because it is registered with the Secretary of State to conduct business in West Virginia and has purposefully availed itself to his forum. Optum transacted or solicited business, derived revenue from products and services, and caused tortious injury in West Virginia—both by acts committed within the State and acts committed outside the State that produced harm within it. It has sufficient minimum contacts to support the exercise of jurisdiction.

91. Venue is appropriate in the Wheeling Division of the Northern District of West Virginia because Optum transacts business in, maintains agents, or is otherwise found in the District, and because a substantial part of the events or omissions giving rise to this action took place, or had their ultimate injurious impact, within the District and Division, and because a substantial part of the events or omissions giving rise to this action took place, or had their ultimate injurious impact, within the District. In particular, at all times, Optum provided pharmacy benefit services, provided mail-order pharmacy services, employed sales representatives, promoted and sold opioids in Brooke, Hancock, Marshall, Ohio and Wetzel Counties within the District and Division, and caused injury to the State of West Virginia in this District and Division.

92. This Court further has venue over this action pursuant to 28 U.S.C. § 1391.

IV. FACTUAL ALLEGATIONS

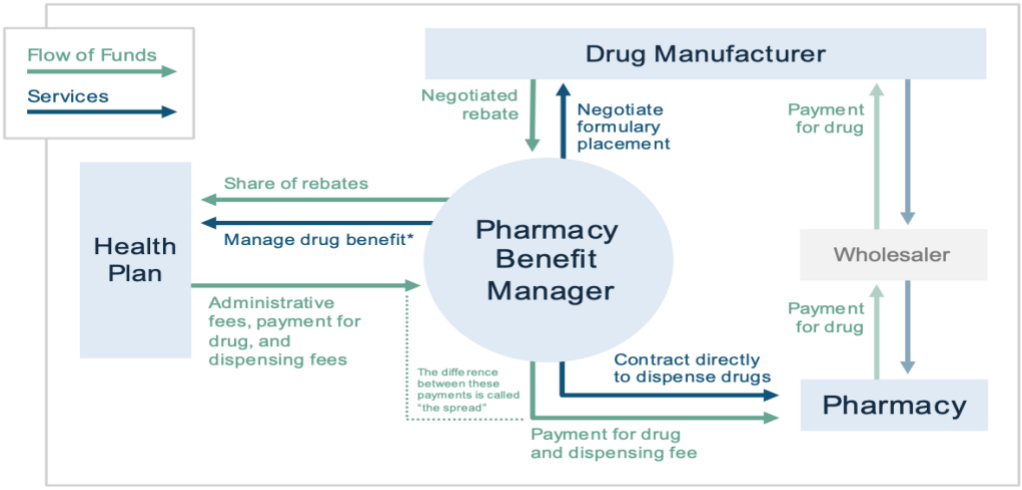
A. The Role of Pharmacy Benefit Managers in Prescription Drug Transactions

1. PBMs Operate on All Sides of Prescription Drug Transactions

93. In the United States, drug distribution typically involves three transactions. A drug manufacturer sells its product to a wholesaler, the wholesaler supplies pharmacies, and those pharmacies then dispense the medications to consumers, with costs shared between the consumer and their health insurance plan.

94. PBMs sit at the center of prescription drug dispensing—they contract with drug manufacturers to determine which drugs are covered by insurers and at what reimbursement rates. They also contract with pharmacies to establish dispensing terms and reimbursement structures. Finally, they are hired by their clients, third-party payors such as health insurance plans, to administer pharmacy benefits for consumers, including processing claims and managing patients' out-of-pocket costs.

95. PBMs contract with their third-party payor health insurance clients to make safe and effective drug therapies available to their covered lives. But they are also paid by drug manufacturers to provide the greatest access to their products, so as to increase sales, with little to no regard for safety or efficacy. And they are also paid by the pharmacies that fill plan beneficiaries' prescriptions, both to verify coverage and to ensure that a prescription is appropriate. Thus, in any given transaction, the PBM, including in this case Optum, may be receiving money from both the insurer client and the pharmacy to exercise independent judgment about whether to authorize payment for a prescription, while also receiving money from the manufacturer to ensure that the sale is made. This business model is unmistakably rife with conflicts of interest and self-dealing, through which PBMs have enriched themselves at the expense of their clients and the public. More so, inherent in the services offered by PBMs in their agreements with the opioid manufacturers (and with pharmacies) are the same services for which they are already ostensibly receiving payment from their clients, albeit with the incentives often running in the opposite direction, as depicted below:



2. PBM Formularies and Financial Incentives

96. By simultaneously engaging with manufacturers, pharmacies, and insurance plans, PBMs, including Optum, wield significant influence over drug prescribing, dispensing, and sales in the United States and in West Virginia through their control of formularies. Formularies—lists of drugs covered by health insurer plans—determine which medications are accessible to patients, under what conditions, and at what costs. Typically structured in tiers, formularies favor certain drugs by offering lower copays for preferred brands, while excluding or disadvantaging nonpreferred alternatives. Manufacturers secure favorable formulary placement by paying a PBM "rebates"[5] or other fees.

97. PBMs offer formularies to clients for managing drug benefits and defining coverage. These formularies directly influence prescribing behavior and patient access: drugs listed on preferred tiers are less expensive for patients, making physicians more likely to prescribe them and patients more likely to fill those prescriptions. Driving utilization through formulary design is not incidental—it is a core function of a PBM business operation.

[5] PBMs do at times share manufacturer rebates with their clients; however, they generally pass through only a portion (if any) of these rebates to their clients and retain the rest as profits.

98. PBMs' clients, including health insurers and government payors, rely heavily on PBMs' expertise in constructing formularies. Even sophisticated clients often adopt a PBM's standard national formularies with no or minimal modification. As a result, PBMs, such as Optum in this case, effectively determine drug access and utilization for millions of Americans, giving them immense leverage in negotiating rebate agreements with drug manufacturers, including opioid producers.

99. As alleged throughout this Complaint, Optum exploited its market dominance to structure standard formularies in ways that expanded access to opioids. It entered into a *quid pro quo* arrangement with opioid manufacturers—lowering barriers to patient access in exchange for increased rebate and other fee payments. These financial incentives compounded over time, as greater opioid sales generated larger rebates and, in turn, higher profits for Optum.

100. Rebates paid by manufacturers are tied to favorable formulary placement, while drugs placed on non-preferred tiers may not generate any rebates at all. Thus, Optum is financially incentivized to prioritize opioids on its formularies in preferred tiers, despite known risks, to maximize rebate income.

101. Higher dispensing volumes also allow Optum to negotiate higher rebates in future contracts, further increasing its revenues. Additionally, Optum profits from spread pricing, where it charges clients more for a drug than it reimburses pharmacies—especially lucrative in the context of generic opioids.

102. Optum also receives significant undisclosed payments from opioid manufacturers in the form of "administrative" or "service" fees, purportedly for formulary management and related services—duties it was already being paid to perform by its clients. By relabeling rebates and using opaque accounting practices, Optum has concealed these financial arrangements,

avoiding contractual obligations to pass through these payments and further obscuring its role in driving opioid utilization. As industry expert Linda Cahn has observed, "[i]f a PBM enters into contracts with drug manufacturers and chooses to give rebates another name—like administrative fees or health management fees or grants—the PBM will arguably eliminate its obligation to pass through the financial benefits to its clients."[6]

103. In sum, Optum had a financially entrenched interest in maintaining and increasing opioid prescriptions because it profited from every angle of the opioid transaction—paid by the manufacturers, the pharmacies, and the payors—all while shaping access and demand through its formularies. Its actions were not passive, they were integral to the design and expansion of a system that prioritized profits over safety, directly contributing to the scale and severity of the opioid crisis.

3. PBMs' Role in Utilization Management

104. In addition to formulary design, PBMs, including Optum in this case, develop and offer standard drug UM programs—rules intended to regulate access to medications. These tools include: (i) quantity limits: caps on the dosage or supply a patient can receive; (ii) step therapy: requiring patients to try alternative treatments before receiving the prescribed drug; and (iii) prior authorizations: requiring a prescriber to justify the medical necessity of a prescription before it can be filled.

105. PBMs, including Optum, typically offer UM programs as part of their standard service packages, which most clients adopt with minimal or no customization, thereby allowing Optum to exert significant influence over drug utilization patterns across the healthcare system.

[6] *See* Jeanne Pinder, "Don't Get Trapped By PBM's Rebate Labeling Games: Managed Care magazine by Linda Cahn" Clear Health Costs (Feb. 26, 2018).

4. PBMs Contract with Pharmacies and Their Oversight of Dispensing

106. As part of their central role in the prescription drug supply chain, PBMs, including Optum, also contract directly with retail pharmacies to facilitate the dispensing of medications to patients.

107. When a patient fills a prescription at an in-network pharmacy, the PBM coordinates payment: the patient pays a copayment, and the PBM reimburses the pharmacy for the balance. This real-time processing eliminates the need for patients to pay out-of-pocket and later seek reimbursement.

108. PBMs determine both the copay amount and the reimbursement rate for each covered medication, figures typically based on pre-set pricing structures tied to their standard formulary. In doing so, PBMs, including Optum, exert significant influence over the actual cost and access to medications at the pharmacy level.

109. Importantly, Optum also receives real-time claims data from pharmacies at the point of sale, as part of its electronic adjudication of claims, which includes determining eligibility for reimbursement and conducting concurrent drug utilization ("cDUR")—a process intended to flag safety concerns such as dangerous drug interactions or high-risk prescriptions like opioids.

110. Optum routinely failed to implement or enforce adequate cDUR protocols for opioids, allowing the widespread and unchecked dispensing of addictive drugs despite having the real-time data and authority to intervene.

B. Optum's Role in the Opioid Epidemic

111. Optum played a central role in fueling the opioid epidemic through a pattern of conduct that promoted the oversupply and overuse of prescription opioids. Optum is legally responsible for: (i) knowingly or negligently colluding with manufacturers to expand opioid supply through misrepresentations and omissions of known risks; (ii) undertaking, but failing to

implement, safe formulary design, UM protocols, and drug utilization review processes, despite publicly representing that it would do so; (iii) deliberately choosing to avoid implementing restrictions, even while possessing detailed data showing that unrestricted opioid access was causing, and would continue to cause, foreseeable harm to West Virginia and its residents; and (iv) violating West Virginia law by failing to maintain required safeguards in both dispensing operations and broader benefit management practices, thereby facilitating diversion and abuse.

112. Through these actions and omissions, Optum not only breached its legal obligations but directly contributed to the widespread harm caused by the opioid epidemic. Its conduct was false, deceptive, misleading, unlawful, intentional, and/or negligent, and warrants accountability under West Virginia law.

1. Optum and the Opioid Manufacturers Colluded to Ensure Virtually Unfettered Access to Opioids

a. Optum Negotiated with the Opioid Manufacturers to Give Opioids Favorable Placement on National Formularies in Exchange for Rebates and Other Fees

113. As summarized above, Optum holds significantly more market power than the drug manufacturers with which it negotiates, giving it the leverage to extract substantial rebates and fees in exchange for favorable formulary placement. This imbalance enabled Optum to enter into secretive agreements with opioid manufacturers—agreements that fueled an illegal scheme to boost opioid sales while hiding key financial terms from its own health plan clients.

114. These arrangements remained largely hidden until confidential documents were disclosed in *In re: National Prescription Opiate Litigation*, Case No. 1:17-md-2804 (N.D. Ohio),

and related proceedings, revealing how undisclosed PBM-manufacturer agreements contributed to the widespread oversupply of opioids across the United States.[7]

115. From the 1990s, Optum operated what were known as "open" formularies, which provided plan coverage for nearly all FDA-approved drugs—albeit with varying degrees of access and cost-sharing. Under this model, manufacturers competed to have drugs strategically positioned on formularies to ensure maximum accessibility and minimal patient cost, thereby increasing utilization. As a result, Optum, and other PBMs, gained significant leverage to extract rebates in exchange for favorable placement.

116. By the 2000s, however, Optum began transitioning from "open" formularies to "closed" formularies as its standard offering. Unlike open formularies, which covered most FDA-approved drugs, closed formularies limit the number of covered drugs and impose tiered benefit structures, effectively controlling access and cost-sharing. For the past two decades, the majority of Optum's covered lives have been governed by these more restrictive formularies.

117. Optum recognized it could leverage the exclusivity provided by "closed formularies" to its financial gain, which it has now done for more than two decades.

118. Indeed, since at least 2000, Optum extracted millions of dollars in rebates and other fees from prescription opioid manufacturers in exchange for preferred formulary placement for the manufacturers' opioid products. The prescription opioid manufacturers were eager participants in

[7] Documents produced in the National Opioid Litigation and cited within this Complaint and other opioid litigations provide countless examples of evidence of the collusion between PBMs, including Optum, with opioid manufacturers to drive sales of opioids in exchange for rebates. *See, e.g., Attorney General Dana Nessel on Behalf of the People of the State of Michigan v. Express Scripts, et. al,* Case No. 24-01567 (Wayne County Ct., Mich. 2024) (citing *In re National Prescription Opiate Litigation – PBM Cases*, No. 17-2804 (N.D. Ohio); *Commonwealth of Kentucky ex. rel. Russell Coleman, Attorney General, v. Express Scripts*, *et. al*, Case No. 24-CI-00594 (Jessamine Circuit Court, Div. I).

this enterprise because of the virtually unrestricted formulary status they purchased for their drugs in exchange for rebates and other fees paid to Optum.

119. Opioid manufacturers quickly recognized that Optum was willing to provide unrestricted formulary placement for opioids on its standard closed formularies in exchange for higher rebates and other financial incentives. For most of the relevant time period, OptumRx granted OxyContin unrestricted, preferred formulary status for most of its standard formularies. Along with the aforementioned lack of prior authorization, OptumRx refused to implement effective quantity limits on prescription opioids.

120. From the outset, opioid manufacturer Purdue Pharma L.P.'s ("Purdue") goal was clear: push OxyContin aggressively. As early as 1996, Purdue instructed its sales force to promote OxyContin as the drug of choice for a wide range of pain conditions, both cancer and non-cancer. The result was staggering—OxyContin sales surged to nearly $2 billion annually by 2003, and prescriptions for non-cancer pain grew nearly tenfold, from 670,000 in 1997 to 6.2 million in 2002.

121. OptumRx allowed OxyContin to have a quantity limit of four tablets a day of any strength, including 80 mg strengths, until 2017. However, quantity limits applied only to specific individual NDCs for opioid medications, meaning a downstream consumer could purchase the quantity limit of multiple different formulations of the same opioid at a time.

122. In 2010, Purdue agreed to pay rebates to OptumRx so long as OptumRx's downstream consumers were able to obtain 320 mg per day of OxyContin, whether through multiple NDCs or four tablets of 80 mg OxyContin a day.

123. But the 320 mg limit did not apply to short-acting opioids. In fact, OptumRx increased its quantity limits for short-acting opioids between 2007 and 2012. For example, the quantity limit for Endo's Opana was 12 tablets a day, or 1,080 tablets for a 90-day supply.

124. By mid-2014, Optum's quantity limits for Purdue's MS Contin were 120 tablets a month, with the 200 mg strength at 90 tablets a month; Janssen's 100 mg Nucynta was 210 tablets per month, with lesser strengths at 180 tablets per month; Endo's Opana was 180 tablets per month; and Purdue's OxyContin was 270 tablets per month. None of these opioids featured a prior authorization.

125. In 2015 and 2016, OptumRx increased the QL on UHG commercial plans. Hydromorphone limits for 2mg and 4mg strengths were increased from six to eight tablets a day. MS Contin limits were increased from three to four tablets a day for the 30 and 60 mg strengths, and from one to two tablets a day for the 200 mg strength due to "PA volume" to override the current QL. The morphine dose equivalent maximum was 360 tablets for UHG commercial plans.

126. Optum has been so successful in working with the opioid manufacturers to optimize their common purpose between formulary placement/UM and rebates and other fees that payments have reached as high as 70% to 80% off wholesale acquisition cost for some opioid drugs.

127. To make matters worse, as the market shifted from branded opioids to generics in the mid-2000s, Optum continued to grant generic opioids unrestricted and preferred placement on its standard formularies because of the profits these drugs generated through spread pricing and in other ways. Indeed, Optum's own internal presentation from 2013 touted generic utilization as a "high driver of revenue and profit," even more so than brand rebates.[8]

b. Optum and the Opioid Manufacturers Used Parity to Limit the Use of Utilization Management Measures for Prescription Opioids

128. Optum had powerful financial incentives to prioritize opioids over safer, often non-pharmacological, alternatives. Opioids generated outsized profits through mechanisms like

[8] OPTUMRX_JEFFCO_0594849, 52.

rebates, fees, and spread pricing. While publicly asserting that UM tools were in place to ensure the safe and effective use of medications, Optum was privately entering into confidential agreements with opioid manufacturers that deliberately undermined those very safeguards.

129. Instead of implementing critical UM measures to limit the inappropriate prescribing of opioids, Optum actively negotiated away those tools in exchange for financial gain. Those UM tools, including prior authorization, step therapy, and dose limitations, could have dramatically curbed the overprescription, misuse, and diversion of opioids in West Virginia and nationwide. Yet Optum agreed not to impose such restrictions, thereby ensuring opioids would remain broadly and easily accessible.

130. Through these confidential negotiations, Optum entered into rebate agreements with opioid manufacturers that contained "parity" and "no disadvantage" provisions—contractual commitments that guaranteed opioid products would not face formulary restrictions unless every competitor in the class was subject to the same limitations. In practice, these provisions ensured that opioids received equal, if not preferential treatment, compared to drugs without the same high risk of addiction.

131. These "parity" and "no disadvantage" provisions had a predictable and devastating effect: they removed key barriers to overprescribing and opened the floodgates to opioid overuse. Optum and opioid manufacturers shared a common purpose—to maximize the distribution of opioids with minimal oversight in service of mutual financial gain.

132. These agreements were detailed and explicit. For example, Optum's template rebate agreement had similar language tying payment of rebates to common treatment of all other opioids in the formulary's therapeutic category. The language in its agreements stated that rebates would only be payable if the opioid manufacturer's product was not "subject to Disadvantaging

including, but not limited to: prior authorization, NDC blocks, counter-detailing, copay differentials, dispensing restrictions, or endorsed targeted messages (electronic edits).[9]

133. As an additional example, the 2011 Rebate Agreement between OptumRx (then known as Prescription Solutions) and Johnson & Johnson for Nucynta (and other J&J drugs) required that it "not be disadvantaged as compared to other Branded or specialty Drugs within the Manufacturer Drug's Defined Drug Market. . . ."[10]

134. The 2012 Catamaran (now part of OptumRx) rebate agreement with Reckitt Benckiser for Suboxone Film required that it "not be subject to disadvantaging including, but not limited to: prior authorization, NDC blocks, counter-detailing, copay differentials, dispensing restrictions, therapeutic conversion programs, therapeutic substitution, other access or reimbursement restrictions, or endorsed targeted messages (electronic edits)."[11]

135. Likewise, in 2012 negotiations between OptumRx and the drug maker Covidien with regard to tiering of its opioid drug, the parties agreed to use the OptumRx "boilerplate disadvantaging language."[12]

136. The 2016 agreement between OptumRx and Depomed with regard to its opioid drug Nucynta required that "[p]rior authorization shall not be allowed unless applied to all other single source branded Drugs in the Defined Drug Market that are on Formulary . . . ."[13]

137. The same was true, upon information and belief, for Teva's 2015 agreement with OptumRx, which required unrestricted access and "parity" between its fentanyl drug Fentora and

[9] OPTUMRX_JEFFCO_0000473712 (3/20/14).

[10] OPTUMRX_JEFFCO_0000006804 (1/1/11), 05.

[11] OPTUMRX_JEFFCO_0000473712 (3/20/14).

[12] OPTUMRX_JEFFCO_0000140266 (6/1/12).

[13] OPTUMRX_JEFFCO_0000011106 (4/1/16), p. 8.

other drugs in its "Defined Drug Market," meaning that there would be no prior authorization limits unless it is applied to all "competing drugs" as well.[14]

138. These lockstep parity provisions effectively neutralized UM measures across the entire opioids class. They ensured no single product would be singled out for oversight, and that the market for prescription opioids would remain insulated from meaningful regulation. The rebate agreements tied payment to this uniform, unrestricted access—prohibiting prior authorizations, step therapy, or other controls unless every competitive product faced identical treatment.

139. The opioid manufacturers knew that UM presented a slippery slope—if more UM were employed, it would ultimately lead to the adoption of restrictions across the entire class of drugs.

140. Ultimately, Optum's coordination with manufacturers around rebate-driven formulary placement and the suppression of UM controls resulted in staggering financial rewards.

c. Optum Misrepresented that It Was Using Formularies to Promote Safe Use and Appropriate Prescribing of Opioids

141. Rather than offering transparency about its dealings with opioid manufacturers, Optum concealed and falsely represented to clients, patients, and the public that its formulary designs were guided by a commitment to safe and appropriate opioid prescribing.

