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

COMMONWEALTH OF KENTUCKY, *ex. rel.*
RUSSELL COLEMAN, ATTORNEY GENERAL,

Plaintiff,

v.

THE KROGER CO.;
Corporation Service Company
421 W. Main Street
Frankfort, Kentucky 40601;

KROGER LIMITED PARTNERSHIP I
d/b/a Peyton's Southeastern
Corporation Service Company
421 W. Main Street
Frankfort, Kentucky 40601; and

KROGER LIMITED PARTNERSHIP II
d/b/a Peyton's Northern
Corporation Service Company
421 W. Main Street
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, Russell Coleman, brings this civil action against Defendants The Kroger Co., Kroger Limited Partnership I d/b/a Peyton's Southeastern, and Kroger Limited Partnership II d/b/a Peyton's Northern (collectively, "Defendants" or "Kroger"), and in support thereof states as follows:

I. INTRODUCTION

1. This civil enforcement action is brought by the Kentucky Attorney General against Defendants The Kroger Co., Kroger Limited Partnership I, and Kroger Limited Partnership II for their role in fueling the opioid epidemic in the Commonwealth through unlawful business practices.

2. Sadly, the phrase "Opioid Epidemic" 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.[1] 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 police force, filled state prisons, affected state-run hospitals and medical

[1] 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 the Federal Government categorizes most opioids as "Schedule II" drugs under the Controlled Substances Act ("CSA") due to their high potential for abuse and potential to cause severe psychological or physiological dependence.[2] (Hydrocodone was a Schedule III drug until its rescheduling to a Schedule II drug in 2014.)

5. From at least 1996, shortly after OxyContin was approved by the Food and Drug Administration ("FDA"), and continuing to the present, Kroger created, fueled, and maintained the opioid epidemic in Kentucky through their retail pharmacies, as dispensers of opioids to the public, as a wholesale distributor of opioids (other than Schedule II opioids), shipping prescription opioid orders to their own pharmacies.[3] Occupying two links in the opioid supply chain, Kroger 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 opioids distributed and dispensed by Defendants in Kentucky were suspicious on their face. As further explained herein, between 2006 and 2014 Kroger stores in Kentucky bought over 4 billion morphine equivalents of opioids, and in its role as a distributor, Kroger shipped over 1 million opioid shipments in Kentucky during the same time period.

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 suspicious orders of controlled substances to the Drug Enforcement Administration ("DEA") and refused to fill and reported

[2] *See* 902 KAR 55:015 §2; 21 C.F.R. 1308.12.
[3] Upon information and belief, Kroger distributed opioids only to their own pharmacies and did not distribute to third-party pharmacies.

suspicious prescriptions for controlled substances in their pharmacies.

8. More specifically, Kroger distributed massive amounts of suspicious opioid orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency to their own Kentucky pharmacies. Defendants shipped 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.

9. At the store level, Kroger 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 Kroger's stores in Kentucky is that they failed to identify, investigate and, where appropriate, refuse to fill suspicious prescriptions, 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 Kroger, a dominant retail pharmacy and distributor who were responsible for over 11% of the toral dosage units of opioids dispensed in Kentucky from 2006-2019 Kroger 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. Indeed, from 2007 to 2014, Kroger, upon information and belief, collectively reported zero suspicious orders from their Kentucky stores.

11. Further, by filling these orders, Kroger 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, Kroger 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, Kroger made dangerous and addictive drugs in America accessible. Accordingly, Kroger — situated to play significant roles as both wholesale distributor and retail pharmacy — acted to maintain or increase its profits and market dominance while creating a public nuisance of historic proportions.

13. Due to Kroger'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 Kroger was that patients would transition their use and abuse to illegal street drugs like heroin, and illicit forms of synthetic fentanyl like carfentanil.

14. Kroger'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. In 2020, Kentucky had the second-highest drug overdose death rate at 49.2 opioid-related deaths per 100,000 residents, behind only West Virginia. In 2021, Kentucky's drug overdose death rate increased to 55.6 opioid-related deaths per 100,000 residents, the fourth-highest death rate in the country. CDC data for later years has not been made publicly available. The Kentucky Office of Drug Control Policy reported 1,964 overdose deaths in 2020, a 49% increase from 2019. In 2021, there was a 14.5% increase in overdose deaths in Kentucky. That year Kentucky comprised 2,250 out of 107,000 national deaths, nearly twice its per capita share of the United States population. In 2022, for the first time in four years, Kentucky saw a slight decrease in drug overdose deaths with still a staggering 2,135.

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. The Commonwealth of Kentucky has been left — in the wake of Kroger'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 Commonwealth's child protective services program, need academic and behavioral supports, and may need lifetime monitoring and interventions.

17. Kentucky has further experienced an intense adverse effect on its workforce due to the opioid crisis, 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. Kroger reaped millions 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 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.

