IN THE COURT OF COMMON PLEAS OF ALLEGHENY COUNTY, PENNSYLVANIA
CIVIL DIVISION

COMMONWEALTH OF PENNSYLVANIA,
acting by and through Allegheny County District Attorney Stephen A. Zappala, Jr.,
Allegheny County District Attorney's Office
Room 303 Courthouse
436 Grant Street
Pittsburgh, PA 15219,

Plaintiff,

v.

CVS INDIANA, LLC
7590 Empire Dr.
Indianapolis, IN 46219-1780,

CVS RX SERVICES, INC.
One CVS Drive
Woonsocket, RI 02895,

CVS PHARMACY, INC.
One CVS Drive
Woonsocket, RI 02895,

PENNSYLVANIA CVS PHARMACY, L.L.C.
One CVS Drive,
Woonsocket, RI 02895

RITE AID CORPORATION
30 Hunter Lane
Camp Hill, PA 17011,

G.D. No. 22-009688

Code: _____

COMPLAINT IN CIVIL ACTION

Counsel of Record for Plaintiff:

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Charles J. Porter, Jr. (No. 43676)
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RITE AID HDQTRS. CORP. :
30 Hunter Lane :
Camp Hill, PA 17011 :
:
ECKERD CORPORATION d/b/a RITE :
AID LIVERPOOL DISTRIBUTION :
CENTER :
30 Hunter Lane, :
Camp Hill, PA 17011 :
:
RITE AID OF MARYLAND, INC. :
2405 York Road, Suite 201 :
Lutherville-Timonim, MD 21093, :
:
RITE AID DRUG PALACE, INC. :
30 Hunter Lane :
Camp Hill, PA 17011, :
:
RITE AID OF PENNSYLVANIA, LLC :
30 Hunter Lane :
Camp Hill, PA 17011, :
:
WALGREEN CO. :
200 Wilmot Rd. :
Deerfield, IL 60015, :
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WALGREEN EASTERN CO., INC. :
200 Wilmot Rd. :
Deerfield, IL 60015, :
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WALGREEN BOOTS ALLIANCE, INC. :
108 Wilmot Rd. :
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WALMART, INC. f/k/a WAL-MART :
STORES, INC. :
702 Southwest 8th Street :
Bentonville, AR 72716, :
:
WAL-MART STORES EAST, LP :
702 Southwest 8th Street :
Bentonville, AR 72716, :

WAL-MART STORES EAST, INC. 702 Southwest 8th Street Bentonville, AR 72716,	:
HBC SERVICE COMPANY 601 Meadowlands Boulevard, Washington, PA 15301	:
and	:
GIANT EAGLE, INC. 101 Kappa Drive, Pittsburgh, PA 15238,	:
Defendants.	:

NOTICE TO DEFEND

YOU HAVE BEEN SUED IN COURT. If you wish to defend against the claims set forth in the following pages, you must take action within TWENTY (20) days after this Complaint and Notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so, the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the Complaint or for any other claim or relief requested by the Plaintiffs. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.

IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

LAWYER REFERRAL SERVICE
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CVS INDIANA, LLC 7590 Empire Dr. Indianapolis, IN 46219-1780,	William G. Brucker (No. 32983) Charles J. Porter, Jr. (No. 43676) Joseph G. Heminger (No. 81780) **BRUCKER AND PORTER** Suite 410, 180 Fort Couch Road Pittsburgh, PA 15241 Tel: (412) 881-6620 bruckerand@aol.com cjporterjr@aol.com jgheminger@aol.com
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PENNSYLVANIA CVS PHARMACY, L.L.C. One CVS Drive, Woonsocket, RI 02895	Jerry R. DeSiderato (No. 201097) Silvio A. Trentalange (No. 320606) Timothy J. Ford (No. 325290) **DILWORTH PAXSON LLP** 1500 Market Street, Suite 3500E Philadelphia, PA 19102 Tel.: (215) 575-7000 jdesiderato@dilworthlaw.com strentalange@dilworthlaw.com tford@dilworthlaw.com
RITE AID CORPORATION 30 Hunter Lane Camp Hill, PA 17011,	

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and :
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GIANT EAGLE, INC. :
101 Kappa Drive, :
Pittsburgh, PA 15238, :
:
Defendants. :
:

Cover Sheet 3

TABLE OF CONTENTS

COMPLAINT

Plaintiff Commonwealth of Pennsylvania (the "Commonwealth" or "Plaintiff"), acting by and through Allegheny County District Attorney Stephen A. Zappala, Jr. ("District Attorney"), brings this public enforcement action against the above-captioned Pharmacy Defendants, distributors and dispensers of prescription opioid drugs, pursuant to the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. §§ 201-1–201-9.3 *et seq.* ("UTPCPL" or "Statute"). In support of this action, the Commonwealth alleges as follows:

INTRODUCTION

1. Fueled by dangerous prescription opioid drugs, Allegheny County (the "County")—like many other cities, counties and states across the country—is now engulfed in an opioid epidemic which has led to a public health and safety crisis of an unprecedented and disastrous nature. The current epidemic in the County is directly attributable to the commercial activities of the Defendants and their false, deceptive and improper marketing, promotion, sale and distribution of prescription opioids for medical use nationally, regionally, and in Allegheny County, in violation of the UTPCPL.

2. As distributors and dispensers of controlled substances, Defendants have special responsibilities to ensure that those drugs do not get into the wrong hands, and to protect the communities they purport to serve. Despite having these responsibilities, and despite having unique knowledge of and access to data and other information to help them fulfill those responsibilities, Defendants failed to maintain effective controls over the diversion of prescription opioids. Instead, Defendants distributed, dispensed and sold far greater quantities of prescription opioids than they knew could be necessary for legitimate medical uses, while failing to report, and to take steps to halt, suspicious orders when they were identified. As a direct result

of their conduct, the County has experienced both a flood of prescription opioids available for illicit use or sale and a population of patients physically and psychologically dependent on them.

3. The Allegheny County District Attorney, in the name of the Commonwealth, brings this action to hold Defendants accountable under the UTPCPL for their role in creating and perpetuating the opioid epidemic in the County and seeks injunctive relief against the Defendants and, through the restoration and/or restitution remedy in the Statute, disgorgement of the revenues acquired by the Defendants as a result of their violations of the Statute, civil penalties provided for under the UTPCPL, and compensation for the losses of the County and other affected persons in interest within the County attributable to those violations, including, *inter alia*, the addiction treatment and prescriber education necessary to abate the epidemic.

4. Prescription opioid drugs distributed and dispensed by Defendants—including brand-name drugs like Kadian, Fentora, Opana, and Duragesic—are powerful narcotic painkillers. Opioids are, and at all times relevant to this action were, dangerous and have significant and severe adverse side effects on users. While they have a proper medical use, if prescribed responsibly, to treat *short-term* acute pain (such as pain associated with medical surgical procedures, accidents, or other medical conditions causing short-term pain) or for end-of-life care.

5. Controlled substances, such as opioid drugs, by definition, are highly subject to abuse and diversion. For this reason, the Commonwealth of Pennsylvania regulates every participant in the chain of distribution which handles controlled substances. To distribute or dispense prescription opioids in the Commonwealth, companies must maintain effective controls against diversion.

6. As a direct and foreseeable result of Defendants' conduct, the County and the Commonwealth are now swept up in what the Center for Disease Control and Prevention (CDC) has called a "public health epidemic" and what the U.S. Surgeon General has deemed an "urgent health crisis."[1] The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose and death; black markets for diverted prescription opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire, or simply could not afford, prescription opioids.

7. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.[2]

8. The CDC estimated that prescription opioid misuse costs the United States $78.5 billion per year, taking into account healthcare expenses, lost productivity, addiction treatment, and criminal justice involvement.[3] In 2015, over 33,000 Americans died as a result of opioid overdose, while an estimated 2 million people in the United States suffered from substance abuse disorders relating to prescription opioids.[4] In the twelve months that ended in September 2017, opioid overdoses claimed 45,000 lives. In the twelve-month period that ended in August 2020, preliminary data shows that 88,295 people died from drug overdoses in the United States, the highest number of ever recorded in a 12-month period and a 27 percent increase from the

[1] *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), http://www.cdc.gov/washington/testimony/2014/t20140429.htm; Vivek H. Murthy, Letter from the Surgeon General, August 2016, http://turnthetiderx.org.

[2] *See* Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

[3] *See* Curtis S. Florence, et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States*, 2013, 54 Medical Care 901 (2016).

[4] *See* Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010-2015*, 65 Morbidity & Mortality Wkly. Rep. 1445 (2016); Substance Abuse and Mental Health Servs. Admin., U.S. Dep't of Health and Human Servs., *National Survey on Drug Use and Health, 2015 Detailed Tables* (2016).

previous year.[5]

9. In Pennsylvania during that time, there was a 17 percent rise in drug overdoses from 4,277 to 7,008.[6] From 1999 through 2016, overdoses killed more than 350,000 Americans.[7]

10. After a comprehensive review of the increased use of prescription opioids for medical purposes and its ill effects during the last 20 years, public health authorities and medical researchers have reaffirmed and acknowledged that there never was satisfactory scientific evidence, during the period when Defendants engaged in the widespread distribution, dispensing, and sale of prescription opioids for long-term daily use, to establish that they were effective in treating chronic pain.

11. They also have concluded that long-term daily use of prescription opioids was unsafe and exposed patients to dangerous, unacceptable risks of addiction, fatal and non-fatal overdoses, other serious adverse health conditions, and that such risks significantly and dangerously increased with the increased use of prescription opioids. In this light, Defendants' activities in aggressively dispensing, distributing, and selling prescription opioids as a treatment for chronic pain were medically and scientifically unfounded, false, deceptive, ethically inexcusable, and unlawful.

12. The opioid epidemic currently plaguing the County and its deleterious impact on public health and safety have created overlapping crises for the County, its residents, and the Allegheny County community as a whole and has adversely affected public and private health

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[5] Vital Statistics Rapid Release, Provisional Drug Overdose Death Counts, CDC, https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm; *see also* John L. Micek, *Pa. to award $2.7M in grants to help fight addiction*, April 13, 2021, https://www.penncapital-star.com/commentary/pa-to-award-2-7m-in-grants-to-help-fight-addiction-tuesday-morning-coffee/.

[6] John L. Micek, *Pa. to award $2.7M in grants to help fight addiction*, April 13, 2021, https://www.penncapital-star.com/commentary/pa-to-award-2-7m-in-grants-to-help-fight-addiction-tuesday-morning-coffee/.

[7] *Understanding the Epidemic*, CDC, https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Aug. 30, 2017).

plans and third-party payors of prescription drug benefits of these health plans and the County and its agencies:

a. Opioid addiction and the adverse health consequences of prescription opioid use have exacted a grim toll of human suffering on users and their families. As a consequence, the legal purchase and use of prescription opioids have placed an enormous burden on public and private health plans in the County and on third-party payors of prescription drug benefits of these plans to defray the costs of the prescriptions and treatment of the adverse side effects of prescription opioids.

b. The opioid crisis—with its attendant increase in crime and family and social dysfunction which tear at the social fabric of the County—is also responsible for a sharp deterioration of public safety, order, economic productivity and the quality of life in the County. As a consequence, the County and its agencies, which are in the front lines of attempting to cope with and contain the epidemic and ensuing adverse impacts on public health and safety, have incurred large, burdensome, unnecessary and avoidable costs in the discharge of their duties.

13. Opioids are regulated as Schedule II controlled substances under Pennsylvania law. *See* 35 P.S. § 780-104 (2). Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. *See id.* The Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally are categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, and may lead to severe psychological or

physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.

14. By now, most Americans have been affected, either directly or indirectly, by the opioid disaster. But few realize that this crisis arose from manufacturers of opioids engaging in a deceptive marketing strategy, together with the deliberate efforts by distributors, including pharmacies, to disregard their legal obligations on opioid distribution and dispensing. Entities in the supply chain acted without regard for the lives that would be trammeled in pursuit of profit.

15. Defendants self-distributed and dispensed hundreds of millions of opioids to their stores located in the County. The addicts created by the wide availability of prescription opioids turned anywhere they could to feed their addictions. As millions became addicted to opioids, "pill mills," often styled as "pain clinics," sprouted nationwide and rogue prescribers stepped in to supply prescriptions for non-medical use. These "pill mills," typically under the auspices of licensed medical professionals, issued high volumes of opioid prescriptions under the guise of medical treatment.

16. Most of the overdoses from non-prescription opioids are also directly related to prescription pills. Many opioid users, having become addicted to but no longer able to obtain prescription opioids, have turned to heroin. According to the American Society of Addiction Medicine, 80% of people who initiated heroin use in the past decade started with prescription opioids—which, at the molecular level and in their effect, closely resemble heroin. In fact, people who are addicted to prescription opioids are 40 times more likely than people not addicted to prescription opioids to become addicted to heroin, and the CDC identified addiction to prescription opioids as the strongest risk factor for heroin addiction.[8]

[8] *Today's Heroin Epidemic*, "Overdose Prevention" tab, Ctrs. for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/opioids/heroin.html (last updated Aug. 29, 2017); *see also Today's Heroin*

17. But rogue prescribers and the existence of a market for heroin do not absolve Defendants. Had Defendants abided by their obligations to provide effective controls and procedures to prevent diversion, to detect, report and stop the shipment of the suspicious orders that rogue prescribers generate, and to only dispense prescriptions for legitimate medical purposes, the supply of diverted opioids would have been contained. Instead, Defendants ignored suspicious activity and cynically turned away from a growing population of addicts so that they could make more money distributing and dispensing pills.

18. As a result, in part, of the proliferation of opioid pharmaceuticals between the late 1990s and 2015, the life expectancy for Americans decreased for the first time in recorded history. Drug overdoses are now the leading cause of death for Americans under 50.

19. As a direct result of what Defendants intended to do—flood the market with opioid drugs—those drugs are now widely diverted and improperly used. While Defendants have made billions,[9] Defendants' conduct has created a national epidemic of opioid overdose deaths and addiction.[10]

20. The Commonwealth brings this suit against Defendants as distributors and dispensers of these highly addictive drugs. Defendants breached their legal duties under *inter alia* the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act, 35 P.S. §§ 780-1 *et seq.*, and the Pennsylvania Wholesale Prescription Drug Distributors License Act, 63 P. S. §§ 391.1 *et seq.*, to identify, monitor, detect, investigate, refuse to ship, and report suspicious orders of prescription opiates and to dispense opioids only for legitimate medical purposes.

Epidemic, Ctrs. for Disease Control and Prevention https://www.cdc.gov/vitalsigns/heroin/index.html (last updated July 7, 2015).

[9] In 2012 alone, opioids generated $8 billion in revenue for drug companies. By 2015, sales of opioids grew to approximately $9.6 billion.

[10] *See* Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

21. The crisis was fueled and sustained by those involved in the supply chain of opioids, including Defendants who failed to maintain effective controls over the distribution and dispensing of prescription opioids, and who instead have actively sought to evade such controls. Defendants have contributed substantially to the opioid crisis by selling, distributing and dispensing far greater quantities of prescription opioids than they know could be necessary for legitimate medical uses, while failing to report, and to take steps to halt suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

22. To redress and punish Defendants' violations of the UTPCPL, the Commonwealth seeks an order from the Court enjoining Defendants from further unlawful opioid drug distributing and dispensing activities in the County and compelling the Defendants to comply with their oversight and reporting obligations under the Federal and Commonwealth Controlled Substances Acts.

23. The Commonwealth also seeks a judgment requiring Defendants to pay the maximum civil penalties available for their violations of the UTPCPL and, by way of restoration and/or restitution, to disgorge all monies acquired or retained by Defendants as a result of their violations in Allegheny County.

24. The Commonwealth also specifically seeks restoration and/or restitution from Defendants to Allegheny County and other injured persons in interest in or doing business in the County, including any health plans, third-party payors, or administrators of prescription drug benefits in the County who paid opioid-related claims, of the monies paid for purchases of opioid prescriptions, treatment of opioid addiction or abuse or related diseases attributable to prescription opioids, and other costs and damages that Defendants' violations of the law caused

and contributed to.

25. The Commonwealth also seeks restoration and/or restitution relief requiring Defendants to pay to the County and the DA its expenditures for (1) increased County services associated with addiction, fatal and non-fatal overdoses, and other adverse health and public safety conditions attributable to prescription opioids manufactured and distributed by Defendants, including the increased emergency response costs, hospitalization, treatment, and other costs; (2) any other monies lost or expenses incurred by the County and the DA as a result of Defendants' violations of the UTPCPL; and (3) all additional legal or equitable relief authorized by law.

JURISDICTION AND VENUE

26. This Court has jurisdiction over this action pursuant to 42 P.S. § 931(a). The amount in controversy exceeds $50,000, exclusive of interest and costs, which is the jurisdictional amount below which a compulsory arbitration referral pursuant to 42 P.S. § 7361(b) would be required.

27. Venue is proper in Allegheny County pursuant to 42 P.S. § 931(c), Pa. R.C.P. 1006(b) and (c)(1), and Pa. R.C.P. 2179(a).

28. This action is not removable to federal court. Among other things, there is insufficient diversity for removal. Further, the claims alleged in this Complaint do not permit federal question jurisdiction to be exercised as the claims do not arise directly or indirectly under the Constitution, laws, or treaties of the United States. This action is also not subject to the jurisdiction of the Class Action Fairness Act of 2005. Further, the assertion of federal jurisdiction over the claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities. Accordingly, any exercise of federal jurisdiction is without

basis in law or fact.

PARTIES

Plaintiff

29. Plaintiff is the Commonwealth of Pennsylvania, acting by and through the Allegheny County District Attorney, pursuant to the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. §§ 201-1–201-9.3.

30. The Allegheny County District Attorney is expressly authorized to bring this action in the name of the Commonwealth under the UTPCPL whenever the District Attorney has reason to believe that any person is using or is about to use any method, act or practice declared by the UTPCPL to be unlawful, and that such proceedings would be in the public interest. 73 P.S. § 201-4.

31. Based on the allegations herein, the District Attorney has reason to believe that Defendants have used, are using or are about to use methods, acts or practices declared by the UTPCPL to be unlawful and that bringing this action is in the public interest.

Defendants[11]

32. At all relevant times Defendants, and each of them, have engaged in the business of, or were successors in interest to, entities engaged in the business of distributing, selling, and/or dispensing prescription opioid drugs to individuals and entities in the Commonwealth of Pennsylvania, including in the County.

[11] The Commonwealth has made its best efforts, based on the information available, to identify all of the corporate entities with responsibilities related to the sale and distribution of opioids in or affecting Allegheny County. If information that becomes available to the Commonwealth alters its understanding or discloses additional entities, the Commonwealth reserves the right to seek to join any such entities as defendants. Furthermore, the Commonwealth recognizes that corporate entities affiliated with the Defendants may possess discoverable information relevant to the Commonwealth's claims, even though those entities have not been named as Defendants. The Commonwealth reserves the right to seek all information relevant to these claims.

1. CVS Entities

33. CVS conducts business as a licensed wholesale distributor and/or dispenser under the following named business entities, among others: CVS Indiana, L.L.C., CVS Rx Services, Inc., CVS Pharmacy, Inc. and Pennsylvania CVS Pharmacy, LLC. At all times relevant to this Complaint, CVS distributed and dispensed prescription opioids throughout the United States, including in the County. CVS Indiana, L.L.C., CVS Rx Services, Inc., CVS Pharmacy, Inc. and Pennsylvania CVS Pharmacy, LLC. are collectively referred to as "CVS."

34. Defendant CVS Indiana L.L.C., is registered to do business in Pennsylvania as an Indiana limited liability company with its principal place of business in Indianapolis, Indiana.

35. Defendant CVS Rx Services, Inc. is registered to do business in Pennsylvania as a New York corporation with its principal place of business in Woonsocket, RI.

36. Defendant CVS Pharmacy, Inc. is registered to do business in Pennsylvania as a Rhode Island corporation with its principal place of business in Woonsocket, Rhode Island. CVS Pharmacy, Inc. is a wholly owned subsidiary of CVS Health Corporation. Defendant CVS Pharmacy, Inc. is both a DEA registered "distributor" and a DEA registered "dispenser" of prescription opioids.

37. Pennsylvania CVS Pharmacy, L.L.C. is registered to do business in Pennsylvania as a Pennsylvania limited liability company with its principal place of business in Woonsocket, RI. Pennsylvania CVS Pharmacy, L.L.C. is in the business of holding and operating all individual CVS pharmacies in Pennsylvania.

2. Rite Aid Entities

38. Rite Aid conducts business as a licensed wholesale distributor and/or dispenser under the following named business entities, among others: Rite Aid Corporation, Rite Aid Hdqtrs. Corp., Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center, Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc., Rite Aid Drug Palace, Inc., and Rite Aid of Pennsylvania, LLC, f/k/a Rite Aid of Pennsylvania, Inc. Rite Aid Corporation, Rite Aid Hdqtrs. Corp., Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center, Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc., Rite Aid Drug Palace, Inc., and Rite Aid of Pennsylvania, LLC, f/k/a Rite Aid of Pennsylvania, Inc. are collectively referred to as "Rite Aid." At all times relevant to this Complaint, Rite Aid distributed and dispensed prescription opioids throughout the United States, including in the County.

39. Defendant Rite Aid Corporation is registered to do business in Pennsylvania as a Delaware corporation with its principal office located in Camp Hill, Pennsylvania. Defendant Rite Aid Corporation, by and through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor and pharmacy operator and also operates retail stores, including in and around the County's geographical area, that sell prescription medicines, including opioids.

40. Defendant Rite Aid Hdqtrs. Corp. is registered to do business in Pennsylvania as a Delaware corporation with its principal office located in Camp Hill, Pennsylvania. Rite Aid Hdqtrs. Corp., by and through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor and pharmacy operator.

41. Defendant Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center is a

subsidiary of Rite Aid Corporation and is registered to do business in Pennsylvania as a Delaware corporation with its principal offices located in Liverpool, New York and Camp Hill, Pennsylvania. Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center distributed prescription opioids throughout the United States, including in the County.

42. Defendant Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. is a subsidiary of Rite Aid Corporation and is registered to do business in Pennsylvania as a Maryland corporation with its principal office located in Camp Hill, Pennsylvania. At all times relevant to this Complaint, Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. distributed prescription opioids throughout the United States, including in the County.

43. Defendant Rite Aid Drug Palace, Inc. is registered to do business in Pennsylvania as a Delaware corporation with its principal place of business located in Pennsylvania.

44. Defendant Rite Aid of Pennsylvania, LLC, f/k/a Rite Aid of Pennsylvania, Inc. is registered to do business in Pennsylvania as a Pennsylvania limited liability company with its principal place of business in Pennsylvania. Rite Aid of Pennsylvania, LLC, is in the business of holding and operating all individual Rite Aid pharmacies in Pennsylvania.

3. Walgreens Entities

45. Defendant Walgreen Co. is registered to do business in Pennsylvania as an Illinois corporation with its principal place of business in Deerfield, Illinois. Walgreen Co. acted as a retail pharmacy in the United States until Walgreen Co. completed the acquisition of Alliance Boots, a British pharmacy giant, in 2014. After this acquisition, the company simply became Walgreens Boots Alliance, Inc. traded on NASDAQ under the symbol WBA.

46. Defendant Walgreens Boots Alliance, Inc. is registered to do business in Pennsylvania as a Delaware corporation with its principal place of business in Illinois. Walgreens Boots Alliance, Inc. describes itself as the successor of Walgreen Co.

47. Walgreen Co. is portrayed as a subsidiary of Walgreens Boots Alliance, Inc. and does business under the trade name Walgreens.

48. Defendant Walgreen Eastern Co., Inc. is registered to do business in Pennsylvania as a New York corporation with its principal place of business in Deerfield, Illinois. Walgreen Eastern Co., Inc. is a subsidiary of Walgreens Boots Alliance, Inc.

49. Defendants Walgreen Co., Walgreens Boots Alliance, Inc. and Walgreen Eastern Co. are collectively referred to as "Walgreens." Walgreens, by and through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor and pharmacy operator and also operates retail stores, including in and around Plaintiff's geographical area, that sell prescription medicines, including opioids. During the relevant time period, and as further alleged below, Walgreens entities also owned and operated pharmacies in the County. At all times relevant to this Complaint, Walgreens distributed and dispensed prescription opioids throughout the United States, including in the County.

50. Walgreens Co. created, implemented, and had the power to enforce policies, practices, and training regarding distribution and sales in all Walgreens distribution and pharmacy sales operations.

4. Walmart Entities

51. Defendant Walmart Inc., ("Walmart") formerly known as Wal-Mart Stores, Inc., is registered to do business in Pennsylvania as a Delaware corporation with its principal place of business in Bentonville, Arkansas.

52. Defendant Wal-Mart Stores East, Inc. is registered to do business in Pennsylvania as a Delaware corporation with its principle place of business in Arkansas. The sole shareholder of Wal-Mart Stores East, Inc. is Walmart Inc., f/k/a Wal-Mart Stores, Inc.

53. Defendant Wal-Mart Stores East, LP is a registered to do business in Pennsylvania as a Delaware limited partnership with its principal place of business in Arkansas.

54. On information and belief, until 2018, Walmart Inc. also acted as a distributor of controlled substances for its pharmacies around the country. From 2000 to approximately May 2018, Walmart Inc. operated at least six distribution centers that distributed controlled substances to its pharmacies in the United States. The distribution centers were located in Bentonville, Arkansas; Rogers, Arkansas; Tifton, Georgia; Crawfordsville, Indiana; Hanford, California; and Williamsport, Maryland. The DEA registrant for those distribution centers was Defendant Wal-Mart Stores East, LP.

55. Defendants Walmart Inc., Wal-Mart Stores East, Inc and Wal-Mart Stores East, LP are collectively referred to as "Walmart." Walmart, by and through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor and pharmacy operator and also operates retail stores, including in and around Plaintiff's geographical area, that sell prescription medicines, including opioids. At all times relevant to this Complaint, Walmart distributed and dispensed prescription opioids throughout the United States, including in the County.

5. Giant Eagle Entities

56. Defendant HBC Service Company ("HBC") is an operating division of Defendant Giant Eagle, Inc. HBC operated as a licensed wholesale distributer in Pennsylvania, licensed by the Pennsylvania Board of Pharmacy. Giant Eagle, Inc. is a Pennsylvania corporation with its principal place of business in Washington, Pennsylvania. At all times relevant to this Complaint, HBC distributed and Giant Eagle, Inc. sold prescription opioids in Pennsylvania and the County specifically. HBC, Giant Eagle, Inc., and related entities are collectively referred to as "Giant Eagle." From 2016 to the present, Giant Eagle also distributed prescription opioids through its GERXDC distribution center, which it then sold in Giant Eagle pharmacies.

6. Agency and Authority

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

FACTUAL ALLEGATIONS COMMON TO ALL CLAIMS[12]

A. Prescription Opioids and Their Adverse Health Effects

58. Opioids are a class of drugs that bind with opioid receptors in the brain and include natural, synthetic, and semi-synthetic opioids. Natural opioids are derived from the opium poppy. Generally used to temporarily relieve pain, opioids block pain signals but do not treat the source of the pain. Opioids produce multiple effects on the human body, the most significant of which are analgesia, euphoria, and respiratory depression.

59. The medicinal properties of opioids have been recognized for millennia, as has their potential for abuse and addiction. Most prescription opioids are natural and semi-synthetic drugs derived from the active ingredients of opium. Prescription opioids include the drug formulations identified herein. The most commonly prescribed are formulations (both branded and generic) of hydrocodone, oxycodone, oxymorphone and hydromorphone.[13]

60. Opium and opium derivatives including prescription opioids have both pain relieving and euphoria-inducing characteristics. The pain-relieving properties of opium have been recognized for millennia. During and after the Civil War, opioids, sometimes known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain, and they were popularly used in a wide variety of commercial products ranging from pain elixirs to cough suppressants to beverages.

61. Unfortunately, prescription opioids pose the same dangers and hazardous side effects associated with opium and opium derivatives such as morphine and heroin, and have a

[12] The allegations in this Complaint are made upon facts, as well as upon information and belief. The Commonwealth reserves the right to seek leave to amend or correct this Complaint based upon analysis of data or other discovery of the ARCOS, IQVIA, and other data and upon further investigation and discovery.

[13] Fentanyl is also a prescription opioid and the subject of deceptive marketing and misuse. Fentanyl is a wholly synthetic prescription opioid that is similar to morphine, but is 50 to 100 times more potent. *See* https://www.drugabuse.gov/drugs-abuse/fentanyl.

high degree of potential for abuse and addiction. Opium (or the active ingredients thereof) is the foundational component of heroin and prescription opioids, and both types of drugs function in an essentially identical fashion.

62. Prescription opioids work by binding to receptors on the spinal cord and in the brain, altering the perception of pain. Opioid addiction is a medical disease that arises from repeated exposure to opioids. It can occur in individuals using prescription opioids to relieve pain under the supervision of a physician at prescribed doses, just as it can occur in individuals using opioids for non-medical purposes.

63. Discontinuing opioid use even after just a few days of therapy can cause patients to experience withdrawal symptoms. The odds an individual will still be on opioids a year after starting a short course increase after only 5 days of being on opioids. Withdrawal symptoms can include anxiety, nausea, vomiting, agitation, insomnia, muscle aches, abdominal cramping, and other serious conditions, which may persist for months or longer after a complete withdrawal from opioids, depending on how long the opioids were used.[14]

64. When opioids are used over time, patients grow tolerant to their analgesic and euphoric effects. As tolerance increases, a patient requires progressively higher doses in order to obtain the same levels of pain reduction to which he or she has become accustomed.[15] At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at an even higher risk of addiction.[16]

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[14] *See, e.g.*, Health Guide: Opiate Withdrawal, The New York Times (2013), http://www.nytimes.com/health/guides/disease/opiate-withdrawal/overview.html?mcubz=3.

[15] M. Katz, Long-Term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith, 170(16) Archives of Internal Med. 1422 (2010).

[16] In a study conducted by Kidner and colleagues, they found that higher doses of opioids (greater than 61 mg/day of morphine equivalents) predicted worse outcomes, including program non-completion, lower rates of return to work, and higher health care utilization. Furthermore, studies have shown that the prevalence of mental health diagnoses increases with increasing duration of opioid use. *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3641146/.

65. Opioids can cause severe respiratory depression (meaning that breathing slows to the point that the body cannot adequately exhale carbon dioxide), coma, and/or death. These serious hazards can occur even when used at prescribed doses, and can affect—sometimes fatally—even users who are not suffering from opioid addiction or opioid use disorder.

66. Up to the mid-1990s, the medical profession viewed opioids as having legitimate uses, but believed that they should be prescribed cautiously and only on a limited basis, because of concerns about addiction, tolerance leading to dose escalation, and physiological dependence resulting in difficulty discontinuing use. Physicians were reluctant to prescribe opioids on a long-term basis for common chronic pain conditions because of their addiction risks and side effects.[17]

67. Due to concerns about their addictive properties, prescription opioids have usually been regulated at the federal level as Schedule II controlled substances since 1970.

68. Medical professionals describe the strength of various opioids in terms of morphine milligram equivalents, or MME. According to the CDC, doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and one study found that patients who died of opioid overdose were prescribed an average of 98 MME/day. Different opioids provide varying levels of MMEs. For example, just 33 mg of oxycodone provides 50 MME.

[17] Andrew Kolodny *et al*., The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction, 562 (Jan. 12, 2015) (hereinafter "Kolodny, Jan. 12, 2015"), https://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957.

B. Defendants Deliberately Disregarded Their Duties to Maintain Effective Controls Against Opioid Diversion

1. Defendants Have a Duty to Prevent Diversion as Distributors and Dispensers

69. Defendants have several responsibilities under Pennsylvania law with respect to control of the supply chain of opioids.

70. First, they must set up a system to prevent diversion, including excessive volume and other suspicious orders. That would include reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. All suspicious orders must be reported to relevant enforcement authorities.

71. Further, they must also stop shipment of any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.

72. Multiple sources, including Pennsylvania statutes and regulations, impose duties on the Defendants to provide effective controls and procedures to guard against theft and diversion of opioid drugs. Multiple sources also impose duties on Defendants to report suspicious orders and to not ship such orders unless due diligence disproves those suspicions.

73. Under the common law, Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By flooding the County with more opioids than could be used for legitimate medical purposes, by failing to provide effective controls and procedures against theft and diversion, and by filling and failing to report orders that they knew or should have known were likely being diverted for illicit uses, Defendants breached that duty and both created and failed to prevent a foreseeable risk of harm.

74. In addition, each of the Defendants assumed a duty, when speaking publicly about opioids and their efforts to combat diversion, to speak accurately and truthfully.

75. Defendants also had multiple duties under Pennsylvania statutes and regulations. Opioids are Schedule II controlled substances. *See* 35 P.S. § 780-104. Opioids are categorized as "Schedule II" drugs because they have a "high potential for abuse" and "abuse may lead to severe psychic or physical dependence." 35 P.S. § 780-104; 28 Pa. Code § 25.72(c).

