

**COMMONWEALTH OF KENTUCKY
FLOYD CIRCUIT COURT, DIV. _____
CIVIL ACTION NO. 18-CI_____**

COMMONWEALTH OF KENTUCKY, ex. rel.
ANDY BESHEAR, ATTORNEY GENERAL,

PLAINTIFF

v.

AMERISOURCEBERGEN DRUG CORPORATION
1300 Morris Drive, Suite 100
Chesterbrook, PA 19087-5594

SERVE: CT Corporation Systems
306 W. Main Street, Suite 512
Frankfort, Kentucky 40601

H.D. SMITH WHOLESALE DRUG COMPANY
3063 FIAT AVENUE
SPRINGFIELD, IL 62703

SERVE:
Corporation Service Company
421 West Main Street
Frankfort, Kentucky 40601, and

H.D. SMITH, LLC
3063 Fiat Avenue
Springfield, Illinois 62703

SERVE
CT Corporation Systems
306 W. Main Street, Suite 512
Frankfort, Kentucky 40601

DEFENDANTS

COMPLAINT

Plaintiff, the Commonwealth of Kentucky (“the Commonwealth”), by and through its
duly elected Attorney General, Andy Beshear, for its Complaint against Defendants,

AmerisourceBergen Drug Corporation, H.D. Smith Wholesale Drug Company, and H.D. Smith, LLC, states as follows:

I. INTRODUCTION

1. This is a public interest lawsuit brought by the Kentucky Attorney General under Kentucky constitutional, statutory, regulatory and common law authority to recover damages, restitution, reimbursement, disgorgement, statutory civil penalties, injunctive relief, and other relief deemed appropriate by the Court from Defendants AmerisourceBergen Drug Corporation (“AmerisourceBergen”), H.D. Smith Wholesale Drug Company, and H.D. Smith, LLC (collectively “Defendants”) as a consequence of its role fueling the opioid epidemic in the Commonwealth through fraudulent, unfair, false, misleading, and/or deceptive business practices.

2. The actions of Defendants, on information and belief, include filling massive and/or “suspicious” orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency from Kentucky pharmacies for prescription opioids, shipping and/or distributing those massive quantities of opioid drugs throughout the Commonwealth, failing to report to appropriate authorities such “suspicious” orders, and failing to halt such excessive and suspicious shipments. On information and belief, these orders were for such large quantities of prescription narcotic pain medication or made so frequently that there could be no associated legitimate medical purpose.

3. The prescription drugs in question, opiates, are narcotic drugs derived from or possess properties similar to opium and heroin, and are categorized as “Schedule II” drugs due to their high potential for abuse and potential to cause severe psychological or physiological

dependence¹. The terms “opioids” and “opioid analgesics” describe the entire class of natural and synthetic opiates.

4. The Food and Drug Administration (“FDA”) originally approved opioid treatment for short-term post-surgical or trauma-related pain, and for palliative (end-of-life) care.² Later, the labels were extended to reach treatment of patients with “chronic pain,” pain lasting more than three months.

5. Following the extension of the label, the companies who manufactured and sold this class of drugs in the United States experienced a boom in their business. However, with this boom came a scourge which infected this country in the form of a public health epidemic caused by widespread addiction to opioids like OxyContin and Percocet, as well as generic forms of oxycodone and hydrocodone. The scourge is now commonly known as the “opioid epidemic.”³ More of a modern plague, the opioid epidemic continues to mushroom, despite widespread media attention, many states taking action, and national government response.

6. While there are many purported causes related to the opioid epidemic, this action is focused solely on the actions of a particular company⁴ (and its affiliates) which was a dominant pharmaceutical wholesaler and market leader. Defendants and other distributors saturated and 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 common sense. On information and belief, Defendants failed to

¹ Codeine, also derived from the opium poppy, is a Schedule III narcotic when in a quantity of less than 90 milligrams per dosage unit. See DEA Drug Schedules <https://www.dea.gov/druginfo/ds.shtml> (last access February 16, 2018).

² Opioid was originally a term denoting synthetic narcotics resembling opiates but increasingly used to refer to both opiates and synthetic narcotics. Stedman’s Medical Dictionary 27th Edition.

³ L. Manchikanti et al., *Opioid Epidemic in the United States* (July 2012) <https://www.ncbi.nlm.nih.gov/pubmed/22786464>.

⁴ Defendant AmerisourceBergen Drug Corporation acquired H.D. Smith in a late 2017, early 2018 transaction.

report red-flag, facially suspicious orders in the Commonwealth and opted instead to reap a windfall off of the wave of addiction.

7. During the creation and inflation of this epidemic, drug wholesalers like Defendants knew of the dangerous, addictive qualities, and high rates of loss and misappropriation (“diversion rates”) of the drugs it shipped.

8. Upon information and belief, Defendants received millions of dollars per year for distributing excessive volumes of opioids into Kentucky. Defendants, in order to maintain or increase their profits and market dominance, situated themselves to play a significant role in creating a public nuisance of historic proportions.

9. As set forth below, shipments of massive quantities of opioids into the Commonwealth by Defendants, particularly to small, sparsely populated, rural counties in Eastern Kentucky, were unfair practices that were suspicious and excessive on their face.

10. As detailed further below, pharmaceutical wholesalers like Defendants are required to “know their customers” and set thresholds for each customer’s anticipated order. When considering both the data available to Defendants regarding the population dynamics of the towns it shipped to and the customer thresholds they created based on said data, Defendants violated several duties charged by law and by the nature of its industry.

11. Due to Defendants’ and other distributors’ continued proliferation of dangerous and addictive prescription opioids, citizens of Kentucky suffered from prescription drug addiction and abuse. A reasonably foreseeable result of this widespread addiction was patients’ transitioning their use and abuse to illegal street drugs like heroin and fentanyl. Additional foreseeable results of these actions include 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 lost lives of thousands of Kentuckians.⁵ Sadly, in 2015 Kentucky had the third highest drug overdose death rate, behind only West Virginia and New Hampshire.⁶ Even worse, in 2016 the Kentucky Office of Drug Control Policy reported more than 1,400 overdose deaths.⁷

12. The citizens of Kentucky are left in the wake of this malfeasance, spread out among our many small towns and cities, endeavoring to restore order and put an end to this public health crisis in the face of wave after wave of excessive opioid distribution.

13. The Commonwealth's response to the health emergency created by Defendants and other distributors includes providing or paying for medical treatment; shouldering the increased financial burden of public health insurance; dispatching emergency services; investigating and prosecuting drug-related crimes; incarcerating perpetrators; supervising and rehabilitating the addicted; preventing, investigating, and treating overdoses; providing foster care for children whose parents are in prison or dead from overdosing, or simply cannot care for them due to addiction; assembling necessary response teams; and tending to the infirm, dying, and dead.

14. The Kentucky Medicaid program alone has paid millions of dollars for medically unnecessary prescriber visits and improper prescriptions as well as addiction treatment and services, including emergency room admissions, inpatient hospitalizations, drug treatment, rehabilitation services, hepatitis treatments, and a multitude of other adverse

⁵ See Nora D. Volkow, M.D. and A. Thomas McLellan, Ph.D., *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, NEW ENG. J. MED., 374;1253-63 (March 31, 2016).