20. This action is against Kroger in its corporate capacity for its unlawful business practices in failing to maintain effective controls against diversion and failing to have proper systems in place to ensure prescriptions are dispensed for legitimate medical purposes. The Commonwealth's claims are not based on the professional services of any individual pharmacist regarding any individual customer. *Commonwealth v. CVS Health Corp.*, No. 21-CI-00445, Order at 5-6 (Ky. Franklin Cir. Ct. Jan. 19, 2022).

II. PARTIES

Plaintiff

21. Plaintiff, the Commonwealth of Kentucky, brings this action, by and through its Attorney General, Russell Coleman, 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. Russell Coleman 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

22. Defendant Kroger Co. is an Ohio corporation registered to do business in the Commonwealth of Kentucky and maintains its principal place of business in Cincinnati, Ohio.

23. Defendant Kroger Limited Partnership I, d/b/a Peyton's Southeastern, a subsidiary of Kroger Co., is an Ohio limited partnership registered to do business in the Commonwealth of Kentucky and maintains its principal place of business in Cincinnati, Ohio. Kroger Limited Partnership I holds a wholesaler license with the Kentucky Board of Pharmacy.

24. Defendant Kroger Limited Partnership II, d/b/a/ Peyton's Northern, a subsidiary of Kroger Co., is an Ohio limited partnership registered to do business in the Commonwealth of Kentucky and maintains its principal place of business in Columbus, Ohio. Kroger Limited Partnership II holds a wholesaler license with the Kentucky Board of Pharmacy.

25. Kroger Co., Kroger Limited Partnership I, and Kroger Limited Partnership II are collectively referred to herein as "Kroger."

26. Kroger operates approximately 2,256 pharmacies across the country. The Department of Pharmacy's website reflects that Kroger maintains two wholesaler licenses and 107 retail chain licenses. Kroger held these license numbers pursuant to multiple statutes and regulations, including the Kentucky Controlled Substances Act ("KY CSA"). Kroger is a dispenser, pharmacy, specialty limited pharmacy, and wholesaler (also referred to herein as distributor) under Kentucky law. *See* KRS 218A.010(11), (12); KRS 218A.170(1), (2); KRS 315.010(19), (28); KRS 315.400(21).

27. Between 2006 and 2014, Kroger stores in Kentucky bought over 4 billion morphine milligram equivalents ("MMEs") of opioids. In its role as a distributor, Kroger shipped over 1 million opioid shipments to Kentucky during this same time period.[4]

III. JURISDICTION AND VENUE

28. The Bullitt Circuit Court has personal jurisdiction over the Kroger defendants, as they are registered with the Secretary of State to conduct business in Kentucky and have 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. Kroger 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

[4] 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

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.

29. Bullitt 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.

30. 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. 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.

31. 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 Kroger. 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).

32. 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.

33. In this Complaint, Plaintiff cites or alludes to federal statutes, regulations, or agency memoranda. Plaintiff does so only to establish Kroger'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*.

34. Venue is appropriate in Bullitt 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 Bullitt Circuit Court.

IV. FACTUAL BACKGROUND

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

1. Duties Owed By Distributors Under Kentucky Law

35. Rather than permitting drug manufacturers to sell opioids directly to consumers, a sophisticated, closed distribution system exists to push these drugs across the nation. This sophisticated system arose out of the need for greater control over abused and addictive prescription drugs and is intended to track and account for controlled substances from point of manufacture to point of use by the ultimate consumer. The closed-system model contemplates manufacturers selling pharmaceuticals to distributors who distribute those pills to pharmacies that dispense the drugs to the ultimate consumer.

36. 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.

37. This closed system imposes specific duties upon wholesale distributors to monitor, identify, halt, and 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.[5] The purpose of these laws is to protect public health and safety.

38. 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).

39. Pharmaceutical distributors such as Kroger are key components of this closed 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

[5] 21 C.F.R. §§ 1301.12, 1301.71-1301.76.

way.

40. 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; 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 administers and enforces the KY CSA.

41. 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.[6] 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, and (3) been convicted under laws relating to drug samples and wholesale or retail drug distribution of controlled substances.[7] Applicants must also certify that they are "in compliance with all applicable federal and state laws and regulations relating to drugs." 201 KAR 2:105.

42. Upon information and belief, Kroger acknowledged this language with each application for license renewal and made sworn representations regarding the same. At all relevant times, Kroger has had a duty to comply with Kentucky's licensure requirements. *See* KRS

[6] 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).
[7] *Id*.

218A.150 (repealed); 201 KAR 2:105 *et seq.*

43. The federal CSA contains many of the same duties for Defendants, which are incorporated into Kentucky law. The Kentucky Board of Pharmacy requires continued demonstration of "[a]cceptable operational procedures, including . . . compl[iance] with all DEA regulations, if applicable." 201 KAR 2:105 § (2(5)(d)). *See also* KRS 218A.170 ("[a]ll sales and distributions shall be in accordance with KRS 218A.200 and the federal controlled substances laws"); *see also* KRS 218A.160(1)(a) (repealed 2018[8]) (requiring "compliance with all applicable federal and state laws and regulations relating to controlled substances"); KRS 218A.1404 ("no person shall dispense, prescribe, distribute, or administer any controlled substance except as authorized by law").

