

COMMONWEALTH OF KENTUCKY
FRANKLIN CIRCUIT COURT, DIV. IV
CIVIL ACTION NO. 18-CI 00056

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

PLAINTIFF

v.

MCKESSON CORPORATION

DEFENDANT

COMPLAINT

The Plaintiff, the Commonwealth of Kentucky (“the Commonwealth”), by and through its duly elected Attorney General, Andy Beshear, for its Complaint against the Defendant, McKesson Corporation (“McKesson”), states as follows:

I. INTRODUCTION

1. This is a public interest lawsuit brought by the Kentucky Attorney General under Kentucky state 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 McKesson as a consequence of its role fueling the opioid epidemic in the Commonwealth through unfair, false, misleading, and/or deceptive business practices.

2. The actions of McKesson 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, shipping drugs into the

Commonwealth without adequate policies and procedures in place to detect suspicious orders, failing to report to appropriate authorities such “suspicious” orders, and failing to halt such excessive and suspicious shipments.

3. The prescription drugs in question, opiates, are derived from or possess properties similar to opium and heroin, and are narcotic drugs categorized as “Scheduled” drugs or controlled substances due to their high potential for abuse and potential to cause severe psychological or physiological dependence. 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.¹ Later, approved use was 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 boon in their business. However, with this boon for drug makers and sellers came a scourge for this country in the form of a public health epidemic caused by widespread addiction to branded opioids like OxyContin and Percocet, as well as generic forms of oxycodone and hydrocodone. The scourge is now commonly known as the “opioid epidemic.”² More of a modern plague, the opioid epidemic continues to mushroom, despite widespread media attention and nationwide government response.

6. While there are many purported causes related to the opioid epidemic, this action

¹ 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.

² L. Manchikanti et al., *Opioid Epidemic in the United States*, available at <https://www.ncbi.nlm.nih.gov/pubmed/22786464>.

is focused solely on the actions of a particular company which was the dominant pharmaceutical wholesaler and market leader. Defendant McKesson flooded and saturated 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. Upon information and belief, McKesson failed to 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, Defendant McKesson knew or should have known of the dangerous, addictive qualities, and high rates of loss and misappropriation (“diversion rates”) of the drugs it shipped.

8. Upon information and belief, Defendant McKesson received millions of dollars per year for distributing excessive volumes of opioids into Kentucky. Defendant McKesson, in order to maintain or increase its profits and market dominance, situated itself 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 McKesson, 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 McKesson are required to “know their customers” and set thresholds for each customer’s anticipated order. When considering both the data available to McKesson regarding the population dynamics of the towns it shipped to, and the customer thresholds they were required to and were solely responsible to create based on said data, McKesson violated several duties charged by law and by the nature of its industry.

11. Due to Defendant McKesson’s 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 carfentanil. The foreseeable results of Defendant McKesson's actions include loss of jobs and productivity, loss of health and enjoyment of life, increased financial burdens to the Commonwealth and its citizens to respond to the devastation caused by the wave of addiction and, most tragically, loss of lives of Kentuckians.³ Sadly, in 2015 Kentucky had the third highest drug overdose death rate, behind only West Virginia and New Hampshire.⁴ Even worse, in 2016 the Kentucky Office of Drug Control Policy reported 1,404 overdose deaths in the state.⁵

12. The citizens of Kentucky are left in the wake of this wrongful and illegal conduct, 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 Defendant McKesson includes the financial impact to health insurance; providing or reimbursing for medical treatment; 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, dead from overdosing, or simply cannot care for them due to addiction; assembling necessary response teams; and tending to the infirm, dying, and dead.

³ 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).

⁴ 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.

⁵ See <https://odcp.ky.gov/Documents/2016%20ODCP%20Overdose%20Fatality%20Report%20Final.pdf>

14. The Kentucky Medicaid program alone has paid millions of dollars for addiction treatment and services, including emergency room admissions, inpatient hospitalizations, drug treatment, rehabilitation services, hepatitis treatments, and a multitude of other adverse consequences of addiction afflicting Kentucky Medicaid recipients who became addicted to the controlled substances that McKesson excessively distributed in the Commonwealth.

