

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

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

PLAINTIFF

v.

WALGREENS BOOTS ALLIANCE, INC.
SERVE: Walgreens Boots Alliance, Inc.
108 Wilmot Road, Deerfield, IL 60015
WALGREEN CO.
SERVE: The Prentice-Hall Corporation System, Inc.
421 West Main Street, Frankfort, KY 40601
WALGREENS MAIL SERVICE, LLC
SERVE: Corporation Service Company
421 West Main Street, Frankfort, KY 40601
WALGREENS SPECIALTY PHARMACY, LLC
SERVE: Corporation Service Company
421 West Main Street, Frankfort, KY 40601
WALGREENS.COM, INC. d/b/a WALGREENS #05823
SERVE: Corporation Service Company
421 West Main Street, Frankfort, KY 40601

DEFENDANTS

COMPLAINT

Plaintiff, the Commonwealth of Kentucky (“Kentucky” or “the Commonwealth”), by and through its duly elected Attorney General, Andy Beshear, brings this civil action against Walgreens Boots Alliance, Inc.; Walgreen Co.; Walgreens Mail Service, LLC; Walgreens Specialty Pharmacy, LLC; and Walgreens.com, Inc. d/b/a Walgreens #05823 (collectively “Walgreens”), and in support thereof states as follows:

I. INTRODUCTION

1. This is a public interest lawsuit brought by the Kentucky Attorney General against Walgreens for its role in fueling the opioid epidemic in the Commonwealth through unlawful

business practices.

2. By the time of filing this Complaint, the phrase “Opioid Epidemic”¹ has lost its shock value and become commonplace in daily conversation. This man-made public-health crisis of improper distribution, improper dispensing, misuse, and abuse of opioids² has impacted the United States in whole, and particularly devastated Kentucky.

3. Opioids are derived from or possess properties similar to opium and heroin, and are categorized as “Schedule II” drugs due to their high potential for abuse and potential to cause severe psychological or physiological dependence.³ As discussed further herein, opioids⁴ like oxycodone and hydrocodone were originally approved by the Food and Drug Administration (“FDA”) for short-term post-surgical and trauma-related pain, and for palliative (end-of-life) care; they are now used to treat chronic pain.

4. Walgreens played a dual role in propagating the Opioid Epidemic within Kentucky’s borders as both a pharmacy dispensing opioids to the public and a wholesale distributor taking and shipping orders to and from its own pharmacies.⁵ During the relevant time period, Walgreens filled two positions on the opioid supply chain: distributor, delivering opioids to its own pharmacies, and dispenser, filling prescriptions of opioids through its own pharmacies and delivering opioids to the ultimate consumers. This dynamic placed Walgreens at a unique and superior position of knowledge with regard to the gross amount of opioids pumped into its stores and poured out onto the streets of Kentucky.

¹ L. Manchikanti et al., *Opioid Epidemic in the United States*, available at <https://www.ncbi.nlm.nih.gov/pubmed/22786464>.

² The terms “opioids” and “opioid analgesics” describe the entire class of natural and synthetic opiates.

³ See 902 KAR 55:015 Section 2; 21 C.F.R. 1308.12.

⁴ Opioid was originally a term denoting synthetic narcotics resembling opiates but increasingly used to refer to both opiates and synthetic narcotics. Stedman’s Medical Dictionary 27th Edition.

⁵ Upon information and belief, Walgreens distributed opioids only to its own pharmacies and did not serve third parties.

5. Upon information and belief, Walgreens pharmacies filled so many opioid prescriptions, that the numbers of opioids dispensed by Walgreens pharmacies were unreasonable on their face. Acting as a distributor, Walgreens received orders for those opioids from its own stores. Upon information and belief, those opioid orders were suspicious on their face due to the unreasonable numbers of opioids being dispensed at the store level, but were nevertheless shipped, rather than flagged, halted and reported.

6. More specifically, upon information and belief, Walgreens filled massive and/or suspicious orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency, from its own pharmacies for prescription opioids. They shipped and/or distributed those massive quantities of opioid drugs throughout the Commonwealth, failed to report to appropriate authorities such suspicious orders, and failed to halt such excessive and suspicious shipments. These orders were for such large quantities of prescription narcotic pain medication that there could be no associated legitimate medical purpose for their use.

7. At the store level, upon information and belief, Walgreens dispensed opioids at such an alarming rate and volume that there could be no legitimate medical purpose associated to their use. The only possible explanation for the massive amounts of opioids pouring into and out of Walgreens' stores in Kentucky, is that an unreasonable portion of the drugs were distributed to individuals suffering from addiction, and/or that the drugs were being misused, abused, or diverted (lost, stolen, or otherwise misappropriated to illegal use). This much is evidenced by the numerous criminal incidents occurring in and around Walgreens stores, some of which involved Walgreens pharmacy employees stealing opioids to feed their own addiction.

8. While there are many purported causes related to the opioid epidemic, this action is focused solely on the actions of Walgreens, a dominant retail pharmacy *and distributor*, with

over 70 retail pharmacy locations within Kentucky. Upon information and belief, Walgreens flooded the Commonwealth of Kentucky with excessive amounts of dangerous and addictive prescription opioids while disregarding its own real-time data, customer thresholds, internal reports, and actual experiences *coming from its own pharmacies*.

9. Upon information and belief, from at least 2006 through the present Walgreens disregarded and overrode its own safeguard systems and raised its own opioid order thresholds, purportedly set in accordance with each pharmacy's anticipated order size. Further, by filling these orders Walgreens failed to report or halt red-flag, facially suspicious orders from its own Kentucky pharmacies.

10. By failing to halt and report suspicious orders of prescription opioids, Walgreens made the most dangerous and addictive drugs in America, also the most accessible. Accordingly, in order, Walgreens situated to play a significant role as both a retail pharmacy, acted in this manner to maintain or increase its profits and market dominance while creating a public nuisance of historic proportions.

11. Due to Walgreens' continued proliferation of dangerous and addictive prescription opioids, citizens of Kentucky suffered from prescription drug addiction, abuse, overdose and death. A reasonably foreseeable result of widespread addiction and accessibility of opioid drugs distributed and dispensed by Walgreens, was patients' transitioning their use and abuse to illegal street drugs like heroin, and illicit forms of synthetic fentanyl like carfentanil.

12. Walgreens' actions caused loss of jobs and productivity, loss of health and enjoyment of life, increased financial burdens to the Commonwealth to respond to the devastation

caused by the wave of addiction and, most tragically, the lost lives of thousands of Kentuckians.⁶ Sadly, in 2015 Kentucky had the third highest drug overdose death rate, behind only West Virginia and New Hampshire.⁷ In 2016 the Kentucky Office of Drug Control Policy reported 1,404 overdose deaths.⁸

13. The Opioid Epidemic is more than just a body count to Kentucky and its people, as communities are losing familiar faces and children are left orphaned by multiple generations of family members lost to addiction.⁹ The citizens of Kentucky, who are spread out among many small towns and cities, were left in the wake of Walgreens' actions, to restore order and put an end to this public health crisis, in the face of a wave after wave of excessive opioid distribution.

14. Kentucky's response to the health emergency created by Defendants includes providing or reimbursing for medical treatment; shouldering the increased financial burden of public health insurance; dispatching emergency services; investigating and prosecuting increased 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 deceased. Moreover, additional services have been needed, due to the substantial increase in babies being born with Neonatal Abstinence Syndrome (NAS) addicted to opioids.

15. The Kentucky Medicaid program alone has paid millions of dollars for medically

⁶ See Nora D. Volkow, M.D. and A. Thomas McLellan, Ph.D., *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, NEW ENG. J. MED., 374:1253-63 (March 31, 2016).

⁷ Rate per 100,000 population age-adjusted to the 2000 U.S. standard population using the vintage 2015 population. Source: National Vital Statistics System, Mortality File, CDC WONDER.

⁸ See Commonwealth of Kentucky Justice & Public Safety Cabinet 2016 Overdose Fatality Report, 2 <https://odcp.ky.gov/Documents/2016%20ODCP%20Overdose%20Fatality%20Report%20Final.pdf>.

⁹ Opioids orphan kids in Kentucky, Dec. 12, 2014, <https://www.cnn.com/2012/12/14/health/kentucky-overdoses/>.

unnecessary prescriber visits and improper prescriptions as well as addiction treatment and services, including emergency room admissions, inpatient hospitalizations, drug treatment, rehabilitation services, HIV and hepatitis treatments, and a multitude of other adverse consequences of addiction afflicting Kentucky Medicaid recipients who became addicted to the controlled substances that Walgreens excessively distributed in the Commonwealth.

16. This action is therefore brought on behalf of the Commonwealth of Kentucky to: (1) stop Walgreens pharmacies from over-dispensing opioids within Kentucky communities; (2) stop Walgreens from filling suspicious orders for opioids placed by its own pharmacies; (3) recover the damages suffered by Kentucky; (4) recoup the expenses, penalties owed, and disgorge the amounts with which Walgreens was unjustly enriched; and, perhaps most importantly, (5) to enjoin and abate the continuing public nuisance, caused in whole or in part, by the actions of Walgreens and force them to help solve the problem they created and knowingly profited from.