⁶ Rate per 100,000 population age-adjusted to the 2000 U.S. standard population using the vintage 2015 population. Source: National Vital Statistics System, Mortality File, CDC WONDER.

⁷ See Commonwealth of Kentucky Justice & Public Safety Cabinet 20116 Overdose Fatality Report, 2 <https://odcp.ky.gov/Documents/2016%20ODCP%20Overdose%20Fatality%20Report%20Final.pdf>.

consequences of addiction afflicting Kentucky Medicaid recipients who became addicted to the controlled substances that Defendants excessively distributed in the Commonwealth.

15. This action is therefore brought on behalf of the Commonwealth to: 1) stop Defendants from fulfilling suspicious orders for opioids; 2) recover the damages suffered by Kentucky and its citizens; 3) recoup the expenses, penalties owed, and disgorge the amounts with which Defendants were unjustly enriched; and, perhaps most importantly, 4) to enjoin and abate the continuing public nuisance caused in whole or in part, by the actions of Defendants and force them to help solve the problem they both created and willingly profited from.

II. PARTIES

Plaintiff

16. Plaintiff is the Commonwealth of Kentucky, by and through its agent, Attorney General Andy Beshear, who is granted the right and duty under law to prosecute actions for abuse of public funds and torts harming the citizens of this state. The Commonwealth of Kentucky is and was a sovereign State and is a body politic created by the Kentucky Constitution and laws of the Commonwealth of Kentucky and, as such, is not a citizen of any State.

17. The Attorney General is the proper party to take action against Defendant for breach of state law and regulation. Andy Beshear is and was the duly elected Attorney General of Kentucky, an independent constitutional officer of the Commonwealth and its chief law enforcement 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 194A.505, KRS 205.8451 through KRS 205.8483, KRS 218A.240, KRS 315.235, KRS 367.170 *et seq.*, to initiate

actions necessary to guard against unauthorized demands against the Treasury of the Commonwealth, 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, its departments and agencies, and its citizens. The Attorney General has determined that these proceedings are in the public interest.

Defendants

18. Defendant AmerisourceBergen Drug Corporation is a Delaware Corporation with its principal place of business in Chesterbrook, Pennsylvania. It is registered to do business with the Kentucky Secretary of State; its registered agent is CT Corporation Systems, 306 West Main Street, Suite 512, Frankfort, KY 40601.

19. Specifically, Defendant AmerisourceBergen distributes pharmaceuticals to retail pharmacy operations, as well as institutional providers like hospitals and county health departments. AmerisourceBergen is the second largest pharmaceutical distributor in North America; along with McKesson Corporation and Cardinal Health, AmerisourceBergen is a “Big Three” distributor. Upon information and belief, Defendant AmerisourceBergen distributed oxycodone and hydrocodone, among other opioids, in the Commonwealth of Kentucky between January 1, 2007, and December 31, 2016.

20. Defendants H.D. Smith Wholesale Drug Company and H.D. Smith, LLC, (collectively “H.D. Smith”) have principal places of business in Springfield, Illinois. H.D. Smith Wholesale Drug Company was registered to do business in the Commonwealth of Kentucky but became inactive as of 2014. Subsequently, in 2014, H.D. Smith, LLC, registered to do business

in the Commonwealth of Kentucky; its registered agent is CT Corporation System, 306 West Main Street Suite 512, Frankfort, KY 40601.

21. Upon information and belief, H.D. Smith participated in pharmaceutical distribution within the Commonwealth of Kentucky during the relevant time period. H.D. Smith hosts a distribution hub in Louisville, Kentucky. The H.D. Smith website specifies that the entity is a wholesale distributor for “independent pharmacies.”

22. Defendant AmerisourceBergen Drug Corporation acquired H.D. Smith in a late 2017, early 2018 transaction.⁸ The three entities are referred to collectively as “Defendants.”

23. Kentucky law mandates that all drug distributors, including Defendants, apply for and receive a license from the Kentucky Board of Pharmacy. KRS 315.402. Additionally, wholesale distributors of controlled substances, including Defendants, must apply for and receive a license from the Kentucky Cabinet for Health and Family Services. KRS 218A.150. Continuing licensure is dependent upon compliance with laws and regulations relating to controlled substances. KRS 218A.160(1)(a), 201 KAR 2:105 Section 3(2)(a), 902 KAR 55.010, KRS 218A.240, and 21 U.S.C. § 823.

24. Upon information and belief, Defendants maintained licensure through the Commonwealth of Kentucky for the wholesale distribution of controlled substances pursuant to multiple regulations, including the Kentucky Controlled Substances Act.

III. JURISDICTION AND VENUE

25. The Floyd Circuit Court has personal jurisdiction over Defendants, as Defendants purposefully availed themselves of this forum by conducting business in the

⁸ AmerisourceBergen Completes Acquisition of HD Smith (January 3, 2018) <https://www.amerisourcebergen.com/abcnew/newsroom/press-releases/amerisourcebergen-completes-acquisition-of-hd-smith>.

Commonwealth and by causing harm as a direct and proximate result of its actions. Defendants 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 good or services in the Commonwealth and/or caused tortious injury by an act or omission in the Commonwealth and/or caused tortious injury in the Commonwealth by an act or omission outside the Commonwealth. Defendants have the requisite minimum contacts with Kentucky necessary to permit this Court to exercise jurisdiction. Defendants designated registered agents for service of process and otherwise consented to the jurisdiction of Kentucky courts.

26. Floyd Circuit Court has subject matter jurisdiction over the claims submitted pursuant to KRS 15.060, KRS 23A.010, KRS 194A.505(8), KRS 205.8469, 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.

27. Plaintiff does not plead any cause of action or request any remedy arising under or founded in federal law. The instant Complaint does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332, as the Commonwealth is not a citizen of any state and this action is not subject to the jurisdiction of the Class Action Fairness Act of 2005.

28. 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 Defendant. 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).

29. 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.

30. In this complaint, Plaintiff cites or alludes to federal statutes, regulations or agency memoranda. Plaintiff does so only to establish Defendants' knowledge, state the duty owed under Kentucky tort and consumer protection 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.

31. Venue is appropriate in Floyd Circuit Court under KRS 452.460, which allows venue in the county where the injury was suffered. Floyd County, like many of the other Counties in the region, has been hard hit by the opioid crisis, ranking in the top ten of Kentucky Counties for overdose deaths per capita from 2012 through 2015.⁹ Floyd County, like many Kentucky counties, has been directly affected by the opioid epidemic and has seen too many of its citizens suffer as a result of the conduct that is the subject of this lawsuit.

IV. THE MEDICAID PROGRAM

32. The Medicaid Program ("Medicaid") operates under Title XIX of the Social

⁹ Kentucky Justice & Public Safety Cabinet, 2016 Combined Annual Report, p. 6.
<https://odcp.ky.gov/Reports/2016%20annual%20report.pdf>

Security Act. Medicaid is a cooperative venture between the Federal and State governments to assist States in the provision of adequate medical care to its most vulnerable citizens, including the poor, the disabled, the elderly, the blind, pregnant women, infants and dependent children.

33. Within broad federal statutory and regulatory guidelines a State: (a) establishes its own eligibility standards; (b) determines the type, amount, duration, and scope of services; (c) sets the rate of payment for services; and (d) administers its own program. The Medicaid program is administered at the federal level by the United States Department for Health and Human Services, Centers for Medicare and Medicaid Services (“CMS”).