142. For years, Optum publicly held itself out as a champion of patient safety and healthcare improvement, claiming that its work promoted better health outcomes and safer prescription drug use. These representations were repeated in SEC filings, public reports, and media interviews, painting a picture of Optum as responsible stewards of public health:

- In its 2008 Annual Report, UHG represented: "Beyond the data and technology, and beyond the numbers and networks, our businesses are made up of people

[14] TEVA_CAOC_08826718 (1/12/17).

who strive, every day, to fulfill our mission by helping people live healthier lives."

- UnitedHealth Group's 2009 Annual Report stated: "Information technology has the power to transform health care. UnitedHealth Group built a $2 billion business, Ingenix [OptumInsight predecessor], around that idea. Ingenix is committed to using the power of health information and analytics to help save lives, improve care and modernize the health care system."

- In UnitedHealth Group's 2011 Annual Report, it stated, "OptumRx is dedicated to helping people achieve optimal health . . . improving quality and safety, increasing compliance and adherence, and reducing fraud and waste."

- Similarly, UnitedHealth Group represented in its 2013 Annual Report that "UnitedHealth is advancing strategies to improve the way health care is delivered and financed . . . ."

143. Yet, these assurances stood in stark contrast to Optum's actual practices—profiting from rebates and fees paid by opioid manufacturers while granting unrestricted formulary access to dangerous drugs like OxyContin. Behind the scenes, Optum prioritized revenue over safety, abandoning the very principles of clinical oversight and care it publicly claimed to uphold.

2. For Over Two Decades—Even After Knowing the Dangers—Optum Conspired With Opioid Manufacturers to Deceptively Market and Promote Opioids

144. Opioid manufacturers launched a coordinated and well-funded campaign to redefine the way opioids were viewed and prescribed in West Virginia. Their goal was to expand the opioid market by convincing prescribers and the public that these highly addictive drugs were safe, effective, and appropriate for long term use.

145. Optum knew that there has never been reliable evidence demonstrating prescription opioids were safe or effective at treating chronic pain long term. Optum further knew that prescription opioids carry serious risks of addiction, particularly when used long term to treat chronic pain. And yet, starting shortly after the release of OxyContin and continuing for years after

the opioid epidemic extended throughout West Virginia, Optum worked with the prescription opioid manufacturers to spread misleading messaging about opioids as a class of drugs. In particular: (1) Optum disseminated the opioid manufacturers' false, deceptive, or misleading messages about chronic pain and addiction to prescribers and patients, and (2) Optum provided research, data, and consulting services to the opioid manufacturers to assist in expanding the opioid market.

146. As one example, in early 2003, representatives from UnitedHealth Group and its subsidiary OptumInsight met with Purdue to present and discuss a joint initiative focused on chronic lower back pain. The purpose of the meeting was to explore a coordinated effort to influence physician prescribing practices and expand the acceptance of opioids for chronic pain management. The initiative involved targeting physicians whose treatment approaches did not align with UnitedHealth's preferred clinical strategies, with the intent of changing their prescribing behavior in favor of increased opioid use.

147. As a result of this meeting, in 2004 OptumInsight and Purdue executed a Master Services Agreement to roll out this program in 2004-2005. The program would include Purdue, UHC, and OptumInsight working together to identify physicians from UHC and OptumInsight's database and then developing comprehensive education materials on the effectiveness of opioids in chronic pain treatment to send to these physicians.

148. OptumInsight and Purdue delivered this information through a series of teleconferences, newsletters, faxes, live meetings, case study monographs, letters, and website and web-based programming directly to physicians.

149. The project, referred to as the United Healthcare Physician Education program, included the following false and misleading messages targeted at UHC prescribing physicians:

- Opioid use is associated with some moderate side effects, but the risk of drug dependence is low;
- Concerns about abuse, addiction, and diversion should not prevent the proper management of chronic and low back pain;
- Opioids are the most effective way to treat pain;
- Opioid addiction does not occur in the chronic pain patient; and
- Certain signs of dependence that sometimes can be confused with addiction are actually "pseudoaddiction."

150. To assist in the marketing efforts of opioid manufacturers, Optum provided multiple opioid manufacturers with lists of all their plan clients as well as the names of physicians who were participating in the plan's provider networks. The manufacturers used this information to target the highest opioid prescribers with pull-through marketing.

151. In addition to assisting in the spread false information about prescription opioids, for years Optum provided the manufacturers with data, research, and consulting services needed to expand the prescription opioid market. For example, OptumInsight helped Purdue generate clinical studies, educational materials, and marketing programs to downplay the addictive properties of OxyContin and expand its use throughout the country.

152. Purdue paid OptumInsight to reverse engineer studies to achieve desired outcomes; create algorithms to identify potential pain patients to suggest OxyContin prescriptions; and create large-scale marketing plans to convince payors that long-term opioid usage was not only useful for many types of pain and did not lead to serious addiction for long-term opioid users.

153. In October of 2002, OptumInsight proposed a "Chronic Pain Management" study and education initiative to present a series of teleconferences to providers in the UHG/UHC

network. The purpose of this educational initiative was to "optimize patient care in the treatment of chronic pain." One of the themes of this report is that "[m]ost specialists in pain medicine and addiction agree that patients with prolong opioid therapy . . . do not usually develop addictive behavior" and to convince the providers that "[o]pioids are effective, have a low addiction potential, and may have fewer long-term side effects than other pain treatments."[15]

154. UHG requested $200,000 to implement the "Chronic Pain Management" initiative. Purdue stated that while that was a big investment, that the return would be high. UHG found that the study "significantly improve[d] the relationship" with Purdue and would "provide outcomes data that can prove valuable in the future with regard to placement and pull-through for United and other major HMOs."[16]

155. When UHC later considered implementing stricter quantity limits on OxyContin, Purdue again turned to OptumInsight to generate "new data." That data, upon information and belief, helped persuade the company to double its quantity limit for OxyContin—a decision that Purdue acknowledged would not harm its sales.[17]

156. In March 2005, OptumInsight prepared an Executive Summary for Purdue to propose "A Usual Care, Multicenter, Open-label, Randomized, 4-month Parallel Group Trial to Compare the Impact of Therapy with OxyContin on Health Outcomes and Research Utilization in Subjects with Moderate to Severe Osteoarthritis Pain of the Hip or Knee." The purpose of the reverse-engineered study was to present evidence to health-system decision-makers of the cost

[15] PPLPC036000014773.

[16] PPLPC035000032658.

[17] PPLPC012000057093; PPLPC012000057095.

effectiveness of treating osteoarthritis with OxyContin.[18] OptumInsight went on to present this study on behalf of Purdue at the International Society for Pharmacoeconomics and Outcomes Research annual meeting in 2005 where it won an award.

157. Because these studies were reverse engineered and constructed in order to advance Purdue's market share of OxyContin, in certain instances members of the medical/health care community pushed back on Purdue's and OptumInsight's joint medical journal publications. When that occurred, the two companies worked together to respond.

158. From 2011 through at least 2015, Purdue and OptumInsight worked together to build a comprehensive, multi-step "aspirational statement" and "evidence-generated" strategies for Butrans, OxyContin, Intermezzo, Targin, and hydromorphone.[19] The goal of this coordinated effort was to identify the best way to position these drugs with the public, patients, providers, and payors to increase utilization and maximize sales.

159. The first phase occurred in April 2012. It included a "Product Review" for each Purdue drug to complete a focused review of product, literature, and on-line information to establish the likely interplay between the product, competitors, and the market access and reimbursement environment.

160. The second phase occurred simultaneously in April 2012 and included "Event Mapping" which was an in-person workshop for the "Satellite [Purdue- OptumInsight] Team."

[18] PPLPC018000065660 (this study was performed by Innovus Research Inc. As noted above, Innovus subsequently merged with Ingenix and then later was renamed "OptumInsight").

[19] The examples below represent OptumInsight's effort with respect to OxyContin. OptumInsight produced similar documents for Purdue for Butrans, Intermezzo, Targin, and Hydromorphone.

The purpose of Event Mapping was to identify "significant events that will affect future evidence generation strategies."[20]

161. The third phase occurred in June 2012; it was called the "Aspirational Value Proposition" phase. During this time, the group would create the "ideal value proposition statement" which "is concise, appeals to payers' strongest decision-making drivers and is evidence based to: (1) identify the burden and unmet need that OxyContin will fulfill; (2) describe the solution provided by OxyContin compared to existing treatments; (3) describe the risks of OxyContin compared to existing treatments; and (4) delineate the economic benefit of OxyContin compared to existing treatments." OptumInsight's OxyContin "value statement" was targeted at moderate to severe pain and to endorse the reformulated OxyContin as lowering abuse, addiction, and diversion rates.[21]

162. The fourth phase occurred in September 2012. It included a "Semi Structured Payer Interview Guide for OxyContin" to gather "insight re: market access and reimbursement considerations."[22]

163. The fifth phase, occurring in November 2012 included reviewing "Results from Payer Interviews OxyContin."[23]

164. The group started the sixth phase in December 2012, called "Evidence Generation Plan for OxyContin." OptumInsight relied on this evidence to revise the "Aspirational Value Proposition," removing the value proposition that "Abuse of prescription opioids (primary and secondary) has substantial impact on society." The reason behind the removal was "Payers value

[20] PPLPC019000665974.

[21] PPLPC018000697326.

[22] PPLPC020000610710.

[23] PPLP004148372; PPLPC018000742542.

pain management. They perceive tamper resistance and abuse deterrence as societal benefits which they cannot further impact unless all products are tamper resistant." OptumInsight's motivation behind the "Payers value pain management" was financially motivated based on aspirational statement #1 "annual total and direct costs of moderate to severe chronic pain in the US are two- to three-fold higher than the economic burden posed by other major conditions such as diabetes, heart disease and obesity."[24]

165. Over time, OptumInsight and Purdue engaged in increasingly elaborate joint campaigns designed to position Purdue's opioids—including Butrans, Intermezzo, and hydromorphone—for favorable treatment by payors, physicians, and the public. This effort included multi-phase marketing initiatives, aspirational value proposition statements, payer interviews, and evidence generation plans, all aimed at framing these drugs as cost-effective, abuse-deterrent, and medically necessary. Key messages emphasized the burden of untreated pain while minimizing the societal harms of opioid misuse, and in at least one instance, OptumInsight recommended removing any reference to the public health costs of opioid abuse to improve the drugs' market positioning.

166. Parallel to these research and messaging efforts, OptumHealth, a UHC subsidiary, launched educational partnerships with Purdue to influence medical staff, case managers, and nurse practitioners.[25] Beginning in the early 2000s, Purdue personnel were introduced to UHC clinical staff through Dr. Michael Rosen, then National Medical Director at OptumHealth. Dr. Rosen played a pivotal role in developing UHC's national formularies through the Pharmacy & Therapeutics Committee, and his son, David Rosen, was a Purdue marketing executive who

[24] PPLP004148287.

[25] PPLPC021000066876; PPLPC022000059801.

leveraged the family connection to promote Purdue's educational initiatives across the UHC network.

167. These initiatives included continuing education programs, pain management seminars, and training materials advocating for greater opioid use. Case managers, triage nurses, and medical directors were all targeted by Purdue-sponsored programming, often co-developed and endorsed by Dr. Rosen. These programs framed the undertreatment of pain as a national crisis and promoted opioids as the most effective solution, while minimizing the risks of addiction and dependence.

168. Included in these programs were a presentation called "Communication to Enhance Collaboration and Outcomes."[26] The presentation was wholly endorsed and coordinated with Optum's Dr. Michael Rosen.[27] The PowerPoint presentation emphasized the "Possible Adverse Effects of Undertreated Pain" and had speaker notes to quote during the presentation that advocated for increased opioid use and stated "[i]f we continue to provide pain care as it has always been provided, patients will continue to suffer needlessly."[28] The same presentation was given to case managers, then expanded to UHC affiliated groups throughout the country, including risk managers, telephone triage nurses, and every case manager.

169. In 2006 and 2007, Dr. Rosen and Purdue worked together on multiple programs, including, upon information and belief, a program called "UHC Educate the Educator."

170. Optum continued to play an active role in increasing opioid utilization and perpetuating the misleading marketing of opioids even after Purdue's 2007 guilty plea to criminal

[26] PPLPC028000120866; PPLPC028000130521.

[27] S*ee* PPLPC020000038112; PPLPC022000050740; PPLPC022000050741.

[28] PPLPC022000051750.

misbranding of OxyContin—a clear acknowledgment by Purdue of the falsehoods it had propagated. Despite this public admission, Optum maintained its partnerships with Purdue and other opioid manufacturers, continuing to disseminate the same deceptive claims about the safety and efficacy of opioids. Regardless of what Optum may have known at the outset of its involvement, by 2007 it had actual knowledge that the representations it was promoting were false.

171. In 2009, Dr. Rosen worked with Purdue to roll out a six month "chronic pain mgmt. program" that would directly link to Purdue's "Partners Against Pain" website."[29] The program would focus on case managers for Optum throughout the country and would focus on Purdue's FACETS modules. The series would be presented by Optum Medical Directors and some Purdue employees. In March 2009, Optum employees reached out to Purdue to facilitate Medical Director Faculty Forum presentations regarding pain. One of the faculty presentations was about how to treat lower back pain with opioids using one of the FACETS topics. Optum distributed the literature for the topic to medical directors. Following this, Purdue held multiple educational seminars with the Medical Directors at Optum to then disseminate this information to hundreds of case managers throughout the country via seminars and literature.

172. From 2003 to at least 2012, OptumInsight conducted similar studies for other opioid manufacturers.

173. In sum, Optum and its affiliated entities played a central and sustained role in facilitating the spread of opioid-related misinformation. By collaborating with Purdue and other manufacturers to produce data, shape educational content, and influence prescribing behavior, Optum helped legitimize and expand opioid use for chronic pain without adequate controls. This

[29] PPLPC028000245007.

long-running partnership contributed materially to the overprescription of opioids and the public health crisis that followed.

3. Optum Had Access to Real-Time Data Regarding Drug Utilization Which Gave It a Unique Vantage Point into the Opioid Epidemic

174. Optum occupied a uniquely privileged position throughout the rise of the opioid epidemic in West Virginia. With unmatched access to vast quantities of prescription data, it had a front-row seat to the surge in opioid prescribing and dispensing, monitoring its trajectory in real time. Its awareness was a direct result of the data it meticulously collected, the insights gleaned through its relationships with clients, drug manufacturers, and healthcare providers, and the clinical evaluations it conducted when making formulary placement decisions. At every step, Optum was singularly positioned to grasp the scope and escalation of the opioid crisis. And yet, it chose to continue participating in, and profiting from, its expansion.

175. Optum had the tools to detect red flags other entities could not. It knew when patients were "doctor shopping," obtaining opioids from multiple prescribers or filling prescriptions at numerous pharmacies. It tracked when patients repeatedly refilled high-risk prescriptions or received dangerous drug combinations—such as opioids, benzodiazepines, and sedatives—that significantly increased the risk of overdose. Optum was also acutely aware when patients transitioned from opioid use to treatment for substance use disorder. Simply put, Optum had an unparalleled, data-driven view of the opioid crisis as it unfolded, pill by pill.

176. Optum's data told a clear and alarming story: the volume of opioids being prescribed, both across the country and in West Virginia, far exceeded what could be medically justified. It knew opioids were being overprescribed and misused. It knew that West Virginia was being flooded with dangerously high quantities of these addictive drugs. Optum had the knowledge, the foresight, and the capability to intervene. But it did not.

177. Instead, it turned its data into profit. Optum monetized the very insights that could have helped mitigate the crisis. It sold detailed claims data that enabled opioid manufacturers to identify which pharmacies and healthcare providers were prescribing and dispensing their opioids—and just as importantly, which ones were not. This intelligence allowed opioid manufacturers to deploy sales forces with laser precision, targeting high-volume prescribers and pharmacies, and fueling even greater market penetration of their opioids.

178. Throughout this period, Optum continued to aggregate, analyze, and profit from enormous volumes of prescription claims data that revealed unmistakable patterns of overuse, abuse, and diversion. No entity in the pharmaceutical supply chain had more visibility into the crisis or a better opportunity to act. Optum knew, or unquestionably should have known, that a public health disaster was unfolding in plain view. Despite its unique position and undeniable awareness, it chose not to intervene. Instead, Optum continued to profit from the epidemic it had the power, and responsibility, to help stop.

a. Optum Tracks Every Prescription Claim It Processes Across All the Health Plans It Serves Which Provided It With Uniquely Granular and Comprehensive Data.

179. Due to its business model, Optum has long had access to an extraordinary volume of highly detailed data. Its role as a PBM gave it the ability to track and analyze information not only at the level of individual prescribers and pharmacies, but also across entire populations of manufacturers, patients, payors, and geographic regions. Its insight into opioid prescribing trends was both uniquely granular and broadly comprehensive.

180. The data available to Optum included key details such as the volume, dosage, and type of opioids being prescribed, the conditions for which they were being prescribed, the identity of the prescribers and pharmacies involved, and the geographic distribution of opioid dispensing.

Optum also had access to dispensing data from its own mail-order pharmacies, further enhancing its visibility into real-time trends in opioid utilization and potential abuse.

181. Optum (and/or its predecessors) has had access to data for its tens of millions of UHC and OptumRx covered lives for the duration of the relevant time period as well, processing millions of prescription claims per day / hundreds of millions a year. Since its inception, Optum has been able to track how many opioids its millions of members are/were receiving, including the quantity of pills, the dosing strengths, the combination of drugs being dispensed, and the travel distance of members to acquire prescription opioids.

182. Similarly, Optum has promoted its ability to use near-real-time data feeds to integrate medical claims data into its intelligent claims engine, and emphasizes that its data systems are designed to flag individuals using both pharmacy and medical claims data.

183. Additionally, OptumRx has promoted its retrospective drug utilization review ("RDUR") program as a comprehensive tool intended to identify problematic prescribing and usage patterns. The program is designed to intervene closer to the point of patient care by flagging concerns such as doctor and pharmacy shopping, early refills, and potentially dangerous drug combinations.[30]

184. Because of all the data it had, Optum was aware that the volume of opioids being prescribed in the United States, and in West Virginia, far exceeded an amount that could possibly be justified as medically necessary or appropriate. Optum knew that opioids were being overprescribed and used inappropriately, and that West Virginia was being flooded with an oversupply of these dangerous drugs.

[30] OPTUMRX_JEFFCO_0000004463 (8/25/20), p.5.

185. To make matters worse, rather than use its data to stop the public health crisis that they were watching unfold, Optum sold its detailed claims data, as well as its clients' formulary and health plan information to Purdue and other opioid manufacturers. The opioid manufacturers then used this data to gain insight into the pharmacies and health care providers who were dispensing and prescribing their opioids (as well as their competitors' products) and more importantly those pharmacies and prescribers who were not prescribing and dispensing their products. This allowed sales representatives of Purdue and the other opioid manufacturers to have laser precision targeting high prescribers and pharmacies in order to aggressively push opioids onto the market.

186. For as long as it has been a PBM, Optum has received, compiled, and analyzed massive amounts of prescription claims data demonstrating that opioids were being over utilized, abused, and diverted. Indeed, Optum had more data on and greater awareness of the opioid epidemic unfolding than any other entity in the pharmaceutical industry. It knew or certainly should have known for decades that opioids were causing a public health crisis.

b. Optum Had Knowledge About the Opioid Epidemic and About Abuse And Diversion

187. According to the United States Centers for Disease Control and Prevention ("CDC"), the escalation of opioid overdose deaths in the United States has occurred in three distinct waves. The first wave began in the 1990s, marked by a sharp increase in the prescribing of opioids and a corresponding rise in overdose deaths involving prescription opioids, including natural and semi-synthetic opioids and methadone—trends that began as early as 1993. The second wave emerged in 2010, characterized by a surge in overdose deaths linked to heroin use. The third wave began in 2013 and has been defined by a dramatic rise in fatalities involving synthetic opioids, particularly illicitly manufactured fentanyl. Together, these waves illustrate the evolving

nature of the opioid crisis and underscore the role that overprescribing and pharmaceutical marketing played in fueling its earliest and most preventable stages.[31]

188. In September 2023, the United States entered what experts are now calling the *Fourth Wave* of the opioid epidemic. A study released by the Center for Social Medicine and Humanities at the University of California, Los Angeles, explains that this new phase is defined by a sharp rise in polysubstance overdose deaths—particularly those involving illicitly manufactured fentanyl combined with stimulants such as methamphetamine and cocaine.[32] By 2021, these two stimulants had emerged as the most common co-involved substances in overdose fatalities. This troubling development reflects a deadly evolution of the crisis—one that began with the overprescribing of prescription opioids and has now continued, expanded, and culminated in a widespread addiction and overdose epidemic fueled by increasingly potent and unpredictable drug combinations.[33]

189. Long before the second wave of the opioid crisis began, Optum was well aware that opioid abuse and misuse posed serious and growing dangers. It knew that opioids were highly addictive and carried a substantial risk of causing serious harm, including death—and it possessed this knowledge for at least two decades. Despite this awareness, it continued to support and profit from the widespread distribution of these drugs.