15. This action is therefore brought on behalf of the Commonwealth to: 1) stop McKesson 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 which Defendant McKesson unjustly enriched itself with; and, perhaps most importantly, 4) to enjoin and abate the continuing public nuisance caused in whole or in part, by the actions of Defendant McKesson and force them to help solve the problem they both created and willingly profited from.

II. PARTIES

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.

McKesson Corporation

18. Defendant, McKesson (“Defendant”), is a multinational, publicly traded corporation which, among its many business pursuits, distributes opioid analgesics within the Commonwealth of Kentucky. Upon information and belief, Defendant distributed oxycodone and hydrocodone, among other opioids, in the Commonwealth of Kentucky between January 1, 2010, and December 31, 2016.

19. Defendant is registered with the Kentucky Secretary of State as a Delaware corporation which may be served through its registered agent for service of process, Corporation Service Company, 421 West Main Street, Frankfort, Kentucky 40601. Defendant’s principal place of business is located in San Francisco, California.

20. Defendant McKesson is licensed in Commonwealth of Kentucky for the wholesale distribution of controlled substances pursuant to multiple regulations, including the Kentucky Controlled Substances Act and KRS Chapter 315. McKesson distributed opioids into Kentucky, at a minimum, from its distribution hub in Washington Courthouse, Ohio, bearing DEA registration RM0220688.

21. Kentucky law mandates that all drug wholesale distributors, including Defendant McKesson, apply for and receive a license from the Kentucky Board of Pharmacy. KRS 315.402. Additionally, wholesale distributors of controlled substances, including Defendant McKesson must apply for and receive a license form the Kentucky Cabinet for Health and Family Services. KRS 218A.150. Continuing licensure is dependent upon the applicant's history of 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; and KRS 218A.240, 21 U.S.C. § 823.

III. JURISDICTION AND VENUE

22. The Franklin Circuit Court has personal jurisdiction over Defendant, as Defendant purposefully availed itself of this forum by conducting business in the Commonwealth and by causing harm as a direct and proximate result of its actions. McKesson has 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. Defendant has the requisite minimum contacts with Kentucky necessary to permit this Court to exercise jurisdiction. Defendant has designated a registered agent for service of process and otherwise consented to the jurisdiction of Kentucky courts.

23. Franklin Circuit Court has subject matter jurisdiction over the claims submitted pursuant to KRS 23A.010, KRS 194A.505(8), KRS 205.8469, KRS 218A.240, 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.

24. 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.

25. 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).

26. 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.

27. In this complaint, Plaintiff cites or alludes to federal statutes, regulations or agency memoranda. Plaintiff does so only to establish Defendant's knowledge, state the duty owed under Kentucky tort or 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.

28. Venue is appropriate in Franklin Circuit Court under KRS 452.460, which allows

venue in the county where the injury was suffered. Where the injury is against the Commonwealth, its agents or employees, or the Commonwealth as a whole, venue is proper in Franklin Circuit Court.

IV. THE MEDICAID PROGRAM

29. The Medicaid Program (“Medicaid”) operates under Title XIX of the Social 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.

30. 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”).

31. The Cabinet for Health and Family Services, 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.

32. 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 McKesson.

V. FACTUAL BACKGROUND

33. 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.⁶

34. 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.⁷

35. Additionally, 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 prescription opioids.⁸

36. 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

⁶ *President's Commission on Combating Drug Addiction and the Opioid Crisis*, at https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf

⁷ Id.

⁸ See *President's Commission, Supra*. 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>.

in 2014.⁹

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

37. 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.

38. 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.

39. 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 use and prescription opioids use.¹⁰

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

⁹ 2015 Overdose Fatality Report, Kentucky Office of Drug Control Policy.

<https://odcp.ky.gov/Documents/2016%20ODCP%20Overdose%20Fatality%20Report%20Final.pdf>.

¹⁰ See Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016) and Ctrs. for Disease Control and Prevention, *MMWR Report* at https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm?s_cid=mm6610a1_w

“[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.”¹¹

B. THE ROLE OF PHARMACEUTICAL DISTRIBUTORS

41. 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. This sophisticated system is intended to track and account for controlled substances from manufacturing to the ultimate consumer.¹²

42. 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 type of diversion and abuse that is complained of herein.

43. 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 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).

44. This closed-system of state and federal authority imposes specific duties upon

¹¹ 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>.

