COMMONWEALTH OF KENTUCKY
FRANKLIN CIRCUIT COURT, DIV. _____
CIVIL ACTION NO. _____

COMMONWEALTH OF KENTUCKY, *ex. rel.*
DANIEL CAMERON, ATTORNEY GENERAL,

Plaintiff,

v.

CVS HEALTH CORPORATION, a Delaware corporation;
Serve: The Corporation Trust Company
1209 Orange Street
Wilmington, Delaware 19801

CVS PHARMACY, INC., a Rhode Island corporation;
Serve: CT Corporation System
306 West Main Street, Suite 512
Frankfort, Kentucky 40601

CVS TN DISTRIBUTION LLC, a Tennessee corporation;
Serve: CT Corporation System
306 West Main Street, Suite 512
Frankfort, Kentucky 40601

CVS INDIANA, LLC, an Indiana corporation;
Serve: CT Corporation System
306 West Main Street, Suite 512
Frankfort, Kentucky 40601

and

KENTUCKY CVS PHARMACY, LLC, a Kentucky corporation,
Serve: CT Corporation System
306 West Main Street, Suite 512
Frankfort, Kentucky 40601

Defendants.

COMPLAINT

JURY TRIAL DEMANDED

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Plaintiff, the Commonwealth of Kentucky ("Kentucky" or "Commonwealth"), by and through its duly elected Attorney General, Daniel Cameron, brings this civil action against Defendants CVS Health Corporation, CVS Pharmacy, Inc., CVS Indiana, LLC, CVS TN Distribution LLC, and Kentucky CVS Pharmacy, LLC (collectively, "Defendants" or "CVS"), and in support thereof states as follows:

I. INTRODUCTION

1. This civil enforcement action is brought by the Kentucky Attorney General against Defendants CVS for their role in fueling the opioid epidemic in the Commonwealth through unlawful business practices.

2. Sadly, the phrase "Opioid Epidemic"[1] has lost its shock value and become commonplace in daily conversation. This man-made public health crisis was caused, extended, and sustained by the oversupply of opioids through improper distribution and dispensing.[2] This epidemic has affected states across the United States and particularly devastated the Commonwealth.

3. While the epidemic has affected the municipalities and counties within the Commonwealth individually, it has also harmed the Commonwealth as a whole. The opioid epidemic has strained Kentucky's resources for services provided by the Commonwealth, including children's services, labor and employment services, housing, recovery support services, and prevention and education efforts, to name a few. The epidemic has also affected the Commonwealth's State Police force, filled state prisons, affected state-run hospitals and medical

[1] L. Manchikanti et al., *Opioid Epidemic in the United States*, available at https://www.ncbi.nlm.nih.gov/pubmed/22786464.
[2] The terms "opioids" and "opioid analgesics" describe the entire class of natural and synthetic opiates.

facilities, and overwhelmed the Kentucky Medical Examiner's Office, among other harms to the Commonwealth.

4. Opioids are derived from or possess properties similar to opium and heroin, and are categorized as "Schedule II" drugs due to their high potential for abuse and potential to cause severe psychological or physiological dependence.[3] (Hydrocodone was a Schedule III drug until its rescheduling in 2014, categorizing it from then on as Schedule II.) Opioids[4] such as oxycodone and hydrocodone were originally approved by the Food and Drug Administration ("FDA") for short-term post-surgical and trauma-related pain, and for palliative (end-of-life) care; they are now used to treat chronic pain.

5. CVS played a dual role in creating, fueling, and maintaining the opioid epidemic within Kentucky's borders — (1) through their retail pharmacies, as dispensers of opioids to the public, and (2) as a wholesale distributor, taking and shipping orders to and from their own pharmacies.[5] Occupying two links in the opioid supply chain, CVS was in a unique and superior position of knowledge with regard to the gross amount of opioids pumped into their stores and poured out onto the streets of Kentucky.

6. The sheer numbers of controlled substances distributed and dispensed by Defendants were suspicious on their face.

7. Defendants knew or should have known, based on the numbers and other red flags of diversion, that they should have stopped shipment and reported the orders to the Drug Enforcement Administration ("DEA") and refused to fill and reported suspicious prescriptions in

[3] *See* 902 KAR 55:015 §2; 21 C.F.R. 1308.12.
[4] Opioid was originally a term denoting synthetic narcotics resembling opiates but increasingly used to refer to both opiates and synthetic narcotics. *See* Stedman's Medical Dictionary 27th Edition.
[5] Upon information and belief, CVS distributed opioids only to their own pharmacies and did not distribute to third-party pharmacies.

their pharmacies.

8. More specifically, CVS shipped massive amounts of suspicious opioid orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency to their own pharmacies. Defendants shipped and/or distributed those massive quantities of opioids throughout the Commonwealth, failed to report to appropriate authorities their own suspicious orders, and failed to halt such excessive and suspicious shipments. These orders were for such large quantities of opioids that there could be no legitimate medical purpose for them.

9. At the store level, CVS also dispensed opioids at such an alarming rate and volume that there could be no legitimate medical purpose for their use. The only possible explanation for such massive amounts of opioids pouring into and out of CVS's stores in Kentucky is that they failed to stop suspicious orders, which in turn fueled individuals' addiction and/or were misused, abused, or diverted.

10. While there are many purported causes related to the opioid epidemic, this action is focused solely on the actions of CVS, a dominant retail pharmacy and distributor. CVS flooded the Commonwealth of Kentucky with excessive amounts of dangerous and addictive prescription opioids while disregarding their own real-time data, customer thresholds, internal reports, and actual experiences of their own pharmacies.

11. Upon information and belief, from at least 2006, CVS disregarded and overrode their own inadequate safeguard systems and raised their own opioid order thresholds, which were purportedly set in accordance with each pharmacy's anticipated order size. Further, by filling these orders, CVS failed to report or halt orders that raised red flags of abuse, misuse, and diversion, and facially suspicious orders from their own Kentucky pharmacies. Additionally, CVS pharmacies continued filling prescriptions with unresolved red flags and failed to develop adequate

policies and procedures to guard against diversion.

12. By failing to halt and report suspicious orders and prescriptions of prescription opioids, CVS made the most dangerous and addictive drugs in America also the most accessible. Accordingly, CVS — situated to play significant roles as both wholesale distributor and retail pharmacy — acted to maintain or increase their profits and market dominance while creating a public nuisance of historic proportions.

13. Due to CVS's continued proliferation of dangerous and addictive prescription opioids, residents of Kentucky suffered from prescription drug addiction, abuse, overdose, and death. A reasonably foreseeable result of widespread addiction and accessibility of prescription opioids distributed and dispensed by CVS was that patients would transition their use and abuse to illegal street drugs like heroin, and illicit forms of synthetic fentanyl like carfentanil.

14. CVS's actions and/or failures to act caused loss of jobs and productivity, loss of health and enjoyment of life, increased financial burdens to the Commonwealth to respond to the devastation caused by the wave of addiction and, most tragically, the loss of lives of thousands of Kentuckians.[6] In 2015, Kentucky had the third highest drug overdose death rate, behind only West Virginia and New Hampshire.[7] In 2016, the Kentucky Office of Drug Control Policy reported 1,404 overdose deaths.[8]

15. The opioid epidemic is more than just a body count to Kentucky. It has plowed through graduating classes, work forces, and entire families, orphaning or separating children who have lost parents, aunts, uncles, and even grandparents to addiction.[9] The Commonwealth of

[6] *See* Nora D. Volkow, M.D. and A. Thomas McLellan, Ph.D., *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, NEW ENG. J. MED., 374;1253-63 (March 31, 2016).
[7] Rate per 100,000 population age-adjusted to the 2000 U.S. standard population using the vintage 2015 population. Source: National Vital Statistics System, Mortality File, CDC WONDER.
[8] *See* Commonwealth of Kentucky Justice & Public Safety Cabinet 20116 Overdose Fatality Report, 2 https://odcp.ky.gov/Documents/2016%20ODCP%20Overdose%20Fatality%20Report%20Final.pdf.
[9] Opioids orphan kids in Kentucky, Dec. 12, 2014, https://www.cnn.com/2012/12/14/health/kentucky-overdoses/.

Kentucky has been left — in the wake of CVS's actions — to restore order and remedy this public health crisis.

16. Kentucky's response to the health emergency created by Defendants has been, and continues to be, facilitated through a multifaceted infrastructure-level public health initiative, spearheaded by its Kentucky Opioid Response Effort ("KORE") program. In response to the epidemic, the Commonwealth of Kentucky is providing or reimbursing for addiction treatment; investigating and protecting Kentucky residents from the effects of increased drug-related crimes; incarcerating perpetrators of drug-related crimes and providing in-prison treatment to those individuals with substance use disorders; preventing, investigating, and treating overdoses and providing harm reduction programs to communities; providing foster care for children whose parents are in prison, incapacitated by addiction, or dead from overdoses; and treating those with addiction-related health conditions. Moreover, additional services have been needed, due to the substantial increase in babies being born with Neonatal Abstinence Syndrome ("NAS") addicted to opioids resulting in immediate consequences to the infants' health. Additionally, children born with NAS and their families often become involved with the State's child protective services program, need academic and behavioral supports, and may need lifetime monitoring and interventions.

17. Kentucky has further experienced an intense effect on its workforce, seeing employers lament the difficulty in finding and keeping workers, experiencing higher turnover, and increased costs to train new employees — all of which have resulted in policy and operational efforts by the Commonwealth to address these workforce issues. Disturbingly, Kentucky's State Medical Examiner's Office has also been overwhelmed by a staggering increase in autopsy requests related to overdose deaths.

18. The Commonwealth of Kentucky brings this civil enforcement action to hold Defendants accountable for creating and fueling the Commonwealth's opioid-induced public health nuisance. CVS reaped billions of dollars in revenues, while causing immense harm to the Commonwealth and its citizens. Defendants, not the taxpayers of Kentucky, should pay for their role in creating and fueling the opioid epidemic and act to remediate the crisis.

19. The Commonwealth expressly does not raise claims nor seek any damages or restitution attributable to moneys paid out by the Commonwealth for prescription opioids through Medicaid or other programs. Additionally, the Commonwealth expressly does not raise claims or seek any damages for the Commonwealth's workers' compensation program.

II. PARTIES

Plaintiff

20. Plaintiff, the Commonwealth of Kentucky, brings this action, by and through its Attorney General, Daniel Cameron, in its sovereign capacity to protect the interests of the Commonwealth and its citizens. The Attorney General is authorized to take action against Defendants for violation of state laws and regulations. Daniel Cameron is the duly elected Attorney General of Kentucky, an independent constitutional officer of the Commonwealth and its chief law officer, with full authority to initiate and prosecute all cases in which the Commonwealth has an interest. The Attorney General is vested with specific constitutional, statutory and common law authority to commence proceedings to enforce KRS 218A.240, KRS 315.235, KRS 367.110 *et seq*., to initiate actions necessary to exercise all common law duties and authority pertaining to the office of the Attorney General under the common law pursuant to KRS 15.020, and pursuant to the Attorney General's *parens patriae* authority, to bring an action on behalf of the Commonwealth and its citizens. The Commonwealth is entitled to the protections

of sovereign immunity. Pursuant to KRS 49.070(14), the filing of this action shall not be construed as a waiver of that immunity and no counterclaim, set-off, recoupment, cross-claim, or other form of avoidance may be asserted in this action against the Commonwealth. The Attorney General has determined that these proceedings are in the public interest.

Defendants

21. Defendant CVS Health Corporation is a Delaware corporation with its principal place of business in Woonsocket, Rhode Island. CVS Health Corporation, through its various DEA-registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor and also operates retail stores, including in and around Kentucky, that sell prescription opioids. Between at least 2006 and, upon information and belief, October 2014, CVS Health Corporation self-distributed prescription opioids, including hydrocodone, to its retail pharmacies located in Kentucky.

22. Defendant CVS Pharmacy, Inc. is 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. CVS Pharmacy, Inc. is both a DEA-registered "distributor"[10] and a DEA-registered "dispenser"[11] of prescription opioids and is registered to do business in Kentucky. CVS Pharmacy, Inc. is registered with the Kentucky Board of Pharmacy to distribute and dispense controlled substances.

23. Defendant CVS Indiana, LLC is an Indiana corporation and a subsidiary of CVS Pharmacy, Inc. CVS Indiana, LLC was licensed by the Kentucky Board of Pharmacy as a wholesale distributor and distributed opioids to CVS pharmacies in Kentucky. CVS Indiana, LLC has been registered as a wholesale distributor with the Kentucky Board of Pharmacy from

[10] 21 U.S.C. § 802(11) and § 822(a)(1).
[11] 21 U.S.C. § 802(10) and § 822(a)(2).

at least 1999 to the present.

24. Defendant CVS TN Distribution LLC is a Tennessee corporation and a subsidiary of CVS Pharmacy, Inc. Since 2008, CVS TN Distribution LLC has been licensed by the Kentucky Board of Pharmacy as a wholesale distributor and distributed opioids to CVS pharmacies in Kentucky.

25. Defendant Kentucky CVS Pharmacy, LLC is a Kentucky limited liability company with its principal place of business in Louisville, Kentucky, whose sole member is CVS Pharmacy, Inc.

26. Upon information and belief, CVS maintained over 100 separate license numbers as a "wholesaler," "out-of-state pharmacy," and "retail pharmacy" in the Commonwealth of Kentucky during the relevant time period. CVS held these license numbers pursuant to multiple statutes and regulations, including the Kentucky Controlled Substances Act ("KY CSA"). CVS is a dispenser, pharmacy, specialty limited pharmacy, and wholesaler (also referred to herein as distributor) under Kentucky law. *See* KRS 218A.010(10), (11), (12), (38); KRS 218A.150(1) (repealed 2018); KRS 218.170(1), (2); KRS 315.010; KRS 315.400(9); 902 KAR 55:010 § 1(4), 201 KAR 2:230.

III. JURISDICTION AND VENUE

27. The Franklin Circuit Court has personal jurisdiction over CVS, as CVS purposefully availed themselves of this forum by conducting business in the Commonwealth and by causing harm as a direct and proximate result of their actions. CVS regularly transacted and/or solicited business in the Commonwealth and/or derived substantial revenue from goods used or consumed or services rendered in the Commonwealth and/or contracted to supply goods or services in the Commonwealth and/or caused tortious injury by an act or omission in the

Commonwealth and/or caused tortious injury in the Commonwealth by an act or omission outside the Commonwealth. Defendants have the requisite minimum contacts with Kentucky necessary to permit this Court to exercise jurisdiction.

28. Franklin Circuit Court has subject matter jurisdiction over the claims submitted pursuant to KRS 23A.010, KRS 315.235, and KRS 367.190 as the claims enumerated herein arise exclusively under Kentucky statutory and common law and from the *parens patriae* authority of the Attorney General to act on behalf of the Commonwealth of Kentucky and its citizens. The Commonwealth's claims are in excess of any minimum dollar amount necessary to establish the jurisdiction of the Court.

29. Kentucky does not plead any cause of action or request any remedy arising under or founded in federal law. The instant Complaint does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332, as the Commonwealth is not a citizen of any state and this action is not subject to the jurisdiction of the Class Action Fairness Act of 2005. There is no federal subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d) because the Commonwealth does not bring this case as a class action or as a mass action, and expressly and permanently disavows the existence of any alleged class or mass. The Commonwealth expressly and permanently does not seek, and disavows, any proposal to try its claims with 99 other persons.