34. The Department for Medicaid Services (“Kentucky Medicaid”) is the single state agency charged with the administration of the Kentucky Medicaid program pursuant to Title XIX of the Federal Social Security Act. 42 U.S.C. 1396a(a)(5), 42 C.F.R. § 431.10. 42 C.F.R. § 100, KRS 12.020 (II)(8)(k), KRS 194A.030(2), Chapter 205 of the Kentucky Revised Statutes, Title 907 of the Kentucky Administrative Regulations and other applicable law.

35. Upon information and belief, Kentucky Medicaid has paid and continues to pay substantial sums for the costs associated with treatment and services provided to opioid-addicted Medicaid beneficiaries whose addiction was created by availability and access to diverted drugs which were distributed in whole or in part by Defendants.

V. FACTUAL BACKGROUND

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

due to drug overdoses. Approximately 6 out of 10 drug overdose deaths are caused by opioids.¹⁰

37. 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. 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.¹¹

38. Additionally, the Substance Abuse and Mental Health Services Administration (“SAMHSA”) Center for Behavioral Health and Statistics Quality (“CBHSQ”) reports that four out of every five new heroin users begin with nonmedical use of prescription opioids.¹²

39. The reality for states like Ohio, West Virginia, and Kentucky is incredibly much worse. Kentucky’s overdose fatalities, already high, increased dramatically in 2015. Overdose deaths of Kentucky residents, regardless of where the death occurred, and non-residents who died in Kentucky, numbered 1,248 in 2015, topping the already unacceptable 1,071 overdose deaths in 2014.¹³ In 2015, drug overdoses accounted for 51.17% of Kentucky’s statewide accidental deaths, more than motor vehicle accidents, fire, drowning and gunshot wounds combined. In 2015, opioids accounted for 46.63% of the statewide total of drug related fatal overdose victims.¹⁴

¹⁰ Letter from President’s Commission on Combating Drug Addiction and the Opioid Crisis to the President of the United States (Nov. 1, 2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

¹¹ *Id.*

¹² *See Id.* *See also* Ctrs. for Disease Control and Prevention, U.S. Dep’t of Health and Human Servs., *Today’s Heroin Epidemic*, <https://www.cdc.gov/vitalsigns/heroin/index.html> (last accessed Feb. 15, 2018).

¹³ *2015 Overdose Fatality Report, Kentucky Office of Drug Control Policy* <https://odcp.ky.gov/Documents/2016%20ODCP%20Overdose%20Fatality%20Report%20Final.pdf>.

¹⁴ *2015 Annual Report, Office of the Kentucky State Medical Examiner* <https://odcp.ky.gov/Reports/2016%20annual%20report.pdf>.

A. OPIOIDS ARE SCHEDULE II, HIGHLY ADDICTIVE DRUGS, KNOWN TO CAUSE USERS TO DEVELOP DRUG SEEKING BEHAVIORS.

40. 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 crisis is estimated to have exceeded \$1 trillion from 2001 to 2017, and is projected to cost an additional \$500 billion by 2020.¹⁵

41. Prescription opioids bind to receptors on the spinal cord and in the brain, dampening the perception of pain. Like heroin, opioids can create a euphoric high, and thereby possess addictive qualities. At certain doses, opioids can slow the user’s breathing, causing respiratory depression and, ultimately, death. With prolonged use, a patient’s tolerance increases, causing a correlating increased need in dose amounts and frequency of administration or use. The increased tolerance also increases the risk of significant side effects and addiction rate as well as decreases the effectiveness of patient weaning.

42. 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.¹⁶

43. Dr. Robert DuPont, former director of the National Institute on Drug Abuse and

¹⁵ See Wilson Hyan, *The Potential Societal Benefit of Eliminating Opioid Overdoses, Deaths, and Substance Use Disorders Exceeds \$95 Billion Per Year*, Altarum Center for Value in Health Care (2017).

¹⁶ See Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016), Ctrs. for Disease Control and Prevention, *MMWR Report* (March 17, 2017) https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm?s_cid=mm6610a1_w.

the former White House drug czar, opines 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.”¹⁷

B. THE ROLE OF PHARMACEUTICAL DISTRIBUTORS

44. Rather than drug manufacturers selling opioids directly to physicians or pharmacies for ultimate dispensing, a sophisticated, closed distribution system exists to push the drugs across the nation.¹⁸ This sophisticated system, born out of an acknowledgement by Congress that greater control was needed over abused and addictive prescription drugs, is intended to track and account for controlled substances from manufacturing to the ultimate consumer.¹⁹

45. For many important reasons, this system relies upon the honesty, integrity, and accountability of prescription drug distributors to be effective. This “closed” chain of distribution was specifically designed by Congress to prevent the diversion and abuse that is complained of herein.

46. States, including Kentucky, enacted similar state laws, rules and regulations in order to regulate the distribution of drugs and provide oversight over this unique industry. The

¹⁷ Transcript, Use and Abuse of Prescription Painkillers, The Diane Rehm Show (Apr. 21, 2011), at <http://thedianerehmshow.org/shows/2011-04-21/use-and-abuse-prescription-painkillers/transcript>.

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

¹⁹ *Id.*

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).

47. This closed-system of state and federal authority imposes specific duties upon wholesale distributors to monitor, identify, halt and, perhaps most importantly, report suspicious orders of controlled substances. 21 C.F.R. § 1301.74; Masters Pharm., Inc. v. Drug Enf’t Admin., 861 F.3d 206 (D.C. Cir. 2017). 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.”²⁰ The end purpose of these laws is to protect the consuming public.

48. Pharmaceutical distributors such as Defendants are one 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 deliver controlled substances only for lawful purposes.

49. Joe Rannazzisi, in his 2012 statement, pointed to the lack of proactive monitoring and vigilance by distributors, including AmerisourceBergen, that “could have prevented millions of controlled substance dosage units from being diverted” by internet pharmacies from 2006 to 2009. ²¹AmerisourceBergen was one wholesaler that paid civil penalties and entered into compliance memorandums of agreement with the government in 2007 for its role in the internet pharmacy diversion. Hydrocodone distribution from its Orlando

²⁰ *Id.*

²¹See footnote 17, *supra*.

facility was of particular concern²².

50. AmerisourceBergen has since agreed to pay Kentucky-neighbor West Virginia \$16 million to settle a lawsuit similar to the one at bar; AmerisourceBergen allegedly distributed 132 million hydrocodone and oxycodone pills to West Virginia between 2007 and 2012.²³ Less than 70 miles from Floyd County, Kentucky, Mingo County, West Virginia, was flooded with over 10.8 million hydrocodone doses from 2007-2012.²⁴

51. To piggyback on the state and federal regulatory schemes, distributors created a system of “self-regulation and best practice sharing” through an industry trade group called the Healthcare Distribution Alliance (HDA), formerly known as the Healthcare Distribution Management Association. According to the HDA, “[h]ealthcare distribution has never been just about delivery. It’s about getting the right medicines to the right patients at the right time, safely and efficiently.”²⁵

52. The HDA created “Industry Compliance Guidelines” that stressed the critical role of each member of the supply chain in distributing controlled substances. These industry guidelines provided: “At the center of a sophisticated supply chain, Distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances

²² AmerisourceBergen Receives DEA Order to Temporarily Halt Distribution of Controlled Substances from Its Orlando, Florida Facility (April 24, 2007) <http://investor.amerisourcebergen.com/news-releases/news-release-details/amerisourcebergen-receives-dea-order-temporarily-halt>, AmerisourceBergen Signs Agreement with DEA Leading to Reinstatement of Its Orlando Distribution Center’s Suspended License to Distribute Controlled Substances (June 22, 2007) <http://investor.amerisourcebergen.com/news-releases/news-release-details/amerisourcebergen-signs-agreement-dea-leading-reinstatement-its>

²³ AmerisourceBergen shareholders reject proposals related to opioid crisis (March 1, 2018) https://www.wvgazettemail.com/news/health/wv_drug_abuse/amerisourcebergen-shareholders-reject-proposals-related-to-opioid-crisis/article_cd0fb615-b87f-5daf-bd85-080d1caf947c.html .