¹² See Statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, Drug Enforcement Administration before the Caucus on International Narcotics Control of the United States Senate at a hearing entitled “Responding to the Prescription Drug Abuse Epidemic” presented on July 18, 2012.

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). The end purpose of these laws is to protect the consuming public.

45. Pharmaceutical distributors such as Defendant McKesson are one of the 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.

46. 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.”¹³

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

48. As the dominant player within the healthcare distribution industry, senior

¹³ See <http://www.hdma.net/about/role-of-distributors>

executives from McKesson historically served on the board of the HDA. McKesson's current President Mark Walchirk serves on the executive committee of this powerful trade group.

49. Distributors, specifically including Defendant McKesson, 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.

50. In order to fulfill their obligations under federal and state laws as well as self-regulation, distributors, specifically including Defendant McKesson, create highly advanced data collection and analytical systems. These sophisticated software systems monitor the inventory and ordering needs of customers in real-time.

C. MCKESSON 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.

51. During the time period January 1, 2010, through December 31, 2016, Defendant boasted a 32.7% market share¹⁴—the largest in the wholesale pharmaceutical distribution industry.

52. The data 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.

53. As perspective, 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

¹⁴Testimony of Joseph T. Rannazzisi, *supra* at fn.13.

Commonwealth. Based upon its market share of 32.7% in the wholesale pharmaceutical distribution industry marketplace, McKesson distributed 100,465,784 doses of Schedule II prescription drugs in the Commonwealth.

54. From January 1, 2010 to December 31, 2016, Defendant McKesson distributed 14,795,664 doses of opioid narcotic medications in Perry County alone, enough for more than 526 doses per person (including children and infants). Perry County's population averaged 28,113 persons during that time almost half of which (13,994) were Medicaid participants during that time.

55. More specifically, based upon market share analysis of the same time period, Defendant distributed 3,716,398 doses of generic oxycodone, and 8,154,619 doses of generic hydrocodone, in Perry County.

56. From 2012 through 2015, Perry County experienced 57 prescription drug overdose deaths.

57. Over the same time period, and in the smaller Owsley County, average population 4,622, Defendant distributed 1,787,452 doses of opioid medications – 386 doses per man, woman, and child. Owsley County's Medicaid-covered population averaged 2,805 persons during that time. From 2012 through 2015, Owsley County experienced 6 prescription drug overdose deaths.

58. From January 1, 2010, through December 31, 2016, Floyd County, Kentucky, 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. Of this amount, based upon its market share of 32.7%, McKesson distributed 18,434,834 doses of opioid drugs in Floyd County. From 2012 through 2015, Floyd County experienced 89 prescription drug overdose deaths.

59. From January 1, 2010, through December 31, 2016, Bell County, Kentucky, 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. Based upon its market share of 32.7% in the wholesale pharmaceutical distribution industry, McKesson distributed 9,839,979 doses of narcotics into Bell County. From 2012 through 2015, Bell County experienced 81 prescription drug overdose deaths.

60. From January 1, 2010, through December 31, 2016, Clay County, Kentucky, 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. Based upon its market share of 32.7% in the wholesale pharmaceutical distribution industry, McKesson distributed 8,315,576 doses of prescription opioids in Clay County. From 2012 through 2015, Clay County experienced 28 prescription drug overdose deaths.

61. These figures are only a snapshot of the gross amount of opioid narcotic doses per county and per person Defendant McKesson distributed, in Kentucky. Upon information and belief, the statistics for county-by-county prescription volume for controlled substances for the preceding years, especially for those years preceding the enactment of House Bill 1 in 2012, are substantially higher and more egregious.

62. The amounts of pills shipped or delivered by McKesson to Kentucky was and is unreasonable, dangerous and facially suspicious.

63. With the systems and technology used by Defendant to collect and analyze robust data, outlined below, Defendant had access to information reflecting the full extent of their lethal over-shipments in Kentucky. Rather than taking steps to protect the end customer from the massive volume of dangerous and addictive drugs, McKesson instead chose to keep the fire hose open and pump addictive pill after addictive pill into the Commonwealth.