30. Likewise, federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the Complaint, as it sets forth herein exclusively viable state law claims against CVS. Nowhere herein does Plaintiff plead, expressly or implicitly, any cause of action or request any remedy that arises under federal law. The issues presented in the allegations of this Complaint do not implicate any substantial federal issues and do not turn on the necessary interpretation of federal law. No federal issue is important to the federal system as a whole under the criteria set

by the Supreme Court in *Gunn v. Minton*, 568 U.S. 251 (2013).

31. Specifically, the causes of action asserted, and the remedies sought herein, are founded upon the positive statutory, common, and decisional laws of Kentucky. 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.

32. In this complaint, Plaintiff cites or alludes to federal statutes, regulations, or agency memoranda. Plaintiff does so only to establish CVS's knowledge, to state the duties owed under Kentucky law, or to explain the hybrid nature of industry oversight, not to allege an independent federal cause of action and not to allege any substantial federal question under *Gunn v. Minton*.

33. Venue is appropriate in Franklin Circuit Court under KRS 452.460, which allows venue in the county where the injury was suffered. Where the injury is against the Commonwealth, its agents or employees, or the Commonwealth as a whole, venue is proper in Franklin Circuit Court.

IV. FACTUAL BACKGROUND

A. CVS's Key Roles In The Opioid Supply Chain Requires Them To Adhere To Legal Duties Designed To Protect Public Health And Safety

1. Duties Owed By Distributors Under Kentucky Law

34. Rather than permitting drug manufacturers to sell opioids directly to consumers, a sophisticated, closed distribution system exists to push these drugs across the nation.[12] This sophisticated system arose out of the need for greater control over abused and addictive

[12] Statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, Drug Enforcement Agency to the Department of Justice Before the Caucus on International Narcotics Control, United States Senate (July 18, 2012); http://docs.house.gov/meetings/IF/IF14/20140407/102093/HHRG-113-IF14-Wstate-RannazzisiJ-20140407.pdf

prescription drugs and is intended to track and account for controlled substances from point of manufacture to point of use by the ultimate consumer.[13] The closed-system model contemplates manufacturers selling pharmaceuticals to distributors who distribute those pills to pharmacies that dispense the drugs to the ultimate consumer.

35. For many important reasons, this system relies upon the honesty, integrity, and accountability of all members of the closed system to be effective. This "closed" chain of distribution was specifically designed by Congress to prevent the abuse, misuse, and diversion that is complained of herein.

36. This closed system imposes specific duties upon wholesale distributors to monitor, identify, halt, and, perhaps most importantly, report suspicious orders of controlled substances. *See* 21 C.F.R. § 1301.74; *Masters Pharmaceuticals, Inc. v. Drug Enforcement Administration*, Decision and Order, 80 Fed. Reg. 55,418 (DEA Sept. 15, 2015). All registrants of the closed distribution system must adhere to specific security, recordkeeping, monitoring, and reporting requirements that are designed to identify or prevent diversion.[14] The purpose of these laws is to protect public health and safety.[15]

37. Kentucky enacted similar laws and regulations relating to the distribution of drugs in order to provide oversight over this unique industry. The Kentucky General Assembly determined and declared that "[t]he regulation of controlled substances in this Commonwealth is important and necessary for the preservation of public safety and public health . . . ." KRS 218A.005(1).

38. Pharmaceutical distributors such as CVS are key components of this closed

[13] *Id.*
[14] *Id.*; *see* 21 C.F.R. §§ 1301.12, 1301.71-1301.76.
[15] *See supra* n. 13.

distribution chain. The role of the pharmaceutical distributor is not simply one of shelf stocker, freight forwarder, or simple shipper. If the closed system is to function properly, distributors must be vigilant in deciding whether a prospective customer can be trusted to sell controlled substances only for lawful purposes. Inherent conflicts of interest arise where, as here, the distributor and the pharmacy are the same. In such cases, the entity charged with monitoring and reporting duties is forced to choose between following the law to its own financial detriment or looking the other way.

39. Until mid-2018, wholesalers of controlled substances were required to apply for a license or renewal of license to operate in Kentucky through the Cabinet for Health and Family Services Office of Inspector General, Drug Enforcement and Professional Practices Branch ("DEPPB"). *See* KRS 218A.150 (repealed). They were also required to be licensed by the Board of Pharmacy. *See* KRS 315.402; KRS 315.406; 201 KAR 2:105. Since mid-2018, the Kentucky Board of Pharmacy is solely responsible for the grants of licenses and renewals of licenses of wholesalers of controlled substances. The DEPPB still administers and enforces the KY CSA.

40. The application for the Kentucky Board of Pharmacy states: "I hereby certify that the foregoing is true and correct to the best of my knowledge. If the registration herein applied for is granted, I certify that this business will be conducted in full compliance with all applicable federal and state laws and that I will make available any or all records required by law to the extent authorized by law" with a signature line directly below.[16] The applications also require acknowledgment of whether an applicant, owner, partner, officer, agent, or employee has (1) been convicted of any felony, (2) had a wholesale distributor license or permit revoked or suspended,

[16] Application for License as a Wholesaler of Controlled Substances, https://pharmacy.ky.gov/Businesses/Wholesale%20Distributor%20License%20Documents/Wholesale%20Distributor%20License%20Application.pdf (last accessed January 16, 2021).

and (3) been convicted under laws relating to drug samples and wholesale or retail drug distribution of controlled substances.[17] They must also certify that they are "in compliance with all applicable federal and state laws and regulations relating to drugs." 201 KAR 2:105.

41. The KY CSA requires that distributors of controlled substances, including opioids, forward a list of lost, destroyed, or stolen medication to the Cabinet for Health and Family Services. KRS 218A.200(6); *see also* 902 KAR 55:010 § 6. The KY CSA imposes additional record keeping requirements on distributors of opioids. *See* KRS 218A.200(2).

42. Upon information and belief, CVS acknowledged this language with each application for license renewal and made sworn representations regarding the same. At all relevant times, CVS has had a duty to comply with Kentucky's licensure requirements. *See* KRS 218A.150 (repealed); 201 KAR 2:105 *et seq*. Distributors of opioids must disclose to the registrant suspicious orders of opioids, meaning those of unusual size and/or frequency, and/or those deviating substantially from a normal pattern.

43. The federal Controlled Substances Act ("CSA") contains many of the same duties for Defendants, which are incorporated into Kentucky law. The Kentucky Board of Pharmacy requires coordination and use of reported opioid distribution and sale data, and continued demonstration of "[a]cceptable operational procedures, including . . . compl[iance] with all DEA regulations." 201 KAR 2:105 § (4)(d); *see also* KRS 205.5634.

44. The CSA requires manufacturers, distributors, and dispensers of controlled substances to adhere to security, recordkeeping, monitoring, and reporting requirements that are designed to protect against diversion.[18]

[17] *Id*.
[18] 21 C.F.R. § 1301.74

45. Defendants are required to "maint[ain] . . . effective controls against diversion" and to "design and operate a system to disclose . . . suspicious orders of controlled substances." 21 U.S.C § 823(a)-(b); 21 C.F.R. § 1301.74. This includes the requirements to monitor, detect, report, investigate, and refuse to fill suspicious orders. *See* 21 U.S.C. § 823; 21 C.F.R. § 1301.74. Distributors are not entitled to be passive observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders *when discovered* by the registrant." 21 C.F.R. § 1301.74(b) (emphasis added). Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id*. Other red flags may include, for example, "[o]rdering the same controlled substance from multiple distributors." *Id*.

46. The system the federal laws refer to is commonly referred to as a suspicious order monitoring system ("SOMS"). SOMS should be designed to recognize and halt orders of suspicious size, pattern, or frequency and allow the distributor to investigate the suspicious order to decide if it must be reported to the DEA. In Kentucky law, KRS 218A.202 directs the Cabinet for Health and Family Services to establish and maintain an electronic system for monitoring Schedule II, III, IV, and V controlled substances. It requires every practitioner or pharmacy that dispenses controlled substances to a person in Kentucky to report specific information to the Cabinet. Data for each controlled substance that is reported must include, but not be limited to, the following: (a) Patient identifier; (b) National drug code of the drug dispensed; (c) Date of dispensing; (d) Quantity dispensed; (e) Prescriber; and (f) Dispenser. *See* KRS 218A.202.

47. These criteria are disjunctive and are not all-inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter, and the order should be reported as suspicious. Likewise, a distributor need not wait for a normal pattern to

develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volumes of controlled substances being shipped to a particular region.

48. The DEA has testified in the federal multi-district litigation pending in the United States District Court for the Northern District of Ohio, Eastern Division, as *In Re: National Prescription Opiate Litigation*, Case No. 1:17-md-02804-DAP ("the MDL-2804"), that:

a. DEA registrants are required to block all suspicious orders of prescription opioids.

b. Shipping a suspicious order is a per se violation of federal law.

c. If a wholesale distributor blocks a suspicious order, it should terminate all future sales to that same customer until they can rule out that diversion is occurring.

d. After the fact reporting of suspicious orders has never been in compliance with federal law.

49. 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 [DEA] must be informed.[19]

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

Indeed, the DEA may revoke a distributor's certificate of registration as a vendor of controlled substances if the distributor identifies orders as suspicious and then ships them "without performing adequate due diligence."[20]

50. 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 Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418, 55,477 (DEA Sept. 15, 2015), *petition for review denied*, 861 F.3d 206 (D.C. Cir. 2017).

51. 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.

52. As an opioid distributor, CVS had a duty, known by way of the licensure practices in Kentucky, to report lost, stolen, or otherwise misappropriated (or "diverted") controlled substances.

53. Generally, Kentucky Administrative Regulations prohibit a distributor of prescription drugs from operating in a manner that endangers public health. *See* 201 KAR 2:105 § 7.

54. Wholesale distributors, including CVS, have a duty to

> establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts

[20] *Masters Pharmaceuticals*, 861 F.3d 206, 212 (D.C. Cir. 2017). The *Decision and Order* was a final order entered by the DEA revoking Masters Pharmaceuticals' certificate of registration, without which Masters Pharmaceuticals could not sell controlled substances. In *Masters Pharmaceuticals*, 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*.

> and to assure that the wholesale distributor prepares for, protects against, and handles crisis situations that affect the security or operation of the facility. These crises shall include fires, floods, or other natural disasters, and situations of local, state, or national emergency.

201 KAR 2:105 § 5.

55. By statute, opioid distributors also have a duty to refrain from engaging in unfair, false, misleading and/or deceptive trade acts or practices. *See* KRS 367.170(1).

56. Finally, under the common law, Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By flooding Kentucky with more opioids than could be used for legitimate medical purposes, by filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, and by failing to maintain effective controls against diversion from their retail stores, CVS breached that duty and both created and failed to prevent a foreseeable risk of harm.

2. Duties Owed By Pharmacies Under Kentucky Law

57. In addition to their duties as distributors, CVS also had a duty to design and implement systems to prevent diversion of controlled substances and to monitor and report suspicious activities in their retail pharmacy operations. Defendants had a duty to analyze data and store-level information for 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) prescriptions of unusual size and frequency for the same patient; (d) prescriptions of unusual size and frequency from out-of-state patients; (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";[21] (g) prescriptions in volumes, doses, or

[21] According to definitions applied by CVS for suspicious order monitoring purposes, "cocktails for opioids are methadone, muscle relaxants, stimulants and benzodiazepines."

combinations that suggested the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) prescriptions for patients and doctors in combinations that were indicative of diversion and abuse.

58. Kentucky law mandates that all pharmacies apply for and receive a license from the Kentucky Board of Pharmacy. *See* KRS 315.035. Until 2018, pharmacies were also required to apply for and receive a license from the Kentucky Cabinet for Health and Family Services. *See* KRS 218A.150, repealed by 2018 Kentucky Laws Chapter 112. Continuing licensure is dependent upon compliance with laws and regulations relating to controlled substances. *See* KRS 218A.160(1) (repealed); *see also* 902 KAR 55.010; KRS 218A.240; 21 U.S.C. § 823.

59. A prescription for opioids, as controlled substances, must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. KRS 218A.180(3)(a).

60. Pharmacists have a corresponding duty, along with the prescriber, to ensure that opioid prescriptions are written for a legitimate patient and for a legitimate medical need in the usual course of practice for the prescriber. *See* KRS 218A.180(3)(a). The responsibility for proper dispensing lies with the pharmacist. *Id.* Pharmacists may refuse to dispense a prescribed controlled substance.[22]

61. Pharmacists may observe a number of "red flags" when trying to determine the validity of a controlled substance prescription, including those enumerated by the Kentucky Board of Pharmacy:[23]

a. Does the pharmacist have a relationship with the prescriber?
b. Does the pharmacist have a relationship with the patient?

[22] Kentucky Board of Pharmacy, Controlled Substances Questions, https://pharmacy.ky.gov/Pages/Controlled-Substances-Questions.aspx (last accessed June 2, 2018).
[23] *Id.*

c. What is the distance a patient is driving to see the prescriber?
d. What is the home address of the patient?
e. In what community is the prescriber practicing?
f. Have people unknown to the pharmacist called asking if a specific medication or a specific manufacturer of a medication is stocked by the pharmacy?
g. When prescriptions are filled for one patient, do many, many more start coming to the pharmacy?
h. Is every patient receiving the exact same prescriptions?
i. Does the prescriber take cash only?

62. Under both federal and state controlled substances laws, the duty to prevent diversion lies with the pharmacy (such as CVS), not the individual pharmacist.

63. Defendants have legal duties specifically with respect to their dispensing practices under the federal Controlled Substances Act ("CSA") as well: "[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."[24]

64. Further, under the federal CSA, 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). All dispensers are required to check 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. *See* 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."[25]

65. The federal CSA does not require separate registrations for practitioners affiliated with registered institutions or for agents of registrants. It is the pharmacy, not the individual

[24] 21 C.F.R. § 1306.04(a).
[25] 2012 Dear Registrant letter to pharmacy registrants, http://ppsconline.com/articles/2012/FL_PDAC.pdf

pharmacist, which is a registrant under the federal CSA. For this reason, individual pharmacists are agents of the pharmacy and the duty to ensure the proper dispensing of controlled substances lies with the pharmacy entity, and not the individual pharmacist alone.[26] The requirements of the federal CSA are consistent with the independent requirements of Kentucky law, and Kentucky law also requires Defendants to adhere to federal requirements. *See* KRS 218A.170 ("All sales and distributions shall be in accordance with KRS 218A.200 and the federal controlled substances laws . . . .").

66. As acknowledged in an article CVS published in the New England Journal of Medicine: "Pharmacies have a role to play in the oversight of prescriptions for controlled substances, and opioid analgesics in particular." 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. The DEA has identified "both pharmaceutical distributors and chain pharmacies as part of the problem" contributing to opioid abuse and related deaths. *Id.*

67. As nationwide chain pharmacies, CVS has a particular "advantage" in meeting their obligations under the federal CSA because these 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." *Id*. at 990. For example, a chain pharmacy should properly use its chainwide dispensing data to identify "high risk prescribers" by "benchmarking" prescription data based on "several parameters," including "volume of prescriptions for high-risk

[26] *Compare 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 alia,* dispensing prescriptions that presented various red flags, *i.e.*, indicia that the prescriptions were not issued for a legitimate medical purpose without resolving red flags).