²⁴ Drug firms poured 780M painkillers into West Virginia amid rise in overdoses (Dec. 17, 2016) https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_99026dad-8ed5-5075-90fa-adb906a36214.html .

²⁵ See Healthcare Distribution Alliance, Role of Distributors <http://www.hdma.net/about/role-of-distributors> (last access February 15, 2018).

they deliver to their customers.” Indeed, the HDA advises all distributors to “Know Your Customer.”

53. As a dominant player within the healthcare distribution industry, senior executives from Defendant AmerisourceBergen historically served on the board of the HDA. Currently, AmerisourceBergen’s Group President of Pharmaceutical Distribution and Strategic Global Sourcing, Robert Mauch, serves on both the Executive Committee and the Board of Directors of HDA, while President of Strategic Global Sourcing, Rich Tremonte, serves on the Board of Directors of HDA Research Foundation.

54. Additionally, Henry Dale Smith, Jr., of H.D. Smith, previously served as the Vice Chairman of the HDA Board.

55. Distributors, including Defendants, are required to establish expected order thresholds for each customer. These thresholds are vital data points used to determine whether prospective orders are unusual in size, deviate from a prior pattern or are unusual in their frequency.

56. In order to fulfill their obligations under federal and state laws as well as self-regulation, Defendants were required to create highly advanced data collection and analytical systems. These sophisticated software systems monitor the inventory and ordering needs of customers in real-time.

57. Upon information and belief, Defendants, by virtue of their data analytics and “know your customer” initiatives, were actually aware of the extent of numerous suspicious orders, but failed to report or halt shipment of them. On further information and belief, Defendants would have been aware that several of their pharmacy customers had indicia of suspicion for diversion or misuse such as (1) individuals traveling long distances to fill

prescriptions; (2) prescriptions for drug “cocktails,” known for their abuse potential, such as oxycodone and Xanax; (3) individuals who arrived together with identical or nearly identical prescriptions; (4) purported pain patients with prescriptions for immediate-release rather than long-acting narcotics; (5) high percentage of cash purchases; and (6) doctors prescribing outside the scope of their usual practice.

C. DEFENDANTS CAUSED OR CONTRIBUTED TO THE OPIOID EPIDEMIC IN KENTUCKY BY OVERSATURATING THE PHARMACEUTICAL MARKET IN FILLING SUSPICIOUS AND FRAUDULENT ORDERS AND FAILING TO REPORT OR HALT THE SAME.

58. The data which is collected by distributors and reported to government regulators is often reported in terms of drug dosage or doses. A dose is the amount of active ingredient in a particular pill or capsule.

59. Per “The Flow of Money Through the Pharmaceutical Distribution System” published by the Leonard D. Schaeffer Center for Health Policy & Economics at the University of California, (June, 2017), Defendant AmerisourceBergen boasted a 31.6% share of the prescription opioid market, second only to McKesson Corporation’s 32.7% market share.

60. 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. Based on its 31.6% market share, AmerisourceBergen would have distributed 97,086,201.9 doses.

61. From January 1, 2010, through December 31, 2016, Floyd County, Kentucky (“Floyd County”), had an average population of 38,638. Pharmacies located in Floyd County filled prescriptions for a total of 56,375,642 doses of opioid narcotic drugs, which represents

895,000 opioid prescriptions filled in Floyd County alone. With a 31.6% market share, Defendant AmerisourceBergen would have contributed 17,814,702.9 of those doses. From 2012 through 2016 Floyd County residents experienced 89 drug overdose deaths, which represents a rate of 46.67 drug overdose deaths per 100,000 men, women and children residing in Floyd County.

62. From January 1, 2010, through December 31, 2016, Bell County, Kentucky (“Bell County”), had an average population of 27,961. Pharmacies located in Bell County filled prescriptions for a total of 30,091,681 doses of opioid narcotic drugs, which represents 477,000 prescriptions in Bell County. With a 31.6% market share, Defendant AmerisourceBergen would have contributed 9,508,971.2 of those doses. From 2012 through 2016, Bell County residents experienced 81 drug overdose deaths.

63. From January 1, 2010, through December 31, 2016, Clay County, Kentucky (“Clay County”), had an average population of 21,047. Pharmacies located in Clay County filled prescriptions for a total of 25,429,897 doses of opioid narcotic drugs, which represents 403,000 prescriptions of opioid drugs in Clay County. With a 31.6% market share, Defendant AmerisourceBergen would have contributed 8,035,847.45 of those doses. From 2012 through 2016, Clay County residents experienced 28 drug overdose deaths.

64. These figures are only a snapshot of the gross amount of opioid narcotic doses per county distributed in part by Defendant AmerisourceBergen, solely in the Commonwealth of Kentucky and not including the doses distributed by H.D. Smith.

65. Based on the above, the amounts of pills shipped or delivered by Defendants to Kentucky would have been unreasonable, dangerous and facially suspicious.

66. On information and belief, with the systems and technology used by Defendants

specifically to collect and analyze robust data, outlined below, Defendants had access to information reflecting the full extent of their lethal over-shipments in Kentucky.

67. As opioid distributors, Defendants knew or should have known of Kentucky's exceedingly high rate of suspicious shipments, and a correlating risk of abuse, misuse, and diversion of prescription opioids. Numerous publications, news sources and studies highlighted the epidemic rate of opioid abuse and overdose rates in Kentucky.

68. Defendants knew, or should have known, that many of the controlled substances that they were providing to customers in the Commonwealth were being obtained through fraudulent prescriptions from physicians who were prescribing controlled substances for illegitimate medical purposes.

69. On information and belief, Defendants were on notice of the "suspicious orders" they were receiving when they shipped massive quantities of controlled substances to pharmacies in areas that lacked the population to support the claimed need. On further information and belief, Defendants shipped these highly addictive prescription opioids to pharmacies in the Commonwealth located in sparsely populated areas in such quantities that they knew, or should have known, the drugs were being diverted for illegal use.

70. Further, Defendants had a duty, known to Defendants by way of the licensure practices in Kentucky, to report diversion of controlled substances. Specifically, wholesalers of controlled substances must 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"). The DEPPB administers and enforces the Kentucky Controlled Substances Act and grants renewals of licenses of wholesalers of controlled substances in part by relying on the information provided by the

applicant.