II. PARTIES

Plaintiff

17. 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.

18. The Attorney General is the proper party to take action against Walgreens 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. 110 *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. The Attorney General has determined that these proceedings are in the public interest.

Defendants

19. Walgreen Co. acted as a retail pharmacy in the United States, until Walgreen Co. completed the acquisition of Alliance Boots, a British pharmacy giant, in 2014. After this acquisition, the company simply became Walgreen Boots Alliance, Inc. traded on NASDAQ under the symbol WBA.

20. Walgreens Boots Alliance, Inc. has three divisions; Retail Pharmacy USA, Retail Pharmacy International, and Pharmaceutical Wholesale. “Walgreens” is considered a retail pharmacy brand under the Retail Pharmacy USA division of Walgreens Boots Alliance.¹⁰ The Pharmaceutical Wholesale Division, “mainly operates under the Alliance Healthcare brand.”¹¹

21. Defendants Walgreen Co.; Walgreens Mail Service, LLC; Walgreens Specialty Pharmacy, LLC; and Walgreens.com, Inc. d/b/a Walgreens #05823, are subsidiaries of Walgreens Boots Alliance. Upon information and belief, they served in the Retail Pharmacy USA and

¹⁰ <http://www.walgreensbootsalliance.com/about/company/retail-pharmacy-usa/>

¹¹ <http://www.walgreensbootsalliance.com/about/company/pharmaceutical-wholesale/>

Pharmaceutical Wholesale divisions of Walgreens Boots Alliance within the Commonwealth of Kentucky. Defendants are collectively referred to herein as “Walgreens.”

22. Upon information and belief, Walgreens has traditionally served as a distributor of generic pharmaceutical products, like generic oxycodone and hydrocodone, to its own stand-alone pharmacy locations known as, “Well Experience” locations. Walgreens also contracted with outside pharmaceutical wholesale distributors to distribute branded pharmaceutical products, such as Purdue Pharma’s OxyContin, to Well Experience locations.

23. Walgreens contracted with Cardinal Health, one of the three largest pharmaceutical distributors in the world, prior to 2013. Upon information and belief, Cardinal Health served as the distributor of branded pharmaceutical products to Well Experience locations until 2013.

24. In 2013, Walgreens allowed its distribution contract with Cardinal Health to expire¹² and entered a ten-year agreement with AmerisourceBergen Drug Company, another one of the three largest pharmaceutical distributors in the world. The agreement with AmerisourceBergen, labeled a “Brand and Generic Distribution Contract,” enabled the companies to, “Streamline the distribution of pharmaceuticals to Walgreens’ stores and leverage global supply chain efficiencies.”¹³ Walgreens represented 30% of AmerisourceBergen’s revenue in 2017, a substantial portion of which was opioid prescriptions.¹⁴ As a part of the blockbuster agreement, Walgreens gained purchase rights to AmerisourceBergen equity, allowing it to further participate in the prescription drug shipment boom in America. Walgreens subsequently exercised these purchase rights, ultimately owning approximately 26% of AmerisourceBergen.

¹² The Walgreens parties to that contract were “Walgreen Co. and Alliance Boots GmbH” until 2014 when it became Walgreens Boots Alliance.

¹³ AmerisourceBergen Announces Strategic, Long-Term Relationship with Walgreens and Alliance Boots, Mar. 19, 2013, <https://amerisourcebergen.gcs-web.com/news-releases/news-release-details/amerisourcebergen-announces-strategic-long-term-relationship>

¹⁴ Walgreens Has Made Takeover Approach to AmerisourceBergen, Feb. 12, 2018 (last viewed June 1, 2018).

25. This equity ownership in AmerisourceBergen provided Walgreens even more information about the rampant problem of suspicious opioid shipments in Kentucky. As part of the transaction, Walgreens has the ability to nominate up to two members of the Board of Directors of AmerisourceBergen.¹⁵ Currently, Walgreen's Co-Chief Operating Officer, who oversees Walgreens' entire business operation, including distribution, sits on the AmerisourceBergen Board of Directors.¹⁶

26. Through ownership and control of AmerisourceBergen, Walgreens has seen firsthand the liabilities created from improper shipments of opioids, as AmerisourceBergen has paid millions of dollars to resolve opioid shipment liabilities.¹⁷ In fact, significant AmerisourceBergen shareholders have pushed for more board oversight into the company's role in the Opioid Epidemic, including heightened reporting requirements and potential claw back of executive compensation as a result of the company's role in the crisis.¹⁸ Unfortunately, Walgreens exercised its control to *resist* these shareholder proposals aimed at combatting the Opioid Epidemic.¹⁹

27. The companies even talked about a total acquisition, but no deal has been reached to date.

28. Upon information and belief, Walgreens utilized Central Pharmacy Operations that provided "central fill" services to its Well Experience locations for a period of time beginning as early as 2009. As described herein, these Central Pharmacy Operations locations served as both

¹⁵ AmerisourceBergen 2018 Proxy Statement at p. 8, <http://investor.amerisourcebergen.com/static-files/6e4bbeea-86a2-4ed1-9e75-bb039e628731> (last viewed June 1, 2018).

¹⁶ AmerisourceBergen Board of Directors Roster, <http://investor.amerisourcebergen.com/5836/ornella-barra> (last viewed June 1, 2018).

¹⁷ Drug distributors fined for failing to report suspicious orders of opioids, February 1, 2017, <https://wvrecord.com/stories/511071502-cardinal-health-amerisourcebergen-settle-pain-pill-lawsuit-for-36-million>

¹⁸ AmerisourceBergen Shareholder proposal dated February 6, 2018, <http://investor.amerisourcebergen.com/static-files/4774a9ae-64b4-4f8d-8da6-2d1ed10993d1> (last viewed June 1, 2018).

¹⁹ AmerisourceBergen 2018 Proxy Statement at pp. 67-77, <http://investor.amerisourcebergen.com/static-files/6e4bbeea-86a2-4ed1-9e75-bb039e628731> (last viewed June 1, 2018).

distributors and dispensaries of opioids. Central Pharmacy Operation centers first existed in Orlando, Florida, and Tempe, Arizona, but were later spread nationwide.²⁰ They currently provide pharmacy support services including customer registration, data entry, patient and provider review, data verification, and telephonic customer counseling.²¹ Pharmacists in Well Experience locations interact with the Central Pharmacy Operation center to assist with resolving customer issues.²²

29. The use of “central fill” practices allowed the company to break down the face-to-face relationship between the patient and pharmacist by outsourcing things like bottling, labeling, prescription review, and data verification.²³ Thus, the cost-effective Central Pharmacy Operation centers acted as both distributors and dispensaries by providing the Well Experience locations medications to dispense and also as a dispensing pharmacy, then mailing the medication to the Well Experience locations to be given to the customer.²⁴

30. In addition to the above, Walgreens is known to have traditional distribution centers, one of which exists north of Kentucky in Perrysburg, Ohio, with another across the Western Kentucky border in Mt. Vernon, Illinois. Upon information and belief, Walgreens acted as a wholesale distributor of opioids to its own free-standing Well Experience locations from these distribution centers as well.

31. Upon information and belief, Walgreens maintained over 100 separate license numbers as a “wholesaler,” “out-of-state pharmacy,” and “retail pharmacy” in the Commonwealth

²⁰ Walgreens’ central fill program to go national, Mar. 1, 2009, <http://www.drugtopics.com/hospitalhealth-system-pharmacy/walgreens-central-fill-program-go-national>.

²¹ Job Opportunities, Central Pharmacy Operations, <https://jobs.walgreens.com/pharmacy> (last viewed May 24, 2018).

²² Pharmacist Drug Store Job Description, <https://jobs.walgreens.com/job/louisville/pharmacist-drug-store/1242/7966253> (last viewed May 24, 2018).

²³ See Local Walgreens stores sending more prescriptions to Orlando to be filled, Apr. 25, 2009, <http://archive.naplesnews.com/business/local-walgreens-stores-sending-more-prescriptions-to-orlando-to-be-filled-ep-398612712-344033902.html/>.

²⁴ See Megan Ribbens, Walgreens to lay off 250+ workers in Orlando, Feb. 2, 2015 <https://www.bizjournals.com/orlando/news/2015/02/02/walgreens-to-lay-off-250-workers-in-orlando.html>.

of Kentucky during the relevant time period. Walgreens held these license numbers pursuant to multiple regulations, including the Kentucky Controlled Substances Act (“KY CSA”). Walgreens is a dispenser, pharmacy, specialty limited pharmacy, and wholesaler (also referred to herein as distributor) under Kentucky law. *See* KRS 218A.010(10), (11), (12), (38); KRS 218A.150(1) (repealed 2018); KRS 218.170(1), (2); KRS 315.010; KRS 315.400(9); 902 KAR 55:010 Section 1(4), 201 KAR 2:230.