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.[9]

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

[8] Even though 218.160(1)(a) was repealed in mid-2018, it established Kroger's duty of care from 2005 through July 2018, or much of the relevant time period.
[9] 21 C.F.R. § 1301.74

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.

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 of the ordered drug family 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 of orders identified as potentially suspicious 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.[10]

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."[11]

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.

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

[11] *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*.

52. As an opioid distributor, Kroger 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.

54. 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).

55. 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, Kroger breached that duty and both created and failed to prevent a foreseeable risk of harm.

2. Duties Owed By Pharmacies Under Kentucky Law

56. In addition to their duties as distributors, Kroger 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;"[12] (g) prescriptions in volumes, doses, or 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.

57. Kentucky law mandates that all pharmacies apply for and receive a license from the Kentucky Board of Pharmacy. *See* KRS 315.035. Kroger must certify compliance with all applicable federal and state laws to maintain its licenses to distribute and dispense prescription opioids.

58. 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).

59. 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.[13]

60. 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

[12] *See, e.g., City & County of San Fran. v. Purdue Pharma L.P.*, --- F. Supp. 3d ---, 2022 WL 3224463, at *37 (N.D. Cal. Aug. 10, 2022) ("Drug cocktails consist of prescriptions for an opioid and a benzodiazepine, and may also include a muscle relaxant. These drug combinations can be abused and present special risks for patients) (internal citations and quotations omitted); *U.S. v. Campbell*, No. 3:17-cr-87-RGJ, 2021 WL 4142676, at *2 (W.D. Ky. Sept. 10, 2021) (quoting testimony presented at trial stating: "In Kentucky we have a thing called the cocktail which is muscle relaxants, benzodiazepines for depression, and opioids."); *U.S. v. Evans*, 892 F.3d 692, 698 (5th Cir. 2018) ("Evans was frequently prescribing a suspicious mix—the combination of an opioid, a tranquilizer, and a muscle relaxer. This assortment, according to Devido, was a well-known and highly abused drug cocktail.").

[13] Kentucky Board of Pharmacy, Controlled Substances Questions, https://pharmacy.ky.gov/Pages/Controlled-Substances-Questions.aspx (last accessed September. 28, 2022).

of Pharmacy:[14]

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

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

62. Defendants have legal duties specifically with respect to their dispensing practices under the federal 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."[15] The duty exists equally with the pharmacy employing the pharmacist.

63. Thus, Defendants, because they are registrants and dispensers, must ensure prior to dispensing that prescriptions of controlled substances are "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). The DEA has recognized that "as dispensers of controlled substances, pharmacists and pharmacy employees are often the last line of defense in preventing diversion."

64. "A prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice." 21 C.F.R. § 1306.06. As the Department

[14] *Id.*
[15] 21 C.F.R. § 1306.04(a).

of Justice's ("DOJ") 2020 lawsuit against Walmart alleges, 21 C.F.R. § 1306.06 requires that a pharmacist's conduct when filling controlled-substance prescriptions adhere to the usual course of a pharmacist's professional practice. The obligation to identify any red flags relating to a controlled-substances prescription, to resolve them before filing the prescription, and to document any resolution of red flags is a well-recognized responsibility of a pharmacist in the professional practice of pharmacy. *United States of America v. Walmart Inc.*, No. 1:20-cv-01744 (D. Del. Dec. 22, 2020).

65. 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."

66. 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 pharmacist, that 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.[16] The requirements of the

[16] *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).

federal CSA are consistent with the independent requirements of Kentucky law, and Kentucky law also requires Defendants to adhere to federal requirements.

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

68. 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.[17] Reasonably prudent distributors and pharmacies would not fall below this standard of care, which foreseeably harms the public health and welfare.

69. 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 prescribed, directions for use, and the name, address, and registration number of the prescriber. *See* KRS 218A.180. Prescriptions for opioids are valid only for 60 days from the date of the prescription. *Id.* Among other record keeping requirements,[18] 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.[19] Reporters are required to

[17] *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).
[18] *See generally* KRS 218A.200.
[19] 902 KAR 55:110 § 2; Rule 1.1, KASPER Controlled Substance Reporting Guide Version 1.5.2, Cabinet for Health and Family Services (2017).

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.[20] 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 §2.

70. Pharmacists are required to counsel patients on matters which the pharmacist believes will optimize drug therapy. *See* 201 KAR 2:210. As described below, Kroger 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.

71. 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).

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

[20] 902 KAR 55:110 § 2; Rule 1.3, KASPER Controlled Substance Reporting Guide Version 1.5.2.

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

73. Kroger 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.

74. On information and belief, Kroger worked with opioid manufacturers and others to promote opioids in the same manner, including by participating in and promoting manufacturer-sponsored continuing education programs that spread falsehoods regarding opioids, downplayed the risks of addiction, and promoted improper prescribing.