76. Under Pennsylvania law, each of the Defendants was required to be licensed by the Pennsylvania Department of Health. 63 P.S. § 391.4; 35 P.S. § 780-106; 28 Pa. Code § 25.113. To receive and maintain this license, each of the Defendants assumed a duty to comply with "all applicable federal and state laws and regulations" and all applicable DEA, State and local regulations. 63 P.S. § 391.6(k).

77. The Pennsylvania Department of Health may revoke, suspend, limit or refuse to issue a license to a licensee for "engaging in conduct which is harmful to the public health, safety or welfare." 63 P.S. § 391.9(b)(7). The Pennsylvania Department of Health may also revoke, suspend, limit or refuse to issue a license to a licensee who has violated the Wholesale Prescription Drug Distributors License Act, 63 P.S. § 391.9(b)(2), or who is making misleading, deceptive, untrue or fraudulent representations in obtaining or seeking to obtain a license or registration. 63 P.S. § 391.9(b)(4).

78. Each Defendant has an affirmative duty under Pennsylvania law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Pennsylvania law requires that distributors and others "maintaining stocks or having controlled substances in production areas or on hand for distribution shall provide effective controls and procedures to guard against theft and diversion of the substances." 28 Pa. Code § 25.61. *See also*

63 P.S. § 391.6(c)(5) (facilities where prescription drugs are stored and handled must be equipped with security systems "that will provide suitable protection from theft and diversion."); 63 P.S. § 391.6(g) (licensee shall "establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs.").

79. Pennsylvania law also requires distributors to ensure that prescription drugs are distributed only for lawful purposes. Licensees must follow written policies and procedures "for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts." 63 P.S. § 391.6(h).

80. The Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act prohibits "the manufacture, delivery, or possession with intent to manufacture or deliver, a controlled substance by a person not registered under this act, or a practitioner not registered or licensed by the appropriate State board." 35 P.S. § 780-113(a)(30). Violation of this provision as to a Schedule II narcotic is a felony. 35 P.S. § 780.113(f)(1).

81. Pennsylvania further prohibits "the furnishing of false or fraudulent material information in, or omission of any material information from any application, report, or other document required to be kept or filed under this act, or any record required to be kept by this act." 35 P.S. § 780.113(a)(28). Violations of these provisions are misdemeanors. 35 P.S. § 780.113(b) & (e).

82. Pennsylvania has declared that "Pennsylvania consumers of prescription drugs will be better assured of safe and effective prescription drug products if the Commonwealth joins with other jurisdictions to require the licensure of all persons who operate facilities from which they engage in the wholesale distribution of prescription drugs." 63 P.S. § 391.2(a)(2). Further, the legislature has declared that "[i]t is the further intent of the General Assembly to promote the

safety and effectiveness of prescription drug products by requiring all persons who operate facilities within this Commonwealth from which they engage in the wholesale distribution of prescription drugs to secure a license and meet minimum quality assurance and operational standards as required by this act." 63 P.S. § 391.2(b).

83. Defendants have violated their duties under the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act and the Wholesale Prescription Drug Distributors License Act.

84. Defendants violated their duties as licensed distributors by selling huge quantities of opioids that were diverted from their lawful, medical purpose, thus causing an opioid and heroin addiction and overdose epidemic in the County.

85. Defendants violated Pennsylvania law when they violated 63 P.S. § 391.6(k): **"**The licensee shall operate in compliance with applicable Federal, State and local laws and regulations. . . . The licensee that deals in controlled substances shall register with the Drug Enforcement Administration (DEA) and shall comply with all applicable DEA, State and local regulations." Defendants thereby had a duty to disclose suspicious orders:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74(b).[18]

86. "Suspicious orders" include orders of an unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. These criteria are disjunctive and are not all-inclusive. For example, if an order deviates substantially from a

[18] Once again, Plaintiff cites federal regulations in this complaint to state the duty owed under Pennsylvania law, *not* to allege an independent federal cause of action or substantial federal question.

normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

87. All suspicious conduct must be reported to relevant enforcement authorities. Further, Defendants must not fill or ship any suspicious prescription or order unless they have conducted an adequate investigation and determined that the prescription or order is not likely to be diverted into illegal channels.[19] Reasonably prudent distributors would not fall below this standard of care, and their failure to exercise appropriate controls foreseeably harms the public health and welfare.

88. Of course, due diligence efforts must be thorough: "the investigation must dispel all red flags indicative that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor 'inform' the [DEA] about the order. Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the Agency must be informed."[20] Indeed, the DEA may revoke a distributor's certificate of registration as a vendor of

[19] *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007) (applying federal requirements no less stringent than those of Ohio); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017) (same).

[20] *Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015).

controlled substances if the distributor identifies orders as suspicious and then ships them "without performing adequate due diligence."[21]

89. To comply with the law, wholesale distributors, including Defendants, must know their customers and the communities they serve. Each distributor must "perform due diligence on its customers" on an "ongoing [basis] throughout the course of a distributor's relationship with its customer." *Masters Pharms., Inc.*, 80 Fed. Reg. 55,418, 55,477 (DEA Sept. 15, 2015), *petition for review denied*, 861 F.3d 206 (D.C. Cir. 2017).

90. Furthermore, both the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act, 35 P.S. § 780-1 *et seq.*, and Pennsylvania Wholesale Prescription Drug Distributors License Act, 63 P. S. § 391.1 *et seq.*, independent and exclusive of any federal law or regulation, required Defendants to maintain controls, procedures and security suitable to protect against theft and diversion of prescription opioid drugs.

91. In addition to their duties as distributors, Defendants also had a duty to design and implement systems to prevent diversion of controlled substances in their retail pharmacy operations. Defendants had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

92. Under the common law, Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. Defendants breached their duty to exercise reasonable care in delivering narcotic substances and both created and failed to prevent a foreseeable risk of harm to the County. As the supply of opioids and the evidence of addiction to and abuse of these

[21] *Masters Pharmaceuticals*, 861 F.3d at 212. The Decision and Order was a final order entered by the DEA revoking Masters Pharmaceutical's certificate of registration, without which Masters Pharmaceutical could not sell controlled substances. In *Masters Pharmaceutical*, the D.C. Circuit Court of Appeals denied a petition for review, leaving intact the DEA's analysis and conclusion in the Decision and Order.

drugs grew, Defendants were again reminded of both the nature and harms of opioid exposure and use.

93. As retailers of controlled substances, Defendants were required to register with Secretary of Health. 35 P.S. § 780-106. In addition, to obtain a permit from the State Board of Pharmacy, the pharmacist, including the corporate parent, must comply with "minimum requirements regarding adequate facilities for safe storage of drugs, and protection from theft of or improper access to controlled substances." 63 P.S. § 390-4. The Pennsylvania Board of Pharmacy sets "standards for dispensing prescriptions, such regulations to be designed to insure methods of operation and conduct which protect the public health, safety and welfare and prevent practices or operations which may tend to lower professional standards of conduct, so as to endanger the public health and welfare." 63 P.S. § 390-4; *see also* 63 P.S. § 390-2.

94. As described above, Pennsylvania law requires Defendants to "operate in compliance with applicable Federal, State and local laws and regulations. . . . The licensee that deals in controlled substances shall register with the Drug Enforcement Administration (DEA) and shall comply with all applicable DEA, State and local regulations." 63 P.S. § 391.6(k).

95. Under Federal law, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." *See* 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, "[t]he 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." Pharmacists must ensure that prescriptions of controlled substances are "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). The DEA has recognized that "as dispensers of controlled

substances, pharmacists and pharmacy employees are often the last line of defense in preventing diversion."[22]

96. Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist. *See also* 63 P.S. § 390-2. Although it acts through its agents, the pharmacy, as the DEA registrant, is ultimately responsible to prevent diversion, as described above.[23]

97. Pharmacy order data provides detailed insight into the volume, frequency, dose, and type of controlled and non-controlled substances a pharmacy typically orders. This includes non-controlled substances and Schedule IV controlled substances (such as benzodiazepines), which are not reported to the DEA, but whose use with opioids can be a red flag of diversion.

98. Defendants may not ignore red flags of illegal conduct and must use the information available to them to identify, report, and not fill prescriptions that seem indicative of diversion. That would include reviewing their own data, relying on their observations of prescribers, pharmacies, and customers, and following up on reports or concerns of potential diversion.

99. Specifically, Defendants had a duty to analyze data and the personal observations of their employees for known red flags such as (a) multiple prescriptions to the same patient using the same doctor; (b) multiple prescriptions by the same patient using different doctors; (c)

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[22] 2012 Dear Registrant letter to pharmacy registrants, http://ppsconline.com/articles/2012/FL_PDAC.pdf; also available at Anda_Opioids_MDL_0000137151 (news release).

[23] *The Medicine Shoppe; Decision and Order*, 79 FR 59504, 59515 (DEA Oct. 2, 2014) (emphasis added); *see also Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*; Decision and Order, 77 FR 62316-01 ("When considering whether a pharmacy has violated its corresponding responsibility, the Agency considers whether the entity, not the pharmacist, can be charged with the requisite knowledge."); *Top RX Pharmacy*; Decision and Order, 78 FR 26069, 62341 (DEA Oct. 12, 2012) (same); *cf. Jones Total Health Care Pharmacy LLC and SND Health Care LLC v. Drug Enforcement Administration*, 881 F.3d 82 (11th Cir. 2018) (revoking pharmacy registration for, *inter ailia*, dispensing prescriptions that prescriptions presented various red flags, i.e., indicia that the prescriptions were not issued for a legitimate medical purpose without resolving red flags).

prescriptions of unusual size and frequency for the same patient; (d) orders from out-of-state patients or prescribers; (e) an unusual or disproportionate number of prescriptions paid for in cash; (f) prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g) volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose. Defendants had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

100. According to law and industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

101. As distributors and as dispensers, Defendants have a duty, and are expected, to be vigilant in ensuring that controlled substances are delivered only for lawful purposes.

102. State and federal statutes and regulations reflect a standard of conduct and care below which reasonably prudent distributors and pharmacies would not fall. Together, these laws and industry guidelines make clear that Defendants possess and are expected to possess, specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription opioids and of the risks and dangers of the diversion of prescription opioids when the supply chain is not properly controlled.

103. Further, these laws and industry guidelines make clear that Defendants have a responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

104. Reasonably prudent distributors and pharmacies would not fall below this standard of care, and their failure to exercise appropriate controls foreseeably harms the public health and welfare.

105. Defendants breached these duties by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities they knew or should have known could not be justified and were indicative of serious problems of overuse of opioids

106. In sum, all Defendants have many responsibilities under Pennsylvania law related to controlling the supply chain of opioids. They must set up a system to prevent diversion, including identifying excessive volume and other suspicious orders by reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. All suspicious orders must be reported to relevant enforcement authorities. They must also stop shipment of any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.

107. Further, these laws and industry guidelines make clear that the Defendants have a duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

108. Each of the Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in the County.

109. Thus, each Defendant owes a duty under Pennsylvania law to monitor and detect suspicious orders of prescription opioids. Each Defendant owes a duty under Pennsylvania law to investigate and refuse suspicious orders of prescription opioids.

110. Each Defendant owes a duty under Pennsylvania law to report suspicious orders of prescription opioids, including suspicious orders originating outside Pennsylvania that would likely result in distribution of Defendants' opioids into the State and the County.

111. Each Defendant owes a duty under Pennsylvania law to prevent the diversion of prescription opioids into illicit markets in the State and the County.

112. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

113. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality in the County and the damages caused thereby.

2. Defendants Were on Notice of Their Duties to Maintain Effective Controls to Prevent Opioid Diversion

114. Defendants earned enormous profits by flooding the country with prescription opioids. Defendants were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and retail sellers of opioids. Yet, instead of taking any meaningful action to stem the flow of opioids into communities, like the County, they continued to participate in the oversupply and profit from it.

115. Through a marketing campaign premised on over a decade of false and incomplete information, manufacturers of prescription opioids engineered a shift in how and when opioids are prescribed by the medical community and used by patients. While opioids had long been reserved for acute pain and cancer pain, where the substantial risk of addiction is less

pronounced, manufacturers of opioids changed that long-standing medical practice by misrepresenting the safety and efficacy of their products, asserting that the risk of addiction was low when opioids were used to treat chronic pain, overstating the benefits and trivializing the risk of long-term use of opioids.

116. After manufacturers of opioids successfully changed the way the medical and scientific communities viewed the risks and benefits of using opioids for chronic pain, as distributors and dispensers of prescription opioids, Defendants could have stopped—or at least mitigated the effects of—the opioid epidemic in the County. Instead, they stood by and raked in profits from selling far more opioids than could have been justified to serve the legal and appropriate market.

117. Each Defendant does substantial business across the United States. This business includes the distribution and dispensing of prescription opioids.

118. ARCOS data confirms that Defendants distributed and dispensed substantial quantities of prescription opioids in the County. In addition, they distributed and dispensed substantial quantities of prescription opioids in Pennsylvania and in other states, and these drugs were diverted from these other states and around Pennsylvania to the County. Defendants failed to take meaningful action to stop this diversion despite their knowledge of it, and contributed substantially to the diversion problem.

119. Defendants developed and maintained extensive data on opioids they distributed and dispensed. Through this data, Defendants had direct knowledge of patterns and instances of improper distribution, prescribing, sale, and use of prescription opioids in communities throughout the country and in the County in particular. Defendants used the data to evaluate their own sales activities and workforce. Defendants also provided data regarding, among other

things, individual doctors to drug companies, which targeted those prescribers with their marketing, in exchange for rebates or other forms of consideration. Defendants data is a valuable resources that they could and should have used to help stop diversion, but they failed to do so.

120. Defendants facilitated the supply of far more opioids that could have been justified to serve a legitimate market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious, as well as to maintain effective policies and procedures to guard against diversion from their retail stores, breached both their statutory and common law duties.

121. For over a decade, Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

122. Each participant in the supply chain of opioid distribution and dispensing, including Defendants, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring, and reporting suspicious activity.

123. According to the CDC, opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the United States. Not all of these prescriptions were legitimate. Yet, Defendants systemically ignored red flags that they were fueling a black market, and failed to maintain effective controls

against diversion at both the wholesale and pharmacy level. Instead, they put profits over the public health and safety.

124. Upon information and belief, this problem was compounded by Defendants' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription for opioid painkillers is legitimate and what measures and/or actions to take when a prescription is identified as potentially illegitimate.

125. Upon information and belief, Defendants also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions. Instead, Defendants put in place policies that required and rewarded speed and volume over safety and the care necessary to ensure that narcotics were distributed and sold lawfully. Defendants consistently put profits over safety in their distribution and sale of prescription opioids.

126. Despite their legal obligations as registrants under Pennsylvania law and the Controlled Substances Act (CSA), Defendants allowed widespread diversion to occur—and they did so knowingly.

3. Defendants Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and Stop Suspicious Orders

127. The law and regulations described above aim to create a "closed" system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle large volumes of controlled substances, and because they are uniquely positioned based on their knowledge of their customers and orders, distributors are supposed to act as the first line of defense in the

movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market. Because of this role, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses as it did here.

128. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

129. Moreover, distributors, including Defendants, received repeated and detailed guidance regarding their obligations to maintain effective controls against diversion.

130. The DEA repeatedly reminded Defendants of their obligations to report and decline to fill suspicious orders. Responding to the proliferation of internet pharmacies that arranged illicit sales of enormous volumes of opioids, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations.

131. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes. Each of the Defendants attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

132. Specifically, in August 2005, the DEA's Office of Diversion Control launched the "Distributor Initiative." The Distributor Initiative did not impose any new duties on distributors, but simply reminded them of their duties under existing law. The stated purpose of the program

was to "[e]ducate and inform distributors/manufacturers of their due diligence responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their [Automation of Reports and Consolidated Orders System ("ARCOS")] data for sales and purchases of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances."[24] The CSA requires that distributors (and manufacturers) report all transactions involving controlled substances to the United States Attorney General. This data is captured in ARCOS, the "automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level—hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions,"[25] described above, from which certain data was recently made public.

133. The DEA has hosted many different conferences throughout the years to provide registrants with updated information about diversion trends and their regulatory obligations. Such conferences have included, for example, an industry conference in which it brought manufacturers, distributors, importers together and Distributor Conferences. The DEA also frequently presented at various other conferences for registrants at the national, state, or local level.

134. Through presentations at industry conferences and on its website, the DEA provided detailed guidance to distributors on what to look for in assessing their customers'

[24] Thomas W. Prevoznik, Office of Diversion Control, Distributor Initiative presentation (Oct. 22, 2013), https://www.deadiversion.usdoj.gov/mtgs/distributor/conf_2013/prevoznik.pdf.

[25] U.S. Dept. of Justice, Drug Diversion Administration, Diversion Control Division website, https://www.deadiversion.usdoj.gov/arcos/index.html.

trustworthiness. As an example, the DEA published "Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances"[26]

135. In addition, the DEA sent a series of letters, beginning on September 27, 2006, to every commercial entity registered to distribute controlled substances. The 2006 letter emphasized that distributors are:

> [O]ne of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.[27]

136. This letter also expressly reminded them that registrants, in addition to reporting suspicious orders, have a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[28] The letter also warned that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[29]

137. The DEA sent a second letter to Defendants on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to "maintain effective controls against

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[26] U.S. Dept. of Justice DEA, Diversion Control Division website, Pharmaceutical Industry Conference (Oct 14 & 15, 2009), *Suggested Questions a Distributor should ask prior to shipping controlled substances*, Drug Enforcement Administration *available at* https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf; Richard Widup, Jr., Kathleen H. Dooley, Esq., *Pharmaceutical Production Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC, *available at* https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

[27] Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Off. of Diversion Control, Drug Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006), filed in *Cardinal Health, Inc. Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51 ("2006 Rannazzisi Letter").

[28] *Id*.

[29] *Id*.

diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[30] This letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[31]

138. The National Association of Chain Drug Stores ("NACDS") is a national trade association that represents traditional drug stores, supermarkets, and mass merchants with pharmacies—from regional chains with four stores to national companies. Most if not all of Defendants serve on the Board of Directors of NACDS. In September 2007, the NACDS, among others, also attended a DEA conference at which the DEA reminded registrants that not only were they required to report suspicious orders, but also to halt shipments of suspicious orders. Walgreens specifically registered for the conference.

139. The DEA's regulatory actions against the three largest wholesale distributors further underscore the fact that distributors such as Defendants were well aware of their legal obligations. There is a long history of enforcement actions against registrants for their compliance failures. For example, in 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against three of Cardinal Health's distribution centers and on December 23, 2016, Cardinal Health agreed to pay the United States $44 million to resolve

[30] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

[31] *Id*.

allegations that it violated the CSA in Maryland, Florida, and New York. Similarly, on May 2, 2008, McKesson entered into an Administrative Memorandum of Agreement ("AMA") with the DEA related to its failures in maintaining an adequate compliance program. Subsequently, in January 2017, McKesson entered into an Administrative Memorandum Agreement ("AMA") with the DEA wherein it agreed to pay a $150 million civil penalty for, *inter alia*, failure to identify and report suspicious orders at several of its facilities.

140. The DEA has also repeatedly affirmed the obligations of Defendants to maintain effective controls against diversion in regulatory action after regulatory action against pharmacies.[32]

141. DEA has repeatedly emphasized that retail pharmacies, including Defendants, are required to implement systems that detect and prevent diversion and must monitor for and report red flags of diversion. When red flags appear, the pharmacy's "corresponding responsibility" under 21 C.F.R. § 1306.04(a) requires it either to take steps (and document those steps) to resolve the issues or else to refuse to fill prescriptions with unresolvable red flags.[33]

142. DEA has identified several types of "unresolvable red flags" which, when presented to a pharmacist, may never be filled by the overseeing pharmacist. These unresolvable red flags include: a prescription issued by a practitioner lacking valid licensure or registration to prescribe the controlled substances; multiple prescriptions presented by the same practitioner to patients from the same address, prescribing the same controlled substances in each presented

[32] *See, e.g., Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*; 77 Fed. Reg. 62,316 (DEA Oct. 12, 2012) (decision and order); *East Main Street Pharmacy*, 75 Fed. Reg. 66,149 (DEA Oct. 27, 2010) (affirmance of suspension order); *Holiday CVS, L.L.C. v. Holder*, 839 F. Supp. 2d 145 (D.D.C. 2012); *Townwood Pharmacy*, 63 Fed. Reg. 8,477 (DEA Feb. 19, 1998) (revocation of registration); *Grider Drug 1 & Grider Drug 2*, 77 Fed. Reg. 44,069 (DEA July 26, 2012) (decision and order); *The Medicine Dropper*, 76 Fed. Reg. 20,039 (DEA April 11, 2011) (revocation of registration); *Medicine Shoppe-Jonesborough*, 73 Fed. Reg. 363 (DEA Jan. 2, 2008) (revocation of registration).

[33] *Pharmacy Doctors Enterprises, Inc. v. Drug Enf't Admin.*, No. 18-11168, 2019 WL 4565481, at *5 (11th Cir. Sept. 20, 2019).

prescription; a high volume of patients presenting prescriptions and paying with cash; a prescription presented to by a customer who has traveled significant and unreasonable distances from their home to see a doctor and/or to fill the prescription at the pharmacy.

143. The DEA has also conducted meetings with retail pharmacies, including the Defendants. For example, in December 2010, DEA hosted a meeting with CVS's representatives and counsel and advised CVS of the "red flags . . . that a pharmacy should be familiar with in order to carry out its corresponding responsibility to ensure that the controlled substances are dispensed for a legitimate medical purpose."[34]

144. Examples of red flags that the DEA identified during its meeting with CVS include:

- many customers receiving the same combination of prescriptions (i.e., oxycodone and alprazolam);
- many customers receiving the same strength of controlled substances (i.e., 30 milligrams of oxycodone with 15 milligrams of oxycodone and 2 milligrams of alprazolam);
- many customers paying cash for their prescriptions;
- many customers with the same diagnosis codes written on their prescriptions (i.e., back pain, lower lumbar, neck pain, or knee pain);
- individuals driving long distances to visit physicians and/or to fill prescriptions.[35]

145. Similarly, in 2011, the DEA took Walgreens "to the woodshed" over its dispensing cocktail drugs and opioids to questionable out of state customers, customers with the duplicate diagnoses, young people, and customers only paying cash. Many of these same red flags were highlighted in the 2009 Walgreens Order to Show Cause and resulting 2011 MOA.

[34] Declaration of Joe Rannazzisi in *Holiday CVS, L.L.C. v. Holder*, 839 F. Supp. 2d 145 (D.D.C. 2012).

[35] *Id.*

146. A more fulsome discussion of the various settlement agreements and enforcement actions against Defendants is below.

147. As another example, in a 2016 presentation to the American Pharmacists Association, the DEA reiterated that retail pharmacies must watch for red flags such as: large numbers of customers who: receive the same combination of prescriptions, receive the same strength of controlled substance prescription (often for the strongest dose), have prescriptions from the same prescriber, and have the same diagnosis code.

148. Many of these red flags are acknowledged in a "Stakeholders" memorandum created by many of the Defendants, including CVS, Rite Aid, and Walgreens, others in the business of selling controlled substances for profit, like Purdue Pharma and Cardinal Health, and their trade organizations, including the HDMA[36] and the NACDS.

149. Other examples of suspicious pharmacy orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

150. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible; (5) prescriptions with

[36] The Healthcare Distribution Management Association ("HDMA"), now known as the Healthcare Distribution Alliance ("HDA"), and prior to 2000, known as the National Wholesale Druggists' Association ("NWDA")) is a national trade association representing distributors that has partnered with the NACDS. The two groups viewed their relationship as a strategic "alliance." CVS also has been a member of the HDA.

quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

151. Suspicious pharmacy orders are red flags for, if not direct evidence of, diversion.

4. Defendants Were Uniquely Positioned to Guard Against Opioid Diversion

152. Not only do Defendants often have firsthand knowledge of dispensing red flags—such as distant geographic location of doctors from the pharmacy or customer, lines of seemingly healthy patients, out-of-state license plates, and cash transactions, and other significant information—but they also have the ability to analyze data relating to drug utilization and prescribing patterns across multiple retail stores. Signs of diversion can be observed through data gathered, consolidated, and analyzed by Defendants. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

153. These data points give Defendants insight into prescribing and dispensing conduct that enables them to play a valuable role in the preventing diversion and fulfilling their obligations under State and Federal law.

154. Each of the Defendants had complete access to all prescription opioid dispensing data related to its pharmacies in the County, complete access to information revealing the doctors who prescribed the opioids dispensed in its pharmacies in and around the County, and complete access to information revealing the customers who filled or sought to fill prescriptions for opioids in its pharmacies in and around the County. Each of the Defendants likewise had complete access to information revealing the customers who filled or sought to fill prescriptions

for opioids in its pharmacies in and around the County, complete access to information revealing the opioids prescriptions dispensed by its pharmacies in and around the County, and complete access to information revealing the opioids prescriptions dispensed by its pharmacies in and around the County. Further, each of the Defendants had complete access to information revealing the geographic location of out-of-state doctors whose prescriptions for opioids were being filled by its pharmacies in and around the County and complete access to information revealing the size and frequency of prescriptions written by specific doctors across its pharmacies in and around the County.

155. Defendants also possessed sufficiently detailed and valuable information that other companies were willing to pay them for it. As both national pharmacy chains and distributors, Defendants have especially deep knowledge of their retail stores' orders, prescriptions, and customers.

156. This is underscored by the fact that Walgreens is able to sell the contents of its patients' prescriptions to data-mining companies such as IMS Health, Inc. In 2010, for example, Walgreen's fiscal year 2010 SEC Form 10-K disclosed that it recognizes "purchased prescription files" as "intangible assets" valued at $749,000,000.[37]

157. Similarly, CVS Caremark's Director of Managed Care Operations, Scott Tierney, testified that CVS's data vendors included IMS Health, Verispan, and Walters Kluwers and that CVS used the vendors for "analysis and aggregation of data" and "some consulting services." He also testified that CVS would provide the vendors with "prescriber level data, drug level data, plan level data, [and] de-identified patient data."[38]

[37] Walgreens Co., *2010 Annual Report*, available at https://www.sec.gov/Archives/edgar/data/104207/000010420710000098/exhibit_13.htm.

[38] Joint Appendix in *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 687134 (U.S.) *245-46 (Feb. 22, 2011).

5. Defendants Disregarded Their Duties to Maintain Effective Controls to Prevent Diversion

a. Defendants Failed to Prevent Diversion Through Illegal Dispensing Due to Common, Systemic Failures

158. Defendants' failure to prevent to diversion through illegal dispensing was a result of two primary and related causes. First, Defendants chose not to have sufficient—or in many instances any—policies, procedures, or processes to ensure that their pharmacies were only dispensing valid prescriptions issued for legitimate medical purposes. Second, Defendants' focus on the profitability of their pharmacies, which was ensured by ever-increasing prescription volume driven by dispensing all prescriptions quickly, made it impossible for their pharmacies and individual pharmacists to carry out their duties under Pennsylvania law to only dispense legal, legitimate prescriptions.

i. Defendants Lacked Dispensing Protocols or Policies

159. Defendants' singular focus on filling all prescriptions as quickly as possible meant that they did not have rigorous dispensing protocols or policies. Such policies would not have only resulted in denying more suspicious prescriptions, but would also slow down the speed at which prescriptions were filled. Instead, Defendants have insisted its dispensing practices operate as a production line which rewarded speed and penalized attention to patient care and safety.

160. Defendants' procedures for filling prescriptions, including controlled substances like opioids, were limited to a basic checks. In large part, these checks served only to ensure clerical accuracy, *i.e.* that the prescription information entered into the pharmacy system and subsequently dispensed to the customer matched the prescription information from the prescriber. These checks included things like ensuring that the name on the prescription was

correct, that the dosage matched the dosage called for by the prescription, that the address was properly printed on the prescription label, *etc*. This was so regardless of whether the doctor's prescription made sense on its face or exhibited red flags of diversion.

161. Critically, Defendants have not had robust policies or protocols about how to address invalid prescriptions. Defendants have had little in the way of checklists, guidance, training, or resources for pharmacists or technicians to consult about whether a prescription was for a legitimate medical purpose and should or should not be filled.

162. Defendants also had no policies or procedures that ensured compliance with or gave guidance to their pharmacists about Pennsylvania laws and regulations related to proper dispensing of controlled substances.

163. To the extent that Defendants did have policies specifically addressing the dispensing of controlled substance prescriptions they were instituted too late, well after the Defendants should have recognized their problems with illegal dispensing. For example, until very recently there has been no guidance from Defendants about when pharmacists needed to question certain medically inappropriate combinations (such as the "Holy Trinity" combination of opioids and muscle relaxers), no guidance about when pharmacists needed to refuse opioids being prescribed for inappropriately long periods of time, and no guidance about identifying the number of pharmacies and/or doctors a patient was seeing.

164. For example, Walgreens only instituted its "Targeted Good Faith Dispensing Policy" in 2013 and only because of a settlement with the DEA required them to.[39] Likewise, only in 2018 did Walmart start to institute measures "aimed at helping curb opioid abuse and misuse" such as "restrict[ing] initial acute opioid prescriptions to no more than a seven-day

[39] *Walgreens Agrees To Pay A Record Settlement Of $80 Million For Civil Penalties Under The Controlled Substances Act*, U.S. Dep't of Just. (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled.

supply," giving Walmart pharmacists access to NarxCare, "a tool that helps pharmacists make dispensing decisions and provides pharmacists with the real-time interstate visibility that currently exists," and conducting additional training and education on "opioid stewardship for its pharmacists, including a pain management curriculum."[40]

165. Even if a pharmacist did identify a prescription that was not issued for a legitimate medical purpose, there was a lack of policies and procedures for the pharmacist to follow after identification.

166. Perhaps most glaringly, Defendants provided no way for pharmacies to record or track the occasions when a pharmacist refused to fill a prescription, few as they were. This deliberate ignorance ensured that a customer could simply try again to get a previously-refused prescription filled without the new pharmacist ever knowing it had been refused before—a critical piece of information. Furthermore, to the extent the Defendants did allow a method to track refusals, the recording of a refusal was onerous and took precious time that was not rewarded in any way. Given the time pressures pharmacists faced, many would choose simply to return the prescription to the customer and lie saying that the pharmacy was out of stock. That way, the pharmacist avoided both a confrontation with the customer which could lead to a customer complaint and the burden of having to record the refusal.

167. As some of the largest corporations in the world, Defendants could have easily invested some of their vast resources into developing uniform protocols that would have given concrete guidance to their pharmacy staff. But Defendants did not even use any of the available public guidance to incorporate into their own practices. Instead, Defendants emphasized their

[40] Press Release, *Walmart Introduces Additional Measures to Help Curb Opioid Abuse and Misuse*, May 7, 2018, https://corporate.walmart.com/newsroom/2018/05/07/walmart-introduces-additional-measures-to-help-curb-opioid-abuse-and-misuse.

profitability metrics, leaving it up to beleaguered pharmacy staff to refuse prescriptions at their own risk.

168. Defendants essentially left the pharmacists on their own to evaluate prescriptions. This led to endemic inconsistency, with many choosing to fill as many prescriptions as possible. This was especially true given the pressures and incentives built into the structure of Defendants' operations not to question prescriptions and to fill as many as possible, as quickly as possible.

169. The problem was particularly acute for hydrocodone prescriptions before 2014. Before that time, hydrocodone was a CIII, not a CII as it is now. That has meant that Defendants' pharmacies paid even less attention to what any reasonable pharmacist knew was a potent and powerful opioid.

170. Even though many well intentioned and reasonably diligent pharmacists who, had they been given the tools and time, might have able to recognize the steadily growing influx of inappropriate opioid prescriptions, Defendants continued to provide no pharmacy procedures, policies, or processes to keep the opioid problem from going off the rails in Pennsylvania and the County.

ii. Defendants Did Not Ensure Legal Dispensing

171. A few examples are illustrative of how Defendants violated their legal obligation to ensure that only valid prescriptions were being filled at their pharmacies.

a) Defendants Did Nothing to Ensure Compliance

172. Even to the extent that Defendants had policies and procedures, Defendants rarely emphasized or enforced those policies.

173. Defendants failed to conduct adequate internal or external audits of its opioid sales to identify patterns regarding prescriptions that should not have been filled and to create

policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

174. To the extent that audits were performed, the checks were only for clerical accuracy and little else. Defendants did not audit to ensure that only prescriptions dispensed were those written for legitimate medical purposes.

175. Furthermore, compliance with applicable laws and regulations regarding dispensing was not stressed or rewarded by Defendants' management. In contrast to routinely recognizing employees for increasing the profitability of pharmacies through increased prescription count or filling prescriptions faster, Defendant failed to promote a culture of compliance surrounding the proper dispensing of prescription medications, particularly controlled substances like opioids.