64. In its position as an opioid distributor, Defendant 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. Indeed, the shipments mentioned above, and others, constitute facially suspicious orders to disproportionately small markets. Numerous publications, news sources and studies highlighted the epidemic rate of opioid abuse and overdose rates in Kentucky.

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

66. McKesson knew, or should have known, it was supplying "pill-mill" pharmacies throughout the Commonwealth.

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

68. Despite an existing duty to the consuming public and both federal and Kentucky law requiring procedural safeguards against diversion of controlled substances, McKesson failed to take any action to effectively prevent, minimize, or reduce the distribution or availability of these dangerous drugs.

69. Defendant 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 Defendant's own sophisticated tracking system, Defendant did not refuse to ship or supply the often abused and highly addictive prescription opioids to Kentucky pharmacies, between 2007 and the present.

70. Additionally, Defendant 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.

71. Defendant's intentional distribution of enormous quantities of prescription opioids throughout Kentucky's small rural communities and towns showed a reckless disregard for the health and safety of Kentucky's citizens.

72. Defendant played a key part in the creation, proliferation, and continuation of the opioid epidemic and the resulting and continuing catastrophic damage in Kentucky.

73. Specifically, Defendant 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.

74. The CDC identified Kentucky as having a statistically significant drug overdose death rate increase from 2014 to 2015.¹⁵ 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.¹⁶ Kentucky has been devastated by the

¹⁵ Drug Overdose Death Data, Centers for Disease Control (CDC), <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last visited October 22, 2017).

¹⁶ See <http://www.healthyamericans.org/reports/drugabuse2013/release.php?stateid=KY> (last accessed on October 21, 2017).

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 2015.¹⁷

75. The overall national opioid prescribing rate declined from 2012 to 2016, and in 2016, the prescribing rate had fallen to the lowest it had been in more than 10 years at 66.5 prescriptions per 100 persons (over 214 million total opioid prescriptions). However, in 2016 52 of Kentucky's 120 counties had an opioid prescription rate higher than 100 prescriptions per 100 persons, eight (8) of which had a rate in excess of 200 prescriptions per 100 persons.¹⁸

76. Kentucky has one of the highest rates of prescriptions for opioids in the nation.¹⁹ These statistics reflect the fact that Kentucky is one of the top states for over-shipment of opioids by Defendant McKesson. Experts agree that this problem must be tackled head on and at the source, that being the distributors who flooded the market.²⁰

77. Defendant McKesson has admitted that it failed to maintain effective controls against diversion of particular controlled substances and thus distributed those drugs into illegitimate medical, scientific or industrial channels by sales to certain of its customers at numerous nationwide McKesson Distribution Centers.²¹ Upon information and belief, and

¹⁷ 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).

¹⁸ <https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html>

¹⁹ http://www.bgdailynews.com/news/kentucky-in-top-states-in-painkiller-prescriptions/article_0d8d0555-47e1-5717-b042-e3d53e7f3ee2.html (7/12/14) (accessed on October 22, 2017)

²⁰ See <http://kentuckytoday.com/stories/prescription-drug-epidemic-must-be-tackled-head-on.6966> (3/32/17) (last visited October 21, 2017).

²¹ Dep't of Justice, U.S. Attorney's Office, Middle District of Florida, *McKesson Agrees To Pay Record \$150 Million Settlement For Failure To Report Suspicious Orders Of Pharmaceutical Drugs* (Jan. 17, 2017), available at <https://www.justice.gov/usao-mdfl/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders>.

consistent with this admission, Defendant McKesson failed to maintain effective controls against diversion in Kentucky distribution centers or centers that distributed opioids into Kentucky, including but not limited to its distribution hub in Washington Courthouse, Ohio.

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

D. DEFENDANT MCKESSON'S CONTINUED OVER-SHIPMENT OF OPIOIDS TO KENTUCKY CAUSED OR CONTRIBUTED TO AN INCREASE IN HEROIN AND FENTANYL USE IN KENTUCKY.

79. 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.

80. 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.

81. Beyond the dangers associated with heroin, a new drug has emerged with far more serious risks; synthetic fentanyl and its analogs like carfentanyl. Addicts, who seek ever increasing doses are compelled by their addiction to advance toward 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.²²

82. 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

²² See <https://odcp.ky.gov/Documents/2016%20ODCP%20Overdose%20Fatality%20Report%20Final.pdf> page 2.