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 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 $1.5 trillion in 2020 alone, based on the most recent estimate from the U.S. Senate's Joint Economic Committee. Once this marketing campaign created

a mass market, Defendants then proceeded to flood it.

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. The New York Times reported, 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.

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. This influx of pharmacy robberies was not limited to Bowling Green; nor was it limited to this particular pharmacy. Pharmacies throughout the state, including, on information and belief, Kroger's more than 100 Kentucky pharmacies, experienced the same unfortunate phenomenon, thus putting Kroger on notice of the dangers of the addictive drugs they were dispensing.

79. As wholesalers self-distributing to their retail stores, Kroger fueled the epidemic on two fronts. Kroger pharmacies in Kentucky bought 465,677,884 dosage units of opioids from 2006-2019, the period for which data from the Automated Reports and Consolidated Ordering

System ("ARCOS") database is available.[21, 22] ARCOS is a data collection system in which manufacturers and distributors report their controlled substances transactions to the DEA. Of that amount, Kroger self-distributed 193,542,080 dosage units of hydrocodone to its pharmacies.

80. Kroger also leaned on outside vendors to augment its supply. Cardinal Health, Inc. ("Cardinal Health") acted as Kroger's predominant third-party opioid distributor. Kroger pharmacies in Kentucky bought 71,840,930 dosage units of oxycodone from Cardinal Health alone from 2006 to 2014.

81. Pharmacies generally do not keep large stocks of drugs, especially highly addictive drugs such as opioids. When they purchase drugs, those drugs are usually rapidly dispensed. Assuming that Kroger dispensed all the opioids that it purchased, as a dispenser, Kroger and its more than 100 Kentucky pharmacies were responsible for over 11% of the total dosage units of opioids dispensed in Kentucky from 2006-2019.

82. 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, Kroger, upon information and belief, collectively reported ***zero*** suspicious orders from their Kentucky stores. Instead, they continued to supply staggering

[21] 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

[22] 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.

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

83. Defendants are 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.

84. 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 controls . . . they also know that these drugs themselves are scheduled controlled substances for a particular 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 or scheduled in that manner because they have the potential to hurt.**

(Emphasis added.)

85. 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. Kroger, among other pharmacies, serves 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.

86. 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.

87. 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."

88. The DEA has repeatedly informed distributors and dispensers, including Kroger, 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.

89. 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.**" (emphasis added). Consistent with that understanding, the NWDA's 1984 Guidelines repeated the same directive.

90. 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.

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

92. The DEA published "Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances," 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.

93. 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."

94. 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."

95. 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 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 is 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.

96. "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."

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

98. 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.

99. 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.

100. The DEA also advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances, including Kroger, 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." The DEA's September 27, 2006 letter also expressly reminded registrants, including Kroger, 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." The same letter reminds distributors, including Kroger, 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."

101. The DEA sent another letter to distributors, including Kroger, 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 to Kroger and other distributors the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."

102. 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.

103. The DEA's regulatory actions against the three largest wholesale distributors, AmerisourceBergen Corporation, Cardinal Health, and McKesson Corporation, further underscore the fact that distributors, such as Kroger, 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's distribution centers and on December 23, 2016, Cardinal Health 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 Memorandum of Agreement ("MOA") with the DEA related to its failures in maintaining an adequate compliance program. Most recently, in January 2017, McKesson Corporation entered into an MOA 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.

104. [redacted]

105. DEA actions were also brought against Kroger, including those discussed below.

D. Due To Their Dual Role As Distributors And Retail Pharmacies, Kroger 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. Kroger 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. Kroger Failed To Maintain Effective Controls Against Diversion

109. As described further below, Defendants failed to fulfill their legal duties and instead, failed to develop compliance programs that identified and stopped suspicious orders and prescriptions, and 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 of the volume of prescription opioids and the public nuisance plaguing Kentucky.

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

110. Kroger failed to implement an effective suspicious order monitoring program. Kroger self-distributed hydrocodone and other controlled substances to its retail pharmacies in Kentucky and elsewhere through its distribution centers called Peyton's. Kroger pharmacies obtained opioids not only through Kroger's self-distribution, but also through outside supplier Cardinal Health, which supplied Kroger with Schedule II products such as oxycodone, among other drugs. Kroger distributed more than 190,000,000 dosage units of hydrocodone products to its stores in Kentucky from 2006-2014, for a population of 4.4 million. Kroger thus funneled far more opioids into Kentucky than could have been expected to serve legitimate medical use and ignored other indicia of suspicious orders. This information, along with the information known only to distributors such as Kroger (especially with its pharmacy dispensing data), would have alerted Kroger to potential diversion of opioids. Yet, upon information and belief, Kroger did not report a single suspicious order in the Commonwealth between 2007 and 2014.

