

IN THE CIRCUIT COURT OF KNOX COUNTY, TENNESSEE  
SIXTH JUDICIAL DISTRICT AT KNOXVILLE

STATE OF TENNESSEE,  
*ex rel.* HERBERT H. SLATERY III,  
ATTORNEY GENERAL and REPORTER,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG  
CORPORATION, a foreign corporation,

Defendant.

JURY DEMAND

Case No. 1-345-19

COMPLAINT

[SUBJECT TO MOTION TO TEMPORARILY SEAL COMPLAINT]

FILED  
CHARLES D. YUSANO III  
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KNOX COUNTY  
CIVIL DIVISION  
KNOXVILLE, TENNESSEE

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1. This civil law enforcement action is brought in the name of the State of Tennessee in its sovereign capacity by Herbert H. Slatery III, Attorney General and Reporter (State or Attorney General), pursuant to Tenn. Code Ann. § 47-18-108 of the Tennessee Consumer Protection Act of 1977, Tenn. Code Ann. §§ 47-18-101–131 (TCPA), against AmerisourceBergen Drug Corporation (Amerisource) to protect the public and to preserve the integrity of the commercial marketplace. The State also brings suit pursuant to the Attorney General’s common law police power to abate and remedy the statewide public nuisance created by Amerisource’s interference with the commercial marketplace and endangerment of the public health. Finally, the Attorney General<sup>1</sup> brings suit pursuant to the Tennessee Racketeer Influenced and Corrupt Organization Act of 1989, Tenn. Code Ann. §§ 39-12-201 to -210 (RICO), to stop and remedy at least six illegal opioid distribution schemes involving oxycodone to Tennessee pharmacies.

2. The State’s enforcement action seeks injunctive relief, civil penalties for Amerisource’s violations of law, disgorgement of its ill-gotten gains, abatement of the public nuisance Amerisource substantially helped to create, and recoupment of the State’s costs. The Attorney General seeks revocation of Amerisource’s registrations to distribute controlled substances in Tennessee, among other relief.

### **I. GENERAL FACTUAL ALLEGATIONS**

3. Opioids are drugs that interact with specific receptors on nerve cells used to reduce the perception of pain. They include the illegal drug heroin, synthetic opioids such as fentanyl, and prescription pain relievers such as oxycodone, buprenorphine, hydrocodone, morphine, codeine, and others.

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<sup>1</sup> The civil RICO claim is brought by the Office of the Attorney General and Reporter pursuant to Tenn. Code Ann. § 39-12-206(e) and is distinct from the other claims which are brought by the Attorney General in the name of the State of Tennessee.

4. Historically, opioids were prescribed in limited circumstances because of long-standing and well-founded fears about their addictive potential and safety. When these historic prescribing patterns began to change, Amerisource sought to capitalize by feeding suspect pharmacies that were satisfying an insatiable appetite for opioids.

5. Prescription opioids are subject to diversion from legitimate medical, research, and scientific channels to unauthorized use and illegal sales. An inflated volume of opioids invariably leads to increased diversion and abuse. Indeed, there is a parallel relationship between the availability of prescription opioid analgesics through pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes. For most people who misuse prescription opioids, the source of their drugs can typically be found in the excess supply of drugs in the community, beyond what is needed for legitimate medical purposes.

6. Pharmaceutical opioids are classified as controlled substances and are unlawful to distribute under Tennessee law, absent limited exceptions. State law prohibits anyone, including a distributor, such as Amerisource, from knowingly participating in the diversion of opioids or from distributing opioids to fill medically unnecessary or illegitimate opioid prescriptions.

7. Under state law, distributors such as Amerisource are placed in special positions of trust and responsibility and are the first line of defense against abuse, diversion, and unlawful prescription opioid trafficking.

8. Amerisource not only failed in this role, it actively subverted it and exploited both its unique position in the supply chain and market power to maximize its profit from its pharmacy customers. Far more than mere truck drivers, Amerisource had detailed knowledge about its pharmacy customers through on-site visits from its sales staff, real-time opioid purchasing data,

opioid order history, and reports from compliance vendors who reported on diversion and highly suspect dispensing practices from its customers.

9. Red flags for possible abuse and diversion from suspect pharmacies, as identified both by Amerisource and the DEA, include high percentages of patients paying for controlled substance prescriptions in cash, cars in the parking lots with out-of-state license plate tags, patients abusing or selling drugs in the pharmacy parking lot, purchasing disproportionate ratios of controlled substances to noncontrolled substances, purchasing disproportionate rates of one family or sub-family of controlled substances compared to other families, purchasing controlled substances from multiple distributors at once, a lack of policies or procedures for dispensing controlled substances or vetting patients, and dispensing dangerous combinations of controlled substances, such as concurrent prescriptions for an opioid, a muscle relaxer, and anti-anxiety medications (known as the Holy Trinity).

10. Between 2006 and 2014, Amerisource distributed over 712 million opioid dosage units in Tennessee, more than any other distributor.<sup>2</sup> It not only knowingly kept pharmacies where diversion was occurring, or was most likely to occur, supplied with opioids—it actually sought out their business.

11. Among other things, Amerisource continued to ship:

- opioids to Food City, a lucrative customer, no matter the amount requested or how high it was above its suspicious order threshold;<sup>3</sup>
- to *one* Knoxville-based pharmacy, Food City #674, more immediate-release oxycodone 30 mg (Oxy 30), one of the most heavily abused and diverted opioids,<sup>4</sup> than it supplied *to at least 38 other individual states*;<sup>5</sup>

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<sup>2</sup> ARCOS.

<sup>3</sup> ABDCMDL00316920.

<sup>4</sup> See ABDCMDL00280928.

<sup>5</sup> ABDCMDL00301692 (data between Oct. 2011 and Jan. 2012).

- hundreds of thousands of oxycodone and other opioid pills to Food City, even after being directly told in a meeting with Actavis, the primary manufacturer of the oxycodone Amerisource was distributing to Food City, that “we know this stuff [is] being diverted,”<sup>6</sup> (as shown below) and only stopped distributing after *Food City* cut off the relationship because its buying group contracted with another primary distributor;<sup>7</sup>

we know this stuff being diverted

- opioids to Jabo’s Pharmacy in Newport, Tennessee *even after one of Amerisource’s own investigators was solicited in the pharmacy parking lot to purchase Oxy 30 tablets*, a drug which Amerisource was supplying to the pharmacy;<sup>8</sup>
- over 1.7 million oxycodone pills to Jabo’s Pharmacy after a “no oxycodone only policy” announced in 2011 by Amerisource Corporate Security and Regulatory Affairs (CSRA) division concerning Jabo’s, which was overridden shortly thereafter by the Company;<sup>9</sup>
- over 800,000 opioids to Pardue’s Pharmacy in Nashville in approximately six months *after* Amerisource was told by its own “former career DEA Special [Agent] and Diversion [Investigator]”<sup>10</sup> to stop shipping it all controlled substances along with the other findings and recommendation set forth in the screen shot below;<sup>11</sup>

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<sup>6</sup> MULTI3537759.

<sup>7</sup> MULTI4122115 (“[Amerisource’s] decision to stop was a business decision since Food City went to a different buying group, not due to SOMS decision.”).

<sup>8</sup> MNK\_NC8505955.

<sup>9</sup> ABDCMDL00315459 (“DNS, Reinstated” Sheet, Row 46); ARCOS; ABC-MSAGC00001988; ABC-MSAGC00002012; ABC-MSAGC0002039.

<sup>10</sup> ABDCMDL00005118.

<sup>11</sup> ABC-MSAGC00000662–67; ABC-MSAGC00001988; ABC-MSAGC00002012; ABC-MSAGC00002039.

### Recommendation

The current details of this assessment indicate concern in continuing to supply controlled substances to Pardue's Pharmacy due to the following:

- No formal, written pharmacy due diligence policy with regard to dispensing of controlled substances.
- Pharmacist dispensing duplicate immediate release opiates to the same patient(s) without noting/confirming an established and legitimate clinical need.
- Pharmacist dispensing the combination of a benzodiazepine, a muscle relaxant and an opiate to the same patient(s) without noting/confirming an established and legitimate clinical need.
- Disproportionate dispensing of controlled substances, specifically schedule two controlled substances.
- Disproportionate amount of prescriptions paid with cash.
- Security concerns due to prior incidents involving significant thefts of controlled substances.
- PIC's state pharmacist's license currently on probation.

My recommendation is to block all controlled substance purchases to Pardue's Pharmacy.

- buprenorphine monopropduct to P & S Pharmacy in Kingsport, Tennessee despite: (i) knowing it was Amerisource's highest dispensing pharmacy for this opioid in the country, (ii) incredibly high percentages of individuals who were paying for their opioids in cash at the pharmacy, (iii) being told by the Pharmacist-in-Charge (PIC) that he did not use the State's Controlled Substances Monitoring Database, (iv) being told by a pharmacy technician that the pharmacy receives at least "50 plus" phone calls per day from new patients looking to see if the pharmacy could fill their buprenorphine monopropduct prescriptions, (v) the fact that the investigator Amerisource hired witnessed approximately 20 to 30 younger customers paying cash for buprenorphine during the limited time he conducted a site visit, among many other things;<sup>12</sup>
- opioids, in particular 8 mg buprenorphine without naloxone (Buprenorphine 8), to Brookside Discount Pharmacy, also in Kingsport, despite knowing: (i) the PIC stated that the street value of \$35-\$40 per dosage unit of Subutex (branded buprenorphine monopropduct) was common knowledge and known by some of her customers, (ii) the pharmacy was filling prescriptions for controlled substances paid for with cash by large groups of patients from Kentucky, Virginia, North Carolina, and West Virginia, including patients of one doctor located two minutes away from the pharmacy on Brookside Drive that even the pharmacist expressed concern about because he only accepted cash and had patients who doctor shopped, (iii) the patient contract for the Brookside Drive provider, who was a top prescriber for the pharmacy expressly stated that he only accepted cash and would charge "overtime" for things like police calls, and charged for dirty urine tests,<sup>13</sup> (iv) the pharmacist having to call the police to remove patients loitering in the pharmacy parking lot, and (v) at least one patient snorting Xanax on the dashboard of their vehicle in the pharmacy parking lot (as shown in the screen shot excerpts of the report and contract shown below);<sup>14</sup>

<sup>12</sup> ABC-MSAGC00000652-59.

<sup>13</sup> ABC-MSAGC00024541.

<sup>14</sup> ABC-MSAGC00000520-22; ABC-MSAGC00024541 (highlighted emphasis added).

No code	Overtime*, <sup>o</sup>	\$5/minute
No code	No Show, Cancel (less than 24 hours notice)	Full fee of time reserved (for Suboxone/Subutex in addition to weekly fee)

**After one No Show, the patient acknowledges SELF DISCHARGING from our service.**  
 Other appointments/services are pro-rated and billed based on this fee schedule.  
 \*These fees apply also to telephone calls, hospital admissions, police calls, listening to tapes, looking at records, writing reports, etc. <sup>o</sup>These may not be reimbursable.

**Cash or cashier's checks ONLY are accepted for payment. Suboxone/Subutex program is \$125.00 per week whether or not the patient sees the doctor or has an appointment. All accounts more than 60 days past due will accrue interest at a rate of 18% annually, pro-rated on a monthly basis. These accounts may be turned over to a collection agency. No further appointments or medication refills are given until such accounts are fully paid. ALL ACCOUNTS MUST BE FULLY PAID BEFORE TREATMENT.**

Alprazolam and Suboxone at her pharmacy. PIC Overton indicated that there are a large group of Kentucky patients that are loitering in the parking lot after getting their prescriptions filled. PIC Overton has to go outside to tell her customers to leave the parking lot. She indicated that she has to contact the local police to get the crowd of customers to disperse. She also stated that one of her customers came into her store and indicated to her that one of her Kentucky customers was crushing up their Xanax tablets and snorting the drugs on the dashboard of their vehicle.

- opioids, in particular Buprenorphine 8, to Gray Pharmacy, in Gray, Tennessee, despite knowing: (i) that the amount of controlled substances being ordered was disproportionate to the community which has a population of just over 1,000 people, (ii) the pharmacy did not have a policy for dispensing narcotic prescriptions, (iii) the pharmacy lied about not servicing pain clinics, (iv) the ratio of controlled substances to non-controlled substances it purchased was about 40%, (v) 35% of prescriptions were paid for with cash, (vi) the pharmacist kept some Schedule II drugs among the stock and in a basket on the counter instead of properly secured as required, and (vii) only one of the top prescribers of controlled substances filled at the pharmacy was permitted to prescribe buprenorphine;<sup>15</sup>
- opioids to Dale Hallow Pharmacy in Celina, Tennessee despite: (i) 90% of prescriptions being dispensed were for controlled substances, (ii) patients driving long distances to the pharmacy, (iii) disciplinary action against the pharmacists, and (iv) the pharmacy dispensing abnormally high rates of buprenorphine without naloxone, until Amerisource was informed by its own truck driver that delivery could not be completed because Drug Enforcement Administration (DEA) agents were conducting a raid of that pharmacy (as shown by the screen shot below), among many others;<sup>16</sup>

<sup>15</sup> ABC-MSAGC0000855.

<sup>16</sup> ABC-MSAGC00024689.



*Due to activity at these locations this morning, my driver was informed by DEA Agents (at both locations) that he would not be allowed make these deliveries today. Once I was contacted, I instructed him to bring both stops back to the hub, and I in turn have contacted our driver that comes down to pick up our Saturday deliveries to stop by and pick up the orders for these two stops and bring them back to the DC this evening. His ETA to arrive and drop these back off at Olive Branch this afternoon is usually 5:30pm CST. Please do not hesitate to let me know if you have any additional questions, issues or concerns regarding this matter. Thanks!*

- opioids to Mehr Drug Store in Bells, Tennessee until its sales representative went for a sales call to the pharmacy, noticed the doors were locked, still tried to go in, and discovered, after an interaction with a police officer inside, that the pharmacy had been permanently closed following a raid (as shown below);<sup>17</sup>

Subject: Account Visit

Hello,

I wanted you to be aware of one of my Customer calls today. My third stop today was at a Pharmacy called Mehr Drug Store. (Bells TN) I walked up to the store I pulled on the front door and noticed it was locked. I looked inside and noticed several police officers all over the Inside of the store. One Police officer came to the door and yelled through the glass, he asked me who I was. I replied to him that I was a sales rep. He said the store was closed 'So I asked him for How Long? He looked at me displayed his badge and stated Forever. I turned and walked away at this time.

Account  
Mehr Drug Store  
Bells TN.

- opioids to 225 Walgreens pharmacies, including many in Tennessee, without completing its own due diligence process even though it suspected (and later still believed) the problematic stores had been “dumped” by Cardinal, the second largest distributor in the country, as part of a DEA probe;<sup>18</sup> and

Jim,

Can we discuss these accounts when you get an opportunity? I'm concerned that these are the high risk accounts that CAH wants to dump ASAP so I want to make sure we have them sized properly and get the correct thresholds set.

Steve Mays  
Senior Director, Corporate Security & Regulatory Affairs

<sup>17</sup> ABC-MSAGC00025852.

<sup>18</sup> ABDCMDL00309948 (emphasis added).

- frequently diverted opioids, such as Oxy 30, to a pharmacy that its sales representative had encouraged to purchase “*whether he needed it or not,*” as shown below:<sup>19</sup>

Background:

\*Purchase through AmerisourceBergen

\*Amerisource Rep advised him to purchase the monthly allotment of Oxy-30 whether he needed or not. As a result of these high volume purchase was placed on SOM list. Amerisource Rep has since been terminated.

12. Aside from its egregious conduct statewide, Amerisource knowingly supplied at least two major and clearly defined opioid diversion rings in Tennessee: an oxycodone ring based in Knoxville and a buprenorphine one based in the Tri-Cities.

13. Amerisource willingly ignored or turned a blind eye to opioid diversion for Tennessee pharmacies that were its money-makers. Amerisource followed a longstanding policy to almost always ship orders to its most profitable customers including grocery stores, chain pharmacies, and hospitals—no matter how suspicious or far above an already high threshold the customer’s order was.<sup>20</sup>

14. The anti-diversion compliance programs and policies that Amerisource created or changed in response to these duties had significant flaws, were designed to minimize the impact on sales of opioids to high volume pharmacies, and yielded to Amerisource’s higher priority to generate profit. In addition, these compliance programs and policies were a low corporate priority, underfunded, fundamentally unsound, applied inconsistently, or completely ignored. Amerisource’s philosophy can be summarized in six words: “Paper” the file. Keep on shipping.

15. Even Amerisource’s senior compliance employees gave confidential compliance information about controlled substances (CS) to its valuable customers (shown in the excerpt

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<sup>19</sup> MNK\_NC05795700 (emphasis added).

<sup>20</sup> ABDCMDL00316920; ABDCMDL00316922; *see also*, ABC-MSAGC00000078.

below concerning Walgreens)<sup>21</sup> and, when making compliance decisions, openly considered the impact on sales that a such decision would have.<sup>22</sup>

**Attachments:** WAG Orders Held.xlsx

Team WAG,

Find attached some data that I believe could be the basis for a part of our discussion. Briefly, the first tab is all WAG locations that had CII order lines flagged by the omp, sorted largest (most lines) to smallest. We can discuss further tomorrow. Thanks.

Ed Hazewski  
Director, Corporate Security and Regulatory Affairs  
AmerisourceBergen Corporation

16. Likewise, Amerisource’s sales representatives would successfully justify opioid threshold increases based solely on loss of sales to competitors, as shown in the excerpt of a threshold request increase, which referenced loss of sales to JM Smith and Harvard Drug, two competitors.<sup>23</sup>

Reason for Threshold Review:  
**(Note: Exceeding the established threshold does not in itself justify a threshold increase in all cases.)**

**Several items have reached the ABC threshold and the items we cannot ship have been ordered from JM Smith and Harvard Drug**

17. Defendant Amerisource inundated Tennessee with excessive amounts of dangerous and addictive prescription opioids, while disregarding its own real-time data, policies and procedures, customer thresholds, internal reports, and common sense. Amerisource knowingly shipped hundreds of millions of opioids to pharmacies in Tennessee despite knowledge based on its own data that diversion was occurring at these locations.

<sup>21</sup> ABDCMDL00282490.

<sup>22</sup> MNK\_NC08505956.

<sup>23</sup> ABC-MSAGC00026085 (highlighted emphasis added).

18. While Amerisource was the third largest distributor nationally, it was the largest opioid distributor in Tennessee between 2006 and 2014. During those eight years, as the opioid epidemic became exponentially worse, Amerisource shipped more opioids to Tennessee pharmacies than any other distributor—approximately 712,112,608 opioid dosage units (ODUs), equal to 12,966,534,918 morphine milligram equivalents (MMEs).<sup>24</sup> That amount is enough for every man, woman, and child living in Tennessee to have received approximately 109 ODU each from Amerisource.<sup>25</sup>

19. Amerisource not only had a disparate impact on Tennessee as a whole, but also on specific areas, such as Knox, Washington, and Sullivan Counties. For example, Amerisource accounted for 40% of the over 6.5 billion MMEs poured into Knox County alone from 2006 to 2014.<sup>26</sup>

20. Amerisource’s opioid business in Tennessee came disproportionately from a tiny fraction of its total retail pharmacy customers—most of which it knew or should have known showed red flags for diversion or routinely dispensed invalid prescriptions. Between 2006 and 2014, Amerisource distributed over five billion MMEs to its *top 20 retail pharmacy customers* in Tennessee, which accounted for 39% of the total MMEs it distributed statewide. To put this into perspective, Amerisource had approximately 1,606 unique customers purchasing opioids from them in Tennessee during those eight years. In other words, *about 0.01% of its customers purchased approximately 39% of all MMEs Amerisource shipped into Tennessee.*<sup>27</sup>

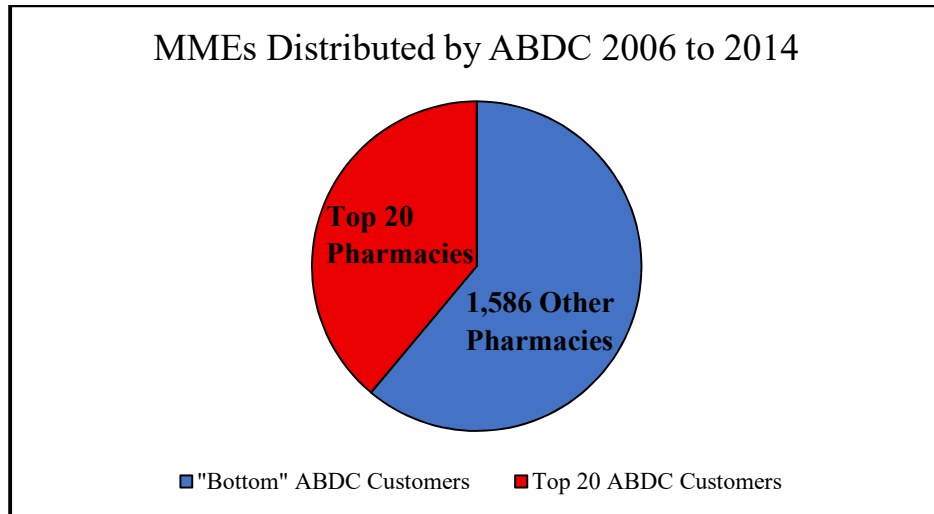
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<sup>24</sup> ARCOS.

<sup>25</sup> In 2014, Tennessee had a population of approximately 6,549,201.  
[https://www.tn.gov/content/dam/tn/health/documents/TN\\_Population\\_by\\_AgeGrp\\_Sex\\_Race\\_Ethnicity\\_-\\_2014.pdf](https://www.tn.gov/content/dam/tn/health/documents/TN_Population_by_AgeGrp_Sex_Race_Ethnicity_-_2014.pdf).

<sup>26</sup> ARCOS.

<sup>27</sup> ARCOS.

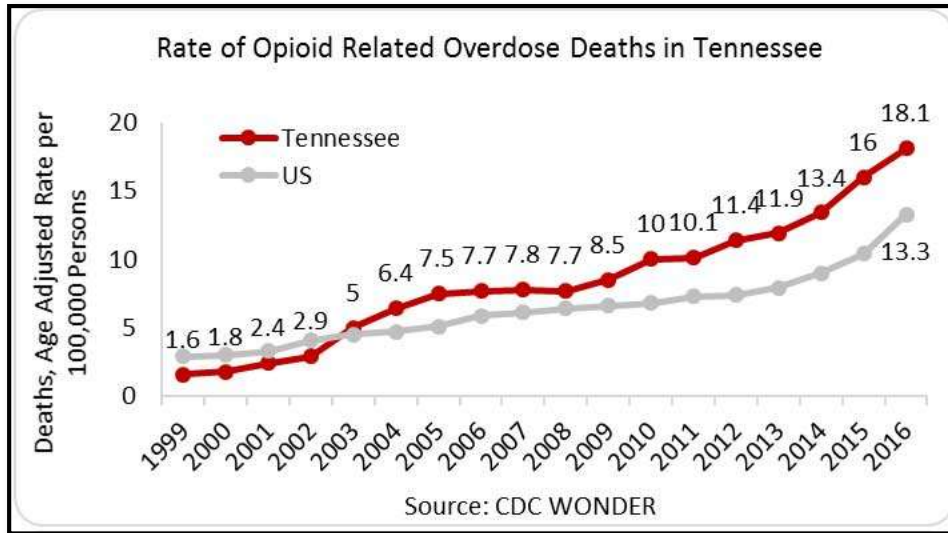


21. There is a direct correlation between the number of opioid prescriptions written and the illicit pharmaceutical drug diversion which is plaguing Tennessee. As the supply of prescription opioids increasingly saturated Tennessee, the rates of overdoses, overdose deaths, babies born with neonatal abstinence syndrome (NAS), and diseases like Hepatitis A and C correspondingly increased. In the past 15 years, the rate of NAS in Tennessee has increased 1,000%.<sup>28</sup> Between 2006 and 2012, the rate of Hepatitis C infections skyrocketed 364% throughout central Appalachia, including Tennessee.<sup>29</sup> Even as the number of opioids being dispensed has finally dropped, Tennessee is still suffering the consequences—2018 was its deadliest year yet for fatal drug overdoses.<sup>30</sup>

<sup>28</sup> <https://www.drugabuse.gov/opioid-summaries-by-state/tennessee-opioid-summary>.

<sup>29</sup> <https://www.tennessean.com/story/opinion/2019/06/04/hepatitis-c-tennessee-get-serious/1298844001/>.

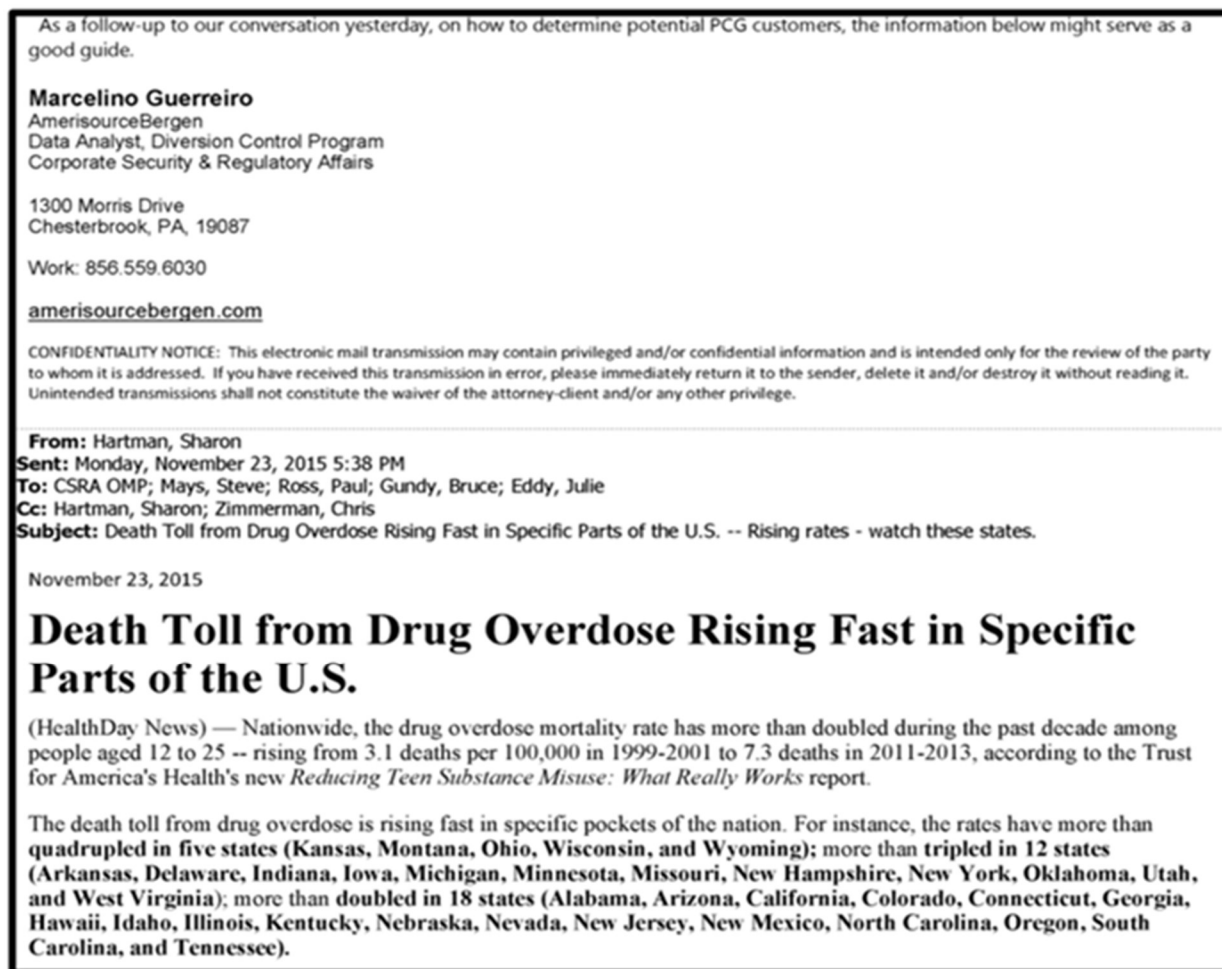
<sup>30</sup> <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>.



22. Amerisource was a substantial cause of the grave effects of opioids in Tennessee. It shipped opioids to pharmacies from which it knew diversion was occurring, failed to conduct proper oversight, failed to properly monitor and report suspicious orders, administered its compliance policies and procedures in an arbitrary and inconsistent manner, worked with its pharmacy customers to game the regulatory system to set high opioid threshold limits or ignore them entirely, and even shipped orders for opioids that it had identified as suspicious. This inertia contributed heavily to one of the root causes of the opioid epidemic—the vast oversupply of prescription narcotics to locations in the state where Amerisource knew or should have known abuse and diversion were occurring.

23. Even one of Amerisource’s own data analysts saw the relationship between the high-volume pharmacies the Company was supplying opioids to and adverse health outcomes. In determining where to potentially deploy Pharma Compliance Group, a consulting firm comprised of former career DEA agents turned compliance consultants referenced below as “PCG,” to perform investigations of pharmacy customers, Amerisource’s data analyst suggested the

Company be guided based on geographic information from the article titled “Death Toll from Drug Abuse Rising Fast in Specific Parts of U.S.”<sup>31</sup>



24. At all relevant times, Amerisource sold, distributed, and placed into the stream of commerce without fulfilling their fundamental duty as a wholesale pharmaceutical distributor to detect, warn of, and prevent the diversion of dangerous narcotics for illicit purposes.

### PARTIES

25. The Plaintiff, State of Tennessee *ex rel.* Herbert H. Slatery III, Attorney General and Reporter, is charged with enforcing the TCPA. Pursuant to Tenn. Code Ann. § 47-18-108, actions for violations of the TCPA may be brought only by the Attorney General in courts of

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<sup>31</sup> ABDCMDL00303264.

competent jurisdiction to restrain violations, to secure equitable and other relief, and to otherwise enforce the provisions of the TCPA. The Attorney General has all common law powers except as restricted by statute, *State v. Heath*, 806 S.W.2d 535, 537 (Tenn. Ct. App. 1990), and is expressly authorized to utilize and refer to the common law in the exercise of his duties pursuant to Tenn. Code Ann. § 8-6-109(a). The Office of the Attorney General and Reporter is the only party authorized to bring civil claims under the Tennessee RICO Act of 1989. Tenn. Code Ann. § 39-12-206(e).

26. Defendant AmerisourceBergen Drug Corporation (Amerisource, or the Company) is a corporation organized under the laws of Delaware with its principal place of business in Chesterbrook, Pennsylvania. Amerisource, through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Tennessee. Together with its parent company, AmerisourceBergen Corporation, Amerisource is the tenth largest company by revenue in the United States, with annual revenue of \$168 billion in 2018.

### **STATE COURT JURISDICTION**

27. The causes of action asserted and the remedies sought in this Complaint are based exclusively on Tennessee statutory, common, and decisional law.

28. The Complaint does not confer diversity jurisdiction upon federal courts pursuant to 28 U.S.C. § 1332, as the State is not a citizen of any state and this action is not subject to the jurisdictional provisions of the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d). Federal question subject matter jurisdiction under 28 U.S.C. § 1331 is not invoked by the Complaint. Nowhere does the State plead, expressly or implicitly, any cause of action or request any remedy that *necessarily* 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. There is no federal issue important to the federal system, as a whole, as set forth in *Gunn v. Minton*, 568 U.S. 251, 258 (2013).

29. In this Complaint, the State occasionally references federal statutes, regulations, or actions, but does so only to establish Amerisource’s knowledge, to explain how Amerisource’s conduct has *not* been approved by federal regulatory authorities, or to reference a *complementary* federal law or regulation to state law, but one in which the federal issue is not “necessarily raised” or “substantial.” See *Dunaway v. Purdue Pharma L.P.*, Case No. 2:19-cv-00038, 2019 WL 221670, \* 6 (M.D. Tenn. May 22, 2019).

#### **SUBJECT MATTER JURISDICTION**

30. As a court of general jurisdiction, the Circuit Court is authorized to hear this matter, based on the TCPA and nuisance claims, the amount at issue, and the relief sought pursuant to Tenn. Code Ann. §§ 16-10-101 and -110.

#### **PERSONAL JURISDICTION**

31. As set forth below, this Court has personal jurisdiction over Amerisource based on its contacts in Tennessee. Among other things, Amerisource has:

- been a licensed wholesale distributor of prescription drugs in Tennessee since 1985;
- transacted business in Tennessee, including through over 460 associates it employs in Tennessee;<sup>32</sup>
- shipped, delivered, or otherwise made opioid products available to pharmacies, hospitals, practitioners, and consumers in Tennessee;
- made sales and/or compliance site visits to the majority of the pharmacies referenced in this lawsuit;

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<sup>32</sup> ABDCMDL00359137 (slide 4 of 11).

- operated a distribution facility in Smyrna, Tennessee (outside of Nashville) and previously operated facilities in Johnson City, Chattanooga, and Antioch (outside of Nashville); and
- operated seven other facilities in other states that distributed controlled substances within Tennessee.

## **VENUE**

32. Venue is proper in Knox County pursuant to the TCPA's specific state enforcement venue provision, Tenn. Code Ann. § 47-18-108(a)(3), because it is a county where the alleged violations took place and is also the county in which Amerisource has conducted or transacted business.

33. Among other conduct, Amerisource distributed extremely high amounts of opioids to numerous pharmacies in Knox County, conducted site visits to customers in Knox County, and, through its sales representatives, made sales calls to current and prospective customers in Knox County. One of the largest pharmacy customers nationwide that Amerisource supplied with opioids, Food City # 674, is located in Knoxville.

## **PRE-SUIT NOTICE**

34. Consistent with Tenn. Code Ann. § 47-18-108(a)(2), the State has provided Amerisource with ten days' advance notice of its intention to initiate legal proceedings.

## **II. SPECIFIC FACTUAL ALLEGATIONS**

### **A. The Role of Distributors in the Pharmaceutical Supply Chain**

35. Due to the risks associated with controlled substances, including abuse and diversion, there is a sophisticated, closed distribution system intended to track and account for these drugs from manufacturing to the ultimate consumer. Generally speaking, the distribution system for prescription opioids involves three key participants: (i) manufacturers that make the

opioids, (ii) distributors that supply the opioids to the pharmacies, and (iii) pharmacies that dispense the opioids to the patients/consumers.

36. The manufacturers, who are at the top of the chain, own the rights to make and market the prescription drugs. They typically own or contract with facilities that manufacture prescription drugs and then sell their products to distributors. After production, many manufacturers send their drugs to distributors for further dispersal.

37. Pharmacies are the final step in the pharmaceutical supply chain before the drugs reach the consumer-patient. Pharmacies purchase drugs from distributors, and occasionally directly from manufacturers, and then take physical possession of the drugs.

38. As the lynchpin in the supply chain, distributors purchase, inventory, and sell pharmaceutical products to a variety of providers, including retail pharmacies, and ensure their safe storage and distribution. States, including the State of Tennessee, license or authorize wholesalers to sell and distribute pharmaceuticals within their borders.

39. Distributors in particular are “viewed as a ‘choke point’”<sup>33</sup> because of their position as the critical link in the chain of supply. Their role is not simply one of a truck driver, shelf stocker, freight forwarder, or passive middleman. They must be vigilant in determining whether a customer can be trusted to receive controlled substances for strictly lawful purposes. Should a distributor deviate from these checks and balances, the closed system subsequently fails in its entire purpose.

40. This is why the closed system of state and federal authority imposes specific duties upon distributors to monitor, identify, halt, investigate, and report suspicious orders of controlled substances. Ultimately, these laws are meant to protect the public.

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<sup>33</sup> ABC-MSAGC00000125.

## **B. Regulatory Context for Distributors**

41. Tennessee state law and its federal counterpart impose a series of overlapping and complementary restrictions on the distribution of controlled substances. *See* Tenn. Code Ann. §§ 39-17-417(a)(2), (3), and (4); Tenn. Code Ann. § 39-17-427; Tenn. Code Ann. § 53-11-301–452; 21 U.S.C. §§ 801–971; 21 C.F.R. §§ 1300–1321. State law authorizes the Tennessee Board of Pharmacy to establish a registration program for manufacturers, distributors, and dispensers of controlled substances. Tenn. Code Ann. § 53-11-301; 21 C.F.R. § 1301 (the CSA giving DEA its authority). Any entity seeking to become involved in the production or chain of distribution of controlled substances in Tennessee, including Amerisource, must first register with the Board of Pharmacy (and, under federal law, the DEA). Tenn. Code Ann. § 53-11-302; 21 U.S.C. § 822; 21 C.F.R. § 1301.11. Registrants are required to comply with all security requirements imposed under that statutory scheme, including the maintenance of “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” Tenn. Code Ann. § 53-11-303; 21 U.S.C. § 823(b)(1). They must “design and operate a system to disclose to the registrant suspicious orders of controlled substances” and inform the Board of Pharmacy and the DEA of suspicious orders when discovered by the registrant. Tenn. Code Ann. § 53-10-312(c); 21 C.F.R. § 1301.74(b).

42. Suspicious orders include those of “unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” Tenn. Code Ann. § 53-10-312(c); 21 C.F.R. § 1301.74(b). These criteria are disjunctive rather than all-inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter, and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop before determining whether an order is suspicious. The size of an order

alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the customer, but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

43. In addition to reporting all suspicious orders, distributors must also stop shipment of any order that is flagged as suspicious and may only ship orders that are flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. In other words, if, after investigating, the distributor has any remaining basis to suspect that a customer is engaged in diversion, it must deem the order suspicious, inform the DEA, and decline to ship the order.

44. Amerisource and all other registrants must likewise report acquisition and distribution transactions to the DEA through its Automation of Reports and Consolidated Orders System (ARCOS) database. Tenn. Code Ann. § 53-10-312; 21 C.F.R. § 1304.33.<sup>34</sup>

45. These requirements, including other federal law and regulations, are adopted and incorporated into Tennessee law.

### **C. Drug Enforcement Administration (DEA) Guidance**

46. These federal and state regulations are consistent with guidance the DEA has given to the industry. "Starting in 2005, the DEA held one-on-one meetings with distributors to remind them of their legal obligation to prevent pills from being diverted to the black market[.]"<sup>35</sup> The

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<sup>34</sup> Unless stated otherwise, references herein to "ARCOS" specifically means the DEA's ARCOS transactional data from January 1, 2006 through December 31, 2014 for 12 different opioid families: buprenorphine, codeine, fentanyl, dihydrocodeine, hydrocodone, hydromorphone, oxycodone, oxymorphone, powdered opium, morphine, meperidine, and tapentadol.

<sup>35</sup> [https://www.washingtonpost.com/national/congressional-report-drug-companies-dea-failed-to-stop-flow-of-millions-of-opioid-pills/2018/12/18/5bc750ee-0300-11e9-b6a9-0aa5c2fcc9e4\\_story.html?utm\\_term=.6b3e78381614](https://www.washingtonpost.com/national/congressional-report-drug-companies-dea-failed-to-stop-flow-of-millions-of-opioid-pills/2018/12/18/5bc750ee-0300-11e9-b6a9-0aa5c2fcc9e4_story.html?utm_term=.6b3e78381614).

DEA sent a letter to all registered distributors, including Amerisource, dated September 27, 2006 to reiterate the responsibilities of controlled substances distributors in view of the prescription drug abuse problem our nation currently faces. The letter emphasized that the distributors are “one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is crucial, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.”<sup>36</sup>

47. The DEA’s September 27, 2006 letter also warned that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly stated that a distributor, in addition to reporting suspicious orders, has a “statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, industrial channels.” The letter also dictated that “a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to suspicious circumstances.”<sup>37</sup>

48. On December 27, 2007, the DEA sent a second letter to all registered manufacturers and distributors, including Amerisource, “to reiterate” that in addition to the general requirement to maintain effective controls against diversion, DEA regulations required all manufacturers and distributors to report “suspicious orders when discovered by the registrant.”<sup>38</sup> The letter further explained:

Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an *independent analysis* of suspicious orders *prior to completing a sale* to determine whether the

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<sup>36</sup> ABDCMDL00046357–60.

<sup>37</sup> ABDCMDL00046357–60.

<sup>38</sup> ABDCMDL00269685 (emphasis in original).

controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

....

[R]egistrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC [§§] 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.<sup>39</sup>

49. In sum, Amerisource, as a distributor, is legally required to: (i) monitor for and identify suspicious orders of controlled substances; (ii) report suspicious orders when discovered; and (iii) decline to ship a suspicious order unless and until, through due diligence, Amerisource can determine that there are no red flags indicating the drugs could be diverted into illegal channels.

#### **D. Industry Guidelines**

50. Industry compliance guidelines established by the Healthcare Distribution Management Association (HDMA), the trade association of pharmaceutical distributors of which Amerisource is a member, explains that distributors are “[a]t the center of a sophisticated supply chain” and therefore “are uniquely situated to perform due diligence to help support the security of the controlled substances they deliver to their customers.”<sup>40</sup> According to HDMA, “[h]ealthcare distribution has never been just about delivery. It’s about getting the right medicines to the right patients at the right time, safely and efficiently.”<sup>41</sup> In addition to legal obligations, the HDMA has

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<sup>39</sup> ABDCMDL00269685–86 (emphasis added).

<sup>40</sup> HDMA *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App’x B at 1).

<sup>41</sup> <http://www.hdma.net/about/role-of-distributors>.

recognized that, “[a]s a central part of the pharmaceutical supply chain, healthcare distributors have a ‘moral obligation’ to help combat the issue.”<sup>42</sup>

51. The guidelines set forth recommended steps in the due diligence process, and note in particular:

If an order meets or exceeds a distributor’s threshold, as defined in the distributor’s monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.<sup>43</sup>

52. In addition to all of the above, distributors, such as Amerisource, that had superior access to information about where opioids were going, how many opioids were ordered, who was ordering them, and had the power to stop or limit shipments, had a duty as companies registered to do business and distribute controlled substances in Tennessee to ensure that opioids were not being diverted. As HDMA itself has recognized, distributors “have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”<sup>44</sup>

## **E. Amerisource’s Diversion Control Program**

### ***i. Overview***

53. Distributors of pharmaceutical opioids, like Amerisource, also have a specific duty to monitor for suspicious opioid orders and customers suspected of diverting or tolerating diversion of opioids by others,<sup>45</sup> both by statute and by industry standard.

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<sup>42</sup> ABC-MSAGC00000299.

<sup>43</sup> *HDMA Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, HDMA, at 9.

<sup>44</sup> See Brief for HDMA and Nat’l Ass’n of Chain Drug Stores as *Amici Curiae* in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enforcement Admin.*, 2016 WL 1321983, \*3 (C.A.D.C. Apr. 4, 2016).

<sup>45</sup> ABDCMDL00004580.



54. Amerisource’s anti-diversion compliance programs and policies were created in response to these duties and had significant flaws, primarily because they were designed to minimize the impact on sales of opioids to high volume pharmacies.

55. The Company prioritized sales over compliance and willingly ignored or turned a blind eye to opioid diversion for Tennessee pharmacies that were its money-makers.<sup>46</sup> Even its thresholds were based on *dollars*, not on the volume of dosage units.<sup>47</sup>

56. Amerisource’s compliance managers, individuals who were supposed to be immune from sales pressure, openly considered the impact that anti-diversion efforts would have on sales at pharmacies purchasing high volumes of opioids when making compliance decisions. Conversely, for an extended period of time, Amerisource’s sales representatives performed much of the Company’s pharmacy customer due diligence—an inherent conflict of interest that Amerisource was warned about expressly by an opioid manufacturer.<sup>48</sup> The Company also not only continued to supply controlled substances to pharmacies that exhibited diversion or strong signs of opioid abuse or diversion, but helped these pharmacies game the system to avoid detection by the DEA, and made this a selling point for customer growth and retention.<sup>49</sup>

57. Ultimately, Amerisource’s Diversion Control Program (DCP) was a low corporate priority—understaffed, underfunded, fundamentally unsound, and lacking the authority to challenge sales staff or otherwise jeopardize the retention of lucrative pharmacy customer accounts, including those in Tennessee.

58. For an extended period of time, *Amerisource had only four to six reviewers nationwide to investigate flagged suspicious orders*, told some of its most valuable customers

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<sup>46</sup> See, e.g., MNK\_NC08506592.

<sup>47</sup> ABC-MSAGC00000169.

<sup>48</sup> MNK\_NC8505954.

<sup>49</sup> ABD̄CMDL00288026.

when they were close to hitting their threshold,<sup>50</sup> made special rules for individual distribution centers which allowed them to automatically release more orders without any investigations or due diligence, and conducted investigations about suspicious orders *after* they had already been shipped. At best, Amerisource’s DCP was inconsistently enforced; at worst, it was completely ignored.

59. Amerisource implemented its compliance policies and programs concerning diversion in three different phases: pre-2007, 2007–2015, and 2015 to present. Pre-2007, the Company had some compliance policies, mostly just based on thresholds, but did not have an overarching, cohesive program. Following an investigation by the DEA in June 2007, Amerisource was required to implement its Diversion Control Program (2007 DCP). Eight years later, the Company purported to overhaul its DCP (2015 DCP), presumably in response to increased pressure from regulators. The 2007 DCP and 2015 DCP had four primary components: (i) New Customer Due Diligence; (ii) the Order Monitoring Program (OMP); (iii) Ongoing Customer Monitoring Activities; and (iv) Training. These components, along with any corresponding pre-2007 policies, are set forth below.

***ii. New Customer Due Diligence***

60. New Customer Due Diligence is the process for onboarding new pharmacy customers and assessing their suitability to purchase controlled substances. The process is meant to fulfill Amerisource’s requirement from the DEA to “know its customers.”

61. From the start, Amerisource consistently made broad exceptions throughout its DCP for its most lucrative customers, including chain pharmacies, from new customer “know your

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<sup>50</sup> ABDCMDL00282490.

customer” due diligence investigations, which were purportedly required for all new retail and distributor accounts.<sup>51</sup>

62. For independent retail pharmacies (i.e., non-chains), Amerisource’s policy was to collect a completed customer questionnaire, conduct a site visit, verify the pharmacist’s license, and conduct online investigation as part of this process, all *prior* to onboarding. The Company largely exempted retail chain pharmacies from this process.<sup>52</sup>

63. A central component of Amerisource’s new customer due diligence has been its Retail Pharmacy Questionnaire, referred to as a “Form 590,” which was “the basis for [Amerisource’s] due diligence investigation and provided a baseline to measure the pharmacy’s ordering habits and to determine any deviation from expected purchasing practices.”<sup>53</sup>

64. When completed, which often did not occur, the Form 590 contained information about any other distributors the pharmacy was currently purchasing controlled substances from, disciplinary history, customer payment methods, percentages of controlled substances, usage numbers for specific high-risk drugs, and top prescribers of opioids, among other questions. And while Amerisource’s Form 590 requested information about prescribing physicians, the Company did not routinely perform new searches on those prescribers as part of the new customer procedure.<sup>54</sup>

65. Under the 2007 DCP, *after* Amerisource received a Form 590, employees were supposed to verify that the potential customer was not listed on its “Do Not Ship List,” as well as verify the pharmacy’s DEA registration and state licensure.

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<sup>51</sup> See, e.g., ABC-MSAGC00000078.

<sup>52</sup> See, e.g., ABC-MSAGC00000078.

<sup>53</sup> ABDCMDL00004581–82.

<sup>54</sup> ABDCMDL00004582.

66. In reality, Amerisource often treated due diligence and Form 590s as an afterthought. In many instances, Amerisource *did not even have* a Form 590 on file for problematic customers for years. For example, as of 2015, Amerisource had no Form 590<sup>55</sup> for P & S Pharmacy in Kingsport, Tennessee, a customer since 2004, despite knowing that this customer was its highest purchaser of a highly abused opioid in the country, had up to 72% of its customers paying for their controlled substance prescriptions in cash,<sup>56</sup> up to 42.4% of all drugs it purchased from Amerisource were opioids, and exhibited many other red flags indicative of diversion.<sup>57</sup>

67. Amerisource did not routinely obtain Form 590s for new chain pharmacy locations—even ones it thought to be problematic. This was vividly demonstrated when Amerisource quickly onboarded 225 Walgreens stores, some of which were in Tennessee, without completing Form 590s over the concerns of Steve Mays, the Company’s Senior Director of CSRA. Mr. Mays feared Cardinal Health, another major distributor and Amerisource’s competitor, which was under investigation by the DEA, was trying to quickly dump these problematic accounts as a result of the DEA probe.

68. The Walgreens discussion was evidenced in a series of related internal e-mails that began on March 27, 2013, and began:

So what would you call the C2 [Schedule II Controlled Substances] Accelerated Walgreens Perrysburg Plan? *The C2 Hyper-Accelerated Perrysburg Plan! You got it, Walgreens called late yesterday afternoon and wants us to take on the attached list of 225 Walgreens accounts next week. We have asked for more time, timeframe not defined currently. However we should prepare for early next week.*

*The NRC team will begin ordering today to support the 225 customers. Corporate Compliance is validating regulatory licensing today.*<sup>58</sup>

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<sup>55</sup> ABC-MSAGC00000653.

<sup>56</sup> Payment in cash in high patient numbers is a sign of diversion because a cash payment makes the drugs more difficult to trace and eliminates quantity and dosage restrictions imposed by insurance reimbursement.

<sup>57</sup> ABC-MSAGC00000653–59.

<sup>58</sup> ABDCMDL00309948–49 (emphasis added).

To which Steve Mays, responded:<sup>59</sup>

Jim,  
Can we discuss these accounts when you get an opportunity? I'm concerned that these are the high risk accounts that CAH wants to dump ASAP so I want to make sure we have them sized properly and get the correct thresholds set.

Steve Mays  
Senior Director, Corporate Security & Regulatory Affairs

69. Amerisource's compliance management never intended to get Form 590s for every Walgreen's account among the 225 stores. Instead, Amerisource floated the idea of having an abbreviated Form 590 just for these Walgreens stores.<sup>60</sup>

70. A few months later, on June 11, 2013, the United States Department of Justice announced that Walgreens had agreed to pay \$80 million for civil penalties under the Controlled Substance Act for "an unprecedented number of record-keeping and dispensing violations." The DEA accused Walgreens of negligently allowing prescription pain killers, specifically including oxycodone, "to be diverted for abuse and illegal black market sales."<sup>61</sup>

71. Based on later discussions, Amerisource believed that Cardinal had in fact dumped these problematic stores on it. When McKesson, the largest distributor in the country, settled with the DEA in 2015, talk of Cardinal's opioid distribution to problematic Walgreens pharmacies resurfaced. Amerisource's CSRA discussed internally via email whether to share the news with the sales team because "[w]e could potentially see [McKesson] dumping problem Accounts and requests to ABC, *it happened before with Cardinal!*"<sup>62</sup>

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<sup>59</sup> ABDCMDL00309948; Mr. Mays would later ask about trying to hire the same Cardinal employees who serviced those problematic accounts. ABDCMDL00278510.

<sup>60</sup> ABDCMDL00280820.

<sup>61</sup> DOJ Press Release, available at <https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled>.

<sup>62</sup> ABC-MSAGC00014584; ABDCMDL00215945 (emphasis added).

72. Sharon Hartman, the Director of Pharmacy Compliance and Diversion Control ultimately responded with the following sarcastic response:<sup>63</sup>

<b>Subject:</b> RE: McKesson - Massive fine and loss of several DC registrations
Can only hope that sales remains "vigilant"
Sharon Hartman, RPh AmerisourceBergen Director, Pharmacy Compliance and Diversion Control Corporate Security & Regulatory Affairs

73. Around this time, under the 2015 DCP, Amerisource again stated that no new customer could come onboard *unless* the Form 590 was fully completed and CSRA had conducted its due diligence review and communicated its approval to the Customer Maintenance Group.<sup>64</sup>

74. Through the 2015 DCP, Amerisource also updated its standard new customer due diligence checklist, which each due diligence investigator was required to fill out and included the investigator's decision on whether to allow the pharmacy to purchase controlled substances. The investigator was to then send the due diligence checklist, along with the Form 590, to the Director of Diversion Control for final review. The Director was supposed to assess whether the file was complete and determine whether he agreed with the investigator's decision.<sup>65</sup>

75. However, Amerisource used the 2015 DCP to set the bar high when it came to suspicions about a new potential customer. And Amerisource employees who reviewed Form 590s were supposed to meet a very high number of factors before raising suspicion.

76. Aside from flaws in its new customer due diligence policy under the 2015 DCP, Amerisource also routinely failed to adhere to that policy. For example, Amerisource sales representatives often coached customers on how to complete the Form 590 without raising red

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<sup>63</sup> ABDCMDL00215945.

<sup>64</sup> ABDCMDL00004588.

<sup>65</sup> ABDCMDL00004589.

flags and many pharmacies were accepted as a customer without receiving a site visit. Even more problematic, Amerisource went years without obtaining completed Form 590s from a significant number of its customers purchasing controlled substances.

77. In May 2016, Amerisource began a project to compile missing due diligence documents, including Form 590s, for all its retail customers. Amerisource ultimately discovered that it was missing due diligence information for approximately 3,000 of its customers,<sup>66</sup> including pharmacies in Tennessee.

78. Over a year later, Amerisource had only 10% of the project.<sup>67</sup> By May 29, 2018, the project was estimated to have been 60% completed.<sup>68</sup> Amerisource did not identify these deficiencies to regulators except for specific requests for specific pharmacies.<sup>69</sup>

79. Even today in 2019, Amerisource does not require new customers to provide usage reports or dispensing data as part of the onboarding process. By relying on these customers to self-report without any documented verification, Amerisource does not fulfill its obligation to know its customers' business practices concerning opioids. Instead, in too many cases, Amerisource does not ask questions it does not want to know the answers to and is content not to inquire too much or document suspicious activity because doing so would place profitable customer relationships at risk.

***iii. Suspicious Order Monitoring Policies and the Order Monitoring Program***

80. Suspicious order monitoring, which was known as the Order Monitoring Program (OMP) under the Company's 2007 and 2015 DCPs, was another primary component of Amerisource's compliance programs.

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<sup>66</sup> ABC-MSAGC00005842; ABC-MSAGC00005844.

<sup>67</sup> ABC-MSAGC00005841.

<sup>68</sup> ABC-MSAGC00005844.

<sup>69</sup> ABC-MSAGC00005846.

81. The Company avoided identifying suspicious orders by establishing extremely high thresholds to determine what triggered a suspicious order review. In addition to thresholds, Amerisource purported to look at “base levels” to identify “especially large single orders,” which is another indicator of diversion.

82. Thresholds, generally speaking, are the maximum amount of a specific product family (e.g., oxycodone or buprenorphine) that a customer could purchase during a set time period. Amerisource initially set thresholds up to and above 300% over the average of other pharmacies within a certain category to identify orders of interest. Amerisource sought to establish high base levels to prevent identifying a significant volume of suspicious orders.

83. An Amerisource CSRA director described the threshold-setting process as follows:

You take all the pharmacies within the category and divide the number of pharmacies to come up with an average volume for the month per drug category. *And there was a multiplier of three.* Any order that was over the threshold amount would be produced [sic] an excessive order report.<sup>70</sup>

84. Sales considerations were intentionally baked into these thresholds. As of 2009, Amerisource had established default thresholds for oxycodone and hydrocodone based on the “*total monthly dollar volume*” of the retail pharmacy to Amerisource—not its total unit volume.<sup>71</sup>

85. Amerisource also made exceptions for its most lucrative customers in its OMP Distribution Center Procedures, telling its staff that for the Department of Defense, hospitals, PharMerica, Kaiser, chain or grocery customers, “and other large, well-known accounts” who exceed their threshold, “approval may be appropriate ... particularly if an order takes a customer just over its threshold at the end of the month” coupled with the pro forma statement to “Remember: Report unusual factors that raise suspicions.”<sup>72</sup>

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<sup>70</sup> ABC-MSAGC00005678; Zimmerman Dep. at 31 (emphasis added).

<sup>71</sup> ABC-MSAGC00000169 (emphasis added).

<sup>72</sup> ABC-MSAGC00000078.



86. In practice, opioids were almost always shipped to chain pharmacies or grocery stores,<sup>73</sup> like Food City in Tennessee, no matter how far above threshold the order was or the quantity requested. This amounted to a huge self-created loophole because, as known to Amerisource, Food City generated huge volumes and revenue from opioids. For example, at least from January 1, 2012 to June 2012, Food City Pharmacies # 674, # 616, and # 694, all based in Knoxville, were the top three Amerisource pharmacy customers in the country for sales of Oxy 30 from Actavis, a major generic manufacturer.<sup>74</sup>

87. Just as the new customer due diligence policies were altered for profit-generating chain pharmacies like Walgreens and its 225 stores, Amerisource made exceptions for its OMP policy involving thresholds for other chain pharmacies. As with grocery stores and hospitals, orders for controlled substances were almost always shipped to chain pharmacies, which the Company defined as any pharmacy that had ten or more locations or any number of locations in two or more states.<sup>75</sup> For a period of time, individual pharmacies within a chain were not even included on the Company's "Do Not Ship List."<sup>76</sup> As explained below, Amerisource created other special exceptions to its threshold policies concerning retail chain pharmacies.

#### *Pre-2007 OMP*

88. Amerisource remained inconsistent in applying in own OMP and threshold policies, which went through several iterations. Prior to 2007, Amerisource's suspicious order monitoring consisted of identifying "orders of interest" based on these thresholds. Suspicious order monitoring was quite literally an afterthought at the Company. Amerisource relied on "order

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<sup>73</sup> Elsewhere, Amerisource appeared to classify Food City as a retail chain pharmacy, rather than a grocery store. See ABDCMDL00316920; ABDCMDL00316922.

<sup>74</sup> ABC-MSAGC00008982.

<sup>75</sup> ABC-MSAGC00000086.