176. Defendants were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by its pharmacies in the County was untenable, and in many areas patently absurd; yet, none of the Defendants took meaningful action to investigate or to ensure that they were complying with its duties and obligations under the law with regard to controlled substances.

b) Defendants Failed to Use Data Available to Prevent Diversion

177. Defendants developed and maintained extensive data on opioids they distributed and dispensed. Through this data, Defendants had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country, and in Pennsylvania and the County in particular. Defendants' data is a valuable resource that they could have used to help stop diversion, but they failed to do so.

178. As early as 2006, The National Association of Chain Drug Stores ("NACDS") issued a "Model Compliance Manual" intended to "assist NACDS members" in developing their own compliance programs, which were to include the use of pharmacy data.[41] The Model Compliance Manual notes that a retail pharmacy may: "[G]enerate and review reports for its own purposes" and refers to the assessment tools identified by CMS in its Prescription Drug Benefit Manual chapter on fraud, waste and abuse, including:

- Drug Utilization Reports, which identify the number of prescriptions filled for a particular customer and, in particular, numbers for suspect classes of drugs such as narcotics to identify possible therapeutic abuse or illegal activity by a customer. A customer with an abnormal number of prescriptions or prescription patterns for certain drugs should be identified in reports, and the customer and his or her prescribing providers can be contacted and explanations for use can be received.

- Prescribing Patterns by Physician Reports, which identify the number of prescriptions written by a particular provider and focus on a class or particular type of drug such as narcotics. These reports can be generated to identify possible prescriber or other fraud.

- Geographic Zip Reports, which identify possible "doctor shopping" schemes or "script mills" by comparing the geographic location (zip code) of the patient to the location of the provider who wrote the prescription and should include the location of the dispensing pharmacy.

179. Defendants did not follow this guidance. For example, Walgreens settled two cases, one in California in 2017 and one in Wisconsin in 2019, that were due in part to a failure of Walgreens to ensure that drug utilization review ("DUR") was completed before dispensing medication.[42] In both cases, the Government alleged that Walgreens defrauded state Medicaid programs because Walgreens did not perform DURs, a condition of payment for the Medicaid

[41] All Defendants are members of NACDS.

[42] U.S. Department of Justice, *Walgreen Co. Agrees to Pay $3.5 Million to Settle Allegations Under the False Claims Act* (Jan. 23, 2019) https://www.justice.gov/usao-edwi/pr/walgreen-co-agrees-pay-35-million-settle-allegations-under-false-claims-act; Suevon Lee, *Walgreens To Pay $9.9M To Settle Medi-Cal Billing Suits*, Law360, (Apr. 20, 2017) https://www.law360.com/articles/915594/walgreens-to-pay-9-9m-to-settle-medi-cal-billing-suits.

claims in California and Wisconsin. As one complaint alleged, Pharmacy staff "simply overrode the restrictions in the computer system to get the prescription paid for by Medi-Cal."

180. Defendants often have firsthand knowledge of dispensing red flags—such as distant geographic location of doctors from the pharmacy or customer, lines of seemingly healthy patients, out-of-state license plates, and cash transactions, and other significant information—but they also have the ability to analyze data relating to drug utilization and prescribing patterns across multiple retail stores. These data points give Defendants insight into prescribing and dispensing conduct that enables them to play a valuable role in the preventing diversion and fulfilling their obligations under Pennsylvania law.

181. Indeed, CVS Health president and CEO Larry Merlo has described the company as "America's front door to health care with a presence in nearly 10,000 communities across the country," which allowed it to "see firsthand the impact of the alarming and rapidly growing epidemic of opioid addiction and misuse."[43]

182. Defendants would also have been able to observe customers, including, for example, customers with insurance coverage making cash payments. They could also identify customers filling prescriptions at multiple pharmacy branches or from different doctors, or patterns of unusual or suspicious prescribing from a particular medical provider.

183. Pharmacies not only saw the amount of opioids dispensed ballooning, but also saw a corresponding increase in the amount of buprenorphine, naloxone, and other treatment drugs also increasing in lockstep, filled at the very same pharmacy chains. Such increases should have been a clear sign that the opioids dispensed at the pharmacy were being abused.

[43] *See, e.g.*, David Salazar, *CVS Health Unveils New PBM, Pharmacy Efforts to Curb Opioid Abuse*, (Sept. 21, 2017), https://drugstorenews.com/pharmacy/cvs-health-unveils-new-pbm-pharmacy-efforts-curb-opioid-abuse.

184. As acknowledged in an article CVS wrote for the New England Journal of Medicine, "[p]harmacies have a role to play in the oversight of prescriptions for controlled substances, and opioid analgesics in particular."[44] As the CVS executives who authored the article explain, chain pharmacies like Defendants have a particular "advantage" in meeting their obligations under the applicable laws because the entities can use "aggregated information on all prescriptions filled at the chain" in order to examine "patterns" of opioids and other "high-risk drugs" and target "inappropriate prescribing." For example, a chain pharmacy should properly use its chain-wide dispensing data to identify "high risk prescribers" by "benchmarking" prescription data based on "several parameters," including "volume of prescriptions for high-risk drugs," "the proportion of the prescriber's prescriptions that were for such [high-risk] drugs, as compared with the volume and proportion for others in the same specialty and region," cash payment, ages of patients, and the prescriber's ratio of "prescriptions for noncontrolled substances with prescriptions for controlled substances." This "[a]nalysis of aggregated data" from chain pharmacies can "target patterns of abuse," in the face of "the growing use of controlled substances and resulting illnesses and deaths." Accordingly, as CVS touts, "innovative use of transparent data is only prudent."

185. Defendants used the data to evaluate their own sales activities and workforce. On information and belief, Defendants also provided data regarding, *inter alia*, individual doctors to drug companies, who targeted those prescribers with their marketing, in exchange for rebates or other forms of consideration.

186. Even beyond making it clear that Defendants' priority is making money, these metrics and measurements show how much data Defendants had about the prescriptions being

[44] Mitch Betses, R.Ph., and Troyen Brennan, M.D., M.P.H., *Abusive Prescribing of Controlled Substances - A Pharmacy View*, N. ENGL. J. MED. 369;11, Sept. 12., 2013, at 989-991.

filled at their pharmacies. But instead of leveraging the data to effectively root our inappropriate prescriptions, the data was used to squeeze every ounce of profit from its pharmacies at the expense of safety and compliance.

c) Defendants Ignored Suspicious Prescribers

187. Despite filling large quantities of controlled substances, including opioids, and even though Defendants regularly acknowledged publicly that the opioid crisis raging nationally, Defendants did not maintain or share with its pharmacy staff information about suspicious health care providers.

188. Defendants did little no tracking to ensure that the prescribers from whom they were being asked to dispense had valid licenses.

189. For example, in September 2014, CVS agreed to pay $1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired. In 2013, CVS agree to pay $ 11 million to resolve allegations it violated the CSA and related federal regulations at its retail stores in Oklahoma and elsewhere in part by filling prescriptions from prescribers who lacked current or valid DEA numbers. The $80 million settlement between Walgreens and the DOJ also included allegations that Walgreens was filling prescriptions written by a physician with an expired DEA registration.[45]

190. Defendants also did not adequately track investigations of and disciplinary actions against prescribers, including criminal indictments against prescribers for illegal prescribing practices. Instead, Defendants chose to keep dispensing blindly, despite the fact that a prescriber

[45] Press Release, U.S. Attorney's Office, Dist. of Colorado, *Colorado U.S. Attorney's Office Participated In Settlement Where Walgreens Agrees To Pay A Record $80 Million For Civil Penalties Under The Controlled Substances Act* (June 11, 2013), https://www.justice.gov/usao-co/pr/colorado-us-attorneys-office-participated-settlement-where-walgreens-agrees-pay-record-80.

being investigated, and especially indicted criminally, would be an extremely relevant fact for a pharmacy to know when evaluating a prescription from that prescriber.

191. As CVS has publicly preached, it is possible and prudent for Defendants to use their data to identify suspicious prescribers. Even with what CVS acknowledged were extremely conservative parameters, it was easily able to identify 42 "outliers" from its own database of over 1 million prescribers.[46] Even then, CVS knew this was only the tip of the iceberg of the problem. CVS admitted that the 42 outliers from a set of 1 million was a "low rate and doesn't really size the problem nationally." Instead, the CVS data analytics project was only aimed at a "very small group at the outset" and was a "proof of concept."[47]

192. The results should have raised alarm bells at CVS and other Defendants that their pharmacies were filling prescriptions for easy-to-identify pill mill prescribers. Even the small number of outlier prescribers accounted for massive (and alarming) amounts of prescriptions. For example, the NEJM article recognizes that in Florida alone, the DEA had closed 254 "pain clinics" as of 2013. Furthermore, there have been many hundreds more health care professionals throughout the U.S. who have been criminally charged and many of them then convicted for their inappropriate prescribing of opioid drugs. Not only have Defendants routinely ignored this ongoing criminal conduct, they have ignored the publicly available information regarding of healthcare professionals who would lose their licenses for over-prescribing opioid drugs. For example, the Pittsburgh Post-Gazette reported that between 2011 and 2015 for Pennsylvania, Ohio, West Virginia, Maryland, Virginia, Kentucky, and Tennessee (the bulk of Appalachia),

[46] Audio Interview, *Interview with Dr. Troyen Brennan on one chain pharmacy's initiative to curb abuse of controlled substances*, available at https://www.nejm.org/doi/full/10.1056/NEJMp1308222.

[47] *Id*.

there were 608 doctors disciplined for overprescribing narcotics.[48] Clearly, the real number of suspicious prescribers dwarf the mere 42 CVS identified.

193. Besides not using data to block more than just a "very small group" of prescribers outright, Defendants did not leverage their data to assist their pharmacies in evaluating prescriptions. Defendants provided only limited information (if at all) to their pharmacies to help them identity potentially fraudulent or medically inappropriate prescriptions. Despite almost exclusively putting the onus of evaluating the prescription on their overworked pharmacy staff, Defendants did not give them tools and insight like data about prescriber's prescribing habits to help them make informed decisions. This problem was particularly acute for "floater" pharmacists who did not have knowledge of the local customers or prescribers.[49]

194. Defendants had no protocols about how to flag prescribers who consistently were writing suspicious or medically inappropriate prescriptions, no protocol about how to flag prescription shopping by customers, or communicate information about trends they were seeing.

195. Even when Defendants did identify suspicious prescribers, they often ignored their legal obligations and instead kept dispensing for them. For example, at Walmart, "even after more than a decade of soaring addiction and deaths had transformed opioids into a national crisis, Walmart had a policy that pharmacists could conduct no 'blanket refusals' that shut off prescriptions written by a particular doctor. Nor would Walmart put doctors on a prohibited list from headquarters, known as a 'corporate block.'"[50] The other Defendants also did not allow

[48] *See* Rich Lord, J. Bardy McCollough, Adam Smeltz, *Special Report: Overdosed – How doctors wrote the script for an epidemic*, Pittsburgh Post-Gazette (May 22, 2016), https://newsinteractive.post-gazette.com/overdosed/.

[49] While most pharmacists work at one store regularly, Defendants routinely use pharmacists that work at multiple different pharmacies, often in diverse, far-flung geographic locations, depending on where they were needed. These pharmacists are known as "floaters."

[50] Jesse Eisinger and James Bandler, *Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment.*, ProPublica, (March 25, 2020), https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment.

corporate blocks until it was too late and even then, made the process overly onerous and underutilized.

b. Defendants' Incentives and Pressure to Fill All Prescriptions as Quickly as Possible

i. Pressures to Fill All Prescriptions Were Chain-Wide

196. Defendants' singular, overarching goal has been profitability. In light of their goal, Defendants' pharmacies have been obligated to fill prescriptions quickly to ensure large volumes of prescriptions were being filled. This focus on driving prescription volume above all else—including their legal obligations and public safety—has driven Defendants' pharmacy operations.

197. Prescriptions make up a significant portion of Defendants' overall revenue. For example, at CVS, as of 2017 its pharmacy division was responsible for more than 67% of its revenue.[51] As of 2019, pharmacy accounts for 74% of Walgreens' sales while retail accounts for a mere 28%.[52] At Walmart, health and wellness accounts for 11% of its nearly $332 billion in U.S. revenue.[53] Prescription sales accounted for 64% percent Rite Aid's total drugstore sales.[54]

198. Thus, for Defendants to be profitable, their pharmacies need to be profitable. For the pharmacies to be profitable, they need to fill as many prescriptions as possible, regardless of the prescriptions' validity.

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[51] Greg McFarlane, *How CVS Makes Its Money*, INVESTOPEDIA, July 23, 2019, https://www.investopedia.com/articles/markets/012315/how-cvs-makes-its-money.asp.

[52] Walgreens Boots Alliance Retail Pharmacy USA, https://www.walgreensbootsalliance.com/about/company/retail-pharmacy-usa/.

[53] Matthew Boyle, *Walmart Trims Pharmacy Jobs as Company Mulls Health Strategy*, BLOOMBERG (June 26, 2019), https://www.bloomberg.com/news/articles/2019-06-26/walmart-eliminating-some-pharmacy-jobs-as-retailer-streamlines.

[54] Rite Aid Corporation Reports Fiscal 2021 First Quarter Results, https://www.riteaid.com/corporate/news/-/pressreleases/news-room/2020/rite-aid-corporation-reports-fiscal-2021-first-quarter-results.

199. The pressure to increase prescription volume coincided with the timing of the opioid epidemic in the County. The Affordable Care Act greatly reduced the reimbursements pharmacies would receive from government programs. By 2013, the reimbursements were down over 20%.[55]

200. The lowering of pharmacy reimbursements could only be offset by filling a greater number of prescriptions. Unfortunately for the County, the timing was perfect for Defendants to capitalize on the opioid epidemic's explosion of pills in order to recoup the lost reimbursements by filling a greater volume of prescriptions much more quickly.

ii. Defendants Pressured and Incentivized Pharmacies to Fill All Prescriptions and Ignore Obligations

201. Defendants put immense pressure on their pharmacists to fill not only all prescriptions but to fill them quickly. The pressure was both applied directly by management as well as indirectly through emphasizing prescription filling speed and volume. Defendants' performance metrics and prescription quotas for retail stores contributed to the supplying of a black market, including in the County.

202. Multiple surveys of pharmacists in states like Missouri, Maryland, and Tennessee reveal the widespread nature of the problems. For example, a survey of over 1,000 Missouri pharmacists revealed that a majority of pharmacists (60%) "said they 'agree' or 'strongly agree' that they 'feel pressured or intimidated to meet standards or metrics that may interfere with safe patient care.' Of those surveyed in Missouri, '[a]bout 60 percent of respondents worked for retail chains, as opposed to hospitals or independent pharmacies.'"[56]

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[55] Adam J. Fein, *Obamacare Will Squeeze Pharmacy Profits*, Drugchannels.net (Oct. 8, 2013). https://www.drugchannels.net/2013/10/obamacare-will-squeeze-pharmacy-profits.html.

[56] Ellen Gabler, *How Chaos at Chain Pharmacies is Putting Patients at Risk*, THE NEW YORK TIMES (Jan. 31, 2020), https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html.

203. Defendants had numerous, in-depth tools that tracked pharmacy performance. These metrics, however, overwhelmingly focused on the profitability of the pharmacy, not patient safety or compliance. Thus, Defendants' constant elevation of various metrics related to things such as prescription count, profitability, and getting prescriptions filled quickly showed their pharmacists what was truly important to Defendants.

204. Pharmacists are directed to meet high prescription count goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There has been little (or no) measurement for pharmacy accuracy or customer safety, or compliance with the Pennsylvania Controlled Substances Drug, Device & Cosmetic Act or Pennsylvania pharmacy laws and regulations.

205. The culture of filling prescriptions quickly to drive volume was built into the electronic software used by Defendants. Defendants used order-filling software that closely tracked the time it took to fill prescriptions and would start a countdown to pressure pharmacists to fill the prescriptions more quickly. These systems did not take into account the complexities of each prescription, so the systems would assign the same amount of time to fill for a customer presenting with numerous red flags the same as one without.

206. In connection with the DEA's investigations described above, the DEA found evidence that Walgreens had a corporate policy encouraging increased sales of oxycodone.[57] As the DEA's September 2012 Order to Show Cause and Immediate Suspension of Registration explains:

> In July 2010, Walgreens's corporate headquarters conducted an analysis of oxycodone dispensing for the prior month at its Florida retail pharmacies and produced an 11 page spreadsheet, ranking all Florida stores by the number of

[57] WAGMDL00387654-666 (September 13, 2012 Order to Show Cause and Immediate Suspension of Registration to Walgreens's Jupiter, Florida Distribution Center).

> oxycodone prescriptions dispensed in June. The spreadsheet was sent to Walgreens's market pharmacy supervisors in Florida on July 29, 2010, with the admonition that they "*look at stores on the bottom end . . . We need to make sure we aren't turning legitimate scripts away. Please reinforce.*" A corporate market director of pharmacy operations did reinforce this message to Florida market pharmacy supervisors, highlighting that their "*busiest store in Florida*" was filling almost 18 oxycodone prescriptions per day, yet "We also have stores doing about a day. Are we turning away good customers?"

207. In 2011, a Walgreens project to "Increase Rx Sales and prescription Counts" instructed pharmacies to "improve C2 business"—i.e. dispense more Schedule 2 controlled substances. This focus on *increasing* controlled substance dispensing—including opioids—continued even after the DEA investigation and $80 million fine. For example, in 2014, the RX Integrity department created a "Pharmacist Controlled Substance Dispensing Opportunities" tool to "identify pharmacists that are dispensing a low rate of controlled substances," and help pharmacists "feel more comfortable in filling controlled substances," specifically focusing on pharmacists dispensing low rates of opioids like "hydromorphone, oxycodone, methadone . . . hydrocodone," and the cocktail drugs comprising the rest of the "holy trinity" of abuse, such as "carisoprodol . . . [and] alprazolam."

208. Walgreens also had a bonus program that factored prescription volume into bonus calculations, and served as an incentive for pharmacies and pharmacy technicians to ignore the "red flags" of diversion. The corporate push for speed (or volume) deterred pharmacists from taking the time to properly examine the prescriptions before them and exercising their corresponding responsibility to prevent diversion.

209. Walgreens emphasized in its policies for pharmacist and pharmacy managers: "The best evidence of a well-run pharmacy is the increase in prescriptions and pharmacy sales." One former Walgreens pharmacist described management critiques for "not going fast enough" in dispensing prescriptions and believed "[t]hey'd like you to fill one a minute if you could." She

recalled there was even a timer to alert her if she was falling behind, and threats of reduced hours or a move to a different store or location.[58] Indeed, Walgreens had a tool, the "PhLOmometer" that tracked the time to fill a prescription. A March 2013 memo confirms that volume and speed targets included controlled substances as late as 2013 and even after the adopting of the GFD policy. Specifically, the memo states, as the response to an "[a]nticipated question" that "GFD concerns doesn't relieve you from trying to attain the numbers that have been set for you." When considering high schedule 2 dispensing at a particular pharmacy in New Jersey in 2012, as the opiate crisis raged, the pharmacy supervisor pushed back against any attempt to reduce supply of oxycodone, focusing on the impact the reduction would make on filled prescriptions and "the bonus tied to" one pharmacy employee.

210. Only as part of its 2013 settlement with the DEA, did Walgreens agree to exclude controlled substances calculations from bonus calculations from 2014 forward. This resulted in a 21% reduction in the number of stores purchasing the 80mg OxyContin—evidence that a minimal effort to implement common sense controls had a tangible impact on sales of the most potent controlled substances (although that reduction did not last, as described above, and Walgreens's volume by 2014 had increased again).

211. Walgreens also lobbied against imposition of caps or limits on the volume of prescriptions a pharmacist may fill. As the *New York Times* reported, pharmacists at chain pharmacies, including Walgreens and Rite Aid have "said it had become difficult to perform their jobs safely, putting the public at risk of medication errors," as they "struggle to fill prescriptions, give flu shots, tend the drive-through, answer phones, work the register, counsel patients, and call doctors and insurance companies . . . all the while racing to meet corporate

[58] *Are Business Tactics at Some Pharmacies Risking Your Health?* (Nov. 8, 2017), https://reachmd.com/news/are-business-tactics-at-some-pharmacies-risking-your-health/1610793/.

performance metrics that they characterized as unreasonable and unsafe . . . ."[59] Instead of reducing performance targets, chain pharmacies including Walgreens seek to assign more dispensing tasks to less qualified—and less expensive—pharmacy technicians.

212. CVS used performance metrics related to its own profits, which would rely, in part, upon the number of prescriptions dispensed. By 2010, CVS had implemented performance metrics that remain publicly available online. CVS's metrics system lacked any measurement for pharmacy accuracy or customer safety. They did, however, prioritize speed and volume, including by requiring pharmacists to meet wait- or fill-time expectations. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. These policies remained in place even as the epidemic raged. Even in 2020, pharmacists described CVS as the "most aggressive chain in imposing performance metrics."[60]

213. Despite CVS's contention that the color indicators on computer screens are meant to help pharmacists with "prioritizing their work," CVS recognized the problems the color coding caused and only recently removed a red indicator for prescriptions that had gone beyond the promised pickup time because pharmacists "felt the color red denoted something negative or alarming."[61]

214. CVS pharmacists' complaints about the company's focus on its metrics are indicative of all Defendants' practices.[62] The CVS pharmacists "criticized the [focus on metrics], saying it pressures them to focus more on corporate criteria than on drug interactions and other safety checks." As Chuck Zuraitis, head pharmacist at a CVS in the Chicago area, said: "You get

[59] *See* Ellen Gabler, *How Chaos at Chain Pharmacies is Putting Patients at Risk*, NEW YORK TIMES (Jan. 31, 2020), https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html.
[60] *Id.*

[61] Sam Roe, Ray Long, and Karisa King, *Pharmacies miss half of dangerous drug combinations*, CHICAGO TRIBUNE (Dec. 15, 2016), https://www.chicagotribune.com/investigations/ct-drug-interactions-pharmacy-met-20161214-story.html.
[62] *Id.*

stressed, and it takes your mind away from the actual prescriptions." Another CVS pharmacist, Deepak Chande, lamented that: "Every prescription is timed and this is the worst of the pharmacist's nightmares." If pharmacists fall behind, the backlog pops up in color on their computer screens, said Chande. "It's an unreal pressure," he said. "Your mind is kind of frantically trying to obey it."

215. As noted above, former pharmacists at both Walgreens and CVS have publicly complained about pressure to put speed ahead of safety. Additionally, CVS has faced discrimination complaints alleging that the company's "Metrics" system set unobtainable goals—or at least, goals that could not be obtained without violating the laws and practice rules governing pharmacists' professional responsibilities, edging out older pharmacists.

216. Walgreens and CVS were not alone in this regard. Rite Aid had performance metrics in place that exacerbated its failures. Without describing individual pharmacies, Daniel Hussar, a nationally-known expert and teacher of pharmacology at Philadelphia's University of the Sciences, commented in the media that the pace and pressure of prescription quotas appeared to be having an impact on accuracy. "The frequency of these errors is increasing greatly," Hussar said; "I've heard some pharmacists say, 'It's a blur as to what happened during the day and I can only pray I didn't make any serious mistakes.'"[63]

217. This pressure and focus on profits would not only lead to mistakes, it also would necessarily deter pharmacists from carrying out their obligations to report and decline to fill suspicious prescriptions and to exercise due care in ascertaining whether a prescription is legitimate.

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[63] *Are Business Tactics at Some Pharmacies Risking Your Health?*, ReachMD citing ksdk.com (Nov. 8, 2017), https://reachmd.com/news/are-business-tactics-at-some-pharmacies-risking-your-health/1610793/.

218. Even if controlled substances are no longer technically included in prescription count metrics, pharmacists would never know that from the closely-tracked metrics disseminated daily. So even if a pharmacist read the fine print buried in pharmacy manuals, the metrics that were actually distributed on a frequent, indeed daily, basis made no effort to exclude controlled substances.

219. Similarly, even if controlled substances were not technically included in the bonus structure for Defendants' pharmacists, denying a customer his or her controlled substances often times would lead to the customer taking all of his or her prescriptions elsewhere. So, for example, if a customer came in with a Holy Trinity cocktail, and the pharmacist properly denied the dispensing of the opioid, the customer would also not fill the benzodiazepine and the muscle relaxer. Frequently, customers also would have other prescriptions, like diabetes medications or other maintenance medications, at the pharmacy as well. If they were denied opioid prescriptions, the customers would in all likelihood take all their business elsewhere. Thus, denying a controlled substance prescription often resulted in losing multiple prescriptions, not just the opioid prescription. For Defendants who put so much emphasis on overall prescription count and profitability, this dynamic further incentivized pharmacies to fill *all* prescriptions regardless of validity.

220. The only things Defendants measured (and thus rewarded) were the sales metrics. This has created a culture where the number of prescriptions filled, their speed, and their corresponding reimbursements were the measures of success at the pharmacy chains. The role of the pharmacist as a healthcare professional serving and counseling patients has been completely lost. Furthermore, the pharmacists have been pressured to be cogs in a prescription filling

machine, rather than the last line of defense against inappropriate and/or medically unnecessary prescriptions.

221. In 2016, the *Chicago Tribune* investigated how pharmacies, including chain pharmacies, fostered environments where "safety laws are not being followed, computer alert systems designed to flag drug interactions either don't work or are ignored, and some pharmacies emphasize fast service over patient safety."[64] The *Tribune* tested 255 pharmacies to see how often pharmacies would dispense dangerous drug pairs without warning patients. As part of the investigation, the Tribune selected pairs of drugs that had serious interactions, including life-threating risks.

222. The results were stark: "Fifty-two percent of the pharmacies sold the medications without mentioning the potential interaction, striking evidence of an industrywide failure that places millions of consumers at risk." As the *Tribune* detailed, "in test after test, other pharmacists dispensed dangerous drug pairs at a fast-food pace, with little attention paid to customers." Chain pharmacies "overall failed 49 percent of their tests."

223. While acknowledging the difficulty in pinning the failure of the pharmacies to catch the dangerous interaction on a single cause, the *Tribune* concluded its interviews and studies pointed to the pharmacies' emphasis on speed as a possible explanation. Several pharmacies dispensed risky drug pairs with no warning in less than 15 minutes, and the *Tribune* found that "pharmacists frequently race through legally required drug safety reviews—or skip them altogether." The *Tribune* also noted that the New Hampshire Board of Pharmacy sampled data from two retail chains in the state and found that "pharmacists spent an average of 80 seconds on safety checks for each prescription filled." Also, "of the pharmacists at stores that

[64] Sam Roe, Ray Long, and Karisa King, *Pharmacies miss half of dangerous drug combinations*, CHICAGO TRIBUNE (Dec. 15, 2016), https://www.chicagotribune.com/investigations/ct-drug-interactions-pharmacy-met-20161214-story.html.

advertised quick service, 4 in 10 said they had made a medication error as a result of hurrying to fill a prescription within a set time." And even though most pharmacies use computer software designed to flag drug interactions, experts say computer alerts are so common that pharmacists can get "alert fatigue" and ignore many of the warnings.

224. According to the *Tribune's* coverage, "Wal-Mart, operator of 4,500 U.S. pharmacies, failed 43 percent of its tests."[65] Further, a Walmart pharmacist commented that she typically filled 200 prescriptions in her daily nine-hour shift, and an even higher volume when working at a different store, equating to two prescriptions per minute.[66] Walgreens, meanwhile, failed a test of whether pharmacists would dispense dangerous drug combinations without warning patients 30 percent of the time.[67]

225. Mayuri Patel, a pharmacist at a Walmart, said to the *Tribune* that she typically filled 200 prescriptions in a nine-hour shift, or one every 2.7 minutes. At another Walmart where she was trained, it was even busier, she said: "We were doing 600 a day with two pharmacists with 10-hour shifts." That works out to one prescription every two minutes.

226. In March 2020, journalists also revealed that Walmart not only ignored reports of suspicious activity from pharmacists concerned that they were filling prescriptions for pill mills, they considered these pharmacists focus misdirected. One internal email showed that in response to a question from a regional manager in 2015 about documenting pharmacists' concerns about doctors believed to be operating pill mills, Walmart's director of Health and Wellness Practice Compliance, Brad Nelson, wrote that "We have not invested a great amount of effort in doing analysis on the data since the agreement [requiring such reporting] is virtually over. *Driving*

[65] *Id.*

[66] *Id.*

[67] *Id.*

sales and patient awareness is a far better use of our Market Directors and Market manager's time."[68]

227. As described above, Walmart refused to allow pharmacies to flag and block all prescriptions from doctors whose prescriptions raised red flags that they were running pill mills. Not only did pharmacists have to refuse each prescription individually, to do so, "a pharmacist had to fill out a form that could take 20 minutes, a bureaucratic hurdle that pharmacists sought to avoid because they were under pressure to fill prescriptions quickly.[69]

228. The result is both deeply troubling and entirely predictable: inappropriate and medically unnecessary prescriptions for opioids flowed out of Defendants' pharmacies and into the County.

229. At least one state Board of Pharmacy has indicated that filling prescriptions quickly leads to pharmacy errors. The Oklahoma BOP cited a CVS for a pharmacy error where the pharmacy filled 194 prescriptions in a six-hour shift. That means the pharmacy was filling an average of 32 prescriptions per hour or nearly one prescription every two minutes.[70]

230. Unlike the data they received about sales metrics, Defendants' pharmacy managers did not get information on the pharmacists who were counseling patients, fully evaluating opioid prescriptions, and otherwise acting properly as pharmacists. Defendants provided no incentives to report suspicious prescribers, patients, or prescriptions.

231. Defendants have directed their pharmacists to meet higher and higher profitability goals that make it difficult, if not impossible, to comply with applicable Pennsylvania law and

[68] Jesse Eisinger and James Bandler, *Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment.*, ProPublica, (March 25, 2020), https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment (emphasis added).

[69] *Id.*

[70] Ellen Gabler, *At Walgreens, Complaints of Medication Errors Go Missing*, NEW YORK TIMES (Feb. 21, 2020), https://www.nytimes.com/2020/02/21/health/pharmacies-prescription-errors.html.

regulations. The metrics adopted by Defendants affected pharmacists' judgment when filling prescriptions and have directly contributed to its failure to prevent medically unnecessary and/or inappropriate prescriptions from being filled.

232. Defendants expected pharmacists to fill orders at such a rapid clip that they did not have the time needed to determine the legitimacy of the prescriptions that came through the pharmacy.

233. Despite any internal company guidelines that may have existed on paper, pharmacists were under constant pressure to fill even highly suspicious orders. Despite frequently seeing prescriptions with red flags, pharmacist who did not fill suspicious prescriptions could impact the metrics of not only his or her store, but also him or herself as an individual.

234. Defendants created a situation where if a pharmacist did his or her job correctly, *i.e.* properly and carefully evaluating every prescription, he or she got penalized.

235. Defendants often elevated customer complaints over the clinical judgment of its pharmacists under the thinly-veiled guise of "customer service." Defendants valued retaining a customer over its pharmacies' legal obligations to only fill medically appropriate prescriptions.

236. As pharmacists quickly found out, if they did the proper due diligence, it took time, time which caused customers to complain, especially when a customer ultimately was denied a prescription as a result of that diligence. Those complaints from drug-seeking customers with medically inappropriate or suspicious prescriptions were not dismissed by Defendants' management. Instead, they were elevated over the pharmacists' duties under the law and looked at by Defendants' management as "poor customer service."

237. In such a harried environment, it was much more difficult for pharmacists to notice red flags that might indicate an opioid prescription may be invalid, and thus more likely that drug seeking customers would obtain inappropriate drugs.

238. Drug-seeking customers often took advantage of the chaotic environment caused by Defendants' understaffing of their pharmacies. The drug-seeking customers were aware that a busy pharmacy meant the pharmacist was less likely to notice they are filling their prescription too early or that the customer had just filled a similar prescription at another pharmacy across the street.

239. Indeed, "a survey by the Institute for Safe Medication Practices (ISMP) revealed that 83% of the pharmacists surveyed believed that distractions due to performance metrics or measured wait times contributed to dispensing errors, as well as that 49% felt specific time measurements were a significant contributing factor."[71]

240. In 2013, the National Association of Boards of Pharmacy (NABP), passed a resolution which cited this survey and additionally stated that "performance metrics, which measure the speed and efficiency of prescription work flow by such parameters as prescription wait times, percentage of prescriptions filled within a specified time period, number of prescriptions verified, and number of immunizations given per pharmacist shift, may distract pharmacists and impair professional judgment" and "the practice of applying performance metrics or quotas to pharmacists in the practice of pharmacy may cause distractions that could potentially decrease pharmacists' ability to perform drug utilization review, interact with

[71] NAPB, Performance Metrics and Quotas in the Practice of Pharmacy (Resolution 109-7-13) (June 5, 2013), https://nabp.pharmacy/performance-metrics-and-quotas-in-the-practice-of-pharmacy-resolution-109-7-13/.

patients, and maintain attention to detail, which could ultimately lead to unsafe conditions in the pharmacy."[72]

iii. Pharmacists Were Overworked and Underpaid

241. During the relevant time period, the responsibilities of the pharmacy staff increased, while the amount of pharmacy staff decreased. The result was that pharmacists and pharmacist staff were burdened with many other tasks and responsibilities so that their ability to comply with not only their own internal policies and procedures regarding dispensing, but the legal requirements for the dispensing of controlled substances became nearly impossible. This result was intentional on the part of Defendants and was part of a vicious cycle. Leaner staff not only saved labor costs, but also resulted in dispensing more suspicious prescriptions because the staff could not take the time to properly vet them.