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." *Id*. 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." *Id.* Accordingly, as CVS touts, "innovative use of transparent data is only prudent." *Id.*

68. As CVS counseled, chain pharmacies 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.

69. 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.[27] Reasonably prudent distributors and pharmacies would not fall below this standard of care, which foreseeably harms the public health and welfare.

70. Under Kentucky law, prescriptions for opioids can be computer generated or stamped, but must be manually signed. *See* KRS 218A.180(4); 902 KAR 55:080. The prescription must be on a security prescription blank. *See* 902 KAR 55:105 § 3. Prescriptions for opioids must include the full name and address of the patient, drug name, drug strength, dosage form, quantity

[27] *See Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enforcement Administration, July 3, 2007) (applying federal requirements no less stringent than those of Ohio); *Masters Pharmaceuticals, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017) (same).

prescribed, directions for use, and the name, address, and registration number of the prescriber. *See* KRS 218A.180(5). Prescriptions for opioids are valid only for 60 days from the date of the prescription. *See also* KRS 218A.180. Among other record keeping requirements[28], all dispensers/pharmacists licensed by the Kentucky Board of Pharmacy that possess a DEA license must register as a Kentucky All Schedule Prescription Electronic Reporting ("KASPER") reporter.[29] Reporters are required to report the dispensing of Schedule II through Schedule V controlled substances, including opioids, no later than the close of business on the business day following the dispensing.[30] Pharmacies must maintain adequate security of controlled substances, see 201 KAR 2:100, and report robberies or thefts of controlled substances. *See also* KRS 315.335. It is considered unprofessional conduct to permit controlled substances to be diverted from a pharmacy. *See* KRS 315.121. Specifically, KRS 315.121 states that unprofessional conduct includes "[s]elling, transferring, or otherwise disposing of accessories, chemicals, drugs, or devices found in illegal traffic when the pharmacist, pharmacy intern, or pharmacy technician knows or should have known of their intended use in illegal activities; [e]ngaging in conduct likely to deceive, defraud, or harm the public, demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist or pharmacy intern, with or without established proof of actual injury; . . . or [f]ailing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful." KRS 315.121(2); 201 KAR 2:205 Section 2.

71. Pharmacists are required to counsel patients on matters which the pharmacist

[28] *See generally* KRS 218A.200.
[29] 902 KAR 55:110 § 2; Rule 1.1, KASPER Controlled Substance Reporting Guide Version 1.5.2, Cabinet for Health and Family Services (2017).
[30] 902 KAR 55:110 § 2; Rule 1.3, KASPER Controlled Substance Reporting Guide Version 1.5.2.

believes will optimize drug therapy. *See* 201 KAR 2:210. As described below, CVS employed performance metrics that undermined pharmacists' ability to do so, and to act as their agents in maintaining controls against diversion at the pharmacy level.

72. It is against the law to make any false statement regarding any prescription, order, report, or record required by the KY CSA. *See* KRS 218A.140(1)(d).

73. Pharmacies, too, are prohibited from engaging in unfair, false, misleading and/or deceptive trade acts or practices. *See* KRS 367.170(1).

B. CVS Played An Outsized Role In Kentucky's Soaring Opioid Supply And Fueled Black Markets For These Highly Addictive Drugs

74. CVS was not alone in causing and maintaining the opioid epidemic gripping the Commonwealth. A deceptive marketing scheme by opioid manufacturers seeking to promote the use of "opioid therapy" to treat chronic pain by understating and falsely trivializing the risks while overselling the benefits also played a role. In doing so, the opioid manufacturers knew of, capitalized on, and actively and intentionally concealed the fact of patient tolerance of the analgesic effects of opioid drugs with the help of Defendants and other chain pharmacies. Meanwhile, the effectiveness of the chronic "opioid therapy" they promoted, as is now known, is a fallacy. The FDA has expressly recognized it was aware of no long-term studies demonstrating the safety and efficacy of opioids for long-term use. Studies show that even opioid treatment for acute pain in an emergency department setting shows no clinically important differences in pain reduction when compared to use of non-opioid pain relievers.[31]

75. The marketing efforts worked. Opioids — once a niche drug — are now the most prescribed class of drugs, above even blood pressure medicine. While Americans represent only

[31] Andrew K. Chang, et al., Effect of a Single Dose of Oral Opioid and Nonopioid Analgesics on Acute Extremity Pain in the Emergency Department, Nov. 7, 2017, *JAMA*. 2017; 318(17):1661-1667, available at https://jamanetwork.com/journals/jama/fullarticle/2661581.

4.6% of the world's population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply. In 2012, opioids generated a combined $8 billion in revenue for drug companies; this revenue exceeded $15 billion in 2016. The cost of the country's opioid epidemic is estimated to have exceeded $1 trillion from 2001 to 2017, and was projected to cost an additional $500 billion by 2020.[32] Once this marketing campaign created a mass market, Defendants then proceeded to flood it. As explained in detail below, CVS also worked with the manufacturers on the marketing side to create the mass market.

76. By flooding the market, Defendants fueled an illicit market that predictably developed. The increased volume of opioid prescribing, not all of which is for legitimate use, correlates directly to skyrocketing addiction, overdose and death, black markets for diverted prescription opioids, and a rise in heroin and fentanyl abuse by individuals who could no longer legally acquire or afford prescription opioids.

77. Defendants were well aware of the far-reaching impact of opioid diversion. As far back as 2001, a former police captain from the Hazard Police Department in southeastern Kentucky stated that the issue was epidemic in the state when discussing the use of OxyContin.[33]

78. Also as far back as 2001, pharmacies in Kentucky were dealing with armed robberies. In Bowling Green, Kentucky, employees of a local pharmacy filled OxyContin bottles with candy as decoys due to being a target of two armed robberies.[34]

79. As wholesalers self-distributing to their retail stores, CVS fueled the epidemic on two fronts. CVS distributed 97,240,700 dosage units of hydrocodone to its pharmacies in

[32] *See* Wilson Hyan, *The Potential Societal Benefit of Eliminating Opioid Overdoses, Deaths, and Substance Use Disorders Exceeds $95 Billion Per Year*, Altarum Center for Value in Health Care (2017).
[33] Francis X. Clines with Barry Meier, "Cancer Painkillers Pose New Abuse Threat," *New York Times*, February 9, 2001, https://www.nytimes.com/2001/02/09/us/cancer-painkillers-pose-new-abuse-threat.html.
[34] Fox Butterfield, "Theft of Painkiller Reflects Its Popularity on the Street," *New York Times*, July 7, 2001, https://www.nytimes.com/2001/07/07/us/theft-of-painkiller-reflects-its-popularity-on-the-street.html.

Kentucky from 2006 to 2014, the period for which data from the Automated Reports and Consolidated Ordering System ("ARCOS") database is available.[35] ARCOS is a data collection system in which manufacturers and distributors report their controlled substances transactions to the DEA. CVS pharmacies in Kentucky bought 97,240,700 dosage units of hydrocodone from its own distribution centers from 2006-2014. Measured by dosage units, CVS was responsible for more than 5.2% of the hydrocodone distributed in the state as a wholesaler.[36]

80. CVS also leaned on outside vendors to augment its supply. CVS pharmacies in Kentucky bought an additional 10,317,945 dosage units of hydrocodone from third party distributors Cardinal Health, A F Hauser, Actavis Pharma, and Quest Pharmaceuticals from 2006 to 2014. Cardinal Health acted as CVS's predominant third-party hydrocodone distributor. CVS pharmacies in Kentucky also bought 43,534,160 dosage units of oxycodone from Cardinal Health alone during this time period.

81. In total, CVS pharmacies in Kentucky bought 151,092,805 dosage units of oxycodone and hydrocodone from 2006 to2014 from its own distribution centers and third-party distributors. This means that as a dispenser, CVS was responsible for nearly 6.1% of the total dosage units of oxycodone and hydrocodone in Kentucky during this time.

82. In a 12-month period ending in May 2020, Kentucky saw a 22% increase in drug overdose deaths. That is greater than the overdose deaths increase nationwide. For every 100,000

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

[36] The opioid purchases disclosed in the ARCOS data serve as an effective proxy for the opioids dispensed by the retail pharmacies, which have no incentive to purchase drugs they do not plan to sell.

Kentuckians, 37 of them fatally overdosed.[37]

83. Given their vertically integrated structure and dual role in the opioid supply chain, Defendants' compliance with the law governing their conduct as wholesaler and retail pharmacy was vital to safeguard consumers and control the rate of addiction, abuse, and diversion of opioids. As detailed below, however, upon information and belief, Defendants wholly failed to follow the law, such that their actions promoted addiction, abuse, and diversion of opioids throughout Kentucky. From 2007 to 2014, CVS, upon information and belief, collectively reported ***zero*** suspicious orders from their Kentucky stores. Instead, they continued to supply staggering quantities of opioids into Kentucky and onto its streets as they continued to place profits above the implementation of effective policies and procedures to guard against diversion.

C. CVS Was Well Aware Of Their Obligations To Prevent Diversion And That Failure To Meet Those Obligations Posed Serious Consequences To Public Health And Safety

84. Defendants are well aware they have an important role to play in this system, and also know, or should know, that their failure to comply with their obligations will have serious consequences.

85. During a 30(b)(6) deposition taken in the MDL-2804, the DEA's Unit Chief of Liaison was asked whether the DEA made it "clear to industry that the failure to prevent diversion was a threat to public safety and the public interest." In response, he testified:

> Yes, I think it's established in 823 [the Controlled Substances Act] where it's part of our -- part of the registrant that is applying to be a registrant understands that they have to maintain effective con-trols . . . they also know that these drugs themselves are scheduled controlled substances for a par-ticular reason, because they're addictive, psychologically and physically they're addictive, so they know that these drugs have these properties within themselves. **So they would understand that these drugs are categorized**

[37] Steve Rogers, Kentucky sees 22% jump in overdose deaths, pandemic cited, *ABC 36 WTVQ*, Dec. 30, 2020, https://www.wtvq.com/2020/12/30/kentucky-sees-22-jump-in-overdose-deaths-pandemic-cited/.

or scheduled in that manner because they have the potential to hurt.

86. Defendants, in their capacity as a wholesale drug distributor and as a mass merchant with pharmacies, have been active in various trade organizations for decades. The National Association of Chain Drug Stores ("NACDS") is one such organization. CVS, among other pharmacies, served on its board. The Healthcare Distribution Management Association ("HDMA"), now known as Healthcare Distribution Alliance ("HDA"), is a national trade association representing distributors that have partnered with NACDS.

87. In 2006, the NACDS issued a "Model Compliance Manual" intended to "assist NACDS members" in developing their own compliance programs. 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.

88. In 2007 and 2008, the HDA began developing "industry compliance guidelines" ("ICG") that aimed to outline certain best practices for the distributors. As part of its development of the ICG, the HDA met with the DEA on at least three occasions. The HDA also sought extensive

input from its membership. The HDA released the ICG in 2008 and emphasized that distributors were "[a]t the center of a sophisticated supply chain" and "uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."

89. The DEA has repeatedly informed distributors and dispensers, including CVS, about their legal obligations, as described above, including obligations that were so obvious that they required no clarification. For example, it is not an effective control against diversion to identify a suspicious order, ship it, and wait weeks to report it to law enforcement, potentially allowing those pills to be diverted and abused in the meantime.

90. The requirement to report suspicious orders at the time — not after the fact — has always been clear. As early as 1984, correspondence between the National Wholesale Druggists' Association ("NWDA"), now the HDA, and the DEA illustrates that the DEA provided clear guidance well before the opioid crisis was unleashed. For example, in one letter to the NWDA, DEA Section Chief Thomas Gitchel emphasized that "the submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting excessive or suspicious orders," noting "**DEA has interpreted 'orders' to mean prior to shipment.**" Consistent with that understanding, the NWDA's 1984 Guidelines repeated the same directive.

91. Defendants received repeated and detailed guidelines from the DEA concerning, for example, their obligations to know their customers and the communities they serve. 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' trustworthiness.

92. The guidelines, input, and communications from the DEA put Defendants on notice of their requirements and obligations.

93. The DEA published "Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances,"[38] which suggests that distributors examine, among other things, the ratio of controlled versus non-controlled orders placed by the pharmacy; the methods of payment accepted; whether, why, and to what extent the pharmacy also orders from other distributors; and the ratio of controlled substances the distributor will be shipping relative to other suppliers.

94. Pharmacies have repeatedly received extensive guidance from the DEA about their duties under the federal CSA. For example, the DEA has provided guidance in the form of its "Pharmacist's Manual: An Information Outline for the Controlled Substances Act of 1970" which is intended to outline the "requirements set up under the Controlled Substances Act of 1970 [*et seq*.] as they affect pharmacy practice."

95. The DEA's guidance emphasizes: "The role of the pharmacist in the proper dispensing of controlled substances is critical both to the health of patients and to safeguard society against drug abuse and illicit diversion. The pharmacist's adherence to the law, together with voluntary service of its objectives, constitute a powerful resource for protecting the public health and safety. . . . The pharmacist is in a pivotal position because it is the pharmacist who dispenses the prescription medication to the ultimate consumer."

96. However, "[p]harmacists must be aware of the various methods and activities employed to divert controlled substances. The primary method is falsified prescription orders. Other methods for diverting controlled substances are: theft from a pharmacy, theft of prescription

[38] U.S. Department 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.

blanks, and willful and intentional diversion by pharmacists." The following non-exhaustive list of red flags as indicators of possible illegal and/or fraudulent prescription orders are provided in the DEA's Manual:

- 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;
- Prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis;
- Prescriptions for "cocktail" drugs frequently abused with opioids, like benzodiazepines, muscle relaxers and/or stimulants;
- Patients who present similar prescription orders from the same practitioners;
- People who are not regular patrons presenting prescription orders from the same physician;
- A dramatic increase in the purchases of controlled substances;
- Patients who travel unusual distances to see a prescriber or to fill a prescription; and
- Patients who pay cash for opioid prescriptions even though they have insurance.

97. "The DEA also expects that pharmacists will make a reasonable effort to determine the identity of the prescriber – if the prescriber is not known to the dispensing pharmacist."

98. Finally, if a pharmacy finds evidence of prescription diversion, the Manual indicates that the local Board of Pharmacy and DEA must be contacted.

99. In addition, in April 1987, the DEA sponsored a three-day "Controlled Substances Manufacturers and Wholesalers Seminar" that was attended by "over fifty security and regulatory compliance professionals representing forty-three major pharmaceutical manufacturers and wholesalers." According to the executive summary of the event, Ronald Buzzeo held a session on "excessive order monitoring programs," wherein he explained:

> [A]ny system must be capable of both detecting individual orders which are suspicious, or orders which become suspicious over time due to frequency, quantity, or pattern. The NWDA system, for example, provides an excellent lookback, or trend system, but the ability to identify one time suspicious orders should not be overlooked as an element of the program. Another area at issue was whether DEA would take action against a registrant which reported an order and then shipped it. DEA pointed out that the company

> is still responsible under their registrations for acting in the public interest. Reporting the order does not in any way relieve the firm from the responsibility for the shipment.