<sup>76</sup> See ABDCMDL00145133; ABDCMDL00145134.

fillers” at its distribution centers to identify and report suspicious orders through a manual process after the orders had already shipped; meaning that even if there were suspicions about the legitimacy of an order, they would ship it first before they reported it to the DEA if it ended up even submitting a report. As noted internally, “[o]rders are shipped at night, so SO’s [(suspicious orders)] would not be identified until the next day.”<sup>77</sup>

89. Also, before 2007, Amerisource’s sole due diligence was limited to checking the customer license and DEA registration. After the suspension of Amerisource’s DEA registration at its Orlando distribution center in 2007, the Company changed its OMP.

#### *2007 OMP*

90. The 2007 OMP consisted of comparing the purchases of a customer against that customer’s peers to identify potentially suspicious orders. Customers were grouped by DEA classification (e.g., hospital, practitioner, retail pharmacy, etc.) and then by size, which was determined by the *total dollar value* of prescription sales.<sup>78</sup> Thresholds were also updated, based on a yearly average of order volume multiplied by a factor, which would in theory limit the amount of product a customer could order in a static 30-day calendar period.<sup>79</sup>

91. Under the OMP, an order that exceeded the threshold limit was classified as an “order of interest,” placed on hold, and then assessed by a reviewer at the distribution center based on “the customer type, whether it ha[d] a known legitimate and well-established need for high volumes of controlled substances and listed chemicals, and the typical ordering patterns for that customer.” The OMP reviewer then had three options based on that limited information: release the order and allow it to be filled, cancel the order, or escalate the order for CSRA review.<sup>80</sup>

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<sup>77</sup> ABC-MSAGC00024100; ABDCMDL00270533.

<sup>78</sup> ABC-MSAGC00000075.

<sup>79</sup> ABDCMDL00004587.

<sup>80</sup> ABDCMDL00004582.

92. If an order of interest was forwarded for review, an Amerisource employee was supposed to use additional data, such as the due diligence and investigative files as well as sales history and purchase data, to determine whether an order should be reported to the DEA as suspicious, rejected as an error, or released for shipment to the customer.

93. While the OMP may have been “designed such that orders reported as suspicious to the DEA were not shipped to the customer,”<sup>81</sup> that was hardly the reality. Amerisource routinely filled orders that were identified as suspicious *without* reporting them to the DEA, reported suspicious orders to the DEA but then shipped them without conducting due diligence, shipped partial orders to avoid reporting, and increased customer thresholds to avoid triggering investigations. Even when it cancelled a suspicious order, it would frequently code the reason as “Administrative,” to avoid having to report it to the DEA.

94. This process also lacked consistency because Amerisource’s order fillers were left to their discretion to subjectively determine what was suspicious. For example, on December 24, 2007, Food City Pharmacy # 674 in Knoxville ordered, among other things, 7,200 Oxy 30 pills. Amerisource ultimately reported this to DEA, yet on Christmas Day December 25, 2007, it shipped all 7,200 Oxy 30 pills to the pharmacy, along with an additional 13,505 doses of oxycodone, morphine, fentanyl, hydrocodone, oxymorphone, and hydromorphone.<sup>82</sup>

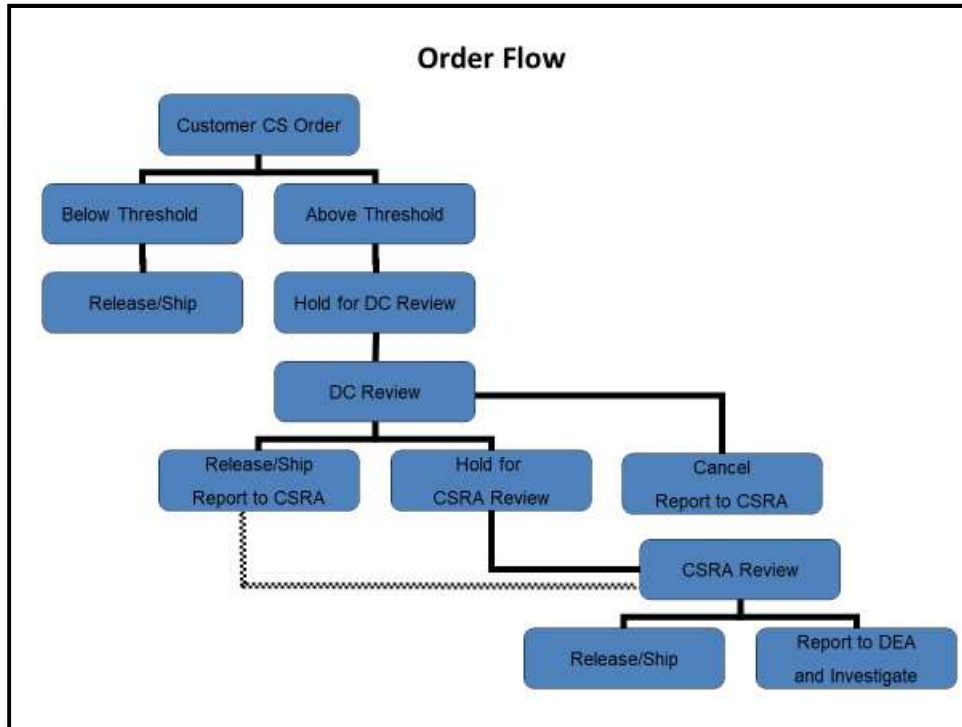
95. While the Company purported to look at other factors, the threshold was most often the only factor considered to determine whether an order was suspicious and, as a result, was manipulated. Simply put, if the order was below the threshold, which was purposefully set high, Amerisource shipped the order an overwhelming majority of the time.

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<sup>81</sup> ABDCMDL00004583.

<sup>82</sup> ARCOS.

96. The determinative role that threshold limits played in Amerisource's decision as to whether an order was identified as suspicious is shown in the internal Amerisource flowchart, which shows the process under the 2007 OMP:<sup>83</sup>



97. In the vast majority of cases, if the order fell below threshold, no further inquiry was made, and Amerisource released and shipped the order.

98. Despite ostensibly overhauling its OMP and Diversion Control Program in June 2007 because of a DEA investigation, Amerisource either paid little attention to the new suspicious order monitoring and other diversion surveillance policies, or applied them arbitrarily<sup>84</sup> and incoherently.

99. Internal emails show that Amerisource prioritized sales over its anti-diversion efforts and did not take compliance efforts seriously. For instance, Dianne Pitts, an employee at

<sup>83</sup> ABC-MSAGC00006617.

<sup>84</sup> See ABDCMDL00268918.

Amerisource's Birmingham, Alabama distribution center, sent the following email in 2007 to Chris Zimmerman, the head of CSRA, in which she explained that Food City pharmacy orders, which were predominantly sent to Tennessee, were being shipped *regardless of what or how much they ordered* and that some employees would release an order for shipment even if it was up to 30% over the already high threshold for that pharmacy.

100. More than just bureaucratic confusion, CSRA routinely bent to the will of Amerisource's sales or business teams before, during, and after 2007 when an OMP or other anti-diversion policy would result in lost opioid sales.

101. Amerisource's CSRA Department also broke protocol and informally assigned different thresholds for different distribution centers based on financial considerations. This included the 30% threshold figure for the Birmingham distribution center, which is also referenced in the above email written by Dianne Pitts on August 29, 2007. The Birmingham distribution center was one of the primary Amerisource distribution centers that supplied some of the largest high-volume opioid pharmacies in Tennessee.

#### *2007 to 2015 OMP*

102. The Company's 2007 to 2015 OMP and other anti-diversion efforts suffered from many of the same problems on their face, and like before, were inconsistently applied or ignored. For example, in 2010, Ed Hazewski, Amerisource's Director of Security and Diversion Control, "agreed" to let its Birmingham distribution center automatically "release orders that were ten percent or less over."<sup>85</sup>

103. Amerisource's continued emphasis on sales over anti-diversion efforts, the Company's failure to conduct suspicious order monitoring at a meaningful time in the process, and

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<sup>85</sup> ABDCMDL00267013.

lack of resources for the Company's OMP and DCP are evidenced in a long, but telling series of email exchanges beginning on December 30, 2010 between Jeff Rehovsky, the Manager of the Birmingham distribution center, and Ed Hazewski. The email exchange between Mr. Rehovsky and Mr. Hazewski was commented on and ultimately extended to other parties.

104. For convenience, emails from Amerisource's distribution center employees are set forth in green and its CSRA employees' emails are set forth in orange below. On December 30, 2010, Mr. Rehovsky started the exchange, writing:<sup>86</sup>

**Sent:** Thu Dec 30 09:16:55 2010  
**Subject:** OMP Issues

Ed,

This is horrific customer service. I fully support the OMP process and the need to have this program, but I do not understand why we cannot find a way to administer it in a way that supports our customers. These orders were sent up last night, and it does not do any good to tell us at 6:46 in the morning that they are approved to ship. I would like to understand how we can improve this process in 2011 so that we can service our customers properly.

Please let me know your thoughts on how this can be improved.

Thanks,

Jeff Rehovsky  
Vice President/  
Distribution center Manager  
AmerisourceBergen  
Birmingham, Alabama

Mr. Hazewski responded:<sup>87</sup>

**Subject:** Re: OMP Issues

I know we've had this conversation and I hear you, but: my team looked at orders through the holiday weekend from home despite the holiday and vacations. One of my team went to a McDonalds in Pittsburgh just to get wi-fi to look at orders. Last night orders were checked until at least 9:30 eastern. Any orders that could be released were. We do all we can to support customer service.

Ed Hazewski

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<sup>86</sup> ABDCMDL00267014.

<sup>87</sup> ABDCMDL00267014.

To which Mr. Rehovsky replied:<sup>88</sup>

**Subject:** RE: OMP Issues

Ed,

If the issue is with the timing of our systems sending the orders up for you to look at, can't we train the local Compliance Manager to release the ones like we had last night were they are just slightly over the threshold and they have been a good long term customer and we do know them? I thought this was the advantage of not having the Compliance Mangers report to the Division so that they could be objective in making sure we are being compliant.

Thanks  
Jeff

And Mr. Hazewski responded back:<sup>89</sup>

**Subject:** Re: OMP Issues

During our most recent call (me, you, Erica and Bobby) I agreed to let your OMP team release orders that were 10 percent or less over. Unless over ruled I am not willing to go beyond that number. I'll defer to Steve and Chris.

Ed Hazewski

105. Commentary about the above email chain ricocheted within Amerisource.

106. In one comment, a Customer Care Manager at the Birmingham distribution center stated that the agreed-upon 10% allowance was really even higher. The email stated:<sup>90</sup>

It was 15% or less and I, we took this as a ground rule for the last day of the month. So we use this rule throughout the whole month?

Bobby Sanders  
Customer Care Manager  
Birmingham Division

107. Chris Zimmerman, the Senior Vice President of CSRA and Mr. Hazewski's boss, and Steve Mays, the Senior Director of CSRA, were included in these exchanges. Mr. Mays agreed to help "get this worked out," to which Mr. Zimmerman replied:<sup>91</sup>

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<sup>88</sup> ABDCMDL00267013.

<sup>89</sup> ABDCMDL00268776; ABDCMDL00267013.

<sup>90</sup> ABDCMDL00267008.

<sup>91</sup> ABDCMDL00268777.

**From:** Zimmerman, Chris  
**To:** Mays, Steve  
**Sent:** Thu Dec 30 22:42:33 2010  
**Subject:** Re: OMP Issues

Thanks, what hell is TN doing, self destruction.

108. Mr. Mays joked back, “Yep! Freshmen!”<sup>92</sup> His response to Mr. Hazewski, however, was more measured and stated:<sup>93</sup>

**Subject:** RE: OMP Issues

Ed,

Let’s discuss Monday and then we can set up a call with Jeff, Erica and his team. I’m a little concerned that we are setting up “one off” agreements with the Birmingham DC over and above the basic OMP requirements. My feeling is that Jeff needs to take ownership and responsibility of this issue and not blame CSRA for reviewing orders that Jeff’s DC has sent to CSRA for investigation. The whole program is designed to allow trained designated individuals at the DC to make decisions about releasing orders based on their “knowledge” of their customer, not some arbitrary percentage over a threshold. It’s never going to be a “black and white” decision. I reviewed these orders and they are not excessive and given the size of the orders, the extra business days this December and the DC’s knowledge of their customers, they should have released these on their own. After we determine what, if any corrective actions CSRA and the DC can take, I will give Joe Short an update.

Thanks,

Steve Mays  
Senior Director, Corporate Security & Regulatory Affairs  
AmerisourceBergen Corporation

109. Mr. Rehovsky, whose distribution center again serviced some of the highest volume pharmacies in Tennessee, remained undeterred and wanted orders to be pushed through as soon as possible, even though it was his team that flagged them for additional investigation.

110. In March 2011, several months after his original e-mail exchange with Mr. Hazewski, he contacted several other distribution center managers to ask:<sup>94</sup>

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<sup>92</sup> ABDCMDL00267011.

<sup>93</sup> ABC-MSAGC00021048.

<sup>94</sup> ABDCMDL00267232.



**From:** Manchester, Ron  
**Sent:** Tuesday, March 29, 2011 8:34 AM  
**To:** Amato, Augusto; Strothers, John; Rehovsky, Jeffery; Brecko, Joe; Cheney, Joe  
**Subject:** RE: OMP

I talked to Bobby about this yesterday and here is what we determined. First of all, it seems like Birmingham and Houston Customers begin to hit allocation thresholds earlier in the month than normal and even when Customers were only over by 3%-6%, orders were being cancelled. That created Customer “noise” around the OMP process. Have we changed our approval methodology at HQ? Second thing is this...Bobby is not happy that orders that arrive in the afternoon are not receiving approval until the next morning. This has the effect of adding 24 hours to the delivery time if the order is approved by HQ.

Our Houston Customers are accustomed to this 24 hour review but Bobby is having trouble getting Birmingham Customers to accept this. I initially misunderstood Jeff’s question yesterday. Just thought I would send this email out for clarification purposes. The main problem from Bobby’s perspective is the turnaround time on approvals for orders that arrive in the afternoon...no same-day approval.

**Ron Manchester**  
Vice President, DCM-Houston  
AmerisourceBergen Corporation

111. Amerisource’s Orlando distribution center manager agreed. His facility was also frequently facing the same issue of Amerisource’s OMP not releasing potentially suspicious orders quick enough to satisfy sales.<sup>95</sup>

112. Parts of this email exchange made its way to senior management at Amerisource including Chris Zimmerman, Steve Mays, and Ed Hazewski. The email expressed frustration with the distribution center managers, stated that the threshold levels are already at 300% over average, stated that they should not “continue emails back and forth on this issue,” stated “when an order is ‘just 3% or 6%’ over its threshold . . . it is actually 303% or 306% over the average purchase for that size pharmacy because we build a 300% float into each threshold,” and noted that the distribution centers that were expressing frustration were distribution centers that had or almost had their DEA registrations suspended. The email string stated:<sup>96</sup>

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<sup>95</sup> ABDCMDL00267232.

<sup>96</sup> ABDCMDL00267230–32 (emphasis added).

**From:** "Zimmerman, Chris" <CZimmerman@amerisourcebergen.com>  
**Sent:** Wed, 30 Mar 2011 16:20:39 -0400 (EDT)  
**To:** "Mays, Steve" <SMays@amerisourcebergen.com>  
**Cc:** "Haczewski, Edward" <EHaczewski@amerisourcebergen.com>; "Gundy, Bruce" <BGundy@amerisourcebergen.com>  
**Subject:** FW: OMP

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I spoke to John and he does not want us to continue the emails back and forth on this issue, which I agree; therefore, I am going to have a phone conversation with Joe explaining the OMP process and its limitations.

I think you should put together a brief "refresher" presentation on OMP for the DCMs that you can present at Shay's meeting. I think you can use some of the points from my email below for your presentation:

1. DC's can release orders if they feel that are not suspicious.
2. Threshold levels are already 300% over average.
3. CSRA can release orders late into the evening; however, if the investigator needs more information to make a decision (call DC/sales/customer, review NCDD file, etc.), this can't be done until the next morning when they can make the appropriate contacts and/or reviews.
4. In addition to state & federal regulations and ABC policy & procedures, ABC has entered into a written agreement with DEA not to release potentially suspicious orders until we have determined they are not suspicious. If ABC deems the order suspicious, we must cancel the order and report that order to DEA within 24 hours.

Ed can probably give you a canned presentation and you can add this information.

Chris

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Joe, can you call me on this issue. We have explained the OMP process several times to Jeff, however he seems to either not understand, or figures CSRA is not appropriately servicing the Birmingham DC with adequate customer service. I do take offense to Jeff's comment below regarding CSRA providing "poor customer service."

First: when an order is "just 3% or 6%" over its threshold (referenced below), it is actually 303% or 306% over the average purchase for that size pharmacy because we build a 300% float into each threshold.

Second: DEA had to approve ABDC's OMP program before DEA would release Orlando's DEA Registration from suspension, and ABDC entered into a written agreement with DEA that ABDC would implement the OMP at all ABC distribution sites.

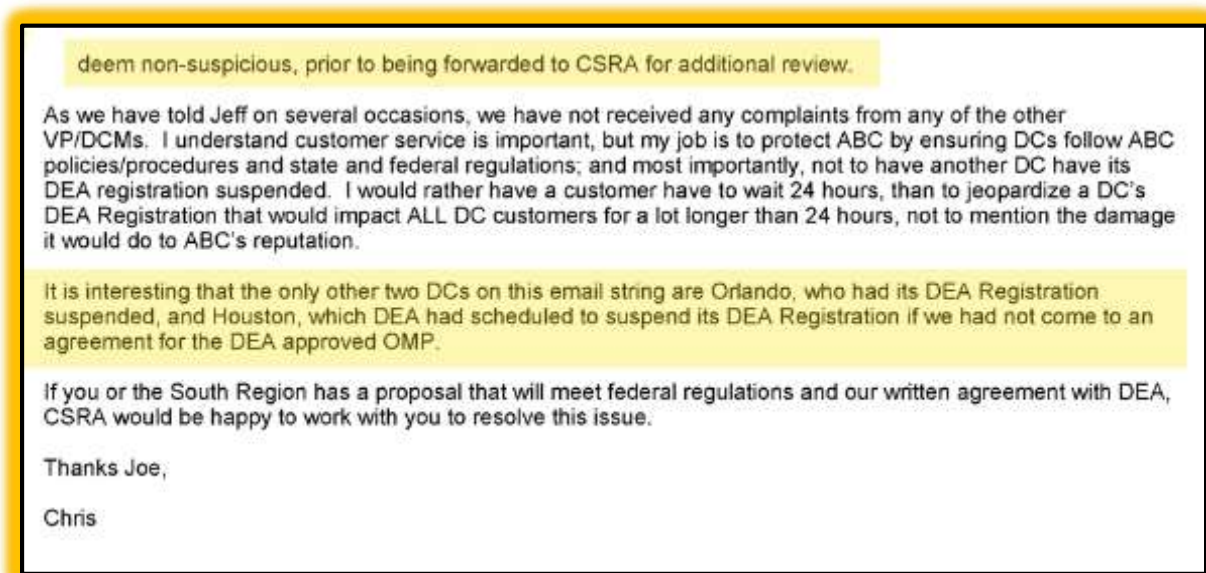
Third: The DC has the ability to release any order; therefore, the only orders that should be coming to CSRA for review are those that the DC has deemed as potentially suspicious.

Fourth: When we review a potentially suspicious order in the late evening, it may require additional investigation before we can release the order, which could include contacting the ABDC sales person, the customer, a review of the customer file, etc. We are prohibited by federal regulations and by our written agreement with DEA, from releasing a potentially suspicious order until the appropriate investigation is conducted. This investigation cannot be conducted "after" the order is released.

There are only three alternatives:

- 1) Not follow the DEA mandated OMP; or
- 2) ABDC provide CSRA with:
  - a. Support to hire resources to staff investigators - 24 hours a day, and
  - b. ABDC sales associates home/cell phone numbers so we can call them 24 hours a day in order to complete the investigation to release the potentially suspicious order; and
  - c. ABDC pharmacy owner or PIC home/cell numbers so we can contact them 24 hours a day in order to complete the investigation to release the potentially suspicious order; or
- 3) Follow existing DEA approved OMP, which includes the DC's ability to release customer orders that they

[page break]



113. Amerisource's overriding consideration of sales over anti-diversion efforts continued long after this 2010 exchange.

114. For example, the special 15% above the threshold allowance referenced in the 2010 email exchange above was more than just a rumor, it was a "rule" and it continued in 2011 and 2012. Comments justifying the release of hundreds of orders that exceeded the thresholds set by Amerisource's CSRA stated "under 15% per bobby sanders,"<sup>97</sup> even for orders as large as 14,400 Oxy 30 pills, manufactured by Actavis.

115. In 2011, 719 orders totaling almost 8,000 bottles of opioids were released into Tennessee because they were less than 15% above the monthly threshold—89% of which were orders for oxycodone, primarily heading east to cities like Knoxville, Newport, and Morristown.<sup>98</sup> In January and February of 2012, at least 102 orders totaling 866 bottles of opioids, 90% of which

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<sup>97</sup> ABC-MSAGC00002109.

<sup>98</sup> ABC-MSAGC00002102.

were oxycodone, were released for shipment by Amerisource because they were “under 15% per bobby sanders.”<sup>99</sup>

116. In and around 2011, Amerisource continued to initially set thresholds at 300% over the average purchasing for similar sized pharmacies, ensuring that thresholds were only hit for orders that far exceeded the norm.<sup>100</sup>

117. Prior to 2012, Amerisource enacted a policy that allowed a customer to have multiple accounts associated with the same DEA number, each with its own corresponding threshold—meaning that orders could be manipulated between accounts.<sup>101</sup>

118. During the same time period, Amerisource’s customers had visibility of where their ordering stood against their threshold. Armed with such information, they were free to order exactly to their limit to avoid risking an order being reported to the DEA, preemptively request a threshold increase from Amerisource, and/or purchase those products from another distributor.<sup>102</sup>

119. Before 2012, Amerisource did not count or consider rejected orders against an accounts’ threshold.<sup>103</sup> This meant that after a pharmacy’s order was rejected for exceeding the threshold, any subsequent orders were not considered in and of themselves—even if the additional orders were themselves signs of diversion.

120. Aside from establishing high thresholds and telling the pharmacy the threshold level, Amerisource also manipulated thresholds in other ways over an extended period of time. For example, Amerisource also helped its customers avoid threshold limits by choosing to post-date invoices for large orders placed at the end of the static 30-day threshold period. For instance,

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<sup>99</sup> ABC-MSAGC00002109.

<sup>100</sup> ABC-MSAGC00000128.

<sup>101</sup> ABDCMDL00268912–16.

<sup>102</sup> See ABDCMDL00268919 (expressing policy change to reduce threshold visibility at distribution center level).

<sup>103</sup> ABDCMDL00268917.

on December 31, 2011, Food City # 674 ordered 24,000 Oxy 30s and Food City # 616 ordered 6,200 tablets of oxycodone. Rather than reject and report these orders to the DEA, Bobby Sanders, the Customer Care Manager at the Birmingham distribution center, stated that they “will be invoiced on 1/2/12.”<sup>104</sup> On January 2, 2012, as planned, the 24,000 tablets of Oxy 30 were shipped to Food City # 674 and the 6,200 tablets of oxycodone were shipped to # 616. This happened again at the end of that month, when Food City # 616 ordered 17,200 doses of oxycodone, that were to “be invoiced on the 1st per bobby sanders.”<sup>105</sup> However, these are far from the only examples. For years, Amerisource employees released tens of thousands of opioids, including some of the most highly abused ones on the market, into Tennessee simply by post-dating hundreds of invoices to the first or second of the following month.<sup>106</sup>

121. Around this time, Amerisource actively worked with pharmacies to manipulate the pharmacy’s opioid orders by cutting or splitting them to get around thresholds—which the DEA has stated is the equivalent of saying that “a little bit of diversion is okay.” For instance, Food City # 674 ordered 57,600 tablets of Actavis’ Oxy 30 from Amerisource on October 23, 2011. Rather than investigate or report the order, Amerisource cut it to 38,400 and shipped the next day along with thousands of additional tablets of oxycodone.<sup>107</sup>

122. A few months later, on Friday, January 27, 2012, Food City Pharmacy # 674 ordered 38,400 Oxy 30s, manufactured by Actavis.<sup>108</sup> Two days later, on Sunday, January 29 at 7:28 p.m., it was “sen[t] for further investigation.”<sup>109</sup> Amerisource decided the order was suspicious and transmitted it to the DEA the day after that, on Monday, January 30 at 3 p.m.<sup>110</sup>

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<sup>104</sup> ABC-MSAGC00002109.

<sup>105</sup> ABC-MSAGC00002109.

<sup>106</sup> *E.g.*, ABC-MSAGC00002213; ABC-MSAGC00002214; ABC-MSAGC00002102; ABC-MSAGC00002109.

<sup>107</sup> ABC-MSAGC00002102; ARCOS; ABC-MSAGC00000491.

<sup>108</sup> ABDCMDL00002092.

<sup>109</sup> ABDCMDL00002092.

<sup>110</sup> ABDCMDL00002092.

However, by Thursday, February 2, Amerisource was shipping Food City # 674 a total of 38,400 Oxy 30s, the *exact* same amount that it reported to the DEA just days earlier; but this time the order was cleverly broken into three (264 bottles, 98 bottles, and 22 bottles, all 100 count bottles of Actavis Oxy 30).<sup>111</sup>

123. In 2012, the DEA investigated Amerisource again for failing to protect against the diversion of controlled substances. That same year, Amerisource introduced additional changes to its OMP that were intended to make the management process “more systemic and less arbitrary.”<sup>112</sup>

124. But Amerisource’s overarching priority of making money, often at the cost of compliance, still prevailed.

125. In a telling note taken around February 1, 2012, an auditor for Mallinckrodt, a manufacturer of generic and branded opioids, memorialized a discussion with Amerisource’s Ed Hazewski. The Mallinckrodt employee stated the following concerning a Baltimore pharmacy:<sup>113</sup>

Drug City Pharmacy/Baltimore MD/Potential new ABC customer account  
Ed Hazewski indicated that ABC is considering taking Drug City Pharmacy/Baltimore MD as a new account, ABC new from conversations with Drug City Pharmacy that Drug City formerly purchased controlled drugs from McKesson. Mallinckrodt Auditors advised Ed that, while ABC business decisions are the responsibility of ABC – ABC may want to be extremely vigilant about taking on new pharmacy accounts given the current focus on high volume pharmacies from the SOM perspective. Ed thanked Mallinckrodt for the advice and indicated he would take the information under advisement, however, Drug City represents a significant amount of sales.



126. Before, during, and after 2012, Amerisource had the same overarching sales consideration for current customers—even those where it knew diversion of opioids was occurring. And even when customers were restricted, blocked, or terminated, Amerisource continued to ship significant quantities of opioids to some Tennessee pharmacies, including pharmacies like Jabo’s

<sup>111</sup> ARCOS.

<sup>112</sup> See ABDCMDL00000161.

<sup>113</sup> MNK\_NC08505956 (emphasis added).

in Newport, Tennessee (discussed in detailed in the pharmacy section). Amerisource ignored its own policy not to ship oxycodone to Jabo’s for six years, shipping it over 1.7 million doses of oxycodone during that time.<sup>114</sup> That is enough dosage units for every Newport resident to have received approximately 262 tablets of oxycodone from Amerisource.

127. In 2013, Amerisource began using its sales team to target retail pharmacies, like Jabo’s Pharmacy, that had two “distinguishing features”: low overall volume (\$50,000 per month or less) and a high percentage of Schedule II controlled substances (CII) compared to their overall volume.<sup>115</sup>

128. Amerisource knew these independent pharmacies were more likely to be sources of opioid diversion and suspicious orders, *but continued to seek their business anyway*. In internal documents, Amerisource acknowledged that these independent pharmacies, which it classified as “Low Dollar Volume / High [Controlled Substances] Ratio” and sought to retain or obtain as customers, “account for the majority of OMP issues.”<sup>116</sup>

**4) Low Dollar Volume / High CS Ratio:** Customers in this category are generally Secondary Accounts, and account for the majority of the OMP issues. Sales, the VP/DCM, and potentially the RVP should closely evaluate the business decision to service these accounts:  
a.) is there a potential to transition this secondary account to primary; or  
b.) is ABC assisting/enabling its competitor's to retain primary accounts by providing these accounts with "high risk" controlled substances because the primary distributor has limited the account's controlled substance quantities to limit its exposure?

129. In the same document, Amerisource instructed its sales associates to ask themselves whether there was a potential to transition what might be a secondary account to primary, or “is ABC assisting/enabling its competitors to retain primary accounts by providing these accounts

<sup>114</sup> ABDCMDL00315459 (Sheet DNS Reinstated, Row 46); ARCOS; ABC-MSAGC00001988; ABC-MSAGC00002012; ABC-MSAGC00002039.

<sup>115</sup> ABDCMDL00278210.

<sup>116</sup> ABC-MSAGC00000100.

with ‘high risk’ controlled substances because the primary distributor has limited the account’s controlled substance quantities to limit its exposure?”<sup>117</sup>

130. Despite these customers “account[ing] for the majority of OMP issues,” Amerisource instructed its sales employees to “challenge [their customers] to grow their overall relationship with Amerisource,” while “advis[ing] them to manage their purchasing of C2s[,]” and “making ABDC your primary wholesaler and shift all purchases to us.”<sup>118</sup>

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<sup>117</sup> ABC-MSAGC00000100.

<sup>118</sup> ABDCMDL00288026.



\*\*\*For Internal Use Only. Not Intended for Distribution\*\*\*

**Sales Talking Points  
Low-Volume Accounts  
July 2013**

If you are like most pharmacies, I know you probably spend most of your time micromanaging your cost of goods in the face of declining reimbursements.

Today, 44% of independent pharmacies earn less than a 2% net profit. That's nearly half of all independent pharmacies!

13%, on the other hand, of independent pharmacies operate at four times that number—an 8% or higher margin.

Independent pharmacies come to AmerisourceBergen because they know that by taking full advantage of our product offerings, resources and expertise, they will be able to attract more patients, retain existing patients and improve their operating efficiencies.

By doing all this, they'll be able to get on the road to higher profitability, and break out of the 2% net profit trap.

As much as I want you to take full advantage of AmerisourceBergen's value, I am rather concerned about your pharmacy for a different reason. Based on your overall volume with us, your percentage of C2 orders is high and may be deemed suspicious by either our OMP system or regulatory authorities. This puts your account with ABDC at significant risk of closure or exposure to regulatory and enforcement agencies actions.

Every day, we read about another independent pharmacy under investigation. I want to make sure that doesn't happen to you. The way I see it, is that you have a couple of options. First, you can make ABDC your primary wholesaler and shift all purchases to us. The second option is we arrange a short-term transition process and you stop buying C2s from ABDC and shift them to whomever your buying other products. The third option would be to do nothing--but this is not a feasible long-term decision--and it's not a good option for anyone.

As I mentioned earlier, independent pharmacies choose ABC because we help them improve their overall profitability. Cost of goods is only a piece of the profit puzzle.

In the short term, we need to fix your purchasing habits from ABDC. Then let's schedule another meeting to review how we can help become one of those pharmacies in the top 13%!

119

131. In the cover e-mail for the talking points, Amerisource expressly told its sales staff to try to turn these “low dollar / high percentage of controlled substance” accounts “into a more significant and mutually valuable customer relationship.” In other words, Amerisource told its

<sup>119</sup> ABDCMDL00278212; ABC-MSAGC00006613.

sales representative to grow accounts from customers who were most likely to engage in diversion and make suspicious opioid orders.<sup>120</sup>

Attached you will find a list of all of our region's accounts with less than (in most cases much less than) \$50,000/month in purchasing, however, this is not their only distinguishing feature. Although these accounts are what we would consider low overall volume, they are also purchasing a high percentage of C2s versus their overall volume.

As such, I need you and your teams to do a few things between now and September 1:

1. Make contact with these customers and challenge them to grow their overall relationship with AmerisourceBergen. There can be no better way to flex your new Challenger skills than to turn what has been a lower-volume account into a more significant and mutually valuable customer relationship.
2. Based on the attached list, send me back any customers who you believe will grow their relationship with us, along with the detail of why you believe this. I also need any customers who have signed a PVA.
3. If we are maintaining our relationship with the customer then you must also advise them to manage their purchasing of C2s. Doing so will greatly benefit their business as it will reduce the risk of closure and regulatory oversight or actions.

132. Later emails in August 2013 make clear that Amerisource was not seeking to grow accounts for just any controlled substance—it was specifically interested in growing smaller accounts with *high percentages of oxycodone and Oxy 30*<sup>121</sup> and targeted over one hundred pharmacies in the South. Essentially, Amerisource gave these smaller pharmacies with high levels of oxycodone an ultimatum—buy more from us or get cut off from ordering all pharmaceuticals.<sup>122</sup>

<sup>120</sup> ABDCMDL00282130 (highlighted emphasis added); ABC-MSAGC00000100.

<sup>121</sup> ABDCMDL00282129.

<sup>122</sup> See ABDCMDL00282130.

**Subject:** Low Volume / High Oxy  
**Attachments:** RVP\_email\_7\_1\_13.docx;Small\_Customers.xlsx;Sales\_Talking\_Points\_7\_1\_13.docx;SOUTH\_Less\_than\_50k\_per\_month\_with\_high\_Oxy\_Results\_06\_05\_13(1).xlsx;FW: Low Volume-High Oxy report (75.4 KB)

Team,

Ed Hazewski is traveling so I spoke with Chris Zimmerman regarding the Low volume high oxy email from yesterday. He informed me he is a bit removed from the details. However, he provided me with a little history (attached) and apparently this something that has been well socialized and somehow it has just never made it on our radar. There is still a disconnect and I will attempt to set up a conference call early next week to discuss. As an example, there are 654 South region accounts on the attached "small customer" file from Chris, whereas there were 105 accounts on the "South less than \$50K per month high oxy" file. So I am not sure if the 549 are considered non-savable or quite the opposite so a conference call does seem to be in order.

Thanks,

James Rice

Manager - Buying Groups  
Community & Specialty Pharmacy  
AmerisourceBergen Drug Company  
ABC Global Extension:102.7017

133. In 2014, Amerisource continued placing sales concerns above its anti-diversion efforts and made special exceptions for its most lucrative customers: retail pharmacy chains.

134. In direct contradiction of its own policy and the DEA's instruction, Amerisource sent Walgreens detailed breakdowns of its threshold data on a weekly basis in 2014. The DEA had previously told Amerisource not to divulge the customer's thresholds to them or indicate how close they were, because it "would allow customers to circumvent the system and not get reported to DEA as suspicious."<sup>123</sup> On paper, Amerisource's own policy also prohibited Amerisource employees from showing a customer its threshold for the same reason.

135. But Amerisource made special exceptions for Walgreens, among others. For instance, in spite of the DEA warning and Amerisource's own written policy, Ed Hazewski sent Walgreens an email on April 8, 2014, with the attachment "WAG Orders Held," which read:<sup>124</sup>

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<sup>123</sup> ABDCMDL00285348-49.

<sup>124</sup> ABDCMDL00282490 (emphasis added).

**Subject:** Data  
**Attachments:** WAG Orders Held.xlsx

Team WAG,

Find attached some data that I believe could be the basis for a part of our discussion. Briefly, the first tab is all WAG locations that had CII order lines flagged by the omp, sorted largest (most lines) to smallest. We can discuss further tomorrow. Thanks.

Ed Hazewski  
Director, Corporate Security and Regulatory Affairs  
AmerisourceBergen Corporation

136. The spreadsheet attached to Mr. Hazewski's 2014 email showed that 11 Walgreens pharmacies in Tennessee had placed 508 orders that were over their thresholds.<sup>125</sup> Of those, only 289 orders had been rejected—*every single rejected order was coded as an administrative error as opposed to a suspicious order, and none were reported to DEA*. The approved orders allowed almost a quarter of a million ODUs that were over Walgreens' thresholds to be shipped into Tennessee. Some of those Walgreens pharmacies had exceeded their thresholds by almost 50%.

137. Several months later, on November 21, 2014, Amerisource again sent Walgreens its "Weekly OMP Statistics." An Amerisource Diversion Control Coordinator responded, "Walgreen's [sic] orders from this morning were mostly way over threshold or duplicates. I'm not sure how much that column [(rejected or approved)] will change to be honest."<sup>126</sup> In response, an Amerisource Corporate Investigator stated:

*I agree that action needs to be taken on WAG's part to make sure they do not order large amounts over threshold. However, I also agree with [the Diversion Control Coordinator], in that there won't be much change. Their solution will be to raise the threshold, which means I'll continue to receive many reviews on a daily basis. I've talked with all the WAG investigators regarding CII orders being reduced, with no success at this point.*<sup>127</sup>

<sup>125</sup> ABDCMDL00282491.

<sup>126</sup> ABDCMDL00306524.

<sup>127</sup> ABDCMDL00306523 (emphasis added).

138. Walgreens also requested that orders submitted by their pharmacies to Amerisource that were over the threshold be cancelled and not reviewed any further.<sup>128</sup> This circumvention of the OMP would allow Walgreens to place potentially suspicious orders without the risk of being reported to the DEA, since Amerisource was only required to report orders it identified as suspicious, which only occurred after Amerisource further reviewed an order. And since Walgreens itself also self-distributed certain opioids to its pharmacies until 2014, there was nothing preventing it from filling the cancelled orders themselves.

139. Amerisource's actions with respect to Walgreens had a negative impact on Tennessee. Two particular Walgreens' locations were among the top twenty pharmacies in Tennessee that dispensed the most opioids. Between 2013 and 2014, Amerisource shipped approximately 1.7 million ODUs and 32.3 billion MMEs to one Walgreens located in East Ridge, with a population of approximately 21,216 residents and approximately 1.6 million ODUs and 52.3 billion MMEs to another Walgreens located in Kingsport, which had a population of approximately 52,627 residents.<sup>129</sup>

#### *2015 OMP to Present*

140. The chronic problems that plagued Amerisource's OMP, DCP, and anti-diversion efforts before 2015 still continue to this day.

141. As evidence of these ongoing problems, Amerisource hired FTI Consulting, Inc. in August 2015 to conduct a review of its OMP. FTI Consulting's audit found the same glaring deficiencies that had plagued Amerisource's programs from the start, including a lack of resources, lack of formal training, employees who felt overburdened by their workload and administrative demands, inconsistent policies, and breakdowns in communications. Even though "regulatory

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<sup>128</sup> ABC-MSAGC00008412; Hazewski Dep., 126:8–12.

<sup>129</sup> ARCOS.

obligations related to diversion control” were among the “Gaps & Risks” identified in the audit, Amerisource took no action and made no changes in response to the report.

142. In short, the audit was a disaster. Among other things, it reported the following (shown in gray below):

The CSRA resources that we interacted with were very knowledgeable with respect to their subject areas, although at times it was challenging to nail down their specific scope of responsibilities. Because the roles and responsibilities of CSRA personnel are somewhat ill-defined, CSRA team members sometimes end up performing activities outside of the purview which detracts from the utilization of these resources. ....

A large volume of work and responsibility falls to CSRA with respect to managing regulatory compliance and security activities, and some team members indicated that it is difficult to keep up with the demands. This may be because they have not received adequate training or because the team is not sufficiently staffed with the necessary resources or expertise.

*For the most part, CSRA team members do not receive much in the way of formal training and instead are, in the best case, provided informal training by being paired with a more experienced resource for a brief onboarding period. As a result, some CSRA personnel feel overwhelmed by the volume of activities they are required to perform, the administrative demands of their position and the lack of direction that they are provided. CSRA needs to standardize, improve, and/or develop more specific training by discipline and job function. The training also needs to address regulatory compliance activities and help CSRA personnel learn to view their activities through a risk management lens. Along the same lines, leadership should review and evaluate the competencies of the Compliance Managers and Clerks to determine where additional training, support or resources may be necessary and focus on improved tracking and managing of resource allocation and workload.*

....

[E]stablishing the delineation of regulatory and compliance responsibilities and defining the rules of engagement by and between CSRA and other corporate departments that are involved with “compliance activities” is critical in terms of defining ABC’s risk management program. ... While it is a good sign that the infrastructure is in place to perform compliance related activities, it does indicate – especially with the run of acquisitions – that compliance responsibilities are too diffuse or their ownership too unclear. That creates the potential that compliance activities are not occurring because “left hand doesn’t know what the right hand is doing”, or because there’s an assumption that someone else in the organization is taking care of it.

....

[T]here is a sense that some compliance and other corporate initiatives do not fully consider the burden that these organizational changes put on the compliance resources. For example, the centralization of certain support functions such as Customer Care and Human Resources did not adequately contemplate the downstream effect in terms of delays and inconsistent information provided to the local Compliance Managers. Not involving CSRA in operational initiatives limits the ability to head off issues that may ultimately present compliance challenges or concerns.

CSRA is very reactive to situations, with certain team members describing their job as “constantly putting out fires.” Being in a perpetual state of reacting to situations makes it difficult to implement and sustain organizational improvements and prevents resources from focusing on assigned projects. CSRA should strive to be more proactive in their activities, which starts by better defining roles, responsibilities and procedures and getting away from the mentality that “this is how we’ve always done it.” As ABC continues to grow and expand into new service offerings, the demands on CSRA will continue to increase and will require team members to be proactive in their work.

CSRA appears to have many initiatives underway to strengthen the efficacy of the group, but remains largely reactive to issues and requests. ....

For the most part, CSRA has good processes in place but struggles with documenting and providing visibility to these efforts. The organization suffers from decentralized and segmented tracking and documentation of information and activities, which results in limited reporting and tracking of workload, as well as lack of access to timely and comprehensive information across CSRA. The risk here is management by intuition, rather than having the data and analysis to support strategic decisions and resource planning.

CSRA personnel have developed personal tools and logs for the tracking of matters and issues, but there is a lack of clear policy guidance on determining what should be elevated to corporate levels or the appropriate channels or departments through which issues should be reported. ....

Across all CSRA functions, and most particularly at the facilities, there is a large volume of paperwork to maintain, to the point some CSRA personnel view their role as administrative rather than regulatory. ....

Many of CSRA’s challenges stem from inefficient and time consuming manual processes and activity tracking that could benefit from improved technology solutions. In fact, CSRA personnel were consistent in stating that the lack of an integrated matter management system creates significant process challenges,

particularly as it relates to managing, tracking, reporting, and documenting department activities and workflows. ....

[With regard to the OMP,] ABC does not have a policy to determine which associate(s) at the distribution center are responsible for reviewing orders. Although all associates who have access to the OMP system are required to be trained in reviewing orders, there is no consistency with respect to who is reviewing these orders. This presents a significant risk area because the company needs to be compliant with DEA regulations and able to explain and defend their decisions.

....

CSRA is responsible for conducting investigations in order to respond to reports of incidents that relate to the internal security, safety and regulatory compliance of the Company or affect its personnel, property, facilities or proprietary interests. There are established processes for conducting investigations, although there are some inconsistencies in defining the roles and responsibilities for handling incidents, incomplete guidance with regard to documenting investigations and a lack of formal training for investigators.<sup>130</sup>

143. Problems have continued even after the FTI audit. As recently as October 4, 2017, Amerisource knew it was releasing orders for high risk item families that were not reviewed by CSRA at all—including orders for oxycodone with acetaminophen, hydromorphone, alprazolam, and codeine with acetaminophen through its Seattle distribution center.<sup>131</sup>

*iv. Ongoing Monitoring of Customer Activity*

144. As a third primary component of its compliance program, Amerisource was supposed to conduct ongoing monitoring of customer activity. In addition to the OMP, the CSRA also performed ongoing monitoring of purchase data, including metrics such as a customer's ratio of controlled substance purchases as compared to non-controlled substances, and targeted site visits of certain retail pharmacies to ensure that the pharmacy "had implemented their own policies and procedures" as well as note potential red flags of diversion.<sup>132</sup>

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<sup>130</sup> ABDCMDL00274105-18 (emphasis added).

<sup>131</sup> ABC-MSAGC00014740.

<sup>132</sup> ABDCMDL00004584.



145. Sometime around 2015, Amerisource partnered with the Pharma Compliance Group (PCG) to conduct investigatory pharmacy customer audits. Amerisource directed PCG’s investigators/consultants to take pictures of the pharmacies, address any red flags identified beforehand by Amerisource, correct pharmacists of areas of noncompliance that they notice, and focus on “investigating the pharmacy’s compliance to the shared responsibility to insure their dispensing of CS [(controlled substances)] is legitimate, [and] their internal processes to mitigate diversion (employee & dispensing).” They were also asked to provide “[i]mpressions from [the] standpoint of documentation/observations.”<sup>133</sup> Following these audits, PCG investigators would prepare reports for review and use by the Diversion Control Team.<sup>134</sup>

146. After the first round of audits in February 2015, there was an internal discussion at Amerisource as to how far the PCG’s reports should go. Sharon Hartman, CSRA’s Director of Pharmacy Compliance and Diversion Control, suggested that PCG include a “[c]onclusion with suggestions for follow up, i.e. continue servicing, dispensing report to review, policy and procedure/improved diversion process to be developed and provided to CSRA, stop servicing, etc.” Some of the initial reports, as discussed below, included such recommendations regarding certain pharmacies in Tennessee. However, Amerisource decided against having these former DEA agents and investigators turned consultants provide their professional recommendations. Instead, David May and Eric Cherveney “discussed this” and “both agreed that we would rather have the PC investigators outline the facts, *but not give an opinion regarding future servicing of the account.*”<sup>135</sup>

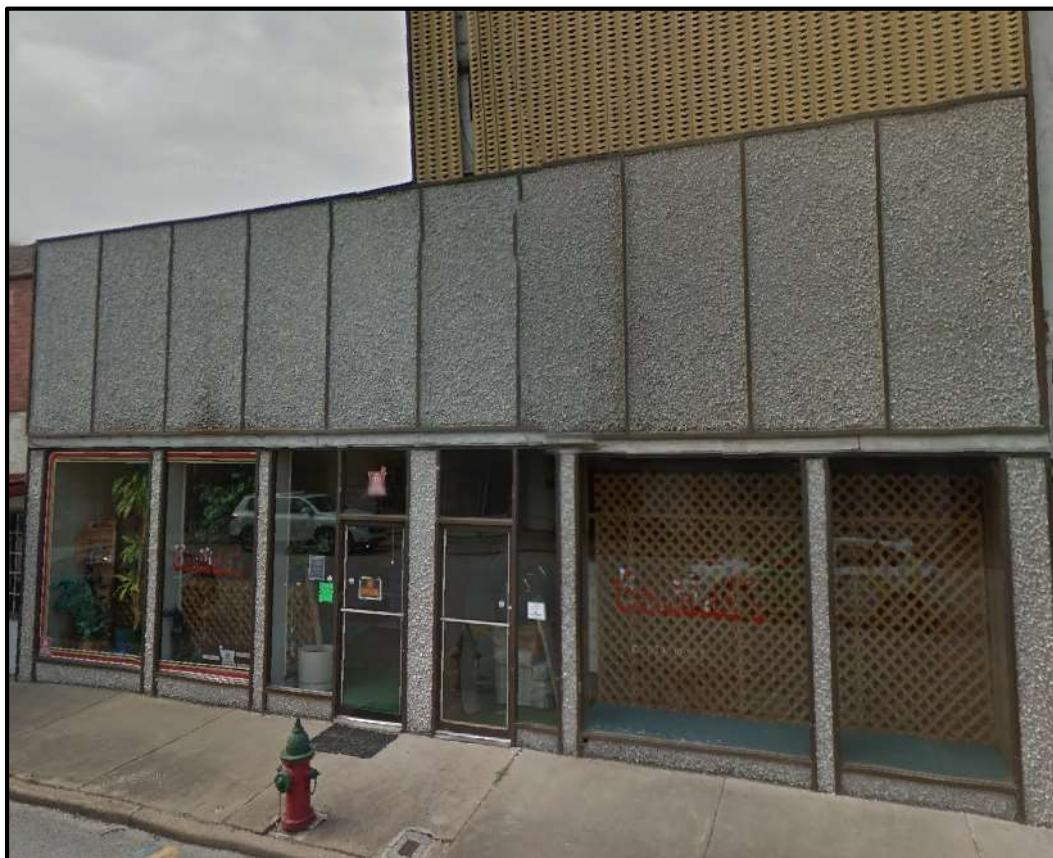
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<sup>133</sup> ABDCMDL00145090.

<sup>134</sup> ABDCMDL00004599.

<sup>135</sup> ABDCMDL00145090 (underlined emphasis in original, italicized emphasis added).

147. Aside from PCG audits, Amerisource’s CSRA also discussed case examples from actual pharmacies. For example, on April 28, 2016 the CSRA met with the Advisory Committee to update them on the status of the OMP enhancement project. Part of the presentation covered “Continuous Customer Due Diligence,” and specifically, pharmacy “case studies.” Two of the three pharmacies discussed were in Tennessee, one of them being Mehr Drug, also known as Bonifield Drug, shown below:



148. Mehr Drug relied on Amerisource as its *sole* supplier of controlled substances for at least eight years, between 2006 and 2014. Mehr Drugs was located at 88 Main Street in Bells, a small West Tennessee town a little over an hour northeast of Memphis with just under 2,500 residents. Between 2006 and 2014, Amerisource distributed approximately 800,000 ODUs and had almost 70% of the market share for Crockett County, where Bells is located.


149. The 2016 case study revealed that, among other things, *controlled substances were being dispensed without prescriptions and crack cocaine was being sold in the pharmacy*:<sup>136</sup>

### Case Studies

Mehr Drug, Bells TN

- Low Volume Customer
- Raided by Local Drug Task Force
- Undercover Purchases of Controls (with and without prescriptions) and Crack Cocaine Directly in the Pharmacy.
- No OMP Issues
- Slightly Elevated Controls to Non-Controls
- Engaged Sales Team for Feedback and Follow-Up
- Feds Have Joined the Investigation

25 8/27/2019 CONFIDENTIAL



150. Notably, Amerisource’s case study did not reveal that the Tennessee Board of Pharmacy had twice requested information on Mehr Drug from Amerisource. The requests were entered into Amerisource’s legal files where they languished for years, forgotten about until two days *after* Mehr Drug was raided by authorities thanks to a gap between the Company’s legal department and CSRA:<sup>137</sup>

**From:** May, David  
**Sent:** Thursday, April 21, 2016 5:08 PM  
**To:** Kabosius, Brian C  
**Cc:** Cherveney, Eric; Coldren, Emily; Campbell, Elizabeth  
**Subject:** RE: Mehr Drug cs invoice request 9 22 2011.doc

Brian,  
I think it would be a good practice to have visibility to any request that comes across your desk from DEA or any state BOP, as well as the corresponding response. Please let me know if this would add any undue burden to your responsibility. In the case at hand, the below pharmacy (Mehr) was raided by state authorities (Tenn BOP) two days ago and the PIC was arrested and immediately surrendered his license. The public information released so far indicates a pretty strong criminal case against the PIC and three store employees. There were two requests in LT under legal for information requests submitted by the Tenn BOP. Generally, CSRA would be aware of such requests and have a corresponding LT matter. In this case I could not locate one, so in the chance that we were unaware, I’m just looking for a way to close that potential gap. I am open to ideas. DM

<sup>136</sup> ABDCMDL00275015.

<sup>137</sup> ABC-MSAGC00025864-65.

151. Mehr Drug’s pharmacist and three technicians, shown below, were arrested in 2016 for unlawful distribution and dispensing of controlled substances for allegedly issuing prescriptions for hydrocodone and Adderall without medical need from August 2014 to April 2016. During what agents called the largest prescription drug raid in years, police found sixteen weapons, including illegal guns, and hundreds of thousands of pills seized or unaccounted for.<sup>138</sup> The police raid was publicly reported on April 20, 2016 and Amerisource finally placed Mehr Drug on its Do Not Ship List on April 21, 2016.

**v. Training**

152. Training was the final primary component of Amerisource’s DCP and, like the other components, it was not a priority. As testament to this, Amerisource conducted limited, generally informal compliance training concerning its anti-diversion efforts with its employees. From 2005 to 2010, Amerisource’s “Regulatory Compliance Training Program,” which was required for each person involved in the handling or record keeping of controlled substances, was initially just *six hours* long and would likely be shorter in subsequent years.<sup>139</sup>

153. Amerisource’s training, when it occurred, primarily consisted of educating compliance employees on the DCP and distribution center employees on identifying potentially suspicious orders.<sup>140</sup>

154. Amerisource specifically trained its sales representatives on how to identify common red flags about prescription drug diversion associated with retail pharmacies. In a 2009 training presentation, Amerisource also instructed sales representatives to report all red flags—though this did not often occur. The presentation stated, “If you observe anything that you suspect

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<sup>138</sup> <https://www.wbbjtv.com/2016/04/20/local-pharmacy-shut-down-after-undercover-drug-sting/>.

<sup>139</sup> ABDCMDL00003745.

<sup>140</sup> ABDCMDL00004581.

may be related to diversion, even if you're not sure, contact a member of Corporate Security and Regulatory Affairs (CSRA's) diversion control team to relay that information.”<sup>141</sup>

155. Amerisource's list of red flags from a 2017 presentation included:

- Long lines of patients standing outside a pharmacy waiting to fill controlled substance prescriptions
- Dispensing prescriptions to patients or from physicians not from local area<sup>142</sup>
- Not selling health and beauty aids and only dispensing drugs
- Dispensing a high percentage of Oxycodone 30 mg prescriptions versus all other Oxycodone strengths being dispensed
- Accepting an unusually large percentage of cash transactions for prescriptions
- A high percentage of cash transactions
- Barred windows & doors
- An armed guard.<sup>143</sup>

156. But this training did not take hold and was largely ignored. Amerisource continued to neglect cohesive, meaningful compliance training, even for these basic topics.

157. For instance, on April 16, 2012, Amerisource's Ed Hazewski sent an email with an attached diversion training presentation to the other CSRA employees, explaining that the it was “aimed at sales associates, inside sales, and customer service reps in addition to any DC associates with an OMP function or those who handle CS.”<sup>144</sup> Mr. Hazewski's colleague, Paul Ross, the Senior Director of CSRA at the time, wrote the following in response:

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<sup>141</sup> ABDCMDL00144508.

<sup>142</sup> “One Amerisource associate described how he observed the activities at a particular pharmacy. He saw several vehicles from Tennessee, West Virginia, and Virginia show up at the pharmacy, typically with more than one person in the vehicle, where the occupants of the vehicle would go in, fill a prescription and then head right back to the highway in the direction of their home state. It is atypical behavior to travel out of state for prescriptions.” ABDCMDL00144507.

<sup>143</sup> ABDCMDL00144511.

<sup>144</sup> ABC-MSAGC00008971.

**Subject:** RE: Draft - Diversion Training

It is amazing how few people recognize the red flags. I certainly believe this will be a useful training.

Paul Ross, R.Ph.  
Sr. Director, Corporate Security & Regulatory Affairs  
AmerisourceBergen Corporation

158. Amerisource also used the same general diversion control training program from 2009 for seven years with no updates, did not make it readily accessible to employees, and did not see that it was enforced consistently.

159. Amerisource's training deficiencies were also referenced in internal emails. For example, in January 2016, Greg Madsen, the CSRA Director of the West Region, emailed Steve Mays, the Senior Director of CSRA, regarding OMP training for all associates and said:<sup>145</sup>

**From:** Madsen, Greg  
**Sent:** Thursday, January 14, 2016 5:04 PM  
**To:** Mays, Steve  
**Subject:** OMP- General Training for all Associates

Steve,

FYI. I received another request during my Bi weekly call this week for an updated OMP general awareness training that is to be given to all associates annually. DC's have created their own OMP training over the years which is all over the board. The last OMP general awareness training that I am aware of was developed by CSRA in 2007. New RPIC training was developed last year by the OMP team and David's team rolled it out to all. There is no OMP general awareness training on our website and the recently revamped OMP RPIC training is not on the web site either. There is a OMP 2009 Conference training on the web site that was put together by Joe Tomkiewz. Not sure if the 2009 presentation should or can be used for the general awareness training.

Just making you aware and we need some clarity on this to forward to our teams. Thanks.

160. In response, Mr. Mays directed him to check with David May, the Vice President of Security and Diversion Control. Mr. Madsen in turn told David May that the "team has piece mealed [sic] something together over the years, but a CSRA created and approved version is what I'm looking for to distribute out to the field."<sup>146</sup> Mr. May agreed that they "absolutely need to update" the general diversion training and ensure that Compliance Managers are providing the

<sup>145</sup> ABDCMDL00151816.

<sup>146</sup> ABDCMDL00151816.

same information at the division level. The Director of Diversion Control, Eric Cherveney, also agreed that “[t]he existing training is sorely outdated” and “ancient history.”

**vi. Red Flag Training**

161. In 2014, Amerisource trained its sales representatives to spot potential red flags for diversion, such as long lines of patients waiting to fill prescriptions for controlled substances, asking them:

[w]hat are your first observations when you arrive in the pharmacy parking lot? One of the criticisms that the Government has levied upon the industry is that if we had just visited certain problem pharmacies and observed the activities, that they would have been so far out of the norm, we would or should have known that something wrong was happening. . . . Generally speaking, you shouldn’t see people loitering outside the pharmacy, either standing or sitting in vehicles with multiple passengers. *Problem pharmacies attract problem clients, because wor[d] spreads very quickly.*<sup>147</sup>

162. Amerisource also trained its sales associates to look at the vehicle registrations for vehicles in customer parking lots from out of the area because “[i]ts [sic] not typical behavior to travel from the next county, never mind the next state, to fill prescriptions.”<sup>148</sup> Patients doing so could be doctor shopping to get ahold of more controlled substances or the prescriber or pharmacy could have a reputation for being a pill mill.

163. One red flag for diversion is a pharmacy which dispenses large quantities of oxycodone that are 12–15% or more of the pharmacy’s total prescription sales.<sup>149</sup> Aside from oxycodone in general being one of the most “likeable” prescription opioids, Oxy 30 pills, known as “blues,” were among the most widely abused and sought-after drug during the height of the epidemic.

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<sup>147</sup> ABC-MSAGC00005966 (emphasis added).

<sup>148</sup> ABC-MSAGC00005967.