III. JURISDICTION AND VENUE

32. The Boone County Circuit Court has personal jurisdiction over Walgreens, as Walgreens purposefully availed themselves of this forum by conducting business in the Commonwealth and by causing harm as a direct and proximate result of their actions. Walgreens 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. Walgreens has the requisite minimum contacts with Kentucky necessary to permit this Court to exercise jurisdiction. Walgreens designated a registered agent for service of process and otherwise consented to the jurisdiction of Kentucky courts.

33. Boone County Circuit Court has subject matter jurisdiction over the claims submitted pursuant to 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. The Commonwealth’s claims are in excess of any minimum dollar

amount necessary to establish the jurisdiction of the Court.

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

35. 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 Walgreens. 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).

36. 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.

37. In this complaint, Plaintiff cites or alludes to federal statutes, regulations or agency memoranda. Plaintiff does so only to establish Walgreens' 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*.

38. Venue is appropriate in Boone County 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 Boone County Circuit Court.

IV. THE MEDICAID PROGRAM

39. 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.

40. 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”).

41. 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.

42. 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 drugs which were distributed in whole or in part by Walgreens.

43. Additionally, upon information and belief, Walgreens pharmacies requested and

accepted Medicaid payment for opioids that were improperly dispensed, over dispensed, or dispensed for no legitimate purpose.

V. DUTIES OWED BY DISTRIBUTORS UNDER KENTUCKY LAW

44. 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”). *See* KRS 218A.150 (repealed). They must also be licensed by the Board of Pharmacy. *See* KRS 315.402; KRS 315.406; 201 KAR 2:105. The DEPPB administers and enforces the KY CSA and grants renewals of licenses of wholesalers of controlled substances in part by relying on the information provided by the applicant.

45. 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.”²⁵ 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.

46. Kentucky law plainly requires that distributors of controlled substances, including opioids, forward a list of lost, destroyed, or stolen medication to the Cabinet for Health and Family Services. KRS 218A.200(6). *See also* 902 KAR 55:010 Section 6. Distributors of opioids have additional record keeping requirements under Kentucky law. *See* KRS 218A.200(2).

²⁵ 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>.

47. 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.²⁶

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

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

50. Generally, Kentucky Administrative Regulations prohibit a distributor from operating in a manner that endangers public health. *See* 201 KAR 2:105 Section 7.

51. A wholesale distributor, including Walgreens, has a duty to

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

²⁶ 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).

against, and handles crisis situations that affect the security or operation of the facility. These crises shall include fires, floods, or other natural disasters, and situations of local, state, or national emergency.

See 201 KAR 2:105 Section 5.

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

VI. DUTIES OWED BY PHARMACIES UNDER KENTUCKY LAW

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

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

55. Advanced Practice Registered Nurses (APRNs) may only prescribe a three (3) day supply of controlled substances, while a Physician's Assistant (PA) is unable to prescribe controlled substances at all. *See* KRS 314.011(8). Prior to 2017, there were no temporal limitations on the ability of a medical doctor to prescribe controlled substances. In 2017, KRS 218A.205 was amended to prohibit the prescription of any more than a three day supply of Schedule II controlled substances, including opioids, unless the practitioner finds it necessary to prescribe more than that based on a limited criteria. *See* KRS 218A.205.

56. Pharmacists have a corresponding duty along with the prescriber to ensure that opioid prescriptions are written for a legitimate patient for a legitimate medical need in the usual course of practice for the prescriber. *See* KRS 218A.180(3)(a). The responsibility for proper dispensing lies on the pharmacist. *Id.* Pharmacists may refuse to dispense a prescribed controlled substance.²⁷

57. Pharmacists may observe a number of “red flags” when trying to determine the validity of a controlled substance prescription, including those enumerated by the Kentucky Board of Pharmacy:²⁸

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

58. Prescriptions for opioids can be computer generated or stamped, but must be manually signed. *See* KRS 218A.180(4), 902 KAR 55:080. The prescription must be on a security prescription blank. 902 KAR 55:105 Section 3

59. Prescriptions for opioids must include the full name and address of the patient, drug name, drug strength, dosage form, quantity prescribed, directions for use, and the name, address,

²⁷ Kentucky Board of Pharmacy, Controlled Substances Questions, <https://pharmacy.ky.gov/Pages/Controlled-Substances-Questions.aspx> (last accessed June 2, 2018).

²⁸ *See Id.*

and registration number of the prescriber. KRS 218A.180(5). Prescriptions for opioids are valid only for 60 days from the date of the prescription. KRS 218A.180.

60. Among other record keeping requirements²⁹, all dispensers/pharmacists licensed by the Kentucky Board of Pharmacy that possess a DEA license must register as a Kentucky All Schedule Prescription Electronic Reporting (KASPER) reporter.³⁰ Reporters are required to report the dispensing of Schedule II controlled substances, including opioids, no later than the close of business on the business day following the dispensing.³¹

61. Pharmacies must maintain adequate security of controlled substances. 201 KAR 2:100, and report robberies or thefts of controlled substances. KRS 315.335. It is considered unprofessional conduct to permit controlled substances to be diverted from a pharmacy. *See* KRS 315.121. Specifically, KRS 315.121 states that unprofessional conduct includes “[s]elling, transferring, or otherwise disposing of accessories, chemicals, drugs, or devices found in illegal traffic when the pharmacist, pharmacy intern, or pharmacy technician knows or should have known of their intended use in illegal activities; [e]ngaging in conduct likely to deceive, defraud, or harm the public, demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist or pharmacy intern, with or without established proof of actual injury; . . . or [f]ailing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful.” *See also* KRS 315.121(2); 201 KAR 2:205 Section 2.

²⁹ *See generally* KRS 218A.200.

³⁰ 902 KAR 55:110 Section 2; Rule 1.1, KASPER Controlled Substance Reporting Guide Version 1.3, Cabinet for Health and Family Services (2017).

³¹ 902 KAR 55:110 Section 2; Rule 1.3, KASPER Controlled Substance Reporting Guide Version 1.3.

62. Pharmacists are required to counsel patients on matters which the pharmacist believes will optimize drug therapy. *See* 201 KAR 2:210.

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

64. Pharmacists, too, have a duty to refrain from engaging in unfair, false, misleading and/or deceptive trade acts or practices. *See* KRS 367.170(1).

VII. FACTUAL BACKGROUND

65. 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. Later, the labels were extended to reach treatment of patients with “chronic pain,” pain lasting more than three months.

66. What launched after the extension of opioid labels can only be described as a concentrated marketing scheme to promote the use of “opioid therapy” to treat chronic pain. The manufacturers of opioid drugs, including those distributed and dispensed by Walgreens, engaged in widespread, aggressive marketing campaigns focused solely on the benefits of their drugs. In doing so, the opioid manufacturers knew of, capitalized on, and actively and intentionally concealed the fact of patient tolerance of the analgesic effects of opioid drugs. They specifically promoted the idea that pain should be a “vital sign.” They further promoted the idea that pain should be treated continuously by long-acting opioids (e.g., OxyContin, MS Contin, Nucynta ER, Duragesic, Opana ER, and Kadian) and supplemented with short-acting, rapid-onset opioids (e.g., Actiq and Fentora) for episodic pain.

67. The marketing strategies employed by opioid manufacturers were intentionally misleading in order to downplay the risks associated with opioid use. As part of their efforts,

opioid manufacturers used unbranded marketing to promote opioid use generally, rather than one specific opioid medication. Manufacturers hid behind third-party physician groups to stay anonymous through their unbranded marketing campaigns, pushing the same misleading and unsupported message that opioids allow patients to have their life back after pain, permit patients to sleep, return to work, and resume physical activity.

68. Marketing efforts by opioid manufacturers, rather than any medical breakthrough, rationalized the prescribing of opioids for chronic pain, thereby opening the floodgates for opioid misuse, abuse, and addiction. Opioid manufacturers even mocked the possibility of addiction while knowing the high risk of addiction associated with their products. The phrase “pseudo-addiction” was used to convince patients that they were not *actually* addicted to opioids, they just thought they were.³² The use of the phrase contradicted both the reality of opioid use, and previous common medical knowledge indicating dependence and addictive behaviors in opioid users.³³

69. Their effectiveness, as is now known, is somewhat of a fallacy. The FDA has expressly recognized it was aware of no long-term studies demonstrating the safety and efficacy of opioids for long-term use. Studies show that even opioid treatment for acute pain in an emergency department setting shows no clinically important differences in pain reduction when compared to use of non-opioid pain relievers.³⁴

70. Still, the marketing efforts worked. Opioids—once a niche drug—are now the most

³² Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide*, at 62 (Waterford Life Sciences 2007). This material was sponsored by the Federation of State Medical Boards, a group representing 70 medical and osteopathic boards in the United States that is substantially funded by Manufacturer Defendants Purdue, Cephalon, and Endo.