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

101. The DEA also advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances that they are "one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[39] The DEA's September 27, 2006 letter also expressly reminded registrants that, in addition to reporting suspicious orders, they 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."[40] The same letter reminds distributors of the importance of their obligation to "be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes" and warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[41]

[39] Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice, to Cardinal Health (Sept. 27, 2006), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51 ("2006 Rannazzisi Letter").
[40] *Id*.
[41] *Id*.

102. The DEA sent another letter to distributors alike on December 27, 2007, reminding them that, as registered distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The DEA's December 27, 2007 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).[42] 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."

103. In September 2007, the NACDS, among others, attended a DEA conference at which the DEA reminded registrants that they were required to not only report suspicious orders, but also to halt shipments of suspicious orders.

104. The DEA's regulatory actions against the three largest wholesale distributors, AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation, further underscore the fact that distributors, such as CVS, were well aware of the legal requirements. 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, Ins.'s distribution centers and on December 23, 2016, Cardinal Health, Inc. agreed to pay the United States $44 million to resolve allegations that it violated the CSA. Similarly, on May 2, 2008, McKesson Corporation entered into an Administrative

[42] Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug. Enforcement Administration, U.S. Department of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder,* No. 1:12-cv00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8 ("2007 Rannazzisi Letter").

Memorandum of Agreement with the DEA related to its failures in maintaining an adequate compliance program. Most recently, in January 2017, McKesson Corporation entered into an Administrative Memorandum Agreement 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.

105. Several DEA actions were also brought against the Defendants, which will be discussed below.

D. Due To Their Dual Role As Distributors And Retail Pharmacies, CVS Was Uniquely Positioned To Guard Against Diversion

106. As vertically-integrated pharmacies and distributors, Defendants have access to additional information that would allow them to identify and prevent diversion. CVS possessed such detailed and valuable information regarding their retail stores' orders, prescriptions, prescribers, and customers that companies known as "data vendors" were willing to pay for it.

107. Defendants had complete access to all prescription opioid dispensing data related to their pharmacies in Kentucky, complete access to information identifying the doctors who prescribed the opioids and the customers who filled or sought to fill prescriptions for opioids, and knowledge of the actual opioid prescriptions dispensed by their pharmacies in and around the Commonwealth. Further, Defendants had complete access to information revealing the geographic location of out-of-state doctors whose prescriptions for opioids were being filled by their pharmacies in and around the Commonwealth of Kentucky and complete access to information revealing the size, frequency, dose, and combinations of prescriptions written by specific doctors and filled by their pharmacies.

108. Defendants, by virtue of the data available to them, were 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 (a sedative

prescribed for anxiety or panic disorders); (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, Defendants ignored these obvious red flags and continued to distribute and dispense excessive and dangerous amounts of opioids in the Commonwealth.

E. CVS Failed To Maintain Effective Controls Against Diversion

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

1. CVS Failed To Maintain An Effective Suspicious Order Monitoring System Or To Complete Necessary Due Diligence

a. Before 2009 CVS Did Not Have A SOM System At All

110. Before 2009, CVS did not have a Suspicious Order Monitoring ("SOM") system. Instead, CVS relied on the 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.

111. CVS did not have a training program to prepare its "Pickers and Packers" to identify orders of unusual size, frequency, or pattern. "Pickers and Packers" are workers in CVS's warehouses who pick up the items on the order form and pack the order for transportation. In a deposition, a CVS corporate representative testified that CVS did not have any written policies, procedures, or protocols with respect to the Pickers' and Packers' obligations, and there were no formal qualifications or training to be employed as a Picker and Packer.

112. CVS did not even begin to design a rudimentary SOM system until 2007. Then, 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 November 2007 neither the final SOP nor the SOM 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." CVS's corporate representative testified that he did not "believe that there was a suspicious order monitoring policy put into place as of that date."

113. Drafts of the SOP demonstrate that CVS understood, or should have understood, that the lack of a SOM policy was unacceptable. The draft SOP provided 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 was finally issued in December 2007, the SOM section still remained incomplete. As of April 2009, it remained so.

114. John Mortelliti, CVS's Director of Loss Prevention, wrote in November 2009 that 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. Ultimately, CVS did not incorporate the final missing section until the end of August 2010, and even then, evidently did so only because of the need to fulfill an apparent promise to provide it to the DEA.

115. In a September 2010 e-mail, Mr. Mortelliti circulated an August 27, 2010 document titled "Suspicious Order Monitoring for PSE/Control Drugs: Summary of Key Concepts & Procedures," which he described as "final approved speaking points for the DEA" should DEA agents question suspicious order monitoring at a CVS facility. In the correspondence, he asked that the recipients "be sure [their team] understands [the material] before presenting so it doesn't look like a prop instead of a tool."

116. As of November 2011, CVS had a "CVS DEA compliance coordinator" in name only. A former CVS employee who held the position at that time has 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."

b. CVS Failed To Remedy Fatal Flaws In The System It Slowly Developed

117. In 2009, 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. But even then the system was inadequate because CVS failed to remedy fatal flaws.

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

119. IRRs were the primary SOM process. As CVS's corporate representative explained in a deposition taken in the MDL-2804 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.

120. 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.

121. CVS's SOM system's algorithm also failed to consider outside vendors orders, meaning that CVS's SOM system would not track how many opioids CVS was ordering from third party distributors 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 waiting to consider outside vendor data until later in the process 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 CVS had full access to the orders its pharmacies placed to outside vendors.

122. Recognizing 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.

123. Still, as late as July 2013, internal e-mails reflect that CVS's primary tool for investigations used stale data that made any analysis, "for the most part, irrelevant and pointless."

124. Not until mid- to late 2014 did CVS fully implement the new SOM system. That same year, all CVS distribution centers stopped distributing Schedule II opioids at the wholesale level.

c. CVS Failed To Perform Due Diligence

125. CVS's SOM system was also inadequate because it did not conduct appropriate due diligence investigation on flagged orders. All orders that appeared on the IRR should have been subjected to a thorough and appropriate due diligence investigation, but only a very small percentage were. From early/mid-2009 through March 2011, Mr. Mortelliti "was taking the first pass through the IRR himself." 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 conduct review and due diligence as he deemed appropriate." At select times in 2012 and 2013, CVS had only one employee reviewing all potentially suspicious orders for every pharmacy in the country. The SOM system would select

certain orders based on a number of factors and "pend" the order. If an order was selected, the CVS SOM manager would review the orders and conduct an "in depth" dive on select orders. Even though the SOM program would identify between 200 and 500 suspicious orders a day, the CVS employee would only have time to do a "deep dive" on 5-6 orders per day. A single employee was responsible for reviewing IRRs for one half of the country over a period covering twelve days ranging from June 14, 2012 to September 6, 2012, during which time CVS investigated a total of seven control substance orders. As of November 21, 2013, CVS had reported only 7 suspicious orders to the DEA across all of its distribution centers and pharmacies in the United States. The first suspicious order CVS ever reported to the DEA was on February 29, 2012.

2. CVS Also Failed To Protect Against Diversion At Its Retail Pharmacies

a. CVS Lacked Adequate Guidance For Its Pharmacists To Detect And Prevent Diversion

126. For many years, CVS did not provide guidance to its pharmacists to detect and prevent the diversion of opioids at its pharmacies nationwide, including Kentucky.

127. Even later than its SOM system, CVS did not begin to develop policies and procedures to protect against diversion at its retail pharmacies until 2011. In June of 2011, CVS developed a policy related to forged or altered prescriptions that contained some of the red flags suggested by the DEA in evaluating prescriptions for Schedule II drugs. These guidelines include but are not limited to, verifying legitimacy of a prescription before dispensing by verifying the identity of the patient, reviewing the patient's profile before filling a prescription for a controlled substance, contacting the prescriber with any concerns about the type, dosage frequency or amount of medication prescribed, and documenting those communications.

128. Not until 2012, years after the opioid epidemic was in full force in Kentucky, did CVS generate a written policy entitled the *Guidelines for Dispensing Controlled Substances* ("2012 Guidelines"), which explained in more detail the red flags or cautionary signals that CVS pharmacists should monitor to prevent diversion and to fulfill their corresponding responsibility to ensure that all controlled substances are dispensed for a legitimate medical purpose.

129. Some of the red flags include prescriptions from practitioners for multiple patients in the same dosage, preprinted or stamped prescriptions, patients who pay in cash, suspected forged or altered prescriptions, or patients that seem visibly intoxicated or incoherent.

130. The 2012 Guidelines advised pharmacists to contact the practitioner with any concerns about the type and quantity of medication and, when dispensing a controlled substance medication such as oxycodone or hydrocodone, "where you have no relationship with the patient and/or the prescriber, you should verify with the practitioner the validity of the prescription, by requesting the diagnosis (request a diagnosis code) and other information relevant to whether the prescription should be filled or declined." The 2012 Guidelines also stated: "Note that this verification process is but one step that a pharmacist should take to ensure that a prescription is issued for a legitimate medical purpose."

131. In 2014, CVS established a written policy entitled "Federal Regulations and CVS Pharmacy Guidelines for Controlled Substances" ("2014 Guidelines") that included additional guidance on dispensing controlled substances, including DEA regulations that require "that controlled substance prescriptions must be issued for a legitimate medical purpose and the regulations place 'corresponding responsibility' on the Pharmacist who fills the prescription."

132. The 2014 Guidelines also referred the CVS pharmacy employee to the 2012 Guidelines.

133. Even so, the sheer volume of controlled substances CVS dispensed in Kentucky indicates that its policies were not applied.

b. CVS Prioritized Speed And Volume Over Safety And Compliance

134. In addition, CVS had performance metrics in place that pressured pharmacists to fill prescriptions, and to fill them quickly, putting profits ahead of safety and compliance.

135. CVS used performance metrics related to its own profits, which relied, 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 meaningful measurement for pharmacy accuracy or customer safety. They did, however, prioritize speed and volume, which required pharmacists to meet wait- or fill-time expectations. Moreover, the bonuses for pharmacists were calculated, in part, on how many prescriptions a pharmacist filled within a year. Opioid prescriptions were even included in the volume goals until 2013, and after that time, the pressure from the metrics' focus on profitability remained. These policies remained in place even as the opioid epidemic raged. In 2020, pharmacists described CVS as the "most aggressive chain in imposing performance metrics."[43]

136. Former pharmacists at CVS have publicly complained about pressure to put speed ahead of safety. Concerning the metrics at CVS, one pharmacist commented, "You get stressed, and it takes your mind away from the actual prescriptions." Another former CVS pharmacist recalled that "[e]very prescription [wa]s timed," and a backlog would pop up in color on pharmacists' computer screens if they fell behind.[44] Additionally, CVS has faced discrimination

[43] *See* 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

[44] Sam Roe, Ray Long, and Karisa King, Contract Reporters, *Pharmacies Miss Half of Dangerous Drug Combinations*, Dec. 15, 2016, http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-pharmacy-met-20161214-story.html

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.

137. More recently, a former CVS pharmacist in North Carolina described being driven to leave his position and open his own pharmacy, where he could work safely. He described working a 13-hour shift with no breaks for lunch or dinner at CVS the day before he left in December 2018, a day on which he filled "552 prescriptions — about one every minute and 25 seconds — while counseling patients, giving shots, making calls and staffing the drive-through." In departing, he let his manager know that he would not "work in a situation that is unsafe." Another pharmacist was so alarmed that he wrote anonymously to the Texas State Board of Pharmacy to caution: "I am a danger to the public working for CVS."[45]

138. 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.

139. This pressure and focus on profits not only led to mistakes, but it also necessarily deterred pharmacists from carrying out their obligations to report and decline to fill suspicious controlled substance prescriptions and from exercising due care in ascertaining whether a prescription was legitimate.

140. 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

[45] 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

measured wait times contributed to dispensing errors, as well as that 49% felt specific time measurements were a significant contributing factor."[46]

141. 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 patients, and maintain attention to detail, which could ultimately lead to unsafe conditions in the pharmacy."[47]

142. Still, according to a 2016 investigation by the Chicago Tribune, as chain pharmacies increasingly promote quick service, "pharmacists frequently race through legally required drug safety reviews — or skip them altogether," missing dangerous drug combinations in the process.[48] A pharmacist too rushed to check for a potentially deadly drug interaction is also likely to be too rushed to check for red flags for diversion, such as prescription "cocktails" or other combinations of highly abused drugs.

143. The DEA explained these red flags for diversion to CVS in December 2010 at a meeting with CVS's representatives and counsel. The DEA identified "red flags . . . that a

[46] 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/.
[47] *Id*.
[48] Sam Roe, Ray Long, and Karisa King, Contract Reporters, *Pharmacies Miss Half of Dangerous Drug Combinations*, Dec. 15, 2016, http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-pharmacy-met-20161214-story.html.

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."[49]

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); and
- individuals driving long distances to visit physicians and/or to fill prescriptions.[50]

145. CVS's lack of adequate policies and procedures to protect against diversion and its failure to enforce policies because of its focus on speed resulted in Kentucky CVS pharmacies drastically oversupplying their communities.

146. The CVS Pharmacy located at 307 Sturgis Road in Marion, Kentucky bought over 2.8 million dosage units of oxycodone and hydrocodone from 2006 to 2014. Marion is located in Crittenden County, which has a population of 9,315. This CVS pharmacy bought enough opioids for every man, woman, and child in Crittenden County to have over 34 pills every year in this time period.

147. The CVS Pharmacy located at 30 South Kentucky Highway 15 in Hazard, Kentucky bought over 6.8 million dosage units of oxycodone and hydrocodone from 2006 to 2014. Hazard is located in Perry County, which has a population of 28,712. This CVS pharmacy bought enough opioids for every man, woman, and child in Perry County to have over 26 pills every year in this time period.

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

148. The CVS Pharmacy located at 1021 West Main St in Princeton, Kentucky bought over 2.8 million dosage units of oxycodone and hydrocodone from 2006 to2014. Princeton is located in Caldwell County, which has a population of 12,984. This CVS pharmacy bought enough opioids for every man, woman, and child in Caldwell County to have over 24 pills every year in this time period.

149. The culture CVS created undermined its pharmacists' and technicians' ability to adequately prevent diversion. CVS's quest for increased sales substantially contributed to the public nuisance in Kentucky. CVS knew these outrageous sales numbers and failed to stop the excessive flow of opioids into the Commonwealth of Kentucky.

c. Repeated DEA Enforcement Actions Confirm CVS' Systemic Failures

150. Nationally, CVS has been investigated for alleged violations of the CSA and has entered into settlement agreements with the DEA to resolve a number of investigations occurring between 2013 and 2019. The allegations include: 1) filling prescriptions from doctors who were not licensed to prescribe Schedule II drugs; 2) failure to timely report significant thefts of controlled substances; 3) failure to have adequate policies and procedures in place to prevent stolen narcotics; and 4) failure of CVS pharmacies to abide by its corresponding responsibilities.

151. One example of a DEA action against CVS for pharmacy activities arose out of two pharmacies in Florida. A CVS Pharmacist-in-Charge admitted to filling prescriptions for a large number of customers who presented the same "cocktail" of combination drugs known to signal abuse or diversion. She said that the majority of the diagnostic codes listed by the prescribing physician for these patients was the same. Twenty of the doctors whose prescriptions were being filled by these two CVS pharmacies in Florida had been the subject of civil and criminal disciplinary actions by the DEA for their prescribing practices. All but 4 of the 20 doctors' offices

were over 200 miles away from the CVS pharmacies filling prescriptions. Pharmacists admitted to filling prescriptions for patients that they believed were not medically necessary. In fact, one Pharmacist-in-Charge stated that she would hide some of her pharmacies' supply of OxyContin 30 mg pills for "the real pain patients."[51] CVS signed the settlement for this matter in December 2014 with payment to the DEA for $22 million.