111. On January 24, 2013, Kroger hired a third-party consultant, BuzzeoPDMA LLC ("Buzzeo"), to evaluate its SOMS program. Buzzeo's analysis culminated in two reports, dated March 12, 2013 and March 25, 2013, in which Buzzeo concluded that Kroger did not even have a Suspicious Order Monitoring System. The reports further described Buzzeo's conclusions

regarding Kroger's inadequate distribution and dispensing practices, including:

- "Kroger line Pharmacists were not familiar with the term 'suspicious order monitoring' and did not remember receiving any information from Kroger's corporate offices regarding prescription 'red flags.' Pharmacists appeared to know in general about their practice responsibilities but were not fully familiar with the term and meaning of 'corresponding responsibility.'"

- "Kroger does not conduct 'due diligence' investigations on new or prospective customers."

- "Kroger does not have an electronic order entry system to analyze orders in real time to determine whether the orders may be suspicious."

- "Kroger does not have SOM Standard Operating Procedures (SOPs) . . . According to [Kroger's existing policies], excessive purchase information will be investigated in the field. There are no instructions to report purchase information or investigative findings to the DEA."

- "Kroger does not furnish adequate corporate training for controlled substance abuse in the context of suspicious order monitoring."

- "[D]istribution center Standard Operating Procedures (SOPs) did not contain any information pertaining to 'suspicious order monitoring.'"

- "An Excessive RX report is prepared at Peyton Northern which contains some potential suspicious order information. However, there was no evidence of any proactive programs or training (official or unofficial) to alert the DEA to a suspicious controlled substance order."

112. Kroger's failure to report suspicious orders is not surprising given Kroger's failure to have a formal SOMS program until 2013. Prior to that time, as detailed in the Buzzeo reports, Kroger had no SOMS standard operating procedures, written SOMS guidelines or employee training, or written SOMS policies. Kroger's review of orders during this time occurred at its Peyton's distribution centers. However, the order review was for purposes of inventory management and ensuring that orders were correctly filled, not for the purpose of suspicious order monitoring.

113. Kroger conducted a monthly manual review of orders that had been shipped during

the previous month to identify orders that were excessive. However, as the DEA has said repeatedly, this after-the-fact review (which was done by one employee for all of the orders from Kroger pharmacies nationwide) was not a sufficient procedure for monitoring suspicious orders because the orders had already been shipped. The procedure could not and did not block suspicious or excessive orders. Furthermore, there were no objective criteria or guidelines the employee followed to identify which orders were excessive and orders of unusual frequency and pattern were not identified.

114. Kroger was well aware that it did not have a SOMS program that could identify, investigate, block, and report suspicious orders as required by the CSA. In June 2013, Kroger further contracted with Buzzeo to develop a SOMS. [redacted] In documents from 2013 describing the scope of this project, Kroger admits that it did not have a system in place to monitor and investigate orders prior to shipment and that it was out of compliance.

115. Minutes from Kroger's Pharmacy Compliance Committee confirm its corporate failings and noncompliance with requirements to maintain effective controls against diversion of controlled substances. Kroger admits [redacted] In a [redacted]

116. In 2013, Kroger developed a SOMS program with the assistance of Buzzeo and began launching the program [redacted] The system included a suspicious order monitoring algorithm that was supposed to flag potentially suspicious orders that would then be pended for investigation. But the SOMS did not work; it flagged too many orders, then flagged too few orders, and there was no mechanism to determine which orders needed to be held and investigated. [redacted] Furthermore, upon information and belief, Kroger stores were still able to place orders through outside vendors, such as Cardinal Health, if Kroger's internal system pended the order.

117. In August of 2014, [redacted] but by then it was too late. In October of 2014, Kroger stopped self-distributing hydrocodone after the drug was rescheduled. Thus, the entire time period that Kroger distributed hydrocodone to its Kentucky pharmacies, it did so under a nonexistent SOMS program or an inadequate and ineffective one.

118. Kroger had a responsibility under state and federal law to identify the suspicious orders that flowed from its distribution facilities. Kroger failed to implement a system that would identify, investigate, and report suspicious orders despite its actual knowledge of drug diversion. Rather, Kroger did not report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into Kentucky.

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

120. Kroger was, or should have been, fully aware that opioids it was distributing into Kentucky through orders that were not monitored by a SOMS or reviewed for indicia of diversion were likely to be diverted; yet, it did not take meaningful action to investigate or to ensure that it was complying with its duties and obligations with regard to controlled substances, including its responsibility to identify and report suspicious orders and not ship such orders unless and until due diligence allayed the suspicion.

2. Kroger Failed To Protect Against Diversion At Its Retail Pharmacies

121. Before 2005, the inadequacy of Kroger's policies and procedures was particularly glaring. DEA began investigating King Soopers and City Market, part of the "Kroger Co. Family of Stores" in response to information concerning potential diversion. Audits at seven Colorado pharmacies revealed "a pattern of non-compliance" with the CSA and federal regulations. Because of record-keeping and security problems, the DEA could not determine from the audit "how many drugs had been lost or diverted," but could tell that "many of the CSA violations were the result of systemic weaknesses present in all King Soopers and City Market pharmacies."