190. As early as 1997, Prescription Solutions alerted Purdue to the potential for abuse linked to OxyContin. By 2001, an executive from UHG raised concerns in correspondence with

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[31] https://www.cdc.gov/overdose-prevention/about/understanding-the-opioid-overdose-epidemic.html.

[32] Friedman, J, Shover, CL, Charting the fourth wave: Geographic, temporal, race/ethnicity and demographic trends in polysubstance fentanyl overdose deaths in the United States, 2010-2021, 118 ADDICTION 12 (Dec. 2023), https://onlinelibrary.wiley.com/doi/10.1111/add.16318.

[33] *Id.*

Purdue, attributing the growing overuse of OxyContin to Purdue's aggressive marketing practices. The executive warned that this promotion had led to increased use and abuse of opioids, rising pharmacy costs, and most critically, a spike in patient harm and death.[34] This demonstrates that Optum and its affiliates were aware of the dangers associated with OxyContin more than two decades ago.

191. Optum knew about the epidemic not only from its own data but also through numerous other sources—one of the most direct being its internal Pharmacy & Therapeutics ("P&T") Committees. These committees are tasked with evaluating the clinical safety, efficacy, and cost-effectiveness of drugs for formulary placement and UM.[35] Typically composed of physicians, pharmacists, and other clinical experts, P&T committees meet regularly and are expected to stay current with peer-reviewed research, FDA guidance, and developments in clinical best practices.[36]

192. Best practices for P&T committee members, as outlined by institutions such as the University of Wisconsin–Madison's Division of Pharmacy Professional Development, emphasize the need to remain informed, objective, and focused on patient-centered outcomes.[37] These committees are expected to seek information from reputable sources—like scientific journals,

[34] PKY181977016.

[35] Zhixiao Wang et al., "Cost-Effectiveness Analysis and the Formulary Decision-Making Process," Journal of Managed Care Pharmacy, Vol. 10, no. 1, pp 48-59 at p. 48 (Jan./Feb. 2004).

[36] Peri Iz, "Study of Pharmaceutical Benefit Management," PricewaterhouseCoopers HCFA Contract No. 500-97-0399/0097, p. 79 (June 2001).

[37] UW-Madison School of Pharmacy, Division of Pharmacy Professional Development, 5 Best Practices for P&T Committee Members, (Sep. 25, 2023), https://ce.pharmacy.wisc.edu/blog/5-best-practices-for-pt-committee-members/.

FDA alerts, and clinical data—and to ensure that formulary decisions are guided by the documented safety and efficacy of each drug.[38]

193. Given these expectations, P&T committee members for Optum knew or at the very least should have known of the well-documented risks associated with opioids throughout the relevant time period. Through its own internal review processes, Optum was in a position to recognize the extent of the epidemic and take corrective action. Instead, it continued to approve and promote widespread access to opioids, despite mounting evidence of harm.

c. Optum Failed to Timely Undertake Actions to Address the Opioid Epidemic that It Helped Create

194. Optum was not only fully aware of the dangers posed by opioids—it also had the authority, the data, and the tools to curb opioid overprescribing, abuse, and diversion. Yet, it willfully chose not to act.

195. With access to vast amounts of claims data, Optum had the ability to detect opioid abuse and patterns of dangerous prescribing. Its systems captured detailed, individually identifiable information on patients, prescribers, and pharmacies—giving them a uniquely powerful vantage point to monitor and analyze opioid utilization trends. It also had access to widely available tools, including algorithms to flag high-risk prescribers and UM protocols designed to control patient drug use. Despite these capabilities, Optum failed to implement timely opioid prescribing limits, failed to use its formulary and UM strategies to stem abuse, and failed to share the critical insights it gained from its data.

196. These inactions occurred while Optum was simultaneously contracting with opioid manufacturers and accepting significant rebates and fees directly tied to opioid utilization, without

[38] *Id.*

restrictions or safeguards in place. For decades, Optum was put on notice from CMS that prescription opioid overuse was fueling a national crisis. It had both the means and the responsibility to intervene but repeatedly chose not to—prioritizing profits at the expense of public health.

i. Optum chose not to use its claims data or its UM offerings or formulary placement to address overprescribing, abuse, and diversion

197. Optum's own claims data and research confirmed the effectiveness of UM tools in reducing inappropriate opioid use, however, Optum also expressed concerns regarding implementing prior authorizations ("PAs") and offering other UM protocols because of lost profits.

198. OptumRx would frequently put PAs on opioid products that did not offer high enough rebates, and thus use the PA to steer use to "preferred" opioids—typically OxyContin products.

199. The best example of this occurred in 2013, OptumRx created a "pay to avoid PA" program on long-acting opioids. This was not a clinical PA; instead, it was a threat to extract higher rebates from the opioid manufacturers. The strategy was simple, make the opioid manufacturers "Pay to avoid a PA." The PA only required documentation of failure of multiple other preferred opioids.[39]

200. Clinically appropriate PAs were not placed on Optum's highest selling long-acting Opioids for OptumRx until January 1, 2018, because the profitability of long-acting opioids would necessitate that any edit would need to be "thoroughly reviewed."[40] This required OptumRx to renegotiate all its current rebate agreements with opioid manufacturers.

[39] OPTUMRX_JEFFCO_0000184961.

[40] OPTUMRX_JEFFCO_0000360057.

201. OptumRx did not offer a standard PA program targeting short-acting opioids until the launch of its Opioid Risk Management Program in late 2017, despite Optum being aware that opioid abuse was driven primarily by short acting generic opioids.

202. Beyond prior authorizations, by no later than 2011, Optum was on notice by the Centers for Medicare and Medicaid Services ("CMS") that all actors involved in delivery of healthcare in the United States needed to take steps to address the overutilization of prescription opioids, which was contributing significantly to the growing opioid crisis.

203. However, even with CMS calling attention to Optum's role and responsibility to prevent opioid misuse, Optum's internal resistance to implementing policies and procedures to significantly reduce opioid abuse continued for years. For instance, in a February 6, 2017 email, Nathan Merrill, the OptumRx Manager of Clinical UM Operations, wrote to David Calabrese, the OptumRx Chief Pharmacy Officer, highlighting concerns with placing prior authorization limits on the opioids Embeda (Pfizer), OxyContin (Purdue), and Opana ER (Endo) because "these are preferred products that are tied to 'significant' rebates,' and that '[b]y adding a PA to these products we jeopardize any rebates we have contracted with the manufacturer.'"[41]

204. In sum, in exchange for lucrative financial benefits from the opioid manufacturers, Optum has stoked the fires of the opioid epidemic by allowing unfettered access on their standard formularies to dangerous, highly addictive opioids with minimal, if any, restrictions.

205. That reality, however, has not deterred Optum from publicly touting their unique ability to alter the course of the opioid epidemic.

206. In 2017, OptumRx announced, "By leveraging OptumRx's clinical, analytics and administrative services and its deep connections to those who can effect change—patients,

[41] OPTUMRX_JEFFCO_0000366595 (2/6/17).

providers and pharmacists—the company is uniquely positioned to help address the opioid epidemic."[42]

207. Optum's Chief Pharmacy Officer, David Calabrese, has made similar statements: "PBMs are uniquely positioned to connect and partner with physicians, pharmacists, patients, pharmaceutical manufacturers, health systems, and other components of the industry, and therefore are better able to drive improvements in education surrounding the dangers of opioid therapy, as well as the various tools available for constituents to positively change the course of this epidemic." Calabrese added, "Our nation's indiscriminate prescribing, dispensing, demand for, and consumption of prescription opioid drugs has led to a scenario in which we now consume more than 80% of the world's supply of prescription opioids and a corresponding death toll due to opioid overdose which is one of the highest in the world."[43]

208. In March 2017, Calabrese gave a talk at a PBM trade association conference titled "Confronting the Crisis We Brought Upon Ourselves: America's Opioid Abuse Epidemic," admitting that "[w]e are all accountable . . . and all part of the solution . . ."[44] Calabrese's presentation discusses the "most effective" way to "[c]lose[] the [f]loodgates" on opioid abuse would be to "capitalizing on the enormous powers we have as a PBM in benefit management, UM and POS claims adjudication edits to deploy much more aggressive interventions that limit exposure to these drugs . . . right out of the gate"[45] Among the tools Calabrese suggests is

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[42] Optum, OptumRx Opioid Risk Management Program Leads to Better Outcomes for Patients and Clients, (Aug. 22, 2017).

[43] Managed Healthcare, Four PBM programs poised to rein in the opioid epidemic, (Jan. 1, 2018), https://www.managedhealthcareexecutive.com/view/four-pbm-programs-poised-rein-opioid-epidemic.

[44] OPTUMRX_JEFFCO_0000017988 (3/24/17).

[45] *Id.*

OptumRx's "predictive modeling capabilities [to identify at-risk patients and monitor physician prescribing patterns] that will allow us much greater leverage in getting ahead of the problems for our members, before it is too late."[46]

209. Speaker notes from an OptumRx sales presentation from the same time period characterize the PBM response to the opioid crisis as a "delayed reaction," declaring that "we can no longer sit idly by and watch":

> Today we are in the midst of one of the most significant healthcare crises in our nation's history, and that is our nation's opioid abuse epidemic . . . .
>
> Sadly, unlike other crises we've faced before, this one is unique in that it is one that we have largely brought upon ourselves. How? Through the over-promotion and over-prescribing of these drugs by our pharm mfgs and physicians; our delayed reaction in intervening as PBMs and MCOs as our death toll rose substantially; and our lax attitudes as a society as a whole with regard to the acceptance; consumption; sharing; storage and propere [sic] disposal of these agents when prescribed to ourselves and our family members.
>
> Because we all share accountability, we at OptumRx, believe we are in a unique position now (unlike that of any of our competitors) to leverage the broad capabilities across our enterprise (Rx, BH, analytics, CM, etc...) and deliver the type of end-to-end solution suite that will deliver a positive impact in decreasing the prevalence of OUD and the fatality rate that we can no longer sit idly by and watch to continue.[47]

210. Despite having been "uniquely positioned" to change the trajectory of the opioid epidemic, Optum instead sat "idly by" for years. Even when Optum began to take some steps to ostensibly address the crisis, the measures were ineffective. For example, although Optum mailed notice letters to "outlier prescribers" in late 2016, no providers were dismissed from the network as a result of the investigation, and Optum never conducted any follow-up analysis to determine whether the letters had any impact on prescribing.

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[46] *Id.*

[47] OPTUMRX_JEFFCO_0000206573 (3/8/17) (emphasis added).

ii. Optum chose not to use its "Drug Utilization Review" tools to address overprescribing, abuse and diversion

211. Compounding its failure to act, Optum also chose not to use its "Drug Utilization Review" tools to address overprescribing, abuse and diversion.

212. Optum also had at its disposal a powerful tool to help control the flow of opioids: its Drug Utilization Review ("DUR") programs. Concurrent DUR ("Concurrent DUR" or "cDUR") is a critical safety mechanism that allows for the real-time evaluation of a patient's drug therapy at the point of sale. It is specifically designed to detect and prevent potential drug-related problems before a prescription is dispensed. These include therapeutic duplication, age- or gender-related contraindications, over- or under-utilization, drug-drug interactions, incorrect dosage or duration, drug-allergy risks, and signs of clinical abuse or misuse.

213. Yet Optum chose not to fully utilize DUR or cDUR to prevent inappropriate opioid prescribing. Optum was unwilling to implement robust cDUR restrictions because doing so would impact its receipt of rebates. In 2017, when OptumRx tried to implement changes which would have used cDUR to control inappropriate opioid usage, there was pushback because it would mean the loss of rebates. In response to these concerns, on March 24, 2017, SVP Calabrese raised the question whether "[i]f our opioid mfg industry partners can't appreciate the magnitude of the problem we are facing [and] the immediacy of the need for intervention[,] . . . I would question whether they are the right partner for us longer term."[48]

214. Later that same day, Robert Lahman, OptumRx SVP Industry Relations, responded that "I agree with you but you also have to be mindful of our [rebate] contracts." Lahman also

[48] OPTUMRX_JEFFCO_0000235659 (3/24/17).

warned Calabrese to "[s]top with the attitude and help us make sure we are compliant with our contracts."[49]

215. Frustrated that OptumRx would delay the changes to its use of cDUR limits resulting from what he saw as "gross overprescribing and overpromotion of these medications . . . [and] the countless deaths," Calabrese later that day sent an irate response to Lahman, telling him: "Maybe you should be the one to take a step back and look at the bigger picture here. I need you on board with doing your job and convincing the [manufacturers] that we drive the ship here in terms of how their drugs get used, not them!"[50]

216. Even when products like Opana ER were set to be withdrawn from the market within a few months for clinical safety reasons, OptumRx refused to put a PA in place that would have prevented new patients from starting on the drug before it was withdrawn from the market because it would "put [Optum's] rebates at risk."[51]

iii. Optum failed to provide effective controls against diversion and/or to prevent the diversion and abuse of opioids

217. Upon information and belief, Optum operated its PBM business and mail-order dispensing businesses through separate corporate entities. However, it was fully aware that prescription opioids posed serious risks of abuse and diversion—and that the Optum Mail Order Pharmacy was legally obligated under West Virginia law and the federal Controlled Substances Act ("CSA") to maintain effective controls to prevent diversion.

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[49] *Id.*

[50] *Id.*

[51] OPTUMRX_JEFFCO_0000430032 (7/19/17).

218. Optum also knew it possessed vast amounts of data capable of supporting those controls, along with a full suite of tools—including standard formularies, UM strategies, and drug utilization review programs—that could have significantly reduced the risk of diversion.

219. Even if the Optum entities that provide PBM services are not themselves subject to DEA oversight, those entities had parallel responsibilities to operate their PBM services with appropriate care in light of the dangers of diversion that the CSA is designed to guard against. Any controls that Optum provided (assuming there were any) could not be effective while its sister companies conducted their PBM activities so as to maximize the volume of opioid sales. Either way, Optum had an obligation to operate its PBM business in such a way as to minimize or reduce the risks that these dangerous drugs would be diverted. All data available to Optum was also available to mail-order dispensing affiliates, and those entities had an obligation to use that data in maintaining effective controls against diversion, but they failed to do so.

4. Two Decades After It Knew Opioids Were Causing a Public Health Crisis, Optum Finally Implemented Protocols to Address the Opioid Epidemic

220. After decades of contributing to increased opioid utilization, Optum finally launched programs aimed at addressing opioid overuse and abuse—but only in late-2017, and only under mounting pressure from clients and federal authorities. Optum's *Opioid Risk Management* ("ORM") program was offered starting in January 2018.

221. The program included a basic set of interventions applied across all clients, as well as optional enhancements for those willing to pay for more robust oversight.[52] These additional measures imposed tighter restrictions on refills, set hard limits on high-risk prescribing behaviors, and offered clinical services to monitor and support members identified as being at elevated risk

[52] OPTUMRX_JEFFCO_0000392019.

of misuse or abuse. Within months of the program's launch, Optum reported measurable reductions in the volume, dosage, and duration of opioid prescriptions across its client base.

222. Notably, Optum could have implemented these opioid-reducing measures at any point over the past two decades as they tracked the opioid epidemic unfolding across the country and in West Virginia. Had Optum created effective protocols to address opioid overutilization, such as those implemented in 2017, when it first knew these drugs were causing a public health crisis, it could have significantly reduced the amount of opioids dispensed throughout the country, including in West Virginia, and reduced the harm caused by the opioid epidemic.

5. Even After Implementing Its Opioid Risk Management Program, Optum Continued Promoting Uncontrolled Opioid Sales Through Its Cash Card and Discount Card Businesses

223. Optum also collects set administrative fees for every opioid paid for with either its own discount card or one of its administered cash cards—which are governed by either Optum Perks, LLC or Optum Discount Card Services, LLC. Cash cards neither adhere to formularies, nor do they have traditional UM controls. Cash cards played a significant role in the opioid epidemic, as they allowed patients whose prescriptions exceeded their insurance plan limits a cheaper way to access opioids.[53] Cash cards could be used by anyone to purchase opioids—including individuals who did not receive benefits from Optum or UnitedHealth Group.

224. Optum counts individuals who utilize its administered cash card—but who do not receive benefits from Optum or UnitedHealth Group—as "members" of Optum. Optum receives administrative fees and other revenue from each opioid prescription paid for with an Optum-administered cash card. Optum issues cash cards for opioids despite knowing that this allows

[53] Kelly Ayotte, THE HILL, Shut the Back Door to America's Opioid Epidemic (July 3, 2018), https://thehill.com/opinion/healthcare/395401-shut-the-back-door-to-americas-opioid-epidemic/.

individuals an "end run around" dispensing controls built into Optum and other payors' formularies. Further, and most importantly, cash cards are not subject to any limits, exclusions or PA controls since members pay the entire amount of the discounted claim.

225. Optum's cash card business took root in approximately 2015, when it realized that an expanded cash card/pharmacy discount service was an opportunity for revenue growth (a realization coinciding with its acquisition of Catamaran, which had a significant cash card business). This included partnering with drug manufacturers, including opioid manufacturers, to further expand its cash card business.

226. Optum explicitly communicated that its cash card business included a lack of opioid controls. In fact, one opioid manufacturer (Collegium) declined to participate in Optum's cash card program due to the lack of opioid utilization controls.

227. At the same time, Optum was advertising and encouraging individuals, whether they were Optum or UnitedHealth Group members or not, to use its various administered cash card and discount programs to purchase opioids.

228. Upon in formation and belief, in 2017, while OptumRx was publicly touting its new ORM program, internal documents reveal that Optum was also unwilling to control any prescriptions administered by Optum Perks or Optum Discount Card Services, and wanted it known that there were "no restrictions on cash cards, ever." When presented with the opportunity to block opioids on its cash cards in 2017, Optum calculated that doing so would cost the business $26 million per year. As a result, Optum decided not to block the use of cash cards for opioid claims. By 2018, Optum served over 3.6 million cash card "members."

229. Despite Optum's public-facing commitment to fighting the opioid epidemic, in June 2018, Optum also refused to block opioid adjudication on its suite of cash cards. This included

a refusal by Optum, its affiliates, and its marketing partners to cease advertising the use of Optum's suite of discount card pricing tools to pay for opioid prescriptions. Optum's stated reason for this refusal was that doing so would cut into the revenue and/or the administration fees Optum collects from opioids.

230. Optum was fully aware its cash cards were being used to abuse, divert, and misuse opioids. For example, upon information and belief, in 2019, David Calabrese wanted to know Optum's exposure when the FBI charged dozens of medical practitioners and pharmacies throughout the country for the illegal prescribing of opioids. An analysis of those "exposure" claims showed a large number of them related to cash card claims administered by OptumRx.

C. The Optum Mail Order Pharmacy Fueled the Opioid Epidemic by Dispensing Billions of Morphine Milligram Equivalents of Opioids

231. Optum played a further critical role in fueling the opioid crisis by operating one of the largest pharmacy networks in the country that purchased, dispensed, and profited substantially from the distribution of opioids. In operating the Optum Mail Order Pharmacy, Optum frequently acted as a direct dispenser of opioids, filling prescriptions itself.

232. Controlled substances, such as opioids, by definition are highly subject to abuse and diversion. For this reason, West Virginia regulates every participant in the chain of distribution that handles controlled substances. To dispense prescription opioids in the State, companies must maintain effective controls against diversion.

233. Congress has found that pharmacies share responsibility for the crisis: "The opioid epidemic . . . has arisen, in part, from the diversion of prescription opioids through illegal

dispensing practices at pharmacies."[54]

234. Optum knowingly violated its duties under the West Virginia Controlled Substances Act ("WVCSA") and the federal Controlled Substances Act ("CSA"), and their implementing regulations.

1. The Applicable Statutes

235. Optum was required to comply with the WVCSA and pharmacy regulations, including, but not limited to, the West Virginia Controlled Substances Act, W. Va. C.S.R. § 15-2-3 (previously W.Va. C.S.R. § 15-2-2), W. Va. C.S.R. § 15-2-4, W.Va. C.S.R. § 15-2-4.4, W.Va. C.S.R. § 15-2-4.5, W. Va. C.S.R. § 15-2-5.1.1 (previously W. Va. C.S.R. § 15-2-4.2.1), W. Va. C.S.R. § 15-2-5.3 (previously W.Va. C.S.R. § 15-2-4.4), W. Va. C.S.R. § 15-2-5 (previously W. Va. C.S.R. § 15-2-4), W.Va. Code § 60A-4-401(a), W. Va. Code § 60A-8-7(c)(1)(I); W. Va. Code § 60A-8-7(c)(3); and W. Va. Code § 60A-3-308(d)(1).