71. Both the initial and renewal applications state “the Cabinet for Health Services shall be notified in the event of any theft of other loss of controlled substances. Any problem, such as pilferage, which develops in a facility, must also be reported.”²⁶ Directly below this instructive paragraph is a paragraph stating “I hereby certify that all answers given in this application are true, complete and correct and I understand that any license issued to me by the Cabinet for Health Services may be suspended or revoked for cause,” with a signature line directly below.

72. In addition, the Kentucky Board of Pharmacy requires initial and renewal applications for License to Operate as a Wholesale Distributor. These applications 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.²⁷

73. Defendants acknowledged this language with each application for license renewal and made sworn representations regarding the same.

74. Despite an existing duty to the consuming public and both federal and Kentucky law requiring procedural safeguards against diversion of controlled substances, Defendants , on

²⁶ Application for License Renewal as a Manufacturer or Wholesaler of Controlled Substances (May 2017), <http://www.chfs.ky.gov/NR/rdonlyres/7F58922D-B496-45A3-B12B-B33BE9727ADB/0/DEPPBCSLicenseRenewalForm05172017.pdf>, Application for a New License as a Manufacturer or Wholesaler of Controlled Substances (May 2017) <http://www.chfs.ky.gov/NR/rdonlyres/3063B7E3-9B49-4569-94EF-777AFA4F2624/0/DEPPBCSNewLicenseApplicationForm05172017.pdf>.

²⁷ Application for License to Operate as a Wholesale Distributor, <https://pharmacy.ky.gov/Businesses/Wholesale%20Distributor%20License%20Documents/Wholesale%20Distributor%20License%20Application.pdf> (last accessed Feb. 16, 2018).

information and belief, failed to take any action to effectively prevent, minimize, or reduce the distribution or availability of these dangerous drugs.

75. Defendants had a legal duty to ensure they were not filling suspicious orders that should have simply been refused. However, despite the existence of suspicious orders, and the information available regarding the same through their own sophisticated tracking system, Defendants, on information and belief, did not refuse to ship or supply the often abused and highly addictive prescription opioids to Kentucky pharmacies, between 2007 and the present.

76. Additionally, on information and belief, Defendants knowingly failed to report suspicious orders in Kentucky from 2007 to the present. This business practice was and is unfair and unconscionable, deceptive, and/or misleading.

77. Defendants' intentional distribution of enormous quantities of prescription opioids, as described above, throughout Kentucky's small rural communities and towns showed a reckless disregard for the health and safety of Kentucky's citizens.

78. On information and belief, Defendants played a key part in the creation, proliferation, and continuation of the opioid epidemic and the resulting and continuing catastrophic damage in the Commonwealth of Kentucky.

79. On information and belief, Defendants shipped millions of doses of highly addictive controlled painkillers into Kentucky, many of which should have been stopped and/or investigated as suspicious orders. This business practice was and is unfair and unconscionable, deceptive, and/or misleading.

80. The CDC identified Kentucky as having a statistically significant drug overdose

death rate increase from 2014 to 2015.²⁸ According to the CDC, Kentucky has the 3rd highest opioid-related overdose rate in the country. Data from 2013 onward shows that Kentucky has the 3rd highest drug overdose mortality rate in the country.²⁹

81. Kentucky has been devastated by the opioid epidemic and the epidemic has not abated. Jefferson County, Kentucky reported 364 overdose deaths in 2016, almost one per day, up from 268 in 2015.³⁰

82. Kentucky has one of the highest rates of prescriptions for opioids in the nation.³¹ These statistics reflect the fact that Kentucky is one of the top states for over-shipment of opioids. Experts agree that this problem must be tackled head on and at the source, that being the distributors who flooded the market.³²

83. Upon information and belief, Defendants failed to maintain effective controls against diversion in its distribution centers within Kentucky, including those in Jefferson and McCracken, as well as centers that distributed opioids into Kentucky.

84. Upon and information and belief, Defendants derived millions of dollars of income from the controlled substances it shipped into the Commonwealth.

D. DEFENDANTS CONTINUED OVER-SHIPMENT OF OPIOIDS TO

²⁸ Drug Overdose Death Data, Centers for Disease Control (CDC), <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last visited October 22, 2017).

²⁹ See <http://www.healthymamericans.org/reports/drugabuse2013/release.php?stateid=KY> (last accessed on October 21, 2017).

³⁰ See Commonwealth of Kentucky, Justice & Public Safety Cabinet, Kentucky Office of Drug Policy 2016 Overdose Fatality Report, available at: <https://odcp.ky.gov/Reports/2016%20ODCP%20Overdose%20Fatality%20Report%20Final.pdf>; (last visited October 22, 2017).

³¹http://www.bgdailynews.com/news/kentucky-in-top-states-in-painkiller-prescriptions/article_0d8d0555-47e1-5717-b042-e3d53e7f3ee2.html (7/12/14) (accessed on October 22, 2017)

³² See <http://kentuckytoday.com/stories/prescription-drug-epidemic-must-be-tackled-head-on,6966> (3/32/17) (last visited October 21, 2017).

KENTUCKY CAUSED OR CONTRIBUTED TO AN INCREASE IN HEROIN AND ILLICIT FENTANYL USE IN KENTUCKY.

85. The rise in prescription opioid use and abuse 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.

86. Heroin produces a very similar high to prescription opioids for a much lower cost. As a result, addicted opioid users soon find themselves turning to street drugs to satisfy the high they crave as a result of addiction created, in part, by irresponsible wholesaler practices.

87. Beyond the dangers associated with heroin, a new drug has emerged with far more serious risks; synthetic fentanyl and its analogs like carfentanil. Addicts, who seek ever increasing doses are compelled by their addiction to spiraling toward advance to both heroin and these synthetic drugs. In 2016, the Kentucky Office of Drug Control Policy reported that 47% of all overdose deaths involved a combination of heroin and fentanyl or fentanyl alone.³³

88. 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.³⁴

89. Distributors licensed to participate in the closed-system, including Defendants, devote substantial resources to ordering and inventory management systems.

90. Specifically, Defendants' inventory system allowed for real-time inventory

³³ Commonwealth of Kentucky Justice & Public Safety Cabinet 2016 Overdose Fatality Report, 2 <https://odcp.ky.gov/Documents/2016%20ODCP%20Overdose%20Fatality%20Report%20Final.pdf>

³⁴ See <https://odcp.ky.gov/Pages/The-Heroin-Epidemic.aspx> (last accessed October 22, 2017).

control and item lookup. These products additionally permit for streamlined ordering, purchasing, reconciliations, and account management.

91. Further, Defendants utilized “lean Six Sigma” methodology, “an analytical approach that emphasizes setting high-quality objectives, collecting data and analyzing the results to a fine degree in order to improve processes, reduce costs and minimize errors.”³⁵

92. On information and belief, Defendants possesses real-time data that fully and accurately depicts the exact amounts of pills, pill type, and anticipated customer order threshold.

93. It is conceivable that such data monitoring systems could, and likely did, track and/or record facially suspicious orders from within the Commonwealth of Kentucky.

94. Additionally, said data likely reflects the grossly inflated orders that caused or contributed to the opioid crisis in Kentucky, including, upon information and belief, where Defendants overrode internal controls or thresholds in order to consistently increase shipment volumes.

95. The Commonwealth has been damaged by Defendants’ unfair, false, misleading, or deceptive acts or practices in the conduct of the pharmaceutical wholesale trade or commerce.