³³ David N. Juurlink, et al. *Dependence and Addiction During Chronic Opioid Therapy*, *J Med Toxicol.* 2012 Dec; 8(4): 393-399, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3550262>

³⁴ Andrew K. Chang, et al., *Effect of a Single Dose of Orla Opioid and Nonopioid Analgesics on Acute Extremity Pain in the Emergency Department*, Nov. 7, 2017, *JAMA.* 2017; 318(17):1661-1667, available at <https://jamanetwork.com/journals/jama/fullarticle/2661581>.

prescribed class of drugs, above even blood pressure medicine. While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply. In 2012, opioids generated a combined \$8 billion in revenue for drug companies; this revenue exceeded \$15 billion in 2016. The cost of the country's Opioid Epidemic is estimated to have exceeded \$1 trillion from 2001 to 2017, and is projected to cost an additional \$500 billion by 2020.³⁵

71. The opioid epidemic in America is unparalleled. On August 10, 2017, President Donald Trump declared America's Opioid Epidemic to be a national emergency. According to the Centers for Disease Control ("CDC"), the most recent data estimates that 142 Americans die every day from a drug overdose. Drug overdoses now kill more people than gun homicides and car crashes combined. Between 1999 and 2015, more than 560,000 people in this country died due to drug overdoses. Approximately 6 out of 10 drug overdose deaths are caused by opioids.³⁶

72. According to the DEA, for every one unintentional opioid overdose death in 2010, there were another 108 persons with abuse or dependency issues, and 733 nonmedical opioid users.³⁷

73. Opioids are the prime contributor to the addiction and overdose crisis. In 2015, nearly two-thirds of drug overdoses were linked to opioids like Percocet, OxyContin, heroin, and fentanyl. Americans consume more opioids than any other country in the world, over 47 doses

³⁵ 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).

³⁶ Letter from President's Commission on Combating Drug Addiction and the Opioid Epidemic to the President of the United States (Nov. 1, 2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

³⁷ See https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2015/march_2015/prevoznik.pdf at 26.

per 1,000 persons per day from 2013-2015.³⁸ 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.³⁹

74. The United States has a dire situation on its hands. The troubling reality for states like Kentucky, Ohio, and West Virginia is sadly much worse. Kentucky's overdose fatalities, which were already high, increased dramatically in 2015. From February 1, 2016, to January 31, 2017, pharmacies in the Commonwealth filled prescriptions for 307,234,816 doses of Schedule II prescription drugs, which breaks down to 69 doses of Schedule II narcotics for every man, woman, and child in the Commonwealth. Overdose deaths of Kentucky residents, regardless of where the death occurred, and non-residents who died in Kentucky, numbered 1,249 in 2015, topping the already unacceptable 1,088 overdose deaths in 2014.⁴⁰ In 2015, drug overdoses accounted for 59.17% of Kentucky's statewide accidental deaths, more than motor vehicle accidents, fire, drowning and gunshot wounds combined. In 2015, opioids accounted for 46.63% of the statewide total of drug related fatal overdose victims.⁴¹

75. The CDC identified Kentucky as having a statistically significant drug overdose death rate increase from 2014 to 2015 and again from 2015 to 2016.⁴² According to the CDC, in 2015 Kentucky and Ohio shared the 2nd highest overdose rate in the country. Data from 2013

³⁸ International Narcotics Control Board Report 2015, Table XIV.1.a., p 226, https://www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2016/NAR_Part_IV_Tables_EFS.pdf, (last accessed June 4, 2018).

³⁹ Letter from President's Commission on Combating Drug Addiction and the Opioid Epidemic to the President of the United States (Nov. 1, 2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

⁴⁰ *2015 Overdose Fatality Report, Kentucky Office of Drug Control Policy* <https://odcp.ky.gov/Documents/2016%20ODCP%20Overdose%20Fatality%20Report%20Final.pdf>.

⁴¹ *2015 Annual Report, Office of the Kentucky State Medical Examiner* <https://odcp.ky.gov/Reports/2016%20annual%20report.pdf>.

⁴² Drug Overdose Death Data, Centers for Disease Control (CDC), <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last visited October 22, 2017).

onward shows that Kentucky has the 3rd highest drug overdose mortality rate in the country.⁴³

76. Kentucky has one of the highest rates of prescriptions for opioids in the nation.⁴⁴ These statistics reflect the fact that Kentucky is one of the top states for over-distribution of opioids by distributors like Walgreens, and one of the top states for the over-dispensing of opioids by pharmacies like Walgreens.

77. In Northern Kentucky, one person died from a drug overdose every 40 hours in 2015. Overdose deaths increased in 2016; Boone County was in the top five counties in Kentucky for heroin-related overdose deaths, fentanyl-related deaths, and deaths related to heroin and fentanyl in combination.⁴⁵ Kenton and Campbell counties were also in the top five counties in Kentucky for heroin-related overdose deaths, fentanyl-related deaths, and deaths related to heroin and fentanyl in combination. Campbell County ranked fifth overall in Kentucky for overdose deaths per capita.⁴⁶ In 2016 alone, these three counties lost 208 people to drug overdoses. The number of lives lost statewide to drug overdoses was nearly five-times that of car accidents. That same year, one in four arrests was opioid related. Opioid-overdose reversal drug naloxone was administered in four out of every seven Emergency Medical Services runs; and on average, seven response calls per day were to drug-related incidents.⁴⁷

78. Opioid addiction and misuse also results in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of naloxone, the

⁴³ See <http://www.healthyamericans.org/reports/drugabuse2013/release.php?stateid=KY> (last accessed on October 21, 2017).

⁴⁴http://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)

⁴⁵ 2016 Overdose Fatality Report, Kentucky Office of Drug Control Policy, <https://odcp.ky.gov/Documents/2016%20ODCP%20Overdose%20Fatality%20Report%20Final.pdf>.

⁴⁶ *Id.*

⁴⁷ New Online Tool Uses Data to Show Impact of Opioids, Oct. 9, 2016, <https://nkyhealth.org/2016/10/09/new-online-tool-uses-data-to-show-impact-of-opioids/?search=opioid>.

antidote to opioid overdose. For example, Louisville Metro Police Major, Eric Johnson, said that the police force administered 123 doses of naloxone in one six-week period between January 1st and February 15th, 2017. One opioid addiction treatment center in Paducah, Kentucky doubled in size to meet the growing needs of the community. The center reports seeing as many 300 patients, of all ages and from all backgrounds, for addiction to prescription opioids, heroin, and fentanyl. Law enforcement officers in Kentucky similarly observed opioid addiction and abuse affecting people across varying ages and demographics.

79. Rising opioid use and abuse have other negative social and economic consequences as well. According to a 2016 study by a Princeton economist, the increase in opioid prescriptions from 1999 to 2015 could account for roughly 20% of the decline in labor force participation for men and 25% for women. Two-thirds of the surveyed men, not in the labor force and taking pain medication daily, said they took *prescription* painkillers—compared to just 20% of employed men.⁴⁸

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

⁴⁸ Alan Krueger, *Where have all the workers gone? An inquiry into the decline of the U.S. labor force participation rate*, https://www.brookings.edu/wp-content/uploads/2017/09/1_krueger.pdf (last accessed June 8, 2018).

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

81. Children have not been spared by the Opioid Epidemic. As of January 2017, there were over 8,000 children in foster care in Kentucky, compared to 6,000 in 2012, most commonly because of their parent's abuse of drugs or alcohol. According to one foster-parent recruiter, the increasing number of children in foster care in Ashland, Kentucky has reached a, "crisis point," as a result of the opioid epidemic.⁴⁹

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

83. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from Neonatal Abstinence Syndrome ("NAS").⁵⁰ These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening.

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

⁴⁹ States hit hard by Opioid Epidemic see increase in foster care kids, North Jefferson News, Jan. 19, 2017.

⁵⁰ See Annual Report, Neonatal Abstinence Syndrome in Kentucky, <https://chfs.ky.gov/agencies/dph/dmch/Documents/DPHNASReport2016.pdf> (last accessed June 8, 2018).

Kentucky Department of Public Health. This translates to about 100 newborns per month. As recently as March 2018, Madison County officials, including healthcare providers and social workers held a conference in order to solve the increasing problem of pregnant women being addicted to opioids. The goal of the conference was to create a plan that would provide support to mothers and families after giving birth, and the plan is currently in process.⁵¹

85. Faced with increased tolerance, addicted people are compelled to seek out higher and stronger doses. Heroin produces a very similar high to prescription opioids for a much lower cost. As a result, addicted opioid users soon find themselves turning to street drugs to satisfy the cravings and withdrawal of addiction created, in part, by irresponsible practices by distributors and pharmacies. The rise in prescription opioid use and abuse 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. 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 use of prescription opioids.⁵² Opioid addiction feeds heroin addiction, as heroin produced similar highs and costs substantially less to the user. According to the CDC, the percentage of heroin users who also use opioid pain relievers rose from 20.7% between 2002 and 2004 to 45.2% between 2011 and 2013. More current studies cement the connection between heroin and prescription opioids.⁵³

⁵¹ <http://www.wkyt.com/content/news/Madison-County-helath-officials-hold-conference-on-helping-drug-addicted-babies-475682753.html> (last visited March 3, 2018.)