236. The Rules of the West Virginia Board of Pharmacy for the West Virginia Uniform Controlled Substances Act are codified in W.Va. C.S.R. § 15-2-1, *et seq.*

237. The West Virginia Uniform Controlled Substances Act requires "every person who manufactures, distributes, or dispenses any controlled substance within this state" to "obtain annually a registration issued by the state board of pharmacy." W. Va. Code § 60A-3-302(a); *see also* W.Va. C.S.R. § 15-2-4 (previously W.Va. C.S.R. § 15-2-3).

238. Optum was registered and had a duty to comply with federal, state, and local laws regarding the distribution of drugs. W. Va. Code § 60A-8-7(c)(1)(I); *see also* W. Va. Code § 60A-

[54] U.S. Senate Homeland Sec. & Governmental Aff. Comm., Ranking Member's Off., *Fueling an Epidemic: A Flood of 1.6 Billion Doses of Opioids into Missouri and the Need for Stronger DEA Enforcement,* at p. 4 (July 12, 2017), https://www.hsdl.org/c/abstract/?docid=812961.

8-7(c)(3) (requiring compliance with guidelines adopted by the United States Food and Drug Administration).

239. The West Virginia Board of Pharmacy has adopted, by reference, the requirements of the federal regulations, 21 CFR Parts 1300-1321, and 21 U.S.C. 801. *See* W. Va. C.S.R. § 15-2-3 (previously W. Va. C.S.R. § 15-2-2).

240. West Virginia state law expressly imposes a duty upon Optum to provide effective controls and procedures to guard against theft and diversion of controlled substances. W. Va. C.S.R. § 15-2-5.1.1 (previously W. Va. C.S.R. § 15-2-4.2.1).

241. Optum had a duty not to breach the standard of care established under West Virginia law and regulations and the federal CSA and its implementing regulations to provide effective controls and procedures to guard against theft and diversion of controlled substances. W. Va. C.S.R. § 15-2-5.1.1 (previously W. Va. C.S.R. § 15-2-4.2.1).

242. West Virginia state law further imposes a duty upon Optum to design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the West Virginia Board of Pharmacy of suspicious orders when discovered "by providing a copy of the information which the wholesale drug distributor provides to the U.S. Drug Enforcement Administration regarding such suspicious orders." W. Va. C.S.R. § 15-2-5.3 (previously W.Va. C.S.R. § 15-2-4.4). Suspicious orders include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id.*

243. Optum had a duty not to breach the standard of care established under West Virginia law and regulations and the CSA and its implementing regulations to report suspicious prescribing and to maintain systems to detect and report such activity. W. Va. C.S.R. § 15-2-5 (previously W. Va. C.S.R. § 15-2-4); *see also* 21 U.S.C. § 823; 21 C.F.R. 1301.74.

244. The WVCSA further prohibits any person "[w]ho is subject to article 3 to distribute or dispense a controlled substance in violation of section [60A-3-]308." W. Va. Code § 60A-4-402(a)(l). Section 60A-3-308 of the WVCSA governs distribution of controlled substances, which is prohibited except by prescription. It provides, for example, that substances included in certain schedules of the law "shall not be distributed or dispensed other than for a medicinal purpose." W. Va. Code § 60A-3-308(d)(l).

245. In addition to the requirement that Optum comply with West Virginia controlled substances law and pharmacy regulations, Optum was also required to comply with federal law including the CSA and its implementing regulations that govern the manufacture, distribution, and dispensing of controlled substances in the United States. The CSA accordingly establishes a closed regulatory system under which it is unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.[55]

246. The CSA and West Virginia law categorize controlled substances in five "Schedules."

247. Schedule II (also called herein CII) contains drugs with "a high potential for abuse" that "may lead to severe psychological or physical dependence," but nonetheless have "a currently accepted medical use in treatment."[56]

248. Schedule III contains drugs in which, although the abuse potential is less than a Schedule II drug, such abuse may lead to moderate "physical dependence or high psychological dependence." Schedule III drugs also have "a currently accepted medical use."[57]

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[55] *See* 21 U.S.C. § 841(a).

[56] 21 U.S.C. § 812(b)(2); *see also* W. Va. Code. § 60A-2-205.

[57] 21 U.S.C. § 812(b)(3); *see also* W. Va. Code. § 60A-2-207.

249. Schedule IV contains drugs that, although having a lower abuse potential than Schedule III drugs, still may lead to a physical or psychological dependence when abused.[58]

250. Schedule V contains drugs that, although having a lower abuse potential than Schedule IV drugs, still may lead to a physical or psychological dependence when abused.[59]

251. The CSA makes it "unlawful for any person knowingly or intentionally to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance" except as specifically authorized.[60]

252. Accordingly, the CSA requires those who manufacture, distribute, or dispense controlled substances to obtain a registration from the DEA.[61] A registrant is only permitted to dispense or distribute controlled substances "to the extent authorized by its registration and in conformity with the [CSA].[62]

253. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the CSA.[63]

254. At all times relevant to this Complaint, Optum has registered its Mail Order Pharmacy with the DEA in Schedules II–V controlled substances. Those DEA registrations authorize Optum-owned pharmacies to "dispense" controlled substances, which "means to deliver

[58] 21 U.S.C. § 812(b)(4); *see also* W. Va. Code. § 60A-2-209.

[59] 21 U.S.C. § 812(b)(5); *see also* W. Va. Code. § 60A-2-211.

[60] 21 U.S.C. § 841(a)(1).

[61] 21 U.S.C. § 822(a).

[62] 21 U.S.C. § 822(b).

[63] 21 U.S.C. § 829.

a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner."[64]

255. Agents and employees of a registered manufacturer, distributor, or dispenser of controlled substances, such as a pharmacist employed by a registered mail order pharmacy like those owned by Optum, are not required to register with the DEA "if such agent or employee is acting in the usual course of his business or employment.[65]

256. Under the CSA, the lawful dispensing of controlled substances is governed by 21 U.S.C. § 829 and more specifically in Part 1306 of the CSA's implementing regulations.[66]

257. Unless dispensed directly by a non-pharmacist practitioner, no Schedule II controlled substance may be dispensed without the written prescription of a practitioner, such as a physician, except in an emergency.[67] Similarly, unless directly dispensed, no Schedule III or IV controlled substance may be dispensed without a written or oral prescription from a practitioner.[68]

258. Such a prescription for a controlled substance may only be issued by an individual who is (a) "authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession" and (b) registered with the DEA.[69]

259. A prescription, whether written or oral, is legally valid under the CSA only if it is issued for "a legitimate medical purpose by an individual practitioner acting in the usual course of

[64] 21 U.S.C. § 802(10), accord 21 U.S.C. § 823(f).

[65] *See generally* 21 C.F.R. § 1306.

[66] *See generally* 21 C.F.R. § 1306.

[67] 21 U.S.C. § 829(a).

[68] 21 U.S.C. § 829(b).

[69] 21 U.S.C. § 822; 21 C.F.R. § 1306.03.

his professional practice.[70] Moreover, "[a]n order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. § 829] and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances."[71]

260. As a result, the "responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."[72] Thus, a pharmacist may not fill a controlled substance prescription unless it has been issued for a legitimate medical purpose.

261. Moreover, "[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually, or employed in a registered pharmacy . . . ."[73]

262. Pharmacists are therefore permitted to dispense a controlled substance in any given instance if, but only if, such dispensing would be in accordance with a generally accepted, objective standard of practice—i.e., "the usual course of his [or her] professional practice" of pharmacy.[74]

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[70] 21 C.F.R. § 1306.04(a).

[71] *Id.*

[72] *Id.*

[73] 21 C.F.R. § 1306.06.

[74] *Id.*

263. Consequently, a pharmacist is required to refuse to fill a prescription if he or she knows or has reason to know that the prescription was not written for a legitimate medical purpose.[75]

264. Unlawful dispensing of controlled substances by a pharmacist may subject the pharmacy or pharmacist to criminal actions and to civil enforcement actions for money penalties or injunctions.[76]

265. A pharmacy also needs to know there is a corresponding responsibility for the pharmacist who fills the prescription.[77] The pharmacist has a legal duty to recognize "red flags" or warning signs that raise (or should raise) a reasonable suspicion that a prescription for a controlled substance is not legitimate. The existence of such indicia obligates the pharmacist to conduct a sufficient investigation to determine that the prescription is actually legitimate before dispensing. A pharmacist's corresponding responsibility extends to the pharmacy itself.

266. A pharmacy cannot ignore red flags indicative of abuse and diversion. On the contrary, "a pharmacist is obligated to refuse to fill a prescription if he knows or has reason to know that the prescription was not written for a legitimate medical purpose."[78] "[W]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid actual knowledge of the real purpose of the

[75] *See* 21 C.F.R. §§ 1306.04, 1306.06.

[76] 21 U.S.C. §§ 842, 843.

[77] United States Department of Justice, Drug Enforcement Administration Office of Diversion Control, Pharmacist's Manual: An Informational Outline of the Controlled Substances Act (Rev. 2020).

[78] *Medic-Aid Pharmacy, Revocation of Registration*, 55 Fed. Reg. 30,043-01 (Dep't of Just. July 24, 1990).

prescriptions.[79] Thus, § 1306.04 requires "pharmacists [to] use common sense and professional judgment," which includes paying attention to the "number of prescriptions issued, the number of dosage units prescribed, the duration and pattern of the alleged treatment," the number of doctors writing prescriptions and whether the drugs prescribed have a high rate of abuse or diversion.[80] "When [pharmacists'] suspicions are aroused as reasonable professionals," they must at least verify the prescription's propriety, and if not satisfied by the answer they must "refuse to dispense."[81]

267. Courts, too, have recognized the obligation of pharmacies not to dispense until red flags are resolved.[82] In *Medicine Shoppe-Jonesborough,* the Sixth Circuit affirmed a pharmacy's liability for filling false or fraudulent prescriptions for controlled substances, concluding that the pharmacy violated § 829 of the CSA and 21 C.F.R. § 1306.04. The Court held "[t]he CSA forbids a pharmacy to dispense a Schedule II, III, or IV controlled substance without a prescription, 21 U.S.C. § 829(a)-(b), which 'must be issued for a legitimate medical purpose by an individual

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[79] *East Main Street Pharmacy, Affirmance of Suspension Order*, 75 Fed. Reg. 66,149-01 (Dep't of Just. Oct. 27, 2010).

[80] *Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy, Inc., Revocation of Registration*, 55 Fed. Reg. 4,729-01, 4,730 (Dep't of Just. Feb. 9, 1990).

[81] *Id.; see also Townwood Pharmacy, Revocation of Registration*, 63 Fed. Reg. 8,477-04 (Dep't of Justice Feb. 19, 1998); *Grider Drug No. 1 & Grider Drug No. 2, Decision & Order*, 77 Fed. Reg. 44,070-01 (Dep't of Justice July 26, 2012); *The Medicine Dropper, Revocation of Registration* 76 Fed. Reg. 20,039-01 (Dep't of Justice Apr. 11, 2011); *Medicine Shoppe-Jonesborough, Revocation of Registration*, 73 Fed. Reg. 364-01 (Dep't of Justice Jan. 2, 2008); *United Prescriptions Services, Inc., Revocation of Registration*, 72 Fed. Reg. 50,397-01, 50,407-8, (Dep't of Just. Aug. 31, 2007).

[82] *See Med. Med. Shoppe-Jonesborough v. Drug Enf't Admin.,* 300 F. App'x 409, 413–14 (6th Cir. 2008); *United States v. Henry,* 727 F.2d 1373, 1378–79 (5th Cir.), *on reh'g,* 749 F.2d 203 (5th Cir. 1984); *Holiday CVS, L.L.C. v. Holder,* 839 F. Supp. 2d 145, 160 (D.D.C.), *vacated and remanded,* 493 F. App'x 108 (D.C. Cir. 2012).

practitioner acting in the usual course of his professional practice,' 21 C.F.R. § 1306.04(a)."[83] Prescriptions that "involved excessive" quantities of drugs and "remedies outside the prescriber's ordinary area of practice" "should have raised red flags at Medicine Shoppe."[84] "By filling these prescriptions anyway. . . the pharmacy not only violated its duties under federal (and state) law to ensure that only proper prescriptions were filled but also put public health and safety at risk."[85]

268. A pharmacy's registration can be revoked because its pharmacists have violated the corresponding responsibility rule and both the pharmacy and pharmacists may be the subject of further discipline.[86]

269. At all times material hereto, Optum, as a DEA registrant, had the duty to "provide effective controls and procedures to guard against theft and diversion of controlled substances."[87]

270. Federal and West Virginia laws and regulations require Optum to act as gatekeepers guarding against the diversion of the highly addictive, dangerous opioid drugs. *See* 21 U.S.C. § 823; 21 C.F.R. § 1301.74; W. Va. C.S.R. § 15-2-5 (previously W. Va. C.S.R. § 15-2-4).

271. Optum failed to meet its duties and obligations under West Virginia and federal law.

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[83] *Med. Medicine Shoppe-Jonesborough,* 300 F. App'x at 412.

[84] *Id.* at 413

[85] *Id.*

[86] United States Department of Justice, Drug Enforcement Administration Office of Diversion Control, *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act* (Rev. 2020) (citing *Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.,* 881 F.3d 823 (11th Cir. 2018)).

[87] 21 C.F.R. § 1301.71(a); *see also*, W. Va. C.S.R. § 15-2-5.1.1 (previously W. Va. C.S.R. § 15-2-4.2.1).

2. Optum Violated West Virginia Law and the Federal Controlled Substances Act

272. The framework of state and federal statutes and regulations, along with industry guidelines, make clear that pharmacies like those Optum owns are expected to use specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the abuse and diversion of prescription narcotics when dispensing medications outside the usual course of professional practice.

273. Optum was on notice that case law and administrative proceedings interpreting the CSA clearly required that its pharmacies must recognize and resolve all "red flags" indicating addiction, abuse and diversion, such as criminal, civil, or administrative actions pending against the prescriber, pattern prescribing, pharmacy shopping, doctor shopping, high abuse potential prescriptions, drug cocktails, and similar indicators.[88]

274. It is not just the single red flags that make the suspicious prescriptions unresolvable, but frequently the fact that there are multiple red flags at one time. So, rather than just looking for unresolvable single red flags, Optum should have been looking for instances when there are multiple red flags in combination, which would make these truly unresolvable.

275. At all times material hereto, Optum has been in the position to recognize those red flags listed above. Upon information and belief, all or some of those red flags were frequently present in hundreds of thousands of prescriptions its pharmacies received during the relevant time

[88] *Holiday v. Holder,* 839 F. Supp. 2d 145; *Pharmacy Drs. Enterprises, Inc. v. Drug Enf't Admin.,* 789 F. App'x 724, 730 (11th Cir. 2019); *Holiday CVS,* 77 Fed. Reg. at 62,318, 62,326, 62,331, 62,344; *East Main Street Pharmacy,* 75 Fed. Reg. at 66,159; *Oak Hill Hometown Pharmacy v. Dhillon,* 418 F. Supp. 3d 124, 131 (S.D.W. Va. 2019); *Jones Total Health Care Pharmacy, LLC,* 881 F.3d at 828; "Centers for Disease Control, CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016," 65 Morb. And Mort. Wkly Rep. (Mar. 18, 2016) https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.

and should have caused Optum's Mail Order Pharmacy to refuse to fill prescriptions and/or report the behavior. However, Optum failed to do so.

276. Optum, as a sophisticated owner of the Optum Mail Order Pharmacy, had the ability to analyze data relating to drug utilization and prescribing patterns across multiple retail stores in diverse geographic locations. Optum tracks every prescription claim it processes across all the health plans it services. Furthermore, Optum could aggregate the data across various entities in the pharmaceutical supply chain, including drug manufacturer, pharmacies, insurers, and patients. Its own data would have allowed Optum to observe patterns or instances of dispensing that are potentially suspicious of diversion or oversupply in particular stores or geographic areas, and of prescribers or facilities that seem to engage in improper prescribing.

277. Rather than use its data to limit problematic opioid utilization or investigate outlier prescribers, Optum sold the data to third-party vendors who in turn resold the data to drug makers like Purdue Pharmaceuticals. Drug makers used these data to stoke increased sales of opioid drugs to physicians throughout West Virginia.

278. Yet, Optum did little to leverage its resources and troves of information to stop or further question the wildly inappropriate prescriptions being written by prescribers until well after the opioid epidemic had reached its peak.

279. Optum did little to fulfill its duties as the last line of defense and failed to ensure that the prescriptions it was filling were issued to legitimate patients for legitimate medical purposes by practitioners acting in the usual course of professional practice, as is evident by the copious amounts of opioids being dispensed by Optum's Mail Order Pharmacy throughout West Virginia and this Judicial District.

280. The absence of controls against diversion is not surprising, given how Optum's Mail Order Pharmacy operated to push virtually all prescriptions out the door, with little or no attempts at identifying or resolving red flags. The pressure on its pharmacists to fill large volumes of prescription made the performance of appropriate due diligence difficult, if not impossible.

281. For instance, upon information and belief, employees at the Optum Mail Order Pharmacy routinely complained of being under significant pressure to fill as many prescriptions as possible in as short an amount of time as possible. Upon information and belief, many of Optum's pharmacists and technicians were fielding upwards of 100 calls a day regarding things like prior authorizations. Even though not all calls dealt specifically with opioids, the sheer volume and pace of the calls hindered pharmacists' ability to vet each prescription carefully, as required by law.

282. Optum also required its prior authorization pharmacists to adhere to strict metrics concerning the number of cases per hour. The minimum number of cases to complete was set at seven per hour. This number of cases is unrealistic for a pharmacist to complete accurately and put undue pressure on pharmacists.

283. Upon information and belief, the pressure on mail order pharmacists was compounded by the constant threat of audits at Optum. Pharmacists were always under pressure because they were subjected to weekly audits to ensure they were meeting the required metrics. The audit would document not only total cases worked during the week, but there would be comments on mistakes, what cases were incorrect, or if any wrong decisions were made. The consequences of a bad audit often included termination for the pharmacist.

284. In 2017, OptumRx SVP David Calabrese emailed his colleagues that unless OptumRx addressed its mail-order opioid dispensing, "[w]e are only contributing to the worsening

of the problem."[89] He noted that OptumRx was dispensing "220K opioid Rx's out of our mail facilities annually at an average number of units per Rx of 187" and warned that "[w]e are talking out of both sides of our mouths if we allow this to continue as it is."[90] Calabrese wrote, "I strongly believe this needs Exec level attention."[91]

285. An OptumRx presentation from 2018 admits that it is a "[c]hallenge for individual rphs to identify controlled substance diversion in mail order setting," and that, prior to implementing a drug of concern review in 2018, OptumRx's pharmacists had "[n]o visibility of possible diversion indicators such as: Multiple patients with same shipping address [and] Multiple patients with same email address."[92] The document also acknowledged, "Due to lack of visibility diversion activity may occur repeatedly for an extended period of time.[93]

286. Despite its legal obligations as licensees and registrants under West Virginia law, Optum, through its operation of the Optum Mail Order Pharmacy, knowingly allowed widespread diversion to occur.

287. The Optum Mail Order Pharmacy dispensed, sold, and shipped far greater quantities of prescription opioids throughout West Virginia than it knew could be necessary for legitimate medical uses.

288. This included shipping opioids to patients of high-volume prescribers targeted by Purdue's opioid marketing campaign, knowingly or recklessly fulfilling illegitimate prescriptions.

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[89] OPTUMRX_JEFFCO_0000366858 (3/10/17).

[90] *Id.*

[91] *Id.*

[92] OPTUMRX_JEFFCO_0000385779 (7/11/18).

[93] *Id.*

289. As a direct result of its conduct, West Virginia has experienced and continues to experience both a flood of prescription opioids available for illicit use or sale and a population of patients with physical or psychological dependence on opioids.

290. In sum, the Optum Mail Order Pharmacy did nothing to fulfill its duties as the last line of defense and failed to ensure that the prescriptions it was filling were issued to legitimate patients for professionally recognized therapeutic purposes (legitimate medical purposes under federal law) by practitioners acting in the usual course of professional practice, as is evident by the copious amounts of opioids being dispensed throughout West Virginia.

291. Optum violated the CSA, West Virginia controlled substances laws and state and federal pharmacy laws and regulations by dispensing controlled substances in violation of its corresponding responsibility under 21 C.F.R. § 1306.04(a) and outside the usual course of pharmacy practice under 21 C.F.R. § 1306.06.