³⁵ AmerisourceBergen’s 2016 Corporate Citizenship Report states: “Across more than 50 manufacturing locations, we’re gaining efficiency through the implementation of lean six-sigma processes, common quality systems and shared sourcing initiatives.” See <https://www.drugstorenews.com/article/supply-chain-improvements-enhance-process-business/> and https://www.amerisourcebergen.com/abcnew/-/media/assets/amerisourcebergen/corporate_citizenship/abc_csr_sustainability_report2016_web.pdf?la=en&hash=2748012731AD2477B98350C1E352C8ADC2CA5CB5 (last accessed Feb. 20, 2018). “Wholesaler Provides Support that Saves Hospitals Money on Pharmaceuticals” (April 8, 2014) <http://www.healthcareix.com/2014/04/wholesaler-provides-support-that-saves-hospitals-money-on-pharmaceuticals/>.

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

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

98. On information and belief, Defendants' actions have caused and will continue to cause the Commonwealth to expend substantial sums of funds from the State Treasury to deal with the effects of epidemic of prescription drug addiction that was substantially fueled by Defendants' illegal and reckless action in flooding the Commonwealth with highly addictive prescription medications without regard for the consequences to the Commonwealth and its citizens.

99. The Commonwealth of Kentucky hereby seeks recuperation of the cost to its society caused by Defendants' failure to act in accordance with the various laws cited herein, general disregard for the law, misrepresentations, actions, and inactions with regard to the distribution of opioids in the Commonwealth's communities.

100. The scope of conduct alleged herein has proximately caused damages to Kentuckians and their government in the form of a multigenerational health care epidemic of addiction, and resulting disease and deaths. On information and belief, 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.

101. 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 epidemic and hold Defendants accountable for their misdeeds.

III. CAUSES OF ACTION

COUNT I CONSUMER PROTECTION ACT VIOLATION

102. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:

103. Kentucky has enacted a Consumer Protection Act to ensure that citizens are protected against predatory or inappropriate actions by sellers of goods. KRS 367.120 “The General Assembly finds that the public health, welfare and interest require a strong consumer protection program to protect the public interest and the well-being of both the consumer public and the ethical sellers of goods and services...”

104. KRS 367.170(1) states that “[u]nfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.” Where such practices occur in the course of “trade” and “commerce”, as those terms are defined in KRS 367.170(1) and KRS 367.110(2), that being: “the advertising, offering for sale, or distribution of any services and any property, tangible or intangible, real, personal or mixed, and any other article, commodity, or thing of value, and shall include any trade or commerce directly or indirectly affecting the people of this Commonwealth”, the Consumer Protection Act applies to penalize the seller and to protect the consumer.

105. With regard to Defendants’ particular practices, the Commonwealth regulates the distribution of controlled substances within its borders. The Kentucky Legislature

promulgated the Kentucky Controlled Substances Act to promote the “preservation of public safety and public health.” KRS 218A.005(1).

106. The Kentucky Controlled Substances Act requires of Defendants, as wholesalers of a Schedule II drug, to record all diverted controlled substances, and forward the record to the Cabinet for Health and Family Services. *See e.g.* KRS 218A.160(1)(a); 218A.170; 902 KY. Admin Reg. 55:010 §4(1)(h),(2)(b); 201 KY. Admin. Reg. 2:105 §2(4)(d)).

107. Both the federal version and the Kentucky Controlled Substances Act create a broad duty on the part of wholesalers to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids. These laws are intended to protect consumers from harm. *See* 21 U.S.C. § 823, 21 CFR 1301.74 and KRS 218A.160(1)(a); 218A.170; 902 KY. Admin Reg. 55:010 §4(1)(h),(2)(b); 201 KY. Admin. Reg. 2:105 §2(4)(d)).

108. The harm stemming from any breach of this law and applicable regulations is foreseeable and should have been known to Defendants.

109. On information and belief, Defendants failed and refused to comply with the Controlled Substances Acts and the reporting requirements imposed therein by wholly failing to report facially suspicious orders and failing to halt distribution when appropriate.

110. On information and belief, Defendants shipped drugs into the Commonwealth without adequate policies or procedures in place to detect suspicious orders.

111. On information and belief, Defendants concealed vital knowledge and information from the Commonwealth of Kentucky, its agents and employees, resulting in significant harm to the citizens and to the public coffers.

112. As a result of Defendants’ violations of the Controlled Substances Acts, vis-à-vis

failing to report and halt suspicious orders, as described herein, the Defendant per se violated the Kentucky Consumer Protection Act.

113. Kentucky has been forced to respond to the increase in addicted persons with a substantial increase in expenditure of resources, for example, for monitoring and prosecuting drug related crimes, emergency response to drug related crimes and medical emergencies, cost of administration of opioid reversal agents such as Naloxone, and those associated with the care of opioid addicted infants.

114. On information and belief, Defendants systematically engaged in distribution that was excessive on its face and knowingly failed to alert patients, providers, and government regulators regarding the extent of suspected diversion of opioids. These false and deceptive practices were the proximate cause of the harm incurred by the Commonwealth. The Commonwealth is entitled to sue for any damages resulting from these unfair trade practices under KRS 367.220.

115. On information and belief Defendants' refusal to comply with applicable laws resulted in the proliferation of disproportionate amounts of opioids within Kentucky when compared to population. While Defendants reaped substantial profits, their actions described above also created an environment ripe for abuse and diversion of opioids. The subsequent and related public health and wellness and financial impact more fully laid bare above, is the reasonably foreseeable result of those actions.

116. The costs and harm suffered by the Commonwealth of Kentucky resulted directly and proximately from Defendants' unfair, false, misleading and deceptive trade practices. Defendants should be held liable for all resulting harm.

COUNT II

PUBLIC NUISANCE

117. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows:

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

119. As described herein, Defendants’ conduct constitutes a public nuisance that, if unabated, will continue to threaten the health, safety and welfare of Kentucky’s citizens.

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

121. On information and belief, Defendants intentionally and/or unlawfully failed to maintain effective controls against diversion through proper monitoring, distributing opioids without reporting, and refusing to halt shipment of suspicious orders in or into the Commonwealth. Such actions were inherently dangerous to the welfare of Kentucky’s communities.

122. Due to these 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 are continuing in nature.

123. Defendants knew of the dangers to public health and safety that diversion of opioids would create.

124. As a result of Defendants' actions described herein, the Commonwealth was forced to deal with drug addiction, related criminal and civil malfeasance and misfeasance, treatment and incarceration costs, and a plethora of providers operating pill mills or otherwise encouraging overutilization of opioids across the state.

125. Defendants' actions set forth above 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, and is proscribed by law. *See Restatement Second*, Torts Section 821B.

126. Defendants are liable for all costs borne by the Commonwealth and its agencies which were proximately caused by the wrongful action of Defendant.

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

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

COUNT III
BREACH OF STATUTORY DUTIES/NEGLIGENCE PER SE

129. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows:

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

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

132. Kentucky Board of Pharmacy requires coordination and use of reported opioid distribution and sale data, and continued demonstration of “acceptable operational procedures, including . . . compl[iance] with all DEA regulations.” 201 KAR 2:105 Section(4)(d), KRS 205.5634.