⁵² 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).

⁵³ 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

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

“[Opioid abuse] is building more slowly, but it’s much larger. And the potential[] for death, in particular, [is] way beyond anything we saw then. . . . [F]or pain medicine, a one-day dose can be sold on the black market for \$100. And a single dose can [be] lethal to a non-patient. There is no other medicine that has those characteristics. And if you think about that combination and the millions of people who are using these medicines, you get some idea of the exposure of the society to the prescription drug problem.”⁵⁴

88. Northern Kentucky, in particular, has witnessed the effects of the Opioid Epidemic and resulting upswing in heroin use.⁵⁵ The Northern Kentucky Health Department logged thirty-seven (37) cases of HIV-positive patients in 2017, with eighteen (18) of those cases reporting injection drug use among their risk factors for contracting the disease. This is a significant increase compared to five (5) HIV cases with injection drug use as a risk factor reported in 2016.⁵⁶ This substantial increase in HIV cases is an unfortunate result of the Opioid Epidemic.⁵⁷

89. Beyond the dangers associated with heroin, a new drug has emerged with far more serious risks; synthetic fentanyl and its analogs like carfentanil. In 2016, the Kentucky Office of Drug Control Policy reported that 47% of all overdose deaths involved fentanyl, either alone or combined with heroin.⁵⁸ 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

⁵⁴ 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>.

⁵⁵ See <https://odcp.ky.gov/Pages/The-Heroin-Epidemic.aspx> (“The growing number of people who began abusing expensive prescription drugs are switching to heroin”) (last accessed June 8, 2018).

⁵⁶ Health officials see increase in HIV infection among individuals who inject drugs, Jan. 9, 2018, <https://nkyhealth.org/2018/01/09/health-officials-see-increase-in-hiv-infection-among-individuals-who-inject-drugs/?search=HIVcount>

⁵⁷ See CDC “Viral Hepatitis” <https://www.cdc.gov/hepatitis/featuredtopics/youngpwid.htm> (last accessed June 4, 2018).

⁵⁸ Commonwealth of Kentucky Justice & Public Safety Cabinet 20116 Overdose Fatality Report, 2 <https://odcp.ky.gov/Documents/2016%20ODCP%20Overdose%20Fatality%20Report%20Final.pdf>

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.⁵⁹

90. As a distributor and pharmacy, Walgreens' compliance with the law was vital to safeguard consumers and control the rate of addiction, abuse, and diversion of opioids. As detailed below, upon information and belief, Walgreens wholly failed to follow the law, such that its actions promoted addiction, abuse, and diversion of opioids throughout Kentucky.

A. ROLE OF WALGREENS IN KENTUCKY'S OPIOID EPIDEMIC

91. Rather than drug manufacturers selling opioids directly to consumers, a sophisticated, closed distribution system exists to push the drugs across the nation.⁶⁰ This sophisticated system arose out of the need for greater control over abused and addictive prescription drugs and is intended to track and account for controlled substances from manufacturing to the ultimate consumer.⁶¹ The closed-system model contemplates manufacturers selling pharmaceuticals to distributors. Hospitals, palliative care facilities, dispensing physicians, and, as here, pharmacies, order pharmaceutical products from the distributors, who distribute such products to them for dispensing to ultimate consumer.

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

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

⁵⁹ *Id.*

⁶⁰ 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>

⁶¹ *Id.*

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.⁶² The end purpose of these laws is to protect the consuming public.

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

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

96. Prescription drug sales account for 69% of the sales within Walgreens’ retail pharmacies.⁶³

97. Walgreens Pharmaceutical Wholesale division generated an operating profit of

⁶² *Id.*

⁶³ <http://www.walgreensbootsalliance.com/about/company/retail-pharmacy-usa/>

\$376 million, with sales of \$13.8 billion, in fiscal 2015. Sales topped \$33 billion in the second quarter of 2018. Walgreens is, by every definition, a pharmaceutical giant.

98. Upon information and belief, opioid distributors, specifically including Walgreens, are required to establish expected order thresholds for each pharmacy that orders opioids. By nature of its dual role as both a retail pharmacy and distributor, Walgreens was required to set thresholds for its own pharmacy stores. 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.

99. In order to fulfill their obligations under federal and state laws, distributors, specifically including Walgreens, created highly advanced data collection and analytical systems. These sophisticated software systems monitor the inventory and ordering needs of customers in real-time.

100. A Walgreens spokesperson described that the Ohio distribution center utilized

“a very sophisticated computer-driven automated storage and retrieval system. Using a very complex conveying system, we use bar coding technology to move cases from one spot to another... Our inventory management system connects our stores and our distribution centers. We have an automated reorder system. Of course, a store manager can adjust his order as he feels is necessary, but we do make use of an automated reorder system.”⁶⁴

101. Accordingly, Walgreens possessed real-time data that fully and accurately depicted the exact amounts of pills, pill type, and anticipated “customer” order threshold for its own stores. It is conceivable that such data monitoring systems could, and likely did, track and/or record facially suspicious orders from Walgreens stores within the Commonwealth of Kentucky.

⁶⁴ See http://www.toledobiz.com/Files/major_stories/tbj_featured0009walgreens.html

102. Acting as a distributor, Walgreens had both the responsibility and ability to recognize, flag, report, and refuse to ship “suspicious orders” for opioids from its pharmacies. Walgreens was on notice of the “suspicious orders” it was receiving when it shipped massive quantities of controlled substances to its own pharmacies in areas that lacked the population to support the claimed need.

103. Additionally, said data likely reflects the grossly inflated orders that caused or contributed to the Opioid Epidemic in Kentucky, including where Walgreens overrode internal controls or thresholds in order to consistently increase shipment volumes. As stated above by a Walgreens spokesperson, the ability to control thresholds was given freely to Walgreens’ store managers.

104. Upon information and belief, Walgreens, by virtue of its data analytics, was actually aware of the extent of numerous suspicious orders, but failed to report or halt shipment of them. Further, Walgreens was aware that several of its pharmacy customers had indicia of suspicion for diversion, abuse 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.

105. Upon information and belief, the amount of pills ordered by Kentucky Walgreens’ stores and subsequently distributed to Kentucky Walgreens’ stores from the Walgreens distribution centers or Central Pharmacy locations, were and are unreasonable, dangerous and facially suspicious.

106. In its position as an opioid distributor and dispensary/pharmacy, Walgreens 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. Upon information and belief, 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, which should have factored into the decisions Walgreens made regarding shipping opioids.

107. Walgreens had a legal duty to ensure it was not filling suspicious orders that should have simply been refused.

108. Further, in 2008, Walgreens entered into a Memorandum of Agreement.⁶⁵ ("2008 MOU") with the Office of Inspector General of the U.S. Department of Health and Human Services, that required Walgreens to enhance and enforce its policies and reporting procedures involving, "The proper and accurate documentation of medical and prescription records" and "The proper and accurate dispensing of prescription drugs, including federal and state law requirements relating to prior authorization." The 2008 MOU also required that Walgreens design procedures to alert its board of any drug dispensing issues and lack of compliance with state and federal laws concerning dispensing of prescription drugs. Thus, an added layer of responsibility was supposed to have existed during the time that Walgreens committed the offensive behavior described herein.

109. On June 11, 2013, the DEA announced an \$80 million settlement with Walgreens which, at the time, was the largest settlement in DEA history ("the 2013 Settlement"). The 2013 Settlement resolved allegations that Walgreens committed an unprecedented number of reporting, recordkeeping and dispensing violations and negligently allowed controlled substances to be

⁶⁵ https://www.dea.gov/divisions/mia/2013/mia061113_appendixa.pdf

diverted for abuse and illegal black market.⁶⁶

110. As part of the 2013 Settlement, Walgreens acknowledged that “Suspicious order reporting for distribution to certain pharmacies did not meet the standards identified by DEA,” in three letters from DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including Walgreens, on September 27, 2006, February 7, 2007 and December 27, 2007. Furthermore, Walgreens acknowledged that certain Walgreens retail pharmacies did on some occasions dispense certain controlled substances in a manner not fully consistent with its compliance obligations under the CSA (21 U.S.C. §§ 801 *et seq.*) and its implementing regulations (21 C.F.R. Part 1300 *et seq.*)”⁶⁷

111. Upon information and belief, despite the existence of suspicious orders, and the information available regarding the same through its own sophisticated tracking system, Walgreens did not refuse to ship or supply the often abused and highly addictive prescription opioids to its Kentucky pharmacies, between 2007 and the present. Additionally, upon information and belief, Walgreens 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.