292. Optum violated the CSA, West Virginia controlled substances laws and state and federal pharmacy laws and regulations each time the Mail Order Pharmacy filled a controlled substance prescription without identifying and resolving those red flags because, *inter alia*:

- They were knowingly filled outside the usual course of professional practice and not for a legitimate medical purpose; therefore, they were not pursuant to a valid prescription under 21 U.S.C. § 829 and thereby violated 21 U.S.C. § 842(a)(1); and
- They were knowingly and intentionally dispensed outside the usual course of professional pharmacy practice in violation of 21 C.F.R. § 1306.06, and therefore such dispensing and delivering of controlled substances was not authorized by the CSA, and thereby violating 21 U.S.C. § 841(a).

293. The opioid crisis alleged herein is a direct and foreseeable result of Optum's actions and inactions. And it was reasonably foreseeable that the State would be damaged thereby.

294. The opioid nuisance alleged herein is a direct and foreseeable result of Optum's actions and inactions. And it was foreseeable that the State would be damaged thereby.

295. Optum failed to maintain effective controls against abuse and diversion or conduct adequate due diligence to ensure opioids were not diverted, resulting in the gross over-dispensing of opioids. Optum thus directly contributed to today's opioid epidemic and corresponding harm to the State.

D. Facts Pertaining to the Formulary & UM Enterprise

296. Optum, its Mail Order Pharmacy, and each of the opioid manufacturers (including Allergan, plc, Johnson & Johnson/Janssen, Endo Health Solutions Inc., Insys Therapeutics, Mallinckrodt Pharmaceuticals, Purdue Pharma, and Teva Pharmaceuticals/Cephalon Inc., referred to collectively as the "Opioid Enterprise Manufacturers" for the purposes of this Section) formed an association in fact enterprise, the "Formulary & UM Enterprise."

297. The Formulary & UM Enterprise was characterized by a common purpose, relationships among members of the Formulary & UM Enterprise, and sufficient longevity to accomplish the common purpose thereof. Optum conducted and participated in the conduct of the Formulary & UM Enterprise through a pattern of racketeering activity.

298. Each member of the Formulary & UM Enterprise knew that prescription opioids were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute pain, and non-cancer pain. Each member of the Formulary & UM Enterprise was also aware that use of prescription opioids carried risks such as addiction, opioid use disorder, overdose, and death. Nevertheless, each member of the Formulary & UM Enterprise joined together into an

association-in-fact enterprise for the common purpose of profiting from an expansion of the market for prescription opioids, and increased prescribing, dispensing, and sales of those drugs.

299. Each member of the Formulary & UM Enterprise sought to fulfill a common purpose through a pattern of mail and wire fraud, and corrupt manufacture, receiving, concealment, buying, selling or otherwise dealing in controlled substances. Specifically, each member of the Formulary & UM Enterprise supported each other member in perpetrating a scheme on the consumers who received prescriptions for prescription opioids and on Optum's clients. Each member of the Formulary & UM Enterprise also supported each other member in possessing and dispensing controlled substances in Schedules II through IV in manners that were not authorized by the federal Controlled Substances Act and West Virginia Controlled Substances Act.

300. For their part, the Opioid Enterprise Manufacturers' illegal marketing and false statements regarding prescription opioids have been well documented. They knew that prescription opioids were dangerous and addictive and, nevertheless, marketed them as safe and non-addictive. These representations furthered the common purpose of the Formulary & UM Enterprise.

301. Optum, for its part, made representations alleged, *see generally supra*, that its business was committed to making decisions about its formulary and UM offerings that were driven by a commitment to the health and safety of its covered lives and was focused on delivering safe healthcare.

302. Optum and opioid manufacturers also knew that Optum's Mail Order Pharmacy received prescriptions that were not for lawful orders of a practitioner. Moreover, Optum and opioid manufacturers knew that Optum's Mail Order Pharmacy was filling illegitimate prescriptions.

303. By these strategies, both Optum and the Opioid Enterprise Manufacturers agreed to further the common purpose of the Formulary & UM Enterprise through a scheme and unlawful possession and dispensing of controlled substances, and to grow the market for prescription opioids by increasing prescribing, dispensing, and sales of prescription opioids.

304. As an example, the Opioid Enterprise Manufacturers contracted and agreed with Optum to coordinate unfettered formulary placement with no or limited UM measures regarding each opioid drug on Optum's standard formulary offerings, such that there would be as little impediment as possible to opioid prescribing and dispensing. From their agreements, each member of the Formulary & UM Enterprise stood to reap significant profits from ever-increasing prescribing, dispensing, and sale of prescription opioids: the Opioid Enterprise Manufacturers from sales of their drugs and Optum from rebates and other fees. As part of these agreements, Optum gave each of the Opioid Enterprise Manufacturers parity terms, ensuring that no Opioid Enterprise Manufacturer's opioid was disadvantaged within each class of opioid analgesics, and provided the Opioid Enterprise Manufacturers with data about the lives that it managed, the prescriptions written by doctors on its plans, and assistance with pull through contracts to assist them in pulling through the formulary decisions which would continue to increase prescribing and sales.

305. These contracts, and further information described below, evidence an agreement between Optum, its Mail Order Pharmacy, and the Opioid Enterprise Manufacturers. Optum and each Opioid Enterprise Manufacturer understood that Optum was going to operate on a fundamentally misleading basis. As alleged more fully herein, Optum promised its clients that it would take actions that would ensure that opioid prescribing and dispensing were safe and cost effective.

306. Optum worked with each Opioid Enterprise Manufacturer in negotiations that were intended to maximize the amount of profit for Optum and the Opioid Enterprise Manufacturers. Discussions of formulary status and prior authorization, for example, were always a vehicle for discussions about the amount of rebates and administrative fees. As the Opioid Enterprise Manufacturers and Optum knew and intended, the end result was always the same—agreements for favorable formulary status without UM so that prescribing, dispensing, and sales could continue to increase.

307. Purported competition among the Opioid Enterprise Manufacturers for increasing market share of their drug against a competitor's drug did not undercut the common purpose of the Formulary & UM Enterprise. For example, Purdue's competition with Endo for market share of OxyContin over Opana did not slow or decrease the prescribing, dispensing, or sale of prescription opioids as a class of drugs. Furthermore, each member of the Formulary & UM Enterprise knew that there would be competition in the market, but each member also knew that their participation in the Formulary & UM Enterprise was necessary to continue growing the market and agreed to work together towards that goal.

308. As alleged more fully herein, the Formulary & UM Enterprise caused direct injury to West Virginia's money and property.

1. Formation of the Formulary & UM Enterprise

309. The Formulary & UM Enterprise was formed primarily in two ways, including the forced dealing of the members with each other in the closed system of controlled substance manufacture, distribution, and dispensing, as well as the members' work together in trade associations and industry working groups like the Pharmaceutical Care Management Association ("PCMA") and other informal groups.

310. First, the formation of the Formulary & UM Enterprise occurred, in part, through the parties' dealings with each other required by the closed system imposed by the CSA. The pharmaceutical industry is extremely insular and part of a "closed system" open only to those who register to do so. Other than its CSA obligations for mail order pharmacies, Optum is one of the very few participants in the chain of controlled substance distribution and dispensing that is not required to register with the DEA. However, in its efforts to secure cost-effective access to controlled substances on behalf of its clients, Optum was forced to work closely with the Opioid Enterprise Manufacturers.

311. Over at least the last two decades, the consolidation and acquisition of pharmacy benefit management companies into ever-larger entities has led to the formation of close personal business relationships between the few remaining PBMs and the Opioid Enterprise Manufacturers that were based on a shared interest in and the common purpose of ensuring the widespread dispensing of opioids.

312. There can be no doubt that Optum and the Opioid Enterprise Manufacturers have maintained close relationships. As business entities, they have been negotiating with each other since the mid-1990s over rebate agreements, contract amendments, re-negotiations, payment discussions, and rebate invoicing. These negotiations often involved high level executives at both companies, and a multitude of emails and phone calls, including personal calls between executives, to iron out details. The contractual dealings between the Opioid Enterprise Manufacturers and Optum created relationships and provided context in which the common purpose of the Formulary & UM Enterprise could develop. These contract negotiations were always geared towards maximizing the number of prescriptions written for Optum's clients and ensuring the most optimal

formulary placement and least amount of UM under Optum's standard offerings so that the prescribing, dispensing, and sales could continue to grow.

313. The formation of the Formulary & UM Enterprise did not happen solely within the formation of the rebate contracts between the Opioid Enterprise Manufacturers and Optum. The Formulary & UM Enterprise also continued to develop through regular non-contractual interactions, including through the use of the U.S. Mail or interstate wire facilities in furtherance of the scheme, including: (1) interactions about the administration of the rebate contracts; (2) pull-through marketing and assistance therewith; and (3) joint participation in trade associations and informal coalitions.

314. Trade associations, informal coalitions, and forums not only provide a basis for the formation of the Formulary & UM Enterprise, but also serve as central conduits for the conduct of and participation in the Formulary & UM Enterprise. The prime example of a trade association through which the Formulary & UM Enterprise developed and operated is the PBM trade association, the Pharmaceutical Care Management Association ("PCMA").

315. PCMA describes itself as "lead[ing] the effort in promoting PBMs and the proven tools they utilize, which are recognized by consumers, employers, policymakers, and others as key drivers in lowering prescription drug costs and increasing access."[94]

316. While PCMA boasts of being the national association representing America's pharmacy benefit managers, it actually has a much broader membership base and focus. As evident from the PCMA website, PCMA membership includes member PBMs and so-called "Affiliate" drug manufacturers and other entities, including numerous Opioid Enterprise Manufacturers as current or former members.

[94] https://www.pcmanet.org/about/.

317. As repeatedly mentioned in the PCMA's annual conference materials, the drug manufacturers are PBMs' most notable business partners.

318. Optum is a member of PCMA and has been heavily involved in that organization's activities, including by having top Optum executives speak at annual meetings and serve on the PCMA's board of directors.

319. Indeed, PCMA has and continues to be governed by PBM executives. An image illustrating the membership in the PCMA is as follows:

320. Active control over the PCMA Board of Directors is important to Optum. For example, in 2024, Dr. Patrick Conway, CEO of Optum, served on the PCMA's Board of Directors.

321. Each year during the relevant period, PCMA has regularly held industry conferences, including its Annual Meeting and Business Forum conferences.

322. Every year, high-level representatives and corporate officers from both Optum and the Opioid Enterprise Manufacturers have attended these conferences to meet in person and engage in discussions, including those in furtherance of the Formulary & UM Enterprise.

323. In fact, many of the Opioid Enterprise Manufacturers have been "Partners," "Platinum Sponsors," or "Presidential Sponsors" of these PCMA conferences.

324. Notably, many of the forums at these conferences are specifically advertised as offering opportunities for private, non-public communications. For example, as Presidential Sponsors of these conferences, the Opioid Enterprise Manufacturers were permitted to host "private meeting rooms" that offer "excellent opportunities for interactions between PBM members, drug manufacturers, and other industry partners."

325. Representatives from Optum and the Opioid Enterprise Manufacturers have routinely met during the Annual Meetings and Business Forum conferences that PCMA holds (and the manufacturers sponsor) each year.

326. In addition, all PCMA members, including Affiliates and registered attendees of these conferences are invited to join PCMA-Connect, "an invitation-only LinkedIn Group and online networking community."

327. As PCMA members and Affiliates, Optum, and the Opioid Enterprise Manufacturers utilized both PCMA-Connect, as well as the meetings facilitated by PCMA (including at conferences), to exchange information and to reach agreements in furtherance of the Formulary & UM Enterprise.

328. Thus, PCMA served as a conduit of information between the Opioid Enterprise Manufacturers and Optum on subjects like access to prescription opioids and facilitated the sharing of information and collaborative partnerships.

329. PCMA hosts regular meetings during which PBMs and Opioid Enterprise Manufacturers, or "Pharma" as they are called by PBMs, can discuss their coordinated and shared objectives/strategies. PCMA's website posts programs for its regular meetings that highlight the close collaboration and partnership between PBMs and the Opioid Enterprise Manufacturers.

330. For example, in describing its 2021 annual meeting in Colorado Springs, Colorado, the PCMA stated on its website that "[t]he event [was] tailored specifically for senior executives from PBMs and their affiliated business partners – most notable drug manufacturers." The description further emphasized that the annual meeting was "an important part of [a PBM's] business strategy."[95]

331. On information and belief, program agendas at PCMA's regular meetings often included topics that focused on strengthening the business relationships between PBMs and manufacturers.

332. Given the foregoing, it is not surprising that Purdue viewed PCMA as a valuable source of information and coordination on subjects regarding prescription opioids and OxyContin. As examples, Purdue employees were notified about meetings at the PCMA conference in 2001 that discussed "oxy attacks as a predatory action on the part of the media or one of your competitors," and Burt Rosen (another Purdue employee) reached out to PCMA in 2014 to find the right person to connect with "on opioids."[96]

333. More broadly, PCMA (including through the regular use of the U.S. Mail or interstate wire facilities in furtherance of the scheme) served as a clearinghouse for communications, discussions, consensus building. Documents confirm that PCMA was a conduit

[95] https://www.pcmanet.org/events/past-events/pcma-annual-meeting-2021/.

[96] PDD8801103934 (3/16/01); PPLPC018001107944 (10/2/14).

through which discussions occurred and consensus could be reached and that specific discussions and work took place around efforts to curb opioid abuse (which would have worked against the common purpose of the Formulary & UM Enterprise).

334. PCMA was not the only way in which Optum and the Opioid Enterprise Manufacturers collaborated. For example, the Controlled Substances Stakeholders Coalition was formed in October 2013 in order to "further collaborate on interprofessional efforts to combat the United States opioid epidemic." At the time of the Coalition meeting in December 2016, these meetings had been ongoing for at least three years with each organization providing "updates for increasing awareness and decreasing misuse and diversion."[97]

335. As alleged more fully herein, Optum actively worked with the Opioid Enterprise Manufacturers in the Formulary & UM Enterprise to avoid taking actions that would have reduced prescribing, thus ignoring its obligations to reduce unsafe and inappropriate prescribing.

336. Members of the Formulary & UM Enterprise also participated in similar stakeholder meetings directly and/or through PCMA regarding topics like red flags and warning signs related to prescribing and dispensing controlled substances. The express purpose of these stakeholder meetings was to foster open channels of communication, foster understandings, and to discuss collaborative actions.[98] Notably, membership in some stakeholder meetings and working groups included some of the Opioid Enterprise Manufacturers' front groups and trade associations (e.g., PhRMA), opioid distributors, the National Association of Chain Drug Stores, and other PBMs and pharmacies.

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[97] *Id.*

[98] PPLPC019001069664 (11/14/2014); PPLPC019001069666 (11/14/2014); PPLPC019001100901 (2/26/2015); PPLPC019001100905 (2/26/2015); PPLPC019001100919 (2/26/2015); PPLPC019001100921 (2/26/2015).

337. The foregoing facts, and as alleged in more detail herein, demonstrate that the Formulary & UM Enterprise arose from personal business relationships developed between the enterprise members in various ways over the course of at least the last two decades.

2. The Common Purpose and Scheme of the Formulary & UM Enterprise

338. The personal business relationships that formed the Formulary & UM Enterprise also allowed for the formation of a common purpose between the Opioid Enterprise Manufacturers and Optum in the Formulary & UM Enterprise. Specifically, the Formulary & UM Enterprise was formed for the common purpose of illegally profiting from an expansion of the market for prescription opioids, and increased prescribing, dispensing, and sales of those drugs.

339. The scheme that furthered the common purpose of the Formulary & UM Enterprise relied on misleading representations from Optum to each one of its clients and to the public that it would structure formulary offerings and perform cDUR benefit services in the interests of its clients and patients to ensure that opioids were prescribed and dispensed only for safe and legitimate reasons. Instead of providing standard formulary and UM offerings that were in its clients' best interests or for safe and legitimate reasons, Optum made decisions that gave the Opioid Enterprise Manufacturers and their prescription opioids unfettered and preferred formulary access, without UM, did not disadvantage any opioid compared with another in the same class or formulary tier, agreed to parity treatment for opioids within the same class and/or formulary, supported the Opioid Enterprise Manufacturers' pull-through marketing, pocketed enormous rebates and other fees, and (through its Mail Order Pharmacy) dispensed prescription opioids without conducting the necessary due diligence.

340. Each member of the Formulary & UM Enterprise played a part and furthered the common purpose of the Formulary & UM Enterprise.

341. For their part, the Opioid Enterprise Manufacturers have been engaged in fraudulent conduct related to the marketing of prescription opioids beginning in the mid-1990s. The Opioid Enterprise Manufacturers engaged in a scheme, including through the regular use of the U.S. Mail or interstate wire facilities in furtherance of the scheme, to grow the market for prescription opioids through the use of branded and unbranded marketing materials, key opinion leaders ("KOLs") to give speaker presentations and publish about prescription opioids, and front groups which would contribute to and publish books, articles, documents, etc., all of which misrepresented the benefits and risks of prescription opioid use.

342. The Opioid Enterprise Manufacturers commonly made the same misrepresentations through common KOLs and Front Groups. For example, each of the Opioid Enterprise Manufacturers made repeated misrepresentations about the risks and benefits of prescription opioids, including:

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

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

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

d. Opioid withdrawal can be avoided by tapering;

e. Long-term opioid use improves functioning;

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

g. OxyContin provides twelve hours of pain relief; and

h. New formulations of certain opioids, labeled abuse deterrent, successfully deter abuse.

343. Each of the Opioid Enterprise Manufacturers made nearly identical representations about their branded drugs and/or unbranded prescription opioids as a class of drugs during the relevant time period.

344. Each of the Opioid Enterprise Manufacturers used similar Front Groups to promote prescription opioid use. As examples, several of the Opioid Enterprise Manufacturers used Front Groups including, the following: the American Pain Foundation, the American Academy of Pain Medicine, the American Pain Society, Federation of State Medical Boards, the Alliance for Patient Access, the United States Pain Foundation, the American Geriatric Society, and the National Initiative on Pain Control.

345. The Opioid Enterprise Manufacturers took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups, ensuring that the Opioid Enterprise Manufacturers were consistently in control of their content and that it stayed on message in favor of more opioid prescribing. The Opioid Enterprise Manufacturers exercised control over and adopted their false and deceptive messages and acted in concert with the Front Groups and, through the Front Groups, with each other to deceptively promote the use of prescription opioids.

346. Each of the Opioid Enterprise Manufacturers used similar KOLs and the strategy of paying opinion leaders and speakers who favored aggressive treatment of pain with prescription opioids. Pro-opioid doctors have been at the hub of the Opioid Enterprise Manufacturers' well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception that opioids were safe and effective for chronic conditions. As examples, multiple Opioid Enterprise Manufacturers used similar KOLs including, but not limited to: Dr. Russell Portenoy, Dr. Lynn Webster, Dr. Perry Fine, and Dr. Scott Fishman.

347. Each of these KOLs and numerous other, lower profile doctors, were paid to speak on behalf of prescription opioids as an unbranded class of drugs. They were used extensively to present the appearance that unbiased and reliable medical research supported the broad use of

prescription opioids. These pro-opioid doctors also began to write, consult on, edit, and lend their names to books and articles. They gave speeches, and they served on committees, all the while encouraging the use of prescription opioids.

348. The Opioid Enterprise Manufacturers also used branded and unbranded advertising and marketing; funded, edited and distributed pro-opioid publications; speakers bureaus and continuing education programs. Furthermore, as alleged above, Optum often facilitated and/or disseminated the Opioid Enterprise Manufacturers' marketing messages directly to doctors who prescribed for patients covered by Optum's clients.

349. One of the primary means by which the Opioid Enterprise Manufacturers disseminated their messaging about prescription opioids was through drug detailing: the practice of sending out pharmaceutical company representatives to provide details about specific branded products in order to persuade prescribers to begin writing (or write more) prescriptions for a specific product.

350. The Opioid Enterprise Manufacturers adopted detailing as a key component of their prescription opioids strategy early on to capitalize on the unbranded marketing—developing carefully crafted marketing strategies and tactics to deliver messages to prescribers through close relationships with sales representatives.

351. Drug detailing is data driven, requiring identification of the prescribers who are writing high or low volumes of prescriptions, targeting places where additional messaging might be effective and to test the effectiveness of messaging. In accordance with common industry practice, the Opioid Enterprise Manufacturers purchased and closely analyzed prescription sales data from companies like IMS Health (now IQVIA) and Optum, which allowed them to track—precisely—the rates of initial and renewal prescribing by individual prescribers.