<sup>149</sup> Hazewski Dep. at 69–72; ABC-MSAGC00020763–66.

164. Given this, Amerisource specifically trained their sales force that “dispensing a high percentage of Oxycodone 30 mg prescriptions versus [sic] all other Oxycodone strengths being dispensed,” was a red flag. They were trained to note irregularities such as whether the doors and windows were barred, whether there was an armed security guard, whether the pharmacy sold health and beauty aids or whether it was just dispensing, and whether the pharmacist was “making statements about particular drugs, like ‘when I was with xyz distributor, I couldn’t get enough Oxy 30 for my customers. That’s not going to happen with you right?’”<sup>150</sup>

165. Amerisource instructed its sales representatives that another red flag of prescription drug diversion was if a pharmacy was accepting an unusually large percentage of cash transactions for prescriptions,” telling its employees to “[l]ook around at the clientele. Do they resemble the clientele you would expect to meet at your local pharmacy when you are filling a prescription for an antibiotic for one of your children? Are you noticing multiple cash transactions while you are there?”<sup>151</sup> Cash transactions were also a way to obtain suspiciously large, potentially illegitimate prescriptions without leaving a paper trail or having to worry about insurance limits. According to the DEA, “cash transactions average 8% or less of all transactions.”<sup>152</sup>

166. Basically, Amerisource trained its sales representatives to look out for “[a]ny sign or indication that the pharmacy is more interested in ‘selling’ drugs, then [sic] ‘dispensing’ drugs is a problem.”<sup>153</sup>

167. Yet in practice, Amerisource looked the other way for many of these red flag “irregularities” as long as the customer was spending enough on controlled substances to justify

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<sup>150</sup> ABC-MSAGC00005969.

<sup>151</sup> ABC-MSAGC00005970.

<sup>152</sup> ABC-MSAGC00005968.

<sup>153</sup> ABC-MSAGC00005968.



the risk. Amerisource knew Food City Pharmacy # 674 had to hire armed, off duty police officers because of the increased number of prescriptions being stolen from its patients.

168. Another potential red flag is if a pharmacy purchases controlled substances from different distribution companies because it allows them to circumvent monitoring programs and other forms of due diligence.

169. Further, Amerisource instructed its CSRA that another red flag is a pharmacy which dispenses dangerous combinations of “controlled substance cocktails,” consisting of multiple prescriptions for a single patient. For example, it is highly suspect for patients to receive an opioid, benzodiazepine, and muscle relaxer (known as the “Holy Trinity”) at the same time or prescriptions for multiple extended release or multiple immediate release opioids, such as OxyContin with Opana ER or Percocet with Lortab.

170. Amerisource also tracked which OMP orders were held, broken down by all orders: Oxy 30 orders; hydrocodone, all other oxycodone, and Oxy 30 orders; and orders for the “Seven Deadly,” or the “Seven Families,” which included hydrocodone, oxycodone, Oxy 30, hydromorphone, promethazine with codeine, pseudoephedrine, and methadone.<sup>154</sup>

#### **F. The Impact of Amerisource’s Faulty Diversion Control Program on Tennessee**

171. Amerisource’s failure to implement and enforce a system to monitor for, detect, and prevent diversion, often looking the other way in the face of known diversion and illegitimate prescriptions or red flag indicators, has had and continues to have a lasting negative impact on Tennessee.

172. With the largest share of the prescription opioid distribution market in Tennessee from 2006–2014, Amerisource shipped more narcotics into the state than anyone else. Although

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<sup>154</sup> ABDCMDL00282433.

the DEA's ARCOS data for later years is not available, Amerisource's market shares likely increased because from 2013 forward, Amerisource became the primary distributor for Walgreens pharmacies nationally, including in Tennessee.<sup>155</sup> Walgreens had the second largest opioid distribution market share in Tennessee for those eight years.

173. The oversupply of opioids caused by the hundreds of millions of ODU's Amerisource dumped into Tennessee is intrinsically linked to rampant and ever-rising rates of abuse, addiction, fatal and non-fatal overdoses, NAS, Hepatitis C, HIV, and drug-related crimes. This is particularly, though not exclusively, evidenced by analyzing data from the many small, sparsely populated, rural towns in the state where the dramatically outsized volume of opioids that were distributed correlates with the outsized negative impact on the health and welfare of these towns.

174. Outliers of outliers abounded in Tennessee. For example, between 2006 and 2014, Amerisource:

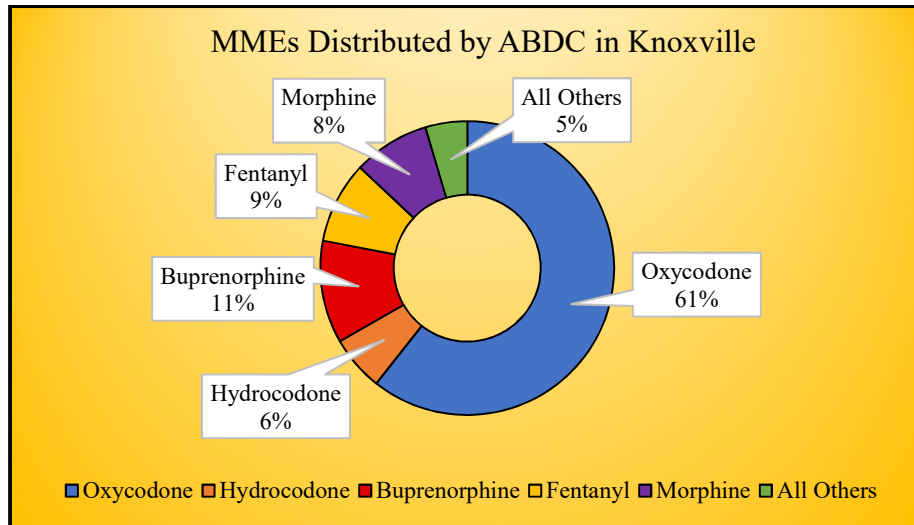
- shipped over 3,213,538 ODU's to Andersonville, a town in East Tennessee with a population of around 400 people, meaning each resident would have received approximately 8,034 ODU's;
- shipped over 4,813,464 ODU's to one pharmacy in Wartburg, Tennessee, which has a population of around 900 people, meaning resident would have received approximately 5,348 ODU's; and
- shipped over 14,347,483 ODU's to Newport, another city in the northeast corner of Tennessee, which has a population of around 6,900 people, meaning each resident would have received approximately 2,079 ODU's.

175. Even Knoxville, with approximately 180,000 residents as of 2011, was flooded with an oversupply of prescription opioids leading it to become the virtual epicenter of Tennessee's epidemic, thanks to in large part to Amerisource.

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<sup>155</sup> ARCOS.

176. Between 2006 and 2014, Amerisource shipped over 2.8 billion MMEs to the city of Knoxville—enough for each resident to have the equivalent of approximately 520 tablets of 20 mg oxycodone.<sup>156</sup>



177. In addition to controlling the market share for Knox County, almost all of the over 91.5 million opioids<sup>157</sup> that Amerisource distributed there between 2006 and 2014 came from its Birmingham, Alabama distribution center; meaning there was no confusion or unawareness as to the volume of opioids it was sending. Over those eight years, Amerisource controlled 40% of Knox County’s opioid market, in terms of MMEs.

178. The high volume of opioids alone should have alerted Amerisource that it was filling suspicious orders, because the amount of opioids it shipped to the state far exceeded what could possibly be dispensed for legitimate prescriptions.

179. The close proximity of many of the pharmacy locations to each other and to which Amerisource was shipping orders should have also raised a reasonable suspicion of diversion and undermining of the closed system.

<sup>156</sup> ARCOS.

<sup>157</sup> ARCOS.

180. For example, in the Tri-Cities area in the northeast corner of Tennessee, Amerisource was aware that it was saturating a community already notorious for its prescription pill problem with yet more pills. Amerisource knew that three particular pharmacies were ordering more buprenorphine from it than any other pharmacies in the country. Speculation that it might be buprenorphine intended for medication assisted treatment (MAT) was roundly disproven given that a vast majority of it was the highest dose available, did not include naloxone, was not prescribed to pregnant women, and almost every patient paid in cash—all hallmarks of diversion and abuse.

181. Amerisource’s Diversion Program Manager, Joseph Tomkiewicz, testified in a 2016 deposition that Tennessee was one of the top ranked states in terms of orders of interest or suspicious orders that were received by Amerisource.<sup>158</sup> He also testified that “Tennessee was another, you know, big hot spot for Oxycodone.”<sup>159</sup> When asked whether he believed there was a prescription drug problem in West Virginia during the time he was employed at Amerisource, he responded, “There is a prescription drug problem everywhere in the country. In terms of prioritizing where, you know, the problem was when I was with Amerisource, West Virginia was not as high on the list as Florida, Georgia, Texas, California and Tennessee were.”<sup>160</sup> When asked about the location of the “geographical hot spots that the Diversion Control Team was aware of,” he again listed Florida, Georgia, Texas, and Tennessee.<sup>161</sup>

182. Amerisource had identified Tennessee, and Knoxville specifically, as hot spots years prior to 2016. On October 20, 2011, Ed Hazewski sent an email to Joseph Tomkiewicz

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<sup>158</sup> ABDCMDL00045949–50, ¶¶ 22–7 (Tomkiewicz Dep., *West Virginia v. ABC*).

<sup>159</sup> ABDCMDL00046013, ¶¶ 14–15 (Tomkiewicz Dep., *West Virginia v. ABC*).

<sup>160</sup> ABDCMDL00046014–15, ¶¶ 21–7 (Tomkiewicz Dep., *West Virginia v. ABC*).

<sup>161</sup> ABDCMDL00046016, ¶¶ 4–14 (Tomkiewicz Dep., *West Virginia v. ABC*).

regarding preliminary visits which read in part, “I would like us to hit all of the Knoxville / Nashville locations since they seem to be hot beds.”<sup>162</sup>

Joe, look at the attached. I would like us to hit all of the Knoxville / Nashville locations since they seem to be hot beds. Could you do some calculating to check the proximity of the other locations to those two?

Ed Hazewski  
Director - Diversion Control Program  
Corporate Security and Regulatory Affairs

183. However, identifying these cities as hot spots and submitting suspicious orders from pharmacies in those cities to the DEA were two different things. Despite Amerisource identifying those two “hot beds,” it only reported to the DEA 0.01% of orders from Knoxville and 0.02% of orders from Nashville as suspicious in 2011.

#### **G. Amerisource’s Oversupply of Oxycodone to Knoxville and Surrounding Area**

184. Oxycodone, which comes in extended release forms such as OxyContin and immediate release forms, is one of the most frequently abused and diverted opioids. Amerisource knew that a pharmacy which dispenses large quantities of oxycodone that are 12–15% or more of a pharmacy’s total prescriptions sales was a red flag.<sup>163</sup>

185. Among types of oxycodone, 30 milligram immediate release oxycodone or “Oxy 30” is one of the most frequently abused and diverted oxycodone products. Amerisource knew this and knew it was often the focus of DEA inquiries and investigations, as evidenced by an internal document that purported to be customer talking points to reduce Oxy 30 thresholds:

#### **Customer Talking Points**

- 30 mg Immediate Release Oxycodone (OY) is generally considered the most frequently abused / diverted Oxycodone product.
- It is often the focus of DEA inquiries and investigations.

<sup>162</sup> ABCDMDL00280718 (emphasis added).

<sup>163</sup> ABC-MSAGC00008957.

186. Amerisource specifically trained its sales force that “dispensing a high percentage of Oxycodone 30 mg prescriptions versus [sic] all other Oxycodone strengths being dispensed,” was a red flag. Amerisource trained its sales associates to note irregularities such as whether the pharmacist was “making statements about particular drugs, like ‘when I was with xyz distributor, I couldn’t get enough Oxy 30 for my customers. That’s not going to happen with you right?’”<sup>164</sup> Eventually, beginning in 2013, Amerisource even established separate thresholds for Oxy 30 from a pharmacy’s larger oxycodone threshold.<sup>165</sup>

187. In spite of this knowledge, Amerisource supplied and continues to supply massive amounts of oxycodone, and Oxy 30 specifically, to a number of pharmacies in Knoxville and the surrounding area.

*i. Food City Pharmacies*

188. Food City, a regional grocery store chain with approximately 60 in-store pharmacies statewide that dispensed controlled substances, was one of Amerisource’s biggest customers of opioids in Tennessee. Arguably no other customer better illustrates the extreme lengths Amerisource was willing to go to turn a profit, how deeply flawed its diversion control program was, and the catastrophic results.

189. Amerisource continued to ship opioids, especially oxycodone, to Food City despite knowing:

- that its shipments of Oxy 30 to three Food City pharmacies were more than Amerisource shipped to 44 individual states between October 2011 and January 2012;<sup>166</sup>
- that it had a policy in which shipment occurred regardless of the amount Food City requested or how high it was above the threshold;<sup>167</sup>

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<sup>164</sup> ABC-MSAGC00005969.

<sup>165</sup> ABDCMDL00280928.

<sup>166</sup> ABDCMDL00301692.

<sup>167</sup> ABDCMDL00316920.

- despite being told by the former DEA career diversion investigators Amerisource hired that Amerisource was at “high risk” of an adverse action against it;<sup>168</sup>
- through Actavis’ diversion specialist that diversion of Oxy 30 from Food City pharmacies was occurring;<sup>169</sup>
- that Food City had been sued at least twice by family members of patients who had suffered fatal opioid overdoses;
- through reports Amerisource possessed, that Food City was the only major pharmacy that would fill prescriptions from a notorious pain clinic located nearby;<sup>170</sup> and
- that three Food City pharmacies were the top dispensers in the country of Actavis’s generic version of Oxy 30; among many, many others.<sup>171</sup>

190. Amerisource supplied opioids to Food City pharmacies in Tennessee from January 19, 2005 to November 15, 2012,<sup>172</sup> in amounts that were orders of magnitude higher than its peers. In fact, at key times, Food City’s peers for opioid consumption were not other individual Amerisource pharmacy customers, but *all of the pharmacies that Amerisource supplied in other states*. As a representative example, Amerisource shipped more Oxy 30 to Food City # 674, which is located at 5941 Kingston Pike in Knoxville, than *it did to 38 other states and the District of Columbia* from October 2011 to January 2012.<sup>173</sup> When # 674’s numbers are combined with those of Food City # 694, which is located at only 2.3 miles away at 284 Morrell Road in Knoxville, Amerisource shipped to these two Knoxville Food City stores more Oxy 30 tablets than it did to *42 other states and the District of Columbia* during the same period.<sup>174</sup> These 42 states are set forth in the graphic below. Blue represents the number of states that received *fewer* Oxy 30s from Amerisource than Knoxville’s Food City # 674 and # 694, from October 2011 to January 2012.

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<sup>168</sup> ABC-MSAGC00024870–71.

<sup>169</sup> MULTI3537758.

<sup>170</sup> ABC-MSAGC00024868–73.

<sup>171</sup> ABC-MSAGC00008982.

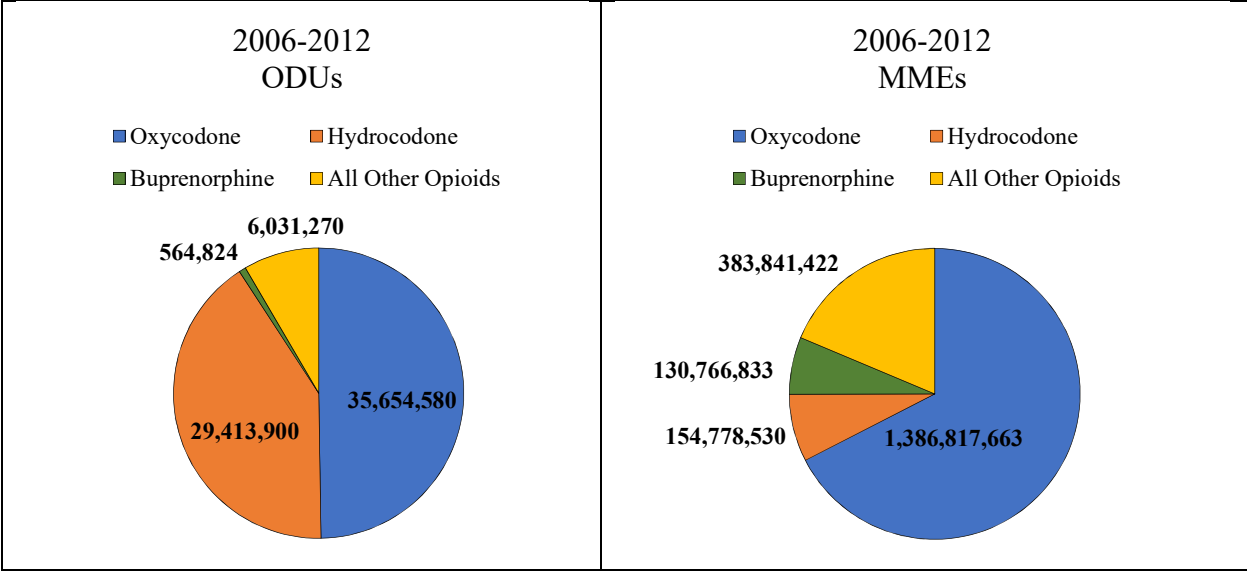
<sup>172</sup> ABDCMDL00171178.

<sup>173</sup> ABDCMDL00301692.

<sup>174</sup> ABDCMDL00301692.








192. As of 2006, the group purchasing organization to which Food City pharmacies belonged, and which included other regional retailers, had brought in over a billion dollars in pharmaceutical sales to Amerisource.<sup>175</sup> Within the buying group, Food City was a major purchaser of opioids.

193. Because it wanted to maintain the relationship with one of its most lucrative customers, Amerisource developed special rules for Food City. For example, Amerisource’s distribution center in Birmingham, which was its main distribution center for Food City, shipped any Food City opioid order no matter how high above the monthly threshold or the amount, as shown in this August 29, 2007 email sent from a Birmingham distribution center employee to Amerisource’s Vice President of CSRA.<sup>176</sup>

<sup>175</sup> MNK\_NC02478280.  
<sup>176</sup> ABCMDL00316920 (highlighted emphasis added).



**From:** Pitts, Dianne  
**Sent:** Wednesday, August 29, 2007 6:40 PM  
**To:** Zimmerman, Chris  
**Subject:** OMP

I need to ask you some questions and I hope that you will keep this e-mail between you and me. I do not want any of the management here to think I am going over their heads but I can not get a straight answer from them about what to release and what not to release out of the OMP file because they all have a different opinion about what should go and what should not go. We also had a compliance coordinator named Laura from Atlanta that came a couple of weeks ago and she told us that whatever they have in their OMP file they always send it to be investigated. Some people here think that if the ovr% is greater than 30% you should send it to be investigated and if it is under 30% release it. They also said that if it is a Food City (chain) go ahead and let it go no matter what the percent is or the amount of items. We also release every hospital and DOD no matter what, which I believe is ok but I am still unsure. Today we were told that we are releasing too many orders, but we have to go by what our manager and supervisors are telling us to do. I do not want to get anyone in trouble I just hope someone can give me and management the right answer we need so that we are all together on this and we do not lose our license or anything. Thank you for your time.

194. Amerisource’s policy of shipping Food City’s opioid orders no matter how high above the monthly threshold or how large the overall amount requested was evidence of Amerisource’s desire for profits above all else. The Company’s policy led it to ship opioids to Food City that were so high that they were indicators of diversion or otherwise illegitimate prescriptions on their face. For example, on November 2, 2010, in a single day, Amerisource shipped the *180,000 tablets* of immediate release oxycodone requested by Food City # 674, 93% of which was Oxy 30.<sup>177</sup> That single-day order by itself was nearly enough to give every man, woman, and child in Knoxville an Oxy 30 tablet.

195. Amerisource not only made up special rules for Food City, allowing shipments of any opioid order no matter how high above its threshold or amount, it made up special rules for flagging suspicious orders from Food City. For instance, from 2009 to 2012, Amerisource only reported a single order from Food City # 674 to the DEA.<sup>178</sup>

196. Amerisource continued to supply Food City with opioids for almost a year after it was directly told by former DEA agents that it hired to conduct an audit of Food City’s opioid dispensing practices that “[t]here is also cause for concern regarding possible adverse action against the Food City Store pharmaceutical drug distributor, Amerisource” and that the underlying prescriptions dispensed by Food City were “**High Risk.**”<sup>179</sup>

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<sup>177</sup> ARCOS.

<sup>178</sup> ABDCMDL00176910 (Sheet Summary by Customer, Row 3351).

<sup>179</sup> ABC-MSAGC00024870–71 (emphasis in original).

197. Amerisource’s opioid shipments were disproportionately made to Knoxville’s Food City # 674, # 694 and # 616, particularly for Oxy 30. For Oxy 30, these three pharmacies ranked first, second, and third in the country for sales of Actavis generic Oxy 30s as of October 2012.<sup>180</sup>

198. According to the DEA’s ARCOS database, between 2006 and 2012, Amerisource shipped 21,088,060 doses of oxycodone to three of the Knoxville Food City pharmacies—enough for every man, woman, and child in the city to have 118 oxycodone pills.<sup>181</sup> When the other 11 prescription opioid families are included for the same period of time, that number of opioids Amerisource shipped to these three pharmacies increases to 28,353,151 ODU—enough for Knoxville residents to have 159 painkillers each.<sup>182</sup> Collectively, Amerisource sent 38,438,602 ODUs to all 15 Food City pharmacies in Knoxville—enough for Knoxville residents to have 215 painkillers each.<sup>183</sup>

199. Even among the three problematic Knoxville stores, Food City # 674 even stood out. The amount of ODUs and MMEs ordered and received from Amerisource between 2006 and 2012 are set forth in the chart below:

**Food City # 674**

<b>City:</b> Knoxville (pop. appx. 178,874)		<b>County:</b> Knox	
<b>ODUs:</b> 22,072,523		<b>MMEs:</b> 954,480,974	
<b>State Rank:</b> 1st	<b>ABC Rank:</b> 1st	<b>State Rank:</b> 1st	<b>ABC Rank:</b> 1st
<b>Years as ABC Customer:</b> 2005 to 2012 <sup>184</sup>		<b>Distribution Center(s):</b> Birmingham	

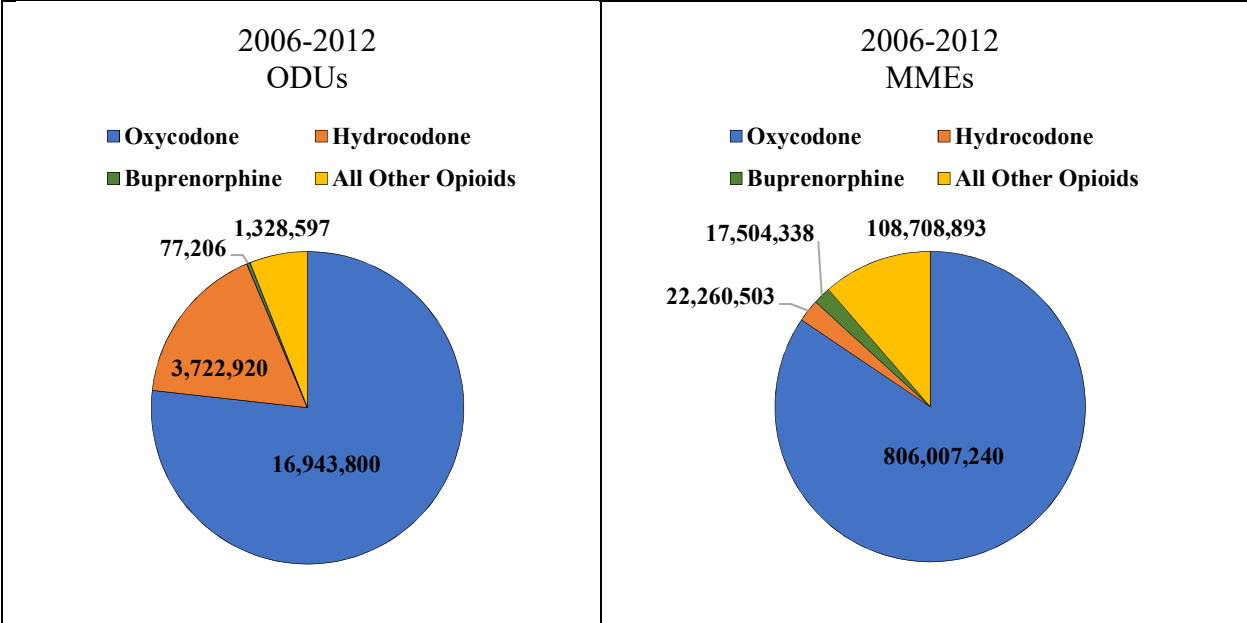
<sup>180</sup> MULTI3537758.

<sup>181</sup> ARCOS.

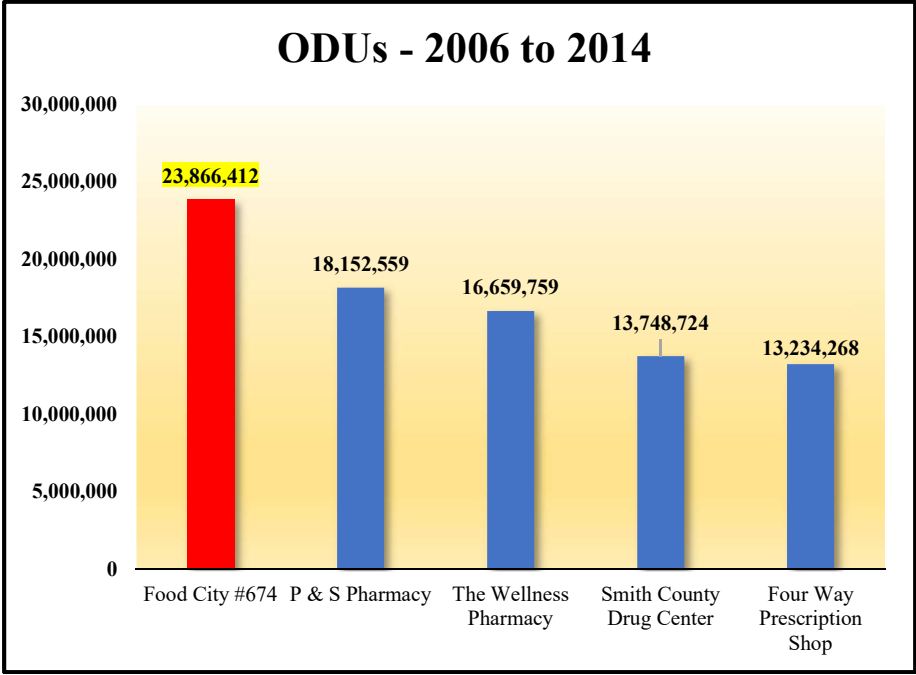
<sup>182</sup> ARCOS.

<sup>183</sup> ARCOS.

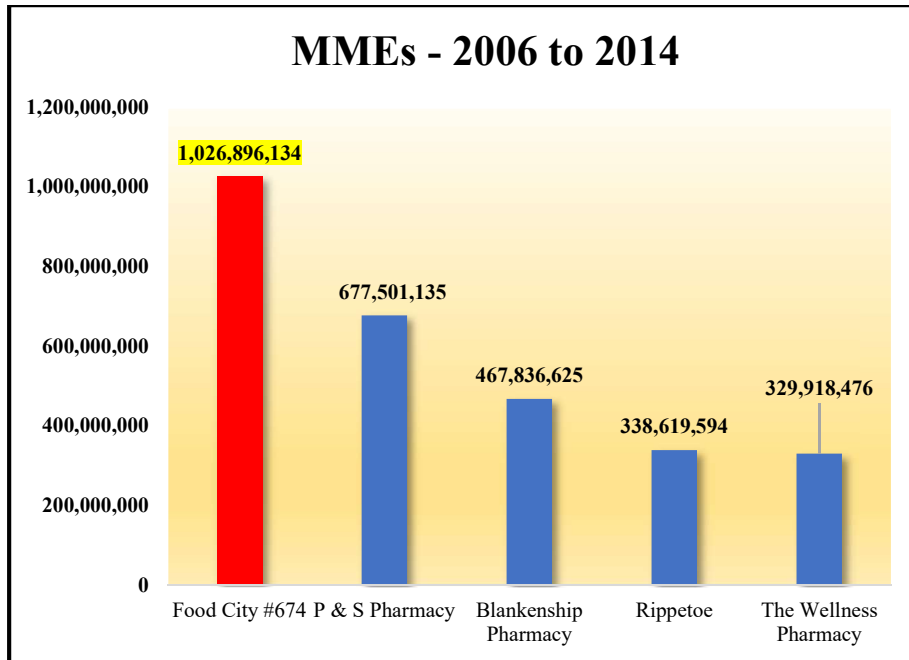
<sup>184</sup> ABDCMDL00171178 (Row 58743).



200. Food City # 674 received more opioids overall, both in terms of ODUs and MMEs, than any other retail pharmacy<sup>185</sup> in Tennessee by a large measure, as shown in the charts below:



<sup>185</sup> Another mail-order pharmacy with no on-site dispensing received more.



201. But, as known to Amerisource, Food City # 674 was not ordering just any opioids. The pharmacy overwhelmingly ordered oxycodone, specifically high-strength OxyContin and Oxy 30, red flags in and of themselves because of their high rate of diversion.

202. Packed with up to 80 milligrams of pure oxycodone per pill, OxyContin had a street value of around \$1 per milligram and quickly emerged as a magnet for diversion and abuse in the Knoxville area.

203. Likewise, generic Oxy 30 also had a relatively high street value and was even easier to abuse, particularly after OxyContin changed its formulation to make it more resistant to certain forms of abuse. Oxy 30 was an early and consistent target for abuse and diversion in Tennessee and Knoxville since it is the strongest immediate release dose of oxycodone available—especially after the reformulation of OxyContin in October 2010.

204. Food City # 674 was located next to Bearden Healthcare Associates, one of the largest and most notorious pain clinics in the state and owned by Drs. Frank and Janet McNiel.

Not coincidentally, the providers at this pain clinic prescribed extremely high volumes of both high-dose OxyContin and Oxy 30.

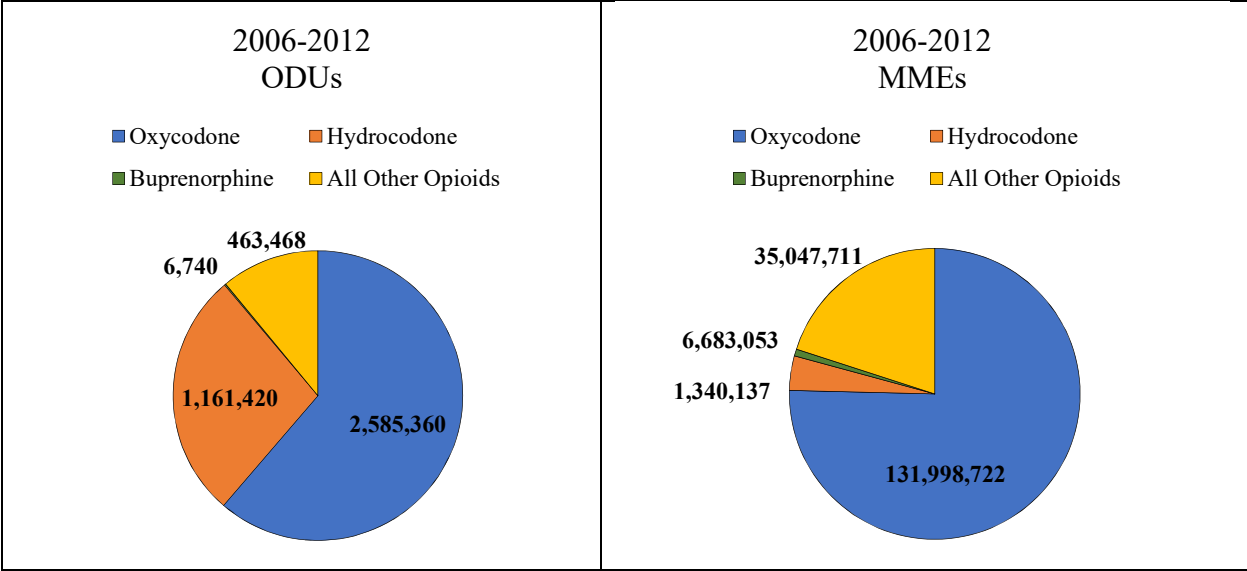
205. Food City # 674 captured the bulk of the oxycodone prescriptions from Bearden Healthcare Associates even though, there was a Walgreens and a CVS which dispensed controlled substances and are located literally yards away across the street from Food City # 674. Food City would honor prescriptions from Bearden Healthcare Associates that others, such as Wal-Mart, Walgreens, and CVS, would not, which was another red flag Amerisource disregarded.

206. Even if it did not have complete visibility into the quantities being purchased by Walgreens and CVS, Amerisource knew that Food City # 674's opioids and oxycodone numbers were orders of magnitude higher than its peers because it did know with high precision how much it was shipping to other Food City pharmacies, other pharmacy customers in Knoxville, other pharmacy customers in Tennessee, and for that matter, other pharmacy customers across the country. And Amerisource knew from this information as well as other reports that opioids, including high-dose OxyContin and Oxy 30 were being diverted from Food City # 674.

207. Amerisource also turned a blind eye for other Food City pharmacies with high volumes of oxycodone. Knoxville's Food City # 694 had nationally high oxycodone numbers as well, but not as high as its sister store, # 674, located just two and a half miles away. The amount of ODUs and MMEs Pharmacy # 694 ordered and received from Amerisource between 2006 and 2012 are set forth in the chart below:

**Food City # 694**

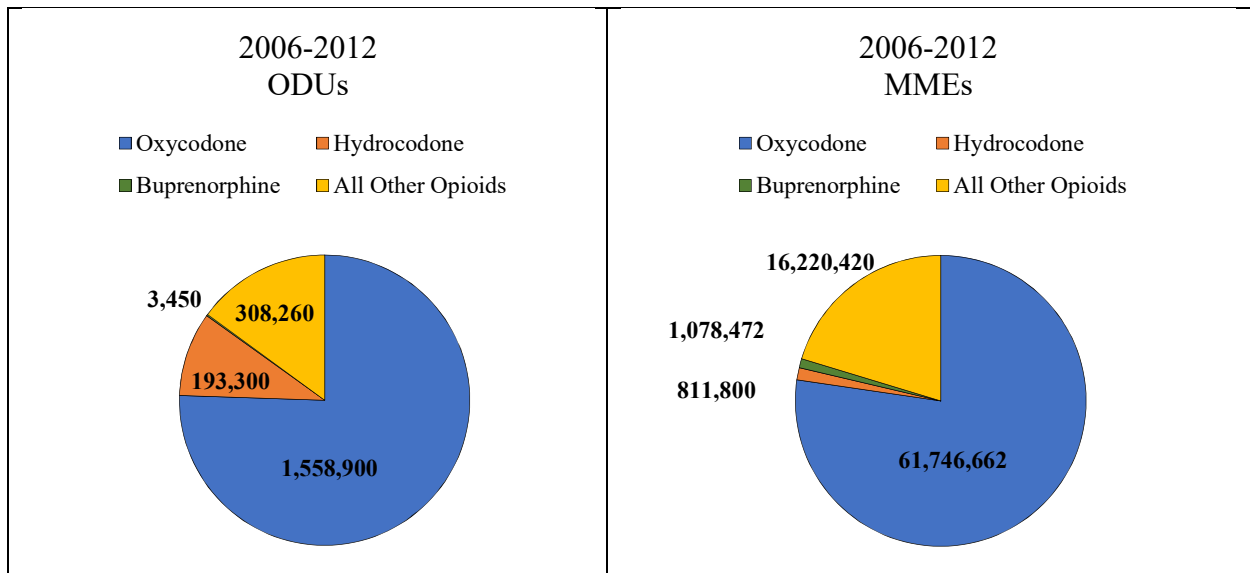
<b>City:</b> Knoxville (pop. appx. 178,874)		<b>County:</b> Knox	
<b>ODUs:</b> 4,216,718		<b>MMEs:</b> 175,069,623	
<b>State Rank:</b> Not in top 20	<b>ABC Rank:</b> 18th	<b>State Rank:</b> 18th	<b>ABC Rank:</b> 10th
<b>Years as ABC Customer:</b> 2005 to 2012		<b>Distribution Center(s):</b> Birmingham	



208. Likewise, Food City # 616, located at 11501 Hardin Valley Road in Knoxville, approximately a 15-minute drive from Food City # 674 and # 694, also ordered disproportionately high numbers of oxycodone. The amount of ODUs and MMEs Pharmacy # 616 ordered and received from Amerisource between 2006 and 2012 are set forth in the chart below:

**Food City # 616**

<b>City:</b> Knoxville (pop. appx. 178,874)		<b>County:</b> Knox	
<b>ODUs:</b> 2,063,910		<b>MMEs:</b> 79,857,353	
<b>State Rank:</b> Not in top 20	<b>ABC Rank:</b> Not in top 20	<b>State Rank:</b> Not in top 20	<b>ABC Rank:</b> Not in top 20
<b>Years as ABC Customer:</b> 2005 to 2012		<b>Distribution Center(s):</b> Birmingham	



209. Red flags abounded at Food City as a whole and especially at Pharmacies # 674, # 694, and # 616 during the time that Amerisource served as Food City’s primary opioid distributor.

210. In 2005, the year that Amerisource began shipping opioids to Food City,<sup>186</sup> the family of Gerald Armstrong sued Food City and Bearden Healthcare after Mr. Armstrong died of an overdose from OxyContin. According to court documents, between 2002 and 2005 Bearden Healthcare clinic providers prescribed him more than 20 different controlled substances, including OxyContin, Diazepam, Xanax, and Paxil—all of which Food City Food City # 674 filled. The Bearden clinic strongly recommended Food City, Pharmacy # 674 in particular, not because of proximity, but because they were one of the few that would fill a Bearden prescription. The Armstrong wrongful death suit was referenced though not identified by name in a later report requested by and received by Amerisource.<sup>187</sup>

211. In August 2007, the same month that Diane Pitts sent her email stating that the Birmingham distribution center’s policy was to ship any opioids order to Food City no matter how

<sup>186</sup> ABDCMDL00171178 (Row 58743).

<sup>187</sup> See ABC-MSAGC00024873.



high above the monthly threshold or the overall amount ordered, was a boon for both Food City and Amerisource. Food City # 674 received its highest volume of opioids from Amerisource ever: around half a million doses of opioids consisting of 333,600 units of oxycodone, 42% of which were Oxy 30. In total that month, Amerisource shipped all Food City pharmacies in Tennessee 962,316 ODU, 47% of which went to Pharmacy # 674.<sup>188</sup>

212. This unrivaled and unchecked supply of opioids that Amerisource distributed to these Tennessee pharmacies had consequences. Others took notice of the volume of controlled substances flowing in and out of Food City # 674. On September 8, 2007 an elderly woman was sprayed in the face with mace and had her prescriptions stolen as she was leaving Food City # 674. Less than a week later, another patient was robbed at gun point in the Food City # 674 parking lot for his controlled substance prescriptions. In fact, it was becoming increasingly common for criminals to wait in the store's parking lot and then follow patients home to rob them of their prescriptions. Incidents like this eventually led Food City to hire armed off-duty police officers as security during pharmacy hours; which, coincidentally, Amerisource knew was also a red flag.

213. Around the same time, residents of Bearden, which is in an affluent area of Knoxville, noticed the high volume of traffic coming in and out of the Bearden Healthcare Clinic and Pharmacy # 674, many with plates from counties all over the state and from other states.

214. Yet, Amerisource continued to keep the flood gates open and only flagged a tiny fraction of Food City's orders. In 2007, Amerisource reported to the DEA only ten of Food City # 674's orders for controlled substances, each one was for oxycodone.<sup>189</sup>

215. Amerisource's lax oversight trend continued. In 2008, Amerisource reported to the DEA only 11 of Food City # 674's orders for controlled substances, all but one were for

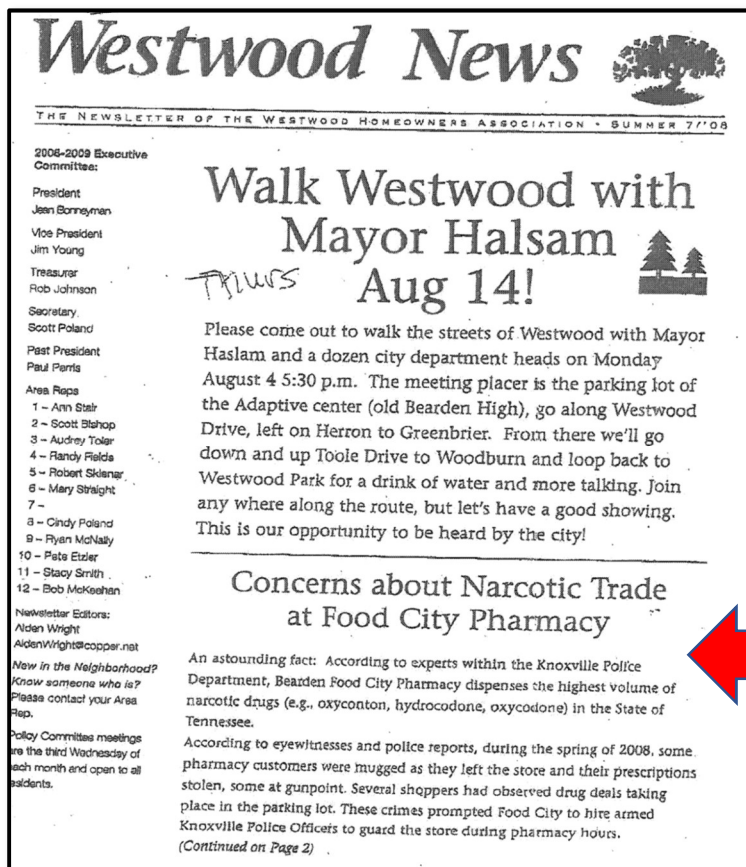
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<sup>188</sup> ARCOS.

<sup>189</sup> ABC-MSAGC00002271.

oxycodone.<sup>190</sup> On September 30, 2008, Food City # 674 ordered, among other things, 54,000 tablets of Oxy 30.<sup>191</sup> One Amerisource document shows that it reported this to the DEA, yet Amerisource’s CSRA comments show that this order *was approved for processing* and fulfilled on October 1, *along with an additional 8,110 ODU*s.<sup>192</sup>

216. Aside from the high numbers of opioids being dispensed, there were credible reports that diversion was occurring at Food City # 674 in 2008. In the summer of 2008, Westwood News, the newsletter of the Westwood Homeowners Association, which was next door to Food City # 674, published a story titled “Concerns about Narcotic Trade at Food City Pharmacy” regarding Food City # 674 and the Bearden Healthcare clinic.



<sup>190</sup> ABC-MSAGC00000472.

<sup>191</sup> ARCOS; ABC-MSAGC00002236.

<sup>192</sup> ABC-MSAGC00000472; ABC-MSAGC00002236.

217. The article stated:

*An astounding fact: According to experts within the Knoxville Police Department, Bearden Food City Pharmacy dispenses the highest volume of narcotic drugs (e.g. oxycontin, hydrocodone, oxycodone) in the State of Tennessee.*

*According to eye witnesses and police reports, during the spring of 2008, some pharmacy customers were mugged as they left the store and their prescriptions stolen, some at gunpoint. Several shoppers had observed drug deals taking place in the parking lot. These crimes prompted Food City to hire armed Knoxville Police Officers to guard the store during pharmacy hours.*

Just around the corner from Food City, at 420 Bearden Road, is Bearden Healthcare Associates, a clinic operated by Drs. Frank and Janet McNeil. According to one local Drug Enforcement Agency [sic] (DEA) official, this clinic, when it comes to overprescribing narcotics, is “the biggest problem in the state.”

*According to Knoxville Police and the DEA, Bearden Food City Pharmacy is the only pharmacy in town still accepting prescriptions from the Drs. McNeil. A group of concerned neighbors has begun meeting to address the issue. Their goal is to persuade Food City to put neighbors first and stop honoring the Drs. McNeil’s narcotic prescriptions at any of the Knoxville Food City pharmacies[.]*

218. The story was picked up by Knoxville’s Alternative weekly paper the METRO PULSE in a piece dated August 21, 2008 and titled “*Drug Zone: Westwood residents allege irresponsible prescription practices at neighborhood Food City and nearby clinic.*” Bearden Healthcare later sued the Westwood Homeowners Association based on the article.


219. Given the publicity, Amerisource likely knew of the Westwood Homeowners Association’s story close to its publication, but it certainly had knowledge by January 2012 when the lawsuit between Bearden Healthcare and Westwood Homeowners Association was referenced in an audit of Food City # 674 provided to Amerisource.<sup>193</sup> Other facts referenced in the Westwood and METRO PULSE story, such as other pharmacies not accepting Bearden prescriptions aside from Food City, were widely known in the community and had to have been known at this time by

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<sup>193</sup> ABC-MSAGC00024870.

Amerisource through its sales representatives, compliance employees, or other employees who were incentivized and told to gather such market intelligence.

220. Amerisource's oversupply of oxycodone continued in 2009. In January of that year, Amerisource shipped 201,700 tablets of oxycodone to Food City # 674. By comparison, at the same time it had the following default thresholds for oxycodone: 12,366 oxycodone ODU's for small retail stores, 24,732 for medium retail stores, and 37,098 for large retail stores.

  
**AmerisourceBergen**

AmerisourceBergen Corporation  
Corporate Security & Regulatory Affairs  
1300 Morris Drive  
Chesterbrook, PA 19087-5594

**MEMORANDUM**

**TO:** Chris Zimmerman  
**FROM:** Ed Hazewski, Kevin Kreutzer, Joseph Tomkiewicz  
**DATE:** January 19, 2009  
**SUBJECT:** RVP Talking Points

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**Background information:**

Retail Small – Total monthly dollar volume < \$100 K.  
Retail Medium – Total monthly dollar volume \$100K - \$249,999.  
Retail Large – Total monthly dollar volume > \$250K.

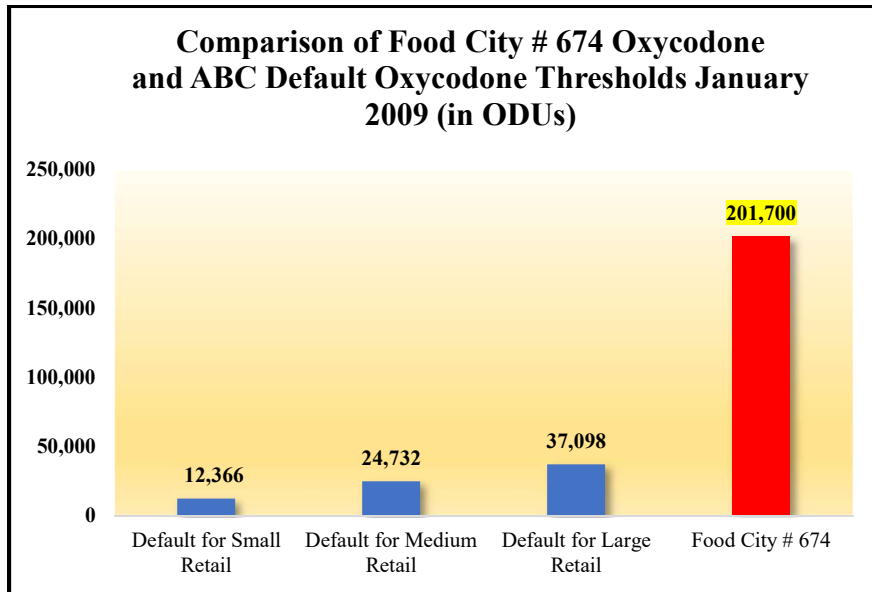
**Current default thresholds for OX and HY:**

	OX	HY
Small	12,366	18,480
Medium	24,732	39,960
Large	37,098	55,440



221. In other words, as shown by the chart below, Food City # 674's January 2009 shipment of oxycodone, 201,700 pills, was 5.4 times the upper threshold for a large retail

pharmacy.<sup>194</sup> In fact, 105,600 ODUs, the amount of Oxy 30 Amerisource shipped to Food City # 674 in January 2009 alone, exceeded the default threshold for a large retail pharmacy for all oxycodone over 2.8 times.

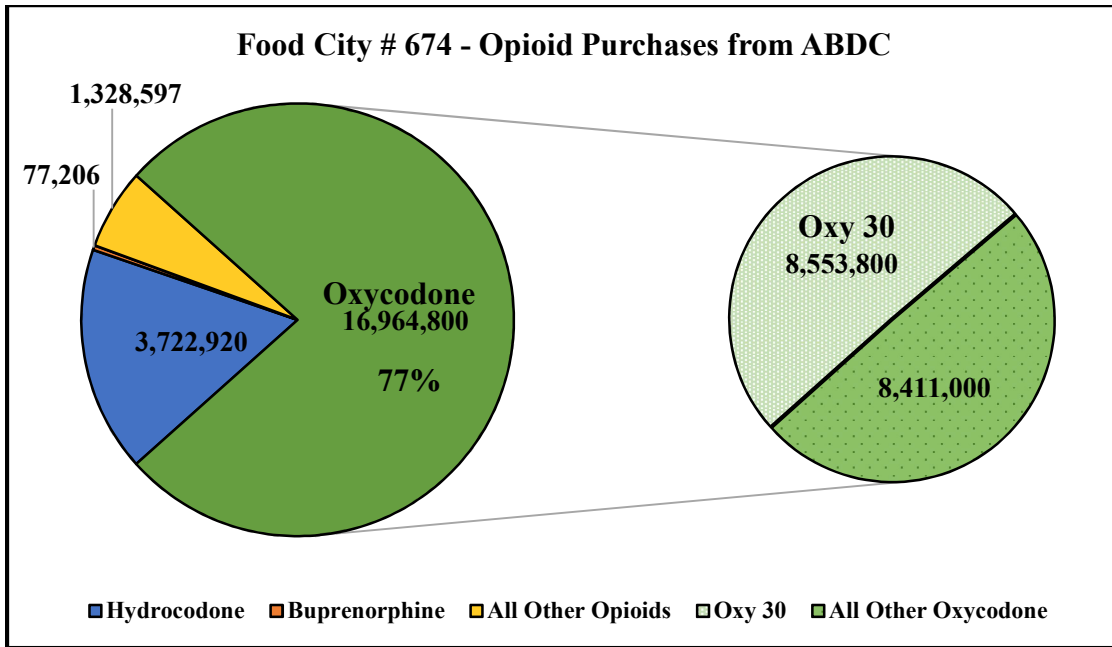


222. In January 2009, when Amerisource shipped 201,700 units of oxycodone to Food City # 674, 52% was Oxy 30.

223. Between March and August of 2009, Food City # 674 purchased 683,800 tablets of Oxy 30 from Amerisource, making it Amerisource's top customer in the country for this narcotic. The second highest Amerisource customer was an independent pharmacy in Florida which bought 325,800 Oxy 30 pills during this time period. In fact, Food City # 674 purchased more Oxy 30 from Amerisource during this timeframe than the second and third pharmacies combined.<sup>195</sup>

<sup>194</sup> ARCOS; ABDCMDL00170181.

<sup>195</sup> ABDCMDL00170181.



224. For Amerisource customers in Tennessee, Food City # 674 purchased more Oxy 30 than the next *twelve* pharmacies *combined*,<sup>196</sup> which is notable because Amerisource shipped an additional 2,244,200 doses of Oxy 30 to 197 different pharmacies across Tennessee.

225. Between September and November of 2009, 89.5% of the orders Food City # 674 placed with Amerisource were for controlled substances,<sup>197</sup> far exceeding the 12% average for its customers, as known to Amerisource.

226. That year, 80% of the 3,047,108 ODUs Food City # 674 received from Amerisource were oxycodone, 32% of which was Oxy 30.

227. Amerisource did not want to stop the flow of money. *Amerisource did not report any Food City pharmacy orders as suspicious to the DEA in 2009.*<sup>198</sup>

<sup>196</sup> ABDCMDL00170181.  
<sup>197</sup> ABDCMDL00170213.  
<sup>198</sup> ABC-MSAGC00002219.

228. *Amerisource did not report any suspicious orders for Food City # 674 again in 2010. Of the ten Food City orders for controlled substances that were reported to the DEA, six were for Food City # 644 (Seymour), three for # 682 (Knoxville), and one for # 611 (Gatlinburg).*<sup>199</sup>

229. Amerisource knew the amounts of oxycodone it was shipping to its customers were suspect. On November 1, 2010, Ed Hazewski subtly admitted that the amount of oxycodone being purchased by pharmacies such as Food City were dubious, at best. On that date, he stated:

Attached is a listing of the top 100 purchasers of OX [oxycodone] products among food/chain/independent customers. You will notice I have highlighted 3 lines, Acme Pharmacy and two QVL locations. [Those] are the *only* customers that I am aware of that market themselves, and have provided supporting documentation, as specializing in pain management. *It is safe to say that any customer on the attached list that we have had contact with have attributed their high volume of OX to “servicing pain management.”* Generally in those cases we request the names and DEA registrations of those high prescribers. *The overwhelming percentage of OX purchasers among the non-highlighted customers is 30 mg oxycodone.* [The highlighted pharmacies] have a more varied product mix.<sup>200</sup>

230. Food City # 674 was the number one retail pharmacy on Amerisource’s list of “top 100 purchasers,” which showed that it received over one million units of oxycodone from Amerisource between April and September 2010, almost 400,000 units more than the runner-up.<sup>201</sup> Tennessee had nine pharmacies make Amerisource’s top 100 list. And on November 2, 2010, the day after this report, Amerisource shipped 180,000 tablets of Oxy 30 in a single day.<sup>202</sup>

231. Amerisource continued to have knowledge that diversion was taking place at Food City pharmacies in Knoxville. On October 20, 2011, Ed Hazewski emailed another Amerisource employee to set up Food City “preliminary visits” in Knoxville and Nashville, which he referred

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<sup>199</sup> ABC-MSAGC00002180.

<sup>200</sup> ABDCMDL00280699 (emphasis added).

<sup>201</sup> ABDCMDL00280763.

<sup>202</sup> ARCOS.

to as “hot beds” and asked for a calculation of the distance between Food City # 674 and # 694 and all of the other Food City pharmacies in Knoxville.<sup>203</sup>

232. Between October 2011 and January 2012, Amerisource shipped over 9.5 million doses of oxycodone to Tennessee, 41% of which was Oxy 30—second only to Florida.<sup>204</sup> During this time, over half of the oxycodone purchased by 24 of the approximately 54 Food City pharmacies was for Oxy 30. Six of those pharmacies had oxycodone shipments with 75% or more Oxy 30.<sup>205</sup>

233. During this time, Amerisource shipped approximately 2.6 million<sup>206</sup> units of oxycodone to Food City pharmacies in Tennessee, 59%<sup>207</sup> of which was doses of Oxy 30.<sup>208</sup> At least a dozen Food City pharmacies in Tennessee were purchasing 50% or more Oxy 30 as part of their overall oxycodone purchases.<sup>209</sup>

234. In fact, 40% of all of the Oxy 30 doses that Amerisource shipped into Tennessee during these four months between October 2011 and January 2012 went to one single Food City pharmacy, which makes sense considering Amerisource shipped more oxycodone to Food City pharmacies in Tennessee than it did to most other states.<sup>210</sup>

235. Food City # 674 was an outlier among outliers. To place in context, the average purchases nationwide for Amerisource pharmacy customers during this time were 817 Oxy 30 and 3,486 for all oxycodone. Even the “Upper Level” average was 13,946 Oxy 30 and 71,034 for all

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<sup>203</sup> ABDCMDL00280718.

<sup>204</sup> ABDCMDL00301692.

<sup>205</sup> ARCOS.

<sup>206</sup> ARCOS.

<sup>207</sup> ARCOS.

<sup>208</sup> ABDCMDL00301692.

<sup>209</sup> ARCOS.

<sup>210</sup> ABDCMDL00301692.



oxycodone. Amerisource shipped Food City # 674 more than *forty-four times* the Upper Level average for Oxy 30 and more than *twelve times* the Upper Level average for all oxycodone.<sup>211</sup>

236. However, Food City’s purchasing of oxycodone was heavily disproportionate even amongst its own stores. Food City # 674 purchased more Oxy 30 from Amerisource between October 2011 and January 2012 than 38 individual states and the District of Columbia. Combined with Food City # 616 and # 694, the three pharmacies purchased over 1.1 million doses of Oxy 30 in just four months.

237. According to Ed Hazewski, in November 2011, “CSRA personnel noticed spikes in the OX [(oxycodone)] purchases at all three [Food City Knoxville] locations.” He then “contacted Mickey Blazer, Director of Pharmacy Operations, and informed him that in order for ABC to continue to service Food City at their current levels we [(Amerisource)] would require a third party consultant to audit all three locations and allow us access to the reports submitted by the consultants.”<sup>212</sup>

238. Amerisource also knew that Food City’s oxycodone numbers were a problem because those figures were given to the DEA. Amerisource now seemingly had four options: (i) do nothing, (ii) stop shipping and end the contract, (iii) continue shipping and bring Food City into compliance, or (iv) continue shipping and make it look like Amerisource was trying to bring Food City into compliance. It chose the latter—the only option that kept the money, and in turn the opioids, flowing.

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<sup>211</sup> ARCOS.

<sup>212</sup> ACTAVIS00074.

239. As part of this effort, Amerisource directed Food City to hire Pharma Compliance Group, which spent November 29, November 30 and December 1, 2011 auditing the three Knoxville Food City pharmacies # 674, # 694, and # 616.<sup>213</sup>

240. The PCG investigators reported the following findings to Amerisource and Food City:<sup>214</sup>

FINDINGS

The high percentage of controlled substances associated with pain management dispensed by the three Food City Store pharmacies is the single most compelling finding revealed during the PCG investigation.