122. Ultimately, the parent corporation, Kroger Co., agreed in October 2005 to a then-record $7 million settlement for the "systemic violations of the [CSA] by the company's pharmacies." Kroger also "agreed to implement a pharmacy compliance program estimated to cost over $6 million dollars in all 1,900 of its pharmacies nationwide." The changes included the Kroger stores in Kentucky. Kroger promised national reforms because it imposed its procedures

at a national level across its "family" of stores, such that the same systemic failures also existed in Kentucky.

123. A DEA press release concerning the settlement highlighted the trust Americans place in "corporations like Kroger" to "ensure that controlled substances aren't diverted to the illicit market." Kroger understood the vital importance of its role as the last line of defense. "As the last person that has the opportunity to speak with a patient or caregiver prior to handing over a medication that has been known to end the lives of so many when diverted or misused, no one can overestimate the responsibility of the pharmacist." Kroger also recognized the "legislative and social intent of regulating controlled substances" as consistent with its mission in "serving the public good."

124. Yet, systemic failures persisted even after the 2005 settlement. Kroger failed to provide training to its pharmacists regarding red flags and corresponding responsibility under federal and state laws and, when training was offered, Kroger failed to ensure it was consistently completed and understood by its pharmacists. Kroger pharmacists reported that they never received information about red flags from Kroger and did not understand the term "corresponding responsibility" or how to incorporate corresponding responsibilities in dispensing opioids. Kroger pharmacists also failed to comprehend the due diligence that they should conduct in determining whether prescriptions should be filled.

125. A May 2006 Standard Operating Procedure, applicable across all Kroger stores, fails to identify red flags such as pattern prescribing, including red flags it would later ask its pharmacists to confirm they understood in 2012. Internal correspondence from 2016 indicated red flags first suggested in 2006 were still not incorporated in Kroger corporate policies. Kroger also developed tools to help pharmacists identify red flags, but only required them to be used in

pharmacy branches that were flagged by outside vendor Cardinal Health's metrics, not on a national scale or based on Kroger's own internal data. Further, it was not until 2016 that Kroger had the benefit of a program to assess a patient's controlled substance history from state prescription monitoring programs, to identify high risk usage including use of cocktail drugs.

126. Kroger formed a Pharmacy Compliance Committee in approximately February 2012. [redacted] The Pharmacy Compliance Committee regularly assessed and evaluated Kroger's compliance with its responsibilities under the CSA, as well as other laws and regulations. Through this assessment the committee noted the following:

- [redacted]
- [redacted]
- "Jeff reported that there are some possible issues with the Suspicious Order Monitoring algorithm and that he is working diligently with multiple individuals to correct several processes that will allow us to better review data and improve monitoring accuracy."

- "Jeff advised the Committee that his team is continuing to work with Buzzeo to correct the Suspicious Order Monitoring (SOM) algorithm that is not operating appropriately and he hopes to have an update by the next meeting."
- [redacted]
- "Martha stated that [compliance] training is by far the weakest area of compliance for the company."
- [redacted] (emphasis added).

127. Discovery will reveal that Kroger knew or should have known that its pharmacies in Kentucky and the surrounding states were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g)

filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. Kroger had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

F. Kroger Worked With Purdue Pharma To Promote Opioids And Improperly Normalize Their Widespread Use

128. Kroger worked with Purdue Pharma in its 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.

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

130. Starting in the 1990s, opioids manufacturers created a carefully orchestrated campaign to change the utilization of prescription opioids in the United States, including Kentucky. Kroger played a role in that campaign. For that campaign to work, the pharmacists employed by Kroger 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.

131. Kroger worked in concert with Purdue 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.

132. Beginning in the early 2000s, Kroger solicited and worked with Purdue on continuing education programs to train Kroger's own pharmacists, including in Kentucky, 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. Kroger also accepted payments from Purdue in conjunction with the continuing education programs.

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

133. 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 292 Americans die every day from a drug overdose. Between 1999 and 2021, more than one million people in this country died due to drug overdoses. In 2021, opioids were involved in 75.4% of drug overdose deaths.

134. 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.

135. 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, and over 34 doses from 2019-2021. 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.

136. The United States has a dire situation on its hands. The troubling reality for states like Kentucky is sadly much worse. 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. Kentucky's overdose fatalities, which were already high, increased dramatically in that same time frame and beyond. 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. Those numbers skyrocketed to 1,964 overdose deaths in 2020 and 2,250 overdose deaths in 2021. State research indicates that an opioid was involved in 90% of all overdose deaths in Kentucky. In 2015, drug overdoses accounted for 59.17% of Kentucky's statewide accidental deaths. The CDC identified Kentucky as having a statistically significant drug overdose death rate increase from 2019 to 2020, noting a nearly 51.4% increase from Kentucky's already elevated death rates. According to the CDC, in 2020 Kentucky had the second highest overdose rate in the country. Data from 2013 onward shows that Kentucky has the third highest drug overdose mortality rate in the country. 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 Kentuckians, 37 of them fatally overdosed.