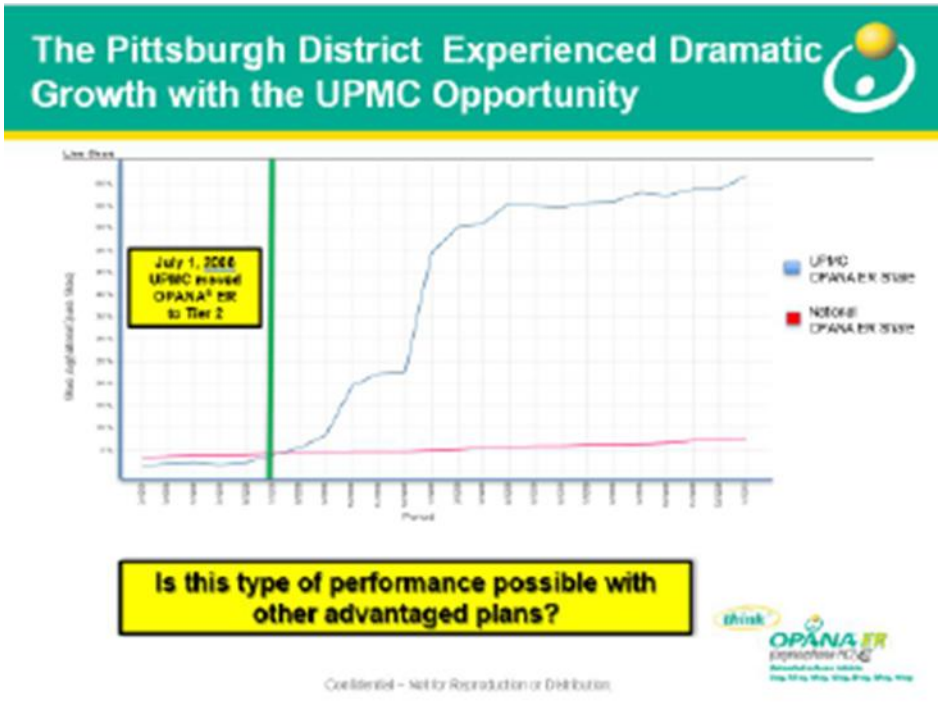
352. The nexus between data and detailing helped drive the formation of the common purpose of the Formulary & UM Enterprise. In return for data and unfettered formulary placement from Optum, the Opioid Enterprise Manufacturers were willing to pay higher rebates and other fees to Optum.

353. Once that occurred, Optum once again supported the Opioid Enterprise Manufacturers' deceptive marketing regarding prescription opioids. After the Opioid Enterprise Manufacturers obtained Optum's data and favorable formulary placement, the Opioid Enterprise Manufacturers' sales personnel immediately began to analyze their managed care or PBM data in order to "pull through" the formulary placement and drive increased sales.

354. Formulary placement was viewed as a "win" and an opportunity to make the rebate agreements profitable by pulling through sales. Sophisticated presentations outlining the exact steps a sales representative should take were often included in the sales training materials. The impact of these agreements and the ability to pull-through increased sales using the PBM data was dramatic:[99]

[99] ENDO-CHI_LIT-00046379, slide 7

355. Using the "Best Practices Identified" of: (1) Identifying the local UHC MC Opportunity; (2) Targeting the Right UHC Customer; (3) Hyper Targeting; (4) Delivering the Right Message; and (5) Consistent Cross-Functional Communication – the Pittsburgh District experienced dramatic growth in sales, as described by Endo:[100]



356. Formulary wins were a boon for each member of the Formulary & UM Enterprise. Each prescription opioid that enjoyed a favorable formulary placement, or continued to enjoy prescribing and dispensing without UM, ensured that all prescription opioids would continue to enjoy unrestricted sales due to the parity clauses that Optum agreed to with each Opioid Enterprise Manufacturer. And, as indicated by the graph cited above, these wins increased sales. And, by increasing sales, the wins increased profits for the Opioid Enterprise Manufacturers whose drugs were sold and for the PBM who received rebates and administrative fees tied to sales.

[100] *Id*. at slides 9 and 10.

357. However, Optum took on obligations to perform and made representations that they would conduct point-of-sale review and take actions to ensure that only safe and legitimate prescriptions were being filled when Optum had no intention of doing so. Had Optum taken the actions they had promised their clients, it would have dramatically reduced medically inappropriate prescribing, sales and dispensing of prescription opioids. As alleged more fully herein, Optum's failure to do so had a significant role in allowing opioids to flood into West Virginia.

358. Optum also paid lip service to its commitment to acting to fight against prescription drugs, including opioids waste and abuse. OptumRx's website, touting its expertise and commitment to fight the opioid epidemic and demonstrating expertise in opioid management: "Optum Rx® implements a multi-dimensional Opioid Risk Management solution to help curb the rising tide of opioid abuse across the United States . . . as part of its commitment to drive opioid safety and prevention."[101]

359. Optum regularly delayed taking actions that could have dramatically reduced medically inappropriate prescribing, sales and dispensing despite promises from it to do the same.

360. A November 3, 2016, email from Bob Lahman, Trade Relations VP at OptumRx explained that OptumRx had agreed to forego measures that would have used prior authorization as a tool to control the prescription of opioids. The explanation reveals how closely each Opioid Enterprise Manufacturer worked with each PBM Defendant: "It was not unusual for any manufacturer to not want a PA on their product, especially if it was a small molecule product, and

[101] Optum, "White Paper: Working to end the opioid epidemic" at. 7 (2018).

very few would have agreed to a rebate where they did not have unrestricted access (no PAs or steps (sic) edits)."[102]

361. When the pressure began mounting to limit access to prescription opioids by use of UM measures like prior authorization, step edit, or days' supply limits, there were serious concerns expressed in 2017 within OptumRx about the impact on the "significant" rebates being received from the drug makers:

From: Merrill, Nathan <Nathan.Merrill@optum.com>
Date: Monday, Feb 06, 2017, 4:09 PM
To: Calabrese, David <David.Calabrese@optum.com>
Subject: RE: BIC

David,

Venkat had concerns about adding a PA to Embeda, Oxycontin, and Opana ER since these are preferred products that are tied to "significant" rebates. By adding a PA to these products we jeopardize any rebates we have contracted with the manufacturer. I wasn't in a position to argue so I just explained that we anticipated there would likely be concerns within this class that we would address later. With BIC scheduled for this Wednesday do you think you would be able to attend to go to battle for us on this one? I know Venkat is going to say we cannot put a PA on those 3 products and I'm not sure there is anything more I can say or do to get around this. I appreciate any feedback you might have.

Thank you,

Nathan Merrill, PharmD, CGP | OptumRx
Manager, Clinical UM Operations

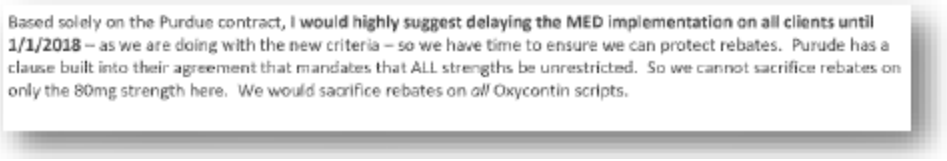
[103]

362. Later, OptumRx employees discussed whether they would be willing to put a hard limit on morphine equivalent dosing (MED) on OxyContin 80 mg to align with the 2016 CDC Prescribing Guidelines. The discussion was immediately interrupted by Brian Sabin, Manager of Industry Relations, who explained that they needed to delay implementation to "ensure we protect rebates" because "we cannot sacrifice rebates on only the 80 mg strength here" as that would mean OptumRx would "sacrifice rebates on *all* OxyContin scripts."[104]

[102] OPTUMRX_JEFFCO_0000446761 (11/3/16).

[103] OPTUMRX_JEFFCO_0000206377 (2/7/17).

[104] OPTUMRX_JEFFCO_0000261777 (6/9/17).


Based solely on the Purdue contract, I **would highly suggest delaying the MED implementation on all clients until 1/1/2018** – as we are doing with the new criteria – so we have time to ensure we can protect rebates. Purude has a clause built into their agreement that mandates that ALL strengths be unrestricted. So we cannot sacrifice rebates on only the 80mg strength here. We would sacrifice rebates on *all* Oxycontin scripts.

105

363. As another example, despite their contractual obligations and their public representations, it was not until 2019 that OptumRx even began to consider exclusion of OxyContin from its formularies.

364. An email exchange in March 2019 between Brian Sabin, Optum Director of Industry Relations, and Venkat Vadlamudi, Optum, raises the question whether they should remove OxyContin from its formularies altogether, "rebate losses be damned," arguing that Purdue caused the opioid epidemic and Optum's continued inclusion of OxyContin on its formularies was "rewarding their bad behavior." He argues that, "[f]rom a purely PR perspective, I think it would look good on us." In response, Vadlamudi states that "[w]e as a company looked into this," but the amount of OxyContin rebates Optum collected "prevented us from doing it." As even Vadlamudi then goes on to admit, "[b]ut times are different now. [I]f you can look into it and model the scenarios maybe we can change."[106]

365. Even as Purdue explored bankruptcy and OptumRx became aware of the potential for lost rebates, the answer was not to discontinue OxyContin's preferred formulary position, but instead to move other drugs into preferred positions in order to ensure the free flow of prescription opioids from another Opioid Enterprise Manufacturer in the Formulary & UM Enterprise.

366. Further, Optum owns and operates the Optum Mail Order Pharmacy. Optum's Mail Order Pharmacy dispensed massive amounts of branded and generic opioids without performing

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[105] *Id.*

[106] OPTUMRX_JEFFCO_0000506200 (3/4/19).

the requisite due diligence on prescriptions or refusing to fill prescriptions that could not be validated through due diligence. As such, the Optum Mail Order Pharmacy provided another mechanism for the goal of the Formulary & UM Enterprise—*i.e.,* the unrestricted increase in prescribing and dispensing of prescription opioids for the profit of the Opioid Enterprise Manufacturers and Optum.

367. By dispensing branded and generic prescription opioids without performing the requisite due diligence on prescriptions or refusing to fill prescriptions that could not be resolved through due diligence, the Optum Mail Order Pharmacy furthered the common purpose of the Formulary & UM Enterprise by facilitating the increased dispensing and sale of prescription opioids. This also violated the law governing dispensing controlled substances in Schedules II through IV in ways that are punishable as felonies under the law.

368. The Formulary & UM Enterprise maintained a common purpose from the late 1990s through to the present day, creating sufficient longevity in their personal business relationships for them to pursue the common purpose of the Formulary & UM Enterprise.

3. Conduct and Participation of the Formulary & UM Enterprise Through a Pattern of Racketeering Activity

369. The common purpose of the Formulary & UM Enterprise was perpetrated through a misleading scheme fulfilled by multiple illegal acts and by unlawful possession and dispensing of controlled substances. Optum's predicate acts constitute a pattern of racketeering activity.

370. The pattern of racketeering activity used by Optum and its Mail Order Pharmacy likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the scheme through which the common purpose was achieved.

371. Use of the mail and wire facilities began with the formation of the Formulary & UM Enterprise. Negotiations and communications about the contracts between Optum and the

Opioid Enterprise Manufacturers occurred through interstate mail and wire facilities and involved meetings, communications, and negotiations about contracts between Optum and the Opioid Enterprise Manufacturers, the Opioid Enterprise Manufacturers' marketing and Optum's assistance therewith, and pull-through marketing which required the transmission of large volumes of data.

372. The Opioid Enterprise Manufacturers and Optum regularly and continuously communicated through the use of the U.S. Mail and interstate wire facilities in furtherance of the common purpose of the Formulary & UM Enterprise and their fraudulent scheme, including discussions of formulary placement, prior authorization limits, step therapy, preferred formulary status and their impact on opioid prescribing and dispensing and, relatedly, rebates and other fees. Importantly, rarely mentioned during these discussions was the impact of the burgeoning opioid epidemic. These discussions were clearly intended to further the common purpose of the Formulary & UM Enterprise, happened over at least the last two decades (beginning with Purdue's work with predecessors of Optum and continuing to involve more Opioid Enterprise Manufacturers over time), and reveal the ongoing personal business relationships that developed between the members of the Formulary & UM Enterprise.

373. Similarly, Optum engaged in significant pull-through marketing assistance with each Opioid Enterprise Manufacturer. Optum, through the regular use of the U.S. Mail or interstate wire facilities in furtherance of the fraudulent scheme, agreed to provide the Opioid Enterprise Manufacturers with preferred formulary placement and prescribing data. This ensured that the unfettered formulary access (granted despite Optum's contrary representations to the public and their clients), would facilitate unrestricted opioid prescribing and dispensing. Pull-through efforts were undertaken after each formulary announcement "win" in order to drive the Opioid Enterprise

Manufacturers' profitability. Optum was not only aware of this pull-through marketing, it actively joined in efforts with the Opioid Enterprise Manufacturers by creating reports about the "value proposition" of unrestricted use of prescription opioids as alleged more fully herein.

374. Finally, Optum and the Opioid Enterprise Manufacturers regularly (and through the regular use of the U.S. Mail or interstate wire facilities in furtherance of the fraudulent scheme) participated in trade industry associations and informal coalitions that provided recurring non-contractual opportunities and forums in which to continue developing personal business relations and in which they formed a common purpose of growing the unfettered use of opioid drugs.

375. Optum engaged in essentially uniform conduct with the Opioid Enterprise Manufacturers whereby Optum granted the Opioid Enterprise Manufacturers' drugs unfettered formulary access (including preferred formulary placement coupled with refraining from UM) despite its public promises and contractual obligations to make formulary and UM decisions in their clients' best interests, and facilitated their pull-through marketing and/or directly facilitated the dissemination of their marketing messages. Optum also provided the Opioid Enterprise Manufacturers with PBM data so that they could pull through the formulary "wins" and drive increased prescribing. At the back end of the scheme, Optum profited from receiving rebates and other fees while the Opioid Enterprise Manufacturers enjoyed increased sales through pull through marketing and unfettered formulary access.

376. The unlawful scheme was advanced through mailings and interstate wire transmissions that constitute racketeering activity. Collectively, these violations constitute a pattern of racketeering activity, through which Optum and its Mail Order Pharmacy and the Opioid Enterprise Manufacturers deceived and intended to deceive West Virginia.

377. Optum and its Mail Order Pharmacy devised and knowingly carried out unlawful scheme using materially false pretenses, representations, promises, or omissions regarding their conduct. Optum promised to perform pharmacy benefit management services, including cDURs, formulary decisions, and UM decisions in their clients' best interests and in ways that would ensure safe and effective prescribing. These promises were made in person, in publications, and through the mail and the wires.

378. Optum and its Mail Order Pharmacy did not intend to comply with their contractual obligations, the promises to their clients, or their public representations. Optum and its Mail Order Pharmacy intended to continue to make decisions and take actions that benefitted the members of the Formulary & UM Enterprise and its common purpose by failing to perform cDURs, granting unfettered formulary access, and blocking implementation of any UM measures, which directly contradicted its public promises and contractual obligations.

379. Optum and its Mail Order Pharmacy intended that its common purpose and scheme to deceive and defraud would, and did, use the U.S. Mail and interstate wire facilities intentionally and knowingly with the specific intent to advance and for the purpose of executing the unlawful scheme.

380. By engaging in its intended conduct, as alleged more fully herein, Optum and its Mail Order Pharmacy engaged in deceptive, misleading, fraudulent, and unlawful conduct constituting a pattern of racketeering activity.

381. Optum and its Mail Order Pharmacy used the U.S. Mail and interstate wire facilities to perpetrate the deceptive, misleading, and fraudulent scheme of the Formulary & UM Enterprise with thousands of communications, publications, representations, statements, electronic transmissions, and payments including, but not limited to:

i. Contracts negotiated and circulated between members of the Formulary & UM Enterprise;

ii. Contracts negotiated and circulated between Optum and its clients;

iii. Public representations by the Opioid Enterprise Manufacturers and Optum about their commitment to addressing misuse, abuse, and diversion of prescription opioids;

iv. Marketing materials about prescription opioids transmitted between the Opioid Enterprise Manufacturers and that were later disseminated by Optum;

v. Communications between Optum and their clients about their commitment to following the terms of their respective contracts;

vi. Communications between the Opioid Enterprise Manufacturers and Optum regarding formulary changes;

vii. Communications between the Opioid Enterprise Manufacturers and Optum regarding and including PBM prescribing data;

viii. Transmission of rebate payments; and

ix. Transmission of payments from the clients of Optum.

382. To achieve the common purpose of the Formulary & UM Enterprise, Optum and its Mail Order Pharmacy and the Opioid Enterprise Manufacturers hid from their clients, patients, regulators and West Virginia: (a) the deceptive, misleading, and fraudulent nature of the scheme; (b) the deceptive, misleading, and fraudulent nature of their representations; (c) their intention to ignore their contractual cDUR obligations; (d) intent to make formulary and UM decisions that failed to limit the medically unnecessary and inappropriate prescribing, sales, or dispensing of prescription opioids or address misuse, abuse, and diversion; and (e) the true nature of the association between each member of the Formulary & UM Enterprise.

383. Each member of the Formulary & UM Enterprise, including Optum and its Mail Order Pharmacy, agreed with the overall objective of the Formulary & UM Enterprise's deceptive,

misleading, and fraudulent schemes and participated by taking action that furthered the common purpose of the Formulary & UM Enterprise.

384. The pattern of racketeering activity involving the unlawful possession and dispensing of controlled substances in Schedules II through IV likely involved thousands, if not millions, of improperly dispensed prescription opioid pills in violation of the CSA and Optum's registration as the Optum Mail Order Pharmacy. Optum knowingly and intentionally possessed and dispensed branded and generic prescription opioids for reasons that were not authorized by the CSA.

385. The predicate acts of the Formulary & UM Enterprise all had the purpose of furthering the opioid epidemic that substantially injured West Virginia's business and property, while simultaneously generating billion-dollar revenue for Optum and its Mail Order Pharmacy. The predicate acts were committed, and/or caused to be committed, by Optum and its Mail Order Pharmacy through their participation in the Formulary & UM Enterprise and in furtherance of the fraudulent schemes, unlawful possession and dispensing of controlled substances, and common purpose thereof.

4. Optum Concealed Its Unlawful Conduct

386. Optum's conduct described herein was concealed from West Virginia and the public at large.

387. Optum intentionally undertook efforts to conceal its conduct by misrepresenting its role in the pharmaceutical marketplace as promoting safe and effective use of opioids, and failing to make public information in its possession and control that would have revealed the truth regarding its relationships with manufacturers and its financial interest in the increased utilization of opioid medications.

388. Optum hid the details of its relationships with opioid manufacturers.

389. West Virginia did not and could not have known that Optum developed its national formularies based on profit and rebates, not based on the safety and efficacy of the medications as they claim.

390. West Virginia did not learn that it had been injured by Optum's actions, the source of those injuries, or that those injuries were part of a pattern of conduct until only recently, until documents revealing those facts were produced in discovery by various entities in *In re: National Prescription Opiate Litigation*, Case No. 1:17-md-2804-DAP (N.D. Ohio) and other opioid litigation, including the documents cited, quoted, and relied on throughout this complaint. These documents—and the facts they contain—have never before been made public, nor have they ever before been in West Virginia's possession, and were not otherwise available to West Virginia before being produced in discovery.

391. Optum undertook efforts, including through the use of the U.S. Mail or interstate wire facilities in furtherance of the fraudulent scheme, to purposefully conceal its wrongful conduct by: (1) manipulating and distorting public information, knowledge, and facts; (2) misrepresenting its role in the pharmaceutical market as promoting safe use and appropriate opioid dispensing; (3) assuring the public and governmental authorities that it was complying with its obligations and was acting to prevent diversion and drug abuse; (4) hiding the true nature of its relationships with the Opioid Enterprise Manufacturers; (5) failing to make public or otherwise produce nonpublic information, over which Optum had exclusive possession, dominion, and control, that would have revealed the truth; (6) entering into overly broad confidentiality agreements with entities in the supply chain with whom it contracted; and (7) by deliberately and fraudulently concealing the truth.

392. Optum intended that its false statements and omissions be relied upon.

393. Optum knew of its wrongful acts and had material information pertinent to their discovery, but concealed that information from West Virginia.

394. Only Optum knew of its widespread misinformation campaign and of its repeated, intentional failures to prevent opioid overutilization and diversion.

395. Due in large part to its deceptive, intentional, and deceitful conduct, the full scope of Optum's wrongful conduct and its central role in the opioid epidemic has not yet come to light.

E. Optum's Facilitation and Encouragement of the Use of Opioids Was a Cause of a Public Health Crisis in West Virginia

396. The opioid epidemic has touched nearly every American, either directly or indirectly, and its toll continues to mount. According to the CDC, prescription opioids have played a direct or indirect role in over 80% of overdose deaths in the United States, a crisis that has worsened over the past two decades. The death toll from opioids has now surpassed fatalities from car accidents and firearms. Today, more than 175 Americans die every day from opioid overdoses.