The Pharma Compliance Group has identified the following "High Risk" factors regarding the impact of the Beardon Healthcare Associates pain clinic to Food City Store Pharmacies 616, 674, and 694:

- Practitioners employed by the Beardon Healthcare Associates are the highest prescribers of total controlled substance prescriptions fulfilled and dispensed by pharmacies 616,674, and 694
- Practitioners employed by Beardon Healthcare Associates prescribe 21% of controlled substances dispensed by pharmacies 616,674 and 694
- Practitioners employed by Beardon Healthcare Associates prescribe extremely high levels of Schedule II controlled substances associated with pain management that are considered high risk by DEA
- Dr. Frank McNeil, Medical Director, Beardon Healthcare Associates, has been the target of several investigations resulting in sanctions by the State of Tennessee Medical Board for overprescribing. He has also been the subject of a lawsuit concerning overdose deaths
- DEA is investigating Dr. McNeil and approximately three years ago executed a search warrant at the Beardon Healthcare Associates location
- DEA has restricted Dr. McNeil's DEA registration, although he is authorized to prescribe controlled substances
- CVS, Walgreens, and Walmart will not accept prescriptions from Beardon Healthcare Associates
- Beardon Healthcare Associates vs. Westwood Homeowners Association

241. PCG also notified Amerisource and Food City in the same 2011 report that (shown in gray below):

The Pharma Compliance Group concerns regarding the Beardon [sic] Healthcare Associates clinic are based on facts articulated in this executive summary. The DEA and other law enforcement and regulatory agencies continue to target DEA registrants that are considered a threat to public safety and welfare. *There is also cause for concern regarding possible adverse action against the Food City Store pharmaceutical drug distributor, Amerisource Corp. The DEA continues to hold DEA registered drug manufacturers and distributors accountable for the dispensing habits of their customers.* The PCG findings are not a repudiation of the pain management philosophy of Dr. McNeil or the practitioners he employs.

<sup>213</sup> See ABDCMDL00268508.

<sup>214</sup> ABC-MSAGC00024867.

*However, it is the finding of the Pharma Compliance Group that the prescribing habits of the Beardon [sic] Healthcare Associates practitioners are a “High Risk” to the business operations and the reputational image of Food City Store pharmacies. While conducting this investigation, PCG investigators made a decision to conduct additional dispensing data analysis from the three pharmacies, focusing on metrics relative to the prescribing habits of the Beardon [sic] practitioners. The specific data analysis relative to the Beardon [sic] Healthcare Associates practitioners is included in this executive summary. PCG determined that it was necessary to provide this analysis because of the unique relationship between volume of controlled substance prescriptions issued by the Beardon [sic] Healthcare Associates that are subsequently dispensed by Food City Pharmacies 616,674, and 694.*

*The data analysis of the “top ten prescribers” of controlled substances reveals that Beardon [sic] Healthcare Associates practitioners are listed in the top ten category in all three pharmacies; they prescribe high levels of pain medications, often in “cocktail combinations” that are sought by those who illicitly seek pain medications.*

*The dispensing data also reveals certain benchmarks measured by PCG Investigators considered “**High Risk**” metrics has determined that *the Beardon [sic] Healthcare Associates are a risk in most categories, specifically as it relates to the dispensing data of certain Schedule II (Oxycodone) and Schedule III (Hydrocodone) products that are a particular concern to the DEA.**

*Furthermore, the high concentration of practitioners specializing in pain management in the Knoxville metropolitan geographical area and the subsequent impact to the three pharmacies overall operations is a concern to PCG Investigators.*

*The PCG investigation identified several practitioners whose prescribing habits the DEA would consider a “**High Risk**”. The practitioners are listed in the prescriber section of the report. A significant concern is the pharmacies filling prescriptions for practitioners located in Georgia and North Carolina. (Please reference Top Prescribers)*

*Food City Store Pharmacy management has instituted pro-active corporate policies to prevent illicit diversion of controlled substances. ....*

*Although the aforementioned policies are necessary due diligence benchmarks, the fact remains that the three Food City Store pharmacies investigated dispense controlled substances significantly above the national average. This is a red flag and a concern to the DEA. The PCG investigation has revealed that the current Food City Store Pharmacy policy lacks a mechanism to determine the business practices of the practitioners and specifically their employers.*

... The PCG investigation has revealed that several of the Food City Store Pharmacy competitors have determined that fulfilling prescriptions from certain pain management clinics and practitioners could result in fines or sanctions from the DEA. *The Pharma Compliance Group investigation has determined that a correlation exists between the refusal of other pharmacies in the Knoxville area to fill prescriptions from specific practitioners and Pain management clinics and the excessive amount of controlled substance prescriptions filled at Food City Pharmacy 616, 674, and 694.*<sup>215</sup>

242. During its investigation, the Pharma Compliance Group also interviewed Dr. Frank McNiel and included a summary in its report that was provided to Amerisource. An excerpt of this portion stated (shown in gray below):

Dr. McNiel said the practitioners at BHCA [(Bearden Health Care Association)] examine about *one hundred patients per day* and the patients are examined every thirty days. The BHCA has *thousands of patients*; however, Dr. McNiel does not know the exact number.

....

Dr. McNiel stated that he has been the target of several law enforcement investigations dating back to 1992, when the *Tennessee Board of Medical Examiners sanctioned him*. Dr. McNiel told the investigators that either *in 2008 or 2009 the DEA executed a federal search warrant at the BHCA offices*. *Approximately forty law enforcement officers were on site including the Tennessee Bureau of Investigation (TBI)*. *During the execution of the warrant law enforcement officials requested and removed specific patient files*. Dr. McNiel was not present during the execution of the warrant. Dr. McNiel told investigators he has not received a status relative to the investigation that is apparently ongoing. *His attorney told him that there is a five year statute of limitations for the charges to be filed*.

*Dr. McNiel said he has been the subject of two wrongful death suits involving overdose deaths. One case alleged that he caused a patient to become addicted to controlled substances*. Dr. McNiel stated that one of the cases brought against him resulted in a negotiated settlement during a mediation process, *partly due to his insurance provider notifying him that he would be personally responsible for the damages if he were found to be negligent subsequent to a trial*. The family of the plaintiff was awarded \$250,000.00. Dr. McNiel said *his malpractice insurance has tripled and that he pays approximately \$85,000.00 per year for coverage*.

Dr. McNiel said that his DEA registration is in a *restricted status because the DEA has not renewed the registration upon its expiration*. Although, he said he is able to write prescriptions for Schedule II through V controlled substances. (not unusual when the registrant is the subject of investigation).

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<sup>215</sup> ABC-MSAG00024870-71 (bolded emphasis in original, italicized emphasis added).

*Dr. McNiel told investigators that the practitioners employed by the clinic have also been targets of various law enforcement and regulatory agencies, one Nurse Practitioner who left BHCA cannot obtain a clean DEA registration.*

*In conclusion, Dr. McNiel told investigators that there is no standard of care for pain management only a standard of fear. He also said that Walgreens, Walmart, and CVS will not accept his prescriptions.<sup>216</sup>*

243. Dr. Frank McNiel was forced to permanently surrender his medical license in March of 2018 after the Tennessee Board of Medical Examiners found that, from 2002 until 2018, Dr. McNiel “prescribed opioids and other controlled substances in amounts and/or for durations not medically necessary, advisable or justified for a diagnosed condition and/or not for legitimate medical purpose; without attempting alternative non-narcotic modalities; and without appropriately monitoring for abuse and diversion.” The Board also found that he improperly supervised his nurses and physician’s assistants, “who continued such excessive prescribing of opioids [in] excessive amounts.” Dr. McNiel was arrested and pled guilty to a federal charge of unlawful distribution in September 2019.<sup>217</sup>

244. On December 2, 2011, Food City’s Vice President of Pharmacy Operations Mickey Blazer emailed Amerisource’s Ed Hazewski to inform him that the PCG investigator along with an Amerisource sales associate had completed DEA compliance audits for these three Food City pharmacies in Knoxville.<sup>218</sup>

245. Amerisource received these DEA compliance audit reports at the end of January 2012 and added the following notes to the Food City due diligence file:

*Food City locations 616, 674 and 694 all located in Knoxville TN have been historically high purchasers of OX products. Prior site visits have been conducted by DEA consultant Mike Mapes as well as Paul Ross of CSRA. Prior reports*

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<sup>216</sup> ABC-MSAGC00024872–73 (emphasis added).

<sup>217</sup> <https://www.knoxnews.com/story/news/crime/2019/09/24/two-east-tennessee-doctors-plead-guilty-pill-dealing-crackdown/2431363001/>.

<sup>218</sup> ABDCMDL00268508.

resulting from those visits have been generally favorable regarding Food City's processes to make certain prescriptions are being dispensed in accordance with the CFR. *During Novembe [sic] 2011 CSRA personnel noticed spikes in the OX purchases at all three locations.* I contacted Mickey Blazer, Director of Pharmacy Operations, and informed him that in order for ABC to continue to service Food City at their current levels we would require a third party consultant to audit all three locations and allow us access to the reports submitted by the consultant. Food City agreed to do so. Attached to this matter are the reports submitted by the consultant. *Of note are the findings concerning the Bearden Clinic and Dr. Frank McNeil. The Food City locations all fill a high percentage of prescriptions from the clinic.* The reports again are favorable regarding Food City's processes but do consider the Bearden Clinic and Dr. McNeil to be high risk. On January 31, 2012 I again contacted Mickey Blazer. I told Blazer that ABC would look favorably on an ongoing relationship between Food City and the Pharma Compliance Group. Additionally ABC would want access [sic] to discuss with the consultants matters of mutual concern. Blazer agreed and will work on a document memorializing our verbal agreement. More to follow.<sup>219</sup>

246. Amerisource continued to ship opioids to Food City pharmacies, including Food City # 674, for almost a full year after the PCG audit took place.

247. According to Ed Hazewski, in May 2012, there were "[d]iscussions between Food City legal counsel and ABC legal counsel."<sup>220</sup>

248. In 2012, following this PCG report and the meeting between legal counsels, evidence of diversion of opioids and oversupply continued. Amerisource even had direct evidence that controlled substances intended for Food City pharmacies were being diverted. For example, an order of hydrocodone was stolen while in transit from Amerisource's Birmingham distribution center to Food City # 669 in Blountville on September 10, 2012, yet the paperwork was not filed with CSRA. This was the eleventh theft the store had experienced in two years.<sup>221</sup> According to Amerisource's own internal documents, the requisite DEA form for thefts and losses was not

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<sup>219</sup> ABC-MSAGC00024358 (emphasis added).

<sup>220</sup> Acquired Actavis\_00761942; ACTAVIS00074.

<sup>221</sup> ABDCMDL00447784.

submitted to a DEA investigator<sup>222</sup> and there are no indications it was submitted to the Tennessee Board of Pharmacy.<sup>223</sup>

249. In April 2012, Anda, another distributor, contacted Mallinckrodt, an opioid manufacturer, to discuss the “three Food City pharmacies in Knoxville,” because it was looking at becoming a secondary distributor for the entire chain.<sup>224</sup> Mallinckrodt created an internal report about its knowledge of Food City:<sup>225</sup>

\* the annualized totals for all oxycodone SKUs, including oxy/APAP was 4.1 million tablets - approximately 1.4 million per store

\* of that, oxycodone 30 mg, made up about 60% or 2.4 million tablets - approximately 800,000 per store

\* the 30-day total for oxycodone 15 mg and 30 mg tablets was 269,000 tablets - annualized = 3.2 million total for these three stores

Of note, Food City told them that Matt Murphy from The Pharma Compliance Group conducts a quarterly audit of their stores.

Thankfully, very little of this is our product. Masters was selling our product to them around a year ago. ABC picked them up and sell very little of our product to them. Additionally, Mike confirmed from the ordering report that it was a competitor's product - not ours. See attached.

As we discussed Bill, please give Ed Hazewski a heads up since they are the only active wholesaler listed for these stores. Let me know what he says.

250. The Chief Security Officer at Mallinckrodt responded to Anda with the following, in which he indicated that Amerisource was reluctant to stop or decrease the large opioid orders because Food City was such a profitable account.<sup>226</sup>

<sup>222</sup> ABDCMDL00447807 (Row 21).

<sup>223</sup> ABDCMDL00447794 (referencing submission to Alabama Board of Pharmacy).

<sup>224</sup> MNK\_NC08506592 (the manufacturer was Covidien, later acquired by Mallinckrodt).

<sup>225</sup> MNK\_NC08506593.

<sup>226</sup> MNK\_NC08506592.

Subject: RE: Food City Pharmacies in Knoxville, TN

On 4/26/12, I spoke with Ed Hazewski, Director of Corporate Security, Amerisource Bergen (ABC) regarding Food City and specifically about the three DEA Registrations listed below. He advised he is well aware of the three Food City Pharmacies that are buying inordinate amounts of Oxycodone 30mg tablets and that he was in the three stores two weeks ago. Also, the Food City hired a retired DEA employee, Matt Murphy to assist them in bringing their program in line. Further, he advised that the three pharmacies have one clinic "Bearden (ph)" that is driving the large numbers. The problem, Ed explained, is the size of Food City as an ABC customer and the fact this is only three of the Food City Pharmacies. He has been told to try to bring them in line.

At that point, I advised Ed that based on the unusually large orders of oxy 30mg tablets, Mallinckrodt is considering putting them on the restricted charge back list. Ed advised that ABC has discussed the same thing, but they would rather fix the problem, if possible. I explained the similarity of Food City and the cardinal issue with CVS in Florida and Ed advised that had also been discussed internally. Ed advised the problem started when a former Director of Food City brought in another distributor (Masters but name not mentioned) to supply additional oxy 30mg tablets to the three pharmacies being discussed. Initially, ABC was unaware of the additional distributor, but began to see their orders for oxy 30mg drop. The then Director advised he was merely dispersing the volume. Eventually, that Director was dismissed and since that time Ed and his group has been working with the three pharmacies.

In addition, Ed advised they are in the process of breaking out oxy 30mg tablets from the rest of the oxy family to give them a better picture and early warning that orders are out of line.

Based on what we now know, I see little exposure to Mallinckrodt/Covidien because of the smaller amounts of oxy 30mg that we are supplying. That being said, the similarity to the Cardinal CVS issue in Florida cannot be ignored. My recommendation is to bring this before the SOM committee to discuss. My personal opinion, put them on the restricted charge back list.

251. A few months later, Actavis, the manufacturer that was supplying a majority of the oxycodone to Food City also became concerned about the volume of its product being distributed by Amerisource because of its own potential liability. Ed Hazewski emailed his CSRA colleagues to inform them that

Nancy Baran, Director of Customer Service and CS Compliance for Actavis, contacted me this afternoon requesting a face-to-face meeting to discuss their SOM Program. Actavis was recently summoned to Washington to meet with the DEA as part of the DEA's manufacturer initiative. The meeting focused on Actavis sales of 15 and 30 mg Oxycodone.<sup>227</sup>

252. On October 22, 2012, Actavis' legal counsel and heads of compliance met with Ed Hazewski, Steve Mays, and Amerisource's legal counsel at Amerisource's headquarters for a "partnership meeting" to discuss suspicious order monitoring and review "ARCOS data specific to Oxy 15mg and Oxy 30mg."<sup>228</sup> Actavis wanted to document its own concerns about

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<sup>227</sup> ABDCMDL00400369.

<sup>228</sup> MULTI3537740, -42, -46.



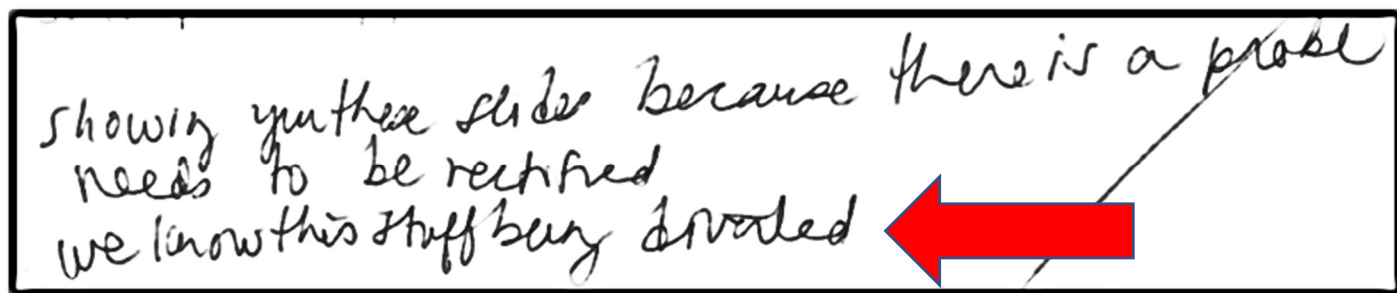
Amerisource's distribution practices and Food City's dispensing practices for Actavis' generic oxycodone.

Rank	Buyer's DEA Number	Buyer's Name	Buyer's City	State	Zip	Total Pills	Total Bottles (DEA ARCOS)	Wholesaler (s)	Actavis CB Jan 1 - June 30 2012	Quantity of Oxy 30mg 100ct - 867 data	Disproportionate Oxy Activity	Comments
1		FOOD CITY PHARMACY #674	KNOXVILLE	TN	37919	628,100	6,281	ABC - BIRMINGHAM	6905	5177	89%	2010: ranked #1 Oxy 15mg and Oxy 30mg, 2011: #1 for 30mg and #29 for 15mg
3		FOOD CITY PHARMACY # 616	KNOXVILLE	TN	37932	279,200	2,792	ABC - BIRMINGHAM	2912	2446	98%	2011: ranked #36 for Oxy 15mg, # 9 for 30mg
5		FOOD CITY PHARMACY #694	KNOXVILLE	TN	37919	227,400	2,274	ABC - BIRMINGHAM	2548	1940	87%	2011: ranked # 17 for Oxy 30mg.
6		WINDSOR PHARMACY	EAST BRUNSWICK	NJ	08816	193,800	1,938	ABC - BETHLEHEM and Wholesaler #2	1905	1548	77%	dual sourcing - 2010: ranked #13 for Oxy 30mg, 2011: ranked # 30 for Oxy 30mg.
11		ROCKY'S MED SHOPPE, LLC	BOGALUSA	LA	70427	151,600	1,616	ABC - HOUSTON	160	140	100%	unable to reconcile DEA units with sales data. Uncertain where customer is getting their supply.
12		KEANSBURG DRUGS	KEANSBURG	NJ	07734	149,100	1,491	ABC - BETHLEHEM,	1608	1286	89%	
15		BELEW DRUG	KNOXVILLE	TN	37917	138,700	1,387	ABC - BIRMINGHAM	1502	1157	85%	
17		HOPKINS PHARMACY	PHILADELPHIA	PA	19128	136,800	1,368	ABC - THOROFARE and Wholesaler # 4	1441	1357	94%	dual sourcing
20		HUMANA PHARMACY INC DBA RIGHTSOURCE	WEST CHESTER	OH	45069	132,900	1,329	ABC - THOROFARE and Wholesaler # 4	1537	918	10%	dual sourcing
21		HEALTHWISE PHARMACY	TAMPA	FL	33614	132,900	1,329	ABC - ORLANDO	1365	936	94%	
26		SHAYONA PHARMACY	PERTH AMBOY	NJ	08861	128,600	1,286	ABC - BETHLEHEM	1401	1126	95%	
28		DISNEY PHARMACY SERVICES	POWELL	TN	37849	119,700	1,197	ABC - BIRMINGHAM	1649	1023	93%	
37		E. HARTMAN LLC DBA DEAL DRUGS	NASHVILLE	TN	37211	110,600	1,106	ABC - PADUACH and Wholesaler #5	1240	378	87%	dual sourcing
41		BYPASS PHARMACY, INC	BECKLEY	WV	25801	107,500	1,075	ABC - RICHMOND	1171	861	92%	
49		HOLLYWOOD DISCOUNT PHARMACY	HOLLYWOOD	FL	33021	101,800	1,018	ABC - ORLANDO	1208	926	91%	

253. At the Actavis showed Amerisource data slides and relayed its serious concerns about Food City and other Tennessee pharmacies. The first of the DEA ARCOS slides from the October 22, 2012 showed fifteen problematic Actavis' pharmacy customers out of its top 50 customers for oxycodone 30 mg that used Amerisource as a distributor. The top three pharmacies that dispensed the most of Actavis' Oxy 30 were Knoxville's Food City # 674, # 694, and # 616 and all were supplied by Amerisource's Birmingham distribution center:

254. Actavis's Director of Customer Service and Controlled Substance Compliance, Nancy Baran, took handwritten, contemporaneous notes on the slides that she used during the meeting and made a point to scan them electronically the next morning to document the meeting.<sup>229</sup>

255. During the meeting, Actavis told Amerisource that Actavis was "showing you these slides because there is a probe[,] "needs to be rectified," and "we know this stuff is being diverted."<sup>230</sup>



showing you these slides because there is a probe  
needs to be rectified  
we know this stuff being diverted

256. Actavis's slides and the notes taken during the meeting laid out in stark terms what Amerisource knew or should have known already about the diversion of opioids it was shipping into Tennessee. Actavis also notified Amerisource that:

- based on the "Total Bottles" column in the slide above, that the "top 3 accounts [which were Knoxville Food City # 674, # 694, and # 616 had] 956,000 [in] 6 mo[nth]," making it "almost 2 mill[ion per] yr. compared [to] 207K [illegible] avg."<sup>231</sup>

<sup>229</sup> MULTI3537738.

<sup>230</sup> MULTI3537759 (emphasis added).

<sup>231</sup> MULTI3537758.

top 3 accounts  
956,000 6mo  
almost 2 mill gr.  
compared  
207K  
hang. W

- out of the “15 accounts all but 4 are sole source,” meaning Amerisource was their only distributor, and “6 out of 15 [pharmacies are in] TN”:<sup>232</sup>

15 accounts  
all but 4 are  
sole source  
6 out 15  
TN

- “5 out [of] 15 Birmingham,” meaning five of the 15 listed pharmacies were receiving their drugs from the Amerisource distribution center in Birmingham (specifically, all three Food City Pharmacies, Belew Drug, and Disney Pharmacy Services):<sup>233</sup>

5 out 15  
Birmingham  
49  
3

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<sup>232</sup> MULTI3537758.

<sup>233</sup> MULTI3537758.

- “4 ac[counts] dual sourced,” [meaning they had two distributors for opioids] including another Amerisource pharmacy customer in Tennessee.<sup>234</sup>

208	926	91%	
4 acts dual sourced			

- “13 out [of] 15 [had] 85% > disproportionate [activity],” meaning that “when looking across all sales to a pharm. This ... represents the portion of oxy as compared [to] everything else in [the] portfolio.”<sup>235</sup>

13 out of 15 85% > disproportionate
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257. Notably, of the thirteen pharmacies listed, *all six* Tennessee pharmacies on the list also had disproportionate oxycodone activity ranging between 85% and 98%, with those percentages reflecting the amount of Oxy 30 ordered compared to all oxycodone.<sup>236</sup>

258. Actavis told Amerisource that the national average in 2011 was “69K unit dose [for] all strengths [with] anything oxy in it.”<sup>237</sup> Based on Actavis’s chart, the amount of Oxy 30 that Amerisource shipped to Food City # 674 during those four months was *over nine times higher* than this national average.<sup>238</sup>

<sup>234</sup> MULTI3537758.

<sup>235</sup> MULTI3537758.

<sup>236</sup> ABC-MSAGC00008982; MULTI3537758.

<sup>237</sup> MULTI3537758.

<sup>238</sup> ABC-MSAGC00008982; MULTI3537758.

national avg 2011 69K. unit dose  
all strengths any Oxy 15

259. The Actavis / Amerisource meeting also focused on problematic pharmacies out of Actavis' top 50 pharmacy customers buying Oxy 15 from Amerisource. Two of the seven problematic pharmacies referenced in the slides were in Tennessee: Food City # 674 and # 616; both of which purchased a combined 55,200 Oxy 15 tablets during those four months.<sup>239</sup>

260. Actavis also presented another slide showing pharmacies other than Food City purchasing Oxy 30 and Oxy 15 from multiple wholesalers, including Okie's Pharmacy and Apple Discount Drugs in Tennessee. Okie's Pharmacy in Maynardville (pop. 2,361) purchased 195,600 doses of Oxy 30 and Oxy 15 from Amerisource and another distributor, making its disproportionate oxycodone activity 85%. Apple Discount Drugs in Clinton (pop. 9,867) purchased 153,300 doses and its disproportionate oxycodone activity was 80%.<sup>240</sup> Okie's Pharmacy's purchases here were enough to give every person in Maynardville 83 pills of oxycodone.

261. Two days after the October 2012, Ed Hazewski emailed Actavis the following "brief synopsis of the due diligence concerning three of the Knoxville Food City locations (shown in gray below):

12/7/07 – E. Hazewski contacted the Knoxville TN Resident Office – DEA on 12/4/2007. *I spoke with diversion investigator [Name Withheld]. I explained ABC's concerns with Food City # 674. [The Investigator] did not give any specific information other than to say that we should [sic] maintain accurate records. [He] did say that he was familiar with the fact that the customer does dispense large*

<sup>239</sup> MULTI3537760.

<sup>240</sup> MULTI3537762.

quantities of oxycodone. ... [The DEA Investigator] did recall a Food City contacting the office several months ago to enlist the DEA's help in dealing with an un-named distributor that was questioning their purchases. [The DEA Investigator] encouraged ABC to contact the office with other concerns with this customer.

3/6/2008 – On March 6, 2008, Paul Ross and Mike Mapes conducted an on-site operation review of the pharmacy's practices related to the pain management clinic's [sic] the pharmacy is servicing. The pharmacy is doing an excellent job in preventing diversion and abuse of controlled substances in its' practice.

1/31/2012 – *Food City locations 616, 674, and 694 all located in Knoxville TN have been historically high purchasers of OX products.* Prior site visits have been conducted by DEA consultant Mike Mapes as well as Paul Ross of CSRA. Prior reports resulting from those visits have been generally favorable regarding Food City's processes to make certain prescriptions are being dispensed in accordance with the CFR.

*During November 2011 CRSA personnel noticed spike in the OX purchases at all three locations. I contacted Mickey Blazer, Director of Pharmacy Operations, and informed him that in order for ABC to continue to service Food City at their current level we would require a third party consultant to audit all three locations and allow us access to the reports submitted by the consultant. Food City agreed to do so.*

*On January 31, 2012 I again contacted Mickey Blazer. I told Blazer that ABC would look favorably on an ongoing relationship between Food City and Pharma Compliance Group. Additionally ABC would want access to discuss with the consultants matters of mutual concern.*

Blazer agreed and will work on a document memorializing our verbal agreement.

2/1/2012 – Following message received from Matt Murphy of Pharma Compliance Group: Mickey called me last evening regarding the managed service contract. Based on his request we will be auditing the three pharmacies we visited in November four times a year. We will also randomly audit 12 additional Food City Pharmacies one time per year.

April 2012 – E. Hazewski visited all three Knoxville locations in conjunction with the quarterly audit of Pharma Compliance Group. Included discussion with Food City Director of Pharmacy Operations and senior management.

*May 2012 – Discussions between Food City legal counsel and ABC legal counsel.*

*June 2012 discussions with controlled substance compliance personnel of interested manufacturer [Actavis].*<sup>241</sup>

262. But Amerisource had known of problems with the large quantities of oxycodone ordered by Food City well before the October 2012 meeting. Amerisource just did not want to do anything about Food City because it was a sizeable account. An April 27, 2012 email between Mallinckrodt employees discussing Food City stated as follows:

*On 4/26/12, I spoke with Ed Hazewski, Director of Corporate Security, Amerisource (ABC) regarding Food City and specifically about the three DEA Registrations listed below. He advised he is well aware of the three Food City Pharmacies that are buying inordinate amounts of Oxycodone 30mg tablets and that he was in the three stores two weeks ago. Also, the Food City hired a retired DEA employee, Matt Murphy to assist them in bringing their program in line. Further, he advised that the three pharmacies have one clinic "Bearden (ph)" that is driving the large numbers. The problem, Ed explained, is the size of Food City as an ABC customer and the fact this is only three of the Food City pharmacies. He has also been told to try to bring them in line.*

*At that point, I advised Ed that based on the unusually large orders of oxy 30mg tablets, Mallinckrodt is considering putting them on the restricted charge back list. Ed advised that ABC has discussed the same thing, but they would rather fix the problem, if possible. I explained the similarity of Food City and the Cardinal issue with CVS in Florida and Ed advised that had also been discussed internally. Ed advised the problem started when a former Director of Food City brought in another distributor (Masters but name not mentioned) to supply additional oxy 30mg tablets to the three pharmacies being discussed. Initially, ABC was unaware of the additional distributor, but began to see their orders for oxy 30mg drop. The then Director advised he was merely dispersing the volume. Eventually, that Director was dismissed and since that time Ed and his group has been working with the three pharmacies.*

In addition, Ed advised that they are in the process of breaking out oxy 30mg tablets from the rest of the oxy family to give them a better picture and early warning that orders are out of line.

Based on what we now know, I see little exposure to Mallinckrodt/Covidien because of the smaller amounts of oxy 30mg that we are supplying. That being said, *the similarity to the Cardinal CVS issue in Florida cannot be ignored. My recommendation is to bring this before the SOM committee to discuss. My personal opinion, put them on restricted charge back list.*<sup>242</sup>

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<sup>241</sup> Acquired\_Actavis\_00761942 (emphasis added).

<sup>242</sup> MNK\_NC08506592 (emphasis added).

263. Eventually, the business relationship Amerisource and Food City ended, but not because of compliance issues or at the direction of Amerisource. *Food City* ended the relationship when its buying group selected another distributor. Amerisource finally stopped shipping opioids to Food City on November 15, 2012.<sup>243</sup> But in the month between the October 22, 2012 meeting with Actavis and its final shipment, Amerisource still managed to send Food City # 674, # 694, and # 616, a total of 236,803 ODUs and 10,511,752 MMEs, 78% of which were oxycodone.<sup>244</sup>

264. Amerisource met with Actavis again on February 7, 2013 for another “partnership meeting,” after which Actavis noted the following:

Food City was the account they [(Amerisource)] discussed with Nancy – they no longer service Food City Mike Mapes) Stopped November 15th. *Six months prior to stopping* they were cutting back qty. shipped (Burden [sic] Clinic in Knoxville, TN) *they had significant quantities shipped. They were aware that the quantities exceeded the threshold, but based on the site visits they felt this was legit. The decision to stop was a business decision since Food City went to a different buying group, not sue to a SOMS decision.*<sup>245</sup>

265. When Actavis, the manufacturer who supplied a vast majority of the Oxy 30 to Food City through Amerisource, found out that Amerisource had finally ceased distribution to Food City, Actavis’ compliance official sent a letter to Ed Hazewski at Amerisource in February 2013 expressing relief. The letter stated:<sup>246</sup>

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<sup>243</sup> MULTI4122115.

<sup>244</sup> ARCOS.

<sup>245</sup> MULTI4122115 (emphasis added).

<sup>246</sup> ABC-MSAGC00009007.



**February 11, 13**

Mr. Ed Hazewski  
Director, Corporate Security and Regulatory Affairs.  
AmerisourceBergen Corporation  
1300 Morris Drive  
Chesterbrook, PA 19087

Dear Mr. Hazewski,

It was a pleasure speaking with both yourself and Joe Tomkiewicz this afternoon regarding our mutual compliance goals relative to Oxycodone HCl 15 mg, tablets 100's (NDC:00228-2878-11) and Oxycodone HCl 30 mg, tablets 100s (NDC: 00228-2879-11).

During our conversation today, we were very pleased to hear that you no longer distribute the before mentioned Actavis products to the Food City pharmacy chain located in Knoxville, TN, and that you will be ceasing distribution to Windsor Pharmacy in East Brunswick, NJ. It is our expectation that you will continue these evaluation efforts and take additional action as necessary. We were also pleased to hear that you reevaluated your ordering threshold limits and have reduced them by 50%. As articulated to you during our conversation, Actavis is requesting a documented summary of these actions as well as the efforts made to re-evaluate and revise current the ordering thresholds.

266. The Actavis letter to Amerisource also stated that, despite the October 2012 meeting where Amerisource indicated it would reduce its oxycodone thresholds, no such reduction had been made:

Also during our discussion, we indicated that a review of the previous six month's ordering of the Oxycodone HCl 15 & 30 mg, products from legacy Actavis indicated no appreciable reduction in order quantities. It is the expectation of Actavis that you will discuss the current ordering behaviors with your purchasing team and based on the recent threshold reduction, rationalize and revise ordering behavior accordingly. It is expected that current pending orders would be cancelled and new orders placed, based on the changes discussed.

267. Overall, Amerisource had ample information throughout its eight-year business relationship with Food City to know that the bulk of the filled opioid prescriptions that Amerisource supplied, specifically for oxycodone, were being diverted or were not legitimate prescriptions. Because of the amount of sales Food City generated, Amerisource chose to ignore this diversion data and abundant red flags for many years and continued shipping opioids to Food City anyway.

**ii. Belew Drug**

268. Located less than 15 minutes from Food City Pharmacy # 674, Belew Drug was another Amerisource pharmacy customer in Knoxville that was among the top 20 pharmacies in the state in terms of MMEs. It was also Amerisource’s sixth highest pharmacy customer in Tennessee in terms of MMEs between 2006 and 2014, making it one of Amerisource’s highest grossing pharmacy customers in the state for years.

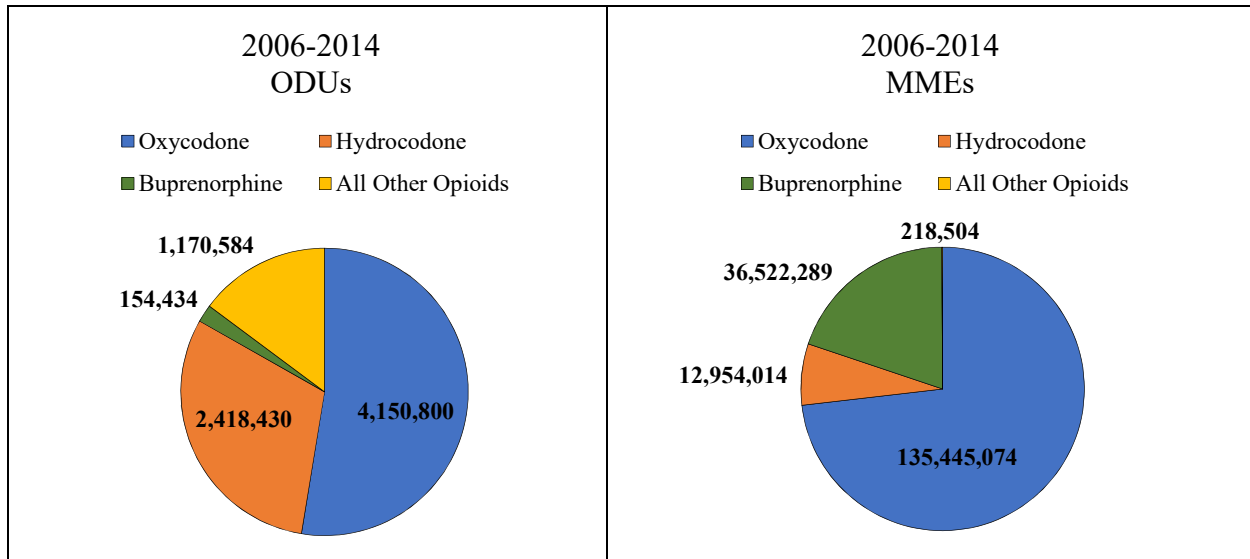
269. Amerisource continued to ship oxycodone and other opioids to Belew Drug despite knowledge that the pharmacy had extremely large quantities and high percentages of Oxy 30 among the oxycodone that it ordered.<sup>247</sup> In addition, Amerisource also knew that Belew Drug had been disciplined by the Tennessee Board of Pharmacy for suspicious dispensing practices, including “accepting medications dispensed from other pharmacies, repacking the medications and returning the packaged medications back to the patients.”<sup>248</sup>

270. Between 2006 and 2014, Amerisource was one of *fifteen* different distributors Belew used to purchase opioids and Amerisource’s opioids accounted for 94% of the MMEs and 85% of the ODUs the pharmacy received during those seven years. Of the approximately 4.2 million doses of oxycodone Amerisource distributed to Belew, 42% was Oxy 30.

<b>City:</b> Knoxville (pop. appx. 178,874)		<b>County:</b> Knox	
<b>ODUs:</b> 7,897,518		<b>MMEs:</b> 253,336,236	
<b>State Rank:</b> Not in top 20	<b>ABC Rank:</b> 9th	<b>State Rank:</b> 16th	<b>ABC Rank:</b> 6th
<b>Years as ABC Customer:</b> 2004 to Present		<b>Distribution Center(s):</b> Birmingham	

<sup>247</sup> ABC-MSAGC00008982.

<sup>248</sup> ABC-MSAGC00024455–60; ABC-MSAGC00029207–09.



271. Amerisource also dramatically increased the amount of buprenorphine it shipped to Belew—8,339% more between 2006 and 2013.

272. In addition to oxycodone and buprenorphine, Amerisource was also willing to ship Belew tens of thousands of doses of fentanyl, the most powerful opioid on the market by a wide margin.

273. In the spring of 2007, Amerisource’s CSRA initiated an investigation of Belew Drug “for elevated purchase numbers in April 2007 of Hydrocodone and Alprazolam[, an anti-anxiety medication]. During that month they purchased 7,800 dosage units of Hydrocodone and 23,600 dosage units of Alprazolam.” At the time, Amerisource’s CSRA noted in the pharmacy’s file that “It is not know [sic] how long Belew has been an ABC customer.” Amerisource’s CSRA also found “no indication of diversion.”<sup>249</sup>

274. In April 2008, Amerisource raised Belew’s monthly oxycodone threshold to 35,000 dosage units.<sup>250</sup>

<sup>249</sup> ABC-MSAGC00024348.

<sup>250</sup> ABC-MSAGC00024348.

275. Between March and August 2009, Amerisource shipped to Belew Drug over 230,000 doses of oxycodone, 42% of which was Oxy 30.<sup>251</sup> Belew was in the top thirty purchasers of Oxy 30 among all Amerisource pharmacy customers nationwide, and rapidly rising.<sup>252</sup>

276. In April 2010, Amerisource decided to raise Belew's oxycodone threshold was raised to 50,000 dosage units per month, "based on historical data."<sup>253</sup>

277. At least by March 2011, Amerisource had reason to know Belew was purchasing additional oxycodone from other distributors. Belew's pharmacist sent Ed Hazewski the pharmacy's dispensing data, per his request. This data revealed to Amerisource that in February 2011, Belew had dispensed 73,146 dosage units of oxycodone, 61% of which was Oxy 30.<sup>254</sup> During that same month, Amerisource had shipped the pharmacy 55,600 oxycodone dosage units, which was over the monthly threshold that Amerisource had set for Belew.<sup>255</sup>

278. In March 2011, Amerisource shipped Belew 69,000 dosage units of oxycodone, again over the threshold Amerisource had set.<sup>256</sup> At the end of March 2011, Amerisource raised Belew's oxycodone threshold to 78,000 dosage units per month.<sup>257</sup>

279. Amerisource also noted that "ABDC is the sole supplier for the customer." However, this was not true and Amerisource knew it based on the dispensing data provided per Amerisource's request. In March 2011, Belew had used Masters Pharmaceutical to purchase an additional 15,800 dosage units of oxycodone, 53% of which was Oxy 30.<sup>258</sup> Belew also purchased oxycodone from KeySource Medical during that same month.<sup>259</sup>

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<sup>251</sup> ARCOS.

<sup>252</sup> ABDCMDL00301692 (Sheet Customer Totals, Row 23549–50).

<sup>253</sup> ABC-MSAGC00024349.

<sup>254</sup> ABC-MSAGC00024392.

<sup>255</sup> ARCOS.

<sup>256</sup> ARCOS.

<sup>257</sup> ABC-MSAGC00024451–52.

<sup>258</sup> ARCOS.

<sup>259</sup> ARCOS.

280. Amerisource, however, was the primary opioid distributor for Belew, however, as shown in the October 2012 “partnership meeting” between Actavis and Amerisource, the distributor shipped Belew Drug 138,700 tablets of Oxy 30 during the first six months of 2012, which constituted 85% of all Actavis oxycodone that Amerisource shipped to the pharmacy. Only fourteen of Amerisource’s pharmacy customers were shipped more of Actavis’ oxycodone.<sup>260</sup>

281. In December 2018, Belew was finally being evaluated by Amerisource’s CSRA, which found that:

- the Tennessee Board of Pharmacy had previously disciplined the owner;
- pharmacist David Belew and the Board of Medicine had disciplined two of the top prescribers, one of whom voluntarily retired his license as a result;
- the Tennessee Board of Pharmacy had also disciplined the owner’s wife, pharmacist Amy Belew,<sup>261</sup> as well as another of Belew’s pharmacists, Brandon Lock;<sup>262</sup> and
- the pharmacy had been disciplined following an inspection by the Board of Pharmacy, which found that Belew’s had not provided patient counseling, had a pharmacy technician with an expired license, and that the pharmacy had been “accepting medications dispensed from other pharmacies, repacking the medications and returning the packaged medications back to the patients.”<sup>263</sup>

282. Despite this December 2018 report containing numerous red flags, Amerisource approved Belew’s anticipated monthly usage, including “24,000 dosage units of oxycodone combination products, 2,300 dosage units of oxycodone 30 mg, 12,800 dosage units of hydrocodone, 3,400 dosage units of Tramadol, 8,000 dosage units of alprazolam, and 600 dosage units of carisoprodol per month.” Belew also projected that it would have 14% cash payments for controlled substances by its customers.<sup>264</sup>

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<sup>260</sup> MULTI3537758.

<sup>261</sup> ABC-MSAGC00024387–91.

<sup>262</sup> ABC-MSAGC00024394–98.

<sup>263</sup> ABC-MSAGC00024455–60; ABC-MSAGC00029207–09;  
<https://apps.health.tn.gov/FacilityListings/Home/ViewPDF/224>.

<sup>264</sup> ABC-MSAGC00024425–29.

## **H. Amerisource's Oversupply of Buprenorphine to the Tri-Cities and Surrounding Area**

283. In addition to Johnson City, Kingsport, and Bristol, the Tri-Cities area also includes small towns such as Gray, which has a population of just over one thousand people. The region is intersected by interstates I-26 and I-81, with I-40, I-77, and I-75 nearby. The Tri-Cities also shares a border with Virginia and is over an hour's drive from both North Carolina to the southeast and Kentucky to the northwest. This location makes it increasingly susceptible to attracting people seeking to abuse and/or divert opioid prescriptions, using tactics such as doctor shopping to game the system.

284. This Tri-Cities region, much like Knoxville, is notorious for prescription pill abuse. Amerisource had ample knowledge of this abuse and diversion, yet continued to oversupply these communities with tens of millions of opioids anyway.

285. Amerisource not only took advantage of this area's appetite for opioids by supplying it with oxycodone and hydrocodone, but it also supplied huge quantities of buprenorphine. Of course, the irony is that buprenorphine is often used to medically treat opioid addiction but since it is itself an opioid, it is also susceptible to abuse and diversion, primarily because it can cause euphoria.

286. Buprenorphine is a controlled substance that is primarily used to treat opioid addiction. It is generally available in two formulations: with or without naloxone. Naloxone is an opioid antagonist, meaning it blocks opioid receptors in the brain and can be used to immediately reverse the effects of an opioid overdose. For patients suffering from opioid addiction, buprenorphine combined *with* naloxone can relieve withdrawal symptoms without side effects such as euphoria. A commonly known brand name for this is Suboxone. Buprenorphine *without* naloxone, also known as "buprenorphine monoprodukt," is often prescribed for pregnant women

since naloxone can harm the fetus and, in limited circumstances, for people first coming off opioids who are experiencing severe withdrawal symptoms. One of the strongest and most diverted forms of buprenorphine is the monoproduct at 8mg, referred to herein as “Buprenorphine 8.” A commonly known brand name for this is Subutex, and it has a street value of approximately \$35–\$45 per dose. The prescribing and dispensing of buprenorphine are tightly regulated, but that does not stop diverters and abusers from seeking out prescribers willing to sell them a prescription and pharmacies willing to fill them. That is how pill mills work. All they need is someone to supply the drugs and look the other way.

287. Among other things, Amerisource *knew* it was supplying buprenorphine pill mills. In the Tri-Cities’ area alone, Amerisource had direct evidence that one Tennessee pharmacy was purchasing more buprenorphine than any other pharmacy in the country to dispense to large groups of doctor-shopping patients who were driving from places like Kentucky, Virginia, North Carolina, and West Virginia to go to a specific doctor, who only accepted cash payments and would write Buprenorphine 8 prescriptions for anyone willing to pay, and this pharmacy accepted what it knew to be medically illegitimate prescriptions for controlled substances in exchange for cash.

288. Between 2006 and 2014, P & S Pharmacy and Brookside Discount Pharmacy (2011 to 2014 for Brookside) accounted for 86% of the Buprenorphine 8 that Amerisource distributed into all of Sullivan County,<sup>265</sup> which had a population of approximately 156,385 residents. During those same seven years, Blankenship Pharmacy and Gray Pharmacy accounted for 92% of the Buprenorphine 8 that Amerisource distributed into all of Washington County, which has a population of approximately of 124,775 residents. Overall, those four pharmacies alone accounted

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<sup>265</sup> ARCOS.

for 67% and 75% of all of the buprenorphine that Amerisource distributed to those counties, respectively.

289. In December 2014, Sharon Hartman, the Director of Pharmacy Compliance and Diversion Control for CSRA, emailed David May, Ed Hazewski, and others in CSRA to share some facts about buprenorphine. She discussed the pharmacological background of buprenorphine, including its uses for the treatment of opioid addiction, but also stated that “[p]rolonged use of buprenorphine can result in physical dependence,” and that “[o]verdoses have primarily involved buprenorphine taken in combination with other central nervous system depressants.” Emphasized prominently in her message though, was the following warning about the restrictions on who is able to prescribe these drugs:<sup>266</sup>

**Under the Drug Addiction Treatment Act (DATA) codified at 21 U.S.C. 823(g), prescription use of this product in the treatment of opioid dependence is limited to physicians who meet certain qualifying requirements, and who have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe this product for the treatment of opioid dependence and have been assigned a unique identification number that must be included on every prescription.**

290. Amerisource’s Diversion Control Coordinator forwarded the message to a CSRA Corporate Investigator, who also received, the email to say:<sup>267</sup>

**Subject:** FW: buprenorphine a few facts

Basically setting up her argument not to increase threshold...here we go

**Kimberly St. John**  
AmerisourceBergen Corporation  
**Diversion Control Coordinator**  
Corporate Security and Regulatory Affairs

291. But again at Amerisource, compliance yielded to sales and the decision was made to increase the thresholds:<sup>268</sup>

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<sup>266</sup> ABDCMDL00296353.

<sup>267</sup> ABDCMDL00296352.

<sup>268</sup> ABDCMDL00296352.



**Subject:** RE: buprenorphine a few facts

She lost on that one. When the majority wants something, she'll cave pretty quickly. I give credit to Eric who pushed for the thresholds to be adjusted now.

**Elizabeth Garcia**  
AmerisourceBergen  
Corporate Investigator  
Corporate Security and Regulatory Affairs

292. The decision to increase buprenorphine thresholds was celebrated, including by CSRA's Diversion Control Coordinator, who stated:<sup>269</sup>

**Subject:** RE: buprenorphine a few facts

Me too. Glad he spoke up!

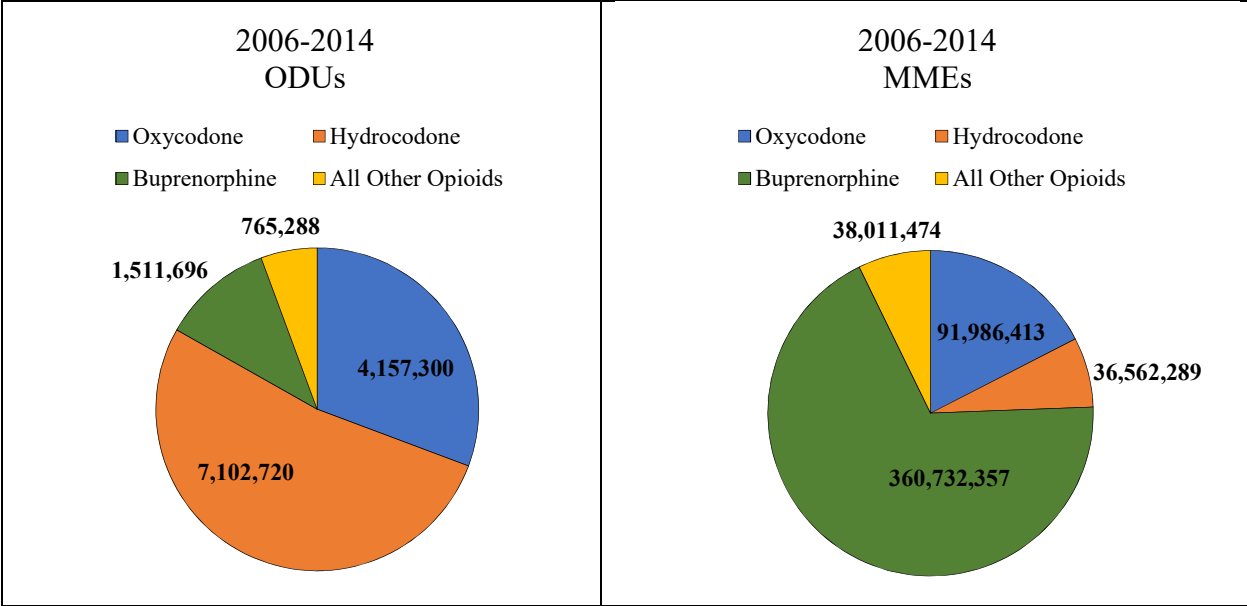
**Kimberly St. John**  
AmerisourceBergen Corporation  
**Diversion Control Coordinator**  
Corporate Security and Regulatory Affairs

293. Amerisource was shipping more buprenorphine to these pharmacies than it was anywhere else in the country and seemed to have little desire to stop.

*i. P & S Pharmacy*

<b>City:</b> Kingsport (pop. appx. 51,274)	<b>County:</b> Sullivan		
<b>ODUs:</b> 13,537,004	<b>MMEs:</b> 527,292,533		
<b>State Rank:</b> 2nd	<b>ABC Rank:</b> 2nd	<b>State Rank:</b> 2nd	<b>ABC Rank:</b> 2nd
<b>Years as ABC Customer:</b> 2004 to Present		<b>Distribution Center(s):</b> Birmingham; Paducah	

<sup>269</sup> ABDCMDL00296352.



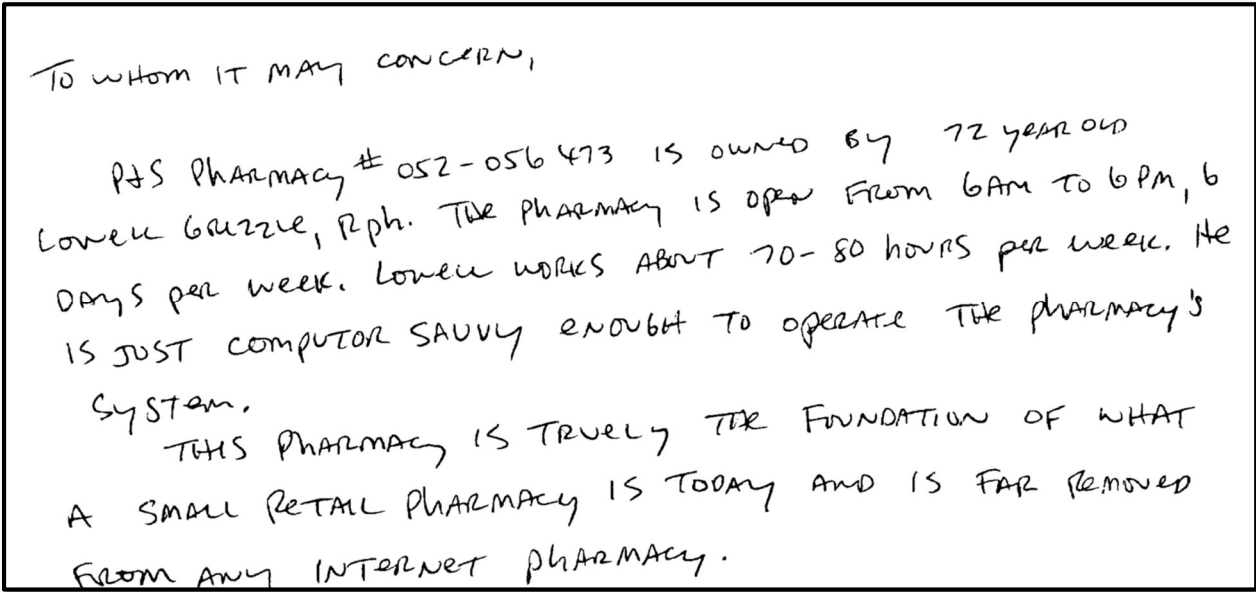
294. P & S Pharmacy, which is owned by its Pharmacist-in-Charge (PIC), Lowell Grizzle, is another independent pharmacy in Kingsport, part of the Tri-Cities area, that Amerisource oversupplied with opioids, particularly buprenorphine, even after it knew that diversion was taking place from the pharmacy. And this problem remains, as Amerisource continues to oversupply buprenorphine to P & S Pharmacy as of June 2019.<sup>270</sup>

295. Amerisource continued to ship buprenorphine to P & S Pharmacy despite knowing it was Amerisource’s highest dispensing pharmacy for buprenorphine monoprodukt in the country; sending a termination letter stating Amerisource would be cutting the pharmacy off from controlled substances; knowing incredibly high percentages of individuals were paying for their opioids in cash at the pharmacy; being told by the PIC at P & S that he did not use the State’s Controlled Substances Monitoring Database; being told by a pharmacy technician that the pharmacy receives at least “50 plus” phone calls per day from new patients looking to see if the pharmacy could fill their buprenorphine monoprodukt prescriptions; and its investigator

<sup>270</sup> ABC-MSAGC00028793 (June 4, 2019 ABDC e-mail stating, “[T]he major issue I’m seeing with this one is the disproportionate amount of Buprenorphine 8mg mono produkt being dispensed, especially in a state where there are clear guidelines surrounding this produkt.”).

witnessing approximately 20 to 30 younger customers paying cash for buprenorphine during the limited time he conducted a site visit, among many other things.

296. Even as a single pharmacy in a small city, P & S is a lucrative account to Amerisource, which was noted by the Company's sales representative who made a point to visit as often as every two weeks.<sup>271</sup> As part of a 2007 "Initial SOM [(Suspicious Order Monitoring)] Investigation Questionnaire" involving hydrocodone,<sup>272</sup> Amerisource's sales representative, Mat Miller, defended P & S and another pharmacy and, in a handwritten note, stated in relevant part:<sup>273</sup>



TO WHOM IT MAY CONCERN,

P&S PHARMACY # 052-056473 IS OWNED BY 72 YEAR OLD LOWELL GRIZZLE, RPH. THE PHARMACY IS OPEN FROM 6AM TO 6PM, 6 DAYS PER WEEK. LOWELL WORKS ABOUT 70-80 HOURS PER WEEK. HE IS JUST COMPUTER SAVVY ENOUGH TO OPERATE THE PHARMACY'S SYSTEM.

THIS PHARMACY IS TRULY THE FOUNDATION OF WHAT A SMALL RETAIL PHARMACY IS TODAY AND IS FAR REMOVED FROM ANY INTERNET PHARMACY.

<sup>271</sup> ABC-MSAGC00029078.

<sup>272</sup> ABC-MSAGC00029086.

<sup>273</sup> ABC-MSAGC00029082 (emphasis added).

BOTH OF THESE ABC CUSTOMERS ARE HIGH VOLUME LOCAL PHARMACIES AND ARE VERY LOYAL TO OUR COMPANY. IT IS THESE TYPES OF PHARMACIES/CUSTOMERS THAT PAY THE SALARIES OF ABC ASSOCIATES, EITHER PEOPLE LIKE ME IN THE FIELD EVERY DAY OR CORPORATE ASSOCIATES WHO ARE NOT FORTUNATE ENOUGH TO HAVE A PERSONAL RELATIONSHIP WITH OUR MANY CUSTOMERS. PLEASE FEEL FREE TO VISIT WITH ME THESE PHARMACIES OR ANY OTHERS IN MY TERRITORY, AT ANY TIME - UNANNOUNCED.

Sincerely, *Dnot*

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER ABC-MSAGC00029082

297. Amerisource’s priority with P & S was profits, not compliance. In a December 2009 threshold increase request from P & S concerning various types of oxycodone, Amerisource’s sales representative’s only justification for increasing the shipment threshold was because otherwise the pharmacy could get these opioids from a competing distributor. Mat Miller stated the following in the threshold increase request:<sup>274</sup>

Reason for Threshold Review:  
 (Note: Exceeding the established threshold does not in itself justify a threshold increase in all cases.)

Several items have reached the ABC threshold and the items we cannot ship have been ordered from JM Smith and Harvard Drug

298. By December 2012, Amerisource had direct knowledge of diversion of hydrocodone that it was supplying to P & S Pharmacy, which was being supplied through Amerisource’s Birmingham distribution center.<sup>275</sup> Mr. Miller “notified Birmingham distribution center and informed them that the customer P and S Pharmacy in Kingsport, TN *had another drug*

<sup>274</sup> ABC-MSAGC00026085 (highlighted emphasis added).  
<sup>275</sup> ABDCMDL478970 (Rows 4771–72).