242. As one pharmacist succinctly put it in an anonymous letter to the Texas State Board of Pharmacy in April 2020: "I am a danger to the public working for CVS."[73]

243. In addition to their "corresponding responsibility" to ensure only valid prescriptions were dispensed, pharmacists were required to take on numerous other tasks. Pharmacists were required to do such things as counsel patients, administer vaccinations, answer phone calls, staff drive-through, operate the register, perform inventory checks and other administrative duties, as well as physically fill controlled substance prescriptions. Pharmacists and pharmacy staff are also required to call "dozens of patients each day, based on a computer-generated list [and] . . . are assessed on the number of patients they reach, and the number who

[72] *Id.*

[73] Ellen Gabler, *How Chaos at Chain Pharmacies is Putting Patients at Risk*, NEW YORK TIMES (Jan. 31, 2020), https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html.

agree to their requests."[74] The numerous tasks imposed on pharmacists and pharmacy staff by the Defendants forced the staff to ignore their corresponding responsibility in order to keep their jobs.

244. As one pharmacist wrote to the Pennsylvania Board of Pharmacy, "The amount of busywork we must do while verifying prescriptions is absolutely dangerous. . . . Mistakes are going to be made and the patients are going to be the ones suffering."[75]

245. The problem of illegal dispensing caused by Defendants' focus on quickly filling prescriptions and increasing the number of prescriptions dispensed was also exacerbated by Defendants' lack of pharmacy staffing. Often, pharmacists were left as the only pharmacist at a location for entire shifts. This greatly cut into the ability of the pharmacist to evaluate each prescription carefully and in accordance with the law.[76]

246. One pharmacist made the connection between less pharmacy staffing and increasing pharmacy errors explicit, writing in a letter to a pharmacy board that she "certainly make[s] more mistakes [because of a lack of staff] . . . I had two misfills in three years with the previous staffing and now I make 10-12 per year (that are caught)."

247. In connection with a Board of Pharmacy investigation into a CVS pharmacy, the lead pharmacist revealed that he had no control over the level of staffing at the store and that he had routinely complained to CVS management about the lack of adequate staff. Against his wishes, "CVS had 'almost completely eliminated pharmacist overlap'—meaning that only one is on duty at a time—and that pharmacists at his store worked about 20 to 30 hours per week

[74] *Id*.

[75] *Id*.

[76] Some states have tried to outlaw pharmacists from working alone. California, for example, passed a law saying no pharmacist could be required to work alone. Regrettably, however, it has been largely ignored since taking effect last year, according to leaders of a pharmacists' union. *See id*.

unpaid so their colleagues were 'not left in an impossible situation.' He also said that internal reports for less severe errors were sometimes not completed because of a lack of time created by staffing issues."[77]

248. Those pharmacists are not alone. The chief executive of the Florida Pharmacy Association said the number of complaints from members related to staffing cuts and worries about patient safety had become "overwhelming" in the past year.[78]

249. The pressure to meet fill-rates and other metrics at an understaffed pharmacy created a stress-filled, chaotic environment where it was simply impossible to ensure only appropriate, medically necessary opioid prescriptions were filled.

250. The experience of Wesley Hickman, a former CVS pharmacist, was typical for pharmacists at Defendants' stores. He described being driven to leave his position and open his own pharmacy, where he could work safely. The day before he quit in December 2018, Hickman worked a worked a 13-hour shift with no breaks for lunch or dinner. During that shift, Hickman was the only pharmacist on duty at the CVS store where he worked and he still "filled 552 prescriptions—about one every minute and 25 seconds—while counseling patients, giving shots, making calls and staffing the drive-through."[79] The next day, Hickman quit because he could no longer work in a situation he felt was "unsafe." "Dr. Hickman felt that the multitude of required tasks distracted from his most important jobs: filling prescriptions accurately and counseling patients. He had begged his district manager to schedule more pharmacists, but the request was denied, he said."

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[77] Ellen Gabler, *At Walgreens, Complaints of Medication Errors Go Missing*, NEW YORK TIMES (Feb. 21, 2020), https://www.nytimes.com/2020/02/21/health/pharmacies-prescription-errors.html.

[78] Ellen Gabler, *How Chaos at Chain Pharmacies is Putting Patients at Risk*, NEW YORK TIMES (Jan. 31, 2020), https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html.

[79] *Id*.

251. It is difficult to contemplate how any pharmacist could and/or would be able to meaningfully comply with any corporate policy regarding red flag analyses or any anti-diversion analysis under such draconian pressures.

252. Walgreens in particular was well aware that its "unreasonable" expectations on pharmacists had "led them to make mistakes while filling prescriptions and to ignore some safety procedures."[80] In fact, the *New York Times* reviewed internal documents showing that Walgreens intentionally ignored these findings.

253. According to the *New York Times*, senior leaders at Walgreens engaged a consultant to review its computer system for filling prescriptions. Instead of taking the feedback about serious issues with Walgreens' dispensing practices, senior executives intentionally ignored the problems and swept them under the rug, ensuring the issues were not fixed. For example, "Amy Bixler, the director of pharmacy and retail operations at Walgreens, told [the consultants] to delete a bullet point last month that mentioned how employees 'sometimes skirted or completely ignored' proper procedures to meet corporate metrics, according to the chat logs and the draft report."[81]

254. The consultant's report also noted that at Walgreens there was "a widespread perception that there is not enough time to respond to all pharmacy tasks." The consultants also found "'multiple reports of improper behavior' that was 'largely attributed to the desire' to meet a corporate metric known as 'promise time,' which ensures that patients get prescriptions filled within a set amount of time."[82]

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[80] Ellen Gabler, *At Walgreens, Complaints of Medication Errors Go Missing*, NEW YORK TIMES (Feb. 21, 2020), https://www.nytimes.com/2020/02/21/health/pharmacies-prescription-errors.html.

[81] *Id.*

[82] *Id.*

255. While the article focused on Walgreens in particular, the article shows how the allegations in this complaint were widespread at Defendants in general. This includes things like the demands chains place on their pharmacists leading to the pharmacists ignoring some safety procedures and the widespread perception among chain pharmacists that there is not enough time to respond to all pharmacy tasks.

256. Defendants' lean staffing and overwhelming pressure on its pharmacies to meet business goals meant that its pharmacists often were not allowed to take breaks during their shifts, further degrading their ability to fully vet prescriptions.

257. The harsh working conditions have meant Defendants have had to settle numerous lawsuits for millions of dollars related to working conditions at its pharmacies, including for lack of breaks.[83]

C. Defendants Failed to Maintain Effective Controls Against Diversion and Contributed to Illegal Diversion in the County.

258. As described further below, Defendants failed to fulfill their legal duties and instead, routinely distributed and/or dispensed controlled substances while ignoring suspicious order and red flags of diversion and abuse. The unlawful conduct by these Defendants is a substantial cause for the volume of prescription opioids plaguing the County.

[83] *See, e.g.,* Alissa Wickham, *Walgreen Shells Out $23M To Settle Wage Class Actions*, Law360 (Mar. 26, 2014), https://www.law360.com/articles/522119/walgreen-shells-out-23m-to-settle-wage-class-actions; Daniel Siegal, *CVS Pharmacists Win OK For $3M OT Deal On 2nd Shot*, Law360 (Nov. 30, 2015), https://www.law360.com/articles/732220/cvs-pharmacists-win-ok-for-3m-ot-deal-on-2nd-shot.

1. CVS

a. CVS Failed to Maintain Effective Suspicious Order Monitoring Systems or to Completely Necessary Due Diligence.

i. CVS Lacked a Genuine Suspicious Order Monitoring System for Much of the Relevant Time Period.

259. CVS distribution centers, in tandem with outside vendors, supplied opioids to CVS pharmacy stores until 2014. CVS self-distributed hydrocodone and hydrocodone combination products to its own stores, of which CVS had approximately 6,000 by 2006 and 9,700 by 2014. Hydrocodone (HCP) was previously a Schedule 3 opioid, but rescheduled to FDA Schedule 2 status October 6, 2014. CVS ceased self-distributing hydrocodone the same day the rescheduling took effect.

260. CVS pharmacies nationwide placed orders with CVS distribution centers through CVS's central mainframe computer ordering system.

261. Before 2009, CVS, which stocked and sold opioids at more than 9,000 stores across the country, lacked any meaningful suspicious order monitoring ("SOM") system. Instead, CVS relied on gut instincts of pickers and packers of the drugs in the distribution center to identify "really big" orders that they believed were simply too large. This, of course, was not an effective SOM system.

262. Moreover, CVS lacked a training program to train its Pickers and Packers how to identify unusual orders of size, frequency, or pattern. CVS also did not have any written policies, procedures, or protocols with respect to the Pickers' and Packers' obligations until August, 2013. And, there were no formal job requirements to be employed as a Picker and Packer.

263. In 2007, with the help of an outside consultant, CVS began work on a Standard Operating Procedure Manual ["SOP"] that was intended to cover all facets of DEA controlled

substances compliance, including suspicious order monitoring. However, by the Summer of 2010, neither the final manual nor the suspicious order monitoring section was complete: Internal documents from that time acknowledge that CVS was "still in the process of writing the Suspicious Order Monitoring Section of the SOP." In fact, in the section of the Standard Operating procedures for Suspicious Order Monitoring it states "**BEING DEVELOPED AND WRITTEN."**

264. Drafts of the SOP Manual, meanwhile, show CVS understood, or should have understood, that this was unacceptable. The draft manual provides that: "CVS is responsible for ensuring compliance with DEA regulatory requirements, and that responsibility cannot be abdicated or transferred to anyone else." Despite this acknowledgement, when the first version of the SOP manual was issued in December 2007 and for multiple revisions thereafter, the SOM section still remained incomplete. And it was not completed until August of 2010. Completion of the Manual in 2010 did not equate to compliance, however.

265. As John Mortelliti, CVS' Director of Loss Prevention, wrote in November 2009, this had become "a big issue with CVS and the DEA," and he was "trying to get a rough draft SOM SOP" before a DEA meeting. CVS only incorporated the final missing SOMS section because of the need to respond to an apparent promise to provide it to the DEA.

266. CVS Indiana was audited and investigated by the DEA for its distribution practices on August 24, 2010. The day after the DEA's audit of CVS's distribution practices began, on August 25, 2010, CVS Pharmacy, Inc. sent a new Standard Operating Procedure, which included for the very first time a policy on SOM. CVS Pharmacy, Inc. internally posted the SOP at 1:35 p.m. on August 26, 2010. The document was hastily put together. The SOM section was actually cut and pasted into the SOP twice.

267. On September 1, 2010, John Mortelliti sent an e-mail to Terrance Dugger who was present during the DEA audit. The subject of the e-mail and the attachment is "DEA Speaking Points," the importance was listed as high. He writes: "Terrence, This is for the DEA. This corrections listed below have been updated. It is ok to review this with the agents."[84]

268. Mr. Mortelitti then sent the same presentation on the same day to another group of CVS employees writing: "These are the final approved speaking points for the DEA agents if they come to one of your facilities and questions suspicious monitoring. It is ok to share this document. Please be sure your team understands it before presenting so it *doesn't look like a prop instead of a tool.*[85] The presentation sent by Mr. Mortelitti to be shared with the DEA was not correct and was not the procedure being used by CVS.

269. CVS had a "CVS DEA compliance coordinator" in name only. A CVS employee who held the position from 2008 to 2014 said that this was only "for reference in SOPs," not her real job. For "personnel purposes," she was never considered the CVS DEA compliance coordinator. Moreover, she had nothing to do with suspicious order monitoring, other than "updating the SOP with what was provided for the program."[86] This, according to CVS's "DEA Compliance Coordinator."

ii. CVS Failed to Remedy Fatal Flaws in the Monitoring System It Slowly Developed.

270. It was only in 2009 that CVS began using a computer algorithm that flagged potentially suspicious orders needing additional investigation. The automated program was delivered by an outside vendor to CVS in December of 2008.

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[84] CVS-MDLT1-0000075299 through CVSMDLT1-000075312

[85] CVS-MDLT1-0000075299 through CVSMDLT1-000075312 (emphasis added).

[86] Deposition testimony of CVS employee Amy Propatier (Nov. 29, 2018) at 79:20-80:7; 80:21-81:2; 82:19-22; 138:21-140:1.

271. CVS called the output of the flagged orders an Item Review Report ("IRR").

272. The SOM algorithm delivered in December 2008 was designed to "pend" (or identify) an order with a score of 0.15 or higher as potentially suspicious. The higher the score the more likely the order was potentially suspicious. In July 2009 CVS reported to the algorithm designer that the SOM model was pending a large number of orders that CVS believed were "not suspicious on their face" and it requested that the model be changed. As a result, revised coefficients for the algorithm were delivered to CVS on August 27, 2009 and the pend score of .15 remained the same. Between June 2010 and August 2010, Mortelliti adjusted the IRR pend score from .15 to .65. The higher the score, the less sensitive the model, flagging fewer potentially suspicious orders for investigation. On February 8, 2011 a completely retuned SOM algorithm with another set of co-efficients was again delivered to CVS by the algorithm designer. The February 2011 changes returned the pend score to .15. CVS again changed the pend score to .65.

273. IRRs were the primary SOM process. A CVS corporate representative explained, on behalf of the company, "for the most part," if an order was not flagged as suspicious under the IRR system, there would be no due diligence of that order. Yet, CVS neglected to provide written instructions for how to perform that critical review until February 29, 2012.

274. CVS's IRR system was deficient and failed in many respects to meet CVS's obligations as a distributor.

275. CVS also learned in 2010 that its SOM algorithm was not working properly because it monitored by drug, not active ingredient, meaning that changes in a drug's description or name caused historical data, necessary for valid calculations, to be lost. Thus, the system was

unable to determine that orders for these drugs exceeded or diverged from prior volumes or patterns.

276. CVS's SOMS algorithm also failed to consider outside vendors orders. In other words, CVS's SOM system would not track how many opioids CVS was ordering from third party distributors such as Cardinal when evaluating whether to distribute opioids to one of its pharmacies. CVS knew this was a problem, as a "[s]tore may order a little from both the OV [outside vendor] and DC [CVS distribution center] to stay under the radar." It also knew that excluding outside vendor data meant CVS "may ship a potentially reportable suspicious order from [its] DC." Stores, including one that had a "68,000 hydrocodone pill loss," could also place telephone orders to outside vendors, into which there was "no visibility . . . until a later time." This deficiency is particularly glaring because, at a corporate level, CVS had full access to the orders its pharmacies placed to outside vendors.

277. Acknowledging the ineffectiveness and deficiencies within its SOM system, CVS hired new consultants in 2012 to troubleshoot its existing SOM systems for the purpose of either fixing the deficient system or developing a new SOM system so as to attempt to become compliant with the law.

278. Still, as late as July 2013, internal e-mails reflect that CVS's primary tool for investigating suspicious orders relied on data that was months or even years old and made any analysis, "for the most part, irrelevant and pointless."[87]

279. Not until mid to late 2014 did CVS fully implement the new SOM system. Even then, CVS encountered problems in evaluating suspicious orders for opioids and its SOM system was entirely lacking. More specifically, CVS implemented a new SOM system in the

[87] CVS-MDLT1-000078116- 000078119; Deposition testimony of CVS employee Kelly Baker (Jan. 24, 2019) at 259:16–262:19.

Indianapolis distribution system in March of 2014. The deployment was further delayed due to system data feed issues that created inaccuracies in the SOM historical data. A risk analysis of the new system was conducted in June of 2014. The risk level was determined to be high for the SOM system in the following categories covering seemingly every aspect of its operation: inconsistent due diligence in SOM analysts reaching out to stores to investigate suspicious orders; inconsistency in documenting due diligence investigations of suspicious orders; lack of engagement by the Management Team; lack of communication between the SOM Management Team and SOM Analysts; lack of resources to handle the rollout of the new SOM system to all distribution centers; lack of clarity in how the new SOM system is identifying suspicious orders. Essentially the key components of a compliant and effective SOM system. That same year, CVS stopped distributing opioids at the wholesale level.

280. Meanwhile, on August 5, 2013, the DEA began another audit and investigation of the CVS distribution center in Indiana. CVS's own documents acknowledge that the DEA's investigation was focused on its failure to maintain a SOM program for controlled substances.

281. In response to queries from the DEA, CVS wrote a letter to the DEA revealing that it had only stopped seven suspicious orders across the entire country. Right before sending the letter the author, Mark Nicastro, head of the CVS distribution center in Indiana, conceded internally that, "I wish I had more stopped orders that went back further." Sadly, while Mr. Nicastro was writing the letter on CVS's behalf to the DEA, he couldn't even locate the SOP for the SOM writing to Pam Hinkle, "For the life of me I can't find the SOP for SOM. Can you send me an electronic copy please? I have been on the logistics website, looked through hundreds of e-mails, nothing. I'm surprised it is not on the website." Ms. Hinkle, Sr. Manager for Logistics,

Quality and Compliance for CVS, responds that she too is unsure of the final version of the SOP SOM. CVS sent the wrong version of the SOP SOM to the DEA.

282. In May of 2014, CVS had a closing meeting with the DEA related to the distribution center audit. According to handwritten notes from a CVS employee who attended the meeting, the "most serious" violation is "failure to design" a SOM system. An internal CVS e-mail summarizing the meeting made a similar statement: DEA determined that CVS "faile[d] to maintain an SOM program." The head of CVS's distribution center in Indiana described Betsy Ferguson's, CVS's in-house counsel, confrontation with the DEA during the meeting writing: "Dan [DEA Agent] finally pushed Betsy's button and the gloves came off. . . . Betsy made it very clear that a letter of admonishment was one thing. Anything other than that and she wanted an opportunity to do a presentation to his boss and her boss about what we do with SOM. Anything more than a letter and we would meet in D.C. in courts just like Walgreens did."

283. The DEA issued its closing letter concluding that CVS failed to design and maintain system to detect suspicious and report suspicious orders for Schedule III-V Controlled Substances as required by Federal law.

iii. CVS Failed to Perform Due Diligence

284. All orders that appeared on the IRR required a thorough due diligence investigation, but only a very small percentage were subjected to appropriate due diligence. From early/mid-2009 through early 2011, one employee, John Mortelliti, who was the Director of Loss Prevention, "was taking the first pass through the IRR himself."[88] According to CVS's corporate witness, "Mr. Mortelliti's practice would have been to review the report on a daily basis and determine whether items on the report warranted further review and due diligence and

[88] Vernazza Dep. Tr. 365:6-13; 368:9-14.

conduct review and due diligence as he deemed appropriate."[89] At select times in 2013, CVS had only one full-time employee in the position of "SOM analyst" reviewing all potentially suspicious orders for every pharmacy in the country. The SOM system would identify orders as potentially suspicious based on a number of factors and "pend" the order. Even though the orders had been identified as potentially suspicious the CVS SOM analysts would conduct an "in depth" dive on only select orders. In fact, the SOM program could identify as many as 1,000 suspicious orders a day; the CVS employee would only do a "deep dive" on one to six orders per day.

285. Even as late as 2012 CVS's SOMS was clearly little more than window dressing. For example, CVS's own SOMS policy specified that if multiple orders for the same store are flagged during the same month, all orders after the first order will ***not*** be investigated and will be *automatically released* based on the release of the first order.

286. As noted above, as of November 21, 2013, CVS only reported seven suspicious orders to the DEA across all of its distribution centers and pharmacies in the United States. The first suspicious order CVS ever reported was on February 29, 2012.

iv. CVS Prevented Other Distributors from Conducting Suspicious Order Monitoring of Its Retail Pharmacies.

287. CVS prevented other distributors from conducting adequate due diligence investigations of suspicious opioid orders. CVS knows that distributors such as Cardinal and McKesson have independent due diligence obligations to monitor all sales of controlled substances for orders which deviate in size, pattern or frequency. To do so effectively, CVS understood that these distributors would require access to its dispensing information. CVS did not provide dispensing information to Cardinal or McKesson. CVS prevented them from obtaining access to critical dispensing information for its pharmacies to conduct adequate due

[89] Vernazza Dep. Tr. 371:15-23.

diligence of its pharmacies. Prior to 2013, Cardinal and McKesson did not investigate CVS' suspicious orders by calling its pharmacies or visiting CVS stores as they did with other pharmacies. Instead, distributors were instructed to contact CVS's loss prevention office at corporate headquarters to inquire about suspicious orders, ensuring that any investigation into CVS ordering of opioids was conducted by CVS alone.

288. As a result, CVS controlled all "due diligence investigations" of its opioid orders.

289. CVS also prevented its distributors from independently determining the appropriate order thresholds for opioids at CVS stores. CVS contractually protected its right to establish and change its threshold requirement for Schedule II controlled substances with Cardinal. The agreement expressly states that CVS has the discretion under the contract to set its threshold quantities for controlled substances at any level CVS deems appropriate.

v. CVS Failed to Implement Effective Policies and Procedures to Guard Against Diversion from Its Retail Stores

290. According to its website, CVS now has more than 9,900 retail locations. At all times relevant herein, CVS pharmacies sold controlled substances, including FDA Schedule II and FDA Schedule III controlled substances otherwise known as opiate narcotics or opioids.

291. "CVS Corporation," not any individual CVS store, is the DEA registrant for each of CVS's pharmacies across the country. CVS renews the DEA licenses for its pharmacies through a "Registration Chain Renewal." From October 2013 through December 2016, CVS headquarters paid more than $5 million to renew the licenses for 7,597 CVS locations.

292. As described above, until October 6, 2014, CVS pharmacies ordered and were supplied FDA Schedule III hydrocodone combination products (HCPs) from a combination of outside vendors and CVS distribution centers. CVS pharmacies also received Schedule II opioids

from outside vendors, with Cardinal acting as its exclusive outside supplier for the entire period for which ARCOS is available.

293. CVS Pharmacy, Inc. instituted, set-up, ran, directed and staffed with its own employees the majority of the SOM functions for its pharmacy stores.

294. CVS also lacked meaningful policies and procedures to guide its pharmacy staff in maintaining effective controls against diversion, even as they evolved over time. Not until 2012 did CVS create guidelines explaining in more detail the "red flags" or cautionary signals that CVS pharmacists should be on the lookout for to prevent diversion and to uphold their corresponding responsibilities to ensure that all dispensed controlled substances are issued for a legitimate medical purpose.

295. Even so, CVS's conduct, and the volume it dispensed in the County, indicates that its policies were not applied. In addition, as discussed further below, CVS had performance metrics in place that pressured pharmacists to put profits ahead of safety.

296. CVS failed to use data held at the corporate level to assist pharmacists in evaluating red flags of diversion. CVS's later dispensing policies and procedures make clear that for the majority of the time CVS has been engaged in the sale and dispensing of opioids, there was no meaningful integration of data and information that was within the possession and control of CVS corporate personnel.

b. CVS Failed to Maintain Effective Controls Against Diversion in the County.

297. CVS owns approximately 35 pharmacies in Allegheny County.[90] Per ARCOS data from 2006 to 2014, 27 CVS pharmacies in Allegheny County, as distributors, self-distributed in the County more than 43 million dosage units of oxycodone, hydrocodone, oxymorphone and hydromorphone.

298. As a vertically integrated distributor and dispenser of prescription opioids, CVS knew or should have known that an excessive volume of pills was being sold into the County and ultimately, onto its streets. CVS's activities as a distributor and a seller or dispenser of opioids are inextricably linked.

299. Because of its vertically integrated structure, CVS has access to complete information regarding red flags of diversion across its pharmacies in and around the County, but CVS chose not to utilize this information and failed to effectively prevent diversion.

300. CVS violated the standard of care for a distributor by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

301. The sheer volume of prescription opioids distributed to and dispensed by CVS pharmacies in and around the County is indicative of potential diversion and required appropriate due diligence.

302. Further, analysis of ARCOS data also reveals that a CVS store located at 510 Brookline Blvd, Pittsburgh, PA 15226, dispensed more than 3.4 million oxycodone and hydrocodone pain pills between 2006 and 2014, the most of any CVS pharmacy in the County

[90] https://www.cvs.com/store-locator/cvs-pharmacy-locations/Pennsylvania.

during that time. Another CVS pharmacy located at 3440 Forbes Avenue, Pittsburgh, PA 15213, distributed more than 3.3 million oxycodone and hydrocodone pain pills between 2006 and 2014.

303. CVS funneled far more opioids into the County, and out of its pharmacy doors, than could have been expected to serve legitimate medical use, and ignored other red flags of diversion, including but not limited to suspicious orders.

304. It cannot be disputed that CVS was aware of the suspicious orders that flowed from its distribution facilities into its own stores. CVS refused to identify, investigate, and report suspicious orders even though CVS knew, or should have been fully aware, that opioids it distributed and sold were likely to be diverted. Conversely, CVS failed to report suspicious orders, failed to meaningfully investigate or reject suspicious orders, and failed to prevent diversion, or otherwise control the supply of opioids flowing into the County.

305. Upon information and belief, CVS failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

306. CVS was, or should have been, fully aware that the opioids being distributed and dispensed by it were likely to be diverted; yet, it did not take meaningful action to investigate or to ensure that it was complying with its duties and obligations with regard to controlled substances, including its responsibility to report suspicious orders and not to ship such orders unless and until due diligence allayed the suspicion.

307. Given CVS's retail pharmacy operations, in addition to its role as a wholesale distributor, CVS knew or reasonably should have known about the disproportionate flow of opioids into Pennsylvania and the County and the operation of "pill mills" that generated opioid

prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, illicit supply and diversion.

308. In addition, CVS knew, or deliberately turned a blind eye, to its pharmacies' role in diversion of dangerous drugs. At the pharmacy level, Discovery will reveal that CVS knew or should have known that its pharmacies in the County, and the surrounding area, were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazapines, or prescription "cocktails"; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. Defendants had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

2. Walgreens

309. Acting as both a distributor and a retail pharmacy chain, Walgreens self-distributed, meaning that its distribution "customers" were its own individual Walgreens pharmacies. Although Walgreens had visibility into red flags of diversion due to its vertically integrated distribution and dispensing practices, it failed to take these factors into account in its SOM program during the vast majority of the time it was distributing prescription opioids. Moreover, its program was wholly inadequate and did not fulfill its duties to prevent diversion. Likewise, Walgreens also failed to maintain effective controls against diversion from its pharmacy stores.

a. Walgreens Delayed Development of a SOMS Program, Instead Relying on After-the-Fact Reports of "Excessive" Orders While Ignoring Red Flags.

310. Though Walgreens had access to significant information about red flags due to its vertical integration with its stores, Walgreens failed to use available information to monitor and effectively prevent diversion.

311. At least as early as 1998, and perhaps as early as 1988, Walgreens began to utilize a series of formulas to identify orders that Walgreens deemed to be suspicious based on the orders' extraordinary size. These orders were listed on a report called the Suspicious Control Drug Order report.

312. Walgreens used two different formulas: one formula from (at least) 1998-2007 and one formula from March 2007 through 2012. These formulas were alike in that they each utilized an average number based on historical orders, applied a three times multiplier to that base number, and then deemed certain orders which were greater than that number to be suspicious. Under the later formula, orders were only listed on the report as being suspicious if the orders exceeded the three times multiplier for two consecutive months in a given time period.

Walgreens based this second formula on the DEA's Chemical Handler's Manual's order monitoring system for listed chemicals.[91]

313. The first variation on this formula was in place until March 2007, even though the DEA warned Walgreens that the "formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient," via a May 2006 Letter of Admonition. The Letter cited Walgreens for controlled substances violations at its Perrysburg Ohio Distribution Center, but highlighted problems that went far beyond that particular facility.

314. The DEA also reminded Walgreens that its suspicious ordering "formula should be based on (size, pattern, frequency)," though Walgreens failed to even examine anything other than the size of an order. When Walgreens did update its program some ten months later, however, it still did not perform the size, pattern, and frequency analysis prescribed by the DEA, continuing to use another "three times" formula.

315. Even with its ample threshold, each Walgreens Suspicious Control Drug Order report could be thousands of pages or more in length.

316. Walgreens did not perform any due diligence on the thousands of orders identified as "suspicious" on the Suspicious Control Drug Order reports, but instead shipped the orders without review.

317. Walgreens did not report the suspicious orders listed on the Suspicious Control Drug Order report until *after* the orders were already filled and shipped. The report was generated on a monthly, nationwide basis, directly contravening regulatory requirements that suspicious orders be reported *when discovered.* In some instances, months may have elapsed between an order's shipment and its subsequent reporting to the DEA, given the requirement,

[91] WAGMDL00400357.

described above, of two consecutive months of exceeding the three times multiplier to trigger reporting.

318. In September 2012, the DEA issued an immediate suspension order ("ISO") regarding one of Walgreens's three Schedule II distribution centers, finding Walgreens's distribution practices constituted an "imminent danger to the public health and safety" and were "inconsistent with the public interest." The DEA further found that Walgreens's Jupiter distribution center failed to comply with DEA regulations that required it to report to the DEA suspicious drug orders that Walgreens received from its retail pharmacies, resulting in at least tens of thousands of violations, particularly concerning massive volumes of prescription opiates. There, the DEA stated: "Notwithstanding the ample guidance available, Walgreens has failed to maintain an adequate suspicious order reporting system and as a result, has ignored readily identifiable orders and ordering patterns that, based on the information available throughout the Walgreens Corporation, should have been obvious signs of diversion occurring at [its] customer pharmacies."

319. In the ISO, the DEA also specifically considered the Suspicious Control Drug Order reports and made the following further findings of fact and conclusions of law[92] regarding the reports and Walgreens's suspicious order monitoring system—applicable across Walgreens's operations:

- "[Walgreens's] practice with regard to suspicious order reporting was to send to the local DEA field office a monthly report labeled 'Suspicious Control Drug Orders.'"
- "[The Suspicious Control Drug] reports, consisting of nothing more than an aggregate of completed transactions, did not comply with the requirement to report suspicious orders as discovered, despite the title [Walgreens] attached to these reports."

[92] *See* WAGMDL00387654.

- Upon review of an example of the Suspicious Control Drug Order report for December 2011, "[Walgreens's] suspicious order report for December 2011 appears to include suspicious orders placed by its customers for the past 6 months. The report for just suspicious orders of Schedule II drugs is 1712 pages and includes reports on approximately 836 pharmacies in more than a dozen states and Puerto Rico."

- Finding that the reports failed to appropriately consider the population and area being served by the pharmacy: "This report from the Jupiter [Florida] Distribution Center covers pharmacies in multiple states and Puerto Rico, yet the average order and trigger amount is the same for a particular drug regardless of the pharmacy's location, the population it serves, or the number of other pharmacies in the area."

- "As made clear in 21 CFR§ 1301.74(b), *Southwood,* and the December 27, 2007 letter to distributors from the Deputy Assistant Administrator for the Office of Diversion Control, suspicious orders are to be reported *as discovered*, not in a collection of monthly completed transactions. Moreover, commensurate with the obligation to identify and report suspicious orders as they are discovered is the obligation to conduct meaningful due diligence in an investigation of the customer and the particular order to resolve the suspicion and verify that the order is actually being used to fulfill legitimate medical needs. This analysis must take place *before* the order is shipped. No order identified as suspicious should be fulfilled until an assessment of the order's legitimacy is concluded."

- "DEA's investigation of [Walgreens] ... revealed that Walgreens failed to detect and report suspicious orders by its pharmacy customers, in violation of 21 C.F.R. §1301.74(b). 21 C.F.R. § 1301.74(b)."

- ". . . DEA investigation of [Walgreens's] distribution practices and policies ... demonstrates that [Walgreens] has failed to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of 21 U.S.C. *55* 823(b)(l and (e)(l). [Walgreens] failed to conduct adequate due diligence of its retail stores, including but not limited to, the six stores identified above, and continued to distribute large amounts of controlled substances to pharmacies that it knew or should have known were dispensing those controlled substances pursuant to prescriptions written for other than a legitimate medical purpose by practitioners acting outside the usual course of their professional practice. . . . [Walgreens has not] recognized and adequately reformed the systemic shortcomings discussed herein."

- "[DEA's] concerns with [Walgreens'] distribution practices are not limited to the six Walgreens pharmacies [for which DEA suspended Walgreens' dispensing registration]."

b. Walgreens Knew Its After-the-Fact Excessive Purchase Reports Failed to Satisfy Its Obligations to Identify, Report, and Halt Suspicious Orders.