397. In addition to the toll on families and loved ones, opioid use imposes significant economy-wide costs. The U.S. Congress Joint Economic Committee estimates the opioid epidemic cost $1.04 trillion in 2018, $985 billion in 2019 and nearly $1.5 trillion in 2020 alone, up 37% from 2017, when the CDC last measured the cost. The rise in fatal opioid overdoses in 2022 suggests the total cost is likely to continue to increase.

398. West Virginia is ground zero of the opioid epidemic that Optum caused, contributed to, and maintained, and the State is experiencing a drug overdose epidemic that is causing devastating social and economic consequences throughout the State.

399. Between 2006 and 2014, the State was flooded with approximately 1.1 billion hydrocodone and oxycodone pills. The massive over-shipment amounts to 611 pain pills for every man, woman, and child in the State.

400. As the volume of prescription opioids flooding into West Virginia increased, so, too, did the death toll. West Virginia has had the highest per-capita opioid overdose death rate in the nation for each of the last ten years. The State also has one of the highest prescription rates of opioids in the United States. West Virginia ranks in the top 10 for the highest rate of prescriptions written for high-dose opioids and extended-release opioids.

401. West Virginia is the state with the highest age-adjusted death rate from opioid use over this time period; in terms of absolute deaths, from 1999 to 2019 there have been a total of 10,054 drug overdose deaths in West Virginia.

402. More specifically, deaths in West Virginia that listed opioids as a cause of death have also increased, from 1.55 per 100,000 in 1999 to 37.27 per 100,000 in 2019. In terms of per capita rates, compared to the national average, West Virginia has had the highest rate of opioid overdose in the country from 1999 to 2019.

403. The increased volume of opioid prescribing and the volume of opioids in West Virginia correlates directly to skyrocketing addiction, abuse, overdose, and death in West Virginia; black markets for diverted prescription opioids; and a concomitant rise in heroin, fentanyl, and methamphetamine abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids.

404. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. When untreated, NAS can be life-threatening.

405. There has also been a startling increase in infants born with NAS in West Virginia.

406. Indeed, the rate of NAS in West Virginia increased over fourfold from 2008 to 2017, from 10.64 per 1,000 births in 2008 to 56.17 per 1,000 births in 2017.

407. In West Virginia, the rate of opioid-related inpatient hospital treatments more than doubled in less than 10 years, from 218 per 100,000 in the first quarter of 2009 to 465 per 100,000 in the second quarter of 2019.

408. Medical and expert evidence indicates that in 2019, the prevalence of Opioid Use Disorder ("OUD") was approximately 4% in West Virginia.

409. Given the approximately 72,032 adults in West Virginia experiencing mild to severe OUD, there have been serious consequences of opioid use to children in West Virginia, with an estimated 42,500 children in West Virginia being exposed to parental opioid use during adolescent development. An estimated 4,000 children in West Virginia have had a parent die from overdose or another opioid-related cause.[107]

410. The opioid epidemic has created a strain on the foster care system, as it is now stretched dangerously thin. Additionally, the majority of foster care system placements in West Virginia are due to parental drug use, a substantial portion of which would be expected to be opioid use given the high burden of addiction in West Virginia. Overall, approximately 13.0 children per 1,000 in West Virginia are separated from families due to concerns about child welfare, which is higher than any other state in the United States.[108]

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[107] The Ripple Effect: National and State Estimates on the U.S. Opioid Epidemics Impact on Children, https://media.uhfnyc.org/filer_public/6e/80/6e80760f-d579-46a3-998d-1aa816ab06f6/uhf_ripple_effect_national_and_state_estimates_chartbook.pdf.

[108] Moving Upstream: Improving Child Welfare in West Virginia Requires Addressing Root Causes of Hardship, West Virginia Center on Budget and Policy, https://wvpolicy.org/moving-

411. The State has been particularly ravaged by the opioid epidemic caused by Optum's wrongful actions. The State has suffered from opioid related addiction, abuse, overdose, and death which has had severe and far-reaching public health, social services, and criminal justice consequences, which have created a significant and unreasonable interference with the public health, the public safety, the public peace, the public comfort and/or the public convenience in West Virginia.

412. As the volume of prescription opioids flooding into West Virginia increased, the State suffered harm caused by the volume of opioids including abuse, addiction, overdose, and death, as well as other harms such as emergency medical services responses for suspected overdoses, emergency department visits for overdose, naloxone administration prior to emergency medical services, increased burden on the treatment and chemical dependence provider system, OUD and opioid use among both adults and adolescents, and neonatal abstinence syndrome ("NAS").

413. Opioid abuse and addiction also cause increased emergency room visits, inpatient hospitalizations, and emergency medical technicians' administration of naloxone, the antidote to opioids.

414. As a result of the increase in overdoses, West Virginia has also sustained high costs related to emergency medical care and first responders.

415. Optum's conduct has also had a significant effect on the increase in crime and related criminal justice expenses within West Virginia.

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upstream-improving-child-welfare-in-west-virginia-requires-addressing-root-causes-of-hardship-2/.

416. While Optum was reaping millions of dollars in profits from its wrongful conduct, the State has been required to allocate substantial public monies and resources to combat the opioid crisis and cope with its fallout.

F. The State's Claims Are Timely

1. Continuing Violation

417. To this day, the State continues to suffer significant harm as a result of the unlawful, wrongful, and tortious conduct of Optum. Optum's conduct has created an ongoing and continuous threat to and significant interference with public health, safety, comfort, and/or convenience.

418. That conduct is ongoing, and the resulting injuries are not isolated or singular but are repeated and continuous in nature. Optum's conduct and/or the resulting injuries are ongoing at least in the following ways:

a. Rampant opioid abuse, addiction, overdose, injuries, and deaths, which persist as a result of Optum's conduct;

b. Opioid over-prescription. As of 2023, 46.4 opioid prescriptions were dispensed per 100 persons in West Virginia;

c. The creation and fostering of an illegal secondary market for prescription opioids, which continues to exist; and

d. Increased costs and expenses for the State relating to healthcare services, law enforcement, the criminal justice system, social services, and/or education systems.

419. The harms have not occurred all at once; instead, they have accumulated and intensified over time. Because Optum's wrongful actions persist, the tort is not complete, and the full extent of the damages has yet to be realized. The unlawful, false, deceptive, or misleading conduct has not ceased, the public nuisance remains unabated, and the actions causing harm continue to this day—inflicting continued injury on the State.

420. Optum's wrongful conduct, which helped to cause or contributed to the opioid epidemic continues to cause harm and remains unabated.

2. Equitable Estoppel and Concealment

421. Optum engaged in a sustained, calculated effort to conceal its central role in fueling the opioid epidemic—deceiving the State of West Virginia, and the public at large. Its conduct included colluding with opioid manufacturers to deceptively market opioids and reshape public perception of their risks, ignoring glaring evidence of misuse, addiction, and diversion apparent in its own data, and leveraging that same data to further support opioid marketing campaigns. Optum placed opioids on its national formularies with preferred status and minimal restrictions in exchange for lucrative rebates and fees, failed to implement effective controls in its Mail Order Pharmacy operations, and turned a blind eye to suspicious prescribers—all while falsely presenting itself as a neutral gatekeeper committed to safety and appropriate medication use.

422. Internally, Optum knew that it was making formulary and utilization decisions based on profitability—not patient safety—but publicly misrepresented its role in the pharmaceutical marketplace. The company repeatedly assured regulators, plan sponsors, and the public that it was acting to prevent diversion and drug abuse, all while concealing the true nature of its financial relationships with opioid manufacturers. It withheld critical information under its exclusive control, entered into overly broad confidentiality agreements, and even initiated legal action to prevent the release of contracts and data that would have revealed its misconduct.

423. This was not passive concealment—it was a deliberate campaign to mislead. Optum's misrepresentations were made in contracts, client communications, public statements, on its website, in publications, and in Congressional testimony. It actively marketed itself as an industry leader committed to preventing misuse and diversion, all while intentionally failing to enforce even the most basic controls against inappropriate opioid prescribing.

424. Optum hid the details of its relationships with opioid manufacturers.

425. The State of West Virginia did not and could not have known that Optum developed its national formularies based on profit and rebates, not based on the safety and efficacy of the medications, as it claimed.

426. As a result of this systematic deception, the State of West Virginia could not have reasonably discovered the full extent of Optum's misconduct.

427. Optum is therefore equitably estopped from asserting any statute of limitations defense. Its repeated misrepresentations and omissions were specifically designed to be relied upon by West Virginia, and West Virginia reasonably relied on those statements in believing Optum was fulfilling its obligations under the law. These misstatements deprived West Virginia of the knowledge necessary to assert claims until now. Accordingly, the limitations period is tolled. West Virginia's claims remain timely because Optum's misconduct was intentionally concealed and has only recently come to light after years of calculated deception.

428. Optum intended its false statements and omissions to be relied upon. Optum knew of its wrongful acts and had material information pertinent to its discovery, but concealed the information from the public, including from the State of West Virginia.

429. Optum knew of its widespread misinformation campaign and of its repeated, intentional failures to prevent opioid overutilization and diversion and concealed this information from the public, including from the State of West Virginia.

430. Due in large part to its deceptive, intentional, and fraudulent conduct, the full scope of Optum's wrongful conduct and its central role in the opioid epidemic has not yet come to light.

G. Successor Liability

431. To the extent that the wrongful acts or omissions alleged herein were committed or omitted by predecessor entities, their respective successor entities are liable for those acts or

omissions because (1) they expressly or impliedly assumed the predecessor's liability, (2) there was a consolidation or merger of predecessor and successor, (3) the surviving entity was a mere continuation of the predecessor or (4) when the transaction is entered into fraudulently to escape liability for the debts and liabilities. To the extent there was no formal merger of predecessor and successor, the respective successor entities are also liable for the wrongful acts or omissions of their respective predecessors based on the doctrine of de facto merger based on the factors of (a) continuity of shareholders resulting from the purchasing corporation paying for the assets with shares of its own stock so the selling corporation stockholders become a constituent part of the purchasing corporation; (b) cessation of ordinary business and dissolution of the predecessor; (c) assumption by the successor of liabilities ordinarily necessary for the uninterrupted continuation of the business of the predecessor; and (d) continuity of management, personnel, and general business operation of the predecessor. The details regarding the foregoing facts are particularly within the knowledge and control of the respective defendants charged with wrongdoing and cannot be pleaded in greater detail by Plaintiff without discovery.

H. Alter Ego Liability

432. To the extent that the wrongful acts or omissions alleged herein were committed or omitted by wholly owned or majority-owned entities, the parent entities are liable for those acts or omissions as alter egos because (1) they dominated and controlled the wholly owned or majority-owned entity and (2) exercised that domination and control to perpetrate a wrong or injustice. The details regarding the foregoing facts are particularly within the knowledge and control of the respective defendants charged with wrongdoing and cannot be pleaded in greater detail by the State without discovery.

I. West Virginia is Entitled to Exemplary Damages

433. As set forth above, Optum deliberately engaged in conduct designed to increase the sales and profitability of opioid medications. Despite knowing that massive and suspicious quantities of opioids were flooding into West Virginia, it failed to take any meaningful steps to curtail deceptive marketing, end preferential formulary placement, or implement UM measures that could have reduced opioid oversupply. Optum had real-time access to data revealing the scope of the crisis, yet it refused to act on that information or use it to prevent diversion. Instead, it actively colluded with opioid manufacturers in the fraudulent promotion and oversupply of opioids; accepted rebates and fees in exchange for favorable formulary placement; removed or weakened critical UM measures and failed to implement effective drug utilization review measures despite purporting to do so; and dispensed massive quantities of opioids through the Optum Mail Order Pharmacy without proper oversight or controls.

434. This ongoing course of conduct was knowing, deliberate, and reckless—inflicting significant harm on public health and safety, and causing widespread economic damage and government liability across the nation. Optum acted with malice and in a manner that constitutes aggravated and egregious fraud, demonstrating conscious disregard for the rights and safety of others, despite the obvious and substantial risk of harm. Its conduct continues to fuel an opioid epidemic that remains unabated in West Virginia. By knowingly abandoning its duties under West Virginia law, exploiting regulatory gaps, and abusing its privileged position as a dispenser of controlled substances, Optum has placed profit above people and perpetuated a public health catastrophe.

V. CLAIMS FOR RELIEF

COUNT ONE

NEGLIGENCE

435. The State adopts, realleges, and incorporates by reference paragraphs 1 through 434 of this Complaint as if fully set forth herein and further alleges as follows.

436. Negligence is established where the defendant owes the plaintiff a duty of care, breaches that duty, and the plaintiff sustains an injury or loss proximately caused by the defendant's breach.

437. Optum owed and continues to owe the State common law and statutory duties to employ reasonable standards of care in the sale, delivery, dispensing, promotion, and gatekeeping control of the supply of highly addictive, dangerous opioids. This includes a duty to not create a foreseeable risk of harm or injury.

438. Optum breached these duties by promoting opioid over-use and by facilitating access to opioids through its standard formulary and UM offerings and its Mail Order Pharmacy, setting in motion a force that created an unreasonable and foreseeable risk of harm and peril for the State. In so doing, Optum acted with actual malice.

439. Optum also undertook and assumed a duty to create formulary and UM offerings based on the health and safety of the public and of the lives covered by the benefit plans that were its clients. Optum represented to the public, as well as to its clients, that it was structuring formulary and UM offerings based on the health and safety of the public and the lives its clients insured, when in fact it was doing the exact opposite and doing it to maximize its own revenue in concert with the opioid manufacturers. Optum knew, at the time that it made these representations to the public and to its clients, that it would not base its formulary and its UM offerings on the health and safety of the covered lives involved, nor of the public, but rather that it would structure,

and were already structuring, formulary and UM offerings solely (or at least primarily) to increase profits to Optum.

440. Optum undertook to render services which it knew, or should have known, were necessary to protect the interests of the State, and failed to do so. As a result, Optum increased the risk of harm to the State and caused injury to the State.

441. Optum had actual or at the very least constructive knowledge of the overuse and oversupply of opioids because of its access to claims and other data which it developed and maintained. Optum also had the ability to curtail the overuse and oversupply of prescription opioids because of its unique gatekeeping function in the pharmaceutical supply chain. Yet, despite this knowledge and ability, Optum refused and failed to take necessary and appropriate actions to prevent the harms which were the foreseeable consequence of its failures, actions and inactions.

442. Optum, having facilitated and set in motion the over-use and over-supply of opioids, had a duty to use reasonable care to prevent and curtail the spreading opioid crisis.

443. Optum breached this duty by failing to exercise reasonable care or skill with respect to its opioid-related conduct. Optum made highly addictive prescription opioids available to the marketplace with the knowledge that it was likely being used for non-medical purposes and/or posed an inherent danger, especially to patients who were using opioids for chronic pain not associated with active cancer, end-of-life or palliative care. Optum knew or reasonably should have known that its breach would foreseeably cause harm to the State.

444. Optum knew or in the exercise of reasonable diligence should have known under the circumstances of this case that the harms suffered by the State were the reasonably foreseeable consequences of Optum's failures, actions and inactions.

445. Optum's conduct also foreseeably created a new secondary market for opioids—supplying both the narcotics for illicit distribution and fueling demand through widespread opioid addiction. The result of Optum's deceptive and improper conduct was not only an explosion of prescription opioids on the black market, but also—predictably—a significant increase in the availability of heroin and synthetic opioids.

446. It was reasonably foreseeable to Optum that the burden of the opioid crisis would fall to the State in the form of social and economic costs. Optum's negligence was a substantial factor in producing harm to the State.

447. The injuries to the State would not have happened in the ordinary course of events had Optum exercised the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of its business in the sale, delivery, dispensing, promotion, and gatekeeping control of opioids.

448. Optum has breached, and continues to breach, its common law duties to the State by, among other things:

a. Failing to exercise reasonable care or skill with respect to its opioid-related conduct;

b. Placing its profit motives above its legal duties and enabling, encouraging, and causing the over-supply and over-use of opioids;

c. Knowingly and intentionally (and/or negligently and recklessly) colluding with the opioid manufacturers in deceptive marketing schemes that were designed to, and successfully did, change the perception of opioids and cause opioid prescribing and sales to skyrocket;

d. Knowingly and intentionally (and/or negligently and recklessly) facilitating the increased use of opioids by giving opioids unwarranted preferred formulary status in standard offerings in exchange for profiting from payments from the opioid manufacturers;

e. Intentionally (and/or negligently and recklessly) maintaining preferred formulary status for OxyContin and other highly abused opioids in standard offerings, despite knowing, or being substantially certain, from its own

extensive data, that addiction, abuse, and illegitimate prescribing of such drugs were rampant;

f. Deliberately (and/or negligently and recklessly) electing not to undertake timely actions utilizing its real-time data that would have drastically reduced the inappropriate prescribing and dispensing of opioids, such as requiring prior authorization, step therapy, limiting days of supply, or excluding OxyContin from its standard formulary offerings;

g. Deliberately (and/or negligently and recklessly) electing not to impose prior authorization requirements or limits on the availability of opioids in its standard formulary offerings in exchange for payments from the opioid manufacturers;

h. Deliberately (and/or negligently and recklessly) electing not to maintain adequate safeguards to dispense opioids in a safe and effective manner and to maintain effective controls against diversion of opioids through its mail-order pharmacies; and

i. Deliberately (and/or negligently and recklessly) electing not to report suspicious prescribers and pharmacies.

449. It was, and remains, reasonably foreseeable that Optum's actions and omissions would result in the harm to the State as described herein.

450. The State of West Virginia has suffered and continues to suffer both injuries and pecuniary losses and harms proximately caused by Optum's breaches. Among other things, and as discussed further herein, the State has experienced an unprecedented opioid addiction and overdose epidemic costing the State millions, paid for by the State, including, but not limited to, health benefit expenditures, treatment services, emergency visits, medical care, treatment for related illnesses and accidents, lost productivity, increased law enforcement and judicial expenditures, increased prison and public works expenditures, increased substance abuse treatment and diversion plan expenditures, lost economic activity, and lost reputation and goodwill. Optum's breaches of the statutory and common-law duties it owed to the State are the proximate cause of this crisis and its resultant harm to the State.

COUNT TWO

VIOLATION OF FEDERAL RICO, 18 U.S.C. § 1961, et seq.; § 1964(c)

451. The State adopts, realleges, and incorporates by reference paragraphs 1 through 434 of this Complaint as if fully set forth herein and further alleges as follows.

452. At all relevant times, Optum was a "person" under 18 U.S.C. § 1961(3) because it was capable of holding, and does hold, legal or beneficial interests in property.

453. As alleged more fully herein, Optum formed an association-in-fact enterprise with each of the Opioid Enterprise Manufacturers, described above as the Formulary & UM Enterprise, for the purpose of carrying out a fraudulent scheme and felonious possession and dispensing of controlled substances to maximize profits for itself and the Opioid Enterprise Manufacturers by increasing sales of prescription opioids through unfettered and preferential formulary access without UM in its standard offerings, despite Optum's promises, representations, and contractual obligations to take actions, including through cDUR, formulary decisions, and UM decisions, that were in its clients' best interests, to ensure safe and medically appropriate opioids were being dispensed, and to address opioid abuse, misuse and diversion.

454. As alleged more fully herein, the Formulary & UM Enterprise consisted of personal business relationships formed through contractual negotiations over decades and participation in and through the PCMA and other informal coalitions and working groups. Evidence of the existence of the Formulary & UM Enterprise can be found in the way in which Optum conducted itself in its formulary and UM offerings, the contracts it negotiated with the Opioid Enterprise Manufacturers that gave them preferential formulary positions and prohibited the implementation of UM measures, the research that it performed for Opioid Enterprise Manufacturers, pull-through marketing and PBM data exchange, its failure to comply with the dispensing requirements of the CSA and West Virginia law, and interactions through PCMA and other informal coalitions.

455. At all relevant times, the Formulary & UM Enterprise (a) had an existence separate and distinct from each of the members; (b) was separate and distinct from the pattern of racketeering in which the members engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the members; (d) was characterized by interpersonal business relationships among the members; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as continuing units.

456. Each member of the Formulary & UM Enterprise conducted, and participated in the conduct of the enterprise, including a pattern of racketeering activity, and shared in the astounding profits.

457. Optum carried out, or attempted to carry out, a scheme to defraud by knowingly conducting and participating in the conduct of the Formulary & UM Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that made use of the mail and wire facilities in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

458. Optum committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e., violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the Formulary & UM Enterprise members committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constituted a "pattern of racketeering activity." The racketeering activity was made possible by the Formulary & UM Enterprise members' regular use of the facilities, services, distribution channels, and employees of the Formulary & UM Enterprise. Optum participated in the scheme to defraud by using mail, telephone, and the Internet to transmit mailings and wires in interstate or foreign commerce.

459. Optum also conducted and participated in the conduct of the affairs of the Formulary & UM Enterprise through a pattern of racketeering activity by the felonious manufacture, importation, receipt, concealment, buying, selling or otherwise dealing in controlled substances, punishable under any law of the United States.