152. The DEA also brought actions against CVS for pharmacy related violations. For example, an investigation by the U.S. Attorney's Office for the District of Rhode Island found that CVS retail pharmacies filled 39 prescriptions for Percocet that CVS pharmacists had reason to know were forged, in violation of the CSA. On April 16, 2019 CVS paid $535,000 for filling invalid prescriptions in Rhode Island pharmacies.[52]

153. In 2018, CVS paid a civil penalty of $1.5 million relating to its failure to timely report the loss or theft of controlled substances in certain of its New York stores, as well as a penalty of $1 million relating to record keeping violations in certain of its Alabama stores.

154. In 2017, CVS entered into a $5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.[53]

155. In February 2016, CVS paid $8 million to settle allegations made by the DEA and the United States Department of Justice ("DOJ") that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA by filling prescriptions with no legitimate medical purpose.

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[51] Declaration of Joseph Rannazzisi, *Holiday CVS, LLC d/b/a CVS/Pharmacy Nos. 5195/219 v. Eric Holder, Jr. et al.*, No. 1:12-cv-191, Doc. 19-6 ¶¶ 38-41 (D.D.C. Feb. 24, 2012).

[52] https://www.dea.gov/press-releases/2019/04/16/cvs-pay-535000-filling-invalid-prescriptions

[53] Press Release, U.S. Attorney's Office E. Dist. of Cal., *CVS Pharmacy Inc. Pays $5M to Settle Alleged Violations of the Controlled Substance Act*, U.S. 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.

156. In October 2016, CVS paid $600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.

157. 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.

158. In June 2016, CVS agreed to pay the DOJ $3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances — mostly addictive painkillers — more than 500 times between 2011 and 2014.

159. In August 2015, CVS entered into a $450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.

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

161. 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.

162. In April 2013, CVS paid $11 million in civil charges relating to allegations that its Oklahoma retail pharmacies created fake DEA license numbers, filled prescriptions for doctors without valid licenses, and improperly labeled prescription vials. A few months later, in August 2013, CVS was also fined $350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.

163. In 2010, CVS admitted to illegally selling pseudoephedrine to criminals who made methamphetamine and agreed to pay $77.6 million to resolve the government investigation.

164. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere were found to have intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.

165. Additionally, in Oklahoma, CVS was investigated for inadequate staffing of its pharmacies:

- Case Number 1568 – CVS #2324: The Oklahoma Board of Pharmacy fined CVS $75,000 and placed the store on a two-year probation after it was investigated for a misfilled prescription. The Board found the pharmacy was not adequately staffed.

- Case Number 1594 – CVS #06021: The Oklahoma Board of Pharmacy fined CVS $16,236.99. The complaint originated from a prescriber concerned about the patient care in the pharmacy due to lack of sufficient pharmacy staffing.

- Case Number 1593 – CVS #10491: The Oklahoma Board of Pharmacy fined CVS $18,814.29. The Board, among others, cited violation of OAC 535:15-3-16, which are the adequate staffing rules for pharmacists and pharmacies.

- Case Number 1595 – CVS #06109: The Oklahoma Board of Pharmacy fined CVS $14,948.34. The Board, among others, cited violation of OAC 535:15-3-16, which are the adequate staffing rules for pharmacists and pharmacies.

166. These investigations into CVS pharmacies demonstrate not just a problem in Oklahoma, but also a nationwide practice of over-working and under-staffing its pharmacies.

167. These enforcement actions and settlements across the country, for over more than a decade, are the product of policies and procedures that were implemented at a national level and would have impacted CVS's operations in Kentucky.

F. CVS Worked With Opioid Manufacturers To Promote Opioids And Improperly Normalize Their Widespread Use

168. CVS was a critical participant in the opioid manufacturers' campaign to create a sea change in the way opioids were used in the United States, including Kentucky. This campaign included spreading false messaging about the addictive nature of prescription opioids, creating the false perception that opioids should be widely used, actively promoting widespread opioid use, improperly increasing opioid sales beyond legitimate uses, and dismantling and undermining the last line of defense that was supposed to exist at the pharmacy level.

169. Instead of playing the critical gatekeeper role that pharmacies were supposed to play, CVS instead helped open the floodgates of dangerous opioid narcotics flooding into Kentucky.

170. Starting in the 1990s, opioids manufacturers created a carefully orchestrated campaign to change the utilization of prescription opioids in the United States, including Kentucky. CVS played a critical role in that campaign. For that campaign to work, the thousands of pharmacists employed by CVS and the patients they served had to be conditioned to accept the sea change in the use of opioids and be "re-educated" about their dangers. For prescription opioids to achieve the blockbuster sales that occurred, their widespread use had to be normalized not only with doctors but also pharmacists and patients.

171. CVS worked in concert with opioid manufacturers to ensure that the false messaging surrounding the treatment of pain and the true addictive nature of opioids was consistent and geared to normalize their widespread use.

172. For example, as early as 2001, CVS worked closely with Purdue Pharma and its un-branded marketing arm, Partners Against Pain ("PAP"), to "fight back" against allegations (later proved to be true) that Purdue's OxyContin was being abused at alarming rates. It was Purdue's PAP website that Purdue, and its "partners," including CVS, utilized to make the claims that the risk of addiction associated with OxyContin was very small.

PURDUE

Stephen L. Seid
Sr. Director, National Accounts and Trade Relations
(203) 588-7315

TO: Jim Lang **FROM:** Steve Seid

RE: **CVS Pharmacy** **DATE:** May 11, 2001

Jim, on May 2, 2001 Don Tasser and I met with three of the key pharmacy people at CVS. They were:

- Barry Jasilli, R.Ph., J.D., Director, Quality Improvement
- Susan DelMonico, R.Ph., J.D., Director, Regulatory Compliance
- Sharon Galzarano, R.Ph., Manager of Professional Practices

The goal of the meeting was to talk about mutually beneficial initiatives with CVS to improve education with their pharmacists. We also wanted to reiterate our position on ensuring availability of OxyContin® for appropriate patients. I think overall the entire meeting was very productive and the CVS people were extremely supportive.

Key issues discussed were as follow:

1. They were resolute in their commitment to good pharmacy practice. Part of that good pharmacy practice is ensuring availability of OxyContin for appropriate patients. Their goal is good patient care.
2. As a group they were vocal, particularly Barry Jasilli, indicating that they felt that Purdue was in many ways being victimized by the situation. That the product is not the issue, but that the abuser is the issue. He indicated that, from his perspective, we should be fighting back even harder. We should be pointing out the benefits of our brand.
3. CVS will be sending out a copy of our Abuse and Diversion Brochure to 4,100 pharmacies. Our letter will be personalized for the CVS pharmacist and cosigned by Barry Jasilli and Susan DelMonico. They will also be sending out a version of the Abuse and Diversion Brochure with their logo.
4. CVS will also put a copy of the Abuse and Diversion Brochure on their intranet site called RxNet.
5. They will be looking to utilize both of our written CE Programs, in particular, for new grads coming to work for CVS.
6. They talked about being more preemptive with our joint educational efforts. We will be setting up at least five programs at this time through CVS.
7. They talked about the possibility of co hosting programs in areas of healthcare professionals. I don't know if there was a unanimous agreement among the CVS people, but we will follow up to see if that is possible. Susan DelMonico will be the point person for CE Programs.

I believe we are garnering some significant support with CVS. Don Tasser will ensure follow up on these key programs.

173. Purdue worked together with CVS to ensure that CVS's own pharmacists were trained by Purdue on many of the misleading marketing messages that would later form the basis for Purdue's 2007 criminal guilty plea and $600 million fine for misleading the public about

OxyContin's risk of addiction and its potential for abuse. CVS's ties to PAP were so deep that it put its own logo on communications from its "partner."

PARTNERS AGAINST PAIN®

CVS/pharmacy

June 2001

Dear CVS Pharmacists:

CVS is proud to participate in Partners Against Pain®, a therapeutic alliance of pharmacists, physicians, nurses, and pain experts, sponsored by Purdue Pharma. We acknowledge the legitimate concern of pharmacists over the diversion of opioid medications.

That's why we recently developed, and have enclosed, "How to Stop Drug Diversion & Protect Your Pharmacy." Included in this guide are such helpful tips from the U.S. Drug Enforcement Administration, such as:

- How to detect prescriptions that have been "rinsed" blank and rewritten
- Confirming prescriptions using a published phone number – not the number on the prescription – if you have doubts about any aspect of it

Treating people in pain is a top priority. Purdue is a leader in educating the healthcare community on effective pain management and the appropriate use of pain medicines. Why? Because we believe that education and open communication are keys to effective pain control.

Along with hundreds of educational programs and brochures, Partners Against Pain sponsors the award-winning website – www.partnersagainstpain.com – which provides pain information, assessment tools, and support – 24 hours a day. We hope you and your customers will visit this site, and that the enclosed brochure will help you in your efforts to serve your customers and protect your pharmacy from drug diversion.

Provide the right patients, with the right pain medicine, at the right dosage, under the right supervision. Together, let's treat the pain. Please share a copy of this letter with your technician.

Sincerely,

Dr. Robert F. Reder, V.P.
Medical Affairs & Worldwide Drug Safety
Purdue Pharma L.P.

Barry Jasilli, R.Ph., JD
Director, Quality Improvement
CVS Corporation

cc: Philip Keough, R.Ph.
Director, Pharmacy Operations

Sharon Galzarano, R.Ph.
Manager, Professional Practices

Susan DelMonico, R.Ph., JD
Director, Regulatory Compliance
CVS Corporation

PURDUE

One Stamford Forum, Stamford, Connecticut 06901-3431 Telephone (203) 588-8000 Fax (203) 588-8850
www.partnersagainstpain.com

174. CVS was so eager to ally itself with Purdue and its profits that it solicited Purdue for its participation in "mutually beneficial" continuing education programs for healthcare providers and pharmacists regarding the diversion and abuse of prescription opioids. The themes of these programs included "how to communicate effectively with patients and physicians regarding appropriate pain management" – frequently "code" for opioids – and "how to resolve potential conflict with a drug 'seeker.'"

175. CVS's role was not limited to expanding the market for prescription opioids. CVS also helped to grow the demand for prescription opioids and contributed to the opioid epidemic in Kentucky and elsewhere by participating in the marketing, advertising and promotion of opioid products with and on behalf of other opioid manufacturers beyond Purdue.

176. One example of this contribution can be found in CVS's work with Endo Pharmaceuticals ("Endo") to increase patient adherence in continuing their use of opioids. In fact, CVS had such an important role in the promotion of Opana ER, a highly abused opioid manufactured by Endo, that it was included as having a crucial role in carrying out one of key sales tactics in Endo's 2012 Business Plan.

177. Through a company called Catalina Health ("Catalina"), Endo targeted OxyContin patients in areas where Opana ER had preferred formulary status. Catalina in turn worked to create a brand loyalty program that kept new patients on their opioids. CVS sent letters to the patients' homes to encourage them to stay on Opana ER – even though prolonged use of opioids increases the risk of addiction, and even though patients in pain presumably need no reminder to continue to take their pain medications. CVS formalized its agreement to promote, market and advertise Endo's opioid products via its "CVS Carecheck Plus Patient Education Service." Under this

agreement, CVS not only contractually agreed to promote Opana ER to its customers (patients) at the point of sale, but even insisted upon reviewing and ***approving*** the specific messaging used.

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

Beneficial for both new and existing products, the *Rx*Deals offering is customized to meet your unique needs and is designed to provide special offers – rebates or off-invoice discounts – to retail chain and independent pharmacies, including CVS and Walgreen's, to help move your product.

Contact your Marketing and Business Development Sales Representative today and *Rx*Deal your way to maximizing your sales!

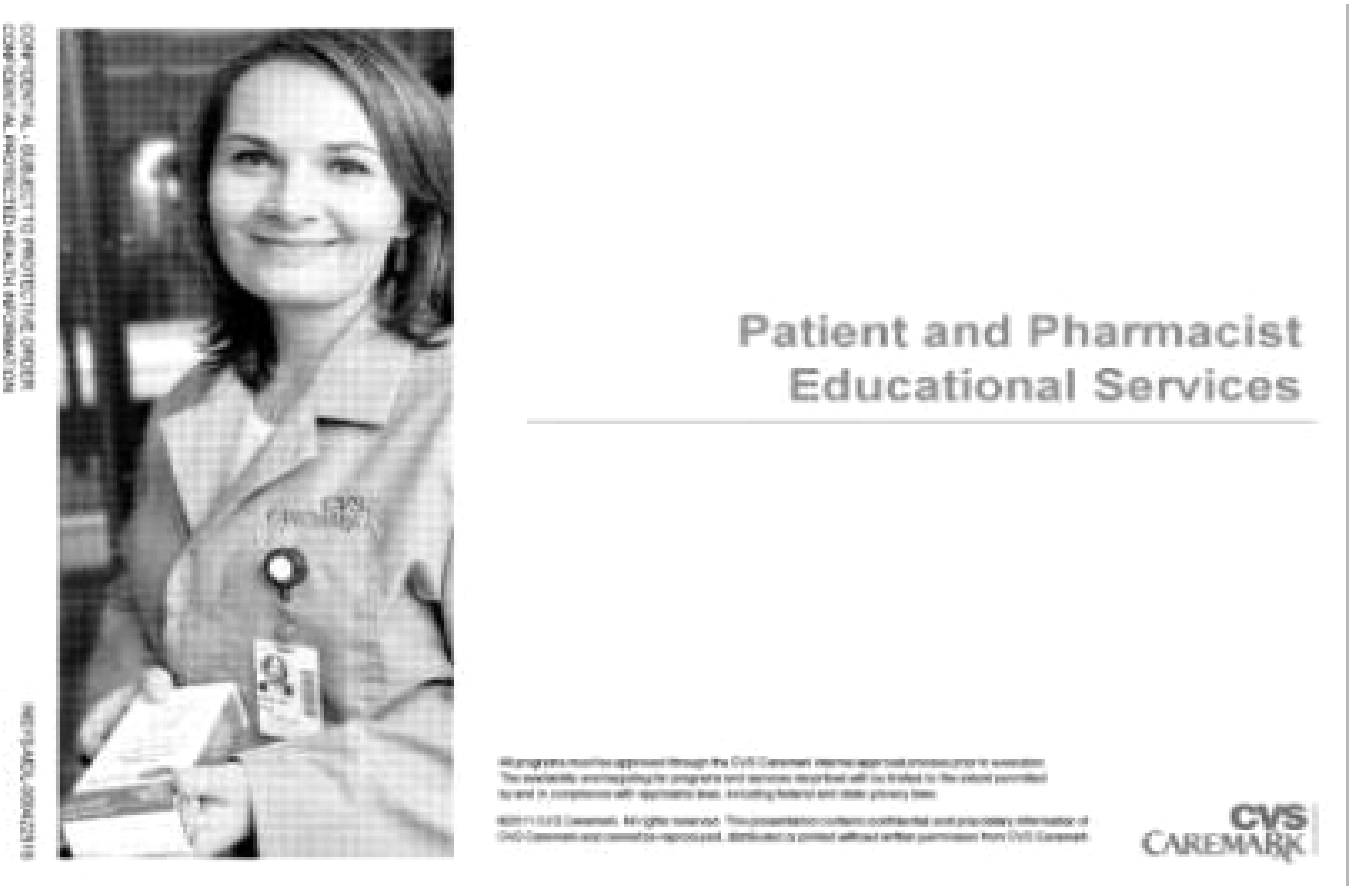
»View this week's *Service* ***Flash***

Thanks and have a great week!