320. Walgreens knew its procedures were inadequate well before the 2012 ISO issued. In addition to the guidance described above, in 1988, the DEA specifically advised Walgreens that "[t]he submission of a monthly printout of after-the-fact sales does *not* relieve the registrant of the responsibility of reporting excessive or suspicious orders."[93] The DEA further advised Walgreens that, while "[a]n electronic data system may provide the means and mechanism for complying with the regulations . . . the system is not complete until the data is carefully reviewed and monitored by the registrant."[94] Despite this instruction, there is no evidence that Walgreens ever took any action related to the Suspicious Control Drug Order report besides generating it and mailing it out. Walgreens has admitted that there is no evidence that Walgreens ever performed a due diligence review on any of the orders listed on the Suspicious Control Drug Order report before shipment. One of the managers for Walgreens's Pharmaceutical Integrity ("RX Integrity") Department stated that, when he was with the Loss Prevention Department, he "basically burned the data on a CD and sent it off. I didn't dive into each individual report or CD" and that he "would look at it briefly, but just to see if the data transferred to the CD, but that's about the extent."[95] In an errata submitted in connection with a deposition in the Opioid MDL, Walgreens acknowledged that it "is currently unaware of due diligence that was performed based on orders being flagged . . . ."[96]

[93] US-DEA-00025683 (emphasis added).

[94] *Id.*

[95] E. Stahmann MDL Dep. (Oct. 16, 2018) at 287:16-23.

[96] *See* E. Bratton Rule 30(b)(6) Deposition Erratum No. 3, Ex. 333.

321. As described above, in May 2006, the DEA told Walgreens again that the formula Walgreens was using to identify suspicious orders for the Suspicious Control Drug Order reports was "insufficient" and "inadequate."

322. Moreover, in September 2007, three Walgreens's senior employees (Dwayne Pinon, Senior Attorney; James Van Overbake, Auditor; and Irene Lerin, Audit Manager) attended the DEA Office of Diversion Control's 13th Pharmaceutical Industry Conference in Houston, Texas. Michael Mapes, Chief, DEA, Regulatory Section, gave a presentation at this Conference relating to suspicious orders, which included the reminder that the CSA "requirement is to report suspicious orders, not suspicious sales after the fact." Participant notes from this meeting indicate that Mr. Mapes advised the audience not to "confuse suspicious order report with an excessive purchase report. They are two different things."

323. Similarly, handwritten notes on an internal document from July 2008 state that "DEA really wants us to validate orders and only report true suspicious orders or what was done to approve orders." They go on to state that "[j]ust reporting these orders is not good enough – need to document what happened."

324. Additionally, in November 2012, the Walgreens' Divisional Vice President of Pharmacy Services reported to Kermit Crawford, Walgreens' President of Pharmacy, Health and Wellness, his notes from meeting with the DEA about reporting suspicious orders, which included the note, "[i]f suspicious - you don't ship."

325. In a December 2008 Internal Audit of its Perrysburg Distribution Center, Walgreens admitted to systemic and longstanding failures in the systems surrounding DEA compliance:

> In our opinion internal controls that ensure compliance with DEA regulations at the Perrysburg DC require improvement. In addition, some of these issues pertain

> to all company DCs and should be addressed to avoid potential DEA sanctions. Specifically, our review found four issues previously cited in the DEA's May 2006 inspection report that are still open. In addition, four issues noted in our previous audit (report dated July 2005) remain un-remediated. Areas requiring the greatest level of improvement are as follows:
>
> DC-wide:
>
> - pseudoephedrine reporting requirements and inventory maintenance
> - suspicious controlled drug order processing and reporting
> - controlled drug reporting, specifically receiving record information
> - lack of formalized CII controlled substance policies and procedures.

326. The Internal Audit goes on to state that "Walgreens is required to have a process to disclose to the DEA any suspicious orders of controlled substances that deviate from the normal size, pattern, and frequency. Any orders that are deemed to be suspicious are required to be reported to the DEA upon discovery." It also notes that while "Walgreens produces monthly Suspicious Controlled Drug Orders report," the audit team recommended discussions continue across multiple departments within Walgreens regarding "reporting suspicious control drug orders" and an "Updated Suspicious Control Drug Order Identification Methodology," with an "Estimated Completion Date for the New Reporting" of "June 30 2009." In this respect, too, it makes clear that the failures described are systemic. The audit also underlined Walgreens's lack of urgency in addressing the problems, indicating that the next "Cross-Functional Meeting" to address the "Updated Suspicious Controlled Drug Order Identification Methodology" would not occur for more than five months, at the end of May 2009.

c. Walgreens Lacked Meaningful Additional Systems to Address the Failures in Its Systems of After-the-Fact Reporting of Certain Orders.

327. Walgreens nominally employed additional procedures within its distribution centers; however, these systems did not address the failings of the Suspicious Control Drug

Order reports. These distribution center systems were not designed to detect suspicious orders of controlled substances, but rather were designed to detect typos or errors in order entry by the stores. Walgreens admits that its Distribution Centers are "more akin to supply warehouses," are "not designed to be a backstop to pharmacists," and that they are not well "equipped to ensure compliance" or to "assist in combatting controlled substance abuse," and "do not have the ability to detect trends in local markets."

328. The Distribution Center ("DC") level procedures are documented in a 2006 Questionable Order Quantity policy, which had two facets: first, it instructed DC personnel to review orders and contact the pharmacy with questions regarding quantities. The policy did not mention reporting suspicious orders until 2010, when it was updated to state that the Corporate Office Internal Audit Department would handle suspicious store orders and inquiries. There is no evidence that the Internal Audit department had any involvement in reporting suspicious orders.

329. The second aspect of this DC level procedures required "pickers," the DC personnel who actually retrieved pill bottles off the shelves and placed them into totes for shipping, to look for "questionable" orders while picking.

330. The only review of the orders identified by the DC level procedures was calling the pharmacy to make sure the order had not been entered in error. Walgreens admitted this procedure was not intended to detect suspicious orders.

331. There is no evidence that any orders were ever reported as suspicious or halted as a result of Walgreens's distribution-center level policies. There is no evidence these procedures resulted in timely reporting of, due diligence on, or non-shipment of any order, including those listed as being "suspicious" on the Suspicious Control Drug Order reports.

332. Walgreens's documents effectively acknowledge that these were not true anti-diversion measures, and it recognized internally that it did not begin creating a suspicious order monitoring ["SOM"] system until March 2008. Specifically, in March 2008, Walgreens finally formed a five department "team" to "begin creating" a SOM program. The new SOM program was not piloted until more than a year later, in August 2009, and even then, the pilot included orders form just seven stores. Not until September 2010 would the program, implemented in pieces and phases, be rolled out chain-wide, and from that point it took several more years to fully implement.

333. Through 2012, Walgreens continued to populate the Suspicious Control Drug Order report with thousands of orders that exceeded Walgreens's "three times" test, showing that Walgreens's post-2009 SOM program did little to mitigate the extraordinary volume of controlled substances being shipped by Walgreens to its pharmacies.

d. Even as It Rolled Out Its New SOM Program, Walgreens Left Significant Gaps and Loopholes in Place and Failed to Report and Perform Due Diligence on Orders It Flagged.

334. Walgreens did not prioritize compliance when instituting its SOM system. Testimony from the Senior Director of the Walgreen's Pharmaceutical Integrity Department, which is charged with supervising Walgreens's SOM system, revealed that even as late as 2012, 2013, and 2014, Walgreens's viewed the SOM system as an inventory control mechanism rather than as a compliance control mechanism.

> Q: Now, Walgreens's system, similar to my alarm, is there to detect a potential red flag. Would you agree with that?
>
> A: It was put in place to ensure that the stores had the proper quantities. Not necessarily to . . . detect a red flag. The whole idea was to make sure that the stores were getting the quantities that they needed based on their peer group.

335. Perhaps because keeping supply moving, as opposed to preventing diversion, was Walgreens's primary focus, the SOM program Walgreens slowly developed had significant gaps or loopholes. For example, for the first few years, the program did not include orders that Walgreens stores were also placing to outside vendors, like Cardinal and AmerisourceBergen, allowing stores to order opioids from Walgreens distribution centers and from Cardinal and AmerisourceBergen, allowing stores to order opioids from Walgreens distribution centers and from Cardinal and AmerisourceBergen, effectively permitting double dipping. It also did not prevent stores from placing an order to an outside vendor if the store attempted to place the order to a Walgreens DC, but was rejected by the new SOM system.

336. The new SOM-lite system also allowed Walgreens's stores to transfer controlled substances between stores and did not review these transfers (known as "interstores") within the SOM program, so that these transfers were not factored into SOM analytics. Additionally, stores could also place ad hoc "PDQ" ("pretty darn quick") orders for controlled substances outside of their normal order days and outside of the SOM analysis and limits. Walgreens could even remove a store entirely from SOM review.

337. Further, although the new SOM algorithm identified more than 389 pages of suspicious orders per week as of August 2010, it failed to identify all the orders that Walgreens had marked as suspicious under its "three times" formulas and previously listed on its Suspicious Control Drug Order reports and submitted to the DEA "on a monthly basis." This "discrepancy" prompted an internal email from an employee in Walgreens's Loss Prevention Department, to Walgreens's Vice President, Distribution Centers and Logistics, suggesting that "the new system should be tested further and enhanced to provide broader coverage of controlled substance activity. The same e-mail stated that "we are not equipped to handle the 389+ pages of ADR4

[suspicious order monitoring] data which are compiled nationwide each week," and asked if his department had "a resource available" to assist. An email in response "recall[ed] the old paper report as being inches thick" and an instruction "in 1985 not to review or contact anyone on the data," and inquired, among other things, "[w]ho from your group has been reviewing the data collected for the past twenty-five years?" and "[a]t present is anyone doing any review on what would be considered suspicious quantities that are physically ordered and are releasing to stores?"

338. Starting in 2010, certain orders that exceeded store-based limits imposed by Walgreens's new SOM system were reduced to the store limit and shipped out. These orders were not reported to the DEA as suspicious, nor were they halted for review. The DEA found that Walgreens's policy of reducing and then filling and shipping suspicious orders without reporting them violated the law:

> This policy ignores the fact that the reporting requirement of 21 CFR § 1301.74(b) applies to *orders*, not shipments. A suspicious order placed by a customer pharmacy is made no less suspicious by application of a system designed to reduce or eliminate such orders prior to shipping. Construing the regulation this way defeats the essential purpose of the suspicious order requirement, which, as I stated in *Southwood*, is "to provide investigators in the field with information regarding potential illegal activity in an expeditious manner."

72 FR at 36501.

339. Walgreens's post-2009 SOM system flagged thousands of items per month as being suspicious. Internal Walgreens documents indicate that, in July 2011 alone, as many as 20,699 orders for controlled substances were "marked suspicious" by the new algorithm. However, very few of these orders received any review, and any review performed was nominal at best. Meanwhile, Walgreens failed to adequately staff the program and to train its employees regarding its requirements.

340. Walgreens cited two people as being primarily responsible for performing due diligence on suspicious orders in the 2009-2012 time period under the new SOM system. The first was a representative from the Loss Prevention department who said her department was "not equipped" to handle review and data analysis for the hundreds of pages of reports being compiled nationwide each week. The second was Barbara Martin, who estimated that she spent somewhere between one and three hours a week reviewing suspicious orders, reviewing only between 10 to 100 of the thousands of orders that were deemed suspicious under the new algorithm. Walgreens did not provide Ms. Martin access to information about the area the store was serving, the order history for comparable stores, or any other data beyond the sales and order history for that store. If an order did not "make sense" to her based on those limited resources, she testified that she would call the store or district manager or pharmacy supervisor. She lacked authority to take "direct action" on an order.

341. Walgreens has previously cited to a series of email exchanges with Ms. Martin and her deposition testimony as exemplars of its due diligence procedures under the post-2009 SOM program. In the emails, which date from January 10-11, 2011 and are between Ms. Martin and a Walgreens Distribution Center ("DC") employee, the DC employee notes that "several stores that are ordering huge quantities of 682971 [30 mg oxycodone] on a regular basis," stating, regarding one store, "we have shipped them 3271 bottles [of 30 mg oxycodone] between 12/1/10 and 1/10/11. I don't know how they can even house this many bottles to be honest. How do we go about checking the validity of these orders?" Ms. Martin noted that the store had average weekly sales of 36,200 dosage units, which was equal to 362 bottles per week, stating, "I have no idea where these stores are getting this type of volume. The last pharmacy I was manager at did about 525 rxs/day and we sold about 500 tabs a month (5 bottles)." Ms. Martin

then told the DC employee that she could call the district pharmacy supervisor to see if he "may be able to shed some light on the subject." Despite the fact that questions had been raised about this store ordering volume in January 2011, the very next month, Walgreens filled and shipped orders totaling another 285,800 dosage units of 30 milligram oxycodone to the same pharmacy, which was located in a town of less than 3,000 people.

342. In her deposition, Ms. Martin stated that she never even attempted to determine the size of the community that was receiving these "huge quantities" of oxycodone. She further testified that she was not near that store, did not have access to the store's prescriptions or patient information, and as noted above, couldn't take any "direct action." Approximately 18 months after this email exchange, as a result of DEA action, Walgreens agreed to surrender its DEA registration for this same store that Ms. Martin reviewed as part of her exemplary "due diligence."

343. In the ISO regarding the Distribution Center, the DEA found specifically regarding the orders that were the subject of these email exchanges: "Based on the evidence available to DEA, none of these orders were reported to DEA as suspicious and all appear to have been shipped, without any further due diligence to verify their legitimacy." The DEA further found regarding this purported "due diligence," that Walgreens "failed to conduct any meaningful investigation or analysis to ensure that the massive amounts of commonly abused, highly addictive controlled substances being ordered by these pharmacies were not being diverted into other than legitimate channels." The DEA noted that "[Walgreens] has been unable to provide any files related to any effort to adequately verify the legitimacy of any particular order it shipped to its customer stores."

344. These failures were not limited to the specific Florida pharmacies and distribution center described above; instead, they reflect systemic failures of Walgreens's SOM system that impacted its distribution in the County, as well. Walgreens admits that the SOM systems and procedures at all of its DCs were the same, including those at the facilities that continued shipping opioids into the County. Accordingly, it is not surprising that, in February 2013, the DEA issued similar Subpoenas and Warrant of Inspection on the Perrysburg DC in Ohio to those issued to the Jupiter DC in Florida. Walgreens employees made plans in preparation for the Perrysburg DC being "shut down" by the DEA, like the Jupiter DC. Within weeks of receiving the six subpoenas and warrant, Walgreens decided to "discontinue distribution of controlled substances from the Perrysburg facility" in order to "eliminate any immediate need for further DEA administrative action" regarding the Perrysburg facility.

345. Further, after the DEA began its investigation, Walgreens held meetings with and informed the DEA that it was implementing "new changes" to "enhance" its SOM program. Internal documents reveal that Walgreens improved its SOM program only "in an effort to convince the DEA that the proposed penalty is excessive."

346. Even so, by November 2012, the program still did not halt the orders for due diligence evaluation or report the orders as suspicious. Further, at that time, the program began to automatically reduce orders that violated ceiling thresholds.

347. There also is no evidence that these flagged or cut orders were reported as suspicious to the regulatory authorities.

348. As a result of the DEA investigation, Walgreens formed the Pharmaceutical Integrity ("Rx Integrity") Team in 2012, purportedly to make sure that those types of failures did not continue. However, the group's true role was protecting Walgreens' Distribution Centers and

stores from losing their DEA licenses. The effort was only for show. Walgreens never provided the Rx Integrity group the resources needed to achieve due diligence on the large number of orders identified by Walgreen's SOM program for the company's 5,000 plus stores.

349. In December 2012, the further enhanced SOM system flagged "14,000 items that the stores ordered across the chain that would have to be investigated" before they could be shipped. Walgreens admitted that yet again it did not have sufficient resources to timely review these orders. Walgreens noted that "[t]he DEA would view this as further failures of our internal processes, which could potentially result in additional pharmacies and distribution centers being subjected to regulatory actions and ultimately prohibited from handling controlled substances." At the time these 14,000 orders were flagged Walgreens Rx Integrity departments was comprised of fewer than five people. Even at its height, Rx Integrity had only eleven employees. Instead of sufficiently staffing the SOM program, Walgreens recognized it had the ability to control its due diligence workload by increasing the stores' ceiling levels, and thereby reducing the number of orders that would hit that ceiling and result in a flag.

350. As described below, Walgreens admits to failures in its suspicious order monitoring prior to 2012. Contrasting the previous system, one of Walgreens's Pharmaceutical Integrity Managers in August 2013 explained:

> The Controlled Substances Order Monitoring system now in place sets limits for each item based on the chain average for that item for stores of similar size. If a particular store fills more of this item than normal and needs additional product we would need to document the reason and increase via a CSO Override . . . . The purpose for this is to ensure we have performed adequate review before sending in additional inventory.
>
> The previous system would continue to send additional product to the store without limit or review which made possible the runaway growth of dispensing of products like Oxycodone, that played a roll [sic] in the DEAs investigation of Walgreens.

351. Yet, even in 2013, orders being flagged as suspicious for review before shipment were "a week old" before they made it to the review team, often "ha[d] already been shipped," and were not being reported.

352. Walgreens never properly equipped its distribution operations to properly monitor for, report, and halt suspicious orders, or otherwise effectively prevent diversion. When it become clear Walgreens would need to devote significant resources to achieve compliance, Walgreens chose instead to cease controlled substance distribution all together. Walgreens stated that "while the financial impact of no longer . . . [self distributing] from the Walgreens DCs was taken into consideration, there is a greater risk to the company in fines and loss of licenses if we continue to sell these items in our warehouses."

e. Walgreens Failed to Put in Place Adequate Policies to Guard Against Diversion at the Pharmacy Level.

353. Although Walgreens purported to have in place "Good Faith Dispensing" ("GFD") Policies for many years, it failed to meaningful apply policies and procedures, or to train employees in its retail pharmacies on identifying and reporting potential diversion.

354. Despite knowing that prescribers could contribute to diversion, and having a separate and corresponding duty with respect to filling prescriptions, from at least 2006 through 2012, Walgreens's dispensing policies, which it titled "Good Faith Dispensing", or "GFD", explicitly instructed pharmacists who "receive[] a questionable prescription" or otherwise were "unable to dispense a prescription in good faith" to "contact the prescriber" and, if "confirm[ed]" as "valid" by the prescriber, to then "process the prescription normal." Further, though Walgreens's policies listed a handful of "questionable circumstances," such as "increased frequency of prescriptions for the same or similar controlled drugs by one presciber[,] for large numbers of patients [,] for quantities beyond those normally prescribed," it is unclear what, if

any, resources Walgreens made available to its pharmacists for checking these vague criteria, which, in any event, became meaningless if a prescriber "confirm[ed]" the prescription as "valid," by calling the prescriber. For example, in 2010 when a pharmacy manager expressed concern about significant numbers of opioid prescriptions from pain clinics, and being help responsible for "excessive c2 rx dispensing," her district supervisor instructed her "not [to] refuse script for large quantities" but simply to "call the MD's, document it on the hard copy[,] and that is all that is needed to protect your license." Despite internally recognizing that "a prescriber of a controlled substance prescription [may be] involved in diversion", Walgreens's GFD policies continued to endorse calling the doctor as a greenlight to any "questionable" prescription.

355. In 2012, Walgreens finally removed the "process the prescription as normal" language from its formal GFD policies, admitting that under the law "it is not enough to get confirmation that the prescriber wrote the prescription." However, Walgreens did little to improve its compliance with its duties.

356. Upon information and belief, Walgreens failed to adequately train its pharmacists and pharmacy technicians on how to prevent diversion, including what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when other suspicious circumstances are present. To be clear, this required no inquiry into whether an opioid prescription was the proper treatment for a particular patient; instead, as a registrant, Walgreens was obligated, and failed, to implement policies and procedures at a corporate level to identify and address signs of diversion. *Compare United States v. Hayes*, 595 F.2d 258 (5th Cir. 1979) ("It is also evident that a pharmacist can fulfill his responsibility under s 1306.04 without practicing medicine. The facts of this case show how a pharmacist can know that prescriptions

are issued for no legitimate medical purpose without his needing to know anything about medical science.").

357. Indeed, during the course of a 2009 DEA investigation into Walgreens dispensing noncompliance, Walgreens internally noted that it currently had "no training" for employees dispensing controlled substances. Meanwhile, Walgreens corporate officers turned a blind eye to these abuses. In fact, a Walgreens corporate attorney suggested, in reviewing the legitimacy of prescriptions coming from Florida, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens's attitude that profit outweighed compliance with the law or protecting public health.

358. Ultimately, in 2011, Walgreens and the DEA entered a Memorandum of Agreement regarding all "Walgreens . . . pharmacy locations registered with the DEA to dispense controlled substances," requiring Walgreens to implement significant nationwide controls lacking in its operations. Walgreen Co. was required to create a nationwide "compliance program to detect and prevent diversion of controlled substances *as required by the . . . (CSA) and applicable DEA regulations*." Pursuant to the MOA, the "program shall include procedures to identify the common signs associated with the diversion of controlled substances including but not limited to, doctor-shopping and requests for early refills" as well as "routine and periodic training of all Walgreens walk-in, retail pharmacy employees responsible for dispensing controlled substances on the elements of the compliance program and their responsibilities under the CSA." Further, Walgreens was required to "implement and maintain policies and procedures to ensure that prescriptions for controlled substances are only dispensed to authorized individuals pursuant to federal and state law and regulations."

359. Walgreens would also make more promises in a 2013 Memorandum with the DEA related to failures to that led to the ISOs described above.

360. Even after development and a relaunch of its GFD policy in response to settlements with the DEA, however, Denman Murray, Director of Rx Supply Chain Retail, stated in an MDL deposition that, "traditionally, we've always treated a controlled substance like any other, [a] widget's a widget to the system."[97]

361. More so, after the GFD "relaunch" in April 2014, a Walgreens "RxIntegrity" presentation focused on Walgreens "Market 25," but also assessing "average market" trends, reported that "pharmacists [were] not being too strict with GFD, nor [were] they losing volume."[98]

362. As with distribution, Walgreens failed to allocate appropriate resources to dispensing compliance and supervision. Walgreens has approximately 26,000 pharmacists, each of whom may receive as many as 400-500 prescriptions a day. In 2013, however, Walgreens internally reported that its District Managers and Pharmacy Supervisors were "challenged to get into the stores" and in a 90-day period, more than a thousand stores did not receive a visit from the managers or supervisors. These supervisory personnel were assigned a "high number of stores" and their time was consumed with "people processes, business planning, market and district meetings," such that supervision in store was being handled informally by "community leaders" who have "limited formal authority."

363. A Walgreens internal audit performed after the 2013 DEA settlement confirms that Walgreens's supervision and compliance failures continue. Among other failings, the audit team noted no formal monitoring program existed to confirm that pharmacies across the chain

[97] *See* D. Murray Dep., 31:20-22 (Jan. 15, 2019).
[98] Market 25 consisted of Indiana, Kentucky, and West Virginia. Similar results reported for Market 3, Florida.

are complying with controlled substance documentation and retention requirements, no monitoring outside of the deficient "store walk program" existed to monitor target drug good faith dispensing requirements and no corporate reporting was being generated, and employees were failing to timely complete Good Faith Dispensing training, such that, at the time of the audit, over 35,000 employees had not completed their required training for that year. Management's response largely was to seek to incorporate additional compliance measures into the store walk procedure.[99] However, documents from 2016 regarding monthly store compliance walks indicate that during the monthly "Compliance Walks" to "verify compliance . . . [with] regulatory requirements in . . . pharmacy areas," substantially no dispensing compliance supervision occurred, outside of ensuring the pharmacy was verifying the patient's address on five sample prescription fills.

364. Unsurprisingly, compliance with GFD and TD GFD has been poor. For example, in 2014 Walgreens discovered a pharmacist who failed to follow GFD for five to six months without being discovered by supervisors. In 2014, RX Integrity noted dozens of stores dispensing opioids without performing the required checks. In certain cases, the pharmacists were unaware of the GFD procedures or had been told by supervisors to disregard them.

365. In 2015, Walgreens performed a "business continuity" audit of a random sample of approximately 2,400 pharmacies to determine whether Walgreens "compliant with the policies/procedures put in place" regarding dispensing pursuant to Walgreens's agreement with the DEA. In Walgreens's own words, "Results were unfavorable." Fewer than 60% of stores were complying with TD GFD with respect to filled prescriptions, 1,160 stores did not have a single refused prescription, and an additional 1,182 stores had refused fewer than 25

[99] *Id*.

prescriptions total in a nine month period. Only 63 out of 2,400 pharmacies had refused 26 or more prescriptions during that same nine months in 2015.

f. Walgreens Assumed Greater Responsibility for Controlling Against Diversion By Discouraging Outside Vendors from Exercising Their Own Oversight.

366. The "Big Three" wholesalers, Cardinal, McKesson, and AmerisourceBergen, gave deferential treatment to chain pharmacies, such as Defendants. An internal Cardinal document for example, stresses that "certain chain pharmacies refuse to allow any sort of administrative inspection by Cardinal or to make certifications" and that large, national chains can "take their billions upon billions of dollars in business to any wholesaler in the country."

367. Thus, for example, in 2008, Cardinal Health prepared talking points for a NACDS Conference about its planned retail chain SOM program, making it clear that the program would "minimize the disruption" to retail chains and that they would "work together" with the pharmacies " to ensure that our Suspicious Order Monitoring program for retail chains does not interrupt" business. Cardinal also provided warnings to chain pharmacies, including Walgreens, that they were approaching thresholds so that the chains could avoid triggering SOM reporting and adjust ordering patterns by, for example, delaying orders or, more often, obtaining a threshold increase. Such "early warnings" were so helpful to Walgreens that as of 2012 Walgreens adopted the concept for its own SOM system for self-distribution, noting internally that by "flagging the stores at 75%," it could "avoid cutting/reducing orders and subsequently not have to report a SOM to the DEA."

368. Preferential treatment of Walgreens ultimately was not enough for Cardinal to keep Walgreens's business, however. In 2013, Walgreens entered a ten-year agreement with

AmerisourceBergen Drug Company. The shift to AmerisourceBergen as its exclusive supplier prompted Cardinal to complain: "we bailed you guys out when you had your [DEA] issues."

369. By 2017, Walgreens accounted for 30% of AmerisourceBergen's revenue.[100] AmerisourceBergen was similarly deferential, allowing Walgreens to "police their own orders and block any order to [AmerisourceBergen ("ABC")] that would exceed ABC's threshold thus triggering a suspicious order being sent to DEA from ABC. Additionally, when AmerisourceBergen received orders from Walgreens "outside the expected usage," Walgreens and AmerisourceBergen met to discuss adjusting thresholds or using "soft blocking." Contrary to DEA guidance and its own stated policy, AmerisourceBergen also shared the threshold limits set by its "order monitoring program" with Walgreens, and also provided Walgreens with weekly SOM statistics. AmerisourceBergen generally would not take action on Walgreens orders that exceeded its thresholds without first talking to Walgreens.[101]

370. Walgreens also owns 26% of AmerisourceBergen's stock. In 2018, after a coalition of AmerisourceBergen shareholders sought greater transparency from its Board related to the "financial and reputational risks associated with the opioid crisis," Walgreens, together with other insiders, reportedly leveraged this position to defeat the proposal, which enjoyed majority support among the independent shareholders.

g. Walgreens Failed to Maintain Effective Controls Against Diversion in the County.

371. As both a distributor and a dispenser, Walgreens ignored red flags of diversion in Pennsylvania and the County.

[100] As a part of its distribution agreement, Walgreens gained purchase rights to AmerisourceBergen equity, allowing it to further participate in the prescription opioid shipment boom in America. Walgreens subsequently exercised these purchase rights, ultimately owning approximately 26% of AmerisourceBergen. As part of the transaction, Walgreens has the ability to nominate up to two members of the Board of Directors of AmerisourceBergen. Currently, Walgreen's Co-Chief Operating Officer sits on the AmerisourceBergen Board of Directors.

[101] Rite Aid received similar accommodations from McKesson, which forwarded it dialed monitoring reports so that Rite Aid could "let [McKesson know] if it needed to make any adjustments to its thresholds." MCKMDL00646634.

372. In the County, as a distributor, Walgreens self-distributed more than 19 million dosage units of oxycodone, hydrocodone, oxymorphone and hydromorphone from 2006 to 2014 per available ARCOS data.

373. Walgreens violated the standard of care for a distributor by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

374. The volume of opioids Walgreens shipped into, and dispensed from locations in, the County was so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

375. Instead, Walgreens funneled far more opioids into the County than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to distributors such as Walgreens (especially with its pharmacy dispensing data), would have alerted Walgreens to potential diversion of opioids.

376. Meanwhile, a Walgreens pharmacy located at 112 W. Stueben Street, Crafton, PA 15205, dispensed over 2 million oxycodone and hydrocodone pain pills between 2006 and 2014.

377. In addition, Walgreens also distributed and dispensed substantial quantities of prescription opioids in other states, and these drugs were diverted from these other states to Pennsylvania and the County. Walgreens failed to take meaningful action to stop this diversion despite its knowledge of it, and it contributed substantially to the opioid epidemic in Pennsylvania and the County.

378. Walgreens also developed and maintained highly advanced data collection and analytical systems. These sophisticated software systems monitor the inventory and ordering needs of customers in real-time and depicted the exact amounts of pills, pill type, and anticipated order threshold for its own stores.

379. Through this proprietary data, Walgreens had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in Pennsylvania, including in the County. It used this data to evaluate its own sales activities and workforce. Walgreens also was in possession of extensive data regarding individual doctors' prescribing and dispensing to its customers, the percentage of a prescriber's prescriptions that were controlled substances, individual prescription activity across all Walgreens stores, and the percentages of prescriptions purchased in cash. Such data are a valuable resource that Walgreens could have used to help stop diversion, but it did not.

380. Upon information and belief, Walgreens, by virtue of its data analytics, was actually aware of indicia of diversion, such as (1) individuals traveling long distances to fill prescriptions; (2) prescriptions for drug "cocktails," known for their abuse potential, such as oxycodone and Xanax; (3) individuals who arrived together with identical or nearly identical prescriptions; (4) high percentage of cash purchases; and (5) doctors prescribing outside the scope of their usual practice or geographic area. However, Walgreens ignored these obvious red flags.

381. Upon information and belief, based on other enforcement actions against the company, Walgreens also failed to adequately use data available to it to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts or

doses of opioids, or to adequately use data available to it to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

382. Upon information and belief, Walgreens failed to adequately analyze and address its opioid sales relative to: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

383. Upon information and belief, based on other enforcement actions against the company, Walgreens also failed to conduct adequately analyze and address its opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if it conducted such reviews, it failed to take any meaningful action as a result.

384. Discovery will reveal that Walgreens knew or should have known that its pharmacies in the County, and the surrounding area were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse.

385. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products

sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. Walgreens had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

386. Walgreens admits its role in the opioid epidemic, stating it has the "ability—and [] critical responsibility—to fight the opioid crisis" as the "nation's largest pharmacy chain" in a time when "[a]ddiction to prescription painkillers, heroin, and other opioids has surged, with opioid overdoses quadrupling in this decade" and "drug overdose deaths—the majority from prescription and illicit opioids" resulting in "more fatalities than from motor vehicle crashes and gun homicides combined." Walgreens also admits the "opioid crisis" is caused by "misuse, abuse and addiction" that result from the "flow of opioids that fuel the epidemic."

3. Rite Aid

a. Rite Aid Failed to Maintain Effective Controls Against Diversion at the Wholesale Level.

387. Rite Aid distributed Schedule III ("CIIIs") controlled substances (*e.g.*, hydrocodone combination products) to its own Rite Aid stores until late 2014.

388. Rite Aid's controlled substance distribution process was fairly simple. Rite Aid used a computerized "auto-replenishment system" (ARS) through which individual Rite Aid pharmacies would generate orders that were sent to the distribution center (DC). If the ARS generated an order that was above Rite Aid's universal 5,000 dosage-unit (DU) threshold, the DC employees filling the order were supposed to manually recognize that the order was above threshold. If they did observe an order over threshold, the only "review" of the order was an attempt to call the pharmacy that placed the order to verify the order amount was correct (*i.e.*, that it was not a "fat-finger" error). If the pharmacy confirmed that the above-threshold order

amount was correct, or if the DC simply could not contact the pharmacy, the order was cut to the threshold and shipped. All the above-threshold orders were supposed to be maintained on a handwritten log containing only basic information about the order.