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.²³

E. DEFENDANT MCKESSON POSSESS SOPHISTICATED DRUG TRACKING SYSTEMS THAT PROVIDE THE COMPANY WITH REAL-TIME DATA WHICH WOULD EXPOSE THE OVER SHIPPING OF OPIOIDS TO KENTUCKY.

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

84. In its 2013 Annual Report to shareholders, McKesson boasted that its Acumax Plus technology provides real-time product availability.

85. Additionally, McKesson revealed that it utilizes “Mobile Manager,” which integrates Acumax Plus to give customers ordering and inventory control, and McKesson Connect to provide real-time item lookup and inventory availability. These products additionally permit streamlined ordering, purchasing, reconciliations, and account management.

86. Further, upon information revealed in the 2013 Annual Report, McKesson employs 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.”

87. Accordingly, Defendant possesses real-time data that fully and accurately depicts the exact amounts of pills, pill type, and the customer order threshold they have set.

88. 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.

²³ See <https://odcp.ky.gov/Pages/The-Heroin-Epidemic.aspx> (last visited October 22, 2017).

89. Additionally, said data likely reflects the exact, grossly inflated orders that caused or contributed to the opioid crisis in Kentucky, including where McKesson overrode its own internal controls or thresholds in order to consistently increase shipment volumes.

F. DEFENDANT'S PAST, ADMITTED INDISCRETIONS PREVENT DEFENDANT FROM DENYING ITS CONTRIBUTION TOWARDS THE KENTUCKY EPIDEMIC.

90. The claims and allegations contained herein are a combination of the past indiscretions by Defendant and their failure to make substantive changes or attempt to follow the law coming to a head.

91. In 2008, Defendant paid the Department of Justice \$13.25 million for failing to comply with its obligations under the Controlled Substances Act. Specifically, the government alleged that McKesson failed to report suspicious orders for opioids.

92. In spite of its substantial monetary penalty resulting from its failure to meet its duties as a controlled substances distributor, McKesson subsequently failed to properly monitor its sales of controlled substances and/or report suspicious orders to the DEA, in accordance with McKesson's obligations under the 2008 Settlement Agreement.

93. On January 17, 2017, the Department of Justice announced another settlement with McKesson: \$150 million to resolve allegations McKesson had violated the Controlled Substances Act by filling millions of orders for drugs, including highly addictive opioids, without sufficient anti-abuse safeguards.

94. Specifically from 2008 until 2013, McKesson supplied various U.S. pharmacies an increasing amount of oxycodone and hydrocodone pills, frequently misused products in the

current opioid epidemic.²⁴

95. As part of the nationwide settlement, McKesson agreed to suspend sales of controlled substances from distribution centers in Colorado, Ohio, Michigan, and Florida for multiple years, which the DOJ touted as the “most severe sanctions ever” agreed to by a Drug Enforcement Administration registered distributor.

96. Upon information and belief, Defendant McKesson continued to fill suspicious orders and over saturate the opioid market in the Commonwealth of Kentucky.

97. In a January, 2017, settlement with the DEA, Defendant McKesson admitted that, at various times during the period from January 1, 2009, through the effective date of the Agreement (January 17, 2017) it “did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious.”

98. The 2017 agreement provided that McKesson “distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice. McKesson admitted to its failure to “maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers. . .at numerous nationwide McKesson Distribution Centers.”

²⁴ Dep’t of Justice, U.S. Attorney’s Office, Middle District of Florida, *McKesson Agrees To Pay Record \$150 Million Settlement For Failure To Report Suspicious Orders Of Pharmaceutical Drugs* (Jan. 17, 2017), available at <https://www.justice.gov/usao-mdfl/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders>.

99. Despite these investigations, enforcement actions, and settlements, McKesson nonetheless has opted to keep pushing these dangerous and addictive pills into Kentucky and elsewhere.

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

101. The Commonwealth has been damaged by McKesson's 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.

102. The Commonwealth has been damaged by the continuing public nuisance created by McKesson's actions by failing to investigate, report, and cease fulfilling "suspicious" orders of controlled substances to pharmacies in the Commonwealth.