112. The number of opioids being requested by Walgreens stores and distributed by Walgreens distribution centers and Central Pharmacy locations was so large that there could have been no legitimate medical use for the opioids when compared to the population being served. Accordingly, Walgreens knew, or should have known, that many of the controlled substances that

⁶⁶ Walgreens Agrees To Pay A Record Settlement Of \$80 Million For Civil Penalties Under The Controlled Substances Act. <https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled>.

⁶⁷ On or about September 27, 2006, February 7, 2007, and December 27, 2007, the DEA's Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including Walgreens (the “DEA Letters”). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b).

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.

113. Walgreens was in a position to recognize and counsel patients exhibiting signs of addiction and abuse. Walgreens was in a position to refuse to dispense opioids to patients who exhibited signs of addiction, abuse, and participation in diversion activities like selling or sharing opioid pills.

114. Kentucky and federal law requires that licensed pharmacists recognize red flags that indicate addiction, abuse and diversion, some of which have been described with particularity by the Kentucky Board of Pharmacy, as referenced above⁶⁸, and the DEA: (1) many customers receiving the same combination of prescriptions or drug cocktails; (2) many customers receiving the same strength of controlled substances, no individualized dosing, and/or multiple prescriptions for the strongest dose of an opioid drug available; (3) many customers paying cash for their prescriptions; (4) customers requesting early refills; (5) many customers with the same diagnosis codes written on their prescriptions; (6) customers driving long distances to visit physicians and/or fill prescriptions; (7) customers arriving in groups, with each customer presenting a prescription issued by the same physician; and (8) customers with prescriptions for opioids written by physicians not associated with pain management (i.e. a gynecologist). Additionally, a pharmacy may be tipped off to addiction, abuse, and diversion where the overwhelming proportion of prescriptions filled by the pharmacy is for opioids.⁶⁹

115. Walgreens, acting as a pharmacy, was in a position to recognize those red flags

⁶⁸ See fn 27-28.

⁶⁹ See https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2015/march_2015/prevoznik.pdf at 139-40.

listed above. Upon information and belief, all or some of those red flags were present during the relevant time period and should have caused Walgreens' pharmacies within Kentucky to refuse to fill prescriptions and/or report the behavior. However, Walgreens failed to do so. Further, Walgreens' own policies discouraged the identification of red flags that may have led to a refusal to fill an opioid prescription.⁷⁰

116. Distribution centers have been described as, "The first line of defense,"⁷¹ and pharmacists the, "Last line of defense."⁷² Walgreens failed to respect its roles as the first line of defense, as a distributor, and the last line of defense, as a pharmacy. For example, Walgreens failed to maintain effective controls against diversion or conduct due diligence to ensure opioids were not diverted, resulting in the gross over-distribution of opioids.

117. For example, in Oviedo, Florida, a single store purchased 80,900 oxycodone dosage units in 2009. The same store purchased 223,500 dosage units in 2010 and grew to 1,684,900 in 2011.⁷³ For context, the national average purchase for the same products for all pharmacies in the United States was 63,294 dosage units in 2009, 69,449 dosage units in 2010,⁷⁴ and 73,000 dosage units in 2011.⁷⁵ It was evident to enforcement agents investigating Walgreens in Florida that, "Walgreens' pharmacists blatantly ignored red flags,"⁷⁶ as discussed *infra*, upon information and belief, Walgreens committed the same or similar wrongful acts and omissions relating to over- dispensing and distribution of opioids in Kentucky.

⁷⁰ See https://www.dea.gov/divisions/mia/2013/mia061113_appendixb.pdf at ¶16.

⁷¹ <https://www.usatoday.com/story/news/nation/2013/06/11/walgreens-drug-oxycodone-license-80-million/2412451/>

⁷² See https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2015/march_2015/prevoznik.pdf at 132.

⁷³ See <https://www.dea.gov/divisions/mia/2012/mia091412.shtml>.

⁷⁴ See https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2015/march_2015/prevoznik.pdf

⁷⁵ See DEA Order to Show Cause and Immediate Suspension of Registration, ¶16(g), Sep. 13, 2012, available at https://www.dea.gov/divisions/mia/2013/mia061113_appendixb.pdf.

⁷⁶ <https://www.usatoday.com/story/news/nation/2013/06/11/walgreens-drug-oxycodone-license-80-million/2412451/>

118. Upon information and belief, Walgreens' corporate policies encouraged the over-distribution and over-dispensing of opioid products. Through bonus programs, Walgreens rewarded its employees to fill as many prescriptions as possible.⁷⁷ Additionally, the DEA found evidence that Walgreens had a corporate policy encouraging increased sales of oxycodone.⁷⁸

119. Further, the DEA found that Walgreens intentionally crafted their policies in such a way as to avoid suspicious order reporting by instructing employees to report suspicious shipments to the store⁷⁹; common sense dictates that Walgreens' pharmacies would simply accept shipments that filled the orders that they submitted without calling attention to the fact they the pharmacy itself submitted a suspicious order. Upon information and belief, the policy resulted in a lack of compliance with reporting requirements. Even Walgreens' compliance efforts during the relevant time period were crafted in such a way as to avoid the collection of information that would suggest noncompliance with state and federal controlled substance laws.⁸⁰

120. These practices were discovered by the DEA in the prior enforcement action which focused on a distribution center in Jupiter, Florida. DEA Administrator, Michele Leonhart, stated in the Order to Show Cause and Immediate Suspension of Registration, "The nature and significance of the problems revealed by DEA's investigation indicate that Respondent's anti-diversion measures are inadequate generally; the problems do not appear to be limited to the pharmacies discussed herein."⁸¹ Further, Ms. Leonhart stated, "To reiterate, my concerns with Respondent's distribution practices are not limited to the six [Florida] Walgreens pharmacies discussed herein."⁸² Upon information and belief, those Walgreens policies and practices also

⁷⁷ See https://www.dea.gov/divisions/mia/2013/mia061113_appendixb.pdf at ¶16.

⁷⁸ DEA Order to Show Cause and Immediate Suspension of Registration, ¶16

⁷⁹ *Id.* at ¶13-14.

⁸⁰ *Id.* at ¶, 23.

⁸¹ *Id.* at ¶21.

⁸² *Id.* at ¶21.

plagued the Walgreens locations in Kentucky, contributing to today's Opioid Epidemic.

121. Upon information and belief, Walgreens intentionally distributed substantial quantities of prescription opioids throughout Kentucky's communities, showing its reckless disregard for the health and safety of Kentucky's citizens.

122. Specifically, upon information and belief, Walgreens 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.

123. Walgreens encountered opioid consumers face-to-face, daily as a part of its business practices. As such, Walgreens was in the best position to make a professional judgment as to the appropriateness of opioid dispensing to any certain patient. Looking at dispensing rates more holistically, Walgreens should have recognized that the numbers of opioids leaving Walgreens stores were unreasonable on their face. Additionally, Walgreens should have determined that the amounts of opioids being ordered by Walgreens stores from Walgreens distribution centers and Central Pharmacy locations were unreasonable on their face.

124. Further, as both the distributor and pharmacy, Walgreens was in a unique position to monitor and control the amounts of opioids being ordered by Walgreens stores from both outside distributors like AmerisourceBergen and Cardinal, as well as the Walgreens distribution centers and Central Pharmacy locations. Upon information and belief, Walgreens failed to monitor its own stores and prevent the over-distribution of generic opioids to its stores from Walgreens distribution centers and Central Pharmacy location, and the over-distribution of name-brand or branded opioids to its stores from third-party distributors.

125. As described, Walgreens' pharmacies filled so many opioid prescriptions that the

numbers of opioids dispensed by their pharmacies were unreasonable on their face. Acting as a distributor, Walgreens received orders for those opioids from its own stores. Those opioid orders were suspicious on their face due to the unreasonable numbers of opioids being dispensed at the store level, but were packed and shipped rather than flagged and reported.

126. Walgreens, acting as a pharmacy, failed to ensure that the prescriptions it was filling were issued to a legitimate patient for a legitimate medical purpose by a practitioner acting in the usual course of professional practice, as is evident by the copious amounts of opioids being dispensed by Kentucky Walgreens stores.

127. Upon information and belief, Walgreens knew or should have known that opioids shipped by Walgreens to fill suspicious orders submitted by its pharmacies, and opioids dispensed by Walgreens pharmacies in violation of Kentucky law, would be paid for by Kentucky Medicaid. Further, Walgreens knew or should have known that the abuse, misuse, and diversion of opioids stemming from improper distribution and dispensing by Walgreens resulted in improper billing for opioids to Kentucky Medicaid.

128. The average consumer would not expect Walgreens, “[a]t the Corner of Happy and Healthy,” of such offensive wrongdoings. However, Walgreens chose cutting costs and maximizing profits over fulfilling its legal duties. Walgreens even had a compliance program named, “Focus on Profits,” that was inconspicuously changed to, “Focus on Compliance,” likely due to a pending DEA investigation.⁸³

129. Through its negligent distribution and dispensing, Walgreens has fostered a culture of opioid addiction and abuse that manifests in many ways within Kentucky, including as

⁸³ *Id.* at ¶18.

increased crime in and around Walgreens stores.