133. To promote public health with regards to the use of opioids, the Kentucky Agency for Substance Abuse Policy (“KY-ASAP”) provides a statewide framework for anti-abuse and anti-diversion practices across the Commonwealth. KY-ASAP is currently being used in many of Kentucky communities as the primary component of a comprehensive drug education/prevention, treatment, and law enforcement programs.³⁶

134. Information and data sharing between all agencies related to prescription drug use or abuse, pursuant to KRS 205.177, serves the purpose of protection of Kentucky’s citizens. These agencies include the Cabinet for Health and Family Services, the Justice and Public Safety Cabinet, and “any other state or local government agency.”

³⁶ See <https://odcp.ky.gov/Pages/Agency-for-Substance-Abuse-Policy.aspx> (last visited October 21, 2017).

135. Finally, additional Kentucky “pill mill” laws, restrict improper access to opiates across the state and put in place reporting and data review protections to be enforced by various state agencies, including but not limited to the state Department of Medicaid (DMS), the Cabinet for Human Resources (CHR), the state Pharmacy Board, the state Office of Drug Control Policy (ODCP), and the Kentucky Board of Medical Licensure (KBML).

136. These laws promote transparency regarding the wholesale, dispersal, and use of opioid analgesics. Each agency may access and share information that protects citizens from drug diversion, medication abuse and misuse, lawful use of state healthcare funds, and all harms incident to violations of those laws and regulations. Distributors who comply with the regulations allow the state agencies to track and analyze risk data and to implement safeguards to protect the public coffers and the citizens of this Commonwealth.

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

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

139. The violations of public safety laws described herein are *prima facie* evidence of negligence. Defendants at the least had a duty to refrain from operating in a manner that endangers the public. Defendants had a duty to maintain effective controls against diversion of

prescription opioids and to guard against, prevent, and report suspicious orders of opioids. Defendants' actions described above breached mandatory, non-delegable legal duties and did not act reasonably.

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

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

142. Accordingly, Defendants' actions constitute negligence per se. Defendants should be held liable for all damages proximately caused by the breach of their statutory duties.

COUNT IV NEGLIGENCE

143. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows:

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

145. Kentucky law has adopted a "universal duty of care" which requires every person to exercise ordinary care in his activities to prevent foreseeable injury. *See T & M*

Jewelry, Inc.v. Hicks ex rel. Hicks, 189 S.W.3d 526 (Ky. 2006).

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

147. A general duty must exist when viewing all of the elements of negligence in this case. Defendants' actions described above constitute gross disregard for the people and government of Kentucky, those who purchased from Defendants and trusted Defendants to comply with laws regarding prescription drug distribution.

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

149. Defendants' breach of these duties was the proximate cause of the harms inflicted upon Kentucky and its citizens. The harm includes, but is not limited to, the financial damages of the Commonwealth in responding to the opioid epidemic and caring for its citizens.

150. The Commonwealth and its residents suffered significant financial and personal damages as a direct and proximate result of Defendants' negligence and misfeasance.

151. Defendants breached the applicable duty of care with regard to prevention of foreseeable injury. Defendants must be held liable for all injuries resulting from their negligence

COUNT V
UNJUST ENRICHMENT

152. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:

153. On information and belief, Defendants created and maintained an artificial market for opioids within the Commonwealth that served only the purpose of spreading the addiction to create a reliable and growing stream of revenue.

154. On information and belief, Defendants received financial benefit from the excessive distribution of opioids across Kentucky. On further information and belief, the clear overuse and diversion was not reported to the appropriate authorities because Defendants did not want to disrupt or diminish its highly profitable business practices.

155. Each year, Defendants renewed their licenses to operate as a pharmaceutical distributor in Kentucky, all the while misusing and abusing its privilege to do so by failing to report and halt suspicious orders and by failing to inform the Commonwealth of Kentucky of its continuing violations.

156. The Commonwealth of Kentucky, through its insurers, including but not limited to DMS, paid direct reimbursement to the pharmacies or insurance programs which were pass through entities in order to allow financial benefits to be received by Defendants.

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

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

**COUNT VI
FRAUD BY OMISSION**

159. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:

160. Under Kentucky law, fraud by omission includes the following four elements: (1) that the Defendant had a duty to disclose a fact or facts, (2) that the Defendant failed to disclose such fact, (3) that the failure to disclose induced the plaintiff to act, and (4) that the plaintiff suffered actual damages therefrom. Rivermont Inn, Inc. v. Bass Hotels & Resorts, Inc., 113 S.W.3d 636, 641 (Ky.Ct.App.2003).

161. Defendants were under a duty required by law, to disclose or report orders of unusual size, orders deviating substantially from a normal pattern, or orders of unusual frequency.

162. On information and belief, Defendants failed to provide the aforementioned reporting required by law, and provided minimal, inaccurate or partial reporting, if any reporting was provided at all. As a direct and proximate result, this Commonwealth acted in reliance on such failure to disclose and suffered grievous injury as a result.

163. The failure to disclose these facts constitutes fraud by omission.

164. Defendants caused harm to Plaintiff due to its clear fraud by omission. Plaintiff is entitled to recover all damages proximately caused by these fraudulent actions.

**COUNT VII
MEDICAID FRAUD KRS CHAPTER 205**

165. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows:

166. KRS 205.8463 is violated when a person “knowingly or wantonly devise[s] a

scheme or plan[s] a scheme or artifice, or enter[s] into an agreement, combination, or conspiracy to obtain or aid another in obtaining payments from any medical assistance program under this chapter by means of any fictitious, false, or fraudulent application, claim, report, or document submitted to the Cabinet for Health and Family Services, or intentionally engage in conduct which advances the scheme or artifice.” KRS 205.8463(1).

167. It is likewise a violation of KRS 205.8463 when any person “intentionally, knowingly, or wantonly make[s], present[s], or cause[s] to be presented to an employee or officer of the Cabinet for Health and Family Services any false, fictitious, or fraudulent statement, representation or entry in any application, claim, report, or document used in determining rights to any benefit or payment.” KRS 205.8463(2).

168. Similarly, KRS 205.8463 is violated when any person to “in any matter within the jurisdiction of the Cabinet for Health and Family Services under this chapter, knowingly, falsify, conceal, or cover up by any trick, scheme, or device a material fact, or make any false, factious, or fraudulent statement or representation, or make or use any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry.” KRS 205.8463(4).

169. Under KRS 205.8469(1), “[t]he Attorney General, on behalf of the Commonwealth, may commence proceedings to enforce KRS 205.8451 to 205.8483.”

170. Additionally, KRS 446.070 provides that “[a] person injured by the violation of any statute may recover from the offender such damages as he sustained by reason of the violation, although a penalty or forfeiture is imposed for such violation.”

171. Defendants’ conduct, as described in the Complaint, violated KRS 205.8463(1), (2), & (4). On information and belief, Defendants, through annual deceptive license renewals

through the Commonwealth's CHFS and Board of Pharmacy, as well as through their failure to identify, track, and reject suspicious orders of addictive prescription opioids: (a) schemed to obtain payment from a medical assistance program through false application or document presented to the CHFS; (b) caused to be presented false or fraudulent claims to the CHFS; and (c) knowingly used or caused to be used a false statement, or statement which concealed or covered up a material fact, to get a false or fraudulent claim paid or approved by a program within the jurisdiction of the CHFS.