103. McKesson's 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 McKesson's illegal and reckless action in flooding the Commonwealth with highly addictive prescription medications without regard for the consequences to the Commonwealth and its citizens.

104. The Commonwealth of Kentucky hereby seeks recuperation of the cost to its society caused by Defendant McKesson's 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 Kentucky communities.

105. 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. Despite being acutely aware of the risks of oversupplying opioids, and despite being acutely aware of the increases in orders which were suspicious, McKesson continued to oversupply opioids to Kentucky.

106. 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 Defendant accountable for their misdeeds.

VI. CAUSES OF ACTION

COUNT I CONSUMER PROTECTION ACT VIOLATION

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

108. 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...”

109. 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 Protect Act applies to penalize the seller and to protect the consumer.

110. With regard to Defendant’s 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).

111. The Kentucky Controlled Substances Act requires of Defendant, as a wholesaler of a Scheduled 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)).

112. 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)).

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

114. Defendant 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.

115. Defendants shipped drugs into the Commonwealth without adequate policies or procedures in place to detect suspicious orders.

116. 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.

117. As a result of Defendant's violations of the Controlled Substances Acts, vis-à-vis failing to report and halt suspicious orders, the Defendants per se violated the Kentucky Consumer Protection Act.

118. 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.

119. Defendant 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 to recover any monies paid out as a result of these unfair trade practices under KRS 367.200.

120. Defendant's refusal to comply with applicable laws resulted in the proliferation of disproportionate amounts of opioids within Kentucky when compared to population. While Defendant reaped substantial profits, it also created an environment ripe for abuse and diversion of opioids. The subsequent and related public health and wellness and financial impact more fully lay bare above, is the reasonably foreseeable result of Defendant McKesson's actions.

121. The costs and harm suffered by the Commonwealth of Kentucky resulted directly and proximately from Defendant's unfair, false, misleading and deceptive trade practices.

Defendant should be held liable for all resulting harm.

**COUNT II
PUBLIC NUISANCE**

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

123. 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.

124. Defendant’s conduct constitutes a public nuisance that, if unabated, will continue to threaten the health, safety and welfare of Kentucky’s citizens.

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

126. Defendant intentionally and/or unlawfully failed to maintain effective controls against diversion through proper monitoring, distributing opioids without reporting, and refusing to fail to fill suspicious orders. Such actions were inherently dangerous to the welfare of Kentucky’s communities.

127. Due to the actions of Defendant, opioid use and abuse in the Commonwealth of

Kentucky increased substantially, with correlating increases in illicit drug use, crime, and overdoses. The effects of Defendant's actions are continuing in nature.

128. Defendant knew or should have known of the dangers to public health and safety that diversion of opioids would create.

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

130. Defendant 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. Defendant's conduct is proscribed by law. See *Restatement Second, Torts* Section 821B.

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

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

133. 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

134. Plaintiff incorporates by reference all other paragraphs of this Complaint as if

fully set forth here, and further alleges as follows:

135. 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.

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

137. 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.

138. To promote public health with regard to the use of opioids, the Kentucky Agency for Substance Abuse Policy 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.²⁵

139. 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.”

²⁵ See <https://odcp.ky.gov/Pages/Agency-for-Substance-Abuse-Policy.aspx> (last visited October 21, 2017).

140. 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 Health and Family Services, the state Pharmacy Board, the state Office of Drug Control Policy (ODCP), and the Kentucky Board of Medical Licensure .

141. 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, unlawful 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.

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

143. Defendant, as the wholesaler and private company, has 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, Defendant hoarded the data and misled the federal and state government regarding the distribution and use of opioid analgesics. Defendants failed to comply with the mandatory reporting and data sharing requirements imposed by Kentucky law.

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

opioids and to guard against, prevent, and report suspicious orders of opioids. Defendant breached mandatory, non-delegable legal duties and did not act reasonably.

145. Additionally and through the aforementioned failures, Defendant failed to maintain “acceptable operational procedures” pursuant to Kentucky law. Defendant’s failure to enact, or simply find guidance in, the framework proposed by Kentucky Agency for Substance Abuse Policy evidences Defendant’s disregard for black letter law, guidelines, recommendations, and other methods to prevent the spread and abuse of prescription opioids.