130. For example, employee thefts of opioids occurred in Walgreens locations throughout Kentucky, with multiple pharmacy technicians and other employees facing arrest and theft charges.⁸⁴ During one instance, a pharmacy technician was observed via in-store surveillance, “Taking handfuls of pills out of bottles in the pharmacy.”⁸⁵

131. Robberies for cash and opioid pills, or even just opioid pills, occur with seeming regularity at Kentucky Walgreens locations. In 2010, an armed robber stole 772 OxyContin pills from a Lexington Walgreens.⁸⁶ One Walgreens robber, wielding a steak knife, asked for the, “Biggest bottle of Percocet they have.”⁸⁷ One Kentucky Walgreens was robbed four times in three months by the same perpetrator,⁸⁸ who was eventually arrested for a total of seven pharmacy robberies.⁸⁹

132. Regarding armed robbery for controlled substances, a Louisville, Kentucky, Sergeant stated, “The motive behind all these robberies was [the perpetrator’s] struggle with drug addiction. Pain pill, heroin addiction is a driving force behind a lot of crime.”⁹⁰

133. Upon information and belief, Walgreens’ internal communications will reveal additional employee and third-party opioid theft, employee opioid addiction issues, failure to properly monitor opioids stored within Walgreens pharmacies, overdoses occurring in and around the store, and unlawful drug transactions occurring in and around the store.

⁸⁴ See <http://www.wdrb.com/story/20148857/former-walgreens-pharmacy-tech-accused-of-drug-thefts>

⁸⁵ See <http://www.wdrb.com/story/26371567/two-walgreens-pharmacy-techs-accused-of-stealing-prescription-meds>

⁸⁶ <http://www.kentucky.com/news/local/crime/article44070414.html>

⁸⁷ <http://www.kentucky.com/news/local/crime/article108570672.html>

⁸⁸ See <http://www.wlky.com/article/suspect-in-walgreens-robbery-charged-in-7-pharmacy-robberies/3747055>

⁸⁹ See <https://www.justice.gov/usao-wdky/pr/louisville-man-charged-robbing-seven-pharmacies-located-jefferson-county-kentucky>

⁹⁰ <http://www.wmcactionnews5.com/story/24351258/chase-crash-leads-to-arrest-in-string-of-pharmacy-robberies>

134. By failing to uphold its legal duties, Walgreens contributed to the addiction, abuse, and diversion cycle that has mushroomed into the Opioid Epidemic. This crisis has impacted Kentucky disparately despite the laws enacted by Kentucky to protect against it. Walgreens failed to establish and adhere to policies and procedures that protected against this public health crisis. Walgreens, as a first- and last- line of defense in the Opioid Epidemic, must be held responsible for its role.

B. INJURY TO KENTUCKY RESULTING FROM WALGREENS' ACTIONS

135. Upon information and belief, the Commonwealth has been damaged by Walgreens' 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.

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

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

138. Walgreens' 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 the epidemic of prescription drug addiction that was substantially fueled by Walgreens' illegal and reckless action in flooding the Commonwealth with highly addictive prescription medications, without regard for the consequences to the Commonwealth and its citizens.

139. The Commonwealth of Kentucky hereby seeks recuperation of the damages and

costs it was forced to expend by virtue of Walgreens' 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.

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

141. 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 Walgreens accountable for their misdeeds.

III. CAUSES OF ACTION

COUNT I CONSUMER PROTECTION ACT VIOLATION

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

143. Kentucky has enacted a Consumer Protection Act to ensure that citizens are protected against predatory or inappropriate actions by sellers of goods. "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..." KRS 367.120.

144. 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.

145. Specifically, those penalties are monetary and may be enforced per willful violation of KRS 367.170.

146. As alleged herein, and upon information and belief, Walgreens committed unfair, false, misleading, and/or deceptive acts with regard to the sale and distribution of opioids within the Commonwealth.

147. As provided under KRS 367.200, "[t]he court may make such additional orders or judgments as may be necessary to restore to any person in interest any moneys or property, real or personal, which may have been paid out as a result of any practice declared to be unlawful by KRS 367.130 to 367.300." The Commonwealth of Kentucky is a "person" for purposes of this statute. KRS 367.200.

148. The unfair, false, misleading, and/or deceptive acts committed by Walgreens constitute a breach of the duties enumerated under Kentucky law, including but not limited to the Consumer Protection Act.

149. Upon information and belief, Walgreens shipped drugs into the Commonwealth without adequate policies or procedures in place to detect suspicious orders, or prevent from the public health crisis that has ensued. Walgreens permitted prescriptions to be filled in violation of Kentucky law and permitted orders for opioids from Walgreens pharmacies to be filled and go

unreported in violation of Kentucky law.

150. Upon information and belief, Walgreens dispensed drugs where the prescription for the drug was not in accordance with the law, including prescriptions that were not written for a legitimate medical purpose and/or by a physician acting outside of his normal practice. Walgreens filled prescriptions despite the existence of red flags indicating abuse, misuse, and diversion.

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

152. Upon information and belief, Walgreens concealed vital knowledge and information from the Commonwealth of Kentucky, its agents and employees, resulting in significant harm to the public coffers.

153. These practices were unfair, misleading, false, and deceptive to consumers within to the Commonwealth of Kentucky.

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

155. Through the actions and omissions described herein, Walgreens engaged in unfair acts in violation of KRS 367.170

156. For each of Walgreens' willful violations of KRS 367.170, the Commonwealth is entitled to recover a civil penalty of not more than two thousand dollars (\$2,000) per violation, or a civil penalty of not more than ten thousand dollars (\$10,000) per violation where Walgreens'

conduct is directed at a person aged sixty (60) or older and Walgreens knew or should have known that the person aged sixty (60) or older is substantially more vulnerable than other members of the public.

**COUNT II
CONSUMER PROTECTION ACT VIOLATION**

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

158. As referenced supra, Kentucky enacted a Consumer Protection Act to ensure that citizens are protected against predatory or inappropriate actions by sellers of goods. Upon information and belief, the laws of Kentucky including the Consumer Protection Act were violated by Walgreens through the filling of unlawful prescriptions at the pharmacy level and the unlawful distribution of opioids to fill suspicious orders at the distribution level. Walgreens violated Kentucky law as both a pharmacy and distributor.

159. Upon information and belief, Walgreens 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 recover any damages resulting from these unfair trade practices under KRS 367.210.

160. Walgreens' failure to comply with applicable laws resulted in the proliferation of disproportionate amounts of opioids within Kentucky when compared to population. While Walgreens reaped substantial profits, they 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 Walgreens' actions.

161. Kentucky has been forced to respond to the increase in addiction and substance abuse disorder 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, costs associated with the care of opioid addicted infants, and costs associated with housing, schooling, and otherwise caring for foster children who have been left orphaned by addicted family members.

162. The harm to Kentucky stems from the wrongful acts and omissions of Walgreens committed while serving in both the distributor and pharmacy role. The costs and harm suffered by the Commonwealth of Kentucky resulted directly and proximately from Walgreens' unfair, false, misleading and deceptive trade practices. Walgreens should be held liable for all resulting damages.

163. Pursuant to KRS 367.200, Walgreens is liable for the restoration of moneys paid by the Commonwealth for the harm described herein that is a direct result of Walgreens' unlawful conduct, including the costs described above and future expenditures for medical care and provision of additional services warranted by this public health crisis.

COUNT III PUBLIC NUISANCE

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

165. Public Nuisances are a, "Class of wrongs which arise from the unreasonable, unwarrantable, or unlawful use by a person of his own property and produces such material

annoyance, inconvenience, discomfort, or hurt that the law will presume a consequent damage." *City of Somerset v. Sears*, 313 Ky. 784, 233 S.W.2d 530 (1950) (quoting 39 Am.Jur., Nuisances, Section 2). The method in which a defendant acts or conducts its operation can, in and of itself, create an actionable nuisance. *See West Ky. Coal Co. v. Rudd*, 328 S.W.2d 156, 160 (Ky. 1959). Such actions are prosecuted under common law principles. *See*: KRS 411.500.

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

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

168. Walgreens intentionally and/or unlawfully failed to maintain effective controls against abuse, misuse, and 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.

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

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

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

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

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

174. As a result of Walgreens' actions, 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.

175. Walgreens 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. Walgreens' conduct is proscribed by law. *See Restatement Second, Torts Section 821B.*

176. Walgreens is liable for all costs borne by the Commonwealth and its agencies, which were proximately caused by the Walgreens wrongful actions.

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

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

COUNT IV
MEDICAID FRAUD KRS CHAPTER 205

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

180. 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).

181. 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).

182. Similarly, KRS 205.8463 is violated when any person, “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).

183. 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.”

184. 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.”