389. After the orders had shipped, Rite Aid monitored its inventory through its Navicase/Naviscript system. The Rite Aid Asset Protection Department used "key performance indicators" (KPIs) to analyze data about ordering from the Rite Aid stores to identify diversion through theft. Yet, as numerous Rite Aid witnesses have testified, Rite Aid did not use the Navicase/Naviscript system to identify—much less report—suspicious orders. Furthermore, assuming that the Navicase/Naviscript could identify suspicious orders, the Navicase/Naviscript data analysis only took place *after* shipment. Moreover, Rite Aid's Rule 30(b)(6) representative in the Opioid MDL, Janet Getzey Hart, testified that the "asset protection KPIs were utilized to review orders and then lead to diversion cases if there were some issues with it," but "*they were not used to report suspicious orders*." (emphasis added).

390. Rite Aid maintained a small, inadequate list of suspicious prescribers but did not make any efforts to identify or report any suspicious orders from stores Rite Aid knew were dispensing prescriptions for those suspicious prescribers. Further, given that orders would have already shipped, Rite Aid did not incorporate "suspicious prescriber" information that it may have collected in determining whether an order from any location was suspicious.

391. Ultimately, Rite Aid's distribution system made it nearly impossible for any order to be identified, much less reported, as suspicious. As a result of the company's policies and procedures, Rite Aid did not—and indeed, could not—identify what was unusual because all Rite Aid DCs had a static, blanket threshold for all Rite Aid stores above which Rite Aid would cut the order. The threshold, which never changed, was set at of 5,000 DUs, per national drug

code (NDC), per order (although Rite Aid does not know why it was set at 5,000 DUs). Rite Aid stores typically ordered once per week, but some stores ordered twice per week and others ordered every two weeks. That means that at its lowest, the Rite Aid threshold was 10,000 DUs per month, per store and at its highest it was 40,000 DUs per month, per store.

392. Despite the extremely high threshold amount, Rite Aid did not have a procedure that required anyone to report an order that came in over the universal threshold as suspicious. Instead, DC employees would "cut" the order down to the threshold and then ship the order. Rite Aid did no due diligence on orders that came in over the blanket threshold. An overwhelming number of the "cut" orders, if not all, were not reported to the DEA until after the fact, if at all.

393. Rite Aid also had little to no records about past order history to determine if an order was suspicious. The Perryman DC kept what was called a "Threshold Log," which contained in hard copy only basic information about orders that exceed the threshold: date of order, store number, item number, item description, quantity ordered, allowable quantity, and the reason for the allowable quantity. But, any use of the log to potentially identify suspicious orders was only done sporadically and after the above-threshold orders were cut and shipped.

394. Additionally, Rite Aid placed the responsibility to identify orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency on employees whom the DEA coordinator at the Rite Aid distribution center, testified were not able to actually do so.

395. Recognizing its failure to have a system, Rite Aid did begin to develop a suspicious order monitoring system for the first time in 2013. In documenting such efforts, Rite Aid stated as follows:

> *The purpose of this project is to develop effective controls against the diversion of controlled substances* and conduct adequate due diligence to ensure that

> controlled substances distributed from the Distribution Centers are for legitimate patient needs. Rite Aid must ensure compliance with 21 U.S.C. 823 and/or C.F.R. 1307.74(b) to detect and report suspicious orders of controlled substances through the Distribution Centers.

396. In the end, however, Rite Aid never adopted the new SOMS because they stopped distributing controlled substances before this system could be implemented.

b. Rite Aid Conspired with McKesson to Avoid Scrutiny of Outside Vendor Orders and Adjust or Avoid Thresholds.

397. Rite Aid conspired with McKesson to avoid suspicious order reporting. McKesson was Rite Aid's exclusive wholesaler for Schedule II controlled substances, including opioids, during the relevant time period. Rite Aid also ordered CIIIs from McKesson during the relevant time period. Rite Aid ordered CIIIs from McKesson not only when it stopped self-distributing in late 2014, but McKesson also supplemented Rite Aid stores' supply of Schedule III controlled substances during the period when Rite Aid self-distributed controlled substances.

398. McKesson provided Rite Aid with notification of stores hitting McKesson's thresholds and regularly granted threshold increases without any due diligence. For example, when a McKesson report revealed a number of Rite Aid stores were at 90% of their threshold and about to be flagged, McKesson offered to—and did—increase the thresholds for *all* Rite Aid locations by 50%. McKesson also forwarded daily monitoring reports to Rite Aid so that Rite Aid could "let [McKesson] know" if McKesson "need[ed] to make any adjustments to current thresholds."

399. On one occasion, Rite Aid noted that over 10% of its stores came close to being blocked, and McKesson simply asked Rite Aid to what percentage it wanted the thresholds increased. McKesson also prompted Rite Aid to delay its orders until the next month in order to avoid hitting monthly thresholds when they were getting close.

400. Rite Aid allowed its stores to order from McKesson without any restriction and failed to take those orders into account in Rite Aid's self-distribution SOM system, negating the effectiveness of Rite Aid's internal controls.

c. Rite Aid Failed to Guard Against Diversion in Distributing to the County.

401. In the County, Rite Aid violated the standard of care for a distributor by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

402. Rite Aid is the largest pharmacy chain in Pennsylvania and has a significant number of its stores in the County, with approximately 65 chain pharmacy locations. In the County, as a distributor, Rite Aid self-distributed more than 46 million dosage units of oxycodone, hydrocodone, oxymorphone and hydromorphone from 2006 to 2014 from 49 pharmacies in the County. In addition, Eckerd Corporation (which Rite Aid bought in 2007) self-distributed another 2.8 million.

403. The volume of opioids Rite Aid shipped into, and dispensed from locations in, the County is so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

404. Rite Aid funneled far more opioids into Pennsylvania and the County than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to distributors such as Rite Aid (especially with its pharmacy dispensing data), would have alerted Rite Aid to potential diversion of opioids. Yet, Rite Aid admits that it *never* identified any suspicious orders before or after shipment, much less reported any suspicious orders to the DEA.

405. Upon information and belief, Rite Aid by virtue of the data available to it, was actually aware of indicia of diversion, such as (1) individuals traveling long distances to fill prescriptions; (2) prescriptions for drug "cocktails," known for their abuse potential, such as oxycodone and Xanax; (3) individuals who arrived together with identical or nearly identical prescriptions; (4) high percentage of cash purchases; and (5) doctors prescribing outside the scope of their usual practice or geographic area. However, Rite Aid ignored these obvious red flags.

406. Rite Aid, therefore, was aware of the suspicious orders that flowed from its distribution facilities. Rite Aid refused to identify, investigate, and report suspicious orders despite its actual knowledge of drug diversion. Rather, Rite Aid failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into the County.

407. Upon information and belief, Rite Aid failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

408. Rite Aid was, or should have been, fully aware that the opioids being distributed and dispensed by it were likely to be diverted; yet, it did not take meaningful action to investigate or to ensure that it was complying with its duties and obligations with regard to controlled substances, including its responsibility to report suspicious orders and not to ship such orders unless and until due diligence allayed the suspicion.

409. Given Rite Aid retail pharmacy operations, in addition to its role as a wholesale distributor, Rite Aid knew or reasonably should have known about the disproportionate flow of opioids into Pennsylvania and the County and the operation of "pill mills" that generated opioid

prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, illicit supply and diversion.

d. Rite Aid Failed to Guard Against Diversion in Dispensing to the County.

410. Rite Aid pharmacies routinely have dispensed opioids in violation of State and Federal laws and regulations. Such conduct was a result of Rite Aid's lack of robust policies and procedures regarding dispensing controlled substances as well as Rite Aid's focus on profitability over its legal obligations and public safety.

411. Rite Aid's dispensing policies and procedures used at all its Rite Aid pharmacies nationally were deficient in many ways. A few examples are illustrative.

412. Rite Aid implemented a policy for dispensing "high-alert" controlled substances for the first time in 2013. The policy was a simple checklist consisting of six steps: (1) receive the prescription; (2) validate the prescription; (3) validate the prescriber; (4) validate the patient; (5) decide to dispense or not to dispense; and (6) report any suspicious activity. Yet Rite Aid provided little to no guidance on how to perform the vague tasks and the policy was little more than words on a page. In another example, Rite Aid only started to alert its pharmacists of attempts to get early refills—a red flag of diversion—in 2016.

413. Rite Aid also did nothing to ensure that even its pro forma policies were being followed. Rite Aid did not audit its pharmacies for compliance with its own controlled substances dispensing policies or compliance with the CSA's requirements regarding legal dispensing.

414. As a sophisticated, national chain pharmacy Rite Aid had the ability to analyze data relating to drug utilization and prescribing patterns across multiple retail stores in diverse geographic locations. Its own data would have allowed Rite Aid to observe patterns or instances

of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.[102]

415. Yet, Rite Aid only started tracking "High Alert data" in September, 2015 at the corporate level. Even then, it did not use the data to effectively comply with its legal onligations to prevent diverison and ensure only legal prescriptions were being filled at its pharmcieis. For example, Rite Aid provided no visibitlity into the data it collected to pharmacists thereby depriving them of an invaluable resource when evaluating presscriptions.

416. In contrast to its lack of robust policies to ensure only prescriptions issued for a legitimate medical purpose were dispensed, Rite Aid had numerous and detailed policies regarding metrics to ensure its profitability. These policies ensured that Rite Aid pharmacists did not have the time, resources, or support to adequately discharge not only their legal duties as pharmacists, but also their alleged duties under Rite Aid's own policies and procedures.

417. For example, in 2011, Rite Aid adopted a policy whereby it promised to fill prescriptions in 15 minutes or less.[103] If a fill took more than 15 minutes, the patient would get a $5 gift card. Rite Aid touted the program as something consumers wanted, but many others recognized the danger such a program was to patients and the practice of pharmacy. Numerous State Boards of Pharmacy objected to the program. As the chair of the Illinois State Board of Pharmacy said: "This is 180 degrees away from everything we are trying to do in moving the pharmacy profession toward being patient information-focused rather than product-focused. And it's counter to our many efforts to improve patient safety."

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[102] *See, e.g., Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,315 (Dep't of Justice Oct. 12, 2012) (decision and order) (DEA expert witness examined dispensing records alone to identify inappropriately dispensed medications).

[103] Drug Topics, *Rite Aid offers 15-minute Rx guarantee*, May 15, 2011, https://www.drugtopics.com/chains-business/rite-aid-offers-15-minute-rx-guarantee.

418. Despite eventually doing away with the 15 minute or less promise, Rite Aid continued to carefully track its pharmacists' speed filling prescriptions, thereby ensuring that the pharmacists were not able to exercise their corresponding responsibility under the law. Rite Aid pharmacies routinely filled prescriptions at a pace of multiple prescriptions per minute.

419. Rite Aid's compensation policies also blocked pharmacists from preventing illegitimate prescriptions from being dispensed. Rite Aid's compensation policies provided bonuses that depended on the number of prescriptions—including opioids—dispensed from Rite Aid pharmacies. Even when Rite Aid eventually, ostensibly removed controlled substances from its bonus calculations, Rite Aid continued to evaluate its pharmacies on their profitability. Indeed, pharmacists' jobs depended on the profitability of the pharmacy; if the pharmacy was not profitable enough staff would be laid off or it would be closed entirely. A pharmacy's profitability is heavily dependent on its prescription volume, including controlled substances. So even if removed from bonus calculations, the amount of prescriptions dispensed by a pharmacy and corresponding effect on a pharmacy's bottom line still acted as a powerful incentive for pharmacies to focus on dispensing *all* prescriptions, instead of only legal ones. Rite Aid did nothing to counter this perverse incentive and, in fact, encouraged profit over patients.

420. The problem of illegal dispensing caused by Rite Aid's focus on quickly filling prescriptions and increasing the number of prescriptions dispensed was also exacerbated by Rite Aid's lack of pharmacy staffing. Often, pharmacists were left as the only pharmacist at a location for entire shifts. This greatly cut into the ability of the pharmacist to evaluate each prescription carefully and in accordance with the law.

421. Rite Aid also evaluated its pharmacies on customer service; perversely though, Rite Aid considered a "service failure" to include refusing to fill prescriptions despite the pharmacy's obligation to do so under the law in certain instances.

e. Rite Aid Failed to Maintain Effective Controls Against Diversion in the County.

422. As a vertically integrated distributor and dispenser of prescription opioids, Rite Aid knew or should have known that an excessive volume of pills was being sold into the County.

423. The sheer volume of prescription opioids distributed to and dispensed by Rite Aid pharmacies in and around the County is indicative of potential diversion and required appropriate due diligence.

424. One Rite Aid store located at 2300 Jane Street, Pittsburgh, PA 15203, dispensed more than 2.6 million oxycodone and hydrocodone pain pills between 2006 and 2014, per available ARCOS data.

425. Discovery will reveal that Rite Aid knew or should have known that its pharmacies in the County, and the surrounding area, were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion

and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. Rite Aid had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

426. Because of its vertically integrated structure, Rite Aid has access to complete information regarding red flags of diversion across its pharmacies in and around the County, but Rite Aid failed to utilize this information to effectively prevent diversion.

4. Walmart

a. Walmart Failed to Maintain Effective Controls Against Diversion.

427. Walmart is the largest private employer in the United States. It employs more than 1.5 million people. But for years, Walmart chose not to assign a single employee to design or operate a system to detect suspicious orders of controlled substances. Walmart chose to do nothing while hundreds of thousands of people were dying, and waited until 2014 to begin to take meaningful action. By that time, it was too late.

i. Walmart Lacked a Suspicious Order Monitoring System for Most of the Relevant Time Period.

428. Walmart "self-distributed" opioids to its retail stores. Specifically, Walmart operated registered distribution centers to supply its own pharmacies with controlled substances from the early 2000s until 2018 when it ceased self-distributing controlled substances. Walmart's conduct is particularly troubling given that it acted both as a self-distributing and dispensing pharmacy for such a long period of time.

429. Prior to 2011, Walmart had not designed any formal system to identify suspicious orders of controlled substances and, therefore, utterly failed to meet its statutory obligations.

430. Walmart has claimed that its hourly employees and associates—who were also responsible for filling orders at Walmart Distribution Centers—monitored the orders they were filling for unusual size, pattern, and frequency. Typically, this "review" involved between 700 and 800 orders a day.[104] Walmart has also claimed that these hourly associates were instructed to alert a supervisor if an order appeared unusual based on their experience and memory.[105]

431. Upon information and belief, Walmart can produce no written evidence of any such instructions to Walmart associates, no evidence of any training that would be required to implement such a procedure, or anyone actually being alerted about an unusual order or performing any follow up inquiry.

432. Walmart failed to provide any guidance to the associates as to what constitutes a "suspicious" order. Instead, Walmart emphasized its associates' subjective judgment based on their "knowledge and experience" as distribution center employees. There is no evidence that any Walmart employee ever flagged an order as suspicious prior to 2011.

433. Walmart purportedly implemented a "monitoring program" that would identify suspicious orders of controlled substances in 2011. This system purportedly was in place until 2015.

434. Walmart's monitoring program was insufficient to identify suspicious orders of controlled substances. The program flagged only very large orders of controlled substances. Specifically, it flagged weekly orders for controlled substances of 50 bottles (5000 dosage units)

[104] *See* Abernathy Dep. at 40:13-21 (Nov. 15, 2018).

[105] *See id.* at 15-18 ("[I]f a quantity stood out that seemed to be not normal *or what they perceived as normal*, they would report that to one of the managers, and we would call the store and ask about, 'Is this order correct?'" (emphasis added)).

or more and orders or more than 20 bottles (2000 dosage units) that were 30% higher than a rolling four-week average for that item. Orders under 2000 units per week were never flagged, meaning that a pharmacy could order 8000 units per month without ever being flagged. Moreover, that meant that even if an order was more than 30% greater than the four-week average, it could not draw an alert unless it also was more than 20 bottles.

435. Under this system, an alert did not mean Walmart would report the order or halt it pending necessary due diligence. To the contrary, upon information and belief, Walmart *never* reported an order flagged by its monitoring program to the DEA as suspicious. In addition, rather than halting the order, Walmart simply cut the order to the amount of the 50 bottles threshold and shipped it. Walmart never reported cut orders to the DEA. Although information regarding flagged orders was available and sent daily to Walmart's headquarters in Arkansas (the "Home Office"), no one from the Home Office ever reviewed or took *any action* regarding flagged orders.

436. This practice continued until mid-2012, when Walmart implemented "hard limits" on opioid orders. Under this approach, weekly orders of Oxycodone 30mg ("Oxy 30") were automatically reduced to 20 bottles. Still, Walmart failed to report the orders to the DEA.

437. During this time period, Walmart also monitored weekly orders of other controlled substances in quantities of more than 20 bottles. Specifically, an "Over 20 Report" was provided to the Home Office in the morning and if nothing was done by mid-afternoon, the orders were filled and shipped. Upon information and belief, there is no evidence of any order in fact being held or reviewed pursuant to this practice.

438. Further, cutting the order did not mean that the Walmart pharmacy would not receive the full supply. Walmart pharmacies also purchased opioids from outside suppliers,

including McKesson and AmerisourceBergen. Pharmacies could place another order with these outside vendors to make up the difference, or in some cases, have orders fulfilled by both Walmart and a third party distributor at the same time. Thus, even though Walmart had the ability to monitor such orders, it chose not to, which allowed its pharmacies to surpass its already high thresholds by simply ordering drugs from a third party.

439. Walmart knew that its monitoring program was insufficient to fulfill its obligations to prevent diversion. For example, in 2013, Walmart acknowledged in an internal presentation that it had not yet designed a compliant system for suspicious order identification, monitoring, and reporting. It also stated that it was "TBD" when Walmart would develop such a system. In June 2014, Walmart again acknowledged that it lacked a compliant monitoring program. Moreover, Walmart acknowledged in 2014 that it had "no process in place" to comply with government regulations and that this created the "severe" risk of "financial or reputational impact to the company."

440. It was not until late 2014 that Walmart's written policies and procedures required orders of interest to be held and investigated.

441. In 2015, Walmart enhanced its suspicious order monitoring policy by implementing store-specific thresholds, but this "enhanced" monitoring program failed to remedy the prior deficiencies.

442. Upon information and belief, it based these thresholds on the standard deviation of a specific pharmacy's order history for each controlled substance. The thresholds also included minimum amounts, below which no orders were flagged under any circumstance, regardless of pattern or frequency.

443. Walmart's corporate designee conceded that thresholds were set for business purposes, not for the purpose of "main[taining] of effective controls against diversion . . . into other than legitimate . . . channels . . . ." Further, for almost all Walmart pharmacies, this minimum was set at 2,000 dosage units per week (or 8,000 dosage units per month). Accordingly, even when Walmart implemented a store specific policy that took into consideration a pharmacy's order history, the program was still woefully deficient because it did not account for changes in ordering patterns. A pharmacy could, for example, go from ordering 10 dosage units of Oxycodone 10 mg per month to 7,999 per month without any order being flagged or reviewed.

b. Walmart Failed to Guard Against Diversion in Distributing into the County.

444. According to data from the ARCOS database, between 2006 and 2014, Walmart distributed more than 8.2 million dosage units of oxycodone, hydrocodone, oxymorphone and hydromorphone to Walmart pharmacies in the County. The volume of opioids Walmart shipped into the County—and then sold from just 7 Walmart pharmacy locations in the County—was so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

445. Instead, Walmart funneled far more opioids into Pennsylvania and the County than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to distributors such as Walmart (especially with its pharmacy dispensing data), would have alerted Walmart to potential diversion of opioids.

446. In addition, Walmart, upon information and belief, also distributed and dispensed substantial quantities of prescription opioids in other states, and these drugs were diverted from

these other states to Pennsylvania and the County. Walgreens failed to take meaningful action to stop this diversion despite its knowledge of it, and it contributed substantially to the opioid epidemic in Pennsylvania and the County.

447. In the County, Walmart violated the standard of care for a distributor by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

448. For years, per capita opioid prescriptions in the County far exceeded the national average and increased in ways that should have alerted Walmart to potential diversion. As a vertically integrated, national retail pharmacy chain, Walmart had the ability to detect diversion in ways third-party wholesale distributors could not by examining the dispensing data from their own retail pharmacy locations.

449. Given the volume and pattern of opioids distributed in Pennsylvania and the County, Walmart was, or should have been aware that opioids were being oversupplied into the state and should have detected, reported, and rejected suspicious orders. Yet, the information available shows it did not.

450. Upon information and belief, Walmart by virtue of the data available to it, was actually aware of indicia of diversion, such as (1) individuals traveling long distances to fill prescriptions; (2) prescriptions for drug "cocktails," known for their abuse potential, such as oxycodone and Xanax; (3) individuals who arrived together with identical or nearly identical prescriptions; (4) high percentage of cash purchases; and (5) doctors prescribing outside the scope of their usual practice or geographic area. However, Walmart ignored these obvious red flags.

451. Walmart, therefore, was aware of the suspicious orders that flowed from its distribution facilities. Walmart refused to identify, investigate, and report suspicious orders despite its actual knowledge of drug diversion. Rather, Walmart failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into Pennsylvania and the County.

452. Upon information and belief, Walmart failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

453. Walmart was, or should have been, fully aware that the opioids being distributed and dispensed by it were likely to be diverted; yet, it did not take meaningful action to investigate or to ensure that it was complying with its duties and obligations with regard to controlled substances, including its responsibility to report suspicious orders and not to ship such orders unless and until due diligence allayed the suspicion.

454. Given Walmart retail pharmacy operations, in addition to its role as a wholesale distributor, Walmart knew or reasonably should have known about the disproportionate flow of opioids into Pennsylvania and the County and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, illicit supply and diversion.

c. Walmart Failed to Maintain Effective Controls Against Diversion from Its County Pharmacies.

455. Walmart, throughout the relevant time period, owned and operated pharmacies throughout the United States, including pharmacies in the County. Through its wholly owned or controlled subsidiary companies, Walmart operates over 4,500 retail pharmacies across the

United States, a mail-order pharmacy, a specialty pharmacy, and six pharmacy distribution centers that distribute to other Walmart entities.

456. Walmart set policies for its pharmacies at the corporate level.[106] Walmart also presented, through nationwide advertising, a public image of the safety and excellence of all the pharmacists the company hired. In a recruitment video for pharmacists on Walmart's YouTube channel, the company shows Walmart pharmacists speaking about working at the company: "the safety and the excellence we carry to our patients is phenomenal," adding that "the culture that our company has [is] respect for the individual, service, and excellence, and, of course, we always have integrity."[107] The commercial also states that Walmart's pharmacists "strive for excellence" and are "passionate about providing quality healthcare."[108]

457. Walmart pharmacies in and around the County received distributions of prescriptions from Walmart's distribution centers and from other wholesale distributors, which enabled these pharmacies to have the same orders filled by both Walmart and a third-party distributor.

458. The volume of prescription opioids dispensed by Walmart pharmacies in and around the County is indicative of potential diversion and required appropriate due diligence.

459. One Walmart store located at 220 Washington Pike, Carnegie, PA 15106, distributed over 1.5 million dosage units of oxycodone and hydrocodone during that time.

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[106] *See, e.g.*, WMT_IN_AG_00000066 ("Walmart has adopted a uniform national policy that is designed to meet or exceed the federal rules and the laws of all states.").

[107] Walmart, *Your Career as a Walmart Pharmacist* (Sept. 25, 2014), available at https://www.youtube.com/watch?v=9VD12JXOzfs.

[108] *Id*.

460. As a vertically integrated distributor and dispenser of prescription opioids, Walmart had unique insight into all distribution and dispensing level data, and knew or should have known that it was dispensing an excessive volume of pills into and around the County.

461. Discovery will reveal that Walmart knew or should have known that its pharmacies in the County, and the surrounding area, were: (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines or prescription "cocktails"; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. Walmart had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

462. Walmart had complete access to all prescription opioid distribution data and dispensing data related to Walmart pharmacies in and around the County. Walmart had complete access to information revealing the doctors who prescribed the opioids dispensed in Walmart pharmacies in and around the County and the customers who filled or sought to fill prescriptions

for opioids in Walmart pharmacies in and around the County. Walmart had complete access to information revealing the geographic location of out-of-state doctors whose prescriptions for opioids were being filled by Walmart pharmacies in and around the County.

463. Despite all of this information, Walmart failed to put in place effective policies and procedures for the dispensing of prescription opioids and failed to provide adequate guidance to its pharmacists on dispensing opioids. Moreover, Walmart's pressure on pharmacists to fill more prescriptions quickly was at odds with a culture and practice of compliance. Incentive awards were tied to the number of prescriptions a pharmacy filled and profit that the pharmacy generated. Upon information and belief, controlled substances were included in Walmart's pharmacy incentive program for most of the relevant time period. In addition, pharmacists were under constant pressure to increase the number of prescriptions they filled, and to increase the overall percentage of pharmacy sales. As a result, upon information and belief, because of Walmart's drive for speed, pharmacists often did not have enough time to sufficiently review a prescription and conduct the appropriate due diligence.

464. Even when Walmart pharmacists suspected diversion based on an individual prescriber's prescribing practices, for years, Walmart did not allow its pharmacists to request blanket refusals to fill. Walmart, however, had always had the ability to do so. Finally, in 2017, Walmart implemented a policy by which individual pharmacists could request such blanket refusals, which would permit the pharmacist to refuse to fill future prescriptions from that prescriber without evaluating each prescription individually. In addition, Walmart also always had the ability to "centrally block" problematic prescribers across all Walmart and Sam's Club pharmacies, but did not establish a procedure to do so until 2017. In the "Practice Compliance"

document describing this policy, Walmart admitted that it may, "in certain situations," have information about prescribing practices that is not available to individual pharmacists:

> While pharmacists are in the best position to determine whether individual prescriptions are appropriate, *additional information may be obtained that is not available to our pharmacists*. Therefore, in certain situations, a prescriber may be identified whose prescribing practices raise concerns about prescribing controlled substances for legitimate medical purposes. After a thorough review, these additional insights may lead Walmart to place a block in Connexus on controlled substance prescriptions from these prescribers.

465. Moreover, Walmart's pressure on pharmacists to fill prescriptions quickly was at odds with a culture and practice of compliance. Incentive awards were tied to the number of prescriptions a pharmacy filled and profit that the pharmacy generated. Upon information and belief, controlled substances were included in Walmart's pharmacy incentive program for most of the relevant time period. In addition, pharmacists were under constant pressure to increase the number of prescriptions they filled, and to increase the overall percentage of pharmacy sales. As a result, upon information and belief, because of Walmart's drive for speed, pharmacists often did not have enough time to sufficiently review a prescription and conduct the appropriate due diligence.

5. Giant Eagle

a. Giant Eagle Failed to Maintain Effective Controls Against Diversion.

466. Although Giant Eagle had access to significant information about red flags due to its vertical integration with its stores, both failed to use available information from indicating red flags in order to more effectively prevent diversion.

467. For nearly the entire five-year period that it distributed hydrocodone combination products ("HCPs"), Giant Eagle had no written suspicious order monitoring (SOM) policy.

468. Rather, by Giant Eagle's own admission, its earliest written SOM policy is dated August 1, 2014. Giant Eagle stopped distributing controlled substances at issue in October 2014. HBC then operated as a distributor of controlled substances without a written SOM policy for all but two (2) months of its time distributing controlled substances.

469. Giant Eagle's August 2014 written SOM policy consisted of four short bullet points which were part of a larger policy. This policy relied on Giant Eagle, Inc.'s corporate office to alert HBC if Giant Eagle pharmacies engaged in suspicious ordering. The policy also directed that HBC would prepare and communicate any history of suspicious orders to the "GE" Pharmacy team "as requested," not making such a report a matter of course. The policy then required GE Pharmacy team, *not HBC,* to notify the DEA "with in [sic] the prescribed three day time limit." In this way, Giant Eagle's actual policy was to delegate its DEA reporting responsibility to its customers' owner.

470. Further, HBC's August 1, 2014 policy does not identify how its SOM system operated, but rather outlines the process for reporting suspicious product orders. The policy does not elaborate on how to identify a suspicious order, nor does HBC's warehouse supervisor recall any specific training to identify suspicious orders. HBC has also admitted in written discovery responses in the Opioid MDL that it provided no "educational, information and/or other programs to any Customer and/or pharmacy/dispenser that it owns and/or controls or other Person, that address diversion, safety, efficacy, misuse and/or prescription of Schedule II Opioids."

471. Giant Eagle's attempt to identify orders of unusual size also was deeply flawed. On October 15, 2013, after approximately four (4) years of distributing HCPs, Giant Eagle finally began to aggregate its customers' controlled substance orders and apply a rudimentary threshold to identify suspicious ordering behavior. From that point until it stopped distributing

HCPs, HBC produced a daily spreadsheet that identified shipments—each of which had already been shipped to the pharmacy—that exceeded the chain-wide ordering threshold for the particular drug. HBC admitted that the threshold report kept track of the shipped quantities, not the ordered quantities, further emphasizing the lack of pre-shipping due diligence.

472. The thresholds themselves were also deficient. HBC set thresholds for controlled substances by taking the average amount *all* of its customers ordered and multiplying by three (3). The effect is that when a customer whose orders for a controlled substance in a month exceeded 300% of the average HBC customer, it was flagged on HBC's threshold report. As HBC since has admitted, setting thresholds by a chain-wide average can result in both false positives (large-volume store consistently orders more than threshold) and false negatives (small-volume stores' relatively large order does not exceed chain-wide threshold).

473. Giant Eagle also repeatedly misrepresented existence of a written SOM policy, its use of algorithms to flag customers' suspicious orders, and its ability to review and stop suspicious orders before shipping to its customers. It even lied to DEA agents when directly asked whether it had HCPs in its warehouse (shortly before hydrocodone's rescheduling after which HBC's registration, which extended only to Schedule III drugs, would expire. More recently, however, HBC's 30(b)(6) representative admitted that it did not have the ability to review and stop suspicious orders before shipping during the entire time HBC distributed opioids.

b. Giant Eagle Failed to Maintain Effective Controls Against Diversion in the County at Wholesale Level.

474. In the County, Giant Eagle violated the standard of care for a distributor by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

475. Through 45 pharmacies in the County, Giant Eagle distributed more than 109 million dosage units, of oxycodone and hydrocodone from 2006 to 2014 in the County, per available ARCOS data—more than any other pharmacy in the County. The volume of opioids it shipped into, and dispensed from locations in, the County is so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

476. Giant Eagle funneled far more opioids into Pennsylvania and the County than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to distributors such as Giant Eagle, especially with its pharmacy dispensing data, would have alerted Giant Eagle to potential diversion of opioids. Yet, upon information and belief, Giant Eagle did not report a single suspicious order in the County between 2007 and 2014.

477. Upon information and belief, Giant Eagle by virtue of the data available to it, was actually aware of indicia of diversion, such as (1) individuals traveling long distances to fill prescriptions; (2) prescriptions for drug "cocktails" known for their abuse potential, such as oxycodone and Xanax; (3) individuals who arrived together with identical or nearly identical prescriptions; (4) high percentage of cash purchases; and (5) doctors prescribing outside the scope of their usual practice or geographic area. However, Giant Eagle ignored these obvious red flags.

478. Giant Eagle, therefore, was aware of the suspicious orders that flowed from its distribution facilities. Giant Eagle refused to identify, investigate, and report suspicious orders despite its actual knowledge of drug diversion. Rather, Giant Eagle failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into Pennsylvania and the County.

479. Upon information and belief, Giant Eagle failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

480. Giant Eagle was, or should have been, fully aware that the opioids being distributed and dispensed by it were likely to be diverted; yet, it did not take meaningful action to investigate or to ensure that it was complying with its duties and obligations with regard to controlled substances, including its responsibility to report suspicious orders and not to ship such orders unless and until due diligence allayed the suspicion.

481. Given Giant Eagle's retail pharmacy operations, in addition to its role as a wholesale distributor, Giant Eagle knew or reasonably should have known about the disproportionate flow of opioids into Pennsylvania and the County and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, illicit supply and diversion.

c. Giant Eagle Failed to Maintain Effective Controls Against Diversion from Its Pharmacy Stores.

482. HBC representatives have admitted that Giant Eagle pharmacy staff have diverted prescription opioids, amounting to tens of thousands of units.

483. Red flags should also have been apparent given that the State of Ohio Board of Pharmacy found that Giant Eagle Pharmacy #4098, in Chardon, Ohio, "from May 1, 2009 through January 21, 2011, fail[ed] to provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs," including hydrocodone.

484. Additional unreported diversion from Giant Eagle pharmacies is evidenced in monthly narcotic audit reports and in the testimony of Giant Eagle Pharmacy District Leader

Fred Bencivengo, who testified as to several instances in a single narcotic audit report where suspected diversions of opioids should have been but were not reported. Pharmacists and their supervisors also list "HBC Warehouse" as the cause of hundreds of missing opioids on these monthly narcotic audits.

485. Giant Eagle also conspired with McKesson to circumvent any meaningful limit on distribution to its pharmacies through McKesson's: (1) daily warnings about thresholds being approached; (2) omitting part of Giant Eagle's orders which would exceed a threshold without notifying DEA of the threshold-exceeding order; (3) and following McKesson's direction to submit to McKesson a request to increase thresholds for its pharmacies approaching or meeting set thresholds.