*control shortage.*<sup>276</sup> Eventually, Amerisource identified one of its own contractor delivery drivers as most likely responsible<sup>277</sup> and knew that “the P&S Pharmacy in TriCity [sic] has been a point of interest for [the Tennessee Bureau of Investigation] and requested all information on these losses.”<sup>278</sup>

299. By 2013, P & S had added buprenorphine to its high volume opioid dispensing portfolio. This is evidenced not just by DEA ARCOS data, but by a letter sent to the DEA from the local congressman on behalf of P & S Pharmacy owner and PIC Lowell Grizzle. The DEA’s response to the congressman’s letter read in part:

Thank you for your correspondence dated June 7, 2013, to the [DEA] on behalf of Lowell Grizzle, a pharmacist, *who states that his wholesaler cannot provide his pharmacy with adequate amounts of buprenorphine or oxycodone due to restrictions placed on the wholesaler by the DEA.* Unfortunately, Mr. Grizzle has received incorrect information regarding DEA’s role in wholesale transactions of controlled substances.<sup>279</sup>

300. After the correspondence to the DEA failed to result in a threshold increase, P & S continued to convince Amerisource to increase its threshold through the Pharmacy’s assigned sales representatives. On April 8, 2014, in an threshold increase request, Amerisource’s Mat Miller, the sales representative for P & S Pharmacy, sought a threshold increase in buprenorphine on the sole basis that “[s]everal stores in the area have cut out sales of Subutex and Suboxone and the patients are trying to find supplies fro [sic] area stores that still have inventory.”<sup>280</sup> Mr. Miller also stated that P & S’s current monthly usage as of April 2014 for Subutex was around 10,000.<sup>281</sup>

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<sup>276</sup> ABDCMDL478970 (Row 4772) (emphasis added).

<sup>277</sup> ABDCMDL478970 (Row 4774).

<sup>278</sup> ABDCMDL00478970.

<sup>279</sup> ABDCMDL00306619 (emphasis added).

<sup>280</sup> ABC-MSAGC00026063.

<sup>281</sup> ABC-MSAGC00026063.

Amerisource approved the Subutex threshold increase request and P & S Pharmacy's monthly threshold as of December 2014, just six months later, was *30,000 units*.<sup>282</sup>

301. Amerisource's sales representative continued to ask for threshold increases for buprenorphine on behalf of P & S Pharmacy. On December 4, 2014, Mr. Miller asked for a threshold increase *to 37,500 units* and justified the increase on the basis that "[p]ain and *drug treatment clinics* in the area are writing the prescriptions *and some chains are turning customers away with these prescriptions* so the patients appear to be coming to area independents."<sup>283</sup> When asked in response by Amerisource's CSRA for basic information about controlled substances filled by the pharmacy in the last 90 days, Mr. Miller became indignant and stated: "I have provided this data at least twice in the past. These guys struggle with technology. *Under the circumstances, cancel this request please.*"<sup>284</sup>

302. By 2015, the DEA had flagged P & S, as known to Amerisource. On February 3, 2015, the DEA arrived at Amerisource's Birmingham distribution center for an audit and as part of that, requested the due diligence files for P & S Pharmacy.<sup>285</sup>

303. On February 5, 2015, an Amerisource Diversion Control Specialist circulated a spreadsheet containing information from a DEA audit of the Birmingham distribution center. The internal spreadsheet contained a list of the top ten retail customers for that distribution center, seven of which were in Tennessee including P & S.<sup>286</sup> The spreadsheet also listed the top ten controlled substances purchased by P & S from August 2014 through January 2015—all of which contained buprenorphine, benzodiazepine, hydrocodone, or oxycodone.<sup>287</sup> Over that six-month

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<sup>282</sup> ABC-MSAGC00026088.

<sup>283</sup> ABC-MSAGC00026069 (emphasis added).

<sup>284</sup> ABC-MSAGC00026071 (emphasis added).

<sup>285</sup> ABDCMDL00401578.

<sup>286</sup> ABDCMDL00249807; ABDCMDL00249815.

<sup>287</sup> ABDCMDL00249815.

period, 52.7% of the drugs ordered by P & S were for controlled substances.<sup>288</sup> To place in context, the next highest percentage of controlled substances on the list of top ten retail customers for the Birmingham distribution center was 25.3%, *less than half*.<sup>289</sup>

304. Amerisource’s knowledge of red flags for diversion at P & S continued to mount. In a Retail Pharmacy On-Site Questionnaire dated June 30, 2015, PCG auditor Edward Sullivan, who visited the Pharmacy at 6:30 a.m. ET with Amerisource’s Mat Miller, observed that:

- P & S was located in a “small strip mall,” attached to a dentist’s office;
- “people [were] milling around outside of the pharmacy,” and five people waiting in the pharmacy area between “20-30 y.o.a Male and female mostly male. Local middle class neighbor, *rough looking street wise person*”;<sup>290</sup>
- “60%” of P & S’s business came from “addiction rehab”;<sup>291</sup>
- one of the P & S pharmacist’s license was on probation and he had had a substance abuse issue in 2004;<sup>292</sup>
- PIC Grizzle was not CMEA self-certified because he claimed the pharmacy did not sell pseudoephedrine products, yet the inspector found that P & S was selling pseudoephedrine;
- P & S was purchasing controlled substances from other distributors;<sup>293</sup>
- P & S was not conducting background checks or drug tests on its employees;<sup>294</sup>
- controlled substances were not securely stored as required;<sup>295</sup>
- 45% of the prescriptions the pharmacy filled were for a controlled substances;<sup>296</sup>
- *65% of its customers were walk-ins*;<sup>297</sup>
- an astounding 71% of its controlled substances were purchased in cash;<sup>298</sup>

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<sup>288</sup> ABCMDL00249807; ABCMDL00249815.

<sup>289</sup> ABCMDL00249815.

<sup>290</sup> ABC-MSAGC00028816 (emphasis added).

<sup>291</sup> ABC-MSAGC00028817.

<sup>292</sup> ABC-MSAGC00028817.

<sup>293</sup> ABC-MSAGC00028819.

<sup>294</sup> ABC-MSAGC00028821.

<sup>295</sup> ABC-MSAGC00028821.

<sup>296</sup> ABC-MSAGC00028822.

<sup>297</sup> ABC-MSAGC00028822.

<sup>298</sup> ABC-MSAGC00028823.

- P & S was not vetting new patients, even ones from out-of-state who were bringing in prescriptions for controlled substances;<sup>299</sup>
- the pharmacy had no system in place to review physicians who wrote an inordinate amount of controlled substance prescriptions and had never cut off or refused to dispense any controlled substance prescription for suspicious prescribers;<sup>300</sup>
- the pharmacy had been inspected by the Tennessee Board of Pharmacy in 2009 and on December 9, 2014, but the pharmacy had retained no paperwork or summary of the visits;<sup>301</sup> and
- P & S had previously alerted authorities to patients who were selling Suboxone in the pharmacy's parking lot.<sup>302</sup>

305. On July 8, 2015, Ed Sullivan of the Pharma Compliance Group completed a report about his June 30, 2015 visit to P & S Pharmacy. The report stated in relevant part (shown in gray below):

P&S Pharmacy has been operating as a retail pharmacy since 1960. (ABC customer ## 100066729) Initial information provided to Consultant Sullivan by ABC indicates that there was *not* an ABC form 590 on file. The information provided to Consultant Sullivan shows that *the pharmacy is the highest purchaser of Buprenorphine in the country of all ABC customers. For Oxycodone based substances, the pharmacy was #2 in its zip code and #8 in the entire state. For Benzodiazepines, the pharmacy was ranked #1 in the state and #22 in the entire country. For Hydrocodone based substances, the pharmacy was ranked #1 in its zip code and #5 in the state of Tennessee.*

During the period June 2014 through June 2015, P&S Pharmacy ordered and dispensed the following controlled substances. *The below controlled substances fall consistently either right at or over the threshold amounts established by ABC.*

**P&S PHARMACY TOP CONTROLLED SUBSTANCES**

<b>Drug</b>	<b>Dosage Units</b>	<b>% All CS</b>
Hydrocodone (solids)	572,900	24.1%
Benzodiazepines	506,640	21.3%
Buprenorphine	347,400	14.6%
Oxycodone	328,600	13.8%
<b>TOTAL:</b>	<b>1,755,540</b>	<b>78.3%</b>

<sup>299</sup> ABC-MSAGC00028823.

<sup>300</sup> ABC-MSAGC00028823–24.

<sup>301</sup> ABC-MSAGC00028818.

<sup>302</sup> ABC-MSAGC00028825.



P&S Pharmacy was asked to provide the top 5 controlled substances prescribers (see below). In addition, the pharmacy provided Mat Miller their controlled substance dispensing data for the month of May 2015. Based on the data provided to Consultant Sullivan, a qualitative analysis was performed of the controlled substances in the 26 operational days in May 2015.

There were 4,232 controlled substance prescriptions filled during this period. The analysis shows that the pharmacy customers paid cash for 72% of all controlled substance prescriptions filled in the month of May 2015, which is approximately 3,038 prescriptions. The analysis performed by ABC for the 12 month period above shows that the pharmacy fills at least *42.4% controlled substances to all net sales*. In addition to ABC, *the pharmacy also purchases controlled substances from Quest Pharmaceutical, Murray, KY, primarily for Benzodiazepines (Alprazolam)*.

The following were the top controlled substances prescriptions filled in the 26 operational days.

*\* It should be noted that all of the Buprenorphine prescriptions were paid for in cash.*

The following are the top five controlled substances prescribers at P&S Pharmacy. Please see attached background information on these physicians.

#### **OBSERVATION #1:**

According to PIC Grizzle, he is concerned about the prescribing practices of the following two pain management physicians. [Provider 1] is a Family Practice physician who is now prescribing for pain management. [Provider 1] is located at [Street Address], Kingsport, TN. Consultant Sullivan reviewed the dispensing data of [Provider 1] and revealed that he prescribed #97 controlled substance prescriptions in the 26 operational days. *[Provider 1] primarily prescribed for #120 to #180 Oxycodone, Hydrocodone and alprazolam #120. The majority of these prescriptions were paid for by cash.*

[Provider 2]. [Provider 2] is a family practice physician located at [Street Address], Kingsport, TN 37660. A review of this physician's dispensing records indicates the following: approximately #52 prescriptions in the 26 operational days for Oxycodone, Methadone, Hydrocodone and Alprazolam. The average dosage unit per prescription is #120.

Consultant Sullivan asked PIC Grizzle if he obtained specific medical diagnoses from the above prescribers or received any objective findings/documents to support the legitimacy of these prescriptions. *PIC Grizzle indicated that he had no specific information other than these physicians prescribe for "pain management" and that he does not usually use the TN PDMP and that he does not contact the physician's office to verify prescriptions. There is no pharmacy/doctor relationship to*

*determine if there is a doctor/patient relationship. There are no pain management contracts or diagnostic codes. Most of the prescriptions for Oxycodone/Hydrocodone/Alprazolam are paid by cash, even when some customers have insurance.*

## **RECOMMENDATION:**

### **DISPENSING NARCOTICS AS PART OF PAIN MANAGEMENT**

Federal, state and local law enforcement has placed an emphasis on the prescribing and dispensing of controlled substances, especially Schedules II through V controlled substances as part of a pain management program.

- It is important to understand that the CSA and DEA regulations have placed big responsibilities on retail pharmacies to determine that any controlled substance prescription is prescribed for a legitimate medical purpose. P&S Pharmacy should take numerous steps to comply with DEA regulations. The Pharmacist along with his Technician, need to know how to validate whether a controlled substance prescription was written for a legitimate medical purpose. The Pharmacy should be utilizing the TN PDMP program on all new controlled substance prescriptions they receive. They need to document any medical diagnosis or objective findings from physician before they fill a pain management controlled substance prescription. The pharmacy should question the prescription if they continue to see family practice physician writing for chronic pain management. All prescriptions should be verified with the prescribing practitioner. Pharmacy personnel should note on the back of the prescription the date, diagnosis for the prescription, and the person taking the information.

*Special attention should be given to the following controlled substances prescriptions: OxyContin 40mg/80 mg; Oxycodone 15 mg/30mg; Methadone 5 mg/10 mg; Hydrocodone 10 mg; and the combination drugs referred to as a "Trinity Cocktail." A Trinity Cocktail is made up of the following controlled substances: Oxycodone or Hydrocodone, Soma/Carisoprodol, and Alprazolam/Xanax.*

## **OBSERVATION #2:**

Consultant Sullivan asked PIC Grizzle why *almost 72% of controlled substance prescriptions were being paid for by cash*. The initial response was that a lot of the medications (Benzodiazepines, Buprenorphine) are not covered under TennCare (Medicaid). *When asked again, PIC Grizzle explained that he tells his customers if they pay in cash for their controlled substance prescriptions, he offers them a reduced price which is cheaper than what a chain pharmacy would charge.* PIC Grizzle went on to say that the insurance companies' reimbursements prices paid to them are much lower than what the pharmacy has to pay for controlled substances.

When Grizzle was asked if his pharmacy was inspected by the DEA, PIC Grizzle indicated that *DEA, along with the Tennessee Board of Pharmacy conducted an inspection of their pharmacy on December 9, 2014.* Consultant Sullivan asked to see the DEA Notice of Inspection on his pharmacy and/or receipt of items taken. PIC Grizzle indicated that the was given no paperwork. DEA retrieved all of the pharmacy's Schedule 3-5 controlled substance invoices with all of their CSOS copies and invoices. They also retrieved the pharmacy's Biennial inventory which was dated March 30, 2013. The DEA investigator, [Name withheld], was assigned to the Knoxville, Tennessee DEA office. The pharmacy's receipts were returned to the pharmacy approximately one month later. The PIC also indicated to Consultant Sullivan that *the DEA investigator made the comment to him that his pharmacy was the second largest purchaser of Buprenorphine in the entire country, with only one other pharmacy located in New Jersey that had purchased a little more.* According to PIC Grizzle, DEA was on site for over 6 hours conducting the inspection.

....

### **OBSERVATION #3:**

*Consultant Sullivan observed that the pharmacy was getting many phone calls during the visit that seemed to be short in duration.* When questioned about these phone calls, PIC Grizzle, along with his nephew, Technician Sutherland, indicated that *the pharmacy receives at least 50 plus phone calls per day from new patients looking to see if the pharmacy could fill their Subutex prescriptions. He explained that the quantity of Buprenorphine that they are currently ordering and receiving from ABC is not enough to take on the numerous calls from new Subutex patients.* PIC Grizzle went on to say that *if he could order more Buprenorphine he would be able to fill these prescriptions for at least 100 more customers.* The physicians are charging these patients \$150.00 per week to get a prescription for Buprenorphine. *The pharmacy is charging their customers \$204.92 cash only for #30 Buprenorphine, 8mg tablets.* There is a great demand for Buprenorphine in the area and there are currently 100 prescribers who are writing for Buprenorphine in the general Tri City area. It was also revealed that *these prescribers do not usually decrease the dosage of the Subutex/Suboxone they prescribe, nor do the patients stop taking the medication, rather, they tend to stay on the drug for long term.*

During the inspection, Consultant Sullivan noticed *many young customers (20-30) coming into the pharmacy paying cash for their Buprenorphine.* Consultant Sullivan asked if this was a common occurrence. Technician Sutherland indicated that *this was "nothing"* and that as the day went on there was *groups of people coming into the store to fill their Buprenorphine prescriptions.*

Consultant Sullivan observed that *all of the customers seemed to know each other and they would congregate/loiter outside in the parking lot talking to each other.*

On some occasions, *the PIC and/or technician would observe some customers selling their medication to others.* The pharmacy would call the local police to report this but by the time they arrived to the store (45 minutes later) the customers would be gone. This information was also discussed with the Tennessee pharmacy board inspector who had contacted the police department to report these occurrences. *PIC Grizzle was concerned that if his pharmacy continued to report these incidences to the local police, they would start looking into the pharmacy's activities with filling these controlled substances.*

It should be noted that after Consultant Sullivan finished and left the on-site inspection with ABC Manager Miller, approximately 45 minutes later, he returned alone and parked across the street from the pharmacy to observe customer activity. *At this time, Consultant Sullivan observed many cars in the parking lot with customers 20-30 years of age standing outside the door of the pharmacy walking in and out of the pharmacy many times and waiting for the prescriptions to be filled. The customer activity was extremely busy during this time.*

**RECOMMENDATION:**

....

*Drug diversion/redistribution of Subutex and Alprazolam is great, especially when patients are paying cash.* If the Pharmacist knows that controlled substances that they had just filled is unlawfully redistributed on their property and has direct knowledge evidence that pharmacist has a legal responsibility to report the information to the prescribing physician and to the local authorities. They must discontinue filling controlled substances for these customers. Like other opiates that are abused, buprenorphine is capable of producing significant euphoria. Information developed from a previous ABC pharmacy inspection PIC in Kingsport TN by this consultant in February 2015 indicated the following: *Kingsport, Tennessee and the surrounding neighborhood referred to as the Tri City area, has a large pharmaceutical drug problem. The Subutex sells on the street in Kingsport for \$30-\$40 per dosage unit.*

**OVERALL OBSERVATIONS/RECOMMENDATIONS:**

Consultant Sullivan had the opportunity to discuss the onsite Due Diligence inspection with Lowell Grizzle and his nephew Charles Sutherland. As noted above, PIC Grizzle has owned and operated his pharmacy for nearly 55 years (1960). His nephew, Charles Sutherland, has worked for his uncle at this pharmacy for 45 years (1970). During this long period of running his pharmacy PIC Grizzle has found it increasingly difficult to compete with the large chain pharmacies and has consistently lost business to the chain pharmacies, who are now filling most of the (legend) maintenance medications or mail order 90 days.

*The pharmacy's percentages of controlled substances to legend medications has been steadily increasing and his billing for insurance claims has been decreasing. The pharmacy has decided that if his customers want to have their controlled substance prescriptions filled at a competitive price that is lower than the rest of the pharmacies in the area, the customers would need to pay for their controlled substances in cash only.*

Consultant Sullivan explained to the PIC the following concerns found during the Due Diligence inspection. *The 72% cash payment for controlled substances is a major "red flag" with DEA and nearly 50% controlled substances to legend drugs as well. The fact that his pharmacy is the number 1 purchaser through ABC of Buprenorphine throughout the country is alarming as is the fact that the DEA has visited his pharmacy and conducted an inspection on December 9, 2014, based on the facts of qualitative analysis we had performed above.*<sup>303</sup>

306. A week later, an internal Amerisource email titled "PCG Customer Review" was circulated on July 16, 2015, which summarized PCG's report on P&S Pharmacy as follows:<sup>304</sup>

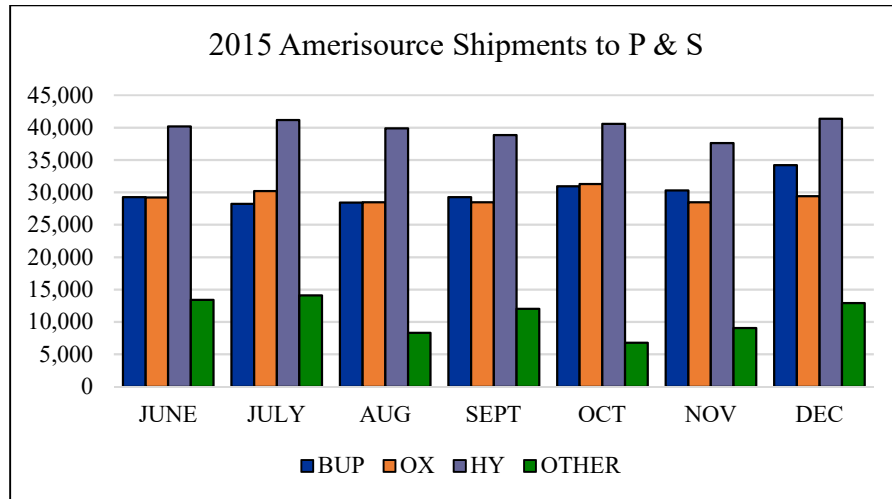
<p>P&amp;S Pharmacy FAST TRACK Red Flags DEA/TN BOP inspection in Dec. 2014 Couldn't find their paperwork No diligence program, doesn't use pdmp One pharmacist - past hx of addiction Abnormal activities in parking lot Does call the police but still continues to dispense to these people Buprenorphine 8mg paid with cash (1169 RX compared to Bup/naloxone 327) 72% Cash Provides discount (lower than chains) for CS when paid with cash Fields phone calls for subutex - could sell more if ABC didn't restrict him</p>
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307. As shown by the volume of dosage units shipped from Amerisource to P & S Pharmacy throughout 2015, the June 2015 PCG report had little impact. It was not "fast tracked." Indeed, from July to December 2015, the volume of buprenorphine *actually increased* by almost 6,000 ODU<sub>s</sub>.<sup>305</sup>

<sup>303</sup> ABC-MSAGC00000652-59 (emphasis added).

<sup>304</sup> ABDCMDL00047170.

<sup>305</sup> ARCOS.



308. A spreadsheet titled “PCG Action” confirmed those 2015 figures in the “Issues and Comments” for P & S, which read “Highest purchaser of B3 [buprenorphine] in nation, HY [hydrocodone], BD, BN [benzodiazepine] purchaser in TN, OX [oxycodone] as well.”<sup>306</sup>

309. Under Follow Up, it read “7/15 – D[avid] M[ay] to review and determine action to be taken.” and “9/30-- elevate to discuss—RED FLAGS” was listed as Additional Follow Up.<sup>307</sup>

310. It still took until March 20, 2016, *nine months after the PCG report*, for Amerisource to send a letter to P & S that purported to terminate it as a customer. The letter stated in relevant part:

In the course of monitoring by members from our Corporate Security and Regulatory Affairs department (CSRA), circumstances were discovered that raise concerns regarding the controlled substances dispensed by P&S Pharmacy (Pharmacy) ... that may place both ABDC and Pharmacy at risk for regulatory action by state and/or federal agencies. **Accordingly, ABDC will suspend all sales of controlled substances to your account.** ABDC will, however, continue to service your account for non-controlled products.

Following a review of the controlled substance ordering activity for Pharmacy, we were troubled by the high ratio of controlled substances purchased versus non-controlled substances. We were also concerned with the fact that Pharmacy was one of the top purchasers of some of the more abused prescription drugs in the State of Tennessee, including Hydrocodone, Oxycodone, Alprazolam and

<sup>306</sup> ABDCMDL00161632.

<sup>307</sup> ABDCMDL00161632.

Buprenorphine. We recognize that Buprenorphine products are used in the treatment of drug addiction, but also are themselves subject to abuse when not used as part of a comprehensive medical treatment plan that is designed to free the patient from the opioid addiction.

Based upon those concerns, we contracted an outside consulting firm with DEA and regulatory compliance expertise who visited the pharmacy on June 30, 2015 and identified other potential indicators for diversion. Specifically, they reviewed a snapshot of dispensing data that revealed a very high percentage of cash as the form of payment for controlled substance prescriptions and exclusively cash for Buprenorphine prescriptions. It was also determined that you do not regularly utilize the Tennessee Prescription Drug Monitoring Program (PDMP) to screen patients who may be abusing prescription drugs. Further, by your own statements, you are concerned with at least two Family Practice Physicians who appear to be primarily involved with pain treatment yet you continue to services them.

Following the visit by the Pharma Compliance associate, we continued to monitor you purchasing activity for a period of time. **Unfortunately a recent review of your account did not reveal any changes** and formed the basis of ABDC's decision not to allow the continued sale of controlled substances to Pharmacy.<sup>308</sup>

311. Aside from being way too late in the process, Amerisource's termination letter suffered from another fundamental problem—*it was not true*.

312. P & S continued ordering its opioids as usual, including the buprenorphine flagged in the PCG report after the letter, and Amerisource continued shipping P & S opioids, including buprenorphine. Between March 25, 2016, the termination date identified in the March 17, 2016 letter, and April 20, 2016, the date of the next letter Amerisource sent to P & S, Amerisource shipped at least *62 buprenorphine orders, 48 oxycodone orders, 33 hydrocodone orders, 8 fentanyl patch orders, and 11 morphine orders*.<sup>309</sup> The 23 orders for Buprenorphine 8 that Amerisource shipped along with the quantities shipped are shown below.

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<sup>308</sup> ABC-MSAGC00026074 (emphasis in original).

<sup>309</sup> ABC-MSAGC00002012; *see also*, ABDCMDL00252011 (showing invoices are smaller subset of orders placed).

Order Number	Item Description Abbreviated	Unit-Str-	Unit-Str-Typ-Cd	Item Form	Item Size	Item NDC	Invoice/Credit Date	Qty Ship	Plant Name	Product Supplier Name	OMP Family Code Description	Account Name	Account Address	Account City	Account State Key	Account Zip Code
1	BUPRENORPHINE	8	MG	TABLET	30	00054017713	3/26/2016	20	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
2	BUPRENORPHINE	8	MG	TABLET	30	00054017713	3/28/2016	30	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
3	BUPRENORPHINE	8	MG	TABLET	30	00054017713	3/29/2016	10	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
4	BUPRENORPHINE	2	MG	TABLET	30	00228315603	3/30/2016	2	ABC DC PELHAM	ACTAVIS PHARMA INC/GENERIC	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
5	BUPRENORPHINE	8	MG	TABLET	30	00054017713	3/30/2016	30	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
6	BUPRENORPHINE	8	MG	TABLET	30	00054017713	3/31/2016	20	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
7	BUPRENORPHINE	8	MG	TABLET	30	00054017713	4/1/2016	10	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
8	BUPRENORPHINE	8	MG	TABLET	30	00054017713	4/2/2016	20	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
9	BUPRENORPHINE	8	MG	TABLET	30	00054017713	4/4/2016	10	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
10	BUPRENORPHINE	8	MG	TABLET	30	00054017713	4/5/2016	20	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
11	BUPRENORPHINE	8	MG	TABLET	30	00054017713	4/6/2016	25	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
12	BUPRENORPHINE	8	MG	TABLET	30	00054017713	4/7/2016	20	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
13	BUPRENORPHINE	8	MG	TABLET	30	00054017713	4/8/2016	10	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
14	BUPRENORPHINE	8	MG	TABLET	30	00054017713	4/9/2016	20	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
15	BUPRENORPHINE	8	MG	TABLET	30	00054017713	4/11/2016	20	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
16	BUPRENORPHINE	8	MG	TABLET	30	00054017713	4/12/2016	10	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
17	BUPRENORPHINE	8	MG	TABLET	30	00054017713	4/13/2016	20	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
18	BUPRENORPHINE	8	MG	TABLET	30	00054017713	4/14/2016	20	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
19	BUPRENORPHINE	8	MG	TABLET	30	00054017713	4/15/2016	10	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
20	BUPRENORPHINE	8	MG	TABLET	30	00054017713	4/16/2016	10	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
21	BUPRENORPHINE	8	MG	TABLET	30	00054017713	4/18/2016	20	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
22	BUPRENORPHINE	8	MG	TABLET	30	00054017713	4/19/2016	20	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497
23	BUPRENORPHINE	8	MG	TABLET	30	00054017713	4/20/2016	20	ABC DC PELHAM	ROXANE LABS MULTISOURCE (PGN)	BUPRENORPHINE SOLID	P AND S PHARMACY	613 WATAUGA ST	KINGSPORT	US/TN	37660-4497

313. Amerisource did not even exercise greater scrutiny of P & S Pharmacy’s orders after sending the two letters to P & S. Only one of P & S’s 41 orders was flagged, and even it was released in April 2016 and not reported to the DEA.<sup>310</sup>

314. Amerisource’s March 17, 2016 termination letter was window dressing to protect itself; the Company never intended to cut off such a lucrative customer. And it was a microcosm of Amerisource’s compliance approach: Paper the file, but keep on shipping opioids.

315. As testament to its compliance window dressing, on April 20, 2016, Amerisource sent PIC Grizzle a letter that conveyed what it had been doing in practice anyway, namely continuing to do business with P & S and supply it with controlled substances. The letter stated (shown in gray below):

Per our previous termination letter for the sale of controlled substances from ABC, dated March 17, 2016, and our subsequent discussions, it was agreed that the CSRA Diversion Control team would provide some suggested best practices that you and your pharmacy associates could implement to decrease the risk of controlled

<sup>310</sup> ABDCMDL00252012.



substance drug diversion from P & S Pharmacy. Assuming you continue to work with us in this manner to address our concerns, we will continue the sale of controlled substances to your pharmacy.

*P & S Pharmacy is one of the largest ABDC purchasers in Tennessee of several highly abused and diverted controlled substance drug families (e.g. hydrocodone, oxycodone, alprazolam and buprenorphine). It is important to understand that the Controlled Substances Act and DEA regulations have placed significant responsibilities on retail pharmacists to determine that any controlled substance prescription is prescribed for a legitimate medical purpose. ....*

All of these questions [regarding how to determine whether a prescription was written for a legitimate medical need] are especially important when, for example, a family practice physician is prescribing large quantities of opioid drugs for a young healthy appearing patient.

....

**RED Flags**

*Several DEA “red flags” were noted around the dispensing report of controlled substances that was received from P & S pharmacy. ...*

*There were a very high percentage of patients paying cash for their controlled substance prescriptions, especially buprenorphine prescriptions. ....*

During the visit to your pharmacy by the PharmaCompliance Group, you intimated that the TN PMP was not utilized as part of the pharmacy’s routine dispensing process. Further communication this fall noted that the pharmacy was going to begin checking PMP.<sup>311</sup>

316. In total, Amerisource identified five highly problematic red flags: high percentage of cash paying patients, doctor shopping patients, prescriptions for excessive doses and/or quantities of doses of controlled substance drugs, trinity combinations (highly diverted, often lethal combination of at least one opioid, a benzodiazepine, and carisoprodol), and immediate release opioid drugs without a long acting opioid for chronic pain treatment. The letter also explained the use of buprenorphine as part of an opioid addiction program but cautioned that Buprenorphine 8 is primarily utilized for initiating therapy and should only be dosed twice a day.<sup>312</sup>

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<sup>311</sup> ABDCMDL00158938–41 (emphasis added).

<sup>312</sup> ABDCMDL00158938–41.

317. An email sent to PIC Grizzle from Amerisource’s CSRA on April 25, 2016 reads in relevant part: “Per your discussions with Dave May, Senior Director CSRA, we have put together some resources and suggestions for you to incorporate into your pharmacy’s processes for dispensing controlled substances to mitigate diversion and abuse.”<sup>313</sup>

318. In 2015, Amerisource flagged 173 of P & S Pharmacy’s orders as ones of interest, all of which were for buprenorphine and 144 were for the highest dose strengths available.<sup>314</sup> Strikingly, Amerisource *did not report a single P & S order to the DEA that year*—despite the abundant evidence of diversion and abuse.

319. In contrast, Amerisource identified 481 of P & S Pharmacy’s orders as ones of interest (slightly under half were for buprenorphine) and reported 38 (17 were buprenorphine) to the DEA in 2014.

320. In an April 28, 2016 presentation to its Advisory Committee on the Diversion Control Program, Amerisource used P & S as a case study for Continuous Customer Due Diligence and a model for its “Rehabilitation Effort.” The slide read:<sup>315</sup>

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<sup>313</sup> ABDCMDL00158937.

<sup>314</sup> ABC-MSAGC00001967.

<sup>315</sup> ABDCMDL00275015.

**Case Studies**  
P & S Pharmacy, Kingsport TN

- High Percentage of Controls to Non-Controls
- Top Purchaser of Buprenorphine (in the U.S.), Hydrocodone, Oxycodone and Benzodiazine
- Comprehensive Site Visit by Outside Contractor
  - > Numerous visual warning signs
- Warning Signs also noted by Sales
- Dispensing Data Evaluation
- Directed Communications with PIC Owner
- Rehabilitation Effort



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321. Yet Amerisource knew that red flags for diversion persisted at P & S and kept supplying it opioids. In 2017, its percentage of controlled substance prescriptions was still at 60% and cash sales remained a primary concern.<sup>316</sup>

322. Problems continued in 2018. An internal email sent on March 9, 2018 summarized orders that were reported to the DEA that week and stated among other things that, despite all of the numerous documented red flags, there was *still* no due diligence on file and the pharmacy was *still* ordering large amounts of opioids, benzodiazepines, and muscle relaxers:<sup>317</sup>

- **P AND S PHARMACY, [REDACTED], Atlanta (039) – AL, 8,000 DU, 3/2**
  - No LT matter found in NetDocs; Two MMS matters: RX165158 and RX175111
  - No due diligence on file
  - OMP Size at 0D04; 275K DU per month; CS usage at 37%
  - BD ranked #1 at 20% (AL is 2<sup>nd</sup>, 15%)
  - *Comments added by A047223 (Carol) - AL is @ 23,540 DU, avg monthly usage is 15,887, 48% increase in normal usage & 8,000 DU for this order is not consistent w/ their normal ordering; #1 in zip for AL & # 8 in state of TN; 37.4% Rx DU = CS, 590 & photos on file from May 2007.*

<sup>316</sup> ABC-MSAGC00026112 (emphasis added).

<sup>317</sup> ABDCMDL00158155 (TNAG redaction for DEA number).

323. In 2018, the DEA and Board of Pharmacy both brought enforcement actions against Mr. Grizzle and his pharmacy. In 2018, Lowell Grizzle paid \$100,000 in civil penalties to settle DEA allegations that he violated the CSA following a DEA audit in November 2014.<sup>318</sup>

324. In the same year, P & S was disciplined by the Tennessee Board of Pharmacy which alleged, in an Order agreed to by P & S, that in 2014:

- [P & S] routinely dispensed large quantities of controlled substances in a manner not consistent with applicable statutes and regulations[;]
- Many of the prescriptions dispensed by [P & S] lacked therapeutic value for the patients[;]
- Many of the customers were receiving the same combination of prescriptions and receiving the same strength of controlled substances[;]
- An audit revealed that numerous individuals were driving long distances to the pharmacy[;]
- Investigation revealed that many prescriptions had the incorrect prescriber, incorrect patient and incorrect labeling on vials. Incomplete information occurred on transferred prescriptions and [P & S] was accepting post-dated prescriptions and receiving constant requests for early refills[;]
- [P & S's] staff failed to check the Controlled Substance Monitoring Data Base. Pharmacy technicians and relief pharmacists were accessing the CSMD with the PIC's log in. many of [P & S'] patients were cash only patients[;]
- [P & S] permitted a pharmacy technician to be in possession of pharmacy keys[; and]
- Investigation also revealed that the pharmacists on duty failed to provide patient counseling for new and refill prescriptions.<sup>319</sup>

325. In August 2018, a Pharma Compliance Group consultant met with PIC Grizzle and submitted another report to Amerisource.<sup>320</sup> The PCG consultant gave P & S an Amerisource “Business Associate Agreement” to sign. Among other things, the report stated (shown in gray below):

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<sup>318</sup> <https://www.timesnews.net/Law-Enforcement/2018/04/27/Kingsport-Pharmacist-pays-100-000-in-civil-penalties>.

<sup>319</sup> <https://apps.health.tn.gov/FacilityListings/Home/ViewPDF/173>.

<sup>320</sup> ABC-MSAGC00028867.

PIC Grizzle never mention [sic] the other Consent Agreement that he entered into with the Tennessee BOP for having a Pharmacy Technician working at P & S Pharmacy without a current license. ....

[PCG Consultant] requested a copy of P&S Pharmacy controlled substances dispensing Standard Operation Procedures (SOP). PIC Grizzle informed that he does not have a written policy; however, PIC Grizzle related that everyone knows what they should do before filling a prescription. [PCG Consultant] requested PIC Grizzle provide him a copy of P&S Pharmacy SOP for dispensing controlled substances. On 8/8/2018 PIC Grizzle e-mailed [PCG Consultant] the final version of the P & S Pharmacy SOP for Dispensing Controlled Substances. ... PIC Grizzle stated he had set a limit of 120 Dosage Units on all controlled substances. However, a review of P&S Pharmacy 90 day dispensing history sent to [PCG Consultant] revealed that some patients receive 180 DU of opioids. ....

PIC Grizzle further stated that 90% of his customers are walk-in[.] ....

On 7/30/2018 PIC Grizzle provided the following list of his Top Five Prescribers of controlled substances ... however, it was not based on the number of dosage units of controlled substances filled but on the number of the prescription [sic] that the practitioner writes. The majority of prescriptions were for Subutex, Suboxone (Schedule III) and Clonazepam (Schedule IV)[.] ....

[PCG Consultant] reviewed the information provided before the on-site visit included several suspicious prescriptions filled for hydrocodone (Schedule II) and alprazolam (Schedule IV) controlled substances to the same patient on the same day. One patient had three prescriptions filled hydrocodone, oxycodone, and oxycontin (Schedule II) controlled substances on the same day. ....

P&S Pharmacy staff could not produce from the computer system Controlled Substances Dispensing Log which is required Title 21 CFR 1304.22(2)(D)(c).

Ultimately, PCG concluded that P & S's "Due diligence was found acceptable[.]"<sup>321</sup>

326. On August 21, 2018, Amerisource's CSRA created a dispensing report about P & S, which stated, among other things:<sup>322</sup>

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<sup>321</sup> ABC-MSAGC00028873.

<sup>322</sup> ABC-MSAGC00028786.

### General

- Overall controlled substance rates of 24% by dosage unit and 32% by prescription
- 60% of all controlled substances filled were for opioids (rate of 19% versus their total Rx)
- Prescriptions paid for in cash accounted for 49% of those filled
- *Rate of 77% for controlled substance prescriptions*
- 69% of all controlled substances prescriptions filled were for benzodiazepine anxiety solids and buprenorphine solids (single ingredient and combination)
- *54% of all oxycodone solids (OX) were for immediate release strengths of 5/10/15/20 milligrams*
- Notable disparity between the number of dosage units purchased and dispensed during roughly the same time, especially as it concerns non-controlled substances

### Patients

*All prescriptions considered*

- 195 of the pharmacy's patients receiving controlled substances (nearly 13% of that relative patient base) received at least 1 prescription for an opioid and no other drug or prescription
- 72 of these patients received at least 1 prescription for buprenorphine solids (B3) and no other drug or prescription
  - *70 of these patients only received 8 mg strengths*
- 58 patients received at least 1 prescription for oxycodone solids and/or hydrocodone solids (OX/OY/HT and/or HY) and no other drug
- 19 of these patients at least 1 prescription for oxycodone solids (OX and/or OY)
- 38 of these patients at least 1 prescription for hydrocodone solids (HT and/or HY)

327. But Amerisource still kept P & S as a customer following the 2018 PCG report and the same problems have continued unabated. Between February 1, 2019 and April 30, 2019, P & S had 764 prescriptions for buprenorphine alone.<sup>323</sup> And to complete the circle, one of Amerisource's Diversion Control Investigators stated on June 4, 2019:

Cash for nearly all [controlled substance prescriptions] is extremely high[; and]

The major issue I'm seeing with this one *is the disproportionate amount of buprenorphine 8mg mono product being dispensed*, especially in a state where there are clear guidelines surrounding this product.<sup>324</sup>

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<sup>323</sup> ABC-MSAGC00028798.

<sup>324</sup> ABC-MSAGC00028793.

*ii. Blankenship Pharmacy*

328. Boone Drugs, Inc. is a company which runs two sister pharmacies in northeast Tennessee. The first is Blankenship Pharmacy, located in Johnson City, and the other is Brookside Discount Pharmacy, which is located in Kingsport, about ten minutes away from P & S Pharmacy.

329. Amerisource continued to ship buprenorphine and other opioids to Blankenship Pharmacy despite knowing:

- that “dozens” of Blankenship patients were receiving a combination of a benzodiazepine (i.e., Valium) along with buprenorphine monoprodukt;<sup>325</sup>
- the concerns that Teva, a manufacturer of buprenorphine monoprodukt, had concerning Blankenship, which was the largest retail purchaser of Teva’s buprenorphine monoprodukt in the country;<sup>326</sup>
- that the pharmacy’s buprenorphine orders had increased 4,954% from 2006 to 2014;<sup>327</sup>
- that an extremely high percentage of its net sales were from opioids and other controlled substances;<sup>328</sup>
- that most of Blankenship’s customers paid cash for buprenorphine and benzodiazepine prescriptions;<sup>329</sup> and
- about the pharmacy’s lack of orders for lower strength doses of buprenorphine monoprodukt.

330. In 2006, Amerisource shipped this small, independent pharmacy 6,630 doses of buprenorphine, 41,300 doses of hydrocodone, and a variety of other opioids.<sup>330</sup> That same year, Qualitest Pharmaceuticals shipped 228,000 doses of hydrocodone that same pharmacy and nothing else.<sup>331</sup> As it did with other customers, Amerisource ignored problematic red flags at Blankenship, such as purchasing controlled substances from multiple distributors.

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<sup>325</sup> ABC-MSAGC00024487.

<sup>326</sup> ABC-MSAGC00024490-91.

<sup>327</sup> ARCOS.

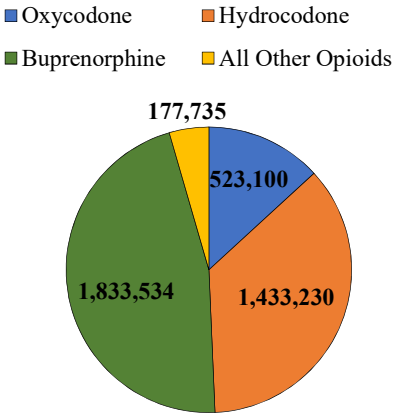
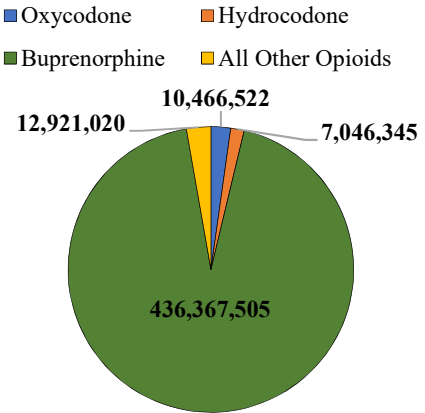
<sup>328</sup> ABCDCMDL00290426 (60.8% as of February 5, 2015); ABC-MSAGC00024488 (showing 36% between Jan. 2, 2019 and Mar. 30, 2019).

<sup>329</sup> ABC-MSAGC00000516; ABC-MSAGC00024488.

<sup>330</sup> ARCOS.

<sup>331</sup> ARCOS.

331. Out of all the pharmacies in Tennessee, Blankenship Pharmacy had the third highest MME overall. Strikingly though, it did not even rank in the top twenty for the state for ODU, which means that the potency of the opioids being dispensed by Blankenship Pharmacy was incredibly high. Blankenship’s overwhelming opioid of choice was buprenorphine, as shown below:

<b>City:</b> Johnson City (pop. appx. 63,152)		<b>County:</b> Washington	
<b>ODUs:</b> 3,967,599		<b>MMEs:</b> 466,801,391	
<b>State Rank:</b> Not in the top 20	<b>ABC Rank:</b> Not in the top 20	<b>State Rank:</b> 3rd	<b>ABC Rank:</b> 3rd
<b>Years as ABC Customer:</b> 2004 to Present		<b>Distribution Center(s):</b> Birmingham; Paducah	
<p style="text-align: center;">2006-2014 ODUs</p>  <p>■ Oxycodone    ■ Hydrocodone ■ Buprenorphine    ■ All Other Opioids</p>		<p style="text-align: center;">2006-2014 MMEs</p>  <p>■ Oxycodone    ■ Hydrocodone ■ Buprenorphine    ■ All Other Opioids</p>	

332. In terms of dollar value, Blankenship Pharmacy was also among Amerisource’s top Tennessee pharmacy customers in 2011 (4th), 2012 (2nd), 2013 (1st), 2014 (2nd), 2015 (2nd), 2016 (3rd), and 2017 (9th).

333. In 2006, Amerisource shipped Blankenship Pharmacy 6,630 doses of buprenorphine. By 2014, in just three years, that number had jumped a *staggering* 4,954% to 335,082 dosage units of buprenorphine.<sup>332</sup>

<sup>332</sup> ARCOS.



334. In October of that year, Amerisource shipped Blankenship 81,055 ODU, almost double what Amerisource had shipped in the previous months.<sup>333</sup> Out of the 1,872 orders placed by Blankenship Pharmacy in 2011, Amerisource reported only three orders (for a total of 990 Suboxone doses in June 2011) as suspicious to the DEA.<sup>334</sup> That same year, Blankenship received over half a million ODUs from Amerisource, approximately 53% of which was buprenorphine.<sup>335</sup>

335. As of February 5, 2015, 60.8% of Amerisource's net sales to Blankenship Pharmacy were for controlled substances—31.3% was buprenorphine, benzodiazepines were 26.4%, and 12.2% were buprenorphine patches.<sup>336</sup>

336. Amerisource's CSRA circulated these figures to Mat Miller, the Amerisource sales representative assigned to Blankenship Pharmacy, in preparation for the PCG audit that Amerisource had requested.

337. PCG Compliance Investigator Edward Sullivan, along with Mr. Miller, conducted the due diligence inspection of Blankenship Pharmacy a week later in February 2015. The pharmacy had already "been reviewed several times by ABC Regulatory affairs due to their increased purchases of Buprenorphine."<sup>337</sup> The PCG report, which Amerisource received, stated in relevant part (shown in gray below):

This Pharmacy has been reviewed several times by ABC Regulatory affairs due to their increased purchases of Buprenorphine. PIC Cobb was asked by ABC to provide support and documentation for its Due Diligence files by standardizing its safeguards for Blankenship Pharmacy as well as the entire Boone Drugs, Inc. pharmacy chain (17) affiliates. Investigator Sullivan spoke about educational needs by the pharmacists, in their continuing education, to include a large concentration on addiction programs.

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<sup>333</sup> ARCOS.

<sup>334</sup> ABC-MSAGC00000472.

<sup>335</sup> ARCOS.

<sup>336</sup> ABDCMDL00290426.

<sup>337</sup> ABC-MSAGC00000516.

**OBSERVATION #1:**

The top controlled substances dispensed and ordered at Blankenship Pharmacy are; buprenorphine solid, benzodiazepine, buprenorphine patch and hydrocodone. There are currently 51 DEA-waived certified prescribers within a thirty mile radius of this pharmacy. The pharmacy appears to have many safeguards in place *if* they follow the guidelines set forth in their SOP for dispensing buprenorphine products. *One area of concern is cash transactions for Buprenorphine transactions* that occur in general and not just in this pharmacy. The use of cash allows an easy way of obtaining this medication and eliminating the insurance paper trail. The top ten dispensing physicians are all data waived... Four of the ten have had adverse disciplinary action taken against their licenses.

338. Several of those buprenorphine prescribers whose prescriptions were filled at Blankenship specialized in family medicine or were general internists, as opposed to addiction specialists.

339. The 2015 PCG report continued:

*Drug diversion/redistribution of Subutex and Alprazolam is an area of concern, especially when patients are paying cash.* Similar to other opiates that are abused, buprenorphine is capable of producing significant euphoria. Brookside Pharmacy has implemented, and will continue to follow, the established SOP for products containing Buprenorphine. This procedure was written by the [pharmacist] from Blankenship Pharmacy *January 15, 2015.*<sup>338</sup>

340. From the report, Amerisource knew that the pharmacy's procedure for dispensing buprenorphine was not written until *one month* prior to the PCG visit.

341. The PCG report's second observation was that Blankenship Pharmacy had not properly maintained documentation of Schedule II controlled substances received from Amerisource, or any other distributors, in violation of 21 C.F.R. §§ 1305.22(g) and .27.<sup>339</sup>

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<sup>338</sup> ABC-MSAGC000000517 (emphasis added).

<sup>339</sup> ABC-MSAGC000000517-18.

342. Amerisource continued to gather information on the owner, Boone Drugs, and Blankenship Pharmacy. For example, a 2015 spreadsheet titled “PCG Action” contained three columns re-created below (but stated verbatim):<sup>340</sup>

Issue and Comments	Follow Up	Additional Follow Up
Support Drug Addiction Facilities with high ratio of buprenorphine (42% of CS)	Dispensing report reviewed, letter f/u Cherveney -maintain close relationship w/DEA data waived MD, <i>high cash – ensure legitimate. Access to Kasper for KY Patients</i> Letter sent 6/12	<i>Letter 6/12 did not terminate but expressed “red flags”.</i> Continue to monitor.

343. For 2015, neither of Boone Drugs’ two pharmacies bothered purchasing the lower dose strength of the buprenorphine monoprodukt—it was all the strongest dose available. Furthermore, this Buprenorphine 8 made up 86% of all the buprenorphine Boone Drugs’ two pharmacies purchased that year.

344. In early February 2016, Mike Dailey, the Amerisource sales executive now assigned to Blankenship Pharmacy, forwarded several questions from CSRA to the Blankenship pharmacist for him to answer:<sup>341</sup>

I’ve reviewed the 590 form for this customer and found that the following points require more information/clarification. Once received, we can move forward with the review process.

Question 5 – Why are the owners located in North Carolina?

Question 13 – Please provide the percentage of prescriptions that are controlled substances.

Question 14 – The expected percentage of controlled substances is fairly high (30%). Why is that? What type of patients does this pharmacy service? What type of area is this pharmacy located in? Do they service hospitals, clinic, etc.? If so, please provide the names.

Question 15B – Discipline was found in regards to John Powell. Could you please provide the specifics of this discipline? Is the pharmacy aware of this? Does the pharmacy perform their own due diligence into prescribers they fill for? Does the pharmacy have policy and procedure when it comes to verifying prescribers?

Photos – Please provide a photo of the back door (exterior), if available.

<sup>340</sup> ABDCMDL00161633 (emphasis added).

<sup>341</sup> ABC-MSAGC00024469.

345. The Blankenship pharmacist's answers provided to Amerisource were less than fulsome:<sup>342</sup>

Question 5 We are owned by Boone Drug, Incorporated, which is based in Boone, NC.  
Question 13 30%  
Question 14 There are more than 60 physicians in the Johnson City area with "X" DEA numbers who routinely prescribe Buprenorphine containing medications. There are also some 10 MAT ("Suboxone") Clinics. We were the first pharmacy in the area to offer these medications and have, therefore, developed close relationships with the physicians, Clinics and staffs. The percentage of controlled drugs we dispense is a natural result. I am confident that if the Buprenorphine medications and associated routine prescriptions for Benzodiazepines were removed from the total, our controlled drug percentage would be comparable to most other retail pharmacies you serve.  
Question 15 John Powell, PA, is a full-time employee of Pain Management Associates in Johnson City. There are 3 supervising physicians at the practice. Each prescription we fill with Mr. Powell as the prescriber contains a notation, placed on the prescription at the time it is written, indicating the supervising physician.

I hope this response adequately addresses your request as well as any concerns which might exist.

346. In particular, the Blankenship pharmacist failed to address what PA John Powell was disciplined for, whether the pharmacy was aware at the time, whether the pharmacy performed due diligence into providers whose prescriptions they filled, and whether the pharmacy had policies and procedures to verify prescribers. Amerisource seemed satisfied, nonetheless.

347. On February 29, 2016, an Amerisource Pharmacy Solutions Specialist sent the following email, copying OMP employees for every distribution center, regarding "Blankenship Control Order." This email again shows how Amerisource's compliance department was pressured to ship more controlled substances more quickly:

All,

*I just received a call from Wayne again concerning their Clonazepam [a benzodiazepine] order. They have attempted to order Clonazepam since Wednesday of last week and not received anything. Their quantity has not increased, they have complied with every request, and this is continuing to happen. It has become a critical situation, where they are in danger of losing business from the lack of delivery. Emily has suggested I complete a consumption review, which I will be happy to do tomorrow, but there is something that we need to do asap in*

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<sup>342</sup> ABC-MSAGC00024469.

*order to slow the disruptions of their business.* I am asking for any help regarding this issue. Thank you in advance.<sup>343</sup>

348. A CSRA investigator emailed the Amerisource salesperson back to inform her that “[a]n order just hit for clonazepam, was evaluated and released. Any adjustments made to this drug family may/may not be made as a result of the consumption review.”<sup>344</sup>

349. Amerisource’s Sharon Hartman, the CSRA Director of Pharmacy Compliance and Diversion Control, emailed the Diversion Control Coordinator for CSRA:

Appears that [the Corporate Investigator] took care of the immediate need for [the benzodiazepine] drug family for Blankenship pharmacy in TN last night.

Have you seen anything come across for this account on [the benzodiazepine] drug family (consumption review)? This is the second e-mail concerning this account with this drug family where it hit OMP and rejected. At that time it was noted that the account was actually purchasing fewer products in that family. Please check .. there must be some reason that there is an issue (smaller pharmacy – maybe peer group) as there hadn’t been a change in their purchasing pattern... if warranted-consider updating the [benzodiazepine] drug family to a calculated override for this account.<sup>345</sup>

350. The Diversion Control Coordinator messaged Ms. Hartman back:

I have had a couple conversation [sic] with the SE [sales executive] on this account regarding this issue. I have instructed them multiple time [sic] to submit a consumption review but I have yet to receive anything.

Once the review comes through the HUB, I will process it immediately and set them up accordingly.<sup>346</sup>

351. However, Ms. Hartman continued to push back:

There is a consistent purchasing of this product for this customer.. In fact [benzodiazepine] has actually decreased over the last 6 months. Please consider adjusting [benzodiazepine] to the calculated override here of **9,533**.

This pharmacy’s primary patients are in opioid addiction programs as demonstrated by the tear sheet below which illustrates [buprenorphine] being their primary CS

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<sup>343</sup> ABC-MSAGC00024482–83 (emphasis added).

<sup>344</sup> ABC-MSAGC00024482.

<sup>345</sup> ABC-MSAGC00024481.

<sup>346</sup> ABC-MSAGC00024480–81.

purchases. Was have previous Dispensing reports from this pharmacy that are save [sic] in lawtrac.<sup>347</sup>

352. The Diversion Control Coordinator replied to Ms. Hartman, and included David May and Eric Cherveney:<sup>348</sup>

Good morning Sharon,

I received a meeting request this morning from Carla Morris (Director) and Jennifer Keaton (SE). They want to have a conversation again in regards to this account. According to them, the customer is very displeased with having orders held and rejected. Since I set their TRD override (9533), they have had only one order rejected on 3/9. All orders after that were held for review and approved by CSRA. FTI is now showing the Calc Override for this family to be 10,083. Should we bump up their calculated override one more time? I've tried explaining our program a couple times to them but I feel as though they are reluctant to listen and are looking for us to take action. Please let me know what suggestions you may have.

353. Of course, Amerisource's final answer, as emailed from Ms. Hartman was to increase the Blankenship monthly threshold override again:<sup>349</sup>

**Subject:** RE: Blankenship Control Order

Yes, please bump it up again. Their physicians are using clonazepam for anxiety related to withdrawal/addiction control with the buprenorphine/naloxone which make up the bulk of their patient population.

I would not take this same approach with BD drug family but suggest that we do for the BN.

If you would like me to participate in this discussion with the SE, please forward the invite. Thanks

354. However, issues with Blankenship Pharmacy's opioid dispensing only continued, and while Amerisource had knowledge of these red flags, it failed to take appropriate action.

355. At the end of August 2017, Joe Tomkiewicz, who now worked at Teva (the current owner of Actavis) as a DEA Compliance Manager, emailed his former colleagues at Amerisource,

<sup>347</sup> ABC-MSAGC00024479 (emphasis in original).

<sup>348</sup> ABC-MSAGC00024477.

<sup>349</sup> ABC-MSAGC00024477.

Eric Cherveney and David May, regarding his concerns about Blankenship Pharmacy’s suspicious consumption of Teva’s buprenorphine. He stated:<sup>350</sup>


**Subject:** End Customer Inquiries

Eric,

We’ve identified a handful of ABC customers where we have some questions on what appears to be their purchases of Teva/Actavis products. I’ve attached End Customer Inquiry forms for each of them where we need to document the justification for the areas of concern that we’ve noted.

Let me know if you have any questions or concerns.

Thanks,

 Joseph Tomkiewicz Manager DEA Compliance

356. One of the pharmacies Teva identified its concerns about to Amerisource was Blankenship Pharmacy, which it noted had ordered 45,300 doses of Buprenorphine 8 in just three months. Teva’s Areas of Concern read:<sup>351</sup>

**Areas of Concern**

For the time period 5/1/2017 though 7/31/2017, Blankenship Pharmacy appears to be the largest recipient of Teva/Actavis of buprenorphine (without naloxone) in the United States.

Because of the expected typical uses of single ingredient buprenorphine (e.g., the treatment of opioid addiction in pregnant women), we would expect quantities to be limited in a retail pharmacy setting.

Please provide each prescriber's DATA 2000 Waiver Identification Number in addition to their DEA registration numbers.

357. Eric Cherveney crafted a “standardized response,” since they anticipated “receiving many more of these kinds of expanded customer inquiries.” It reads:<sup>352</sup>

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<sup>350</sup> ABDCMDL00144257.  
<sup>351</sup> ABDCMDL00144262.  
<sup>352</sup> ABDCMDL00144256.

Good afternoon Joe.

Please see attached response to your customer inquiry. Please note that AmerisourceBergen Corporation (ABC) will not provide customer dosage unit sales data, prescriber information or the additional information you're requesting to outside parties, as all of this information is considered proprietary. However, ABC does provide certain high level customer information, as indicated per our response. If Teva Pharmaceuticals (Teva) feels additional information is necessary as part of your due diligence responsibilities, we suggest that you obtain that information directly from the end customer. We hope the information provided is of use. ABC is committed to meeting applicable regulatory guidance and protecting the integrity of our country's pharmaceutical supply chain. We appreciate Teva's partnership in complying with all federal and state regulatory requirements related to diversion control.

Please feel free to contact me if you have any questions regarding the information provided. Thank you.

358. Amerisource brushed aside Teva's request for documentation about this known problem pharmacy. Amerisource's proposed "high level customer information" for Blankenship was the following:<sup>353</sup>

Blankenship Pharmacy  
ABC has a current file on this customer and monitors all purchase activity. No diversion related concerns at this time.

359. In the end, Amerisource decided against providing a written response to Teva in favor of trying to have a face-to-face conversation about Blankenship.<sup>354</sup>

360. Regardless of whether there was a face-to-face meeting, Amerisource still continued shipping controlled substances, especially buprenorphine and benzodiazepines, to Blankenship.

361. An Amerisource analysis from the beginning of October 2018 shows a large part of the reason why Amerisource may have been hesitant to terminate Blankenship Pharmacy as a customer—Suboxone was 61.3% of the sales dollar volume and buprenorphine was second at 27.7%.<sup>355</sup>

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<sup>353</sup> ABDCMDL00144256.