185. Walgreens’ conduct, as described in the Complaint, violated KRS 205.8463(1), (2), & (4). Walgreens, through annual deceptive license renewals through the Commonwealth’s CHFS and Board of Pharmacy as a pharmacy and a distributor, as well as through their failure to identify, track, and reject suspicious orders of addictive prescription opioids and failure to refuse to fill unlawful prescriptions: (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.

186. Walgreens 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’s Medicaid program would necessarily be paying for prescription opioids that were improperly diverted for non-medically necessary and improper abuse. Walgreens submitted claims to Kentucky Medicaid and financially benefitted from the excessive and non-medically necessary distribution of these prescription narcotics.

187. Walgreens’ misrepresentations were material, because if the Commonwealth had knowledge of Walgreens’ failure to comply with state and federal law, Walgreens’ 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 Walgreens.

188. By virtue of the above-described acts, Walgreens 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.

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

190. Walgreens' actions constitute Medicaid fraud in violation of KRS 205.8463 such that Plaintiff is entitled to recover damages in an amount to be proved at trial together with penalties, fines, interest and other remedies permitted by law.

COUNT V
MEDICAID FRAUD KRS CHAPTER 194A

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

192. 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."

193. Walgreens, 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). Walgreens 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's Medicaid program would necessarily be paying for prescription opioids that were improperly diverted for non-medically necessary and improper abuse. Walgreens submitted claims to Kentucky Medicaid and financially benefitted from the excessive and non-medically necessary distribution of these prescription narcotics.

194. Walgreens' misrepresentations were material, because if the Commonwealth had knowledge of Walgreens' failure to comply with state and federal law, Walgreens' 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 Walgreens.

195. Upon information and belief, Walgreens schemed to obtain benefits from an assistance program through false representations and intentionally engaged in conduct that advanced the scheme. Walgreens furthered that scheme by submitting annual deceptive license renewals to the Commonwealth's CHFS and Board of Pharmacy as a pharmacy and distributor, and by failing to identify, track, and not distribute suspicious orders of addictive prescription opioids, and failure to refuse to fill unlawful prescriptions.

196. 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."

197. 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.”

198. By engaging in the conduct set forth above, Walgreens 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 Walgreens’ actions.

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

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

201. Because of the above violations of KRS 194A.505(6), the Commonwealth is entitled to recover from Walgreens 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 VI
BREACH OF STATUTORY DUTIES/NEGLIGENCE PER SE

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

203. 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.

204. As noted above, Walgreens violated the Kentucky Medicaid Fraud Statute, KRS 205.8463, and the Kentucky Medical Assistance Fraud Statute, KRS 194A.505.

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

206. 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.

207. 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.⁹¹

208. As a distributor and, separately, a pharmacy, Walgreens had separate and distinct, though equally important, reporting requirements regarding dispensing and ordering of opioids.

209. The Kentucky Legislature promulgated the KY CSA to promote the, “Preservation of public safety and public health.” KRS 218A.005(1). The KY CSA requires of Walgreens, as distributors of a Schedule II drug, to record all incidences of diversion of controlled substances,

⁹¹ See <https://odcp.ky.gov/Pages/Agency-for-Substance-Abuse-Policy.aspx> (last visited October 21, 2017).

including opioids, and forward the record to the Cabinet for Health and Family Services. KRS 218A.200. *See also* 218A.170; 902 KAR 55:010; 201 KAR 2:105 Section 2(4)(d).

210. The KY CSA further requires that Walgreens create, maintain, and adhere to policies and procedures that protect against public health crisis, such as the Opioid Epidemic. *See* 201 KAR 2:105 Section 5(4).

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

212. The KY CSA creates a broad duty on the part of wholesalers to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids. These laws are intended to protect consumers from harm. *See* KRS 218A.200 (record keeping); 21 CFR 1301.74 and KRS 218A.160(1)(a) (repealed); 218A.170; 902 KAR. 55:010 Section 4(2)(b); 201 KAR 2:105 Section 2(4)(d)).

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

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

215. 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 state

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

216. These laws promote transparency regarding the wholesale, dispersal, and use of opioid analgesics. Each agency may access and share information that protects against 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 Commonwealth.

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

218. Further, as discussed supra, KRS 194A.505(6) provides: “No person shall, with intent to defraud or deceive, devise a scheme or plan a scheme or artifice to obtain benefits from any assistance program by means of false or fraudulent representations or intentionally engage in conduct that advances the scheme or artifice.” Likewise, KRS 205.8463 is violated through fraud or misrepresentation to the Cabinet of Health and Family Services. *See* KRS 205.8463(2), (4).

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

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

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

222. Additionally and through the aforementioned failures, Walgreens failed to maintain "acceptable operational procedures" pursuant to Kentucky law. Walgreens' failure to enact, or simply find guidance in, the framework proposed by KY-ASAP evidences Walgreens' disregard for black letter law, guidelines, recommendations, and other methods to prevent the spread and abuse of prescription opioids.

223. Walgreens' 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.

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

225. Accordingly, Walgreens' actions constitute negligence per se. Walgreens should

be held liable for all damages proximately caused by the breach of their statutory duties.

COUNT VII NEGLIGENCE

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

227. 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."

228. 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).

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

230. Walgreens' actions constitute gross disregard for the people and government of Kentucky, and those who purchased from Walgreens and trusted Walgreens to comply with laws regarding prescription drug distribution.

231. 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 Walgreens.

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

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

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

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

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

237. The Commonwealth suffered significant financial damages as a direct and proximate result of Walgreens' negligence and misfeasance.

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

COUNT VIII UNJUST ENRICHMENT

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

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

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

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

243. Each year, Walgreens 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.

244. 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 Walgreens.

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

246. Walgreens should be required to disgorge all such unjust enrichment and to reimburse the Commonwealth for all sums to which Walgreens was not entitled.

COUNT IX FRAUD BY OMISSION

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

248. 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).

249. Walgreens 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. Walgreens should have reported such orders coming from its own pharmacies, but failed to do so.

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

251. Walgreens shipped drugs into the Commonwealth without adequate policies or

procedures in place to detect suspicious orders, or prevent from the public health crisis that has ensued. Walgreens permitted prescriptions to be filled in violation of Kentucky law and permitted orders for opioids from Walgreens pharmacies to be filled and go unreported in violation of Kentucky law.

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

253. Walgreens further failed to refuse to fill prescriptions where substantial red flags were present. Instead, in violation of Kentucky law, Walgreens permitted prescriptions to be filled where red flag warnings indicated abuse, misuse, and diversion. Further, in order to supply the opioids for these unlawful prescriptions to its pharmacies, Walgreens filled suspicious orders for opioids and failed to report them in violation of Kentucky law.

254. Walgreens failed to provide the aforementioned reporting required by law, and submitted deceptive annual license renewals with the Commonwealth's CHFS and Board of Pharmacy as a pharmacy and a distributor. Walgreens 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.

255. The failure to disclose these facts, as a distributor and pharmacy, constitutes fraud by omission.

256. Walgreens 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 X

PUNITIVE DAMAGES

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

258. 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).

259. Walgreens' 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.

260. Further, acting as a pharmacy, Walgreens dispensed opioids at such an alarming rate and volume that there could be no legitimate medical purpose associated to their use. The only possible explanation for the massive amounts of opioids pouring into and out of Walgreens' stores in Kentucky is that an unreasonable portion of the drugs were distributed to a person suffering from addiction, and/or that the drugs were being misused, abused, or diverted

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

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

263. 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 Walgreens pursuant to KRS 411.184.

264. 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).

265. 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).

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

IV. PRAYER FOR RELIEF

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

- A. Declaring that Walgreens committed willful violations of KRS 367.170;
- B. An Order permanently enjoining Walgreens, 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 Walgreens, 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 Walgreens committed repeated violations of KRS 205.8463;
- D. Declaring that Walgreens has engaged in conduct, acts, or practices which resulted in fraudulent, erroneous, or illegal payments out of the Kentucky State Treasury.
- F. Permanently enjoining Walgreens 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 Walgreens, from continuing their unlawful conduct, acts and practices, including:
 1. Preventing Walgreens from continuing to violate Kentucky laws;
 2. Mandating that Walgreens promptly notify the appropriate authorities of any and all suspicious orders for controlled substances as received from parties who are located in Kentucky;
 3. Mandating that Walgreens submit their system for determining suspicious order to those Kentucky authorities for prior approval, and to enjoin Walgreens from distributing any controlled substance in Kentucky for any non-legitimate medical purpose;
 4. Mandating that Walgreens provide Plaintiff with the assistance necessary to address the addiction and the resulting destruction left by Walgreen's actions to abate the damage they have caused and are continuing to cause; and
 5. Otherwise abate the public nuisance caused in whole or in part by Walgreens.
- G. 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 Walgreens' unlawful conduct;
- H. Awarding civil penalties of \$2,000 for each willful violation of the Kentucky Consumer Protection Act pursuant to KRS 367.990(2);

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

Respectfully submitted,

ANDY BESHEAR
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