The Marketing and Business Development Sales Team

Jeff Foreman, RPh
Vice President, Strategic Purchasing / Branded Purchasing
Office: 614.757.6674
jeff.foreman@cardinalhealth.com

179. Marketing, advertising and promoting opioids was not a new practice for CVS. In fact, CVS had been advertising these services to manufacturers for years. For example, CVS made at least one pitch to Insys, a company whose senior executives were recently criminally convicted for their unlawful marketing, to help sell its especially potent opioid, Subsys, a liquid form of fentanyl.



180. CVS also touted the reach of its communications and explained the science behind its sophisticated marketing, advertising and promotional services.

Pharmaceutical Services

Get the medicine Right.....

...with the right educational communications.

NewScript Rx
Clinical FoCVS
Rx Literature Display
Rx Edge®
CareCheck Plus
ExtraCare

Communicate your product's unique clinical benefits to thousands of targeted individuals.

CVS CAREMARK

Pharmaceutical Services: Overview

RPh	**NewScript** **Clinical FoCVS**	**MEDICAL PUBLICATIONS TO RETAIL PHARMACISTS** Clinical reviews of targeted products or recently launched products published in hard copy and electronically.
Retail Stores Patient Messaging	**Rx Literature Display** **Rx Edge** **CareCheck Plus** **ExtraCare**	**STRATEGEICALLY PLACED INFORMATION FOR PATIENTS** Executed across all CVS retail locations, literature directed towards patients within store aisles and at point of sale.

CVS CAREMARK Rx

181. CVS recognized its expertise in ensuring that opioid manufacturers like Insys were able to reach their intended market by using CVS's promotional programs, which are designed to "deliver results."

182. Through CVS's NEWScript program, CVS claimed to be perfectly poised to assist with new product launches.

NewScript: hard copy & electronic

CVS NEWScript:

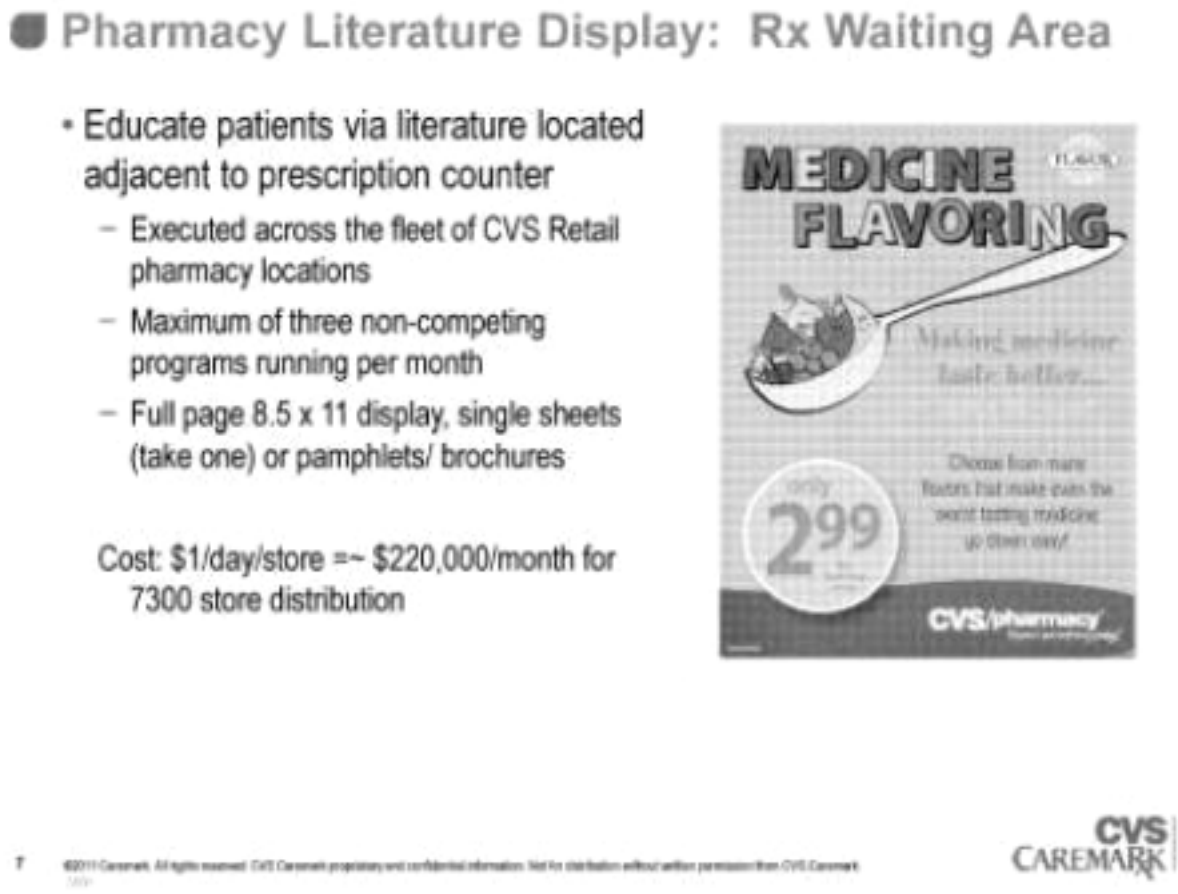
Designed for new product launches.

Prepares pharmacists for first scripts to arrive.

- **Brief summary (one page) authored by CVS' Clinical Department**
- **Designed to create immediate pharmacist awareness of brand launch.**
- **Publication is strategically timed-typically 1 week prior to product arriving at store**
- **Published in hard copy format and soft copy format as follows:**
  - Hard Copy distribution to entire chain via red bag delivery (internal delivery system)
    - ~ 7,300 stores, ~23,000 pharmacists
  - Posted to CVS Intranet site (RxNet)
  - Email communication to stores with link direct link to RxNet NEWScript
- **Lead time is 4 weeks**
- **Base cost: $40,000 (addl options available)**

CVS CAREMARK

183. CVS even offered Insys the chance at having a literature display in its waiting areas and to help Insys "target patients" using its signature ExtraCare consumer loyalty card database.



G. CVS Fueled, Sustained, And Expanded An Opioid Epidemic In Kentucky

184. The opioid epidemic in America is unparalleled. On August 10, 2017, President Donald Trump declared America's opioid epidemic to be a national emergency. According to the Centers for Disease Control ("CDC"), the most recent data estimates that 142 Americans die every day from a drug overdose. Drug overdoses now kill more people than gun homicides and car crashes combined. Between 1999 and 2015, more than 560,000 people in this country died due to

drug overdoses. Approximately 6 out of 10 drug overdose deaths are caused by opioids.[54]

185. According to the DEA, for every one unintentional opioid overdose death in 2010, there were another 108 persons with abuse or dependency issues, and 733 nonmedical opioid users.[55]

186. Opioids are the prime contributor to the addiction and overdose crisis. In 2015, nearly two-thirds of drug overdoses were linked to opioids like Percocet, OxyContin, heroin, and fentanyl. Americans consume more opioids than any other country in the world, over 47 doses per 1,000 persons per day from 2013 to 2015.[56] In 2015, the amount of opioids prescribed in the United States was enough for every American to be medicated around the clock for three weeks.[57]

187. The United States has a dire situation on its hands. The troubling reality for states like Kentucky, Ohio, and West Virginia is sadly much worse. Kentucky's overdose fatalities, which were already high, increased dramatically in 2015. From February 1, 2016, to January 31, 2017, pharmacies in the Commonwealth filled prescriptions for 307,234,816 doses of Schedule II prescription drugs, which breaks down to 69 doses of Schedule II narcotics for every man, woman, and child in the Commonwealth. Overdose deaths of Kentucky residents, regardless of where the death occurred, and non-residents who died in Kentucky, numbered 1,249 in 2015, topping the already unacceptable 1,088 overdose deaths in 2014.[58] In 2015, drug overdoses accounted for

[54] Letter from President's Commission on Combating Drug Addiction and the Opioid Epidemic to the President of the United States (Nov. 1, 2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.
[55] *See* https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2015/march_2015/prevoznik.pdf at 26.
[56] International Narcotics Control Board Report 2015, Table XIV.1.a., p 226, https://www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2016/NAR_Part_IV_Tables_EFS.pdf, (last accessed June 4, 2018).
[57] Letter from President's Commission on Combating Drug Addiction and the Opioid Epidemic to the President of the United States (Nov. 1, 2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.
[58] 2015 Overdose Fatality Report, Kentucky Office of Drug Control Policy https://odcp.ky.gov/Documents/2016%20ODCP%20Overdose%20Fatality%20Report%20Final.pdf.

59.17% of Kentucky's statewide accidental deaths, more than motor vehicle accidents, fire, drowning, and gunshot wounds combined. In 2015, opioids accounted for 46.63% of the statewide total of drug related fatal overdose victims.[59]

188. The CDC identified Kentucky as having a statistically significant drug overdose death rate increase from 2014 to 2015 and again from 2015 to 2016.[60] According to the CDC, in 2015 Kentucky and Ohio shared the 2nd highest overdose rate in the country. Data from 2013 onward shows that Kentucky has the 3rd highest drug overdose mortality rate in the country.[61]

189. Kentucky has one of the highest rates of prescriptions for opioids in the nation.[62] These statistics reflect the fact that Kentucky is one of the top states for over-distribution of opioids by distributors like CVS, and one of the top states for the over-dispensing of opioids by pharmacies like CVS.

190. Overdose deaths increased in 2016 in the Commonwealth.[63] That year, 1,404 drug overdose deaths occurred in Kentucky.[64] The number of lives lost statewide to drug overdoses was nearly five-times that of car accidents, and one in four arrests were opioid related. The opioid-overdose reversal drug naloxone was administered in four out of every seven Emergency Medical Services runs; and on average, seven response calls per day were to drug-related incidents.[65]

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[59] *2015 Annual Report, Office of the Kentucky State Medical Examiner* https://odcp.ky.gov/Reports/2016%20annual%20report.pdf.
[60] Drug Overdose Death Data, Centers for Disease Control (CDC), https://www.cdc.gov/drugoverdose/data/statedeaths.html (last visited October 22, 2017).
[61] *See* http://www.healthyamericans.org/reports/drugabuse2013/release.php?stateid=KY (last accessed on October 21, 2017).
[62] http://www.bgdailynews.com/news/kentucky-in-top-states-in-painkiller-prescriptions/article_0d8d0555-47e1-5717-b042-e3d53e7f3ee2.html (7/12/14) (accessed on October 22, 2017)
[63] 2016 Overdose Fatality Report, Kentucky Office of Drug Control Policy, https://odcp.ky.gov/Documents/2016%20ODCP%20Overdose%20Fatality%20Report%20Final.pdf.
[64] *Id*.
[65] New Online Tool Uses Data to Show Impact of Opioids, Oct. 9, 2016, https://nkyhealth.org/2016/10/09/new-online-tool-uses-data-to-show-impact-of-opioids/?search=opioid.

191. Opioid addiction and misuse also resulted in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of naloxone, the antidote to opioid overdose. For example, Louisville Metro Police Major, Eric Johnson, said that the police force administered 123 doses of naloxone in one six-week period between January 1 and February 15, 2017.[66] One opioid addiction treatment center in Paducah, Kentucky doubled in size to meet the growing needs of the community. The center reports seeing as many as 300 patients, of all ages and from all backgrounds, for addiction to prescription opioids, heroin, and fentanyl. Law enforcement officers in Kentucky similarly observed opioid addiction and abuse affecting people across varying ages and demographics.

192. Rising opioid use and abuse have other negative social and economic consequences as well. According to a 2016 study by a Princeton economist, the increase in opioid prescriptions from 1999 to 2015 could account for roughly 20% of the decline in labor force participation for men and 25% for women. Two-thirds of the surveyed men, not in the labor force and taking pain medication daily, said they took *prescription* painkillers — compared to just 20% of employed men.[67]

193. Prescription drug abuse causes an increase in crimes such as domestic violence, burglaries, and thefts. An estimated 90% of defendants in Floyd County are prosecuted for crimes related to prescription drug abuse or diversion. A report from a 2012 Prescription Drug Abuse Summit in Kentucky noted that the "pill explosion" had increased armed robberies to six per month in areas of Kentucky, when there were previously two to three per year in the same area. One corrections officer estimated that nearly all of the inmates in a Woodford County jail were

[66] Beth Warren, *Louisville EMS slammed with 151 overdose calls*, Courier Journal, https://www.courier-journal.com/story/news/local/2017/02/15/louisville-ems-slammed-151-overdose-calls/97938040/

[67] Alan Krueger, Where have all the workers gone? An inquiry into the decline of the U.S. labor force participation rate, https://www.brookings.edu/wp-content/uploads/2017/09/1_krueger.pdf (last accessed June 8, 2018).

struggling with addiction, that almost all of the inmates with drug problems started with abusing opioids, and that 90% of the crimes for which they were convicted were drug related.[68]

194. Children have not been spared by the opioid epidemic. As of January 2017, there were over 8,000 children in foster care in Kentucky, compared to 6,000 in 2012, most commonly because of their parents' abuse of drugs or alcohol. According to one foster-parent recruiter, the increasing number of children in foster care in Ashland, Kentucky has reached a "crisis point" as a result of the opioid epidemic.[69]

195. School districts have also seen a dramatic increase in suspensions of high school students, relating to possession of, distributing, or being under the influence of prescription drugs.

196. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from NAS.[70] These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life threatening.

197. NAS has become a great source of concern within the Commonwealth. In Kentucky, from August 1, 2014 until July 31, 2015, there were 1,234 cases of NAS reported to the

[68] Cara Salvatore, *Walgreens' Dual Role Helped Spur Ky. Opioid Crisis, AG Says*, Law360, https://www.law360.com/articles/1054196/walgreens-dual-role-helped-spur-ky-opioid-crisis-ag-says
[69] States hit hard by opioid epidemic see increase in foster care kids, North Jefferson News, Jan. 19, 2017.
[70] *See* Annual Report, Neonatal Abstinence Syndrome in Kentucky, https://chfs.ky.gov/agencies/dph/dmch/Documents/DPHNASReport2016.pdf (last accessed June 8, 2018).

Kentucky Department of Public Health. This translates to about 100 newborns per month. As recently as March 2018, Madison County officials, including healthcare providers and social workers, held a conference in order to solve the increasing problem of pregnant women being addicted to opioids. The goal of the conference was to create a plan that would provide support to mothers and families after giving birth, and the plan is currently in process.[71]

198. Faced with increased tolerance, addicted people are compelled to seek out higher and stronger doses. Heroin produces a very similar high to prescription opioids for a much lower cost. As a result, addicted opioid users soon find themselves turning to street drugs to satisfy the cravings and withdrawal of addiction created, in part, by irresponsible practices by distributors and pharmacies. The rise in prescription opioid use and abuse has triggered resurgence in heroin abuse, imposing additional burdens on states and local governments that address heroin use and addiction, including in the Commonwealth of Kentucky.