146. Defendant’s 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.

147. 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 actions of Defendant McKesson. Costs of harm to the public are logically traceable to Plaintiff, who is charged with the general protection of the Commonwealth.

148. 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

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

150. 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."

151. 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).

152. 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, Defendant had a general duty to protect Kentucky's citizens by the nature of the business in which it engaged.

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

154. 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 in the disproportionate influx of opioids to low-populated areas. The resulting harms were foreseeable and known to Defendant.

155. Defendant's breach of these duties were 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.

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

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

**COUNT V
UNJUST ENRICHMENT**

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

159. Defendant 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.

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

161. Each year, Defendant renewed its license 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.

162. 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 Defendant.

163. Defendant was 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).

164. Defendant should be required to disgorge all such unjust enrichment and to

reimburse the Commonwealth for all sums to which Defendant were not entitled.

**COUNT VI
FRAUD BY OMISSION**

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

166. 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).

167. Defendant McKesson was 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.

168. Defendant failed to provide the aforementioned reporting required by law. Defendant 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.

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

170. Further, Defendant admitted to prior violations of the federal Controlled Substances Act.²⁶ Thus, Plaintiff reasonably inferred that Defendant conducted business within

²⁶ ²⁶ Dep't of Justice, U.S. Attorney's Office, Middle District of Florida, *McKesson Agrees To Pay Record \$150 Million Settlement For Failure To Report Suspicious Orders Of Pharmaceutical Drugs* (Jan. 17, 2017), available at <https://www.justice.gov/usao-mdfl/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders>.

the Commonwealth of Kentucky in such a way as to violate the Kentucky Controlled Substances Act.

171. Defendant 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

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

173. 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).

174. 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 made or 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).

175. 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, fictitious, 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).

176. 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.”

177. 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.”

178. McKesson’s conduct, as described in the Complaint, violated KRS § 205.8463(1),(2) & (4). McKesson, through its annual deceptive license renewals through the Commonwealth’s CHFS and Board of Pharmacy as well as its failure to identify, track, and not distribute 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.

179. McKesson through its duty 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 prescriptions opioids that were improperly diverted for non-medically necessary and improper abuse. McKesson financially benefits from the excessive and non-medically necessary distribution of these prescription narcotics.

180. McKesson’s misrepresentations were material because if the Commonwealth had known of McKesson’s failure to comply with state and federal law, McKesson’s license to distribute prescription opioids would have been suspended or not renewed, and, pursuant to both state and federal law, said shipments would not have been made by Defendant.

181. By virtue of the above-described acts, McKesson knowingly made, used, or

caused to be made or used false records and statements, and omitted material facts, to induce the Commonwealth to continue and renew its distribution license and obfuscate the presence of suspicious prescription drug orders and distribute same throughout the Commonwealth.

182. By reason of McKesson's 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 McKesson's deceptive operations, and costs of addressing the public health crisis caused or substantially contributed to by that scheme, are direct and proximate results of Defendant's violations as alleged herein and a significant financial burden on the Commonwealth.

183. Plaintiff voluntarily waives any right to recover federal share of any Medicaid cost funding.

184. Defendant's actions constitute Medicaid fraud such that the Plaintiff is entitled to recover monies expended, in addition to penalties, fines and interest.

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

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

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

187. 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."

188. McKesson, 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).

189. McKesson, through its annual deceptive license renewals through the Commonwealth's CHFS and Board of Pharmacy as well as its 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.

190. 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."

191. 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."

192. By engaging in the conduct set forth above, McKesson 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 on behalf of Kentucky Medicaid beneficiaries in the future as a result of these prescription opioids.

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

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

195. Because of the above violations of KRS 194A.505(6), the Commonwealth is entitled to recover from McKesson all reasonable expenses that the court determines have been necessarily incurred by the Commonwealth in the prosecution of this action in accordance with the provisions of KRS 194A.990(6).

COUNT IX PUNITIVE DAMAGES

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

197. 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).

198. Defendant's 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.

199. 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.

200. Defendant's intentional and willful actions were the direct and proximate cause of

the losses suffered by the Commonwealth.

201. 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 or oppression. 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.

202. 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. See *Horton v. Union Light, Heat & Power Co.*, 690 S.W.2d 382, 389 (Ky. 1985).

203. 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. *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).