<sup>354</sup> ABDCMDL00157021.

<sup>355</sup> ABC-MSAGC00024493.



362. On March 26, 2019, Joe Tomkiewicz, who now worked at Teva as a DEA Compliance Manager, emailed his former colleagues at Amerisource, Eric Cherveney and David May, regarding his concerns about Blankenship Pharmacy's suspicious consumption of Teva's buprenorphine. Mr. Tomkiewicz stated:

Subject: Blankenship Pharmacy

CAUTION: This email originated from outside of the organization. DO NOT CLICK links or open attachments unless you recognize the sender and know the content is safe.

Eric & Dave,

We see an ABC customer in Tennessee, Blankenship Pharmacy (BB8923004), which according to the recently released ARCOS data for Aug 18 through Jan 19, appears to have purchased a total of 63,810 dosage units of buprenorphine, of which, it appears that 51,810 dosage units have been Teva buprenorphine 8mg (00228-3153-03), which does not contain naloxone. Note that for the time period Aug 18 through Jan 19, this pharmacy appears to have been the largest retail purchaser of 00228-3153-03 in the US.

363. Mr. Tomkiewicz then quoted Tennessee law, and warned that:

According to Tennessee Code §53-11-311 (b)(1)—

Any prescription for buprenorphine mono or for buprenorphine without use of naloxone for the treatment of substance use disorder shall only be permitted to a patient who is:

- (A) Pregnant;
- (B) A nursing mother; or
- (C) Has a documented history of an adverse reaction or hypersensitivity to naloxone.

We can find no information demonstrating that this retail pharmacy is specializing in treating pregnant women or nursing mothers, nor can we find any relationship with any medical practice that appears to specialize in treating pregnant women or nursing mothers. Do you have any information you can share that would support the quantity of buprenorphine 8mg (00228-3153-03) that this pharmacy has been purchasing?

Best regards,



Joseph Tomkiewicz  
Manager DEA Compliance

364. Amerisource’s Eric Cherveney and David May asked a CSRA investigator to “do a quick review of this customer, and drill down on their B3 [buprenorphine tablet] family[.]”<sup>356</sup>

365. A few hours later, Mr. May emailed Mr. Cherveney and Mr. May back regarding the Blankenship buprenorphine issue:<sup>357</sup>

Subject: RE: Blankenship Pharmacy

I am familiar with this pharmacy from prior reviews. We will have to engage the pharmacy on the B3 issue – do you want to pass off to Debbie? DM

366. But Mr. Cherveney preferred to wait, despite years of red flags known to Amerisource. He stated:<sup>358</sup>

Subject: RE: Blankenship Pharmacy

I’d like to see what we have in file first. If we need to order a 90 day dispensing, I’d prefer we do that initially, and get it analyzed. Once that comes in, we can move forward accordingly.

Emily, do we have a recent dispensing for this customer? EC

367. Amerisource’s CSRA analysis of the dispensing data was circulated internally on April 17, 2019.

368. Unsurprisingly, an Amerisource Diversion Control Inspector emailed Mr. Cherveney and Mr. May to report that:

Good Morning All,

The dispensing data for Blankenship Pharmacy was recently received. There are dozens of patients receiving a combination of a benzodiazepine along with buprenorphine. Additionally, 61% of the total buprenorphine dispensed is the 8mg mono product which seems unusual due to the laws regarding this product in Tennessee.

Moreover, the Inspector reported that Blankenship was again using additional, secondary distributors to purchase many more controlled substances:

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<sup>356</sup> ABC-MSAGC00024490.

<sup>357</sup> ABC-MSAGC00024489.

<sup>358</sup> ABC-MSAGC00024489.

Purchasing:

I was locked out of ARCOS at the time of the review, but their purchasing through ABDC is less than 50% of what they are actually dispensing for multiple drug families.

369. Amerisource had knowledge of numerous other red flags from the Blankenship dispensing review, such as 54% of total controlled substance prescriptions were paid for in cash (for buprenorphine prescriptions, 63% were paid for in cash), and 36% of the prescriptions dispensed were for controlled substances, most of which were for buprenorphine:<sup>359</sup>

Dispensing Review (1/2/2019 – 3/30/2019):

- 5,913 total Rx's (Avg. 1,971/month)
- 36% controls by Rx
- 24% controls by DU
- 46% of CS DU's are Buprenorphine (Avg. 11,974 DU's/Month)
  - 61% - Buprenorphine 8mg mono product
- 28% of CS DU's are Benzodiazepines (Avg. 7,312 DU's/Month)
  - 35% - Clonazepam 1mg
  - 18% - Clonazepam .5mg
- 113 total patients receiving an opioid in conjunction with a benzodiazepine
- 94 of 113 (83%) of the opioid/benzo combinations contain buprenorphine as the opioid
- Cash for controls is elevated due to most of the buprenorphine and benzodiazepine Rx's being paid with cash

370. Amerisource's review of Blankenship's top prescribers further revealed the following, among other things:<sup>360</sup>

<b>Top 10 Prescribers of CS Rx</b>	<b>% CS</b>	<b>% CS Paid \$</b>	<b>Notes</b>
Prescriber 1	85%	82%	Addiction Medicine/Psychiatry, DW/275. 19 total patients receiving buprenorphine. 10 of these 19 are receiving a benzodiazepine in conjunction with buprenorphine. 76% of the buprenorphine dispensed was the mono product 8mg.
Prescriber 2	98%	23%	Addiction Medicine/Family Medicine. DW 275. 6 out of 9 total patients receiving buprenorphine are also receiving a benzodiazepine.
Prescriber 3	95%	78%	Family Medicine. DW 275. 2009 Discipline – Engaging in the practice of medicine while physically or mentally

<sup>359</sup> ABC-MSAGC00024488.

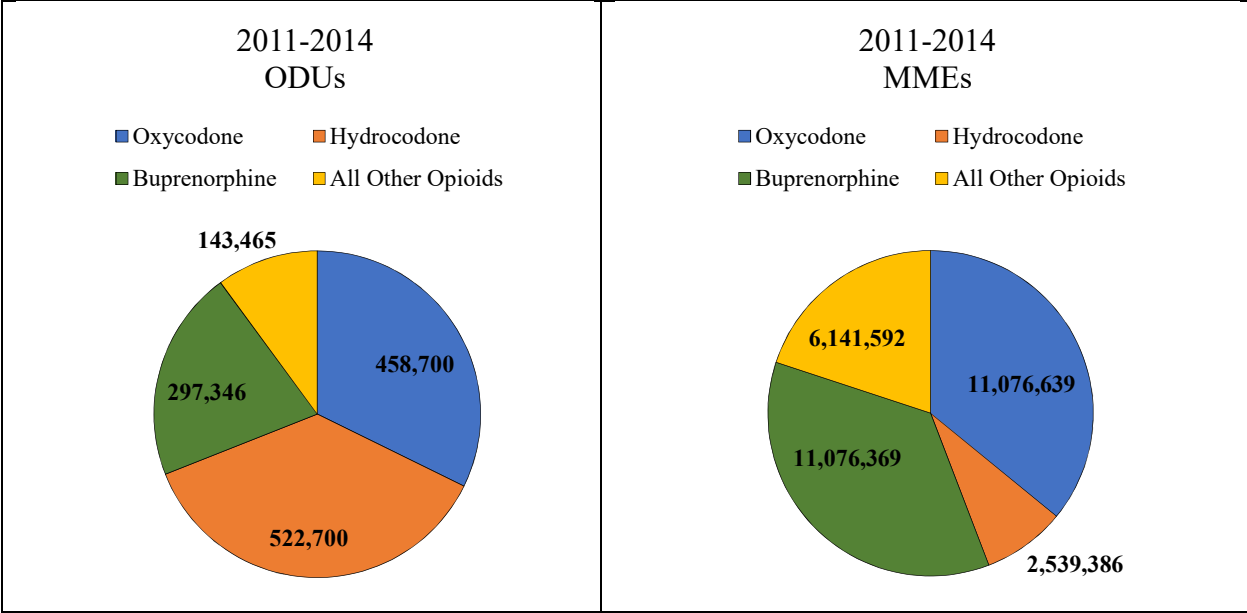
<sup>360</sup> ABC-MSAGC00024488 (selection recreated verbatim by TNAG).

			unable to safely do so, habitual intoxication or personal misuse of any drugs or the use of intoxicating liquors, narcotics, controlled substances or other drugs or stimulants in such a manner as to adversely affect the person’s ability to practice medicine; and conviction of a felony, conviction of any offense under state or federal drug laws, or conviction of any offense involving moral turpitude. 50% of patients receiving buprenorphine also received a benzodiazepine. 72% of Buprenorphine is the 8mg mono product
Prescriber 4	100%	64%	Internal Medicine. DW 275. 50% of patients receiving buprenorphine are also getting a benzodiazepine. 75% of buprenorphine is the 8mg mono product
Prescriber 5	89%	78%	Internal Medicine. 5 of 17 patients receiving buprenorphine are also receiving a benzodiazepine. 83% of buprenorphine is the 8mg mono product.
Prescriber 6	98%	74% <sup>0</sup>	Emergency Medicine. 1985 discipline – Unprofessional conduct, fraud, or deceit, gross malpractice; prescribing practices 6 of 13 patients receiving buprenorphine are also receiving a benzodiazepine. 63% of Buprenorphine dispensed was the 8mg mono product.
Prescriber 7	86%	65%	Addiction Medicine/Family Medicine. 54% of buprenorphine dispensed was the 8mg mono product. 4 patients received a benzodiazepine along with buprenorphine
Prescriber 8	95%	99%	Addiction Medicine/... /Anesthesiology.
Prescriber 9	88%	91%	Addiction Medicine/Internal Medicine. 100% of buprenorphine dispensed was the 8mg mono product.
Prescriber 10	78%	88%	Addiction Medicine/Internal Medicine. 99% of buprenorphine is the 8mg mono product.

371. Faithful as ever, Amerisource was *still* shipping buprenorphine to a pharmacy they knew had ongoing abuse and diversion for *years*.

**iii. Brookside Discount Pharmacy**

<b>City:</b> Kingsport (pop. appx. 51,274)		<b>County:</b> Sullivan	
<b>ODUs:</b> 1,422,211		<b>MMEs:</b> 90,720,565	
<b>State Rank:</b> Not in top 20	<b>ABC Rank:</b> Not in top 20	<b>State Rank:</b> Not in top 20	<b>ABC Rank:</b> Not in top 20
<b>Years as ABC Customer:</b> 2011 to 2017		<b>Distribution Center(s):</b> Birmingham; Paducah	



372. Brookside Discount Pharmacy (pictured below), also owned by Boone Drug, was another independent pharmacy in the Tri-Cities area with an outsized appetite for buprenorphine, fed by rampant abuse and diversion, and supplied by Amerisource.



373. Amerisource continued to ship buprenorphine and other opioids to Brookside Pharmacy despite:

- having a contract from one of Brookside’s main prescribers that stated that he would only accept cash, charged overtime for responding to “police calls,” and charged customers \$150 to stay in his treatment program if they had a dirty opioid urine screen;<sup>361</sup>
- knowledge that Brookside’s PIC stated that Brookside’s customers told her that Subutex sells on the street in Kingsport for \$35-\$40 per unit;<sup>362</sup>
- knowledge that Brookside’s controlled substance customers included many individuals from Kentucky, West Virginia, and North Carolina; and
- knowledge that Brookside’s orders of buprenorphine compared with total buprenorphine had jumped from 12% to 81% between 2012 and 2014 respectively and that the absolute orders of buprenorphine had increased exponentially from 4,230 in 2012 to 140,000 units in 2014.<sup>363</sup>

374. Opioid sales at Brookside Pharmacy really picked up between 2012 and 2013, when Amerisource *doubled* the amount of oxycodone and fentanyl it was sending to the pharmacy. The amount of buprenorphine Amerisource shipped to Brookside Pharmacy increased the most though, from approximately 36,400 units to 85,050 units. But Amerisource was not shipping them just any buprenorphine—12% of the units purchased in 2012 were for the purest, strongest form of buprenorphine; by 2013, Amerisource was shipping an incredible 74%.<sup>364</sup> In 2014, Brookside was ordering close to 140,000 units of buprenorphine, and 81% was Buprenorphine 8.

375. Amerisource’s sales representative for Brookside was Mat Miller, who was also the Company’s sales representative for Blankenship Pharmacy, P & S Pharmacy, and Rippetoe, Inc. (d/b/a Howard’s Pharmacy). Mr. Miller was the person who generally communicated between the pharmacy and Amerisource, including requesting increases in Brookside’s thresholds, which he did frequently and aggressively.

376. For example, on June 24, 2013, Mr. Miller relayed a Request for Threshold Review form to Amerisource’s CSRA for Buprenorphine 8 and listed the reason as “The customer has

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<sup>361</sup> ABC-MSAGC00000521–22.

<sup>362</sup> ABC-MSAGC00000520.

<sup>363</sup> ARCOS.

<sup>364</sup> ARCOS.

requested an increase in current threshold due to an increased number of prescriptions coming from several treatment centers in the area.”<sup>365</sup> Notably, the line that requests the customer’s anticipated monthly usage was left blank as shown in the excerpt below:

Customer’s Anticipated Monthly Usage of Specific Drug Family: _____
Reason for Threshold Review: <b>(Note: Exceeding the established threshold does not in itself justify a threshold increase in all cases.)</b>
<b>The customer has requested an increase in current threshold due to an increased number of prescriptions coming from several treatment centers in the area.</b>

377. A few weeks later on July 3, 2013, the following note was added to Brookside’s file at Amerisource:

Customer has requested a threshold increase to accommodate an increase in business from “prescriptions coming from several treatment centers in the area.” They’ve requested the increase for the B3 family of drugs, buprenorphine solids. A listing of six high prescribers was provided, *one of which was found to have a disciplinary order on file which is still current. The doctor, [Provider 3] will remain on probation until on or about 11/18/2013.*<sup>366</sup>

378. In response, Amerisource’s CSRA overrode the buprenorphine threshold for Brookside and increased it to 13,100 dosage units.<sup>367</sup>

379. Later, on August 26, 2013, Mr. Miller submitted another Request for Threshold Review to Amerisource’s CSRA on behalf of Brookside Pharmacy, this time for the entire buprenorphine family, which included a plea from the pharmacist to increase the threshold “significantly[:]”<sup>368</sup>

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<sup>365</sup> ABC-MSAGC00024617.

<sup>366</sup> ABC-MSAGC00024665 (emphasis added).

<sup>367</sup> ABC-MSAGC00024669.

<sup>368</sup> ABC-MSAGC00024662.

**Please allow an increase in the threshold for the buprenorphine family as there is a new substance treatment clinic in town and the store is getting more patients coming in. Thanks, Mat**

Mat,  
Here's the info you requested: Top 3 doctors prescribing suboxone tabs, film and buprenorphine are  
[REDACTED] DEA# [REDACTED]  
[REDACTED] DEA# [REDACTED]  
[REDACTED] DEA# [REDACTED]

The NDC's are 12496-1208-03(suboxone 8/2mg film)  
65162-0415-03(bupre.naloxone 8/2mg tabs)  
00054-0177-13(buprenorphine 8mg)

We dispense 12,400 mth on the suboxone family  
Hydrocodone is in this same class they are all c3's we dispense 8,600/mth

If there's anyway possible it needs to be increased significantly the last time it was only increased by 1,000 that's no where near where we need to be our numbers show we are filling this amt.so please do what you can to get this # increased more.

380. Two days later, the following note was added to Brookside's file at Amerisource:

An additional threshold review request was made by the customer on 8/26 as a result of the override expiring on 8/6. Their consumption levels across all families is low, *with the exception of the one in question* [buprenorphine] and [Oxy 30], ... As a result, the override of 8,800 dosage units has been put into place until 9/27 at which time and [sic] additional review will be conducted.<sup>369</sup>

381. On September 5, 2013, Mr. Miller again requested a buprenorphine threshold increase for Brookside Pharmacy, with the anticipated customer monthly usage of 9,500 units, and the reason that was given was: "There is a treatment clinic in the area that generates more prescriptions for this type of drug family."<sup>370</sup>

382. On September 9, 2013, Amerisource adjusted the override to 9,500 units of buprenorphine for Brookside Pharmacy's monthly threshold.

383. In January 2014, Mr. Miller made another request to Amerisource's CSRA for more buprenorphine on behalf of Brookside, which was noted in the file as: "Due to *another* increase

<sup>369</sup> ABC-MSAGC00024665 (emphasis added).

<sup>370</sup> ABC-MSAGC00024660.



suboxone (buprenorphine) thresholds, a request of dispensing data was made through the account manager on 1/6/14, the data was received on 1/7/14.”<sup>371</sup>

384. Yet even this Amerisource threshold increase was still not enough for Brookside Pharmacy. On July 15, 2014, Mat Miller requested that the buprenorphine threshold be increased to approximately “13,000” per month because “[t]he customer had been getting product to meet the 13,000 units per month. They are not asking for more than the 13k they had been set at. We have recently cut and held orders and they have only gotten 10,500 in the last month. Please set the threshold for the 2 item numbers at 13k per month- no more.”<sup>372</sup>

385. Mr. Miller also asked Brookside to send Amerisource the item numbers and monthly quantities for “products that we have order problems with, please.”<sup>373</sup>

386. Brookside’s response to Amerisource stated as set forth below:

*We are at 10,500 per month as of this past month (because we haven’t been able to get our regular orders in) but we normally do 13,000 a month. I was just told by supervisor w/cust.service that once the increase request has been put in by you and approved by OMP dept. it should NEVER go back to the amt.we originally started at??? What is going on? We need to be at 13,000.*<sup>374</sup>

Mr. Miller forwarded this response to Amerisource’s compliance department as pressure to more quickly approve orders.<sup>375</sup>

387. Later in July 2014, Amerisource sent Brookside 15,450 doses of buprenorphine.<sup>376</sup>

388. The upward push continued. Mat Miller submitted yet another request for an increase in buprenorphine thresholds on August 14, 2014 and as a result, Amerisource’s CSRA again increased Brookside Pharmacy’s buprenorphine “threshold to 13,100 dosage units.”<sup>377</sup>

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<sup>371</sup> ABC-MSAGC00024669 (emphasis added).

<sup>372</sup> ABC-MSAGC00024626.

<sup>373</sup> ABC-MSAGC00024625.

<sup>374</sup> ABC-MSAGC00024625 (emphasis added).

<sup>375</sup> ABC-MSAGC00024665.

<sup>376</sup> ARCOS.

<sup>377</sup> ABC-MSAGC00024669.

389. On February 12, 2015, PCG Inspector Sullivan and Mr. Miller met with the Brookside PIC to conduct a due diligence inspection for the pharmacy, the same day the two men audited Blankenship Pharmacy.

390. The beginning of the February 2015 PCG report to Amerisource stated that Brookside Pharmacy “has increased its business services as a pharmacy that dispenses Buprenorphine prescriptions for new addiction services practitioners/physicians in the Kingsport tri-city Tennessee area. An increase has been completed on their Buprenorphine threshold.”<sup>378</sup>

391. The first observation from the PCG report sent to Amerisource was as follows (set forth in gray below):

The top controlled substances dispensed in order at Brookside Pharmacy are: Alprazolam, Buprenorphine, Hydrocodone, and Oxycodone. *The controlled substances that are dispensed are: 26% Benzodiazepine, 15.3% Subutex, 14% Lortab and 12.9% Oxycodone.* The physicians will prescribe Subutex *in conjunction with Alprazolam.* PIC Overton stated that Kingsport TN and the surrounding neighborhood of the pharmacy has a *large pharmaceutical drug problem.* PIC Overton further stated that *Subutex sells on the street in Kingsport for \$35-\$40 per dosage unit.* Investigator Sullivan asked how she knows this information. PIC Overton explained that it is common knowledge and that *some of her customers informed her of these prices.* It was also revealed that *these prescribers do not usually decrease the dosage of the Subutex/Suboxone they prescribe nor do the patients stop taking the medication, rather, they tend to stay on the drug long term.*<sup>379</sup>

392. The second observation from PCG’s Brookside report was just as damning:

Michael R Martin, MD [DEA number], Psychiatry & Neurology: *prescribes Alprazolam and Subutex to many patients from Kentucky, which is approximately 75 miles away.* PIC Overton indicated that *Dr Martin is her biggest concern as a controlled substance prescriber.* *Dr Martin’s patients from Kentucky fill Klonopin, Adderall, Alprazolam and Suboxone at her pharmacy.* PIC Overton indicated that *there are a large group of Kentucky patients that are loitering in the parking lot after getting their prescriptions filled.* PIC Overton has to go outside to tell customers to leave the parking lot. *She indicated that she has to contact local police to get the crowd of customers to disperse.* *She also stated that one of her customers came into her store and indicated to her that one of her Kentucky customers was*

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<sup>378</sup> ABC-MSAGC00000520.

<sup>379</sup> ABC-MSAGC00000520 (emphasis added).

*crushing up their Xanax tablets and snorting the drugs on the dashboard of their vehicle.*

*On another occasion, one of the Kentucky customers walked into the pharmacy and she believed the customer just put out a marijuana joint before entering the pharmacy. The entire pharmacy reeked of marijuana when he came in to pick up his Alprazolam and Subutex prescriptions. In addition, PIC Overton indicated that she ran a PMP in Kentucky on a patient who was attempting to fill an Alprazolam prescription that was just written by Dr. Martin. The PMP indicated that the customer from Kentucky had just received a prescription for Alprazolam written the day before from a Kentucky doctor. PIC Overton refused to fill the prescription and contacted Dr. Martin and informed him about the prescription filled in Kentucky. Dr. Martin still continues to write Alprazolam prescriptions for this patient.*

*Dr. Michael Martin Psychiatry 1936 Brookside Drive, Suite C, Kingsport, TN: Dr. Martin does not accept insurance payments. He does not participate in Medicare/Medicaid or TennCare. He requires full payment by cash or cashier's check only, at the time of service up front. According to the PIC, Dr. Martin's price list is as follows: the Psychiatric evaluation: \$300, office outpatient visit every 28 days \$150.00, Buprenorphine prescription Monday, Wednesday, or Friday every week: \$125.00; Phone visit/conversation 20 minutes \$150.00. Please see attached.*

#### **RECOMMENDATION:**

*It was discussed with PIC Overton and Mat Miller that she should contact the owner of Boone Drugs, John Stacy RPH and inform him, after the inspection, of the concerns she has with dispensing controlled substances for Dr. Michael R Martin and the concerns surrounding the Kentucky customers. Referring to the new SOP procedure on Buprenorphine products, the procedure states the following: Starting January 15, 2015, Boone's Drugs, Inc., d/b/a/ Brookside Discount Pharmacy will only accept new patients who reside in Tennessee or Virginia. Customers who reside in Kentucky, West Virginia North Carolina will be maintained. However, there are concerns which were articulated above by PIC Overton. The patients from Kentucky that Dr. Martin is prescribing for should not be filled anymore, based on the concerns the PIC has indicated above.<sup>380</sup>*

393. Amerisource had other information relevant to Brookside, including a copy of Dr. Martin's patient contract referenced in the PCG report. In addition to red flags pointed out in the PCG report, the patient contract clearly stated multiple times that he was a cash-only provider.<sup>381</sup>

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<sup>380</sup> ABC-MSAGC00000521-22 (emphasis added).

<sup>381</sup> ABC-MSAGC00024541.

- Full payment by cash or cashier’s check **ONLY** is required at the time of service *BEFORE* you see the doctor.
- If you have health insurance it should be understood that this is a contract between you and your insurance company. **I DO NOT ACCEPT ANY INSURANCE.**
- If you wish to use insurance for payment or you plan to submit a claim for reimbursement, we suggest that you receive treatment from a preferred provider.
- Your doctor’s bill is an agreement between you and your doctor.

394. Dr. Martin’s contract, that Amerisource possessed, also:

- listed charges for other services, such as \$5 per minute for “Overtime,” for “telephone calls, hospital admissions, police calls, listening to tapes, looking at records, writing reports, etc.”;
- repeated “**Cash or cashier’s checks ONLY are accepted for payment[;]**” and
- stated that the “Suboxone/Subutex program is \$125.00 per week whether or not the patient sees the doctor or has an appointment[;]”<sup>382</sup>

as shown in the screenshot below:

\*These fees apply also to telephone calls, hospital admissions, **police calls**, listening to tapes, looking at records, writing reports, etc. °These may not be reimbursable.

**Cash or cashier’s checks ONLY are accepted for payment. Suboxone/Subutex program is \$125.00 per week whether or not the patient sees the doctor or has an appointment. All accounts more than 60 days past due will accrue interest at a rate of 18% annually, pro-rated on a monthly basis. These accounts may be turned over to a collection agency. No further appointments or medication refills are given until such accounts are fully paid. ALL ACCOUNTS MUST BE FULLY PAID BEFORE TREATMENT.**

395. Under the patient contract in Amerisource’s possession, patients could pay a minimum of \$150 for an “Unsatisfactory drug screen (more or less than Michael R. Martin, MD has prescribed for patient[;])” to avoid being discharged, as shown below:

No code	Unsatisfactory drug screen (more than or less than Michael R. Martin, MD has prescribed for patient [you]); grounds for discharge: minimum	\$150
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396. Again, Amerisource continued to ship opioids to pharmacies that Amerisource knew showed *textbook* red flags for pill mills.

<sup>382</sup> ABC-MSAGC00024541 (emphasis in original).

397. In addition to the PCG report, Amerisource had completed an internal questionnaire<sup>383</sup> which provided even more red flag information on Brookside, including

- Brookside needing an *armed* security guard for “crowd control”;

11. Does the pharmacy have a security guard?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO PIC indicated that she would like an armed security officer to help her with crowd control and the Kentucky customers loitering outside.
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- and also included suspicious customer profiles;

14. Observe patients in the pharmacy area. a. How many patients are there? b. What is the average age? c. What is the general gender? d. What is the general appearance?	4 customers, average age is approximately 22-30 years old mostly male, unkempt and messy.
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- Brookside filling prescriptions for Dr. Martin while not being licensed in the states where it knew it was dispensing controlled substances;

34. What states does the pharmacy dispense drugs into?	Virginia (border state) Kentucky (Dr. Martin patients) Tennessee
35. Is the pharmacy licensed in all of the states that it dispenses CS?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO

- knowledge that Brookside had controlled substances, including Schedule IIs, that were mixed in with non-controlled pharmaceuticals and that every person who worked in the pharmacy had access to the controlled substances, in violation of DEA regulations;

<sup>383</sup> ABC-MSAGC0002454–57.

<p>61. Are Schedule II controlled substances stored in a securely locked, substantially constructed safe or cabinet?</p> <p>a. If not are they dispersed throughout the pharmacy's stock of other legend drugs?</p> <p>b. Are Schedule III through V controlled substances stored in a securely locked, substantially constructed safe or cabinet?</p> <p>c. If not, are they dispersed throughout the stock of other legend drugs?</p> <p>List individuals who have access to controlled substances</p>	<p><input type="checkbox"/> YES      <input checked="" type="checkbox"/> NO</p> <p><input checked="" type="checkbox"/> YES      <input type="checkbox"/> NO</p> <p><input type="checkbox"/> YES      <input checked="" type="checkbox"/> NO</p> <p><input checked="" type="checkbox"/> YES      <input type="checkbox"/> NO</p> <p>Paige Overton [REDACTED]  [REDACTED] Certified  Technicians, [REDACTED]  Technicians</p>
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- Brookside had no system in place to monitor for potentially dangerous or reckless prescribers;

<p>70. Does the pharmacy have a system in place to review physicians who write an inordinate amount of controlled substance prescription?</p>	<p><input type="checkbox"/> YES      <input checked="" type="checkbox"/> NO</p>
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- Brookside accepting cash payments that are 52% above the average; and

<p>c. Cash/credit card or debit card or pharmacy charge account</p>	<p><input checked="" type="checkbox"/> YES      <input type="checkbox"/> NO 60%</p>
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- supposedly refusing to fill prescriptions written by Dr. Martin.

<p>74. Has the pharmacy cut off and/or refuse to dispense any CS RX written by a prescriber?</p> <p>a. Why?</p> <p>b. Is a data base maintained to communicate "do not fill" to other RPh?</p> <p>c. What prescribers have been</p>	<p><input checked="" type="checkbox"/> YES      <input type="checkbox"/> NO</p> <p>Any prescriber who wrote a c/s too early; this is documented within the computer notes.</p> <p><input checked="" type="checkbox"/> YES      <input type="checkbox"/> NO</p>
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398. Yet in the very next question, Amerisource acknowledged that Brookside Pharmacy dispensed controlled substances to Dr. Martin’s out-of-state patients, presumably the same Kentuckians loitering outside of the pharmacy.

placed on list?	Who : Dr Martin
75. Does the pharmacy dispense controlled substances to out of area OR out-of-state patients?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
a. If yes, what states? Explain.	Kentucky (Dr. Martin patients)
b. What percentages of customers who receive controlled substances are from out of state?	10%
78. Has the pharmacy ever alerted the police or the Board of Pharmacy to patients who appear to be suspicious?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
	Contacted the local police on numerous times to disperse Kentucky (Dr. Martin) from loitering in the parking lot

399. Yet this answer was not the only untruth that Brookside told the PCG inspector and included in the report. Question 39 asked when the pharmacy was last inspected by the Tennessee Board of Pharmacy and whether there were any findings. The response reads “Date January 29, 2014 no issues.” However, the Tennessee Board of Pharmacy *had* found issues, namely, that Brookside PIC Paige Overton failed to have a pharmacy technician register with the Tennessee Board of Pharmacy from the beginning of his employment up until the inspection occurred—approximately a year and a half.<sup>384</sup>

400. The Amerisource Questionnaire for Brookside further noted that the pharmacy utilized Harvard Drug as another distributor, saying it had a “[v]ery minimal” percentage of business. The business Harvard Drug was getting, however, was more buprenorphine purchases from Brookside.<sup>385</sup>

<sup>384</sup> [https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/9901\\_22878\\_052914](https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/9901_22878_052914).

<sup>385</sup> ARCOS.

401. In addition, the Amerisource Questionnaire stated that one of the two top prescribing physicians for Brookside was the same Kingsport pain clinic owner who specialized in family medicine and was also listed as a top prescriber for P & S Pharmacy.

402. Ever hesitant to “terminate” a cash flow, Amerisource again looked the other way as compliance yielded to sales. A July 15, 2015 internal Amerisource email titled “PCG Customer Review” summarized the consultant’s report on Brookside as follows:<sup>386</sup>

Brookside Pharmacy -  
**Need to schedule call with chain owner Johnny Stacy = Boone Drug**  
F/U letter. Rather than termination - probation(?) based on several actions that must be taken, including updating/strengthening anti-diversion policy

403. An internal Amerisource spreadsheet titled “PCG Action” cited the following red flags about Brookside in 2015:

Request 3 Mo. Dispensing Report. Letter 3/25 deadline 4/17 -- *Review Dr. Martin Rx in particular.* Dispensing Report received 4/13 & reviewed by SH. Summary provided. *Dr. Martin- stop dispensing BD Rx for KY patients.* Get access to VA pdmp. *Better understanding of DEA Data Waived MD, prescribing patterns (why Bup 8 vs. bup/nal), expectation to see titration , Cash red flags.* Early July Schedule call w/owner Stacy & then determine action.

and also:

Several open discussions with PIC Wayne & Owner Johnny re: addiction clinic physicians & active communication with MDs. Concern re: servicing cash payment patients from KY and legitimacy validated. Programs not available in KY, KY Medicaid not reimbursing.<sup>387</sup>

404. A summary from a June 2015 Amerisource CSRA discussion regarding Brookside revealed that its ratio of controlled substances to noncontrolled substances was 39% and that it was among the highest purchasers of benzodiazepine, buprenorphine, and hydrocodone for Amerisource pharmacy customers nationwide.<sup>388</sup> Even more importantly, this Amerisource report

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<sup>386</sup> ABDCMDL00047171 (emphasis in original).

<sup>387</sup> ABDCMDL00161633 (emphasis added).

<sup>388</sup> ABC-MSAGC00024593.



showed that the pharmacy was *still* filling prescriptions from Dr. Michael Martin. In fact, “449 [prescriptions were] filled for patients from Kentucky which is greater than 20 miles from the pharmacy. Vast majority (375RX) were from [buprenorphine] class prescribed by Dr. Michael Martin.”<sup>389</sup> The report also revealed that Brookside was filling prescriptions from patients as far away as Florida, for a patient from Tennessee whose doctor was located in Pennsylvania, for many patients who were on Oxy 30 with no long acting medicine regimen, for many patients who paid with “CASH” for prescriptions even though they had insurance, patients were receiving the Holy Trinity of controlled substances. Amerisource’s conclusion of the analysis stated:

**Conclusion:**

Brookside PIC Paige Overton expressed concerns around the dispensing of subutex prescribed by the great number of DATA waived physicians prescribing buprenorphine products for addiction programs in the immediate TN/VA area. Her concern stemmed from not seeing titration of this drug or conversion to buprenorphine/naloxone or discontinuation over time as would be expected for addiction programs. Paige related that she is aware that buprenorphine has a high street value in the region and her ability to insure the drug is prescribed for a legitimate reason is difficult to vet. Despite the fact that PIC is aware of the risk and responsibilities there is the additional red flag of cash payment for CS prescriptions.

- Dr. Michael Martin is a local physician who only accepts cash from patients and is a high prescriber of benzodiazepines for patients residing in Kentucky (about 70 miles from pharmacy).
  - SOP for buprenorphine excludes servicing KY patients
    - **Suggest pharmacy’s SOP needs to expand to all CS prescriptions, thereby stop dispensing CS drugs for Martin’s KY patients.**
- The percentage of controlled substance prescriptions paid for by cash is 44.7%
  - 50.8% were written for buprenorphine 8mg
    - SOP notes that the patient and physician has been vetted and RPh has checked the PMP for all CS fills
      - If following own SOP and validating prescriptions unsure why PIC is uncomfortable with these dispenses.
      - Is the reason for greater percentage of buprenorphine versus buprenorphine/naloxone due to decreased cost for patients that do not have prescription insurance coverage?
        - **PIC should gather information from each physician’s practice concerning how new patients are vetted for their program, patient contracts, urine testing, algorithm approach (choice of buprenorphine vs. combo, titration).**

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<sup>389</sup> ABC-MSAGC00024593.

405. Dr. Michael Martin was disciplined by the Tennessee Board of Medicine in May 2016 and the Stipulations of Fact from the Consent Order stated:

From in or around January 2010 to in or around January 2015, Respondent provided treatment for addiction to numerous patients which included prescribing buprenorphine and buprenorphine related products and Respondent did not sufficiently justify the prescribing in your patients' charts.

Respondent failed to document adequate support for diagnoses sufficient to justify the treatment rendered and failed to integrate consultations, previous hospitalizations and other medical information into the treatment plan.

Respondent prescribed controlled substances and other medications without documenting a written treatment plan and without performing physical exams.

For instance, Respondent prescribed benzodiazepines to patient A.E. without providing any documented medical justification. Likewise, Respondent prescribed both Suboxone and benzodiazepines to patients N.M., A.M., G.K., and C.W. without documenting medical justifications for that prescribing. Respondent also prescribed Suboxone, Xanax, and Adderall to patient G.K. without providing documentation of sufficient medical justification to support that prescribing.

406. Even as recently as 2017, 70% of the buprenorphine that Amerisource sent to Brookside was Buprenorphine 8.<sup>390</sup>

*iv. Gray Pharmacy*

407. Gray Pharmacy was another pharmacy buying more buprenorphine from Amerisource than most other pharmacies in the country. The pharmacy is located in Gray, a rural town of about 1,222 in the Tri-Cities' area and is about 15 to 20 minutes by car from either Johnson City or Kingsport. Gray Pharmacy was also a crucial part of Amerisource's oversized buprenorphine sales in the Tri-Cities region.

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<sup>390</sup> ABC-MSAGC00002039.



408. Amerisource continued shipping buprenorphine and other opioids to Gray Pharmacy despite knowing that, among other things:

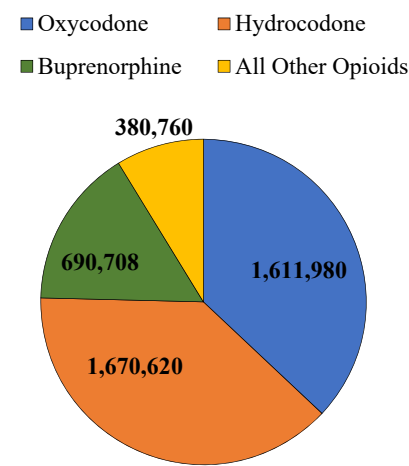
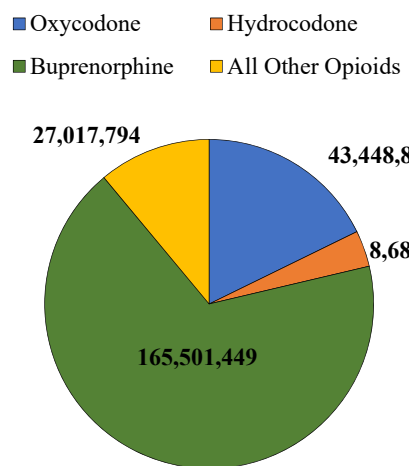
- it was dispensing opioids to out of state patients;
- 40% of its prescriptions as of February 2017 were paid for with cash or a credit card;
- 40% of the prescriptions dispensed at the pharmacy were for controlled substances; and
- the pharmacy was not being truthful when it told Amerisource that it did not fill opioid prescriptions for pain clinics.<sup>391</sup>

409. Despite having a population that is barely four-figures and being located in Washington County, which contains cities significantly larger than it, Gray Pharmacy received more opioids between 2006 and 2014 than any other pharmacy in the entire county. Gray Pharmacy was also ranked seventh by total MMEs out of all of Amerisource's pharmacy customers

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<sup>391</sup> ABC-MSAGC00029101-03.

in Tennessee between 2006 and 2014—a fact made even more outrageous considering Amerisource did not begin distributing to Gray Pharmacy until December 2009.<sup>392</sup>

<b>City:</b> Gray (pop. appx. 1,222)		<b>County:</b> Washington	
<b>ODUs:</b> 4,354,068		<b>MMEs:</b> 244,652,014	
<b>State Rank:</b> Not in top 20	<b>ABC Rank:</b> Not in top 20	<b>State Rank:</b> 7th	<b>ABC Rank:</b> 8th
<b>Years as ABC Customer:</b> 2009 to 2017		<b>Distribution Center(s):</b> Birmingham	
<p style="text-align: center;">2009-2014 ODUs</p>  <p>■ Oxycodone      ■ Hydrocodone ■ Buprenorphine      ■ All Other Opioids</p>		<p style="text-align: center;">2009-2014 MMEs</p>  <p>■ Oxycodone      ■ Hydrocodone ■ Buprenorphine      ■ All Other Opioids</p>	

410. Gray Pharmacy remained one of Amerisource’s top customers in Tennessee by sales dollar value from 2011 through 2015. It also ranked in the top 15 of Amerisource customers in Tennessee with the highest number of suspicious orders for a Tennessee pharmacy that Amerisource reported to the DEA in 2013, 2014, and 2015.

411. Of the 6.6 million ODUs shipped to Gray Pharmacy between 2009 and 2014, Amerisource was responsible for 65%—that is enough for every citizen of Gray to have 3,563 opioid doses each.<sup>393</sup>

<sup>392</sup> ABDCMDL00170221.

<sup>393</sup> ARCOS.

412. Between 2009 and 2014, Amerisource was also responsible for 76% of the 320,392,588 MMEs shipped to Gray Pharmacy—which is equivalent to Amerisource giving everyone in Gray approximately 4,449 Oxy 30 pills *each*.

413. On February 14, 2014, an Amerisource sales representative filled out a Retail Pharmacy Questionnaire for Gray Pharmacy which again confirmed that Gray was dispensing prescriptions for out-of-state patients; that 25–30% of the prescriptions being dispensed were for controlled substances; that one of Gray’s top prescribers was a suspicious buprenorphine prescriber previously identified in Amerisource’s due diligence for other pharmacies; that 40% of prescriptions filled at Gray were paid for with cash or a credit card; and that Gray dispensed approximately 30,000 tablets of oxycodone, hydrocodone, tramadol, alprazolam, and carisoprodol per month.<sup>394</sup>

414. Amerisource kept shipping opioids to Gray Pharmacy as its opioid order numbers kept rising. In January 2014, Amerisource had distributed close to 65,304 opioid dosage units to Gray. After a slight dip to 63,979 opioid dosage units in February 2014, March 2014 was even higher, with Amerisource distributing 72,310 opioid dosage units to Gray Pharmacy.<sup>395</sup>

415. PCG Consultant Frank Younker visited Gray Pharmacy on the morning of January 26, 2016 to conduct a pharmacy review on behalf of Amerisource. The PCG report, which was submitted on February 2, 2016 noted the following, among other things (as shown in gray below):

Gray Pharmacy is a licensed retail pharmacy located in the town of Gray, Tennessee, population approximately 1,222 (2010 census). The pharmacy is *located several hundred yards from a major busy 4 lane interstate highway*. The pharmacy is located in a small semi developed business complex with a handful of business[es], which include a funeral parlor, police supply business, a barber shop and a respiratory business, which is located above the pharmacy.

....

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<sup>394</sup> ABC-MSAGC00029101–03.

<sup>395</sup> ARCOS.

Upon arriving, there was one vehicle parked in front of the pharmacy, and a few parked at the back lot (presumably employees' as that is where Hall also parked). *There was an early/mid 20's college type male in the pharmacy upon arrival.* The rest of the people present were employees behind the pharmacy counter.

... Kilgore just graduated from Pharmacy school about 2 years ago. Gray Pharmacy also employs 2 other Pharmacists: Pharmacist Glenn Hall, The owner and Pharmacist Tim Coffey. The store also employs several Pharmacy Technicians. Coffey is a relief, part time pharmacist.

The most recent Tennessee State Pharmacy Board Inspection was completed on April 7, 2015 by [a State Inspector. The Inspector] noted several issues some of which were corrected on site, others addressed in a follow-up letter to the board. Some issues noted included; storage of syringes, refrigerator temperature, and requiring of counseling new pharmacy graduate. Also, when Kilgore was named PIC, there was no new Inventory done. ... Kilgore advised the pharmacy fills approximately 200 +/- prescriptions per day and approximately 5500 +/- per months with *approximately 40% +/- of the prescriptions comprised of controlled substances. This percentage is considered excessive.* Kilgore stated that he will work on ways to reduce that percentage, and when he takes over ownership he will make a few changes as well. ... Kilgore advised approximately 40% are insurance, 25% are Medicare/Medicaid (most Medicaid) and about 35% *are cash/credit card.*

Thru ABC Sales Representative Mike Dailey, Gray Pharmacy provided Consultant Younker with a "top 5" list of controlled substance prescribers for Gray Pharmacy. Of the below listed *only [one of the providers] is a Suboxone Prescriber.*

The top 5 are listed in order along with their DEA Numbers.

[Provider] MD

[Provider] NP

[Provider] NP

[Provider] MD

[Provider] MD

[One of the top providers] has a licensed "Pain Management" Clinic ...

[Another top provider] paid \$4.25 million dollars settlement for submitting false claims, misbranded/un-approved drugs. He also has a Licensed "Pain Management Clinic" ...

Gray Pharmacy does not have a policy for dispensing narcotic prescriptions. Kilgore stated that it is something he hopes to have in place in the near future. ....

Kilgore advised that all Schedule II and Schedule III controlled substances are stored in a large 2 door locked storage cabinet in the office area. Additionally, some CII's are dispersed among stock such as the Oxy 10mg and 20mg but only a bottle or two as they dispense those forms frequently. The CII's are in the locked cabinet.

Consultant Younker looked at the current basket of CII's that were on the counter and noticed an Rx for Oxy 20mgSR as well as regular Oxy20mg for the same patient. Additionally, there were some RX's from the TN Pain Institute, (Gary Moore MD).

....

Gray Pharmacy has several cameras located throughout the store with a monitor located in the back office. There is no camera looking at the front parking lot. ... The local Police Department (Johnson City Police, covers the area) is located approximately 5-7 minutes away and responds to the alarms, or any calls for assistance by pharmacy employees. The pharmacy had a night-time burglary in September 2014 where numerous controlled drugs were stolen. The individuals gained entry by prying open the front door, and were gone when police arrived. The pharmacy has since opted to chain the front door, in addition to the lock at night using a heavy metal chain. Consultant Younker does not think this is adequate enough given the rural area of the store.

### **Recommendations:**

*The current details of this assessment indicate high concern in continuing to supply large volumes of controlled substances to Gray Pharmacy. The high volume of Controlled Drugs to Non-Controlled drugs is high at 40%. The statement of Kilgore on his questionnaire that no pain clinics are served, seem to fly in the fac[e] that numerous physicians with practices Licensed "Pain Clinics" had prescriptions being filled. It should be noted no traditional "Pain Clinics" exist, just physicians who have large pain patient practices, and must be licensed by the State of TN as "Pain Clinics"[] The lack of a Controlled Substance Dispensing protocol is troubling at best, even though Kilgore advised he was going to have one in place in the near future. The security needs to be upgraded some, especially the front entrance especially since they had a large night-time burglary in September 2014 and continue to use the same front door, with just an added chain lock.*

Kilgore was writing down several recommendations as the interview continued. This Consultant's recommendation to the store was to get a Controlled Drug Dispensing Protocol, reduce the Controlled Drug to Non-Controlled Drug percentage down significantly, add a few extra security cameras, continue to monitor the prescribers writing habits and if the pharmacist feels or objects to any prescription being presented that they think are not for a legitimate reason they are well within their rights to refuse to fill.

Kilgore stated again that he hopes to take over ownership of Gray Pharmacy in July of 2016 and implement several changes and updates to the store and its practices. *Therefore, it is recommended that ABC reduce the volume of controlled drugs to Gray Pharmacy until such time it can demonstrate to ABC, by way of submission of documents that a Dispensing Protocol is in place, that steps have been taken to greatly reduce the percentage of controlled drugs dispensed to the non-controlled drugs and that additional security has been put in place to safeguard the drugs.*<sup>396</sup>

416. Dr. Gary Arlen Moore, the provider noted in the PCG report regarding TN Pain Institute, was disciplined by the Tennessee Board of Medicine in April 2016. According to the Stipulations of Fact in the Consent Order, the Tennessee Department of Health reviewed the records of 21 of Dr. Moore's patients and found that:

- “the treatment Respondent provided included prescribing narcotics and other medications and controlled substances in amounts and/or for durations not medically necessary, advisable, or justified for a diagnose condition[;]”
- he “failed to make appropriate, individualized diagnoses and/or failed to document adequate support for diagnoses sufficient to justify the treatment rendered and failed to integrate consultations, previous hospitalizations and other medical information into the treatment plan[;]”
- “prescribed controlled substances and other medication without documenting a written treatment plan with regard to the use of controlled substances and other medication[;]”
- “prescribed narcotics and/or other controlled substances to persons when the quantity, duration and method was such that the persons would likely become addicted to the habit of taking said controlled substances and failed to make a bona fide effort to cure the habit of such persons or failed to document any such effort[;]” and
- “provided few modalities of treatment other than the prescription of controlled substances.”<sup>397</sup>

417. For months after receiving the PCG report, Amerisource still did not reduce the volume of opioids it shipped to Gray Pharmacy.

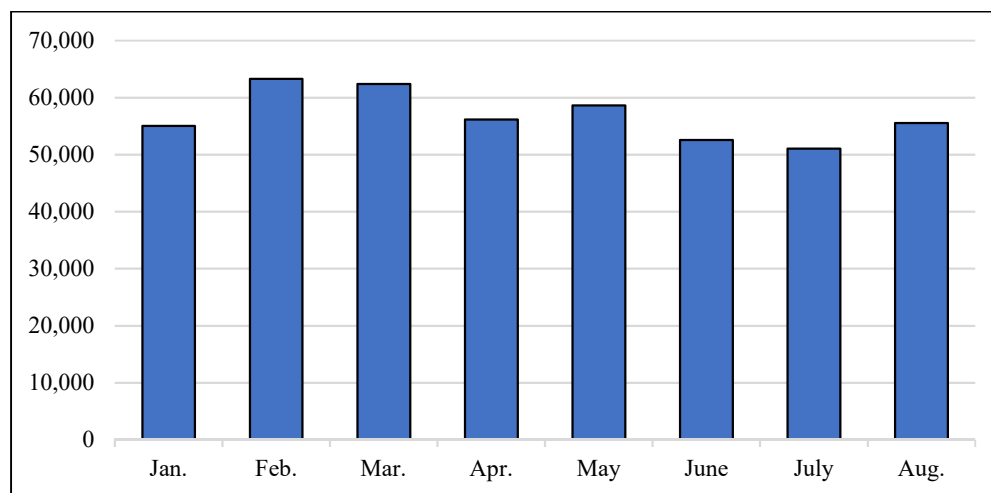
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<sup>396</sup> ABC-MSAGC00000855-59 (emphasis added).

<sup>397</sup> [https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606\\_29619\\_031616](https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_29619_031616).



418. Amerisource distributed the following amounts of opioid dosage units, all over 50,000 ODU's per month, to Gray Pharmacy for the first eight months of 2016:<sup>398</sup>



419. On February 28, 2017, the Amerisource sales associate assigned to Gray Pharmacy sent the pharmacy several questions that CSRA requested be answered, yet Gray Pharmacy's answers were evasive and combative. For example, when asked why the pharmacy's ratio of controlled substances to non-controlled substances was 30%, Gray Pharmacy attributed its high rate of controlled substances in part to "[t]he addition of hydrocodone to the CII listing,"<sup>399</sup> which is in and of itself suspicious, since hydrocodone was still a controlled substance prior to becoming Schedule II. Additionally, the rescheduling had occurred *three years* earlier in 2014.

420. But Gray Pharmacy was not the only pharmacy in the small town of Gray, Tennessee that Amerisource kept well-stocked with opioids. Arguably even more shocking is the amount of opioids Amerisource sent to all three of the retail pharmacies located in Gray. With 5,246,489 ODU's and 264,328,564 MMEs between 2009 and 2014, Amerisource gave the residents

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<sup>398</sup> ARCOS.

<sup>399</sup> ABC-MSAGC00029117.

of this town 4,293 ODU's and 216,308 MMEs each. That is equivalent to approximately 4,806 tablets of Oxy 30 to each resident.<sup>400</sup>

## **I. Amerisource's Oversupply of Opioids to Other Parts of Tennessee**

### ***i. Pardue's Pharmacy***

421. Amerisource's knowledge of diversion and illegitimate prescriptions being dispensed at Tennessee pharmacies was not confined to the East Tennessee region. Amerisource had knowledge of other pharmacies across the state including Pardue's Pharmacy, located at 1900 Patterson Street in Nashville.

422. Amerisource continued shipping oxycodone and other opioids to Pardue's Pharmacy despite knowing that:

- Amerisource's own former DEA diversion investigator had recommended Amerisource stop shipping controlled substances to the Pardue's;<sup>401</sup>
- a former Pardue's pharmacy technician was arrested for stealing oxycodone from the pharmacy;
- the only licensed pharmacist at Pardue's had his license put on probation by the Tennessee Board of Pharmacy;
- the pharmacist stated that he "[is] not comfortable with the amount of controlled substances being dispensed" by Pardue's;
- one of Pardue's main prescribers for controlled substances was a doctor whose practice was located 47 miles away from the pharmacy in Clarksville;
- 80% of Pardue's prescriptions dispensed were for controlled substances; and
- 60% of the Pardue's patients paid in cash, among many other clear indicators of diversion.<sup>402</sup>

423. Pardue's utilized three distributors, including Amerisource, to purchase its mountains of opioids. Yet it was Amerisource that was responsible for distributing 99.6% of the MMEs and 97.5% of the ODU's that Pardue's received between 2006 and 2014.

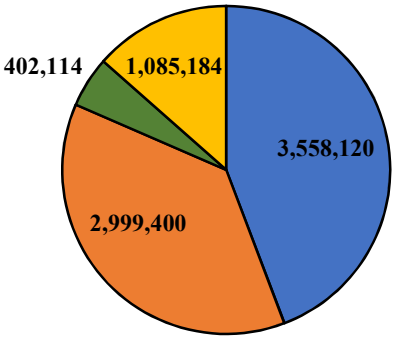
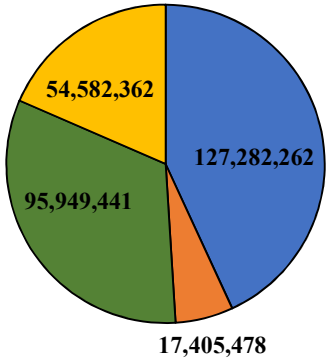
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<sup>400</sup> ARCOS.

<sup>401</sup> ABC-MSAGC00000662-67 (emphasis in original).

<sup>402</sup> ABC-MSAGC00000662-67 (emphasis in original).

424. Amerisource supplied Pardue’s Pharmacy consistent with the facts stated below:

<b>City:</b> Nashville (pop. appx. 429,421)		<b>County:</b> Davidson																					
<b>ODUs:</b> 8,044,818		<b>MMEs:</b> 295,119,543																					
<b>State Rank:</b> Not in the top 20	<b>ABC Rank:</b> 4th	<b>State Rank:</b> 10th	<b>ABC Rank:</b> 4th																				
<b>Years as ABC Customer:</b> 2004 to 2017		<b>Distribution Center(s):</b> Birmingham; Paducah; Antioch; Lockbourne																					
<p style="text-align: center;">2006-2014 ODUs</p> <p> <span style="color: blue;">■</span> Oxycodone      <span style="color: orange;">■</span> Hydrocodone  <span style="color: green;">■</span> Buprenorphine      <span style="color: yellow;">■</span> All Other Opioids </p>  <table border="1"> <caption>2006-2014 ODU Data</caption> <thead> <tr> <th>Drug</th> <th>Quantity</th> </tr> </thead> <tbody> <tr> <td>Oxycodone</td> <td>3,558,120</td> </tr> <tr> <td>Hydrocodone</td> <td>2,999,400</td> </tr> <tr> <td>All Other Opioids</td> <td>1,085,184</td> </tr> <tr> <td>Buprenorphine</td> <td>402,114</td> </tr> </tbody> </table>		Drug	Quantity	Oxycodone	3,558,120	Hydrocodone	2,999,400	All Other Opioids	1,085,184	Buprenorphine	402,114	<p style="text-align: center;">2006-2014 MMEs</p> <p> <span style="color: blue;">■</span> Oxycodone      <span style="color: orange;">■</span> Hydrocodone  <span style="color: green;">■</span> Buprenorphine      <span style="color: yellow;">■</span> All Other Opioids </p>  <table border="1"> <caption>2006-2014 MME Data</caption> <thead> <tr> <th>Drug</th> <th>Quantity</th> </tr> </thead> <tbody> <tr> <td>Oxycodone</td> <td>127,282,262</td> </tr> <tr> <td>Buprenorphine</td> <td>95,949,441</td> </tr> <tr> <td>All Other Opioids</td> <td>54,582,362</td> </tr> <tr> <td>Hydrocodone</td> <td>17,405,478</td> </tr> </tbody> </table>		Drug	Quantity	Oxycodone	127,282,262	Buprenorphine	95,949,441	All Other Opioids	54,582,362	Hydrocodone	17,405,478
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425. On December 3, 2014, Pardue’s account manager at Amerisource requested a threshold increase for three different formulations of buprenorphine. The only reason that the Amerisource sales representative provided for the threshold review was: “Customer Requesting Threshold Review for Increase.” Pardue’s requested 100 boxes of Suboxone 8 mg, 6 boxes of Zubsolv (buprenorphine with naloxone), and 221 boxes of Buprenorphine 8. The request also listed the top five prescribers of controlled substances.<sup>403</sup> Amerisource approved the threshold increase for Pardue’s the very next day.<sup>404</sup>

<sup>403</sup> ABDCMDL00317669.

<sup>404</sup> ABDCMDL00317668.

426. On June 11, 2015, PCG Consultant Bill Stivers and Amerisource Sales Representative Mike Dailey met with the Pharmacist in Charge of Pardue's, James Pickle for an on-site visit. The PCG report contained the following red flags (shown in gray below):

Pardue's Pharmacy is a licensed retail pharmacy collocated in a two story building *with several medical offices and a dental office* in downtown Nashville, Tennessee. The building is adjacent to the medical campus of St. Thomas Midtown Hospital. *A large chain pharmacy is located across the street from Pardue's Pharmacy. ...*

Wendell Pardue is the sole owner of Pardue's Pharmacy. *Wendell Pardue voluntarily retired his Tennessee pharmacist's license in 2014.* Mr. Pardue was disciplined by the Tennessee Board of Pharmacy in 2009 for failing to provide patient consultation; the pharmacy license was also issued a disciplinary action which resulted in a \$500 fine. ... Rph Pickle is a licensed pharmacist in Tennessee and has a current and active license. Rph Pickle has been employed at Pardue's Pharmacy since 2013. *Rph Pickle's Tennessee pharmacist's license is currently listed as "on probation".* Rph Pickle received disciplinary action in 2003 (ten year probation ...) due to testing positive for marijuana. *Rph Pickle advised he has not provided the Tennessee Board of Pharmacy proof of completion of his disciplinary action contract which has resulted in his probationary status being maintained beyond the initial ten year [sic] period. ... Rph Pickle is currently the only licensed pharmacist employed at Pardue's Pharmacy. ...*

The most recent state pharmacy board inspection was completed on 4/6/2015 .... The pharmacy inspection noted a new controlled substance inventory was to be completed "immediately" as the most recent inventory was taken 3/7/2013.