199. The Substance Abuse and Mental Health Services Administration) Center for Behavioral Health and Statistics Quality reports that four out of every five new heroin users begin with use of prescription opioids.[72] Opioid addiction feeds heroin addiction, as heroin produces similar highs and costs substantially less to the user. According to the CDC, the percentage of heroin users who also use opioid pain relievers rose from 20.7% between 2002 and 2004 to 45.2% between 2011 and 2013. More current studies cement the connection between heroin and prescription opioids.[73]

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[71] http://www.wkyt.com/content/news/Madison-County-health-officials-hold-conference-on-helping-drug-addicted-babies-475682753.html (last visited March 3, 2018).

[72] *See id. See also* Centers for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/index.html (last accessed Feb. 15, 2018).

[73] *See* Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016), Ctrs. for Disease Control and Prevention, *MMWR Report* (March 17, 2017) https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm?s_cid=mm6610a1_w.

200. Dr. Robert DuPont, former director of the National Institute on Drug Abuse and former White House drug czar, opined that opioids are more destructive than crack cocaine:

> "[Opioid abuse] is building more slowly, but it's much larger. And the potential[] for death, in particular, [is] way beyond anything we saw then. . . . [F]or pain medicine, a one-day dose can be sold on the black market for $100. And a single dose can [be] lethal to a non-patient. There is no other medicine that has those characteristics. And if you think about that combination and the millions of people who are using these medicines, you get some idea of the exposure of the society to the prescription drug problem."[74]

201. Northern Kentucky, in particular, has witnessed the effects of the opioid epidemic and resulting upswing in heroin use.[75] In Northern Kentucky, one person died from a drug overdose every 40 hours in 2015. The Northern Kentucky Health Department logged 37 cases of HIV-positive patients in 2017, with 18 of those cases reporting injection drug use among their risk factors for contracting the disease. This is a significant increase compared to the 5 HIV cases with injection drug use as a risk factor reported in 2016.[76] The substantial increase in HIV cases is another tragic result of the opioid epidemic.[77]

202. Beyond the dangers associated with heroin, a new drug has emerged with far more serious risks: synthetic fentanyl and its analogs like carfentanil. In 2016, the Kentucky Office of Drug Control Policy reported that 47% of all overdose deaths involved fentanyl, either alone or combined with heroin.[78] The increases in opioid related overdose deaths coincides with increases

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[74] Transcript, Use and Abuse of Prescription Painkillers, The Diane Rehm Show (Apr. 21, 2011), at http://thedianerehmshow.org/shows/2011-04-21/use-and-abuse-prescription-painkillers/transcript.

[75] *See* https://odcp.ky.gov/Pages/The-Heroin-Epidemic.aspx ("The growing number of people who began abusing expensive prescription drugs are switching to heroin") (last accessed June 8, 2018).

[76] Health officials see increase in HIV infection among individuals who inject drugs, Jan. 9, 2018, https://nkyhealth.org/2018/01/09/health-officials-see-increase-in-hiv-infection-among-individuals-who-inject-drugs/?search=HIVcount

[77] *See* CDC "Viral Hepatitis" https://www.cdc.gov/hepatitis/featuredtopics/youngpwid.htm (last accessed June 4, 2018).

[78] Commonwealth of Kentucky Justice & Public Safety Cabinet 20116 Overdose Fatality Report, 2 https://odcp.ky.gov/Documents/2016%20ODCP%20Overdose%20Fatality%20Report%20Final.pdf

in heroin and fentanyl use across the country, and has been shown to be closely tied to opioid pain reliever misuse and dependence. Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use, specifically among persons who report past-year dependence or abuse.[79]

H. Injury To Kentucky Resulting From CVS's Actions

203. Upon information and belief, the Commonwealth has been damaged by Defendants' unfair, false, misleading, or deceptive acts or practices in the conduct of the pharmaceutical wholesale trade or commerce by failing to investigate, report, and cease fulfilling "suspicious" orders of controlled substances to pharmacies in the Commonwealth.

204. Upon information and belief, the Commonwealth has been damaged by Defendants' negligent and/or intentional and reckless actions by failing to investigate, report, and halt "suspicious" orders of controlled substances to pharmacies in the Commonwealth.

205. Upon information and belief, the Commonwealth has been damaged by the continuing public nuisance created by Defendants' actions by failing to investigate, report, and halt "suspicious" orders of controlled substances to pharmacies in the Commonwealth.

206. Upon information and belief, the Commonwealth has been damaged by Defendants' unfair, false, misleading, or deceptive acts or practices in the conduct of the pharmaceutical dispensing by failing to investigate, report, and cease dispensing "suspicious" prescriptions of controlled substances at their pharmacies in the Commonwealth.

207. Upon information and belief, the Commonwealth has been damaged by Defendants' negligent and/or intentional and reckless actions by failing to investigate, report, and cease dispensing "suspicious" prescriptions of controlled substances at their pharmacies in the Commonwealth.

[79] *Id.*

208. Upon information and belief, the Commonwealth has been damaged by the continuing public nuisance created by Defendants' actions by failing to investigate, report, and cease dispensing "suspicious" prescriptions of controlled substances at their pharmacies in the Commonwealth.

209. Defendants' actions have caused and will continue to cause the Commonwealth to expend substantial sums of funds from the Commonwealth's Treasury to deal with the effects of the opioid epidemic that was substantially fueled by Defendants' illegal and reckless action in flooding the Commonwealth with highly addictive opioid prescriptions, without regard for the consequences to the Commonwealth and its citizens.

210. The Commonwealth of Kentucky hereby seeks recuperation of the damages and costs it was forced to expend by virtue of Defendants' failure to act in accordance with the various laws cited herein, general disregard for the law, misrepresentations, actions, and inactions with regard to the distribution and dispensing of opioids in the Commonwealth's communities.

211. The scope of conduct alleged herein has proximately caused damages to Kentucky in the form of a multigenerational health care epidemic of addiction and resulting disease and deaths. Despite being acutely aware of the risks of oversupplying opioids, and despite being acutely aware of the increases in orders which were suspicious, Defendants continued to oversupply opioids to Kentucky.

212. The Attorney General, in fulfilling his duties and exercising his authority under Kentucky law, brings this action to stop the harmful conduct, reverse the effects of the opioid epidemic, and hold Defendants accountable for their misdeeds.

V. CAUSES OF ACTION

COUNT I
Deceptive Acts and Practices in Violation of Kentucky Consumer Protection Act (KRS 367.110 *et seq.*)

213. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

214. Kentucky's Consumer Protection Act ("KCPA"), KRS 367.110 *et seq.*, prohibits "[u]nfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce." KRS 367.170.

215. Under KRS 367.190, "[w]henever the Attorney General has reason to believe that any person is using, has used, or is about to use any method, act or practice declared by KRS 367.170 to be unlawful, and that proceedings would be in the public interest," he may seek injunctive relief.

216. The Commonwealth is included among the persons in interest to whom the Court may order restoration of money or property under KRS 367.200.

217. The unfair, false, misleading, and/or deceptive acts committed by Defendants constitute a breach of the duties enumerated under Kentucky law, including but not limited to the KCPA.

218. At all times relevant to this Complaint, CVS violated the KCPA by engaging in unfair, false, misleading, and/or deceptive acts or practices in the distribution and dispensing of opioids, as well as by working with opioid manufacturers to promote opioids. These acts or practices are unfair in that they are unconscionable, offend public policy, and are immoral, unethical, oppressive, or unscrupulous.

219. Defendants' unfair, false, misleading, and/or deceptive acts or practices include, but are not limited to the following: Defendants shipped prescription opioids into the Commonwealth without adequate suspicious order monitoring systems, policies, and procedures in place and without the necessary due diligence to detect and prevent suspicious orders or prevent the public health crisis that has ensued. Defendants failed to maintain adequate policies and procedures to detect and prevent diversion at their retail pharmacies. Defendants permitted prescriptions to be filled in violation of Kentucky law and permitted orders for opioids from their pharmacies to be filled and go unreported in violation of Kentucky law. Defendants dispensed prescription opioids where the prescription for the drug was not in accordance with the law, including prescriptions that were not written for a legitimate medical purpose and/or by a physician acting outside of his normal practice. Defendants filled prescriptions despite the existence of red flags indicating abuse, misuse, and diversion. Defendants further failed to refuse to fill prescriptions where substantial red flags were present. Instead, Defendants filled prescriptions and dispensed opioids where it was facially apparent that the opioids would be misused, abused, and otherwise diverted. Finally, Defendants also worked with opioid manufacturers to promote opioids.

220. In addition, Defendants concealed vital knowledge and information from the Commonwealth of Kentucky, its agents and employees, resulting in significant harm to the public coffers.

221. These acts constitute an inherent violation of the KY CSA, which was created in the interest of protecting Kentucky consumers.

222. For each of Defendants' willful violations of KRS 367.170, the Commonwealth is entitled to recover a civil penalty of not more than two thousand dollars ($2,000) per violation, or

a civil penalty of not more than ten thousand dollars ($10,000) per violation where Defendants' conduct is directed at a person aged sixty (60) or older and Defendants knew or should have known that the person aged sixty (60) or older is substantially more vulnerable than other members of the public.

COUNT II
Continuing Public Nuisance

223. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

224. Public Nuisances are a "Class of wrongs which arise from the unreasonable, unwarrantable, or unlawful use by a person of his own property and produces such material annoyance, inconvenience, discomfort, or hurt that the law will presume a consequent damage." *City of Somerset v. Sears*, 313 Ky. 784, 233 S.W.2d 530 (1950) (quoting 39 Am. Jur., Nuisances, Section 2). The method in which a defendant acts or conducts its operation can, in and of itself, create an actionable nuisance. *See West Ky. Coal Co. v. Rudd*, 328 S.W.2d 156, 160 (Ky. 1959). Such actions are prosecuted under common law principles. *See* KRS 411.500.

225. Defendants' conduct constitutes a public nuisance that, if unabated, will continue to threaten the health, safety, and welfare of Kentucky's citizens.

226. Defendants sold, distributed, and dispensed opioid analgesics that lacked any legitimate medical or scientific purpose. Defendants unlawfully distributed and dispensed prescription opioids where Defendants knew, or reasonably should have known, such opioids would be diverted and/or used illegally.

227. Defendants intentionally and/or unlawfully failed to maintain effective and adequate controls against abuse, misuse, and diversion. Defendants did not have proper

monitoring, distributed suspicious orders of opioids without reporting, and failed to refuse to fill suspicious orders or prescriptions. Such actions were inherently dangerous to the welfare of Kentucky's communities.

228. As both a distributor and pharmacy, Defendants failed and refused to comply with the KY CSA, and the reporting requirements imposed therein, by wholly failing to report facially suspicious orders and failing to halt distribution and dispensing when appropriate.

229. Defendants shipped drugs into the Commonwealth without adequate policies or procedures in place to detect suspicious orders or prevent the public health crisis that has ensued. Defendants permitted prescriptions to be filled in violation of Kentucky law and permitted orders for opioids from Defendants' pharmacies to be filled and go unreported in violation of Kentucky law.

230. Defendants dispensed opioids where the prescription for the drug was not in accordance with the law, including prescriptions that were not written for a legitimate medical purpose and/or were written by a physician acting outside of his normal practice.

231. Defendants further failed to refuse to fill prescriptions where substantial red flags were present. Instead, Defendants filled prescriptions and dispensed opioids where it was facially apparent that the opioids would be misused, abused, and otherwise diverted.

232. Defendants also worked in concert with opioid manufacturers to spread false messaging about the addictive nature of prescription opioids, creating the false perception that opioids should be widely used, actively promoting widespread opioid use, improperly increasing opioid sales beyond legitimate uses, and dismantling and undermining the last line of defense that was supposed to exist at the pharmacy level. Defendants invited manufacturers to train and provide messaging to Defendants' pharmacists to ensure that those pharmacists would continue to fill as

many prescriptions as possible. These efforts also contributed to the massive increase in the number of opioids that were distribute and dispensed by Defendants and others, and they contributed to the public nuisance that currently exists in the Commonwealth.

233. Due to the actions of Defendants, opioid use and abuse in the Commonwealth of Kentucky increased substantially, with correlating increases in illicit drug use, crime, and overdoses. The effects of Defendants' actions created a public nuisance that is continuing in nature.

234. As a result of Defendants' actions, the Commonwealth was forced to utilize its limited resources to address drug addiction, crime, treatment and incarceration costs, and a plethora of providers operating pill mills or otherwise encouraging overutilization of opioids across the state.

235. Defendants caused a substantial and unreasonable interference with the public health, safety, welfare, peace, comfort and convenience, and ability to be free from disturbance and reasonable apprehension of danger to person or property.

236. Defendants are liable for all costs borne by the Commonwealth and its agencies, which were proximately caused by the Defendants' wrongful actions.

237. In addition to damages for past public nuisance by Defendants, Plaintiff requests relief barring any further such misconduct by Defendants in the Commonwealth, and more significantly, Plaintiff seeks to hold Defendants liable for abating, or cleaning up, the issues they have created.

238. Abatement of the now deep-rooted addiction and substance use disorders among Kentucky residents is a complex, expensive, and lengthy process. Defendants must be held accountable for their role in creating this nuisance, and correspondingly, are necessary parties to

the abatement.

COUNT III
Unjust Enrichment

239. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

240. Defendants created and maintained an artificial market for opioids within the Commonwealth that only served the purpose of spreading addiction and creating a reliable and growing stream of revenue.

241. Defendants received financial benefit from the excessive distribution and dispensing of opioids across Kentucky. The clear overuse and diversion was not reported to the appropriate authorities, because Defendants did not want to disrupt or diminish their highly profitable business practices.

242. Defendants were in the best position, as a pharmacy and distributor, to access information regarding opioid use and abuse, to refuse to fill prescriptions for prescription opioids that violated state law, and to prevent addiction by counseling patients who exhibited red flag signs indicating opioid misuse and abuse. Further, Defendants were in the best position to know of over-distribution of prescription opioids through their own information gathering systems.

243. Each time before expiration, Defendants renewed their licenses to operate as distributors and pharmacies in Kentucky, all the while misusing and abusing their privileges to do so by failing to report and halt suspicious orders, and by failing to inform the Commonwealth of Kentucky of their continuing violations.

244. Defendants were unjustly enriched and received an inequitable financial benefit as a result of their unlawful action. *See Rose v. Ackerson*, 374 S.W.3d 339, 343 (Ky. App. 2012).

Defendants should be required to disgorge all such unjust enrichment and to reimburse the Commonwealth for all sums to which Defendants were not entitled.

245. The Commonwealth expressly does not raise claims or seek any damages or restitution attributable to moneys paid out by the Commonwealth for prescription opioids through Medicaid or other programs. Additionally, the Commonwealth expressly does not raise claims or seek any damages for the Commonwealth's workers' compensation program.

COUNT IV
Negligence

246. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

247. Recovery for negligence requires establishment of the elements of duty, breach of duty, causation, and damages. *See*, *e.g.*, *Lewis v. B & R Corp.*, 56 S.W.3d 432, 436-37 (Ky. App. 2001). Duty is a fluid and elusive concept, and the court's decision regarding the existence of a duty is described as a "[p]olicy determination." *Id.*

248. Kentucky law has adopted a "universal duty of care," which requires every person to exercise ordinary care in his activities to prevent foreseeable injury. *See T & M Jewelry, Inc. v. Hicks ex rel. Hicks*, 189 S.W.3d 526 (Ky. 2006).