486. The sheer volume of prescription opioids distributed to and dispensed by Giant Eagle pharmacies in and around the County is indicative of potential diversion and required appropriate due diligence.

487. Discovery will reveal that Giant Eagle knew or should have known that its pharmacies in the County, and the surrounding area, were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse.

Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. Giant Eagle had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

488. One Giant Eagle pharmacy located at Edgewood Towne Center, Pittsburgh, PA 15218, dispensed more than 4 million oxycodone and hydrocodone pain pills between 2006 and 2014, per available ARCOS data.

D. Multiple Enforcement Actions Against Defendants Confirm Their Compliance Failures.

489. Defendants have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the Defendants have been repeatedly penalized for their illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the Defendants.

490. Numerous diversion prosecutions have occurred in which prescription opioid pills were procured from the Defendants. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

491. The litany of actions against Defendants demonstrate that they routinely, and as a matter of standard operating procedure, violated their legal obligations under Pennsylvania laws and regulations that govern the distribution and dispensing of prescription opioids.

492. On information and belief, Defendants knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in the community.

493. On information and belief, because of (among other sources of information) regulatory and other actions taken against the Defendants directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sale data that they developed and monitored, the Defendants were well aware that their distribution and dispensing activities fell far short of legal requirements.

1. CVS

494. CVS is one of the largest companies in the world, with annual revenue of more than $150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations, including in Pennsylvania. Due to its size and market penetration, CVS could have been a force for good in connection with the opioid crisis. But like other Defendants, CVS valued profits over people.

495. CVS is a repeat offender and recidivist: the company has paid fines totaling over $40 million. It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations.

496. As recently as July 2017, CVS entered into a $5 million settlement regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.[109]

497. This fine was preceded by numerous others throughout the country.

498. In February 2016, CVS paid $8 million to settle allegations that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties and filled prescriptions with no legitimate medical purpose.[110]

499. In October 2016, CVS paid $600,000 to settle allegations that stores in Connecticut failed to maintain proper records.[111]

500. In September 2016, CVS entered into a $795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.[112]

501. In June 2016, CVS agreed to pay the DOJ $3.5 million to resolve allegations that 50 of its stores filled forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.[113]

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[109] *CVS Pharmacy Inc. Pays $5M to Settle Alleged Violations of the Controlled Substance Act*, U.S. Dep't of Just. (July 11, 2017), https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violations-controlled-substance-act.

[110] *United States Reaches $8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances*, U.S. Dep't of Just. (Feb. 12, 2016), https://www.justice.gov/usao-md/pr/united-states-reaches-8-million-settlement-agreement-cvs-unlawful-distribution-controlled.

[111] *CVS Pharmacy Pays $600,000 to Settle Controlled Substances Act Allegations*, U.S. Dep't of Just. (Oct. 20, 2016), https://www.justice.gov/usao-ct/pr/cvs-pharmacy-pays-600000-settle-controlled-substances-act-allegations.

[112] Dialynn Dwyer, *CVS Will Pay $795,000, Strengthen Policies Around Dispensing Opioids in Agreement With State*, Boston.com (Sept. 1, 2016), https://www.boston.com/news/local-news/2016/09/01/cvs-will-pay-795000-strengthen-policies-around-dispensing-opioids-in-agreement-with-state.

502. In May 2015, CVS agreed to pay a $22 million penalty following an investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."[114]

503. In September 2014, CVS agreed to pay $1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.[115]

504. In August 2013, CVS was fined $350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.[116]

505. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.[117]

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[113] *CVS to Pay $3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions*, U.S. Dep't of Just. (June 30, 2016), https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filled-fake-prescriptions.

[114] *United States Reaches $22 Million Settlement Agreement With CVS For Unlawful Distribution of Controlled Substances*, U.S. Dep't of Just. (May 13, 2015), https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-agreement-cvs-unlawful-distribution.

[115] Patrick Danner, *H-E-B, CVS Fined Over Prescriptions*, San Antonio Express-News (Sept. 5, 2014), http://www.expressnews.com/business/local/article/H-E-BCVS-fined-over-prescriptions-5736554.php.

[116] Andrew Knittle, *Oklahoma Pharmacy Board Stays Busy, Hands Out Massive Fines at Times*, NewsOK (May 3, 2015), http://newsok.com/article/5415840.

[117] *CVS to Pay $11 Million To Settle Civil Penalty Claims Involving Violations of Controlled Substances Act*, U.S. Dep't of Just. (Apr. 3, 2013), https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penalty-claims-involving-violations-controlled.

2. Walgreens

506. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than $118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal year 2017.

507. Walgreens also has been penalized for serious and flagrant violations of its duties to prevent diversion. Indeed, Walgreens agreed to pay $80 million to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black-market sales.[118]

508. The settlement resolved investigations into violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

509. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.[119]

510. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of

[118] *Walgreens Agrees To Pay A Record Settlement Of $80 Million For Civil Penalties Under The Controlled Substances Act*, U.S. Dep't of Just. (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled.

[119] Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.* (Drug Enf't Admin. Sept. 13, 2012).

prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens' attitude that profit outweighed compliance with its legal obligations or the health of communities.[120]

511. Walgreens' settlement stemmed an investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.[121]

512. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).[122]

513. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

514. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use

[120] *Id.*

[121] *Id.*

[122] *Walgreens to Pay $200,000 Settlement for Lapses with Opioids*, APhA (Jan. 25, 2017), https://www.pharmacist.com/article/walgreens-pay-200000-settlement-lapses-opioids.

sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.[123]

3. Rite Aid

515. With approximately 2,500 stores in 18 states, Rite Aid is the largest drugstore chain in Pennsylvania and the fourth-largest in the United States, with dispensing revenue of more than $11 billion in 2019. In March 2018, Rite Aid completed a sale to Walgreens of 1,932 Rite Aid stores for $4.3 billion. Prior to that Rite Aid had operated 4,600 stores in 31 states and the District of Columbia.

516. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined $5 million in civil penalties for its violations of the CSA.

517. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and federal regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of Federal law.

518. Confirming its systemic failures to implement and adhere to adequate controls against diversion, Rite Aid has repeatedly faced enforcement actions.

519. As recently as January 2019, it paid $177,000 into the Naloxone Fund for the State of Massachusetts to resolve allegations that failed to follow regulations designed to prevent substance use disorder in its dispensing of controlled substances, including opioids. Evidencing

[123] *Id.*

the systemic nature of the problem, Rite Aid, as part of the agreement, agreed to improve its dispensing practices.

520. In 2018, Rite Aid also agreed to pay a $300,000 settlement for filling Schedule III controlled substances prescriptions in excess of the maximum dosage units allowed to be dispensed at one time.

521. In 2017, Rite Aid paid $834,200 in civil penalties to resolve allegations by the DEA that Rite Aid pharmacies in Los Angeles dispensed controlled substances in violation of the CSA. The DEA's "investigation revealed the incorrect or invalid registration numbers were used at least 1,298 times as a result of Rite Aid's failure to adequately maintain its internal database."[124] Further evidencing the lack of internal controls, the settlement also "resolve[d] allegations that Rite Aid pharmacies dispensed, on at least 63 occasions, prescriptions for controlled substances written by a practitioner whose DEA registration number had been revoked by the DEA for cause."[125]

4. Walmart

522. The systemic issues described above are reflected in numerous enforcement actions and investigations that demonstrate the Walmart put profits and sales ahead of compliance, its customers and communities, and public safety.

523. For example, in 2009, the DEA issued a Show Cause order seeking to revoke the registration of a Walmart pharmacy in California. The order alleged that the pharmacy:

> (1) improperly dispensed controlled substances to individuals based on purported prescriptions issued by physicians who were not licensed to practice medicine in California; (2) dispensed controlled substances . . . based on Internet prescriptions

[124] DEA, *Rite Aid Pays $834,200 Settlement for Alleged Controlled Substances Act Violations in Los Angeles* (March 9, 2017), https://www.dea.gov/press-releases/2017/03/09/rite-aid-pays-834200-settlement-alleged-controlled-substances-act.

[125] *Id.*

> issued by physicians for other than a legitimate medical purpose and/or outside the usual course of professional practice . . . ; and (3) dispensed controlled substances to individuals that [the pharmacy] knew or should have known were diverting the controlled substances.

524. In 2011, Walmart and the DEA agreed to a secret settlement outlined in a Memorandum of Agreement ("2011 MOA") arising out of the investigation.[126] According to the MOA agreement, that same Walmart pharmacy in California had been filling prescriptions "for other than a legitimate medical purpose and/or outside the usual course of professional practice in violation of federal and state law" and had "dispensed controlled substances to individuals that [the pharmacy] knew or should have known were diverting the controlled substances." The pharmacy was allegedly dispensing controlled substances based on prescriptions that lacked valid DEA numbers and allegedly refilling controlled-substances prescriptions too early.

525. Upon information and belief, the failures described in the 2011 MOA were not limited to California, but reflected systemic failures at the corporate level. Indeed, the 2011 MOA, which required Walmart to maintain a "compliance program" states that it is applicable to "all current and future Walmart Pharmacy locations."

526. Following the 2011 MOA, Walmart was supposed to revamp its dispensing compliance program, but still, its policies and procedures remained deficient.

527. Instead, systemic failures continued, and Walmart's national corporate office not only failed to insist that Walmart implement adequate controls against diversion, they ignored concerns raised by Walmart pharmacists.

528. One internal document from 2015, for example, notes concerns from a Walmart pharmacist that "his leadership would not support his refusing to fill any 'legitimate' (written by

[126] Jesse Eisinger and James Bandler, *Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment.*, ProPublica, (March 25, 2020), https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment.

a Dr.) prescriptions and he stated that his current volume/staffing structure doesn't allow time for individual evaluation of prescriptions[.]" When this pharmacist refused to fill a customer's controlled substance prescription because the customer was attempting to fill it too soon, the Market Health & Wellness Director for that store complained to management that the pharmacist "sent a customer to a competitor" and "expressed significant concern about how 'sending customers away' would impact the sales figures for the store," and insisted that "the store needs to fill every available prescription."

529. In October 2018, U.S. Department of Justice ("DOJ") had evidence that Walmart pharmacies in Texas dispensed opioids that killed customers who overdosed on the drugs. "The pharmacists who dispensed those opioids had told the company they didn't want to fill the prescriptions because they were coming from doctors who were running pill mills," but their pleas "for help and guidance from Walmart's corporate office" fell on deaf ears.[127] Pharmacists in a number of other states also sought help from Walmart's corporate office, also to no avail. Walmart compliance officials failed to take action in response to these alarms. "Instead, they repeatedly admonished pharmacists that they could not cut off any doctor entirely."[128] Even if they believed the doctor was operating a pill mill, rather than providing genuine medical care, "[t]hey could only evaluate each prescription on an individual basis."[129] In fact, a 2011 document from Walmart Regulatory Affairs regarding the "Proper Prescriber-Patient Relationship" stated, "Blanket refusals of prescriptions are not allowed. A pharmacist must make an individual

[127] Jesse Eisinger and James Bandler, *Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment.*, ProPublica, (March 25, 2020), https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment.

[128] *Id.*

[129] *Id.*

assessment of each prescription and determine that it was not issued based on a valid prescriber-patient relationship or a valid medical reason before refusing to fill."

530. A Texas federal prosecutor, in connection with an investigation that began in 2016, described a systemic problem. The investigation showed Walmart's issue was not a few rogue employees. Rather, "Walmart had a national problem."[130] The investigation reportedly revealed that between 2011 and 2017, "Walmart pharmacists repeatedly filled prescriptions that they worried were not for legitimate medical purposes, including large doses of opioids and mixtures of drugs the DEA considered red flags for abuse.[131] They did so even though Walmart pharmacists in Texas, Maine, North Carolina, Massachusetts, Kansas and Washington state all "raised alarms to the company's national compliance department about doctors."[132] Regarding one Texas doctor who was later convicted of illegal distribution of opioids, a Walmart pharmacist wrote: "We are all concerned about our jobs and about filling for a pill mill doctor. . . Please help us."[133] Another described the same doctor as a "problem," a "liability for us," and a "risk that keeps [him] up at night," cautioning "[t]his is a serious situation."[134]

531. Similarly, in September 2016, a Walmart pharmacist in Pennsylvania advised that a doctor was "under investigation by the DEA for what we believe is a pill mill operation," and that Rite Aid had begun refusing to fill his prescriptions, prompting prescriptions from this prescriber, which were "*almost solely narcotic and controlled prescriptions*" to double.[135] Still,

[130] *Id.*

[131] *Id*.

[132] *Id.*

[133] *Id.*

[134] *Id.*

[135] *Id.*

Walmart adhered to its policy of requiring a case-by-case analysis of prescriptions from the suspected pill mill placed with any Walmart pharmacy; it would not block the prescriber in its system or allow a "blanket" refusal to fill. Walmart was more concerned with the potential sale than it was with preventing diversion.

532. Upon information and belief, Walmart also failed to adequately use data available to it to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts or doses of opioids, or to adequately use data available to it to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

533. Upon information and belief, Walmart also failed to conduct adequately analyze and address its opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if it conducted such reviews, it failed to take any meaningful action as a result.

534. In addition, Walmart has had received more than 50 "Letters of Admonition" from the DEA for its prescribing practices from 2000 to 2018.[136]

E. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement.

535. When a distributor does not report or stop suspicious orders, or a pharmacy fails to maintain effective policies and procedures to guard against diversion, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action—or may not know to take action at all.

[136] *Id*.

536. Despite their conduct in flooding Pennsylvania and other states with dangerous and unreasonable amounts of opioids, Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion.

537. In its 2011 MOA, Walgreens agreed to undertake several different anti-diversion measures. Yet, as a DEA official explained in a subsequent Order to Show Cause and Immediate Suspension of its registration that was issued a mere month later and pertained to Walgreens's Jupiter Florida Distribution Center, Walgreens's "anti-diversion" measures appeared to be primarily self-serving:

> [W]hen a company undertakes to survey its stores for regulatory compliance, then selectively edits that survey for the explicit purpose of avoiding evidence of its own non-compliance, as Walgreens apparently did in May 2011, claims of effective remedial measures have less credibility. I gave significant weight to the fact that Walgreens appears to have deliberately structured certain of its antidiversion measures to avoid learning about and/or documenting evidence consistent with diversion. At best, I regard this as deliberate indifference on Walgreens'[s] part as to its obligations as a DEA registrant.
>
> My confidence in Walgreens'[s] remedial measures is lessened further by the fact that this manipulation of the compliance survey occurred just one month after Walgreens entered into a nationwide Memorandum of Agreement (MOA) with DEA to resolve an Order to Show Cause issued to a San Diego Walgreens pharmacy based on allegations of unlawful dispensing. . . . Walgreens'[s] effort to enact . . . [a compliance] program in Florida appears to have been, in part, intentionally skewed to avoid actually detecting certain evidence of possible diversion.

538. Despite the behavior described above, Walgreens nevertheless publicly portrayed itself as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs.

539. In August of 2018, after journalists at the *Washington Post* disclosed information gleaned from the ARCOS data regarding the staggering number of opioids Walgreens distributed and sold, Walgreens again publicly promoted itself as being and "ha[ving] been an industry leader in combatting this crisis in the communities where our pharmacists live and work."

Walgreens further asserted that "Walgreens pharmacists are highly trained professionals committed to dispensing legitimate prescriptions that meet the needs of our patients."[137]

540. Yet, in January 2020, Walgreens released a Board Report on Oversight of Risks Related to Opioids. There, it claimed that: "In recent years, the Company has implemented a number of operational changes that it believes have helped to reduce its risk with respect to its dispensing of prescription opioids. The Company is focused on the continuous improvement of its controlled substances compliance program, implementing enhancements to prevent, identify and mitigate the risk of non-compliance with federal and state legal requirements."[138] It went on to tout its "Good Faith Dispensing policy," as "provid[ing] the foundation for our pharmacists to understand their roles and responsibilities when dispensing prescriptions for controlled substances."[139] It also claimed that "the Company conducts its own voluntary, independent review of controlled substance purchase orders placed by our pharmacies, providing an additional layer of review above and beyond the legally required monitoring performed by the wholesalers."[140] There, Walgreens' Board acknowledged that the "fundamental elements of an effective compliance program include," among other things, "[w]ritten policies, procedures, and standards of conduct setting forth the Company's expectations and requirements for operating all business activities in an ethical and compliant manner"; "[o]versight of the Compliance Program by the Global Chief Compliance and Ethics Officer, Compliance and Ethics Officers for each

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137 https://www.washingtonpost.com/investigations/distributors-pharmacies-and-manufacturers-respond-to-previously-unreleased-dea-data-about-opioid-sales/2019/07/16/7406d378-a7f6-11e9-86dd-d7f0e60391e9_story.html (Aug. 2019).

138 https://s1.q4cdn.com/343380161/files/doc_downloads/governance_guidelines/Board-Report-on-Oversight-of-Risk-Related-to-Opioids-June-2019-rev.-August-2019.pdf

139 *Id.*

140 *Id.*

operating division, and Compliance and Governance Committees"; and, "[a]uditing and monitoring."[141]

541. With respect to compensation, the Board stated: "[w]e have a strong pay-for-performance philosophy." Accordingly, its "Compensation and Leadership Performance Committee," the Board explained, "aims to incent leaders to support the Company's culture and model desired behaviors, ensuring ethical behavior and mitigating risks, through ongoing monitoring, reviewing and governance of all incentive plans."[142]

542. Yet, at the end of January 2020, the *New York Times* revealed that Walgreens had not reformed its policies putting speed ahead of safety and pharmacists continued to feel pressed to do more with less.[143]

543. Citing company documents, it shows that Walgreens contuse to tie bonuses to achieving performance metrics. Walgreens, in response instated that errors were rare and that "it made 'clear to all pharmacists that they should never work beyond what they believe is advisable.'"[144] Similarly, CVS assured that "[w]hen a pharmacist has a legitimate concern about working conditions, we make every effort to address that concern in good faith."[145]

544. Meanwhile, the *New York Times'* coverage disclosed that a CVS form for staff members to report errors internally asked whether the patient poses "a 'media threat.'"[146] According to the article, "[t]he American Psychiatric Association is particularly concerned about

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[141] *Id.*

[142] *Id.*

[143] Ellen Gabler, *How Chaos at Pharmacies Is Putting Patients at Risk*, NEW YORK TIMES (Jan. 31, 2020), https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html.

[144] *Id.*

[145] *Id.*

[146] *Id.*

CVS, America's eighth-largest company, which it says routinely ignores doctors' explicit instructions to dispense limited amounts of medication to mental health patients."[147] The group's president further observed that ""[c]learly it is financially in their best interest to dispense as many pills as they can get paid for[.]

545. Following its Texas settlement, Walmart claimed that the agreement pertained to a small number of stores in that state, and claimed Walmart was "eager to comply with the law."[148] A Walmart spokesperson further claimed that: "We take record keeping seriously[,]" and "[w]e continuously review our processes at our pharmacies to ensure they are accurate and in full compliance with the law."[149]

546. More recently, Walmart reportedly claimed to be cooperating with a federal investigation and "taking action to fix its opioid dispensing practices."[150] In fact, however, Walmart subsequently "acknowledged that it halted its cooperation in mid-2018."[151]

547. Rite Aid similarly claims to be committed to working with "both federal and state agencies to help reduce the opioid epidemic that is impacting our communities throughout the United States."[152]

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[147] *Id.*

[148] Associated Press, *Wal-Mart Settles Drug Records Accusation*, (Jan 7, 2009), http://prev.dailyherald.com/story/?id=262762.

[149] *Id.*

[150] Jesse Eisinger and James Bandler, *Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment.*, ProPublica, (March 25, 2020), https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment.

[151] *Id.*

[152] Rite Aid, Pharmacy, Health Information, https://www.riteaid.com/pharmacy/healthinformation

548. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, all Defendants through the NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:[153]

- "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."
- "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process."
- "DEA regulations that have been in place for more than 40 years require distributors to *report* suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders)."
- "A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy."
- "Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash."

549. Through the above statements made on their behalf by their trade association, and other similar statements assuring its continued compliance with their legal obligations, Defendants not only acknowledged that they understood their obligations under the law, but further affirmed that their conduct was in compliance with those obligations. In doing so, Defendants further delayed efforts to address the growing opioid epidemic.

550. Through the above statements and others, Defendants not only acknowledged that they understood their obligations under the law, but created the false and misleading impression that their conduct was in compliance with those obligations.

[153] Brief for HDMA and NACDS, 2016 WL 1321983, at *3-4, 25.

551. By misleading the public and the County about the effectiveness of their controlled substance monitoring programs, the Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that Plaintiff now asserts. Plaintiff did not know of the existence or scope of Defendants' industry-wide deception and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

F. Defendants' False and Deceptive Marketing and Distribution of Opioids Has Been a Substantial Cause of the Current National, Regional, and Allegheny County Prescription Opioid Epidemics.

1. The National Prescription Opioid Epidemic

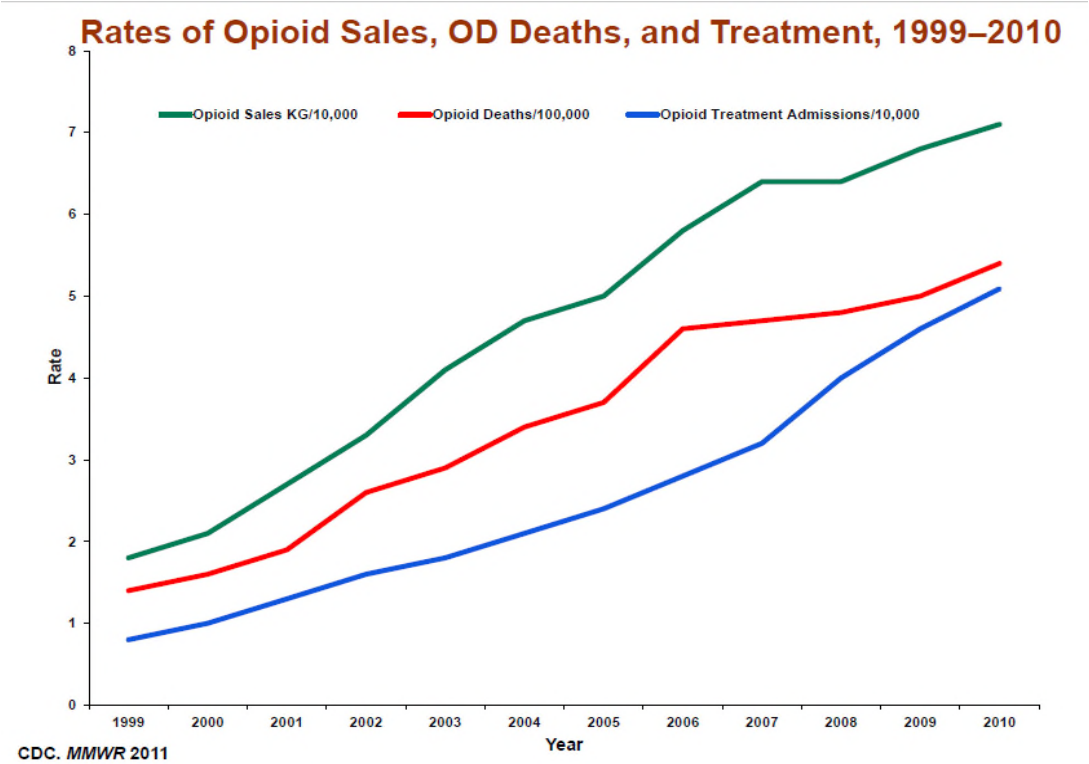
552. Starting in or about 1996—and coinciding with a rapid increase in prescription opioid use for medical purposes as more fully set forth herein—the United States has experienced an opioid epidemic which has been characterized as the worst drug epidemic in its history. In the public health community, an epidemic is defined as a sharp increase in the prevalence of a disease (or diseases) within a discrete period of time.[154] The principal disease associated with the opioid epidemic is opioid addiction, also known as opioid use disorder.

553. Opioid addiction, like other forms of addiction, is a chronic medical condition. It is treatable. Unfortunately, for a variety of reasons, including a shortage of and limitations on private and public resources, the presence of shame and stigma, and the presence of barriers to treatment, only a small percentage of patients who need treatment actually receive the right types of treatment and levels of care, in the right settings, for the right lengths of time. In the absence of proper treatment the disease of addiction is progressive and, all too often, fatal.

554. In 2011, the CDC published an analysis of opioid use from 1999–2010 which indicated a sharp increase nationally in the prevalence of opioid addiction and opioid use

[154] Principles of Epidemiology in Public Health Practice, Third Edition: An Introduction to Applied Epidemiology and Biostatistics (2017), https://www.cdc.gov/ophss/csels/dsepd/ss1978/lesson1/section11.html.

disorder. The study found a 900% increase in opioid users seeking treatment for opioid addiction in the period 1999–2010. As reflected in the following graph, the sharp increase in opioid addiction during this period has also led to a sharp increase in both fatal and non-fatal opioid overdoses, as well as other opioid-related adverse health effects (Figure 1):[155]



555. In the period 1999–2014, the CDC estimated that there were 165,000 overdose deaths in the United States associated with prescription opioid use,[156] and since that time Allegheny County Fatal Overdose Trends reports an additional 365,000 deaths,[157] for a national total of more than 530,000 deaths in the 1999–2020 period. Overdose deaths in the United State have alarmingly surged by about 30% between 2019 and 2020. In past six years, total national

[155] Andrew Kolodny, M.D., Responding to the Prescription Opioid and Heroin Crisis: An Epidemic of Addiction, at 23 (2016), http://www.pdmpassist.org/pdf/TTAC_Opioid_Policy_Research_Collaborative_20170726.pdf; Vital Signs: Overdoses of Prescription Opioid Pain Relievers – United States, 1999-2008, CDC (Nov. 4, 2011) (similar graph), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm.

[156] CDC Guideline, March 18, 2016, at pg. 2, 18, *supra* note 8.

[157] "Allegheny County Overdose Trends," Allegheny County Department of Human Services.

overdose deaths have surpassed the total deaths in prior 16 years by more than 200,000. Public health authorities estimate that, for every opioid overdose death, there are 30 non-fatal overdoses.[158] Thus, in the period 1999–2020, an estimated 15.9 million non-fatal opioid overdoses have occurred, with approximately 2.4 million being in 2020 alone. Overdose treatment cost estimates range between $500 for an ER visit to $11,000 per admitted hospital stay, and up to $20,000 per ICU stay[159], while ongoing opioid addiction treatment with methadone, buprenorphine or naltrexone cost between $6,000 to $14,000 per year.[160] One 2017 study suggests a $6,000 national average per treatment cost, which for the 1999–2020 period aggregates to over $95 billion. In terms of Allegheny County, with 5,634 overdose deaths in the period 2008–2020, this translates to 169,020 non-fatal overdoses with a resultant estimated treatment cost of $1.0 billion.

556. The CDC has acknowledged the presence of an "opioid epidemic," also referred to as an "opioid overdose epidemic."[161] Similarly, a 2017 report by the U.S. Drug Enforcement Agency noted that the "opioid overdose crisis . . . is a public health and public safety emergency."[162] The U.S. Department of Health and Human Services recognized the existence of

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[158] Andrea Hsu, Hospitals Could Do More for Survivors of Opioid Overdoses, Study Suggests, NPR (Aug. 22, 2017), http://www.npr.org/sections/health-shots/2017/08/22/545115225/hospitals-could-do-more-for-survivors-of-opioid-overdoses-study-suggests.

[159] *See* "Opioid Overdoses Costing U.S. Hospitals an Estimated $11 Bill Annually," Premier, Inc. (Jan. 3, 2019), https://www.premierinc.com/newsroom/press-releases/opioid-overdoses-costing-u-s-hospitals-an-estimated-11-billion-annually.

[160] *See* National Institute on Drug Abuse Research Report, p. 22 (rev. June 2018).

[161] CDC Guideline, March 18, 2016, at pg. 3, 34, *supra* note 8; *accord* CDC Press Release, CDC Launches Campaign to Help States Fight Prescription Opioid Epidemic (Sept. 25, 2017), https://www.cdc.gov/media/releases/2017/p0925-rx-awareness-campaigns.html (recognizing "opioid epidemic").

[162] Analysis of Overdose Deaths in Pennsylvania, 2016, Drug Enforcement Agency Philadelphia Division and the University of Pittsburgh, at pg. 5 (July 2017) (hereinafter "*Analysis of Overdose Deaths in Pennsylvania*, July 2017"), https://www.overdosefreepa.pitt.edu/wp-content/uploads/2017/07/DEA-Analysis-of-Overdose-Deaths-in-Pennsylvania-2016.pd_-1.pdf.

an "opioid crisis" and stated that the "United States is in the midst of a prescription opioid overdose epidemic."[163]

557. The U.S. Surgeon General also noted in 2016 that opioid use has led to an "urgent health crisis" that specifically coincided with "heavy marketing of opioids to doctors."[164] Similarly, the National Institutes of Health identified the drug industry's "aggressive marketing" as a major cause of the opioid epidemic: "Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and *aggressive marketing by pharmaceutical companies*."[165]

558. On October 26, 2017, the President of the United States declared a "public health emergency" caused by opioid addiction.[166] The action allows for shifting of resources within certain government programs to help people eligible for those programs receive treatment for opioid addiction and use disorder.[167]

559. On January 10, 2018, Pennsylvania Governor Tom Wolf declared the opioid (and heroin) epidemic in Pennsylvania to be a statewide disaster and public health emergency.

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[163] Opioids: The Prescription Drug & Heroin Overdose Epidemic, U.S. Dept. of Health and Human Services (2017), https://www.hhs.gov/opioids.

[164] Opioid Crisis Message from the US General Surgeon General, (Aug. 2016), https://amersa.org/opioid-crisis-message-from-the-us-surgeon-general/ (emphasis added).

[165] America's Addiction to Opioids: Heroin and Prescription Drug Abuse (2014) (emphasis added), https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

[166] White House Office of the Press Secretary, President Donald J. Trump is Taking Action on Drug Addiction and the Opioid Crisis (Oct. 26, 2017), https://www.whitehouse.gov/the-press-office/2017/10/26/president-donald-j-trump-taking-action-drug-addiction-and-opioid-crisis; *see also* The President's Commission on Combating Drug Addiction and the Opioid Crisis (Nov. 1, 2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

[167] *Id*.

2. Increases in Prescription Opioid Sales By Defendants As a Result of Their False and Deceptive Marketing and Distribution Were a Substantial Factor in the Current National Opioid Epidemic.

560. As reflected above, over the past two decades, the rates of prescription opioid sales, opioid addiction, and opioid overdose deaths have risen together and closely track each other.

561. In 2017, the CDC noted that "[p]rescription opioid-related overdose deaths and admissions for treatment of opioid use disorder have increased in parallel with increases in opioids prescribed in the United States, which quadrupled from 1999 to 2010."[168] Similarly, it noted in 2016 that "[s]ales of opioid pain medication have increased in parallel with opioid-related overdose deaths."[169]

562. The direct correlation between increases in sales of prescription opioids and opioid addiction and overdoses prompted the CDC and other public health authorities to conclude that the unprecedented increase in the use of prescription opioids for medical purposes substantially contributed to both opioid epidemics in the period 1999-2014.[170] The CDC gathered data relating to prescription opioid usage using sales of prescription opioids as a measure of prescription opioid usage, and correlated these data with data relating to admissions for treatment of opioid use disorders and overdose deaths.

563. As can be seen from the graph *supra*, which correlates prescription opioid addiction and overdoses starting in 1999, sharp, dramatic increases in the sale of prescription opioids for medical purposes closely track sharp, substantial increases in addiction as measured

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[168] Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015, at pg. 1 (July 7, 2017), https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6626a4.pdf.

[169] CDC Guideline for Prescribing Opioids for Chronic Pain, The Center for Disease Control and Prevention, at pg. 2 (March 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.

[170] *Id.* at pg. 2.

by treatment admissions (as previously described) and fatal overdoses.[171]

564. Using the above data and analysis, the CDC and other researchers have concluded that the increase in prescriptions of opioid drugs for daily use to treat chronic pain substantially contributed to the epidemics in opioid addiction and overdoses.[172]

565. Public health authorities have also concluded that prescription opioid use is responsible not only for the addiction and overdose epidemics relating directly to prescription opioids, but also for the multi-year surge in non-prescription, illegal opioid use, including the use of heroin. Apparently, as law enforcement and public health authorities and the medical profession have begun to limit the improper use of prescription opioids and for other reasons (including the high price of prescription opioids), which have reduced the supply of prescription opioids for legal use, many prescription opioid users suffering from opioid addiction have turned to heroin available on the black market.[173]

566. Based on the growing weight of scientific evidence, public health experts have concluded that the current opioid epidemics of addiction and overdoses have been caused primarily by opioid pain relievers marketed and sold by Defendants and others for long-term daily use to treat chronic pain. Studies show that the vast majority of patients who die from an overdose were first exposed through prescription opioids.[174]

567. The CDC has concluded that unless and until the prescription of opioids by the medical community is reduced to appropriate levels, the current epidemics of opioid addiction

[171] Kolodny, Jan. 12, 2015, at 560, *supra* note 7.