137. Kentucky has one of the highest rates of prescriptions for opioids in the nation. These statistics reflect the fact that Kentucky is one of the top states for over-distribution of opioids by distributors like Kroger, and one of the top states for the over-dispensing of opioids by

pharmacies like Kroger.

138. The number of lives lost statewide to drug overdoses in 2020 was more than two-and-a-half times that of car accidents. In Northern Kentucky, the opioid-overdose reversal drug naloxone was administered in 30% of Emergency Medical Services runs in 2018-2019; and on average, 23 response calls per day were to drug-related incidents.

139. 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. 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.

140. 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.

141. Prescription drug abuse causes an increase in crimes such as domestic violence, burglaries, and thefts. 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 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.

142. Children have not been spared by the opioid epidemic. As of September 2022, there were over 8,500 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.

143. 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.

144. 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. 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.

145. NAS has become a great source of concern within the Commonwealth. In 2020, there were 993 NAS births in Kentucky, accounting for 19.4 births for every 1,000 live births among Kentucky residents, more than double the national average. The rate skyrockets in

Appalachian areas of the state. In 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.

146. Most of the overdoses from non-prescription opioids are also directly related to prescription pills. Numerous studies show that prescribed opioid use causally increases the risk of heroin use, and the risk of unregulated synthetic opioid use and exposure, especially in recent years.

147. Faced with increased tolerance, addicted people are compelled to seek out higher and stronger doses. Many opioid users, having become addicted to but no longer able to obtain prescription opioids or trapped in a cycle of addiction that causes those who suffer from the disease to need stronger and more potent drugs, have turned to heroin, fentanyl, and other illicit drugs. According to the American Society of Addiction Medicine, 80% of people who initiated heroin use in the past decade started with prescription painkillers—which, at the molecular level, closely resemble heroin.

148. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain. As such, heroin produces a very similar high to prescription opioids for a much lower cost. Indeed, opioids are akin to medical-grade heroin. 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.

149. Cross-sectional studies of samples recruited based on non-medical prescription

opioid use and/or heroin use consistently find strong evidence of a relationship. Even among those who use opioids medically, there is a higher risk of transition to heroin use than among those who never use prescription opioids. Heroin and synthetic opioids use began an exponential increase after 2010, and overdose rates due to heroin and synthetic opioids continued to climb. The increases in heroin use largely occurred among individuals who are or were prescription opioid users. Among individuals who use prescription opioids, heroin use increased by 138% from 2002-2004 to 2011-2013, and the connection is particularly strong among young adults. The vast majority of individuals who use heroin began with prescription opioid use, and even small increases in progression to heroin use creates a significant public health burden. 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.

150. 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. Opioid addiction feeds heroin addiction, as heroin produces similar highs and costs substantially less to the user. In fact, people who are addicted to prescription painkillers are 40 times more likely to become addicted to heroin, and the CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. 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.

151. 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."

152. Northern Kentucky, in particular, has witnessed the effects of the opioid epidemic and resulting upswing in heroin use. 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. The substantial increase in HIV cases is another tragic result of the opioid epidemic. Throughout the Commonwealth, there were 368 new infections of HIV in 2018.

153. Beyond the dangers associated with heroin, a new drug has emerged with far more serious risks: synthetic fentanyl and its analogs like carfentanil. Fentanyl is a powerful opioid prescribed for cancer pain or in hospital settings, that, in synthetic form, has made its way into Kentucky communities. Carfentanil, a powerful synthetic derivative of fentanyl, has increasingly been found in heroin and fentanyl sold illicitly. Carfentanil is approximately 10,000 times more potent than morphine and 100 times more potent than fentanyl. In fact, Carfentanil is so strong that it is typically used in veterinary medicine to sedate large wild animals such as elephants and has been researched as a chemical weapon. A dose the size of a grain of salt can rapidly lead to deadly overdose in humans. The proliferation of carfentanil was associated with a significant spike in opioid overdose deaths in 2016-2017, before its presence in the illicit drug market began decreasing. However, several data sources indicate that in 2022 and 2023, carfentanil began

resurging, including in Kentucky.

154. Available evidence indicates that fentanyl and other high-potency opioids have been adulterating the supply of both heroin and illicitly manufactured prescription opioids. Given the evidence that prescription opioid use is causally related to heroin use, prescription opioid use is also responsible for the increase in fentanyl and other synthetic opioid harms. Indeed, individuals who use prescription opioids who both obtain illicitly manufactured prescription opioids, as well as heroin, will be potentially exposed to fentanyl, increasing the risk of overdose and death. Available evidence from San Francisco County, for example, indicates that between 2018 and 2020, people who use heroin transitioned to using fentanyl, indicating that the pathway between heroin and fentanyl, and thus prescription opioids and fentanyl, has the same causal components. Because the heroin supply has been contaminated with high-potency synthetic opioids (e.g., fentanyl) since approximately 2013, prescription opioid use is also causally related to the increase in synthetic opioid morbidity and mortality. Approximately 70-80% of fentanyl-involved opioid deaths are attributable to prescription opioid use, whether fentanyl is unintentionally used when mixed in heroin, or intentionally used, given that the pathway to use from prescription opioids to fentanyl is the same as with heroin.