Rph Pickle advised the pharmacy is currently purchasing *all product from Amerisource.*

Rph Pickle advised the pharmacy fills approximately 70 total prescriptions per day and approximately 1,500 per month with approximately *80% of the prescriptions comprised of controlled substances.* Rph Pickle further *stated approximately 80% of all controlled substance prescriptions filled at Pardue's Pharmacy are comprised of schedule two controlled substances.* Rph Pickle did not provide any specific reason regarding the disproportionate number of controlled substances being comprised of schedule two products. Rph Pickle did state *"I am not comfortable with the amount of controlled substances being dispensed and I am thinking about quitting."* Rph Pickle also recalled an incident in the past year when *a patient was arrested in the parking lot while snorting Subutex.* Rph Pickle advised approximately 90% of the prescriptions are received via walk - in and 10% are received via facsimile. Rph Pickle advised *60% of the prescription payment method is comprised of cash, 30% is Medicare / Medicaid with the remaining 10% being third party insurance.*

Rph Pickle advised the pharmacy does fill prescriptions written by physicians associated with pain management clinics. The following pain clinic, also located on Patterson Street, was observed by Consultant Stivers on controlled substance prescriptions filled at Pardue Pharmacy:

APRN [Provider]  
[DEA #]  
Supervising practitioner – Dr. [Provider]  
Comprehensive Pain Specialists  
2400 Patterson Street  
Nashville, TN

The following physician is listed as the #2 prescriber of controlled substances at Pardue's Pharmacy in data provided by Sales Representative Dailey and is licensed as a pain management clinic in Tennessee:

*Dr. Samson K. Orusa* (internal medicine / adolescent medicine)  
[DEA #]  
261 Stone Crossing Drive (*approximately 47 miles from pharmacy*)  
Clarksville, TN 37042

Rph Pickle advised another pain management clinic, which closed due to bankruptcy in March 2015, was located on the second floor of the building where Pardue Pharmacy is located.

....

... A burglary occurred at the pharmacy on 10/4/2014 and was reported to the Nashville Police Department. A significant amount of various schedule two controlled substances were reported missing via DEA 106 form. Rph Pickle advised no arrests have been made as of 6/11/2015. ... Rph Pickle also advised a former pharmacy technician was arrested in Panama City Beach, FL in 2013 in possession of oxycodone which was stolen from Pardue's Pharmacy.

....

Rph Pickle advised all schedule II controlled substances are stored in a locked, metal cabinet behind the pharmacy counter. Consultant Stivers did note damage to the cabinet apparently a result of the burglary in 2014. Rph Pickle advised he and Pharmacy Technician Leah Morgan are the employees with access to the controlled substances cabinet.

Consultant Stivers observed a *uniformed security guard who is stationed in the entrance hallway directly in front of the pharmacy entrance*. Rph Pickle advised

each business occupying the building contributes to the expense of maintaining the security guard.

Rph Pickle advised the *pharmacy does not maintain a formal, written controlled substance dispensing policy*. Consultant Stivers suggested Rph Pickle draft and implement written pharmacy policy with regard to dispensing controlled substances.

Rph Pickle stated he *dispenses the combination of benzodiazepine, a muscle relaxant and a narcotic to the same patient "every few days" and acknowledged he was aware of both the known abuse potential and risk of CNS depression* when taking this combination of medications. Rph Pickle advised he was *aware of other combinations of medications which could be offered/dispensed without the risks* associated with the combination of benzodiazepine, a muscle relaxant and a narcotic.

Rph Pickle advised he *dispenses more than one immediate release opiate to the same patient(s)*. Rph Pickle stated in his medical opinion "one should be ER" if a patient is receiving more than one opiate and further *stated he "should not" be dispensing more than one immediate release opiate to the same patient* however he stated "*I get some patients*". Rph Pickle further stated "*when I started we had lines out the door, people milling in the lot*" and "*I quit filling for several doctors due to high controlled substance utilization*". Consultant Stivers inquired of Rph Pickle regarding his patient/customer base to which Rph Pickle replied "*I have some questionable patients*" and "*I may have gotten lax*". Consultant Stivers inquired of Rph Pickle if he could describe a situation when dispensing duplicate immediate release opiates to the same patient is clinically appropriate; *Rph Pickle could not provide a response*.

Rph Pickle advised he does utilize the Tennessee state funded prescription drug monitoring program to obtain patient prescription history for "new" patients with a controlled substance prescription or any "suspicious" controlled substance prescription (high quantity)".

....

Consultant Stivers was provided via email from Sales Representative Mike Dailey a list of the top five (5) prescribers of controlled substances for the past ninety (90) days from Pardue's Pharmacy. Consultant Stivers confirmed the accuracy of the list with Rph Pickle. ... The #2 prescriber of controlled substances, **Doctor Samson K. Orusa** – Internal Medicine / Adolescent medicine, entered into a pre-trial diversion agreement for Medicaid fraud in 2005. The #4 prescriber of controlled substances, **Doctor Jan A. Mayer** – Psychiatry, Neurology, Suboxone treatment, Alcohol and Drug addiction treatment, is currently Federally excluded due to a felony conviction / incarceration in 2001 related to mail fraud. The #5 prescriber of controlled substances, **ARNP Cindy J. Scott**, filed for bankruptcy in

2014 and her prescriptions for narcotics under Medicare Part D are “substantially above average” as compared to others in this medical specialty.

Consultant Stivers observed approximately five pharmacy customers appearing as lower socio economic status.

....

Consultant Stivers provided his business card to Rph Pickle and requested Rph Pickle forward any revised pharmacy policy implemented after the on-site visit; as of the date of this report no revised policy has been received.

### **Recommendation**

The current details of this assessment indicate concern in continuing to supply controlled substances to Pardue’s Pharmacy due to the following:

- No formal, written pharmacy due diligence policy with regard to dispensing of controlled substances.
- Pharmacist dispensing duplicate immediate release opiates to the same patient(s) without noting/confirming an established and legitimate clinical need.
- Pharmacist dispensing the combination of benzodiazepine, a muscle relaxant and an opiate to the same patient(s) without noting/confirming an established and legitimate clinical need.
- Disproportionate dispensing of controlled substances, specifically schedule two controlled substances.
- Disproportionate amount of prescriptions paid with cash.
- Security concerns due to prior incidents involving significant thefts of controlled substances.
- PIC’s state pharmacist’s license currently on probation.

*My recommendation is to block all controlled substance purchases to Pardue’s Pharmacy.*<sup>405</sup>

427. Notably, all three of the top five prescribers mentioned in the PCG report have been arrested, lost their license, or are practicing on a restricted license. For instance, Samson Orusa was a Clarksville pain clinic doctor who was arrested in 2018 on charges of drug trafficking and

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<sup>405</sup> ABC-MSAGC00000662–67 (bolded emphasis in original, italicized emphasis added).

healthcare fraud after undercover investigators witnessed what they described as “cattle calls” in the waiting room and millions made from cash-only transactions.<sup>406</sup>

428. Similarly, Cindy Scott, a Nurse Practitioner from Nashville, was mentioned in the report and disciplined by the Tennessee Board of Medicine in 2016 for her “haphazard and unprofessional prescribing practices,” including over-prescribing controlled substances, prescribing controlled substances without legitimate medical need, prescribing improper and dangerous combinations of opioids, and failure to properly document her treatment.<sup>407</sup> The Board also noted that Ms. Scott was among the top 50 Tennessee prescribers of controlled substances between 2012 and 2014. In 2018, Ms. Scott entered into a settlement with the DEA last year which required her to surrender her DEA registration and pay \$32,000.<sup>408</sup>

429. A July 15, 2015 Amerisource internal email titled “PCG Customer Review” summarized the consultant’s report on Pardue’s as follows:<sup>409</sup>

<p>Pardue Pharmacy 90% CS, 60% cash, PIC agrees that has become lax. Some trinity combos, high quantities Has improved as he had cut off a few MD but remains dispensing very large amounts of CS <b>Consultant suggests terminate service &amp; I agree.</b></p>
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430. The Amerisource PCG Action spreadsheet stated “high % of CS purchased” as an issue, and the Follow up read “f/U LETTER sent 7/17, requested 3 mo. CS DR [dispensing report] & Diversion PP [policies and procedures] due 8/4[.] 7/23- talk w/PIC Pickle, getting report together & will fax PP.”

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<sup>406</sup> <https://www.tennessean.com/story/news/health/2019/02/14/tennessee-pain-clinic-samons-orusa-opioids-undercover-investigation/2863256002/>.

<sup>407</sup> [https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1702\\_8060\\_112916](https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1702_8060_112916).

<sup>408</sup> <https://www.justice.gov/opa/pr/tennessee-chiropractor-pays-more-145-million-resolve-false-claims-act-allegations>.

<sup>409</sup> ABDCMDL00047171.



431. Amerisource again failed to terminated service and instead shipped Pardue's Pharmacy approximately 24,295 more ODU's that month.<sup>410</sup>

432. Approximately one year later in April 2016, the rate of prescriptions for controlled substances at Pardue's had dropped only slightly to 76.5% which is still an astronomically high number.<sup>411</sup>

433. Not only did Amerisource not follow the Pharma Compliance Group's recommendation to block the shipment of all controlled substances to Pardue's, Amerisource did not slow down its shipments to the problematic pharmacy.

434. Amerisource shipped over 1,102,711 opioid dosage units to Pardue's Pharmacy after the report was sent on June 26, 2016 until January 6, 2017.

435. Amerisource never added Pardue's Pharmacy to its "Do Not Ship" List.<sup>412</sup>

**ii. Jabo's Pharmacy**

436. Jabo's Pharmacy, pictured below, is located in Newport, Tennessee, a town with approximately 7,000 residents that is located between Knoxville, Tennessee and North Carolina.



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<sup>410</sup> ARCOS.

<sup>411</sup> ABDCMDL00140883.

<sup>412</sup> See ABDCMDL00049089.

437. Amerisource continued shipping oxycodone and other opioids to Jabo’s Pharmacy

despite knowing that:

- a Jabo’s customer who exited the pharmacy tried to sell Oxy 30 to the Amerisource investigator who was conducting surveillance of the pharmacy in the parking lot;<sup>413</sup>
- it has previously established a “No oxycodone only” shipping rule for Jabo’s<sup>414</sup> and quickly abandoned it; and
- it had been told by Mallinckrodt that Amerisource’s policy of having its own sales representatives conduct suspicious order monitoring was a conflict of interest,<sup>415</sup> among many others.

438. Unsurprisingly, Jabo’s was also one of Amerisource’s top 15 customers in Tennessee every single year between 2011 and 2015. Over the course of three months in 2014, Jabo’s purchased \$1,746,492 worth of pharmaceuticals from Amerisource.<sup>416</sup>

439. Jabo’s relied on at least *nine* distributors to supply it with opioids between 2006 and 2014, with Amerisource accounting for 89% of the MMEs and 81% of the ODUs during that time:

<b>City:</b> Newport (pop. appx. 7,000)		<b>County:</b> Cocke	
<b>ODUs:</b> 8,251,454		<b>MMEs:</b> 248,205,033	
<b>State Rank:</b> 13th	<b>ABC Rank:</b> 7th	<b>State Rank:</b> 14th	<b>ABC Rank:</b> 7th
<b>Years as ABC Customer:</b> 2004 to Present		<b>Distribution Center(s):</b> Birmingham; Paducah	

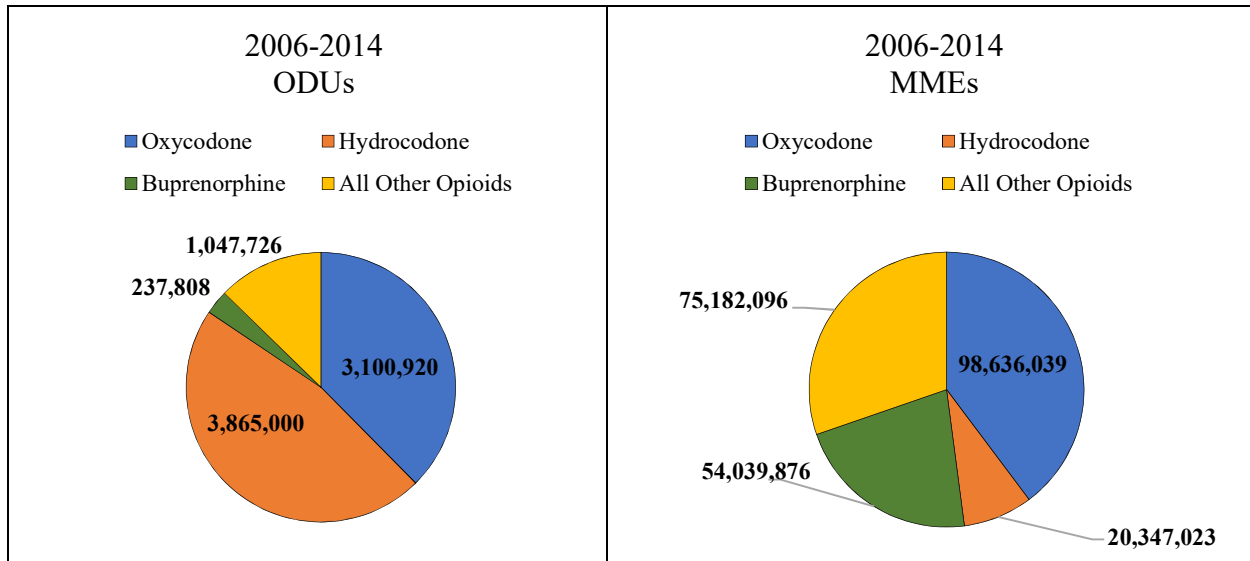
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<sup>413</sup> MNK\_NC8505955.

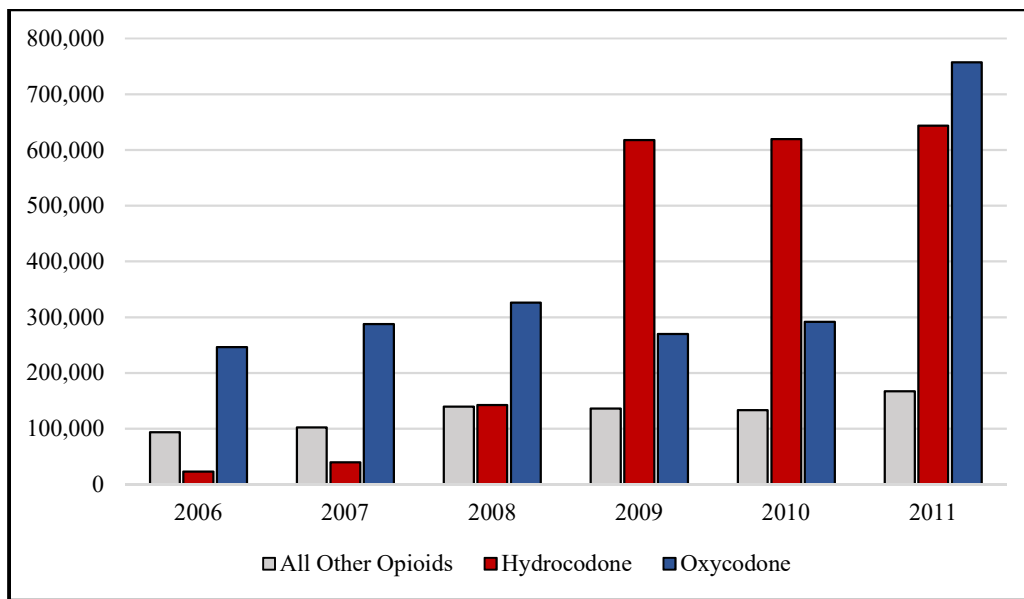
<sup>414</sup> ABDCMDL00315459.

<sup>415</sup> MNK\_NC8505954.

<sup>416</sup> ABDCMDL00171178.



440. As shown below, Amerisource increased the amount of oxycodone dosage units that it shipped to Jabo's by 160% between 2010 and 2011:<sup>417</sup>



441. Amerisource briefly halted sales of controlled substances to Jabo's Pharmacy in 2011, but quickly reversed course. Mallinckrodt documented Amerisource's business decision as follows:<sup>418</sup>

<sup>417</sup> ARCOS.

<sup>418</sup> MNK\_NC8505955.

Jabos Pharmacy (TN)

ABC provided Mallinckrodt information by e-mail (December???) that they have discontinued selling controlled drugs to this pharmacy, however, ABC stated in the meeting with Mallinckrodt 02/01/12 that they have reconsidered their decision and are continuing business with Jabos. Mallinckrodt expressed concern about this decision when ABC indicated that a customer who exited Jabos during ABC surveillance of the Jabos parking lot attempted to sell Oxy 30 to the ABC investigator. ABC indicates that they have fired the ABC sales rep who formerly called on Jabos because ABC determined that the sales rep was incorrectly representing Jabos Pharmacy business in asking ABC to increase Jabos controlled substance purchasing limits.

442. Amerisource's reconsideration of whether to begin shipping opioids to Jabo's again occurred only a few months after Mallinckrodt auditors explicitly expressed concern to Amerisource that Amerisource's sales team had a conflict of interest in performing suspicious order monitoring (SOM) reviews of the pharmacies. Ed Hazewski attempted to assuage Mallinckrodt's concerns by "indicat[ing] he has trained the Sales team on SOM warning signs."<sup>419</sup>

When Mallinckrodt auditors expressed concern about a possible conflict of interest in having the ABC Sales team performing SOM reviews of the pharmacies, ABC Compliance Director indicated he has trained the Sales team on SOM warning signs.

443. Amerisource's policy, namely allowing its sales representatives to conduct suspicious order monitoring reviews of pharmacies, was in fact a fundamental conflict of interest.

444. As of February 2013, the average Amerisource retail customer's ratio of Oxy 30 to all oxycodone purchases was 9.7%.<sup>420</sup> Amerisource knew that 24% of the oxycodone it was shipping to Jabo's in February 2013 was Oxy 30.

445. On November 18, 2013, years after Jabo's initially became an Amerisource customer, the following red flags were entered into Jabo's due diligence file:

Jabo's Pharmacy, [DEA license # withheld], is an existing ABC customer submitting an updated [Form] 590. The PIC is Jeremy Sherrod, license #8524 and the owner is Donald Francis. *Disciplinary action was found against the owner as they are also a pharmacist. In 2005 their license was put on probation for 3 years as a result of a state audit which found drug shortages and surplus and Rx's and drug invoices either missing or not properly filled. Also, in 2012, the board found that a pharmacy technician was not properly registered with the state, and that*

<sup>419</sup> MNK\_NC8505954.

<sup>420</sup> ABD\_CMDL00280924.

*their license was expired for nearly 8 months during their employment. A list of high prescribers is noted on the 590. All were clear and web searches were negative except for Thomas Conway. In 1997 they were fined for pre-signing prescription pads and leaving it with their nurse practitioner in order to allow them to write Rx's for controlled substances. All pertinent documentation is attached to this matter. The customer's anticipated monthly usage includes 22,000 units of oxycodone combination products, 23,000 units of alprazolam, and 200 units of carisoprodol per month. 20% controls projected as well as 5% cash.*<sup>421</sup>

446. Jabo's Pharmacy was listed as "No OX [oxycodone] only" as of December 7, 2011 due to an Amerisource CSRA investigation,<sup>422</sup> and this remained the status through at least 2018 on Amerisource's Do Not Ship spreadsheet.<sup>423</sup> Amerisource continued shipping oxycodone to Jabo's for years after the original "No OX only" designation. Since it first banned the sale of oxycodone to Jabo's in 2011 until September 2017, Amerisource shipped the pharmacy approximately 1.7 million tablets of oxycodone, which is still enough to provide Newport residents with about 258 doses of oxycodone each.<sup>424</sup>

447. Amerisource also failed to hold orders placed by Jabo's that Amerisource identified as suspicious, even when it reported those orders to the DEA. For example, on May 22, 2011, Amerisource reported four of Jabo's orders for a total of 4,600 units of immediate-release oxycodone. However, Amerisource still shipped all 4,600 units to Jabo's.

448. After the February 2015 audit of Amerisource's Birmingham distribution center, the DEA requested due diligence reports for ten pharmacies, including Jabo's.<sup>425</sup>

449. As of today, Amerisource is still shipping Jabo's controlled substances.

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<sup>421</sup> ABC-MSAGC00024361 (emphasis added).

<sup>422</sup> ABDCMDL00315459; ABDCMDL300250.

<sup>423</sup> ABDCMDL300250.

<sup>424</sup> ARCOS.

<sup>425</sup> ABDCMDL00141361.

**iii. Rippetoe, Inc., d/b/a Howard's Pharmacy**

450. Rippetoe, Inc., which does business under the name Howard's Pharmacy, is located in Morristown, a city in the northeast region of Tennessee about an hour away from Knoxville. It received more opioids from Amerisource, both in terms of dosage units and MMEs, than any other pharmacy in Hamblen County.

451. Amerisource's sales representative advised Rippetoe's pharmacist to purchase the monthly allotment of Oxy 30 "whether he needed it or not."<sup>426</sup> Amerisource continued shipping oxycodone and other opioids to Rippetoe Pharmacy despite knowing that:

- the pharmacy had a ratio of 38% of controlled substances to non-controlled substances as of 2011;<sup>427</sup>
- 75% of the oxycodone it purchased in January 2012 was Oxy 30;<sup>428</sup>
- Rippetoe dispensed invalid prescriptions for huge amounts of the "Holy Trinity" (a combination of opioids, muscle relaxers, and anti-anxiety medications) to young patients who drove long distances to fill the prescriptions;<sup>429</sup> and
- oxycodone manufacturer Mallinckrodt had concerns about the pharmacy and restriction of the pharmacy's chargebacks, among many others.<sup>430</sup>

452. Rippetoe was yet another Amerisource independent pharmacy customer with some of the highest rates of oxycodone consumption in the nation.

<b>City:</b> Morristown (pop. appx. 29,137)		<b>County:</b> Hamblen	
<b>ODUs:</b> 7,879,479		<b>MMEs:</b> 277,200,724	
<b>State Rank:</b> 9th	<b>ABC Rank:</b> 10th	<b>State Rank:</b> 4th	<b>ABC Rank:</b> 5th
<b>Years as ABC Customer:</b> 1993 to 2017		<b>Distribution Center(s):</b> Birmingham; Antioch	

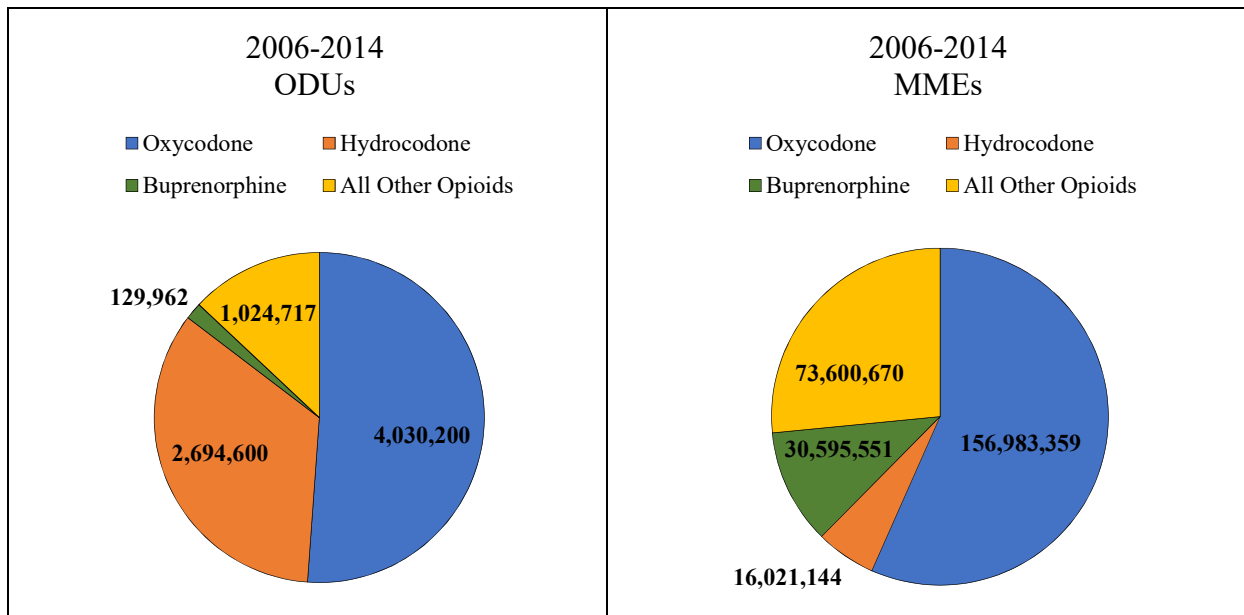
<sup>426</sup> MNK\_NC05795700.

<sup>427</sup> MNK\_NC00156219.

<sup>428</sup> ARCOS.

<sup>429</sup> ABC-MSAGC00024921-23 (emphasis added).

<sup>430</sup> ABDCMDL00315459.



453. During those same seven years, Rippetoe relied on *ten* other distributors, in addition to Amerisource, to purchase opioids. However, Amerisource was still Rippetoe’s primary distributor, responsible for shipping 82% of the MMEs and 74% of the ODUs to the pharmacy between 2006 and 2014.

454. As early as May 2007 Amerisource flagged Rippetoe for “possible excessive quantities of hydrocodone.”<sup>431</sup> It also noted that approximately 30% of the pharmacy’s purchases from Amerisource were for controlled substances.

455. Between March and August 2009, Amerisource shipped Rippetoe almost a quarter of a million doses of oxycodone, 32% of which were Oxy 30. Only three pharmacies in Tennessee ordered more Oxy 30 during this time, two of which were Food City Pharmacy # 674 and Belew Drugs.

<sup>431</sup> ABC-MSAGC00029090.

456. A Mallinckrodt Pharmacy Information Sheet, collected as part of the manufacturer's own due diligence and dated October 17, 2011, noted numerous concerns it had regarding both Rippetoe and Amerisource, beginning with the pharmacy's purchasing statistics:<sup>432</sup>

Statistics:  
% Controlled Substances vs. Non-Controlled Substances: 38% CS to non  
Volume of controlled substances: tablets per month approx. \$161,000 CS sales  
Top product by volume: oxycodone 30 mg  
Volume of oxycodone family: tablets from 5/10 through present; approx. per month: 64,500  
Volume of Oxycodone 30 mg tablets: per month 32,700  
% of Oxycodone Sales that are 30 mg tablets versus all oxycodone SKUs: 50%  
% Cash sales versus non-cash sales for CS (as reported by pharmacy):  
Other: Requested updated questionnaire.

457. Mallinckrodt's Pharmacy Information Sheet also reported that Amerisource had performed zero due diligence site visits while sales representatives visited the pharmacy once a month. Most notably, however, were the comments made by Mallinckrodt compliance employee Karen Harper.<sup>433</sup>

Karen Harper Notes: Customer since 03/04, medium risk based on volume. Have requested an updated questionnaire. No visits by Compliance. Don't have photographs in the file, they are coming. This customer is in Tennessee market and "always on the radar".

458. In January 2012, Rippetoe purchased 68,000 units of oxycodone from Amerisource, 75% of which was Oxy 30. That figure declined a few months later in or around May 2012, after Amerisource adjusted Oxy 30 thresholds across the board for all of its retail pharmacy customers. Rippetoe's oxycodone threshold was reduced from 65,000 to 37,098,<sup>434</sup>

<sup>432</sup> MNK\_NC00156219.

<sup>433</sup> MNK\_NC00156219.

<sup>434</sup> MNK\_NC08505943.



which it stayed within for a few months. However, by September 2012, Amerisource was already shipping the pharmacy thousands more units in excess of the set monthly threshold.

459. Also by September 2012, Amerisource knew that Mallinckrodt was so concerned with Rippetoe's purchasing of its controlled substances, that Mallinckrodt blocked the pharmacy by refusing to issue chargebacks.<sup>435</sup> Rippetoe's utilized more than one distributor, but Amerisource supplied 82% of its opioids in 2012.

460. Amerisource's sales team continued to apply pressure on its compliance department. On February 7, 2013, Amerisource sales representative Mat Miller emailed his diversion control manager, Joe Tomkiewicz, to provide information and justifications for Rippetoe's Oxy 30 consumption, and explained that "Steve and Linda Rippetoe are trying their best to cooperate with us as we look into the Oxy 30 sales. I've made no promise that this report will result in an *increase* in their threshold."<sup>436</sup>

461. The next day, Mr. Miller sent an update to Amerisource that "FYI- I just got blessed [(cussed)] out today by Steve Rippetoe because we cut his threshold again- very upset. It is fair to say he is 'at risk' of moving away from ABC."<sup>437</sup>

462. Mr. Tomkiewicz responded to Mr. Miller that even though he was not done with his analysis, "it is probably fair to say we're looking at least another reduction in oxy 30 in addition to several other products."<sup>438</sup>

463. This decision "surprised" Amerisource's district director in sales, who added that while she "[does] not fully understand the way the mix or percentages are calculated," she was

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<sup>435</sup> MNK\_NC08505964.

<sup>436</sup> ABC-MSAGC00024925 (emphasis added).

<sup>437</sup> ABC-MSAGC00024925.

<sup>438</sup> ABC-MSAGC00024925.

still “surprised a reduction is being considered *especially when the customer believes an increases [sic] are warranted.*”<sup>439</sup>

464. A few days later, Amerisource’s Mr. Tomkiewicz circulated his prescription data analysis about Rippetoe and noted the following:<sup>440</sup>

Rippetoe was noted to have filled controlled substances for a total of 418 prescribers. 106 of these prescribers were noted to have commonly written for either oxycodone IR 30mg or 15mg without a corresponding long-acting product, and/or, for a commonly abused cocktail consisting of an opiate (hydrocodone or immediate release oxycodone), a benzodiazepine (alprazolam, clonazepam or diazepam) and carisoprodol. These 106 prescribers (list is attached), many of whom are Nurse Practitioners and Physicians' Assistants, wrote for the following percentages, based on tablets, of selected controlled substances at Rippetoe:

- 70.7% of all alprazolam
- 91.9% of all carisoprodol
- 69.4% of all clonazepam
- 73.8% of all diazepam
- 67.2% of all hydrocodone/apap
- 85.8% of all oxycodone 30mg
- 87.2% of all oxycodone 15mg
- 73.9% of all other oxycodones
- 84.7% of all methadone

465. Amerisource’s analysis also included examples of suspicious dispensing by Rippetoe’s:

Some noted patients included:

- A 27 year old patient was prescribed by a physician 56 miles from the pharmacy:
    - on 11/16/12 - 168 tablets of oxycodone 30mg
    - 56 tablets of carisoprodol 350mg
    - 56 tablets of clonazepam 1mg
    - on 12/14/12 - 168 tablets of oxycodone 30mg
    - 56 tablets of carisoprodol 350mg
    - 56 tablets of clonazepam 1mg
    - on 1/12/13 - 298 tablets of oxycodone 15mg
    - 56 tablets of carisoprodol 350mg
    - 56 tablets of clonazepam 1mg
- all paid for in cash

as well as:

<sup>439</sup> ABC-MSAGC00024925 (emphasis added).

<sup>440</sup> ABC-MSAGC00024921–23.

- A 27 year old patient was prescribed by a nurse 45 miles from the pharmacy:
  - on 11/1/12 - 28 tablets of alprazolam 1mg paid via cash
  - 72 tablets of oxycodone 30mg paid via cash
  - 40 tablets of oxycodone 30mg paid by 3rd party payor
  - on 11/29/12 - 112 tablets of oxycodone 30mg paid via cash
  - 28 tablets of alprazolam 1mg paid via cash
  - on 12/27/12 - 28 tablets of alprazolam 1mg paid via cash
  - 72 tablets of oxycodone 30mg paid via cash
  - 40 tablets of oxycodone 30mg paid by 3rd party payor

and, among others:

- A 31 year old patient who received:
  - on 11/5/12 from a physician 35 miles from the pharmacy:
    - 30 tablets of alprazolam 0.5mg
    - 30 tablets of carisoprodol 350mg
    - 30 tablets of hydrocodone/apap 5/325
    - 30 tablets of Lyrica 75mg
  - on 11/30/12 from an emergency room physician 43 miles from the pharmacy:
    - 30 tablets of hydrocodone 7.5/500
  - on 12/7/12 from a nurse in the same zip code as the pharmacy:
    - 60 tablets of alprazolam 0.5mg
    - 120 tablets of hydrocodone/apap 7.5/500
    - 60 tablets of Lyrica 75mg
  - on 1/10/13 from yet another physician near the pharmacy:

60 tablets of alprazolam 1mg  
 90 tablets of carisoprodol 350mg  
 60 tablets of hydrocodone/apap 10/325

466. Amerisource also identified concerns for Rippetoe related to cash payments and early refills for buprenorphine with naloxone, as shown below:

Additionally the customer's patterns of Suboxone Film dispensing is also disconcerting with regard to their mix of cash and 3rd party payor. It appears that the pharmacy is filling prescriptions for cash as "refill-too-soon," which suggests that such patients on addiction therapy are not adhering to their dosing. For example:

- A 23 year old patient who was prescribed by a physician 38 miles from the pharmacy:

11/14/12 - 14 filmtabs paid for via 3rd party payor

11/21/12 - 4 filmtabs cash

11/21/12 - 14 filmtabs 3rd party

11/23/12 - 1 filmtab cash

11/27/12 - 24 filmtabs 3rd party

11/27/12 - 3 filmtabs cash

11/27/12 - 4 filmtabs cash

11/28/12 - 28 filmtabs 3rd party

11/28/12 - 3 filmtabs cash

12/11/12 - 1 filmtab cash

12/12/12 - 28 filmtabs 3rd party

12/13/12 - 1 filmtab cash

12/14/12 - 1 filmtab cash

12/14/12 - 1 filmtab cash

12/15/12 - 1 filmtab cash

12/17/12 - 1 filmtab cash

12/18/12 - 1 filmtab cash

12/20/12 - 1 filmtab cash

12/26/12 - 28 filmtabs 3rd party

1/9/13 - 28 filmtabs 3rd party

1/10/13 - 2 filmtabs cash

1/11/13 - 4 filmtabs cash

1/12/13 - 1 filmtabs cash

467. Mr. Tomkiewicz concluded his emailed analysis of Rippetoe with the following:

While we will not tell the customer that they cannot fill for the prescribers we've identified, we are adjusting their thresholds based on the percentages noted above, for the products so identified. Additionally, for the products for which they've been given an override above the default threshold for a Large customer, we will remove the override. In order to minimize disruption, we will do this in a two-step process, moving halfway immediately, and the rest of the way on 3/1/2013. All new thresholds are attached.

468. Amerisource's threshold chart for Rippetoe, dated February 12, 2013, revealed previous threshold figures and showed that seven of the ten controlled substance family thresholds had been increased by an override:<sup>441</sup>

<sup>441</sup> ABC-MSAGC00024936.

Type	OMP	Old Threshold	Interim 2/12/13 - 2/28/13	Threshold Effective 3/1/13	Notes			
Override	BD	45,000	29,125	13,250				
Override	BN	10,000	6,550	3,100				
Default	CR	30,000	16,250	2,500				
Override	HY	55,440	36,970	18,500				
Override	MO	12,000	9,500	7,000	Final Threshold is Default for a Large			
Override	MT	24,000	20,500	17,000	Final Threshold is Default for a Large			
Override	OM	10,000	8,500	7,000	Final Threshold is Default for a Large			
Override	OX	37,098	23,549	10,000				
Default	OY	8,000	4,600	1,200				
Default	PH	7,000	4,750	2,500				

469. A month later, in March 2012, Amerisource assured Mallinckrodt that it had reduced Rippetoe’s oxycodone threshold levels from 65,000 dosage units per month to 37,098, which Mallinckrodt documented as well.<sup>442</sup>

470. By September 2013, however, Mallinckrodt had decided Rippetoe was still too much of a risk so it restricted the pharmacy’s chargebacks.<sup>443</sup>

471. Shortly after that decision, Rippetoe contacted Mallinckrodt directly to inquire about getting off of its “SOM list.” An internal Mallinckrodt document discussing the situation also included the following background information relating to Amerisource’s distribution to Rippetoe:<sup>444</sup>

Background:  
 \*Purchase through AmerisourceBergen  
 \*Amerisource Rep advised him to purchase the monthly allotment of Oxy-30 whether he needed or not. As a result of these high volume purchase was placed on SOM list. Amerisource Rep has since been terminated.

472. Actavis, another opioid manufacturer, also expressed concern regarding Rippetoe during its October 2012 partnership meeting with Amerisource.

<sup>442</sup> MNK\_NC08505943.

<sup>443</sup> ABDCMDL00315459.

<sup>444</sup> MNK\_NC05795700.

473. Yet Amerisource did not decrease the number of opioids that it kept on shipping to Rippetoe. Between June and November of 2013, Rippetoe had a 1,252% increase in the amount of hydrocodone it purchased from Amerisource.<sup>445</sup> During those same six months, Rippetoe's purchases of oxycodone from Amerisource *increased by 135%*.<sup>446</sup>

474. Several months later, in April 2014, the owner of Rippetoe's called Mallinckrodt again to report that "Amerisource would not come in and do a review as [Mallinckrodt] requested."<sup>447</sup>

475. In November 2016, Rippetoe was still attempting to persuade Mallinckrodt to let it purchase Mallinckrodt controlled substances, yet Mallinckrodt did not want to take the risk and told the pharmacy that it would require the crucial middleman, Amerisource, to do its due diligence first.<sup>448</sup>

Steve,

Per our telephone call, Howards Pharmacy requests Suspicious Order Monitoring ("SOM") re-evaluation. Mallinckrodt has developed a procedure to standardize the process for reinstating a restricted pharmacy once Mallinckrodt has ceased honoring chargebacks for that pharmacy.

Given that the wholesaler/distributor is responsible for sales of Mallinckrodt product to the pharmacy named, the wholesaler/distributor will be asked to provide the necessary information to facilitate our further SOM assessment of that pharmacy. Further, it is expected that the wholesaler/distributor will communicate directly with the pharmacy on these matters, as opposed to the pharmacy contacting Mallinckrodt. You may choose to utilize a third party consultant as opposed to a wholesaler/distributor if you like. If you choose this avenue, I could provide you a listing of outside consultants that other pharmacies have utilized to review their pharmacy/processes/procedures/security. Some of these organizations are operated by former DEA officials. Mallinckrodt does not endorse the consultants, but is merely identifying them as consultants for you to consider. The decision to retain a consultant is solely up to you.

Any information you obtain either from your wholesaler/distributor or an outside consultant and share with Mallinckrodt will be considered in our evaluation of your pharmacy.

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<sup>445</sup> ABDCMDL00171064.

<sup>446</sup> ABDCMDL00171069.

<sup>447</sup> MNK\_NC02396424.

<sup>448</sup> ABC-MSAGC00024932.

476. In March 2017, Amerisource’s sales representative Mat Miller was still trying to help Rippetoe “get back into good standing with Mallinckrodt,” and he forwarded Mallinckrodt’s letter to the CSRA Diversion Control Coordinator, Emily Coldren.<sup>449</sup>

477. Ms. Coldren sent Rippetoe’s information and Mr. Miller’s request to Sharon Hartman and Eric Cherveney in Amerisource’s CSRA department, saying that “Rippetoe (Howard’s Pharmacy) is looking for Mallinckrodt reinstatement. Please advise if we can move forward with requesting dispensing and policy/procedure.”<sup>450</sup>

478. Ms. Hartman responded with confusion as to why Mallinckrodt suspended Rippetoe, and opining that a PCG audit on behalf of Amerisource was not necessary:

Subject: RE: Howard's Pharmacy (100064571) - Mallinckrodt

Yes, I agree that would be our next step.  
Do we know exactly why this pharmacy was placed on the list in the first place? Would take in consideration as any review of their data is performed. Please add a BOBJ report to the file as background also.  
I do not think a PCG audit would be in order for this pharmacy.  
Please validate with Mike D that ABDC is the primary supplier for all medications for this customer.

Thank you.

Sharon Hartman, RPh  
AmerisourceBergen  
Director, Pharmacy Compliance and Diversion Control  
Corporate Security & Regulatory Affairs

479. Mr. Cherveney agreed that n PCG audit was necessary despite Mallinckrodt’s repeated concerns:<sup>451</sup>

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<sup>449</sup> ABC-MSAGC00024930.

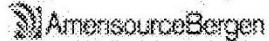
<sup>450</sup> ABC-MSAGC00024929.

<sup>451</sup> ABC-MSAGC00024928.

**Subject:** RE: Howard's Pharmacy (100064571) - Mallinckrodt

I agree. Nothing indicating an suspicious activity for this customer and PCG is not necessary. Let's pull the preliminary information and we'll notify MKT. Thx.

Eric Cherveney  
Director – Diversion Control  
Corporate Security & Regulatory Affairs



480. From April 2016 to May 2018, Rippetoe's ratio of controlled substances to total prescriptions dispensed was between 20% and 25%, but 55% to 65% of those were identified by Amerisource as "high risk."

481. On September 29, 2017, Amerisource completed a Retail Pharmacy Questionnaire for Rippetoe and revealed, among other things, that one of the top prescribing physicians for whom Rippetoe dispensed controlled substances was Dr. William Williams, a physician who co-owned a pain management clinic, Family Medical Clinic of Morristown, with a Physician's Assistant whom he supervised.

482. Dr. Williams was disciplined by the Tennessee Board of Medicine in 2015 because he failed to: (i) supervise his Physician's Assistant's (PA) pain management practice, review or sign off on charts in which his PA prescribed controlled substances to patients, (ii) appropriately monitor patients for compliance, adequately respond to signs of noncompliance such as repeated failed urine drug screens, and (iii) his records showed insufficient diagnoses, histories, physical exams, and treatment plans for the prescribed amounts, combinations, and dosages of controlled opioids, benzodiazepines, and other controlled substances. As a result, the Tennessee Board of



Medicine placed Dr. Williams' license on probation for five years until 2020 and he agreed to voluntarily surrender his pain management clinic certificate.<sup>452</sup>

483. On July 13, 2018, an Amerisource CSRA Diversion Control Coordinator who worked on CSRA validation for Rippetoe reported the following to Sharon Hartman:<sup>453</sup>

Top five prescribers on DNS:

- Karen Beets
- Tracy Stratton
- William Williams

William J Williams found to be on probation in 2015 for a term of 5 years (2020). Please let me know how to proceed or how you would advise to proceed.

484. Thus Amerisource knew that three of Rippetoe's top five prescribers were on the Do Not Ship list, or "DNS." However, *Amerisource's Do Not Ship spreadsheet did not list any of the three providers.*<sup>454</sup>

485. The same Amerisource email also attached license verifications for those three prescribers, which revealed Dr. Williams' two-year-old disciplinary action<sup>455</sup> and that all of the top prescribers aside from Dr. Williams were either APRNs or PAs. Amerisource also checked where APRNs Karen Beets and Tracy Sutton practiced, and knew they were located between 40 minutes to an hour away from Rippetoe, respectively.<sup>456</sup>

486. Nevertheless, Amerisource approved Rippetoe's due diligence and kept them as a customer.<sup>457</sup>

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<sup>452</sup> ABC-MSAGC00028942-50.

<sup>453</sup> ABC-MSAGC00028940.

<sup>454</sup> ABDCMDL00300250 (May 22, 2018).

<sup>455</sup> ABC-MSAGC00028940-50.

<sup>456</sup> ABC-MSAGC00028954-67.

<sup>457</sup> ABC-MSAGC00029013.

*iv. Other Illustrative Pharmacy Examples*

487. Amerisource was the primary distributor for half of the 20 pharmacies in Tennessee that received the most MMEs between 2006 and 2014. But there were other problematic pharmacies that Amerisource serviced in Tennessee.

488. For instance, Apple Discount Drugs, located in Clinton, Tennessee with a population of about 9,800, received approximately 441,200 units of oxycodone in 2011, which jumped to 549,700 in 2012—278,800 units from Amerisource and 270,900 from HD Smith. The oxycodone number dropped slightly in 2013 when HD Smith reduced its shipment by almost one hundred thousand. Amerisource dropped around 20,000 units.

489. Okie’s Pharmacy, located in Maynardville, Tennessee with a population of about 1,800, had utilized as many as eight distributors in one year to purchase controlled substances.

490. Amerisource continued shipments to both Apple Discount Drugs and Okie’s Pharmacy despite direct knowledge that Amerisource’s pharmacy customers were utilizing more than one distributor for controlled substances. For instance, based on an October 22, 2012 “Partnership Meeting” with Actavis, Amerisource knew that between January 1, 2012 and October 15, 2012, both Okie’s Pharmacy and Apple Discount Drugs were sourcing Oxy 30 and Oxy 15 from them and another distributor. Amerisource also knew that Okie’s Pharmacy and Apple Discount Drugs had 85% and 80% “disproportionate oxy activity,” respectively.<sup>458</sup> Amerisource nevertheless continued shipping the two pharmacies just as much oxycodone.

491. In a final illustrative example, two years after Amerisource began selling controlled substances to Dale Hollow, it became one of Amerisource’s top 15 customers by sales dollar value in Tennessee.<sup>459</sup> Dale Hollow was yet another Tennessee pharmacy with glaring red flags, such

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<sup>458</sup> ABC-MSAGC00021020.

<sup>459</sup> ABC-MSAGC00002012.

as 90% of prescriptions dispensed were for controlled substances, patients driving long distances to the pharmacy, disciplinary action being taken against the pharmacists, and dispensing abnormally high rates of buprenorphine monoproduct, that Amerisource overlooked for the sake of sales. Amerisource only halted sales to Dale Hollow Pharmacy in the small town of Celina after its delivery driver reported that he was unable to complete the shipment due to the DEA shutting down the pharmacy in April 2019.

### **III. AMERISOURCE IS SUBSTANTIALLY RESPONSIBLE FOR THE OPIOID EPIDEMIC IN TENNESSEE**

492. The United States has approximately 4.4% of the world's population, but accounts for the vast majority of opioids consumed globally, including oxycodone, buprenorphine, and fentanyl.

493. This imbalance occurs not because Americans or Tennesseans experience pain at higher rates than their global or national peers or have greater access to healthcare. Rather, it is due in large part because of oversupply from distributors like Amerisource, the largest distributor of opioids in Tennessee from 2006 to 2014.

494. Within the United States, Tennessee accounts for disproportionately high rates of per capita opioid consumption generally.

495. Tennessee still had the third highest prescription rate in the country in 2017<sup>460</sup> and the CDC measured Tennessee as having among the most opioids prescribed per person in the country.<sup>461</sup> Tennessee has also continued to have some of the highest rates of prescription opioid abuse in the nation, particularly in the eastern part of the state. In 2017, the nationwide rate of

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<sup>460</sup> <https://www.cdc.gov/drugoverdose/maps/rxstate2017.html>.

<sup>461</sup> <https://www.cdc.gov/vitalsigns/opioids/infographic.html>.

drug-related deaths was 21.7 per 100,000 people.<sup>462</sup> Tennessee's rate of drug-related deaths was higher than the national average at 26.6,<sup>463</sup> and within Tennessee, some Eastern counties had almost triple the national average, like Knox County at 68.4 and Anderson County at 60.3.<sup>464</sup>

496. Amerisource supplied a substantial portion of Tennessee's prescriptions and high MME levels came from oxycodone, buprenorphine, and fentanyl.

497. Data from the DEA's ARCOS database confirms that Amerisource distributed what it knew to be dangerous quantities of prescription opioids throughout Tennessee. Between 2006 and 2014, Amerisource supplied Tennessee with over 712 million dosage units of opioids and nearly 13 billion MMEs—enough for approximately 111 ODU and 2,031 MMEs for every Tennessean. Notably, these numbers continued to rise throughout the epidemic. And, in actuality, these figures are even higher because this data only accounts for the 12 most common opioid-related DEA drug codes and excludes the last five years.

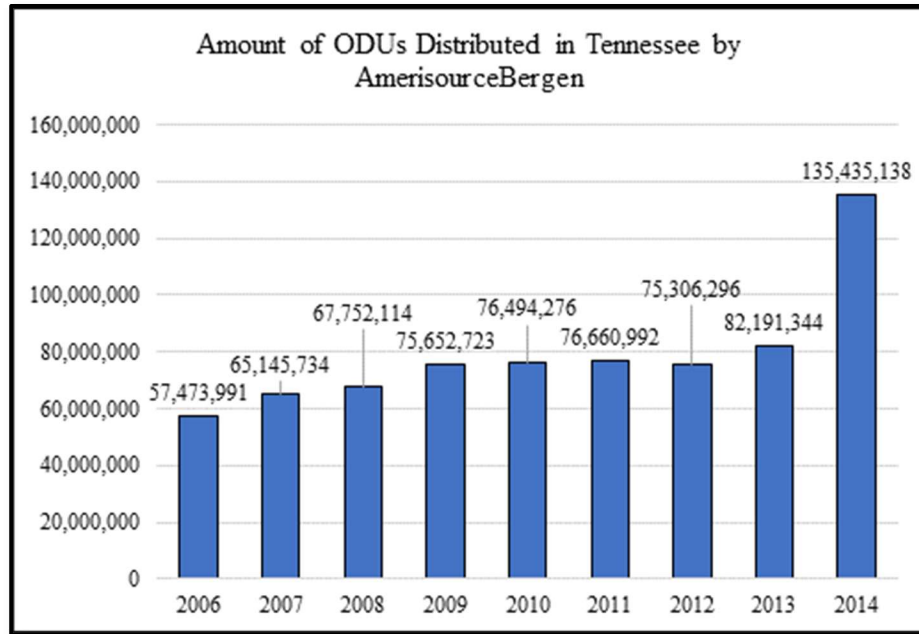
498. The chart below represents the ODUs shipped by Amerisource into Tennessee between 2006 and 2014, a 136% increase:

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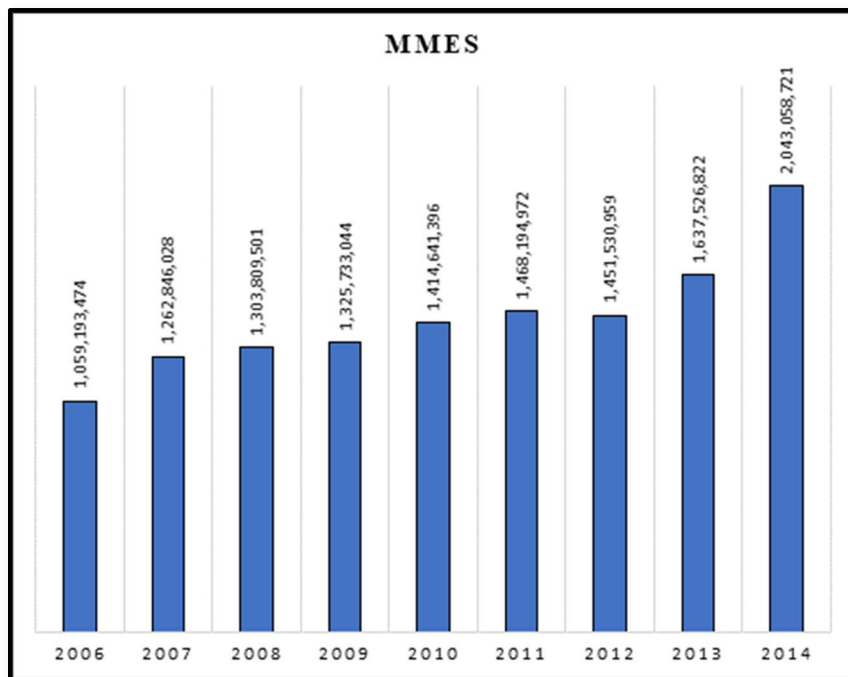
<sup>462</sup> *Drug Overdose Deaths*, U.S. CENTERS FOR DISEASE CONTROL, available at <https://www.cdc.gov/drugoverdose/data/statedeaths.html>.

<sup>463</sup> *Drug Overdose Deaths*, U.S. CENTERS FOR DISEASE CONTROL, available at <https://www.cdc.gov/drugoverdose/data/statedeaths.html>.

<sup>464</sup> *Knox County Regional Forensic Center Drug-related Death Report*, KNOX COUNTY REGIONAL FORENSIC CENTER, available at [https://knoxcounty.org/rfc/pdfs/KCRFC\\_DRD\\_Report\\_2017.pdf](https://knoxcounty.org/rfc/pdfs/KCRFC_DRD_Report_2017.pdf) (slide 30 of 111).

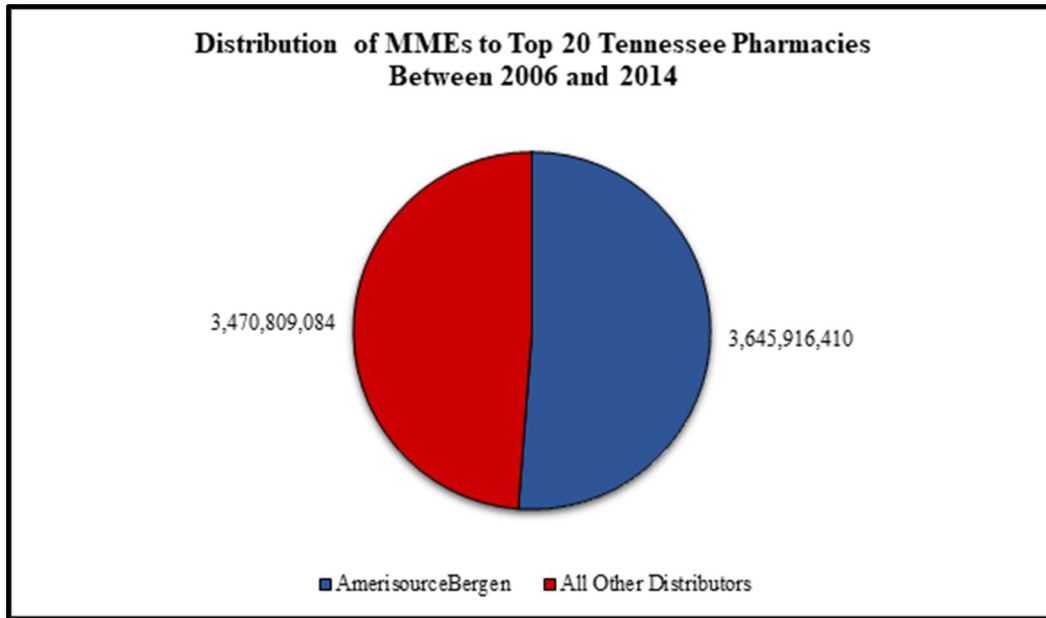


499. The amount of opioids Amerisource shipped into Tennessee as measured in MMEs increased 93% between 2006 and 2014.



500. Amerisource accomplished this massive increase in opioid sales by targeting Tennessee's high-volume pharmacies. Half of the 20 pharmacies ranked highest in Tennessee for

MMEs between 2006 and 2014 were supplied almost exclusively by Amerisource. The following chart shows how much Amerisource contributed to each of those 20 pharmacies:



Rank	Pharmacy Name	MMEs	ABC %
1	Food City Pharmacy # 674	1,026,896,134	92.9%
2	P & S Pharmacy	677,501,135	77.8%
3	Blankenship Pharmacy	467,836,625	99.7%
4	Rippetoe, Inc.	338,619,594	81.8%
7	Gray Pharmacy	320,392,588	76.3%
10	Pardue's Pharmacy	296,376,351	99.6%
13	Disney Pharmacy Services	286,290,023	71.1%
14	Jabo's Pharmacy	279,874,819	88.6%
16	Belew Drug	270,258,454	93.7%
18	Food City Pharmacy # 694	252,202,235	69.4%

501. Amerisource's shipped buprenorphine to Kingsport pharmacies, Oxy 30 to Knoxville Food City Pharmacies # 674, # 694, and # 616, and other opioids into Tennessee in such mind-boggling numbers that Amerisource *had* to know that abuse or diversion of its opioids was rampant and was not based on valid prescriptions. In fact, on too many occasions, Amerisource *did* know and kept shipping opioids to these problem pharmacies anyway.

502. Among distributors, Amerisource was one of the most audacious and effective in Tennessee. While it was third in size nationally, it was first in Tennessee. Amerisource routinely ignored red flags and obvious signs of diversion at pharmacies it distributed to in order to capture market share and make up ground on its larger rivals.

503. Amerisource's aggressive distribution to suspect pharmacies and other conduct has played a substantial role in creating and prolonging the opioid epidemic in Tennessee. Amerisource's conduct led to widespread addiction, abuse, diversion, overdoses, deaths, and other negative consequences which forced the State and its political subdivisions to spend significant resources in an ongoing attempt to handle the crisis.

504. Amerisource's sales associates pushed pharmacies to order as many opioids as possible and Amerisource encouraged its sales representatives to generate business from the very pharmacy customers that it knew were more likely to have suspicious orders.

505. Amerisource knew the consequences of aggressive and unlawful distribution for a controlled substance—and went full-steam ahead anyway for over a decade.

506. Despite ongoing knowledge over a period of many years that Tennessee had very high rates of abuse of oxycodone, buprenorphine, and fentanyl, Amerisource continued to instruct its sales representatives to visit, and continue to visit, some of the most notorious pharmacies in Tennessee, as well as engaged in other practices where there were red flags or outright signs of abuse and diversion of opioids.

507. Amerisource's sales representatives and compliance employees observed and ignored red flags for abuse or diversion of opioids during sales calls or during audits with pharmacists who would ultimately be arrested, convicted, or have their professional licenses disciplined for conduct related to their dispensing of controlled substances.

508. Signs of abuse or diversion, such as cars with license plates from distant places in pharmacy parking lots, packed stores, disproportionate numbers of cash-paying patients, and signs directed to cash-paying patients, were readily apparent to Amerisource’s sales representatives when they visited customers in Tennessee—especially when they made repeated sales calls.

509. Amerisource had detailed dispensing data that told the company exactly which providers were prescribing opioids, and which pharmacies were dispensing these opioids.

510. Amerisource’s efforts to thwart abuse and diversion of opioids and other opioids were anemic at best. The compliance policies Amerisource did create were inadequate, inconsistently administered, and all too often yielded to Amerisource’s higher priority of generating sales.

511. Amerisource did not take compliance seriously. In the rare instance in which a sales representative or compliance employee reported a pharmacy for red flags for abuse or diversion or made a recommendation to stop shipping all controlled substances, Amerisource often did nothing about it.

512. Even when Amerisource terminated shipments of controlled substances on paper, it continued to ship controlled substances, including opioids, in practice to these problem pharmacies.