460. Optum committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 841 makes it unlawful for any person to knowingly or intentionally manufacture, distribute, dispense, or possess with intent to manufacture, distribute or dispense, a controlled substance except as authorized by Subchapter I of the CSA. A violation of § 841 in the case of controlled substances on Schedule II is punishable by not more than 20 years' of imprisonment, or not less than 20 years' imprisonment if death or serious bodily injury results from the use of such substance. Similarly, a violation of § 841 in the case of controlled substances on Schedule III is punishable by not more than 10 years' imprisonment, or not less than 15 years' imprisonment if death or serious bodily injury results from the use of such substance. Similarly, a violation of § 841 in the case of controlled substances in Schedule IV is punishable by not more than 5 years' imprisonment. All three violations of § 841 are felonies.

461. Optum's Mail Order Pharmacy is a registrant as defined in the CSA. Its status as a registrant imposes obligations on it to ensure that it only dispenses "to the extent authorized by [its] registration and in conformity with the [CSA]."

462. Optum registered its Mail Order Pharmacy with the DEA to dispense Schedule II-V controlled substances. Its DEA registration only authorized its own pharmacy to "dispense" controlled substances, which "means to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner."

463. The Formulary & UM Enterprise's predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The Formulary & UM Enterprise violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme of the Formulary & UM Enterprise;

b. Wire Fraud: The Formulary & UM Enterprise violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme of the Formulary & UM Enterprise; and

c. Felony Controlled Substance Violations: Optum violated 21 U.S.C. § 841 by knowingly or intentionally possessing and dispensing controlled substances for reasons and purposes not authorized by the Controlled Substances Act.

464. The Formulary & UM Enterprise conducted its pattern of racketeering activity in this jurisdiction and throughout the United States.

465. The Formulary & UM Enterprise aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses, and the 21 U.S.C. § 841 offense.

466. The members of the Formulary & UM Enterprise, with knowledge and intent, agreed to the overall objective of the Formulary & UM Enterprise, including the fraudulent scheme and felonious possession and dispensing of controlled substances, and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing, distributing, and dispensing prescription opioids.

467. Indeed, for the Formulary & UM Enterprise's fraudulent scheme to work, each member of the Formulary & UM Enterprise had to agree to implement their necessary portion of the Formulary & UM Enterprise's activities in the manner alleged above.

468. As alleged more fully herein, the Formulary & UM Enterprise engaged in a pattern of related and continuous predicate acts for years. The predicate acts were each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

469. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured West Virginia's business and property, while simultaneously generating billion-dollar revenues and profits for the Formulary & UM Enterprise. The predicate acts were conducted by members of the Formulary & UM Enterprise and in furtherance of its fraudulent scheme.

470. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

471. Many of the precise dates of the Formulary & UM Enterprise's actions at issue here have been hidden by Optum and the members of the Formulary & UM Enterprise and cannot be alleged without complete access to Optum's books, records, and dispensing data. Indeed, an essential part of the successful operation of the Formulary & UM Enterprise alleged herein depended upon secrecy.

472. It was foreseeable to Optum and members of the Formulary & UM Enterprise that West Virginia would be harmed when they engaged in the fraudulent scheme that forms the common purpose of the Formulary & UM Enterprise and the pattern of racketeering activities alleged herein.

473. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

474. The Formulary & UM Enterprise members' violations of law and their pattern of racketeering activity directly and proximately caused West Virginia injury in its business and property.

475. The Formulary & UM Enterprise members' pattern of racketeering activity logically, substantially, and foreseeably caused an opioid epidemic. West Virginia was injured by the Formulary & UM Enterprise's pattern of racketeering activity and the opioid epidemic that its members created through their actions.

476. Members of the Formulary & UM Enterprise knew that the prescription opioids at the center of their pattern of racketeering activity were extremely dangerous, highly addictive, prone to diversion, abuse and misuse, and often caused overdose and death. They were also aware that placing those drugs in favorable formulary positions without UM controls in place would grow the market for prescription opioids through increased prescribing, dispensing and sales. They were also aware that the growth in prescribing, dispensing and sales would be driven, in large part, by oversupply, addiction, and misuse and abuse. Members of the Formulary & UM Enterprise also knew that the oversupply, addiction, misuse and abuse would result in the writing of illegitimate prescriptions about which the Optum Mail Order Pharmacy would need to conduct due diligence or refuse to fill.

477. Nevertheless, members of the Formulary & UM Enterprise engaged in a scheme of deception, which utilized the mail and wires as part of their fraud, in order to increase prescribing of prescription opioids, and to provide the Opioid Enterprise Manufacturers' drugs unfettered formulary access without limits from UM. Members of the Formulary & UM Enterprise also

engaged in felonious possession and dispensing of controlled substances by filling prescriptions without performing due diligence and failing to refuse to fill prescriptions, thereby providing the Formulary & UM Enterprise with unfettered and illegal possession and dispensing by Optum's Mail Order Pharmacy.

478. West Virginia was and continues to be damaged in its business and property by reason and as a result of the Defendants' conduct of the Enterprise through the pattern and practice of racketeering activity described herein, which was a logical, direct, foreseeable and substantial cause of the opioid epidemic.

479. Specifically, West Virginia's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

a. Losses caused by the decrease in funding available for West Virginia's public services resulting from the diversion of funds to public services addressing the opioid epidemic;

b. Costs for providing healthcare and medical care, additional therapeutic services, prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;

d. Costs associated with providing police officers, firefighters, and emergency and/or first responders with naloxone, an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

e. Costs associated with emergency response by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

f. Costs for providing treatment of infants born with opioid-related medical conditions, or born addicted to opioids due to drug use by a mother during pregnancy;

g. Costs for providing mental health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;

h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the slow of opioids into West Virginia, arrest and prosecute street-level dealers, to prevent the opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;

i. Costs associated with increased burden on West Virginia's judicial system, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;

j. Costs associated with providing care for children whose parents are suffering from opioid-related disability or incapacitation;

k. Loss of tax revenue due to the decreased efficiency and size of the working population in West Virginia;

l. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and

m. Losses caused by diminished property values in the form of decreased business investment and tax revenue.

480. West Virginia's injuries were proximately caused by Optum's racketeering activities because they were a logical, substantial, and foreseeable cause of West Virginia's injuries. But for the opioid-addiction epidemic created by Optum's conduct, West Virginia would not have lost money or property.

481. West Virginia's injuries were directly caused by the pattern of racketeering activities by the members of the Formulary & UM Enterprise.

482. West Virginia is most directly harmed and there are no other plaintiffs better suited to seek a remedy for the economic harms at issue here.

483. West Virginia seeks all legal and equitable relief as allowed by law, including, inter alia, actual damages; treble damages; equitable and/or injunctive relief in the form of court-supervised corrective communication, actions and programs; forfeiture as deemed proper by the

Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest, including, inter alia:

a. Actual damages and treble damages, including pre-suit and post-judgment interest;

b. An order enjoining any further violations of RICO;

c. An order enjoining any further violations of any statutes alleged to have been violated in this Complaint;

d. An order enjoining the commission of any tortious conduct, as alleged in this Complaint;

e. An order enjoining any future marketing or misrepresentations;

f. An order enjoining future decisions by Optum that prioritize rebates and profits over patient safety and proper, clinically based, decision-making regarding formulary status, PA, step therapy or UM measures related to prescription opioids;

g. An order enjoining Optum's Mail Order Pharmacy from dispensing prescriptions without conducting proper due diligence and documenting that due diligence before dispensing any prescriptions;

h. An order compelling Defendants to make corrective advertising statements that shall be made in the form, manner and duration as determined by the Court;

i. An order enjoining any future lobbying or legislative efforts regarding the manufacture, marketing, distribution, prescription, or use of opioids;

j. An order requiring Optum to disclose publicly all documents, communications, records, data, information, research or studies concerning the health risks or benefits of opioid use;

k. An order establishing a West Virginia foundation for education, research, publication, scholarship, and dissemination of information regarding the health risks of opioid use and abuse to be funded by Optum in an amount to be determined by the Court;

l. An order enjoining any diversion of opioids or any failure to monitor, identify, investigate, report, and halt suspicious prescribing, dispensing, abuse, or diversion of opioids;

m. An order requiring Optum to publicly disclose to federal and state law enforcement all documents, communications, records, information, or data,

regarding any prescriber, facility, pharmacy, clinic, hospital, manufacturer, distributor, person, entity or association regarding prescribing, dispensing, abuse, or diversion of opioids;

n. An order divesting Optum of any interest in, and the proceeds of any interest in, the Formulary & UM Enterprise, including any interest in property associated therewith;

o. Dissolution and/or reorganization of any trade industry organization, or any other entity or association associated with the Formulary & UM Enterprise identified in this Complaint, as the Court sees fit;

p. Dissolution and/or reorganization of any Defendant named in this Complaint as the Court sees fit;

q. Suspension and/or revocation of licenses, registrations, permits, or prior approvals granted to Defendants, entities, associations or enterprises named in the Complaint regarding the prescribing or dispensing of opioids;

r. Forfeiture as deemed appropriate by the Court; and

s. Attorney's fees and all costs and expenses of suit.

COUNT THREE

VIOLATIONS OF THE WEST VIRGINIA CONSUMER CREDIT AND PROTECTION ACT

484. The State adopts, realleges, and incorporates by reference paragraphs 1 through 434 of this Complaint as if fully set forth herein and further alleges as follows.

485. The West Virginia Consumer Credit and Protection Act ("WVCCPA") prohibits an entity from using "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce."[109]

486. Optum's conduct, as alleged herein, involves "trade or commerce" within the meaning of the WVCCPA.

[109] W. Va. Code § 46A-6-104.

487. Optum's actions, as detailed above, constitute unfair or deceptive acts or practices that are prohibited by the WVCCPA.

488. Violations of statutes enacted to protect the consuming public or to promote a public interest are unfair or deceptive acts or practices. *See Final Order, State of West Virginia, ex rel. Darrell V. McGraw, Jr., Attorney General v. David McCuskey et al.,* Kanawha County Circuit Court, Civil Action No. 01-C-3041, Mar. 13, 2003. *See also Pabon v. Recko,* 122 F. Supp. 2d 311, 314 (D. Conn. 2000); *Lemelledo v. Beneficial Management Corp. of America,* 674 A.2d 582 (N.J. Super. Ct., App. Div. 1996); *Winston Realty Co., Inc. v. G.H.G., Inc.,* 331 S.E.2d 677 (N.C. 1985).

489. Each occurrence of a failure to abide by laws and rules enacted to protect the consuming public or to promote a public interest constitutes an unfair or deceptive act or practice in violation of the WVCCPA, W. Va. Code § 46A-6-104.

490. Optum's unfair, deceptive, and unconscionable acts or practices, or the effects thereof, are continuing, will continue, and are likely to recur unless permanently restrained and enjoined.

491. Consequently, the State seeks all available relief under the WVCCPA, including, but not limited to, disgorgement, restitution, civil penalties, equitable relief, injunctive relief, and attorneys' fees and costs.

492. As part of its WVCCPA action, the State expressly does not raise claims or seek any damages attributable to the Medicaid or Medicare programs or any other federal programs. Additionally, as part of its WVCCPA action, the State expressly does not raise claims or seek any damages for the State's workers' compensation program, nor does it raise claims or seek damages on behalf of any state agencies.

COUNT FOUR

PUBLIC NUISANCE

493. The State adopts, realleges, and incorporates by reference paragraphs 1 through 434 of this Complaint as if fully set forth herein and further alleges as follows.

494. Optum intentionally and/or negligently and recklessly caused, created, contributed to, and/or maintained a public nuisance which proximately caused injury to the State and interfered with public rights, including the public rights to health and safety, in the State.

495. Through its conduct, detailed throughout this Complaint, Optum has played a central role in fueling and prolonging the opioid epidemic in West Virginia. Its actions have significantly contributed to the widespread misuse, addiction, and diversion of prescription opioids throughout the State. *See* Restatement (Second) of Torts § 821B.

496. Optum acquired and used vast troves of data on opioid prescribing and utilization in West Virginia. Yet instead of using this data to prevent harm, it used the information to increase profitability by promoting and facilitating access to opioids—despite clear and mounting evidence of abuse, overprescribing, and diversion.

497. Optum's misconduct includes, but is not limited to:

a. Colluding with opioid manufacturers to ensure opioids received favorable formulary placement and remained widely available, despite known risks;

b. Accepting manufacturer payments in exchange for declining to impose prior authorization requirements or other utilization controls;

c. Failing to act on evidence from its own claims data indicating abuse, overprescribing, and dangerous drug combinations ("cocktails") involving opioids;

d. Failing to maintain effective controls to prevent diversion in its PBM services and mail-order pharmacy operations; and

e. Dispensing opioids without adequate safeguards and in violation of the West Virginia Controlled Substances Act and related pharmacy regulations.

498. Optum placed its profit motives above its public health responsibilities, actively promoting opioids for conditions where they were neither safe nor effective. It misrepresented the risk of addiction and failed to take reasonable steps to curb abuse—despite having the authority and ability to do so.

499. As a direct and foreseeable result, the opioid epidemic has devastated West Virginia, causing:

a. Skyrocketing rates of opioid addiction, overdose, and death;

b. The birth of opioid-dependent infants;

c. Collapse of workforce productivity;

d. The proliferation of an illegal secondary market for opioids; and

e. Significant burdens on the State's healthcare, law enforcement, and social services systems.

500. Optum had a duty to the State and its residents to act reasonably in delivering, dispensing, managing, and promoting opioids. That duty arose from its unique gatekeeping role in the pharmaceutical supply chain and from the foreseeability of harm posed by its conduct. It breached that duty in multiple, ongoing ways.

501. Optum's actions were a substantial factor in creating and sustaining the public nuisance. Without its conduct—including its formulary decisions, collusion with manufacturers, failure to act on red flags, and facilitation of widespread access—opioid misuse and the resulting epidemic would not have occurred at this scale in West Virginia.

502. The nuisance created by Optum is substantial, unreasonable, and continuing. The resulting harm—including death, addiction, social disorder, and financial loss—is far greater than any purported benefit of its conduct.

503. Optum exercised control over the instrumentalities of the nuisance: it controlled access to prescription opioids, colluded in their promotion, and managed formulary and UM systems that drove opioid proliferation in the State.

504. West Virginia has suffered both generalized harm to its public and proprietary harm to its property and resources as a result of this nuisance. These injuries include extraordinary costs for healthcare, criminal justice, emergency response, child protection, and public health—costs that go well beyond the ordinary obligations of government.

505. The nuisance is abatable, but Optum lacks the capacity and trustworthiness to perform the abatement, having consistently elevated profit over safety and public health.

506. The State seeks a judgment requiring Optum to fund abatement of the public nuisance and to cease further nuisance-creating conduct. The State also seeks compensatory damages, punitive or exemplary damages, attorneys' fees, costs, and all other appropriate legal and equitable relief under West Virginia law.

507. At all relevant times, Optum was (or reasonably should have been) aware of, and understood, its legal obligations under the federal Controlled Substances Act (21 U.S.C. § 801, *et seq.),* the West Virginia Controlled Substances Act, W.Va. Code C.S.R. § 15-2-1, *et seq.,* and applicable West Virginia pharmacy laws and regulations regarding the dispensing of prescription opioids.

508. In its sale and dispensing of opioids, and "cocktails" of opioids and other drugs, in this District and the state of West Virginia, Optum violated federal law, including, but not limited to, 21 U.S.C.A. §§ 829, 841, 842 and 21 C.F.R. §§ 1301.71, 1306.04, 1306.06, and West Virginia law, including, but not limited to, W. Va. C.S.R. § 15-2-3 (previously W.Va. C.S.R. § 15-2-2), W. Va. C.S.R. § 15-2-4, W.Va. C.S.R. § 15-2-4.4, W.Va. C.S.R. § 15-2-4.5, W. Va. C.S.R. § 15-2-

5.1.1 (previously W. Va. C.S.R. § 15-2-4.2.1), W. Va. C.S.R. § 15-2-5.3 (previously W.Va. C.S.R. § 15-2-4.4), W. Va. C.S.R. § 15-2-5 (previously W. Va. C.S.R. § 15-2-4), W.Va. Code § 60A-4-401(a), W. Va. Code § 60A-8-7(c)(1)(i); W. Va. Code § 60A-8-7(c)(3); and W. Va. Code § 60A-3-308(d)(1). Optum's violations of these laws were committed knowingly and/or negligently and recklessly.

509. At all relevant times, Optum knew or reasonably should have known that prescription opioids were dangerous because, *inter alia*, these drugs are defined under federal and state law, and are generally recognized, as substances posing a high potential for abuse, addiction, and death.

510. West Virginia recognizes that not every societal harm supports a public nuisance claim. But the opioid crisis is no ordinary harm. It is a manmade, preventable public health catastrophe—unprecedented in scale—that has shattered families, strained public resources, and devastated the State. Given the crisis's magnitude, foreseeability, and systemic nature, West Virginia respectfully submits that it meets the threshold for public nuisance liability. In doing so, the State does not contend that the lawful distribution of other regulated products necessarily gives rise to similar claims.

COUNT FIVE

CIVIL CONSPIRACY

511. The State adopts, realleges, and incorporates by reference paragraphs 1 through 434 of this Complaint as if fully set forth herein and further alleges as follows.

512. As alleged in these paragraphs, Optum and the opioid manufacturers engaged in concerted action to accomplish an unlawful objective, or a lawful objective by unlawful means—namely, the unfettered sale and dispensing of vast quantities of opioids in West Virginia, without

regard to patient safety, impact, or compliance with state law. Each of the Optum defendants either actively participated and/or aided and abetted in pursuance of this common purpose.

513. Specifically, opioid manufacturers contracted and agreed with PBMs, including Optum, to coordinate unfettered formulary placement with no or limited UM measures regarding each opioid drug in Optum's standard offerings, such that there would be as few impediments as possible to opioid prescribing and dispensing. These contracts relied on an underlying fraudulent scheme designed to ensure unfettered access to PBM formulary offerings. The opioid manufacturers understood that Optum was going to operate on a fundamentally fraudulent basis. As alleged more fully herein, Optum promised its clients that it would implement safeguards to ensure the safe prescribing and dispensing of opioids. However, Optum had no intention of implementing such measures for opioid manufacturers' branded and generic drugs. Doing so would have significantly reduced its rebates, dispensing revenue, and other fees. Simultaneously, Optum operated its Mail Order Pharmacy in a manner that permitted the dispensing of obviously illegitimate prescriptions without intervention.

514. As detailed herein, Optum and the opioid manufacturers committed numerous overt acts to further the conspiracy's objectives that were unlawful under West Virginia law.

515. At all relevant times, Optum was aware of the enterprise's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct in the form of increased sales, distributions, and prescriptions of opioids.

516. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, Optum committed overt acts in furtherance of its conspiracy.

517. As an intended result of the intentional wrongful conduct as set forth herein, Optum has profited and benefited from the opioid epidemic it helped cause, thereby harming West Virginia.

518. As a proximate result of Optum's and its co-conspirators, the opioid manufacturers', intentional wrongful conduct, West Virginia has incurred substantial costs including, but not limited to, law enforcement action for opioid-related drug crimes, for addiction treatment, and other services necessary for the treatment of populations addicted to prescription opioids, and the other harms alleged herein. Similarly, abating the vast societal harms Optum and its co-conspirators caused will require extensive efforts and substantial resources.

519. West Virginia seeks to impute liability for West Virginia's other claims on Optum for the wrongful conduct of its co-conspirators, the opioid manufacturers, and to hold Optum jointly and severally liable for that conduct.

520. Additionally, as discussed above, the conduct of Optum and its co-conspirators, the opioid manufacturers, was fraudulent, malicious, and/or grossly negligent. For this reason, West Virginia seeks to recover punitive/exemplary damages.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, the State of West Virginia, respectfully requests the Court order the following relief, including:

a. Abatement of nuisance;

b. Actual damages;

c. Treble or multiple damages and civil penalties as allowed by statute;

d. Punitive damages;

e. Exemplary damages;

f. Disgorgement of unjust enrichment;

g. Equitable and injunctive relief in the form of Court-enforced corrective action, programs, and communications;

h. Forfeiture, disgorgement, restitution, and/or divestiture of proceeds and assets;

i. Attorneys' fees;

j. Costs and expenses of suit;

k. Pre- and post-judgment interest; and

l. Such other and further relief as this Court deems appropriate.

VII. JURY DEMAND

Plaintiff, the State of West Virginia, *ex rel.* John B. McCuskey, in his capacity as Attorney General, demands trial by jury on all issues so triable.

Dated: December 8, 2025

Respectfully submitted,

JOHN B. MCCUSKEY,
ATTORNEY GENERAL OF WEST VIRGINIA

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