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

VII. PRAYER FOR RELIEF

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

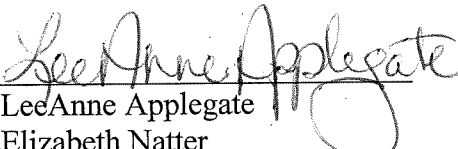
- A. Declaring that McKesson committed willful violations of KRS 367.170;
- B. An Order permanently enjoining McKesson, and it's employees, officers, directors, agents, successors, assigns, affiliates, merged or acquired predecessors, parent or controlling entities, subsidiaries, and any and all persons acting in concert or participation wit McKesson, 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 McKesson committed repeated violations of KRS 205.8463;
- D. Declaring that McKesson has engaged in conduct, acts, or practices which resulted in fraudulent, erroneous, or illegal payments out of the Kentucky State Treasury.
- E. Temporarily enjoining McKesson and its 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 McKesson, from continuing their unlawful conduct, acts and practices, including:
 - 1. Prevents Defendant from continuing to violate Kentucky laws;
 - 2. Mandates that Defendant promptly notify the appropriate authorities of any and all suspicious orders for controlled substances as received from parties who are located in Kentucky;
 - 3. Mandates Defendant submit their system for determining suspicious order to those Kentucky authorities for prior approval, and to enjoin Defendant from distributing any controlled substance in Kentucky for any non-legitimate medical purpose;
 - 4. Otherwise abates the public nuisance caused in whole or in part by Defendant's actions; and
 - 5. Mandates Defendant 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.
- F. Permanently enjoining McKesson and its 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 McKesson, from continuing their unlawful conduct, acts and practices, including:

1. Prevents Defendant from continuing to violate Kentucky laws;
 2. Mandates that Defendant promptly notify the appropriate authorities of any and all suspicious orders for controlled substances as received from parties who are located in Kentucky;
 3. Mandates Defendant submit their system for determining suspicious order to those Kentucky authorities for prior approval, and to enjoin Defendant from distributing any controlled substance in Kentucky for any non-legitimate medical purpose;
 4. Mandates Defendant provide Plaintiff with the assistance necessary to address the addiction and the resulting destruction left by Defendant's 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 Defendant
- G. Awarding treble damages pursuant to KRS 205.8467 and KRS 446.070 to the Kentucky Medicaid program on account of the damages caused to it as a result of McKesson's unlawful conduct;
- H. Awarding restitution to the Kentucky Medicaid program on account of the damages caused to it as a result of McKesson's unlawful conduct;
- I. Awarding civil penalties of \$2,000 for each willful violation of the Kentucky Consumer Protection Act pursuant to KRS 367.990(2);
- J. Awarding civil penalties of \$10,000 for each violation of the Kentucky Consumer Protection Act pursuant to KRS 367.990(2), where McKesson's conduct is directed at a person aged sixty (60) or older and the Defendants knew or should have known that the person aged sixty (60) or older is substantially more vulnerable than other members of the public;
- K. Awarding punitive damages against McKesson pursuant to KRS 411.184;
- L. Awarding the Commonwealth of Kentucky its costs and attorneys' fees;
- M. Awarding the Commonwealth of Kentucky prejudgment interest as permitted by law;
- N. For a trial by jury on all issues so triable; and
- O. Award such other relief to which the Commonwealth is entitled or the Court deems appropriate and just.

Respectfully submitted,

ANDY BESHEAR
ATTORNEY GENERAL

By: 
LeeAnne Applegate
Elizabeth Natter
Charles W. Rowland
Assistant Attorneys General
Commonwealth of Kentucky
Office of the Attorney General
Office of Consumer Protection
1024 Capital Center Drive, Suite 200
Frankfort, Kentucky 40601
Elizabeth.Natter@ky.gov
LeeAnne.Applegate@ky.gov
Charlie.Rowland@ky.gov
(502) 696-5300

C. David Johnstone
Brian C. Thomas
Assistant Attorneys General
Commonwealth of Kentucky
Office of the Attorney General
Office of Medicaid Fraud and Abuse Control
1024 Capital Center Drive, Suite 200
Frankfort, Kentucky 40601
David.Johnstone@ky.gov
Brian.Thomas@ky.gov
(502) 696-5300