155. In 2021, the Kentucky Office of Drug Control Policy reported that fentanyl was detected in more than 70% of all overdose deaths. The increases in opioid related overdose deaths coincides with increases 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.

156. 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' unlawful action in flooding the Commonwealth with highly addictive opioid prescriptions, without regard for the consequences to the Commonwealth and its citizens.

157. The scope of conduct alleged herein has proximately caused a multigenerational health care epidemic of addiction and resulting disease and deaths in Kentucky. 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.

158. 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
Unfair and Deceptive Acts and Practices in Violation of Kentucky Consumer Protection Act (KRS 367.110 *et seq.*)

159. 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.

160. 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.

161. 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.

162. 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.

163. At all times relevant to this Complaint, Kroger violated the KCPA by engaging in unfair, false, misleading, and/or deceptive acts or practices in the distribution and dispensing of opioids. These acts or practices are unfair in that they are unconscionable, offend public policy, and are immoral, unethical, oppressive, or unscrupulous.

164. 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 failed to fulfill their corresponding responsibility because they 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 failed to adequately train pharmacy employees to exercise their corresponding responsibility, identify red flags indicating abuse, misuse, and diversion, and report potential 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.

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

165. All the while, Defendants affirmatively misrepresented to the Commonwealth, to maintain a license to distribute and dispense controlled substances, that it was in full compliance with all applicable laws and regulations. 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 their continuing violations.

166. 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.

167. Defendants had access to information and data pointing to diversion that is

unavailable to government entities and did not share that information and data.

168. 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.

COUNT II
Continuing Public Nuisance

169. 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.

170. The Attorney General represents the citizens of this Commonwealth and can "institute equitable proceedings for the abatement of public nuisances which affected or endangered the public safety of convenience." *Hancock v. Terry Elkhorn Mining Co., Inc.*, 503 S.W.2d 710, 715 (Ky. 1973). To this end, the Attorney General may bring suit against a public nuisance in Kentucky to protect the Commonwealth's citizens to abate public safety concerns.

171. A public nuisance "includes maintaining a condition of things which is prejudicial to the health, safety, comfort, property, sense of decency, or morals of the citizens at large." *Maum v. Commonwealth*, 490 S.W.2d 748, 749 (Ky. 1973). Certainly, the flooding of the Commonwealth with an exorbitant number of opioids qualifies as a public safety concern. Opioids are a highly addictive drug that contribute to high addiction and overdose rates in the Commonwealth.

172. Interference with the public's quality of life and common right to health and safety is the violation of a public right. Prior cases, which surround similar fact patterns, have found that the influx of large quantities of opioids have caused adverse consequences and violated public rights. *See Commonwealth v. CVS Health Corp.*, No. 21-CI-00445, slip op. (Ky. Franklin Cir. Ct. Jan. 19, 2022); *Commonwealth v McKesson Corp.*, No. 18-CI-00056, slip op. (Ky. Franklin Cir.

Ct. May 21, 2019); *Commonwealth v. Endo Health Sols., Inc.*, No. 17-CI-01147, slip op. (Ky. Franklin Cir. Ct. July 10, 2018); *Commonwealth v. Walgreens Boots All., Inc.*, No. 18-CI-00846, slip op. (Ky. Boone Cir. Ct. July 22, 2019). The influx of large amounts of opioids is detrimental to public health and safety, which is a public right for all citizens. Defendants' actions constitute a public nuisance, which is continuing, due to the impact of over-distributing dangerous drugs to Kentucky citizens, which is prejudicial to Kentucky citizens' health and safety.

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

174. 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.

175. 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 conduct adequate due diligence and/or refuse to fill suspicious orders and suspicious prescriptions. Defendants ignored their corresponding responsibility and dispensed opioids that were not written for a legitimate medical purpose and/or by a physician acting outside of his normal practice. Defendants filled prescriptions despite red flags indicating abuse, misuse, and diversion. Defendants failed to adequately train pharmacy employees to exercise their corresponding responsibility, identify red flags indicating abuse, misuse, and diversion, and report potential diversion. Defendants disregarded their duty to analyze their own pharmacy order and/or dispensing data to detect red flags of misuse, abuse, and diversion. Such actions were inherently

dangerous to the welfare of Kentucky's communities.

176. 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.

177. 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.

178. 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.

179. 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.

180. 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.

181. 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.

182. 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.

183. Defendants are liable for all costs to abate the public nuisance borne by the Commonwealth and its agencies, which were proximately caused by the Defendants' wrongful actions.

184. 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.

185. 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.

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. 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;

D. Ordering Defendants to abate the public nuisance caused in whole or in part by Defendants;

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

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

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

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

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

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

Dated: February 12, 2024

Respectfully submitted,

RUSSELL COLEMAN
ATTORNEY GENERAL

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