249. The applicable statutes and administrative regulations, as previously referenced herein, impose a duty on every opioid distributor to maintain and report data and to take affirmative action with regard to unusual volume or suspicious orders. However, beyond the statutory obligations, Defendants had a general duty to protect Kentucky's citizens by the nature of the business in which they engaged.

250. Defendants' actions constituted gross disregard for the people and government of

Kentucky, and those who purchased from Defendants and trusted Defendants to comply with laws regarding prescription opioid distribution.

251. It was industry knowledge that an abundance of potent opiates, and a lax tracking and reporting system, would provide opportunity for diversion, misuse, and overprescribing. The foreseeable risk of misuse and diversion is immediately apparent when discussing the disproportionate influx of opioids to low-populated areas. The resulting harms were foreseeable and known to Defendants.

252. Defendants failed and refused to comply with the KY CSA and the reporting requirements imposed therein by wholly failing to report facially suspicious orders and failing to halt distribution when appropriate.

253. Defendants shipped drugs into the Commonwealth without adequate policies or procedures in place to detect suspicious orders or prevent the public health crisis that has ensued. In violation of Kentucky law, Defendants permitted opioid prescriptions to be filled where red flag warnings indicated abuse, misuse, and diversion. Further, in order to supply the opioids for these unlawful prescriptions to its pharmacies, Defendants filled suspicious orders for opioids and failed to report them in violation of Kentucky law.

254. Defendants dispensed prescription opioids where the prescription for the drug was not in accordance with the law, including prescriptions that were not written for a legitimate medical purpose and/or were written by a physician acting outside of his normal practice.

255. Defendants further failed to refuse to fill prescriptions where substantial red flags were present. Instead, Defendants filled prescriptions and dispensed opioids where it was facially apparent that the opioids would be misused, abused, and otherwise diverted.

256. Defendants' breach of these duties was the proximate cause of the harms inflicted

upon Kentucky. The harm includes, but is not limited to, the financial damages of the Commonwealth in responding to the opioid epidemic and caring for its citizens.

257. The Commonwealth suffered significant financial damages as a direct and proximate result of Defendants' negligence.

258. Defendants breached the applicable duty of care with regard to prevention of foreseeable injury. Defendants are liable for all injuries resulting from their negligence.

259. The Commonwealth expressly does not raise claims or seek any damages or restitution attributable to moneys paid out by the Commonwealth for prescription opioids through Medicaid or other programs. Additionally, the Commonwealth expressly does not raise claims or seek any damages for the Commonwealth's workers' compensation program.

COUNT V
Breach of Statutory Duties/Negligence Per Se

260. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

261. Violation of a statute gives rise to a private right of action where the injured is within the class of persons the statute intended to be protected. This is true even where the statute is penal in nature and provides no civil remedy and extends to Kentucky administrative regulations concerning public safety adopted pursuant to an enabling statute.

262. Generally, Kentucky law expressly prohibits distributors from operating in a manner that endangers the public. *See* 201 KAR 2:105 § 7.

263. Kentucky Board of Pharmacy requires coordination and use of reported opioid distribution and sales data, and continued demonstration of, "Acceptable operational procedures, including . . . compl[iance] with all DEA regulations." *See* 201 KAR 2:105 § (4)(d), KRS

205.5634.

264. To promote public health with regards to the use of opioids, the Kentucky Agency for Substance Abuse Policy ("KY-ASAP") provides a statewide framework for anti-abuse and anti-diversion practices across the Commonwealth. KY-ASAP is currently being used in many Kentucky communities as the primary component of a comprehensive drug education/prevention, treatment, and law enforcement program.[80]

265. As a distributor and, separately, a pharmacy, Defendants had separate and distinct, though equally important, reporting requirements regarding dispensing and distributing opioids.

266. The Kentucky Legislature promulgated the KY CSA to promote the "[p]reservation of public safety and public health." KRS 218A.005(1). The KY CSA requires of Defendants, as distributors of controlled substances, to record all incidences of diversion of controlled substances, including opioids, and forward the record to the Cabinet for Health and Family Services. *See* KRS 218A.200. *See also* 218A.170; 902 KY Admin Reg. 55:010; 201 KAR 2:105 §2(4)(d).

267. The KY CSA further requires that Defendants create, maintain, and adhere to policies and procedures that protect against public health crisis, such as the opioid epidemic. *See* 201 KAR 2:105 §5(4).

268. Additionally, Defendants were required to ensure that opioid prescriptions filled by Defendants' pharmacies were written for a legitimate patient for a legitimate medical need in the usual course of practice for the prescriber. *See* KRS 218A.180(3).

269. The KY CSA creates a broad duty on the part of wholesalers to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids. These laws are intended to protect consumers from harm. *See* KRS 218A.200 (record keeping); 21 CFR 1301.74

[80] *See* https://odcp.ky.gov/Pages/Agency-for-Substance-Abuse-Policy.aspx (last visited October 21, 2017).

and KRS 218A.160(1)(a) (repealed); 218A.170; 902 KY. Admin Reg. 55:010 §42(b); 201 KAR 2:105 §2(4)(d)).

270. Defendants had a corresponding responsibility as a dispenser of opioids to observe red flags, refuse to fill prescriptions that were not written in accordance with the law, and counsel patients where necessary to optimize drug therapy. Defendants had a duty to provide adequate security and ensure that opioids were not being diverted.

271. Upon information and belief, Defendants failed and refused to comply with the KY CSA, and the reporting requirements imposed therein, by wholly failing to report facially suspicious orders and failing to halt distribution when appropriate.

272. Finally, additional Kentucky "pill mill" laws restrict improper access to opiates across the state and put in place reporting and data review protections to be enforced by various state agencies, including but not limited to, the state Department of Medicaid, the Cabinet for Health and Family Services, the state Board of Pharmacy, the state Office of Drug Control Policy, and the Kentucky Board of Medical Licensure.

273. These laws promote transparency regarding the wholesale distribution, prescribing, and use of opioids. Each agency may access and share information that protects against drug diversion, abuse and misuse, lawful use of state healthcare funds, and all harms incident to violations of those laws and regulations. Distributors who comply with the regulations allow the state agencies to track and analyze risk data and to implement safeguards to protect the Commonwealth.

274. The implementation of these programs and the sharing of information among these agencies is meaningless without the honest participation of wholesalers like Defendants.

275. Further, KRS 194A.505(6) provides: "No person shall, with intent to defraud or

deceive, devise a scheme or plan a scheme or artifice to obtain benefits from any assistance program by means of false or fraudulent representations or intentionally engage in conduct that advances the scheme or artifice." Likewise, KRS 205.8463 is violated through fraud or misrepresentation to the Cabinet of Health and Family Services. *See* KRS 205.8463(2), (4).

276. Upon information and belief, Defendants, as the wholesalers and private companies, have access to information that is otherwise unavailable to governmental entities striving to protect and care for their citizens. This information or data includes the real time transaction level records, the customer order thresholds, and the actual order and inventory records. However, Defendants hoarded the data and misled the federal and state government regarding the distribution and use of opioid analgesics. Defendants failed to comply with the mandatory reporting and data sharing requirements imposed by Kentucky law.

277. Specifically, Defendants' acts and omissions as alleged herein violated the above-referenced statutes, including KRS 205.8463, KRS 194A.505, and statutes implemented as public safety laws.

278. Defendants' violations of KRS 205.8463, KRS 194A.505, and other public safety laws are *prima facie* evidence of negligence. Defendants, at the least, had a duty to refrain from operating in a manner that endangered the public. Defendants had a duty to maintain effective controls against diversion of prescription opioids, secure the prescription opioids in their possession, and to guard against, prevent, and report suspicious orders of opioids. Defendants breached mandatory, non-delegable legal duties and did not act reasonably as a distributor and pharmacy, separately and together.

279. Additionally, and through the aforementioned failures, Defendants failed to maintain "acceptable operational procedures" pursuant to Kentucky law. Defendants' failure to

enact, or simply find guidance in, the framework proposed by KY-ASAP demonstrates Defendants' disregard for black letter law, guidelines, recommendations, and other methods to prevent the spread and abuse of prescription opioids.

280. Defendants' actions constituted negligence per se, as they are facial violations of existing law and regulations. The violations promoted the misuse and diversion of opioids across the Commonwealth.

281. Indeed, Kentucky has been harmed, as stated above, including through increases in addictions, the need for enforcement and treatment (including treatment of infants), and even deaths due to the actions of Defendants. Costs of harm to the public are logically traceable to Plaintiff, who is charged with the general protection of the Commonwealth.

282. Accordingly, Defendants' actions constitute negligence per se. Defendants are liable for all damages proximately caused by the breach of their statutory duties.

283. The Commonwealth expressly does not raise claims or seek any damages or restitution attributable to moneys paid out by the Commonwealth for prescription opioids through Medicaid or other programs. Additionally, the Commonwealth expressly does not raise claims or seek any damages for the Commonwealth's workers' compensation program.

COUNT VI
Civil Conspiracy

284. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

285. Defendants engaged in a civil conspiracy by unlawfully dispensing prescription opioids and/or distributing opioids into Kentucky.

286. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation

in conjunction with their unlawful dispensing of prescription opioids and/or distribution of opioids into Kentucky.

287. Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders and diversion of opioids.

288. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly caused the injuries alleged herein.

289. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

290. Defendants' conduct in furtherance of the conspiracy described herein was not mere parallel conduct, because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue engaging in their unlawful conduct.

291. Defendants' conspiracy and actions and omissions in furtherance thereof, caused the direct and foreseeable losses alleged herein.

292. Defendants' actions demonstrated both malice and aggravated and egregious fraud. Defendants engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct has a great probability of causing substantial harm.

293. Defendants' misconduct alleged in this case is ongoing and persistent.

COUNT VII
Punitive Damages

294. The Commonwealth realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

295. Punitive damages are given to a plaintiff over and above the full compensation for their injuries, for the purpose of punishing the defendant, teaching him not to do it again, and deterring others from following his example. *See Hensley v. Paul Miller Ford, Inc.*, 508 S.W.2d 759, 762 (Ky. 1974).

296. Defendants' repeated and excessive shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities, demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others, and justifies an award of punitive damages.

297. Further, acting as a pharmacy, Defendants dispensed prescription opioids at such an alarming rate and volume that there could be no legitimate medical purpose associated to their use. The only possible explanation for the massive amounts of opioids pouring into and out of Defendants' stores in Kentucky was that they were distributed to satisfy addiction and/or that the drugs were being misused, abused, or diverted.

298. Kentucky has suffered severe loss in terms of addiction, overutilization, diversion, law enforcement costs, increased cost of treating addiction, social ills related to addiction, and untimely death as a result of overdose and related illnesses.

299. Defendants' intentional and willful actions were the direct and proximate cause of the losses suffered by the Commonwealth.

300. For these reasons, KRS 411.184 authorizes an award of punitive damages upon a showing by clear and convincing evidence that the Defendants acted with fraud, oppression or malice. In addition, a plaintiff may show entitlement to punitive damages where the defendant has acted with gross negligence. *See Williams v. Wilson*, 972 S.W.2d 260, 264 (Ky. 1998). Plaintiff is entitled to the imposition of punitive damages against Defendants pursuant to KRS 411.184.

301. Gross negligence is a "[w]anton or reckless disregard for the lives, safety or property of others." *Phelps v. Louisville Water Co.*, 103 S.W.3d 46, 51-52 (Ky. 2003). The threshold for the award of punitive damages is whether the misconduct was "outrageous" in character, not whether the injury was intentionally or negligently inflicted. *Horton v. Union Light, Heat & Power Co.*, 690 S.W.2d 382, 389 (Ky. 1985).

302. In a case where gross negligence is used as the basis for punitive damages, gross negligence has the same character of outrage justifying punitive damages, as willful and malicious misconduct in torts, where the injury is intentionally inflicted. Just as malice need not be expressed and may be implied from outrageous conduct, so too may wanton or reckless disregard for the rights of others be implied from the nature of the misconduct. *Id*. at 389-90. A finding of gross negligence clearly requires more than a failure to exercise ordinary care; it requires a finding of a failure to exercise even slight care such as to demonstrate a wanton or reckless disregard for the rights of others. *See Phelps*, 103 S.W.3d at 51-52. *See also People's Bank of Northern Kentucky, Inc. v. Crowe Chizek & Co., LLC*, 277 S.W.3d 255, 268 (Ky. App. 2008).

303. Defendants engaged in fraudulent conduct and gross negligence that resulted in harm to the Plaintiff. As such, Plaintiff is entitled to punitive damages against Defendants.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that the Court grant the following relief:

A. Declaring that Defendants committed willful violations of KRS 367.170;

B. An Order permanently enjoining Defendants, and their employees, officers, directors, agents, successors, assigns, affiliates, merged or acquired predecessors, parent or controlling entities, subsidiaries, and any and all persons acting in concert or participation with Defendants, from future false, misleading, deceptive, and/or unfair acts or practices in relation to their shipment of controlled substances to the Commonwealth pursuant to KRS 367.190;

C. Permanently enjoining Defendants and their employees, officers, directors, agents, successors, assigns, affiliates, merged or acquired predecessors, parent or controlling entities, subsidiaries, and any and all persons acting in concert or participation with Defendants, from continuing their unlawful conduct, acts and practices, including:

1. Preventing Defendants from continuing to violate Kentucky laws;

2. Mandating that Defendants promptly notify the appropriate authorities of any and all suspicious orders for controlled substances as received from parties who are located in Kentucky;

3. Mandating that Defendants submit their system for determining suspicious orders to those Kentucky authorities for prior approval, and to enjoin Defendants from distributing any controlled substances in Kentucky for any non-legitimate medical purpose;

4. Mandating that Defendants provide Plaintiff with the assistance necessary to address the addiction and the resulting destruction left by Defendants' actions to abate the damage they have caused and are continuing to cause; and

5. Otherwise abate the public nuisance caused in whole or in part by Defendants.

D. Awarding civil penalties of $2,000 for each willful violation of the Kentucky Consumer Protection Act pursuant to KRS 367.990(2);

E. Awarding civil penalties of $10,000 for each violation of the Kentucky Consumer Protection Act pursuant to KRS 367.990(2), where Defendants' conduct was directed at a person aged sixty (60) or older, where Defendants knew or should have known that the person aged sixty (60) or older is substantially more vulnerable than other members of the public;

F. Awarding pecuniary damages for ongoing, past, and future losses and expenditures for addressing the opioid epidemic, except as otherwise limited;

G. Awarding punitive damages against Defendants pursuant to KRS 411.184;

H. Awarding the Commonwealth of Kentucky its costs and attorneys' fees;

I. Awarding the Commonwealth of Kentucky prejudgment interest as permitted by law;

J. Awarding any other relief to which the Commonwealth is entitled, or the Court deems appropriate and just;

K. For a trial by jury on all issues so triable;

L. Awarding such other relief as this Court deems just and fair.

Dated: June 2, 2021

Respectfully submitted,

DANIEL CAMERON
ATTORNEY GENERAL

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