[172] CDC Guideline, March 18, 2016, at 2, *supra* note 8.

[173] Approximately 80% of individuals who begin using heroin made the transition from initial prescription opioids. *See* Kolodny, Jan. 12, 2015, at 560, *supra* note 7.

[174] Kolodny, Jan. 12, 2015, at pg. 563, *supra* note 7; *CDC Guidelines*, March 18, 2016, at pg. 2, *supra* note 8.

and overdoses will not be contained.[175] Even then, it may take decades before the populations addicted as a result of the current opioid epidemic to be appropriately treated.

568. Chronic pain patients and others—from the users to their loved ones and communities at large—have been devastated by the prescription and use of opioids for medical uses. Some estimates of long-term prescription opioid users developing addiction are frighteningly high: one study found that between 30% and 40% of all long-term users of opioids experience problems with opioid use disorders.[176] According to the CDC, *91 Americans die every day from an opioid overdose*.[177]

569. The opioid epidemic has led to many more overdose deaths than the heroin epidemic of the 1970s and crack cocaine epidemic of the 1980s and 1990s, prompting public health officials and commentators to conclude that the current opioid epidemic is the worst drug epidemic in U.S. history, worse than the previous heroin and crack cocaine epidemics combined.[178]

3. The County's Prescription Opioid Epidemic.

570. Like the nation, Allegheny County is also in the grips of a prescription opioid epidemic that has created a public health and safety emergency of unprecedented dimensions.

571. The County's public health and safety opioid emergency includes historically high incidences of opioid addiction and use disorder and of opioid-related deaths and non-fatal

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[175] Kolodny, Jan. 12, 2015, at pg. 565, *supra* note 7; *CDC Guidelines*, March 18, 2016, at pg. 2, *supra* note 8.

[176] J. Boscarino *et al*., Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria, 30(3) Journal of Addictive Diseases 185 (2011); J. Boscarino *et al*., Risk Factors for Drug Dependence Among Outpatients on Opioid Therapy in a Large US Healthcare System, 105(10) Addiction 1776 (2010).

[177] Opioid Overdose, Understanding the Epidemic, Centers for Disease Control and Prevention, (2017), http://www.cdc.gov/drugoverdose/epidemic/index.html (emphasis added).

[178] Andrew Kolodny, M.D., Responding to the Prescription Opioid and Heroin Crisis: An Epidemic of Addiction, at pg. 4 (2016), http://www.pdmpassist.org/pdf/TTAC_Opioid_Policy_Research_Collaborative_20170726.pdf.

opioid overdoses. It also includes other adverse health effects of opioid addiction and use disorder including historically high incidences of babies born with opiate withdrawal conditions, and an unprecedented increase in new Hepatitis C infections caused by opiate injections.

572. The epidemic has also been accompanied by an unprecedented level of opioid-related emergency room visits and hospitalizations; extensive provision of emergency response services by County agencies in reviving and transporting overdose victims; and the expenditure of enormous resources by county agencies.

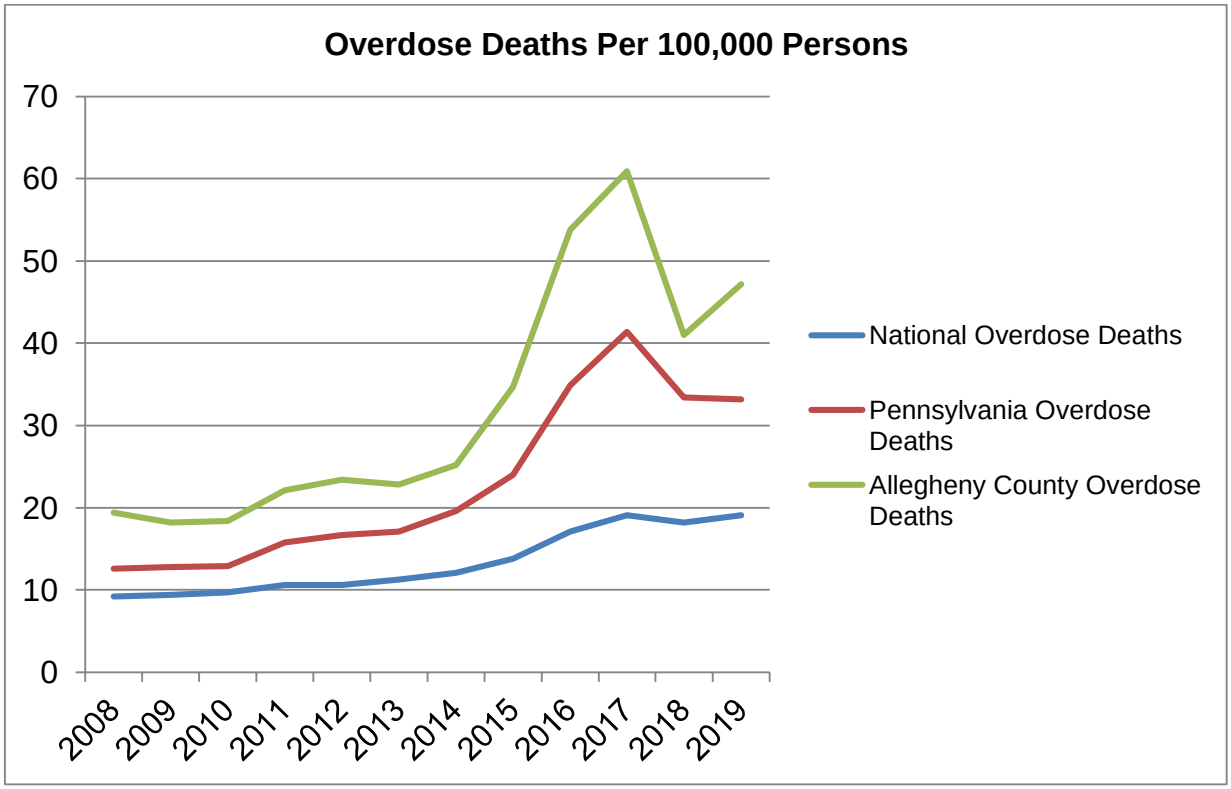
573. All of these circumstances—opioid deaths, opioid-related emergency department visits and hospital admissions, and drug overdoses requiring naloxone, as well as widespread, severe family and social dysfunction as discussed above—are recognized, direct, and quantifiable measures of the adverse public health and safety impact on Allegheny County due to the opioid epidemic, which was caused in substantial part by Defendants' deceptive marketing and/or distribution.

a. The Adverse Health Effects from Opioids in Allegheny County.

574. The opioid epidemic and public health crisis in Allegheny County exceeds national and statewide levels.

575. Opioid overdose deaths in Allegheny County have rapidly increased while also exceeding state and national levels (Figure 2):[179]

[179] "Allegheny County Overdose Trends," Allegheny County Department of Human Services.



576. In 2019, Allegheny County overdose deaths per 100,000 persons exceeded national levels by 2.47 times and state levels by the Pennsylvania average by 1.42 times.[180] During the time period from 2015–2019, Allegheny County overdose deaths per 100,000 were on average approximately three times higher than the national average.

577. According to the Allegheny County Health Department, there were thousands of visits to hospital emergency departments in Allegheny County for drug overdoses from 2016 through 2020, a significant share of which were for opioid overdoses:

[180] *Id.*

Allegheny County Emergency Department Visits, 2016–2020 (Figure 3)

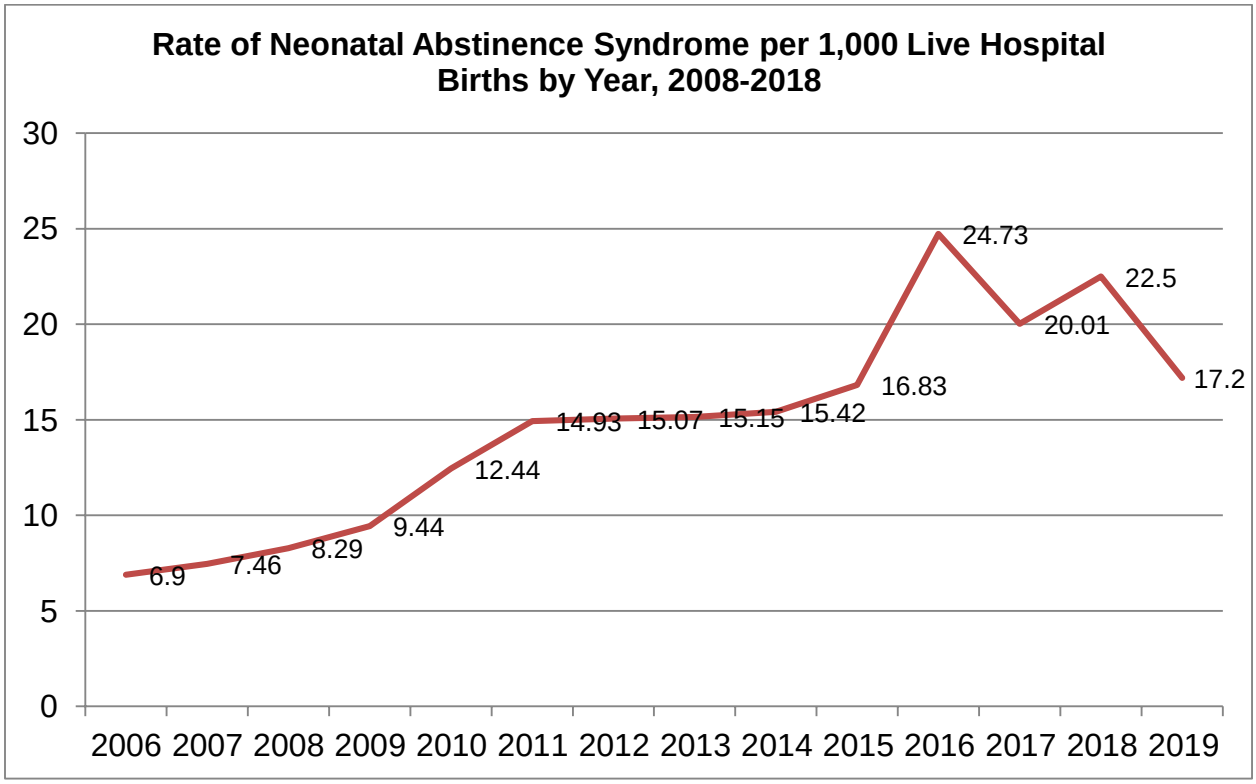
Year	Emergency Department Visits for All Drug Overdoses	Emergency Department Visits for All Opioid Overdoses
2016	2,620	761
2017	5,105	1,845
2018	3,887	1,044
2019	4,088	1,060
2020	3,980	1,196

578. In 2020, assuming 47% of patients are treated and released and 53% of patients are treated and admitted, the cost to Allegheny County hospitals would reach an estimated $42,985,233.[181]

579. Opioid use during pregnancy can lead to neonatal abstinence syndrome (NAS) and may interfere with a child's brain development and may result in subsequent consequences for mental functioning and behavior. In Allegheny County, Allegheny County Health Department statistics indicate that the rate of NAS increased from 6.9 per 1,000 live births in 2006, to 22.5 per 1,000 live births in 2018. The following graph illustrates the drastic increase in NAS in Allegheny County (Figure 4):[182]

[181] Based on treatment and admission estimates and average treatment costs in "Opioid Overdoses Costing U.S. Hospitals an Estimated $11 Bill Annually. *See* Andrea Hsu, Hospitals Could Do More for Survivors of Opioid Overdoses, Study Suggests, NPR (Aug. 22, 2017), http://www.npr.org/sections/health-shots/2017/08/22/545115225/hospitals-could-do-more-for-survivors-of-opioid-overdoses-study-suggests.

[182] Information gathered by Allegheny County Department of Health.



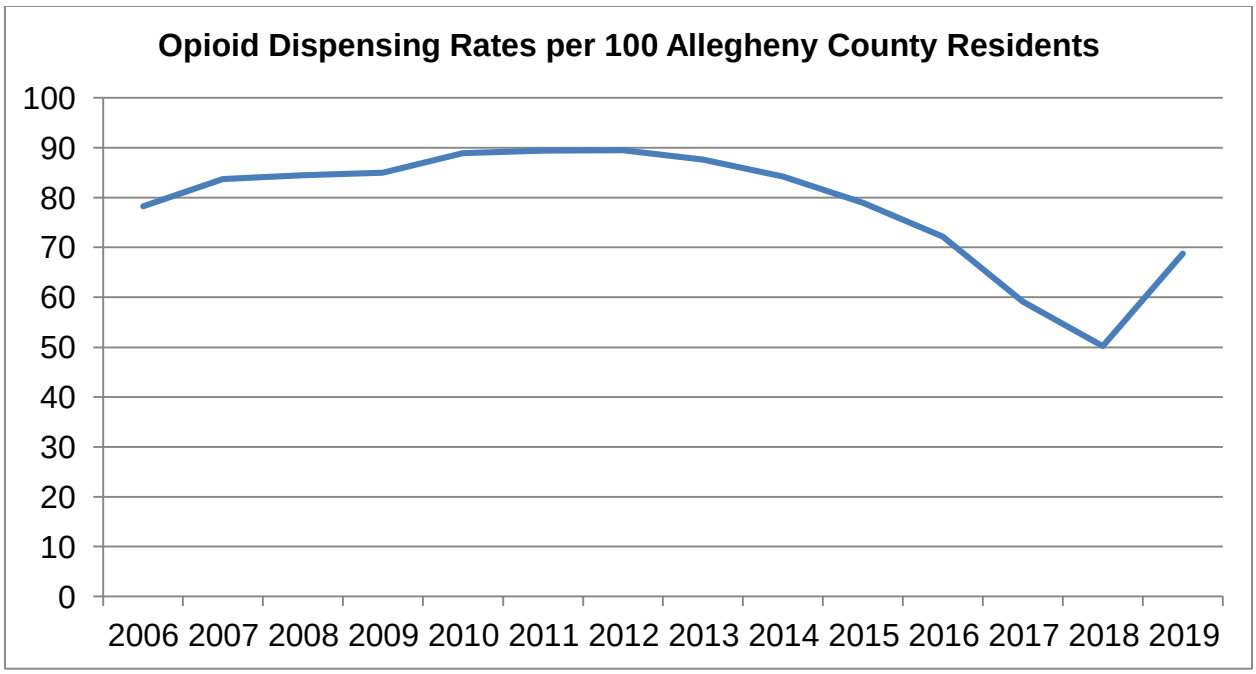
580. Opioid use can also lead to infectious diseases such as hepatitis C virus (HCV) as a result of using needles to inject opioids.[183] If left untreated, HCV can result in liver cirrhosis, cancer, and end-stage liver disease. Incidences of HCV have increased in Allegheny County due to the opioid epidemic.

581. Similarly, opioid abuse can lead to other health problems such as right-sided heart valve infections as a result of using needles to inject opioids. The incidence of right-sided heart valve infections has increased rapidly over the past decade as a consequence of the opioid epidemic.[184]

[183] Sean Murphy *et al.*, Association Between Hepatitis C Virus and Opioid Use While in Buprenorphine Treatment: Preliminary Findings (2015) ("The prevalence of hepatitis-C-virus (HCV) infections is high among opioid-dependent individuals."), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4638227/.

[184] M. Daubresse, *et al.*, Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010, 51(10) Med. Care 870-78 (2013). Hospitalizations for Heart Infection Related to Drug Injection Rising Across the US, Science Daily (Sept. 1, 2016), https://www.sciencedaily.com/releases/2016/09/160901092818.htm.

582. The following graph reflects the use of prescription opioids in Allegheny County as measured by the number of prescriptions written for opioid pain relievers from 2006–2019 (Figure 8):[185]



583. Every day, 172 people die across the country from an opioid-related overdose and over 5,160 patients are given emergency treatment for misusing them. In Allegheny County, an average of almost two people per day died from opioids between 2016 and 2020. Many others are swept into a cycle of addiction and abuse with which they will struggle their entire lives. As many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in primary care settings struggle with addiction. In 2014, almost 2 million Americans were addicted to prescription opioids and another 600,000 to heroin. From 1999 to 2020, about 530,000 people have died in the U.S. from overdoses related to prescription opioids - more than the number of Americans who died in World War II. Since 2012, opioid overdose deaths have more than doubled, from approximately 10.6 deaths per 100,000 to 24.5 deaths per 100,000 in 2020. During

[185] U.S. County Opioid Dispensing Rates, Centers for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/maps/rxcounty2014.html (last visited Jan. 27, 2021).

the five year period from 2015 to 2020 there has been approximately one overdose death in Allegheny County *every 12 hours*. Additionally, for every overdose death, it is estimated that there are approximately ten persons who survive, but require overdose related medical treatment.

4. The Opioid Epidemic in Allegheny County Has Caused the County to Incur Substantial Increased Costs for Which Defendants Are Responsible.

584. As noted above, approximately 1,023 people were treated for opioid-use disorder in Allegheny County hospitals from 2016 to 2018 alone. The County incurred significant increased costs for these services during this period, as well as similar such costs for other periods.

585. The number of persons treated actually understates the extent of opioid addiction and treatment need because patients participating in addiction treatment represent only a fraction of those with an opioid use disorder. National data establish that roughly one out of every ten people with a substance use disorder actually obtain treatment for the specific disorder.[186] Extrapolating on this basis, if there were 1,023 Allegheny County residents who received specialty treatment for an opioid use disorder from 2016 through 2018, there were roughly 10,230 residents who likely needed treatment and did not seek it.[187]

[186] Rachel Lipari *et al.*, America's Need for and Receipt of Substance Use Treatment in 2015, Substance Abuse and Mental Health Services Administration (Sept. 29, 2016), https://www.samhsa.gov/data/sites/default/files/report_2716/ShortReport-2716.html.

[187] Even that number is an undercount, because it includes only Allegheny County residents who receive treatment through the County's publicly-funded health system, and does not include others such as those residents who receive from the County private insurance or other forms of coverage and payment.

586. Opioid addiction has also had major impacts on the County's criminal justice system.[188] The opioid epidemic has caused an increase in crime, arrests and incarceration for opioid-related offenses.

587. As noted above, opioid-related crimes include theft of money or property to help finance opioid addiction; theft of prescription opioids from friends, relatives or others; unlawful possession or trafficking of opioids; and crimes committed while under the influence of opioids.

588. Public safety and criminal justice costs directly attributable to the opioid epidemic include increased costs for police resources, district attorney resources, public defender resources, judicial system resources, prison resources, and increased costs in the form of property losses due to crimes. Nationally, these costs have been calculated to be $7.6 billion per year for prescription opioid abuse and dependence.[189] Based on the disproportionate severity with which the opioid epidemic has impacted Allegheny County relative to the rest of the country, the County has suffered a disproportionate share of these financial burdens as a percentage of its population. Based on the national cost per year for prescription opioid abuse and dependence in 2013, adjusted for Allegheny County's population and its rate of overdoses higher than the national average in 2013, a rough estimate of these additional costs in Allegheny County would be approximately $59.39 million per year.

589. In addition, Allegheny County has been awarded grants to provide services to individuals with a substance use disorder in Allegheny County. The services include prevention, intervention, treatment and case management services. These monies are provided as "Drug and

[188] Ltr. from Nat'l Assoc. of Attorneys General to America's Health Insurance Plans, at pg. 1-2 (Sept. 18, 2017) ("State and local governments alone spend nearly 8 billion dollars a year on criminal justice costs related to opioid abuse.") (citing sources), http://www.naag.org/assets/redesign/files/sign-on-letter/Final%20NAAG%20Opioid%20Letter%20to%20AHIP.pdf.

[189] Florence, *et al.*, The Economic Burden of Opioid Overdose, Abuse, and Dependence in the United States, *2013*, Medical Care, Vol. 54, No. 10, at pg. 903 (October 2016).

Alcohol Services – Non Block Grant" in the Allegheny County Grants, Special Accounts and Agency Funds Budgets:

Year	Total Grant Amount
2013	$20,094,070
2014	$15,476,519
2015	$13,250,000
2016	$15,016,829
2017	$15,834,255
2018	$15,835,000
2019	$19,000,000
2020	$22,200,000
2021	$21,200,000

590. Allegheny County also administers the Court of Common Pleas of Allegheny County Drug Court Program, a state-funded program that involves the identification and evaluation for placement of drug and alcohol offenders. The program involves client participation and treatment. These moneys are provided as "PCCD – Drug Court/IP Grant" in the Allegheny County Grants, Special Accounts and Agency Funds Budgets:

Year	Total Grant Amount
2013	$1,360,733
2014	$1,444,664
2015	$2,248,686
2016	$2,660,509
2017	$2,700,000
2018	$3,250,000
2019	$2,530,000
2020	$2,680,000
2021	$2,969,300

591. Other County Agencies have also been forced to expend additional resources as a result of the opioid epidemic.

592. In addition to the many social services costs set forth above, the County has spent significant amounts of money each year for purchases of prescription opioids (and related medical services) for its employees.

593. The County pays prescription drug costs for covered employees through its employee healthcare and workers' compensation plans. Through these plans, the County pays for opioids prescribed by physicians to covered employees, their family members, and others.

594. The County pays significant sums for the costs of visits to doctors' offices when covered employees and their family members visit doctors to obtain opioid prescriptions. Many such individuals visit their doctors on a recurring basis due to the long-term nature of opioid treatments.

595. The County pays significant costs for opioid addiction treatment for covered employees and their family members. These costs include, *e.g.*, addiction counseling, rehabilitation costs (inpatient and outpatient), overdose costs (ambulance and emergency room visits), and costs to treat infants born with NAS.

596. The County also pays for medical care needed to treat opioid side effects such as opioid-induced constipation, and other health effects such as hepatitis C virus (HCV) and heart valve infections.

597. National data establish that medical costs incurred by insurers increase by an average of approximately $15,000 per annum for individuals who suffer from opioid abuse or addiction.[190] The County incurs no less than this amount for medical costs per year for each affected employee or family member abusing or addicted to opioids that it insures.

[190] Noam Kirson *et al.*, The Economic Burden of Opioid Abuse: Updated Findings, Journal of Managed Care & Specialty Pharmacy, at pg. 437 (April 2017) ("Opioid abusers generate an average of $14,810 in excess costs to payers in the 6 months before and after the initial abuse episode."), *available at* http://www.jmcp.org/doi/pdf/10.18553/jmcp.2017.16265.

598. Similarly, the County pays for its own workers' compensation and disability plan, through which it pays disability costs and related benefits for covered employees. Coverage includes payments for wages while absent from work, and medical costs including doctor's visits and prescription opioid purchases, among other things.

599. Many County employees have been prescribed opioids in connection with injuries sustained at work. Those employees often remain out of work for extended periods of time due to prolonged opioid dependence. The National Council on Compensation Insurance has noted there is "ample evidence that long-term opioid use leads to longer [worker's compensation] claim duration, long-term disability, higher costs, and higher medical expenses."[191] In light of the addictive nature of opioids, the County has incurred costs for workers' compensation claims for longer periods than it otherwise would absent Defendants' conduct in creating the opioid epidemic.

600. The County has experienced lost productivity as a result of employees' work absences due to opioid abuse and addiction, and lost productivity in workers who do show up for work but are impaired by opioid use or withdrawal.

601. From 2011 through 2017, Allegheny County spent over $4.5 million on opioid prescriptions alone in its health plan program, and over $700,000 on opioid prescriptions in its workers' compensation program.

5. Increased Costs to Other Affected Persons in Interest in the County from the Opioid Epidemic.

602. Residents and other affected persons in interest in or doing business in the County paid considerable sums for opioid prescriptions and incurred significant health care and other

[191] NCCI Issues Report: Worker's Compensation 2012, at pg. 24, http://www.akleg.gov/basis/get_documents.asp?session=29&docid=2112.

costs related to opioids during the period of Defendants' false and deceptive marketing and distribution of the drugs.

603. Defendants derived considerable revenue from these affected persons in interest during the period of Defendants' false and deceptive marketing and distribution of opioids.

604. Defendants are liable by way of restoration and/or restitution for these costs and revenues.

6. Plaintiff's Claims Are Against Defendants, Not Individual Pharmacists.

605. The responsibility for dispensing is not limited to pharmacists, pharmacies, or holders of dispensing registrations. Rather, Plaintiff alleges that the owners of the pharmacies, *i.e.* the corporate parents, are responsible for the failure to ensure the dispensing practices of its pharmacies and pharmacists were legal and because the corporate parents directly inhibited its pharmacists' ability to perform their legally mandated duties. *See United States v. City Pharmacy, LLC*, No. 3:16-CV-24, 2016 WL 9045859, (N.D. W.Va. Dec. 19, 2016); *United States v. Stidham*, 938 F. Supp. 808, 814 (S.D. Ala. 1996); *United States v. Poulin*, 926 F. Supp. 246, 250, 253 (D. Mass. 1996); *United States v. Robinson*, No. 12-20319-CIV, 2012 WL 3984786, (S.D. Fla. Sept. 11, 2012).

606. This is so regardless of whether the parent is a registrant under Pennsylvania law or whether the parent is the entity or person actually doing the dispensing. Indeed, Pennsylvania law requires all "persons" to be registered and licensed, and to comply with its laws and regulations related to the distribution and dispensing of controlled substances, and includes corporations and other legal entities in its definition of "person." *See* 63 P.S. § 390-2; 35 P.S. § 780-106; 63 P.S. § 391.4; 63 P.S. §390-4.

607. Defendants are responsible for the dispensing practices in their stores. Defendants exerted day-to-day operational control from the top down, with the national, corporate entities designing and implementing uniform policies and procedures (to the extent they existed) that governed how all pharmacies in the chain were to operate, including the exact conduct at issue—actual dispensing and anti-diversion efforts. Defendants' control also intentionally resulted in a pharmacy environment that did not encourage, and in many instances did not even allow, pharmacists to fulfill their corresponding responsibility as pharmacists.

608. Plaintiff's claims are based on the Defendants' *own* duties, their *own* conduct in establishing dispensing policies and procedures, their *own* failure to make use of the data they themselves had regarding the dispensing of illegitimate prescriptions, and their own failures to properly train their employees regarding their duties under the Pennsylvania Controlled Substance, Drug, Device & Cosmetic Act and related laws and regulations.

609. At the most fundamental level, the purpose of the Pennsylvania Controlled Substance, Drug, Device & Cosmetic Act and corresponding regulations is to create a closed system for delivery of controlled substances and prevent the distribution of controlled substances outside of that system. To allow the entity that fully controls the operations of the pharmacies (such as the corporate parent of a chain pharmacy) to escape responsibility because of corporate structure would defeat the purpose and intent of the Pennsylvania Controlled Substance, Drug, Device & Cosmetic Act and the Pennsylvania Unfair Trade Practices and Consumer Protection Law.

COUNT I
VIOLATION OF PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW, 73 P.S. §§ 201-1 – 201-9.3
(AGAINST ALL DEFENDANTS)

610. Plaintiff incorporates by reference all paragraphs set forth above as if fully set forth herein at length.

611. This Count does not sound in fraud.

612. The UTPCPL prohibits persons from employing "[u]nfair methods of competition" and "unfair or deceptive acts or practices," which are defined to include, *inter alia*, the following conduct:

a. "Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services." 73 P.S. § 201-2(4)(ii);

b. "Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have . . . ." 73 P.S. § 201-2 (4)(v); or

c. "Engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding." 73 P.S. § 201-2 (4)(xxi).

613. Defendants are persons under the UTPCPL.

614. Defendants violated the UTPCPL in that their conduct as alleged herein caused a likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of the drugs at issue.

615. Defendants violated the UTPCPL in that by their conduct as alleged herein they represented that the drugs at issue had sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have.

616. Defendants violated the UTPCPL in that by their conduct as alleged herein Defendants engaged in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding.

617. Under Pennsylvania law, an act or practice is unfair or deceptive if it had the capacity to deceive, or was likely to deceive, a substantial portion of the public, and was likely to make a difference in the purchasing decision.

618. Defendants' conduct as alleged herein constitutes unfair or deceptive acts or practices in violation of the above provisions of the UTPCPL in that:

a. Defendants knowingly failed to disclose the material facts that *inter alia* they were not in compliance with laws and regulations requiring that they maintain a closed distribution system, protect against addiction and severe harm, and specifically monitor, investigate, report, and refuse suspicious orders. Defendants knowingly misrepresented to regulators and the public that their distribution services and methods for preventing diversion were safe and effective when they were not. But for these knowing and material factual misrepresentations and omissions, Defendants would not have been able to receive and renew licenses to sell opioids.

b. Defendants intentionally misrepresented their compliance with their affirmative legal obligations to provide effective controls to guard against diversion and to identify and report suspicious orders of prescription opioids, and prevent the shipping and sale of suspicious orders of prescription opioids to retailers and health care providers;

c. Defendants knew or should have known that their deceptive and misleading statements regarding the effectiveness of their monitoring systems in identifying, blocking, and reporting suspicious orders and preventing diversion of prescription opioids created the

misleading impression that the Defendants were providing to law enforcement the names of prescribers they knew or should have known to be facilitating the over-prescription and diversion of opioid drugs, while simultaneously distributing opioid drugs to those same prescribers;

d. Defendants' conduct, including their deceptive representations and concealments of material fact, created a significant likelihood of confusion and/or misunderstanding as to the safety, efficacy, and risks of opioids, including the risks associated with the use of opioids for chronic pain;

e. Defendants' conduct had a tendency to deceive a substantial segment of the target audiences in the Allegheny County area, and their misrepresentations and concealments of material facts were likely to be misinterpreted in a misleading way; and

f. Defendants' acts and practices—taken individually and collectively—were likely to make a difference in the prescribing decisions of doctors; usage and purchasing decisions of patients; the formulary decisions of PBMs; and the payment decisions of end-payors like the County, because their misrepresentations and other wrongful acts were specifically designed to mislead and convince these individuals and groups that Defendants were complying with their legal duties to prevent diversion and working with law enforcement to prevent diversion.

619. As a direct result of the foregoing acts and practices, Defendants have received, or will receive, income, profits, and other benefits, which they would not have received if they had not engaged in violations of the UTPCPL as alleged herein.

620. As direct result of their foregoing acts and practices in violation of the UTPCPL, Defendants have caused the County and its affected residents and other persons in interest to incur and continue to incur enormous costs and expenses related to the purchase of opioids and the consequences of dealing with the opioid epidemic.

621. The County operates as a consumer when it purchases goods or services, which it does when it pays for the procurement of and/or reimbursement for prescription opioids.

622. The County was injured in that the Defendants' deceptive and misleading statements regarding the effectiveness of their diversion monitoring systems in identifying, blocking, and reporting suspicious orders and preventing diversion of prescription opioids led to the County believing that Defendants' distribution services and methods for preventing diversion were safe and effective when they were not.

623. But for Defendants' deceptive conduct in violation of the UTPCPL, the County would not have expended millions of dollars in connection with the purchase or reimbursement of prescription opioids or the treatment for opioid addiction, opioid use disorder, or any other opioid-related adverse health effect involving the opioid epidemic. As a direct and proximate result of Defendants' deceptive conduct, the County has been injured.

624. Allegheny County has suffered economic injuries that are direct, ascertainable, and quantifiable. The County's damages constitute both an "ascertainable loss of money or property" and "actual damages" for purposes of 73 P.S. § 201-9.2(a).

625. The Court "may, in its discretion, award up to three times the actual damages sustained." 73 P.S. § 201-9.2(a).

626. The County is entitled to treble damages in light of the severe, willful, and long-running nature of Defendants' conduct, the opioid epidemic it caused, and the resulting harm to public health and safety.

627. The County is also entitled to an award of its litigation costs and attorneys' fees pursuant to 73 P.S. § 201-9.2(a).

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for the following:

a. injunctive relief to enjoin Defendants' continued violations of the UTPCPL as requested in detail above;

b. damages to the fullest extent available by law in excess of $50,000, exclusive of interest and costs;

c. treble damages;

d. litigation costs (including expert fees) and attorneys' fees;

e. prejudgment interest; and

f. such other and further relief as the Court deems just and proper.

Respectfully submitted,

By: _____

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VERIFICATION

I, William Petulla, hereby state that I am a Deputy District Attorney in the Allegheny County District Attorney's Office, and that I have authority to make this verification on behalf of the Commonwealth and the Allegheny County District Attorney. The averments in the Complaint are true and correct to the best of my knowledge, information and belief. I understand that false statements made herein are subject to the penalties of 18 Pa. C.S.A. § 4904 relating to unsworn falsification to authorities.

Date: 8/5/22