172. On information and belief, Defendants through their duties to identify and track suspicious orders of prescription drugs, knew or should have known that, as a natural consequence of its actions, the Commonwealth would necessarily be paying for prescription opioids that were improperly diverted for non-medically necessary and improper abuse. On further information and belief, Defendants financially benefitted from the excessive and non-medically necessary distribution of these prescription narcotics.

173. Defendants' misrepresentations were material because if the Commonwealth had knowledge of Defendants' failure to comply with state and federal law, Defendants' licenses to distribute opioids would have been suspended or not renewed, and, pursuant to both state and federal law, said shipments would not have been made by Defendants.

174. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to obfuscate the presence of suspicious prescription drug orders and induce the Commonwealth to continue and renew its distribution license in order to improperly distribute same throughout the Commonwealth.

175. By reason of Defendants' unlawful acts, the Commonwealth has been damaged,

and continues to be damaged, in a substantial amount to be determined at trial. Costs of prescriptions filled due to Defendants' deceptive operations, and costs of addressing the public health crisis caused or substantially contributed to by that scheme, are direct and proximate results of Defendants' violations as alleged herein and a significant financial burden in the Commonwealth.

176. Defendants' actions described herein constitute Medicaid fraud such that Plaintiff is entitled to recover moneys expended, in addition to penalties, fines, and interest.

177. Defendants should be held liable for all such costs, fines, remedies, and penalties as permitted by law.

**COUNT VIII
MEDICAID FRAUD KRS CHAPTER 194A**

178. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows:

179. KRS 194A.505(6) provides: "No person shall, with intent to defraud or deceive, devise a scheme or plan a scheme or artifice to obtain benefits from any assistance program by means of false or fraudulent representations or intentionally engage in conduct that advances the scheme or artifice."

180. On information and belief, Defendants, by reason of the acts and/or omissions set forth herein, with the intent to defraud or deceive, devised a scheme or artifice to obtain benefits from the Kentucky Medicaid program and intentionally engaged in conduct that advanced said scheme, in violation of KRS 194A.505(6).

181. Defendants, through annual deceptive license renewals through the Commonwealth's CHFS and Board of Pharmacy as well as through their failure to identify,

track, and not distribute suspicious orders of addictive prescription opioids, schemed to obtain benefits from an assistance program through false representations and intentionally engage in conduct that advanced the scheme.

182. KRS 194A.505(8) provides: “The Attorney General on behalf of the Commonwealth of Kentucky may commence proceedings to enforce this section, and the Attorney General shall in undertaking these proceedings exercise all powers and perform all duties that a prosecuting attorney would otherwise perform or exercise.”

183. KRS 194A.990(5) provides: “Any person who violates KRS 194A.505(1) to (6) shall, in addition to any other penalties provided by law, forfeit and pay a civil penalty of payment to the cabinet in the amount of all benefits and payments to which the person was not entitled.”

184. By engaging in the conduct set forth above, Defendants violated KRS 194A.505(6), and the Kentucky Medicaid program, as a direct and proximate result, paid for opioid prescriptions that were not medically necessary. Additionally, Kentucky Medicaid has and will be required to make payments for ongoing medical treatment and care associated with opioid use, misuse, and abuse, on behalf of Kentucky Medicaid beneficiaries in the future as a result of Defendants’ actions.

185. Because of the above violations of KRS 194A.505(6), the Commonwealth is entitled to recover damages from Defendants in an amount to be proved at trial.

186. Because of the above violations of KRS 194A.505(6), the Commonwealth is entitled to recover from Defendants civil penalties in the amount of all benefits and payments to which Defendants were not entitled in accordance with the provisions of KRS 194A.990(5).

187. Because of the above violations of KRS 194A.505(6), the Commonwealth is

entitled to recover from Defendants all reasonable expenses that the court determines have been necessarily incurred by the Commonwealth in prosecution of this action in accordance with the provisions of KRS 194A.990(6).

**COUNT IX
PUNITIVE DAMAGES**

188. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows:

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

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

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

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

193. For these reasons, KRS 411.184 authorizes an award of damages upon a showing by clear and convincing evidence that the defendant acted with fraud, oppression or

malice. In addition, a plaintiff may show entitlement to punitive damages where the defendant has acted with gross negligence. See Williams v. Wilson, 972 S.W.2d 260, 264 (Ky. 1998). Plaintiff is entitled to imposition of punitive damages against the Defendant pursuant to KRS 411.184.

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

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

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

IV. PRAYER FOR RELIEF

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

- A. Declaring that Defendants committed willful violations of KRS 367.170;
- B. An Order permanently enjoining Defendants, and their employees, officers, directors, agents, successors, assigns, affiliates, merged or acquired predecessors, parent or controlling entities, subsidiaries, and any and all persons acting in concert or participation with Defendants, from future false, misleading, deceptive, and/or unfair acts or practices in relation to their shipment of controlled substances to the Commonwealth pursuant to KRS 367.190;
- C. Declaring pursuant to KRS 446.070 that Defendants committed repeated violations of KRS 205.8463;
- D. Declaring that Defendants engaged in conduct, acts, or practices which resulted in fraudulent, erroneous, or illegal payments out of the Kentucky State Treasury.

- E. Permanently enjoining Defendants and their employees, officers, directors, agents, successors, assigns, affiliates, merged or acquired predecessors, parent or controlling entities, subsidiaries, and any and all persons acting in concert or participation with Defendants, from continuing their unlawful conduct, acts and practices, including:
 - 1. Prevent Defendants from continuing to violate Kentucky laws;
 - 2. Mandate that Defendants promptly notify the appropriate authorities of any and all suspicious orders for controlled substances as received from parties who are located in Kentucky;
 - 3. Mandate Defendants submit their system for determining suspicious order to those Kentucky authorities for prior approval, and to enjoin Defendants from distributing any controlled substance in Kentucky for any non-legitimate medical purpose;
 - 4. Mandate Defendants provide Plaintiff with the assistance necessary to address the addiction and the resulting destruction left by Defendants' actions to abate the damage they have caused and are continuing to cause; and
 - 5. Otherwise abates the public nuisance caused in whole or in part by Defendants.

- F. Awarding treble damages pursuant to KRS 205.8467 and KRS 446.070 as well as restitution to the Kentucky Medicaid program pursuant to KRS 194A.990 on account of the damages caused to it as a result of Defendants' unlawful conduct;

- G. Awarding civil penalties of \$2,000 for each willful violation of the Kentucky

Consumer Protection Act pursuant to KRS 367.990(2);

- H. Awarding civil penalties of \$10,000 for each violation of the Kentucky Consumer Protection Act pursuant to KRS 367.990(2), where Defendants' conduct was directed at a person aged sixty (60) or older and Defendants knew or should have known that the person aged sixty (60) or older is substantially more vulnerable than other members of the public;
- I. Awarding punitive damages against Defendants pursuant to KRS 411.184;
- J. Awarding the Commonwealth of Kentucky its costs and attorneys' fees;
- K. Awarding the Commonwealth of Kentucky prejudgment interest as permitted by law;
- L. Awarding any other relief to which the Commonwealth is entitled or the Court deems appropriate and just; and
- M. For a trial by jury on all issues so triable.
- N. Award such other relief as this Court deems just and fair;

Respectfully submitted,

ANDY BESHEAR
ATTORNEY GENERAL

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