513. The enormous number of opioid prescriptions written and filled in Tennessee based on Amerisource shipments has equated to a substantial number of Tennesseans who have become addicted to opioids. A 2015 published meta-analysis of 38 studies evaluating opioid misuse, abuse, and addiction in chronic pain patients found rates of addiction averaging between 8–12%,<sup>465</sup>

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<sup>465</sup> Kevin E. Vowles, *Rates of Opioid Misuse, Abuse, and Addiction in Chronic Pain: A Systematic Review and Data Synthesis*, PAIN, 569, 156:4 (Apr. 2015).



though the actual percentage is most likely higher because of those misclassified as physically tolerant.

514. Most people addicted to opioids started with prescription painkillers. According to the federal government's Substance Abuse and Mental Health Services Administration (SAMHSA), it is estimated that 221,000 (or 4.56%) of the 4,850,000 adults in Tennessee have used prescription opioids for non-medical purposes. Of these, it is estimated that, as of 2014, at least 69,100 were addicted to opioids and required treatment for opioid abuse and 151,900 had risky prescription opioid use.<sup>466</sup>

515. The State and its political subdivisions have spent significant public resources on treatment, toxicology reports, law enforcement, corrections, intervention programs, drug courts, prosecution, probation, and child welfare related to opioids, including oxycodone, buprenorphine, and fentanyl, and more funds are desperately needed to address this ongoing public health crisis.

516. Opioid use, morbidity, and mortality have increased exponentially nationwide and across Tennessee in the years since Amerisource first began aggressively distributing opioids into Tennessee.

517. In 2016, Tennessee had 22,944 nonfatal overdoses, 15,001 of which were outpatient visits and 7,943 were inpatient stays.<sup>467</sup> In 2017, 6,879,698 opioid prescriptions were written in Tennessee and there were 1,268 opioid-related overdose deaths, equaling a rate of 19.3 deaths per 100,000 persons—69 % higher than the national rate of 13.3.<sup>468</sup>

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<sup>466</sup> *Prescription for Success*, TENNESSEE DEPARTMENT OF MENTAL HEALTH AND SUBSTANCE ABUSE SERVICES, 4 (2014) available at [https://www.tn.gov/content/dam/tn/mentalhealth/documents/Prescription\\_For\\_Success\\_Full\\_Report.pdf](https://www.tn.gov/content/dam/tn/mentalhealth/documents/Prescription_For_Success_Full_Report.pdf).

<sup>467</sup> <https://www.tn.gov/health/health-program-areas/pdo/pdo/data-dashboard.html>.

<sup>468</sup> *Id.*; see also, *Tennessee Opioid Summary*, NATIONAL INSTITUTE ON DRUG ABUSE, available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/tennessee-opioid-summary>.

518. SAMHSA has stated that the number of individuals enrolled in substance use treatment in Tennessee has varied between 16,590 in 2011; 19,115 in 2012; 14,149 in 2013; and 22,445 in 2015.<sup>469</sup>

519. Similarly, SAMHSA has stated that the number of Tennesseans enrolled in an opioid treatment program and receiving Medication Assisted Therapy (MAT), excluding those receiving MAT through a private physician, totaled 5,371 in 2011; 6,079 in 2012; 2,422 in 2013; 4,421 in 2015; 5,280 in 2016; and 6,561 in 2017.<sup>470</sup> Similarly, the number of individuals receiving the treatment drug buprenorphine with naloxone at substance abuse facilities in Tennessee has climbed from 299 in 2011; 475 in 2012; 488 in 2013; 1,179 in 2015; to 1,217 in 2017.<sup>471</sup>

520. A significant number of Tennesseans still need treatment. In Tennessee, only about 10.6% of individuals aged 12 or older with illicit drug dependence or abuse received treatment within the year prior to being surveyed.<sup>472</sup>

521. The State's opioid epidemic has also had a negative impact on infants, children, the elderly, and families generally.

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<sup>469</sup> *Behavioral Health Barometer Tennessee, Vol. 4*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, 13 available at [https://www.samhsa.gov/data/sites/default/files/Tennessee\\_BHBBarometer\\_Volume\\_4.pdf](https://www.samhsa.gov/data/sites/default/files/Tennessee_BHBBarometer_Volume_4.pdf) (hereinafter *Behavioral Health Barometer Tennessee*).

<sup>470</sup> *Behavioral Health Barometer Tennessee*, 13; *2016 State Profile – Tennessee*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, available at [https://www.dasis.samhsa.gov/webt/state\\_data/TN16.pdf](https://www.dasis.samhsa.gov/webt/state_data/TN16.pdf).

<sup>471</sup> *Behavioral Health Barometer Tennessee*, 14; *2017 State Profile – Tennessee*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, available at [https://www.dasis.samhsa.gov/webt/state\\_data/TN16.pdf](https://www.dasis.samhsa.gov/webt/state_data/TN16.pdf).

<sup>472</sup> K. Edwards, *Opioid Abuse in Tennessee*, TENNESSEE DEPARTMENT OF MENTAL HEALTH & SUBSTANCE ABUSE SERVICES (citing SAMHSA Center for Behavioral Health Statistics and Quality, 2014), p. 1, available at [https://www.tn.gov/content/dam/tn/mentalhealth/documents/Opioid\\_Abuse\\_in\\_TN\\_July\\_2015.pdf](https://www.tn.gov/content/dam/tn/mentalhealth/documents/Opioid_Abuse_in_TN_July_2015.pdf).

522. Tennessee is sixth in the nation for rates of opioid-related hospital admissions among senior citizens. In 2005, 467 out of every 100,000 Tennesseans aged 65 and older spent time hospitalized from opioid related use. By 2015, that rate more than doubled to 1,055.<sup>473</sup>

523. Opioid use and misuse have increased the numbers of infants suffering from NAS, a withdrawal syndrome that occurs in babies exposed to opioids in utero. The number of NAS cases attributable to prescription opioids has been disproportionately high in Tennessee. A 2015 NAS report prepared by the Tennessee Department of Health shows that “[w]hen categorized into mutually exclusive categories of exposure, 48.5% of cases were exposed to prescription drugs only, 26.8% were exposed only to illicit or diverted drugs, and 23.2% were exposed to a mix of prescription and illicit or diverted drugs.”<sup>474</sup>

524. In Tennessee, the rate of NAS was *three times* the national average between 2009 and 2012 and has been more than *ten times* the national average in areas of East Tennessee.<sup>475</sup> In 2013 and 2014, Tennessee had NAS ratios of 25.5 and 28.5 per 1,000 live births respectively.<sup>476</sup>

525. Parental substance abuse is a major risk factor for child fatalities, child maltreatment, and involvement with the child welfare system. Children removed from their home as a result of parental substance abuse are likely to remain in foster care longer and have significantly lower rates of adoption. A higher rate of adoption indicates that children removed from their homes remain in foster care longer and are less likely to exit from foster care to reunite

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<sup>473</sup> Anita Wadhvani, *Opioid-related Hospitalizations More than Triple for Tennessee Seniors*, THE TENNESSEAN, available at <https://www.tennessean.com/story/news/2017/08/13/opioid-related-hospitalizations-more-than-triple-tennessee-seniors/545556001/> (citing the U.S. Agency for Healthcare Research and Quality).

<sup>474</sup> A.M. Miller, *Neonatal Abstinence Syndrome Surveillance Annual Report 2015*, TENNESSEE DEPARTMENT OF HEALTH 5 (2015), available at [https://www.tn.gov/content/dam/tn/health/documents/nas/NAS\\_Annual\\_report\\_2015\\_FINAL.pdf](https://www.tn.gov/content/dam/tn/health/documents/nas/NAS_Annual_report_2015_FINAL.pdf).

<sup>475</sup> Paul Campbell, M.D., PhD, *Neonatal Abstinence Syndrome in East Tennessee: Characteristics and Risk Factors among Mothers and Infants in One Area of Appalachia*, J. HEALTH CARE POOR UNDERSERVED 1293-1408, 28(4) 2017.

<sup>476</sup> *Id.*

with biological parents. Children with parents that abuse opioids are also much more likely to then abuse opioids.

526. While Amerisource's conduct and distribution of opioids continues unabated towards many of the pharmacies referenced herein, the wave of addiction, death, and other harm continues to flow from Amerisource's conduct even at pharmacies it no longer supplies.

#### **IV. FACTS PERTAINING TO CLAIMS UNDER TENNESSEE RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ("RICO") ACT**

527. Amerisource engaged in separate schemes to unlawfully sell and distribute oxycodone,<sup>477</sup> a Schedule II narcotic, to at least six pharmacies in Tennessee: Pardue's Pharmacy in Nashville, Jabo's Pharmacy in Newport, P & S Pharmacy in Kingsport, and Food City Pharmacies # 674, # 694, and # 616 in Knoxville, to increase Amerisource's profits and sales and grow its share of the narcotic painkiller market in Tennessee through repeated and sizeable shipments of oxycodone after knowing that significant diversion from these pharmacies was occurring and that the pharmacies were filling invalid prescriptions.

528. Amerisource's management, officers, and employees, who approved shipments of opioids after knowing that significant diversion from these pharmacies was occurring and that the pharmacies were filling invalid prescriptions, generally acted with the intent to benefit the corporation.

529. The scheme devised, implemented, and conducted by Amerisource was a common course of conduct designed to ensure that Amerisource unlawfully increased its sales and profits through shipments to pharmacies from which diversion was occurring and that were filling invalid prescriptions. It would repeat this scheme with the six pharmacies referenced below.

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<sup>477</sup> For purposes of civil RICO, the Attorney General has excluded oxycodone with acetaminophen from the calculations. If added, the numbers expressed below would, in the overwhelming majority of cases, be higher.

**A. Amerisource's Jabo's Pharmacy Oxycodone Supply Scheme  
(At least February 2, 2012 to January 4, 2018)**

530. Amerisource knew that oxycodone, a Schedule II opioid, was being diverted in significant numbers from Jabo's Pharmacy, and knew that Jabo's Pharmacy was filling invalid prescriptions, yet it continued to supply Jabo's Pharmacy with oxycodone, continued its contract with Jabo's Pharmacy, and knowingly received revenue from oxycodone it knew was going to be diverted or was based on invalid prescriptions.

531. Amerisource knew from when it first began shipping Schedule II opioids to Jabo's Pharmacy that it was located in Newport, Tennessee, a town of 7,000 people.

532. At least by December 7, 2011, Jabo's Pharmacy was listed by Amerisource as "No OX [oxycodone] only" following an in-house CSRA investigation,<sup>478</sup> and remained in this status, at least on Amerisource's do-not-ship list, as late as 2018.

533. On February 1, 2012, Amerisource's compliance officers had a meeting with their compliance counterparts at Mallinckrodt, a manufacturer of oxycodone. At the meeting, Amerisource stated that it had already reconsidered its December 2011 "No OX [oxycodone] only" decision and began shipping controlled substances, including oxycodone, to Jabo's again.<sup>479</sup>

534. Amerisource even continued to ship oxycodone to Jabo's after the February 1, 2012 meeting, in which Mallinckrodt representatives expressed deep concern to Amerisource's compliance officers, after Amerisource "*indicated that a customer who exited Jabo's during ABC surveillance of the Jabos parking lot attempted to sell Oxy 30 to the ABC investigator.*"<sup>480</sup>

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<sup>478</sup> ABDCMDL00315459.

<sup>479</sup> MNK\_NC8505955.

<sup>480</sup> MNK\_NC8505955.

535. Amerisource continued to know based other information that significant diversion of the oxycodone it was shipping to Jabo's was being diverted or was not based on valid prescriptions in 2013.

536. As of February 2013, Amerisource knew that Jabo's Pharmacy's purchasing ratio of Oxy 30 to oxycodone was significantly higher than its peers. Amerisource knew that 24% of the oxycodone Amerisource was shipping to Jabo's was Oxy 30 and Amerisource's average retail customer's ratio of Oxy 30 to all oxycodone was 9.7%.<sup>481</sup>

537. By at least November 18, 2013, Amerisource knew:

- Jabo's Pharmacy had a high anticipated monthly usage of "Holy Trinity" opioid combination prescriptions, which are commonly diverted, including for 22,000 units of oxycodone combination products, 23,000 units of alprazolam, and 200 units of carisoprodol per month;
- The Tennessee Board of Pharmacy took disciplinary action against the owner who was also a pharmacist;
- in 2005, the Pharmacy's license was put on probation for three years as a result of a state audit which found controlled substance shortages, and controlled substance invoices either missing or not properly filled;
- in 2012, the Board found that a pharmacy technician was not properly registered with the state, and that the technician's license was expired for nearly eight months during his or her employment; and
- in 1997, the Pharmacy was fined when a pharmacist provided pre-signed prescription pads for controlled substances to nurse practitioners affiliated with the Pharmacy.<sup>482</sup>

538. Between February 2, 2012, the day after Amerisource's compliance officers met with Mallinckrodt representatives, and September 18, 2017, Amerisource shipped approximately 20,418.3 *grams* of oxycodone, of which 5,865 grams was Oxy 30—all while knowing that

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<sup>481</sup> ABDCMDL00280924.

<sup>482</sup> ABC-MSAGC00024361 (emphasis added).

significant diversion was occurring from Jabo's and the pharmacy was routinely dispensing invalid prescriptions.

539. Between November 19, 2013, the day after Amerisource's internal report about Jabo's, and September 18, 2017, Amerisource shipped approximately 13,416.8 *grams* of oxycodone and 4,662 *grams* of Oxy 30, specifically, to Jabo's Pharmacy.

540. Every month or nearly every month between February 2, 2012 and September 18, 2017, Amerisource shipped and later received payment for 200 grams of oxycodone or more.

541. Details of every shipment Amerisource made for oxycodone by month in milligrams and grams from February 2, 2012 to September 18, 2017 are set forth in **Attachment 1**, which is incorporated by reference.

542. While complete data is not presently available, Amerisource was still shipping oxycodone to Jabo's Pharmacy at least by January 4, 2018, when Amerisource still had order thresholds for oxycodone for Jabo's Pharmacy.<sup>483</sup>

543. Aside from being conducted by the same company (Amerisource) and many of the same employees within the company, Amerisource's scheme with respect to Jabo's Pharmacy involved the same financial motive, the same Schedule II controlled substance (oxycodone), the same method of commission (in which Amerisource ignored signs of diversion and invalid prescriptions being dispensed from the pharmacy), and was interrelated to Amerisource's conduct with respect to the five other pharmacies referenced herein.

**B. Amerisource's Knoxville Food City Oxycodone Supply Schemes  
(At least October 23, 2012 to November 15, 2012)**

544. Amerisource knew that oxycodone, a Schedule II opioid, was being diverted in significant numbers from Food City Pharmacy # 674, # 694, and # 616, and knew that these Food

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<sup>483</sup> ABDCMDL00238575.

City pharmacies were filling invalid prescriptions. But it continued to supply these pharmacies with oxycodone, continued its contract with buyers for Food City, and knowingly received revenue from these opioids it knew were going to be diverted or were based on invalid prescriptions.

545. Amerisource, its compliance managers, and its distribution center managers had intentionally created and followed a policy towards Food City as of August 29, 2007 to “go ahead and let it go no matter what the percent is [above threshold] or the amount of items.”<sup>484</sup>

546. Soon after November 30, 2011, Amerisource and its compliance managers, through a detailed investigative report from former career DEA officials it hired to investigate Food City:

- were told that Amerisource was at “high risk” of liability for supplying Food City with opioids, including oxycodone and hydrocodone;<sup>485</sup>
- knew Food City had a “unique relationship” with Bearden HealthCare Associates whose prescribers were listed in the top ten category at # 674, # 694, and # 616 for controlled substances and often prescribed “high levels of pain medications, *often in ‘cocktail combinations’ that are sought by those who illicitly seek pain medications*[:];”<sup>486</sup>
- were told by their investigators that *34% of all controlled substance prescriptions from Bearden were comprised of “Holy Trinity” cocktail combinations of oxycodone, Alprazolam, and Soma, which are sought by those who illicitly seek pain medications*; <sup>487</sup>
- knew that “several of the Food City Store Pharmacy competitors have determined that fulfilling prescriptions from certain pain management clinics and practitioners could result in fines or sanctions from the DEA[:];”<sup>488</sup>
- knew that its own investigators had determined “that a correlation exists between the refusal of other pharmacies in the Knoxville area to fill prescriptions from specific practitioners and Pain management clinics and the excessive amount of controlled substance prescriptions filled at Food City Pharmacy 616, 674, and 694[:];”<sup>489</sup> and

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<sup>484</sup> ABDCMDL00316920.

<sup>485</sup> ABC-MSAGC00024870.

<sup>486</sup> ABC-MSAGC00024871; *see also*, ABC-MSAGC00024875.

<sup>487</sup> ABC-MSAGC00024875.

<sup>488</sup> ABC-MSAGC00024871.

<sup>489</sup> ABC-MSAGC00024871.



- knew Dr. Frank McNeil, the owner of Bearden Healthcare Associates, had his DEA registration in restricted status because the DEA did not renew his registration, his clinic had been raided by authorities, and had been the subject of two wrongful death suits involving fatal opioid overdoses.<sup>490</sup>

547. Amerisource and its compliance managers knew by at least February 9, 2012 that Amerisource had shipped more Oxy 30 to Food City # 674 from October 2011 to January 2012 than it did to pharmacies in *38 entire states*.<sup>491</sup>

548. On October 22, 2012, Actavis' legal counsel and heads of compliance met with Ed Hazewski, Steve Mays, and Amerisource's legal counsel at Amerisource's headquarters for a "partnership meeting" to discuss suspicious order monitoring and review "ARCOS data specific to Oxy 15mg and Oxy 30mg."<sup>492</sup>

549. At the meeting, Actavis showed Amerisource data slides and relayed its serious concerns about Food City and other Tennessee pharmacies. One of the DEA ARCOS slides from the October 22, 2012 showed fifteen problematic Actavis' pharmacy customers out of its top 50 customers for Oxy 30 that used Amerisource as a distributor. The top three pharmacies that dispensed the most of Actavis' Oxy 30 were Knoxville's Food City # 674, # 694, and # 616.

550. Actavis's Director of Customer Service and Controlled Substance Compliance, Nancy Baran, took handwritten, contemporaneous notes on the slides that she used during the meeting and made a point to scan them electronically the next morning to document the meeting.<sup>493</sup>

551. During the meeting, Actavis told Amerisource that Actavis was "showing you these slides because there is a probe[,] that "needs to be rectified," and "we know this stuff [is] being diverted" referring to the oxycodone at Food City pharmacies.<sup>494</sup>

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<sup>490</sup> ABC-MSAGC00024873.

<sup>491</sup> ABDCMDL00301691; ABDCMDL00301692 (Customer Totals and State Totals Tab).

<sup>492</sup> MULTI3537740, -42, -46.

<sup>493</sup> MULTI3537738.

<sup>494</sup> MULTI3537759.

552. Amerisource was expressly told at the October 22, 2012 meeting that the Actavis oxycodone it was shipping to the Food City Pharmacies # 674, # 694, and # 616 was being diverted and it continued to supply Food City Pharmacies # 674, # 694, and # 616 with oxycodone and other controlled substances.

553. Ultimately, Amerisource stopped shipping oxycodone and other opioids to Food City on November 15, 2012, not because of compliance concerns, but because *Food City*, through its buying group, had chosen another supplier.

554. Amerisource shipped approximately 1,146 *grams* of oxycodone to Food City # 674 between October 26, 2012 and November 15, 2012 and 548 *grams* of Oxy 30, specifically, to Food City # 674 between October 23, 2012 and November 15, 2012—all while knowing that significant diversion was occurring from Food City and the pharmacy was routinely dispensing invalid prescriptions.

555. Details of shipments Amerisource made to Food City # 674 for oxycodone by month in milligrams and grams after October 22, 2012 are set forth in **Attachment 2**, which is incorporated by reference.

556. Amerisource shipped approximately 495 *grams* of oxycodone to Food City # 694 between October 23, 2012 and November 15, 2012 and 342 *grams* of Oxy 30 to Food City # 694 between October 23, 2012 and November 15, 2012—all while knowing that significant diversion was occurring from Food City and the pharmacy was routinely dispensing invalid prescriptions.

557. Details of shipments Amerisource made to Food City # 694 for oxycodone by month in milligrams and grams after October 22, 2012 are set forth in **Attachment 3**, which is incorporated by reference.

558. Amerisource shipped approximately 702.5 *grams* of oxycodone to Food City # 616 between October 23, 2012 and November 13, 2012 and 702 *grams* of Oxy 30 to Food City # 616 between October 23, 2012 and November 13, 2012—all while knowing that significant diversion was occurring from Food City and the pharmacy was routinely dispensing invalid prescriptions.

559. Details of shipments Amerisource made to Food City # 616 for oxycodone by month in milligrams and grams after October 22, 2012 are set forth in **Attachment 4**, which is incorporated by reference.

560. Aside from being conducted by the same company (Amerisource) and many of the same employees within the company, Amerisource's scheme with respect to Food City Pharmacy # 674, # 694, and # 616 involved the same financial motive, the same Schedule II controlled substance (oxycodone), the same method of commission (in which Amerisource ignored signs of diversion and invalid prescriptions being dispensed from the pharmacy), and was interrelated to the Amerisource's conduct with respect to the three other pharmacies referenced herein. Moreover, Amerisource's conduct with respect to just oxycodone at Knoxville Food City Pharmacies # 674, # 694, and # 616 was interrelated as it involved the same Amerisource distribution center and many of the same employees at both Amerisource and Food City.

**C. Amerisource's Pardue's Pharmacy Oxycodone Supply Scheme  
(At least July 16, 2015 to January 6, 2017)**

561. Amerisource knew that oxycodone, a Schedule II opioid, was being diverted in significant numbers from Pardue's Pharmacy, knew that Pardue's Pharmacy was filling invalid prescriptions, and was told to stop shipping controlled substances to Pardue's Pharmacy by a former DEA investigative group the company hired, yet Amerisource continued to supply Pardue's Pharmacy with oxycodone, continued its contract with Pardue's Pharmacy, and knowingly

received revenue from oxycodone it knew was going to be diverted or was based on invalid prescriptions.

562. On June 26, 2015, Amerisource was told in a report by PCG, the compliance investigation group it hired, which was comprised of former career DEA Special Agents and Diversion Investigators, that Amerisource should “block all controlled substance purchases to Pardue’s Pharmacy.” The June 26, 2015 report also made the following recommendations:<sup>495</sup>

Recommendation
<p>The current details of this assessment indicate concern in continuing to supply controlled substances to Pardue’s Pharmacy due to the following:</p> <ul style="list-style-type: none"><li>• No formal, written pharmacy due diligence policy with regard to dispensing of controlled substances.</li><li>• Pharmacist dispensing duplicate immediate release opiates to the same patient(s) without noting/confirming an established and legitimate clinical need.</li><li>• Pharmacist dispensing the combination of a benzodiazepine, a muscle relaxant and an opiate to the same patient(s) without noting/confirming an established and legitimate clinical need.</li><li>• Disproportionate dispensing of controlled substances, specifically schedule two controlled substances.</li><li>• Disproportionate amount of prescriptions paid with cash.</li><li>• Security concerns due to prior incidents involving significant thefts of controlled substances.</li><li>• PIC’s state pharmacist’s license currently on probation.</li></ul> <p>My recommendation is to block all controlled substance purchases to Pardue’s Pharmacy.</p>

563. The recommendation to block all controlled substance purchases was based on findings in the June 26, 2015 report that stated that:

- Pardue’s was currently purchasing “all product from AmerisourceBergen[;]”
- the only licensed pharmacist at Pardue’s Pharmacy had his pharmacist license on probation;
- the pharmacist admitted that he “[is] not comfortable with the amount of controlled substances being dispensed[;]”
- Pardue’s pharmacist admitted “I have some questionable patients” and “I may have gotten lax” regarding his patient/customer base;
- the second biggest prescriber for controlled substances at Pardue’s Pharmacy was a doctor based in Clarksville whose practice was 47 miles away from the Pharmacy;

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<sup>495</sup> ABC-MSAGC00000667.

- 80% of the Pardue’s prescriptions were controlled substances and that 80% of those were Schedule II controlled substances;
- 60% of the Pardue’s patients paid in cash;
- the last controlled substance inventory Pardue’s Pharmacy had completed was over two years old;
- the sole owner had voluntarily retired his Tennessee pharmacist license in 2014;
- a former Pardue’s pharmacy technician was arrested for stealing oxycodone from the pharmacy in 2013;
- a patient had been arrested in the parking lot within the last year for snorting Subutex;
- “a significant amount of various schedule two controlled substances were reported missing” following a burglary at the pharmacy on October 4, 2014;
- a uniformed security guard was stationed in the entrance hallway directly in front of the pharmacy;
- the Pharmacy did not have a formal, written controlled substance dispensing policy;
- Pardue’s pharmacist admitted he dispenses the “Holy Trinity,” the combination of an opioid, muscle relaxer, and anti-anxiety medication that produces both an extreme euphoric effect and danger of overdose “every few days[;]” and
- the pharmacist admitted he was dispensing more than one immediate release opiate to the same patient(s) despite knowing he “should not[.]”<sup>496</sup>

564. Amerisource knew of and reviewed the Pardue’s Pharmacy report. Amerisource’s own Director of Pharmacy Compliance and Diversion Control agreed that Amerisource should terminate service in an internal e-mail on July 15, 2015, which stated, in relevant part:<sup>497</sup>

Pardue Pharmacy  
 90% CS, 60% cash, PIC agrees that has become lax.  
 Some trinity combos, high quantities  
 Has improved as he had cut off a few MD but remains dispensing very large amounts of CS  
**Consultant suggests terminate service & I agree.**

<sup>496</sup> ABC-MSAGC00000662–67 (emphasis in original).

<sup>497</sup> ABDCMDL00047172.

565. Amerisource did not block all controlled substance purchases to Pardue's Pharmacy and continued to ship the pharmacy oxycodone and other Schedule II opioids well after Amerisource's senior compliance officers knew of the recommendation from the former DEA investigator group it hired and Amerisource's own Director of Pharmacy Compliance and Diversion Control to terminate service to Pardue's Pharmacy.

566. Between July 16, 2015, the day after Amerisource's Director of Pharmacy Compliance and Diversion Control recommended terminating service to Pardue's and January 6, 2017, Amerisource shipped approximately 5,179.5 *grams* of oxycodone to Pardue's, and 2,457 grams of Oxy 30, specifically—all while knowing that significant diversion was occurring from Pardue's and the pharmacy was routinely dispensing invalid prescriptions.

567. Every month or nearly every month between July 16, 2015 and January 6, 2017, Amerisource shipped Pardue's Pharmacy and later received payment for 200 grams of oxycodone or more.

568. Details of shipments Amerisource made to Pardue's Pharmacy for oxycodone by month in milligrams and grams after July 16, 2012 are set forth in **Attachment 5**, which is incorporated by reference.

569. Aside from being conducted by the same company (Amerisource) and many of the same employees within the company, Amerisource's scheme with respect to Pardue's Pharmacy involved the same financial motive, the same Schedule II controlled substance (oxycodone), the same method of commission (in which Amerisource ignored signs of diversion and invalid prescriptions being dispensed from the pharmacy), and was interrelated to the Amerisource's conduct with respect to the five other pharmacies referenced herein.

**D. Amerisource's P & S Pharmacy Oxycodone Supply Scheme  
(At least July 16, 2015 to April 30, 2019)**

570. Amerisource knew that Schedule II opioids were being diverted in significant numbers from P & S Pharmacy, and knew that P & S Pharmacy was filling invalid prescriptions, yet it continued to supply P & S Pharmacy with Schedule II opioids, continued its contract with P & S Pharmacy, and knowingly received revenue from these opioids it knew were going to be diverted or were based on invalid prescriptions.

571. Amerisource knew that from August 2014 to January 2015, 52.7% of the drugs ordered by P & S were for controlled substances and the next highest percentage on the top ten retail customer list for the Birmingham distribution center was 25.3%, less than half.<sup>498</sup>

572. Amerisource knew as of June 30, 2015 that 71% of P&S's prescriptions were purchased by patients in cash.<sup>499</sup>

573. On or around July 8, 2015, Amerisource and its compliance managers knew, through a detailed investigative report from a former career DEA official it hired to investigate P & S that:

- The P & S pharmacist-in-charge and technician “would observe some customers selling their medications to others[,]” had reported some incidents to police, but that the pharmacist-in-charge “*was concerned that if his pharmacy continued to report these incidences to the local police, they would start looking into the pharmacy’s activities with filling these controlled substances[;]*”
- The former DEA investigator Amerisource hired personally observed that P & S was getting many phone calls during the visit that “seemed to be in short duration” and when questioned about these calls, the pharmacist-in-charge along with another employee “indicated that the pharmacy receives at least 50 plus phone calls per day from new patients looking to see if the pharmacy could fill their Subutex prescriptions[;]”

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<sup>498</sup> ABDCMDL00249815.

<sup>499</sup> ABC-MSAGC00028823.

- The former DEA investigator Amerisource hired personally noticed “many young customers (20-30) coming into the pharmacy paying cash for their Buprenorphine,” was told by the P & S pharmacy technician that this quantity of individuals was “nothing,” and later observed groups of people coming into the store to fill their buprenorphine prescriptions.
- P & S was the highest dispenser of buprenorphine from Amerisource in the country and that patients paid for all of their buprenorphine prescriptions in cash;
- P & S was the highest dispenser of benzodiazepines from Amerisource in the state;
- P & S was the eighth highest dispenser of oxycodone from Amerisource in the state;
- P & S was the fifth highest dispenser of hydrocodone from Amerisource in the state;
- P & S did not usually use the Tennessee Controlled Substance Monitoring Database;
- “Most of the prescriptions for Oxycodone/Hydrocodone/Alprazolam are paid by cash, even when some customers have insurance[;]” and
- 72% of controlled substance prescriptions were being paid for in cash.

574. A week later, an internal Amerisource email titled “PCG Customer Review” was circulated on July 16, 2015, which summarized the former DEA investigator’s report on P&S Pharmacy as follows:<sup>500</sup>

<p>P&amp;S Pharmacy  FAST TRACK  Red Flags  DEA/TN BOP inspection in Dec. 2014  Couldn’t find their paperwork  No diligence program, doesn’t use pdmp  One pharmacist - past hx of addiction  Abnormal activities in parking lot  Does call the police but still continues to dispense to these people  Buprenorphine 8mg paid with cash (1169 RX compared to Bup/naloxone 327)  72% Cash  Provides discount (lower than chains) for CS when paid with cash  Fields phone calls for subutex - could sell more if ABC didn’t restrict him</p>
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<sup>500</sup> ABDCMDL00047170.



575. As previously stated, Amerisource waited until March 17, 2016, almost nine months from the investigative report, to send P & S a letter that purported to terminate its agreement to ship controlled substances to P & S. Amerisource continued shipping controlled substances, including Schedule II opioids like oxycodone well after March 25, 2016, the termination date in the letter. Further, Amerisource did not even exercise greater scrutiny of P & S Pharmacy's orders after sending the two letters to P & S. Only one of P & S's 41 orders was flagged, and even it was released in April 2016 and not reported to the DEA.<sup>501</sup>

576. Amerisource sent another letter on April 20, 2016 stating that it would continue to supply P & S with controlled substances.

577. From July 16, 2015, the date Amerisource acknowledged reading the P & S report submitted on July 8, 2015, Amerisource shipped approximately 6,434 *grams* of oxycodone to P & S between July 17, 2015 and September 18, 2017 and 1,755 *grams* of Oxy 30 to P & S # 616 between July 17, 2015 and September 16, 2017—all while knowing that significant diversion was occurring from P & S and the pharmacy was routinely dispensing invalid prescriptions.

578. From April 20, 2016, the date of Amerisource's "reinstatement" letter, Amerisource shipped approximately 3,835 *grams* of oxycodone to P & S between April 21, 2016 and September 18, 2017, and 915 *grams* of Oxy 30 to P & S between April 25, 2016 and September 16, 2017—all while knowing that significant diversion was occurring from P & S and the pharmacy was routinely dispensing invalid prescriptions.

579. Every month or nearly every month between July 16, 2015 and September 18, 2017, Amerisource shipped P & S Pharmacy and later received payment for 200 grams of oxycodone or more.

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<sup>501</sup> ABDCMDL00252012.

580. Details of shipments Amerisource made to P & S for oxycodone by month in milligrams and grams after July 16, 2015 are set forth in **Attachment 6**, which is incorporated by reference.

581. In August 2018, a Pharma Compliance Group consultant met with PIC Grizzle and submitted another report to Amerisource.<sup>502</sup> Among other things, the report stated (shown in gray below):

PIC Grizzle never mention [sic] the other Consent Agreement that he entered into with the Tennessee BOP for having a Pharmacy Technician working at P & S Pharmacy without a current license. ....

[PCG Consultant] requested a copy of P&S Pharmacy controlled substances dispensing Standard Operation Procedures (SOP). PIC Grizzle informed that he does not have a written policy; however, PIC Grizzle related that everyone knows what they should do before filling a prescription. [PCG Consultant] requested PIC Grizzle provide him a copy of P&S Pharmacy SOP for dispensing controlled substances. On 8/8/2018 PIC Grizzle e-mailed [PCG Consultant] the final version of the P & S Pharmacy SOP for Dispensing Controlled Substances. ... PIC Grizzle stated he had set a limit of 120 Dosage Units on all controlled substances. However, a review of P&S Pharmacy 90 day dispensing history sent to [PCG Consultant] revealed that some patients receive 180 DU of opioids. ....

PIC Grizzle further stated that 90% of his customers are walk-in[.] ....

On 7/30/2018 PIC Grizzle provided the following list of his Top Five Prescribers of controlled substances ... however, it was not based on the number of dosage units of controlled substances filled but on the number of the prescription [sic] that the practitioner writes. The majority of prescriptions were for Subutex, Suboxone (Schedule III) and Clonazepam (Schedule IV)[.] ....

[PCG Consultant] reviewed the information provided before the on-site visit included several suspicious prescriptions filled for hydrocodone (Schedule II) and alprazolam (Schedule IV) controlled substances to the same patient on the same day. One patient had three prescriptions filled hydrocodone, oxycodone, and oxycontin (Schedule II) controlled substances on the same day. ....

P&S Pharmacy staff could not produce form the computer system Controlled Substances Dispensing Log which is required Title 21 CFR 1304.22(2)(D)(c).

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<sup>502</sup> ABC-MSAGC00028867.

Ultimately, PCG concluded that P & S’s “Due diligence was found acceptable[.]”<sup>503</sup>

582. Amerisource continued to have knowledge of strong indicators of diversion and invalid prescriptions in 2018. On August 21, 2018, Amerisource’s CSRA created a dispensing report about P & S, which stated, among other things:<sup>504</sup>

General

- Overall controlled substance rates of 24% by dosage unit and 32% by prescription
  - 60% of all controlled substances filled were for opioids (rate of 19% versus their total Rx)
- Prescriptions paid for in cash accounted for 49% of those filled
  - *Rate of 77% for controlled substance prescriptions*
- 69% of all controlled substances prescriptions filled were for benzodiazepine anxiety solids and buprenorphine solids (single ingredient and combination)
- *54% of all oxycodone solids (OX) were for immediate release strengths of 5/10/15/20 milligrams*
- Notable disparity between the number of dosage units purchased and dispensed during roughly the same time, especially as it concerns non-controlled substances

Patients

*All prescriptions considered*

- 195 of the pharmacy’s patients receiving controlled substances (nearly 13% of that relative patient base) received at least 1 prescription for an opioid and *no other drug or prescription*
  - 72 of these patients received at least 1 prescription for buprenorphine solids (B3) and *no other drug or prescription*
    - *70 of these patients only received 8 mg strengths*
  - 58 patients received at least 1 prescription for oxycodone solids and/or hydrocodone solids (OX/OY/HT and/or HY) and *no other drug*
    - 19 of these patients at least 1 prescription for oxycodone solids (OX and/or OY)
    - 38 of these patients at least 1 prescription for hydrocodone solids (HT and/or HY)

583. But Amerisource still kept P & S as a customer following the 2018 PCG report and continued to ship it oxycodone as late as April 30, 2019.<sup>505</sup>

584. Aside from being conducted by the same company (Amerisource) and many of the same employees within the company, Amerisource’s scheme with respect to P & S Pharmacy

<sup>503</sup> ABC-MSAGC00028873.

<sup>504</sup> ABC-MSAGC00028786.

<sup>505</sup> ABC-MSAGC00028798.

involved the same financial motive, the same Schedule II controlled substance (oxycodone), the same method of commission (in which Amerisource ignored signs of diversion and invalid prescriptions being dispensed from the pharmacy), and was interrelated to the Amerisource's conduct with respect to the five other pharmacies referenced herein.

## **V. VIOLATIONS OF THE LAW**

### **COUNT I: TENNESSEE CONSUMER PROTECTION ACT**

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

586. Amerisource's distributing, selling and offering of opioid products, as alleged herein, both constitutes and affects "trade," "commerce," and/or a "consumer transaction" as defined in Tenn. Code Ann. § 47-18-103(19) and as those terms have been interpreted by the Tennessee Supreme Court in *Fayne v. Vincent*, 301 S.W.3d 162, 175 (Tenn. 2009) and elsewhere.

587. The opioids Amerisource distributed as alleged herein constitute "goods" as defined in Tenn. Code Ann. § 47-18-103(7) and were obtained for use by individuals primarily for personal purposes.

588. Opioid medications referenced herein are Schedule II and III controlled substances. Tenn. Code Ann. §§ 39-17-408, -410. Distribution of a controlled substance, at least generally speaking, is unlawful by default. *See* Tenn. Code Ann. §§ 39-17-417, -418, -419.

589. Controlled substances that are diverted or that are not procured through a valid prescription are unlawful. Prescriptions that are not in the usual course of professional treatment or in legitimate and authorized research are invalid. *See* Tenn. Code Ann. §§ 39-17-417(a), -418(a), -419. *See also*, 21 C.F.R. § 1306.04(a). Many of the opioid prescriptions referenced herein

that were supplied by Amerisource were not issued for a legitimate medical purpose and were not in the usual course of professional treatment or for legitimate and authorized research.

590. Selling or offering to sell opioids to pharmacies from which diversion is known to be occurring or invalid prescriptions are known to be dispensed, as alleged herein, constitutes the act or practice of directly or indirectly selling or offering for sale any good that is illegal or unlawful to sell in the state in violation of Tenn. Code Ann. § 47-18-104(b)(43)(C) in each instance.

591. By engaging in the above conduct concerning highly-addictive and potentially deadly pharmaceutical drugs that affect consumer health and safety, Amerisource has also caused or is likely to cause substantial injury to consumers or other persons which, due to the addictive potential of the underlying products and known downstream consequences, is not reasonably avoidable and is not outweighed by countervailing benefits to consumers or competition. Thus, Amerisource has violated Tenn. Code Ann. § 47-18-104(a) in each instance.

592. As alleged herein, Amerisource knew about downstream diversion and abuse of the opioids it supplied to pharmacies and it actively enabled it for the sake of profit.

593. “Persons,” as defined in Tenn. Code Ann. § 47-18-103(13), have suffered loss by reason of Amerisource’s acts as referenced herein.

## **COUNT II: COMMON LAW NUISANCE**

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

595. Through the actions described above, Amerisource has contributed to and/or assisted in creating and maintaining a condition that has interfered with public health, endangered

the lives and health of Tennessee residents, and interfered with the operation of the commercial market.

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

597. Amerisource intentionally and/or unlawfully failed to maintain effective controls against diversion through proper monitoring, distributing opioids without reporting, and refusing to cease filling suspicious orders. Such actions were inherently dangerous to the health and welfare of residents of Tennessee.

598. Opioid medications referenced herein are Schedule II and III controlled substances. Tenn. Code Ann. § 39-17-408. Distribution of a controlled substance, at least generally speaking, is unlawful. *See* Tenn. Code Ann. §§ 39-17-417, -418, -419.

599. Controlled substances that are diverted or that are not procured through a valid prescription are unlawful. Prescriptions that are not in the usual course of professional treatment or in legitimate and authorized research are invalid. *See* Tenn. Code Ann. §§ 39-17-417(a), -418(a), -419. *See also*, 21 C.F.R. § 1306.04(a). The opioid prescriptions referenced herein were not issued for a legitimate medical purpose and were not in the usual course of professional treatment or for legitimate and authorized research.

600. Further, knowingly participating in the diversion of opioids by shipping to pharmacies where diversion is occurring or for invalid prescriptions is not authorized by or consistent with any law governing Amerisource.

601. Both the Tennessee Drug Control Act, similar state law, and the federal Controlled Substances Act create a broad duty on the part of distributors to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids. *See, e.g.*, Tenn. Code Ann. § 53-11-303; 21 U.S.C. §§ 823(b), (e), 21 C.F.R. § 1301.74. Amerisource violated this duty as set forth above.

602. Amerisource also has a duty not to participate in the diversion of opioids and other controlled substances or to otherwise distribute or sell opioids unlawfully. *See* Tenn. Code Ann. §§ 39-17-408; -417; -418, -419; -427; Tenn. Code Ann. §§ 53-11-303, -401. *See also*, 21 U.S.C. §§ 823(b), (e). Amerisource violated this duty as set forth above.

603. Amerisource also has a specific duty under both state and a complementary federal law to report suspicious orders of opioids to the Tennessee Board of Pharmacy and the DEA. Tenn. Code Ann. § 53-10-312; *see also* 21 C.F.R. § 1301.74(b). Amerisource violated this duty as set forth above. In fact, until June 2019, Amerisource had not reported a single suspicious order from any Tennessee pharmacy to the Tennessee Board of Pharmacy.

604. Amerisource also violated this duty because it failed to report and refused to halt shipments of facially suspicious orders and concealed vital knowledge and information about the pharmacies referenced above from the State of Tennessee, its agents and employees, resulting in significant harm to its citizens and public coffers.

605. While Amerisource's degree of care is not relevant in a common law nuisance suit brought by the sovereign State, Amerisource behaved negligently, recklessly, or intentionally as set forth above.

606. Through the actions described above, Amerisource has contributed to and/or assisted in creating and maintaining a condition that endangers the life or health of Tennessee residents and that unreasonably interferes with or obstructs rights common to the public.

607. While Amerisource distributed oxycodone, buprenorphine, and other opioids as set forth above, opioid use, abuse, addiction, and overdose deaths have increased throughout Tennessee. Locations, such as the offices of high-dispensing pharmacies, have attracted those addicted to opioids as well as drug dealers and robbers, which, though not necessary to show for a nuisance action brought by the sovereign State, were foreseeable.

608. The greater demand for emergency services, law enforcement, addiction treatment, children's services, foster care, and other social services places an unreasonable burden on governmental resources including the State and its political subdivisions.

609. Amerisource expanding the market for prescription opioids in Tennessee by knowingly distributing massive quantities of opioids to pharmacies from which diversion was occurring or where invalid prescriptions were routinely filled, has created an overabundance of opioids available for criminal use and fueled a wave of addiction, abuse, injury, and death.

610. Amerisource's actions described above were a substantial factor in opioids becoming widely available, used, and all too often abused in Tennessee.

611. But for Amerisource's actions, opioid use would not have become so widespread in Tennessee, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists could have been substantially averted or mitigated. Amerisource's actions have and will continue to injure and harm many residents throughout Tennessee for many years to come.

612. While tort-based standards are not applicable to a public nuisance suit brought by the sovereign State, the public nuisance and associated financial and economic losses were



foreseeable to Amerisource, which knew or should have known that its conduct through its distribution practices as set forth above were creating a public nuisance.

613. Despite knowledge of diversion and the dispensing of invalid prescriptions, Amerisource intended for the pharmacies referenced above to fill those prescriptions and to keep filling those prescriptions. A reasonable person in Amerisource's position would foresee not only an expanded market, but the other likely and foreseeable results of Amerisource's conduct—the widespread problems of opioid addiction and abuse—particularly regarding Buprenorphine 8 in the Tri-Cities area, oxycodone in the Knoxville area, and the other locations referenced herein throughout the State.

614. Amerisource was on notice and aware of signs both that Tennessee health care providers were prescribing unreasonably high numbers of opioids and that the broader use of opioids in Tennessee were causing the kinds of harm described in this Complaint.

615. Amerisource's business practices generated a new and very profitable circular market in Tennessee with the distribution of opioids—providing both the profitable supply of narcotics for its pharmacy customers to dispense and sell, as well as causing addiction which fueled the demand to buy more.

616. Amerisource acted without express authority of a statute in its conduct referenced above.

617. The health and safety of Tennessee residents, including those who use, have used, or will use opioids, as well as those affected by abusers of opioids, is a matter of great public interest and of legitimate concern to the State. Tennesseans have a right to be free from conduct that endangers their health and safety and that interferes with the commercial marketplace. Amerisource's conduct interfered in the enjoyment of these public rights.

618. As part of its nuisance action, the State does not seek any damages attributable to TennCare, Medicaid, or Medicare.

### **COUNT III: CIVIL RICO**

#### **Violation of the Tennessee Racketeer Influenced and Corrupt Organization Act of 1989, Tenn. Code Ann. § 39-12-204(a)**

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

620. Oxycodone is a Schedule II controlled substance that is unlawful to distribute in Tennessee absent limited exceptions. *See* Tenn. Code Ann. §§ 39-17-417(a)(2), (3), and (4).

621. To fit within an exception, registered distributors must “lawfully possess” a controlled substance as authorized under Tenn. Code Ann. §§ 39-17-401 to -455, Tenn. Code Ann. §§ 53-11-301 to -311, or Tenn. Code Ann. §§ 53-11-401 to -413. *See* Tenn. Code Ann. § 39-17-427. *No* provision in the Tennessee Code Annotated allows a registered distributor to *knowingly* ship a Schedule II narcotic, such as oxycodone, to a pharmacy where diversion is occurring and from which the pharmacy is dispensing invalid prescriptions.

622. In fact, it is unlawful for a registrant, such as Amerisource, to distribute or dispense a controlled substance that is *not* authorized by the registrant’s registration to an authorized person such as a pharmacist. *See* Tenn. Code Ann. § 53-11-401(a)(1). The registrant’s registration is based, among other things, on “[m]aintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels.” *See* Tenn. Code Ann. § 53-11-303(a)(1).

623. “Racketeering activity” means to commit or to attempt to commit “an act for financial gain that is a criminal offense involving controlled substances, and the amount of controlled substances involved in the offense is included under § 39-17-417(i) and (j) and its

subdivisions. . .” Tenn. Code Ann. § 39-12-203(9). The burden of proof to show criminal predicate acts is a preponderance of the evidence standard in a civil RICO action.

624. Knowingly shipping over 200 grams (200,000 mg) of oxycodone after Amerisource knew that significant diversion was occurring from a pharmacy and that a pharmacy was dispensing significant quantities of invalid prescriptions, constitutes “racketeering activity” within the meaning of the Tennessee RICO Act of 1989.

625. Amerisource shipped at least 200 grams of oxycodone every month or nearly every month to Jabo’s Pharmacy between February 2, 2012 and September 18, 2017, Pardue’s Pharmacy between July 16, 2015 and January 6, 2017, P & S Pharmacy between July 17, 2015 and September 18, 2017. Amerisource shipped at least 200 grams of oxycodone to Food City Pharmacies # 674, # 694, and # 616 from October 23, 2012 to November 15, 2012.

626. A “pattern of racketeering activity” means engaging in at least two incidents of racketeering conduct “that have the same or similar intents, results, accomplices, victims, or methods of commission or otherwise interrelated by distinguishing characteristics and are not isolated incidents . . .” Tenn. Code Ann. § 39-12-203(6).

627. Aside from being conducted by the same company (Amerisource), Amerisource’s schemes with respect to Jabo’s Pharmacy, Knoxville Food City # 674, # 694, # 616, Pardue’s Pharmacy, and P & S Pharmacy involved the same financial motive, many of Amerisource’s same employees, the same Schedule II controlled substance (oxycodone), some of the same Amerisource distribution centers that shipped the oxycodone, many of the same red flags for diversion or invalid prescriptions, the same method of commission (in which Amerisource ignored signs of diversion and invalid prescriptions being dispensed from the pharmacy), and were interrelated.

628. Amerisource has engaged in a pattern of racketeering activity by:

- Shipping, as detailed in **Attachment 1**<sup>506</sup> (incorporated herein), at least 20,418.3 *grams* of oxycodone and 5,865 grams of Oxy 30, specifically, to Jabo's Pharmacy at least between February 2, 2012, the day after the meeting with Mallinckrodt where Jabo's was discussed, and January 4, 2018, while knowing that significant diversion was occurring from Jabo's and the pharmacy was routinely dispensing invalid prescriptions;
- Shipping, as detailed in **Attachment 2** (incorporated herein), approximately 1,146 *grams* of oxycodone and 548 grams of Oxy 30, specifically, to Food City # 674, at least between October 26, 2012, four days after Amerisource's meeting with Actavis in which Amerisource was told diversion from Food City was occurring, and November 15, 2012, while knowing that significant diversion was occurring from Food City # 674 and the pharmacy was routinely dispensing invalid prescriptions;
- Shipping, as detailed in **Attachment 3** (incorporated herein), approximately 495 *grams* of oxycodone and 342 grams of Oxy 30, specifically, to Food City # 694, at least between October 23, 2012, after Amerisource's meeting with Actavis in which Amerisource was told diversion from Food City was occurring, and November 15, 2012, while knowing that significant diversion was occurring from Food City # 694 and the pharmacy was routinely dispensing invalid prescriptions;
- Shipping, as detailed in **Attachment 4** (incorporated herein), approximately 702.5 *grams* of oxycodone and 702 grams of Oxy 30, specifically, to Food City # 616 at least between October 23, 2012, after Amerisource's meeting with Actavis in which Amerisource was told diversion from Food City was occurring, and November 15, 2012, while knowing that significant diversion was occurring from Food City # 616 and the pharmacy was routinely dispensing invalid prescriptions;
- Shipping, as detailed in **Attachment 5** (incorporated herein), approximately 5,179.5 grams of oxycodone and 2,457 grams of Oxy 30, specifically, to Pardue's Pharmacy at least between July 16, 2015, after Amerisource's Director of Pharmacy Compliance and Diversion Control recommended terminating service to Pardue's and January 6, 2017, while knowing that significant diversion was occurring from Pardue's and the pharmacy was routinely dispensing invalid prescriptions; and

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<sup>506</sup> Attachment 1 contains monthly oxycodone shipment information from February 2, 2012 to September 18, 2017, but Amerisource shipped oxycodone as late as January 4, 2018. See ABDCMDL00238575.

- Shipping, as detailed in **Attachment 6**<sup>507</sup> (incorporated herein), at least 6,434 grams of oxycodone and 1,755 grams of Oxy 30, specifically, to P & S at least between July 17, 2015, after Amerisource compliance officers acknowledged reading the P & S report from the former DEA investigative group Amerisource hired, and April 20, 2019, while knowing that significant diversion was occurring from P & S and the pharmacy was routinely dispensing invalid prescriptions.

629. As a corporation, Amerisource constitutes an enterprise consistent with Tenn. Code Ann. § 39-12-203(3). Amerisource's receipt of money from the shipments of oxycodone referenced above was part of the operation of the corporation.

630. In deciding to continue Amerisource's business relationship with these six pharmacies and receive payments for oxycodone shipments and other controlled substances after knowing that significant diversion from these pharmacies was occurring and the pharmacies were routinely dispensing invalid prescriptions, Amerisource's management, officers, and employees acted with the intent to financially benefit the corporation.

631. By knowing that significant diversion was occurring from these pharmacies and that the pharmacies were routinely dispensing invalid prescriptions and intentionally continuing to ship and accept payments for oxycodone, a Schedule II, controlled substance in the quantities referenced above, Amerisource has violated Tenn. Code Ann. § 39-12-204(a) and has, with criminal intent, received money, directly or indirectly, from a pattern of racketeering activity and to further the operation of its business.

632. This action, concerning the Office of the Attorney General and Reporter's RICO claim, has been brought *within* five years of the termination of the oxycodone shipments and receipt of money at issue and has also been brought *within* five years of the cause of action accruing to the Office of the Attorney General.

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<sup>507</sup> Attachment 6 contains monthly oxycodone shipment information from July 17, 2015 to September 18, 2017, but Amerisource shipped oxycodone as late as April 20, 2019. See ABC-MSAGC00028798.

633. While not determinative, the Tennessee Attorney General's Office and Amerisource executed a Tolling Agreement covering its distribution and shipment practices of opioids, among other things, beginning October 19, 2017 that was effective until September 28, 2019.

## **VI. PRAYER FOR RELIEF**

WHEREFORE, PREMISES CONSIDERED, Plaintiff, the State of Tennessee, *ex rel.* Herbert H. Slatery III, Attorney General and Reporter, pursuant to the TCPA, the Attorney General's general statutory authority, the Attorney General's authority at common law, and this Court's equitable powers, prays:

1. That this Complaint be filed without cost bond as provided by Tenn. Code Ann. §§ 20-13-101 and 47-18-116;

2. That process issue and be served upon Amerisource requiring it to appear and answer;

3. That this Court adjudge and decree that Amerisource has engaged in the aforementioned acts or practices that violate the TCPA;

4. That pursuant to Tenn. Code Ann. §§ 47-18-108(a)(1), (a)(4), and (a)(5), this Court permanently enjoin and restrain Amerisource from engaging in the aforementioned acts or practices which violate the TCPA;

5. That pursuant to Tenn. Code Ann. § 47-18-108(b)(1), this Court make such orders or render such judgments as may be necessary to restore to any person, as defined in Tenn. Code Ann. § 47-18-103(13), who has suffered any ascertainable loss, as defined in Tenn. Code Ann. § 47-18-2102(1), including statutory interest, and requiring that Amerisource pay all costs of distributing and administering the same, including through the use of third-party administrator;

6. That this Court make such orders or render such judgments as may be necessary to disgorge the profits and ill-gotten gains Amerisource realized by reason of the alleged violations of the TCPA;

7. That this Court adjudge and decree that Amerisource pays a civil penalty of \$1,000 to the State for each violation of the TCPA, as provided by Tenn. Code Ann. § 47-18-108(b)(3);

8. That this Court enter judgment against Amerisource and in favor of the State for the reasonable costs and expenses of the investigation and prosecution of this action, including attorneys' fees, costs and expert and other witness fees, as provided by Tenn. Code Ann. §§ 47-18-108(a)(5) and (b)(4), and other state law;

9. That an order be entered that provides for abatement of the public nuisance Amerisource has created, the equitable costs of abating this nuisance, an award to the State for damages in an amount to be determined at trial, and any other relief or remedy allowable under state law;

10. That all costs, including discretionary costs, in this case be taxed against Amerisource;

11. That a jury be empaneled to hear and decide all appropriate matters; and

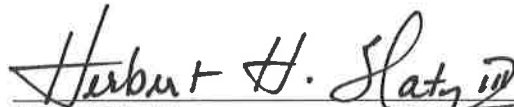
12. That the Court order a suspension or revocation of Amerisource's registration as an authorized wholesaler and distributor of controlled substances in Tennessee pursuant to Tenn. Code Ann. § 39-12-206(a)(4);

13. That the Court subject all property, including money, derived from or realized through conduct in violation of the Tennessee RICO Act of 1989 to civil forfeiture pursuant to Tenn. Code Ann. § 39-12-206(b);

14. That the Court grant any other relief authorized by the Tennessee RICO Act of 1989, Tenn. Code Ann. §§ 39-12-201 to -210, including prohibiting Amerisource from shipping controlled substances to pharmacies and others where it knows diversion is occurring or invalid prescriptions are being filled pursuant to Tenn. Code Ann. § 39-12-206(a)(2); and

15. That this Court grant the State such other and further relief as this Court deems just and proper.

Respectfully submitted,



**HERBERT H. SLATTERY III**, B.P.R. NO. 9077  
Attorney General and Reporter



**MARGARET ROWLAND**, B.P.R. No. 33513  
Assistant Attorney General

**BRANT HARRELL**, B.P.R. No. 24470  
Senior Assistant Attorney General

**OLHA RYBAKOFF**, B.P.R. No. 24254  
Senior Assistant Attorney General

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## GLOSSARY

**ABC / ABDC** – acronym for Amerisource

**Benzo or Benzodiazepine** – an anti-anxiety medication (e.g., Valium)

**CAH** – stock abbreviation for Cardinal Health that is also used generally for Cardinal

**C2 or CII** – shorthand for Schedule II Controlled Substances

**CSRA** – Amerisource’s Corporate Security and Regulatory Affairs Department

**DEA** – Drug Enforcement Administration

**DCP** – Diversion Control Program

**Form 590** – shorthand for an internal document in which Amerisource asked customers for information about other distributors, disciplinary history, customer payment methods, percentages of controlled substances dispensed, usage numbers for specific high-risk drugs, and top prescribers of opioids, among other questions

**HDMA** – Healthcare Distribution Management Agency, a pharmaceutical distributor-specific trade group

**MME** –morphine milligram equivalents, a standard unit of measurement to assess pain relieving (but not euphoria) potential among opioids

**Naloxone** – an opioid antagonist that blocks opioid receptors in the brain that is commonly used to revive opioid overdose victims

**ODU** – Opioid Dosage Unit

**OMP** – Order Monitoring Program

**Oxy 30** –immediate release oxycodone 30 mg

**PCG** – Pharma Compliance Group, a third-party vendor comprised of former career DEA Special Agents and Diversion Investigators with which Amerisource contracted

**PIC** – Pharmacist-in-Charge

**Rph** – Registered Pharmacist

**SOM** – Suspicious Order Monitoring

**Subutex** – the brand name for buprenorphine without naloxone

## INDEX OF KEY FIGURES

**Cherveney, Eric (ABDC)** is currently Amerisource's Director of Diversion Control and Security. Previously, he was Supervisor of Regulatory Compliance within Amerisource's East Region. He previously worked at Bergen Brunswick Corporation before its merger with Amerisource.

**Baran, Nancy (Actavis)** was a Director of Customer Service and Controlled Substance compliance who took handwritten notes on slides she used in a meeting with Amerisource concerning Oxy 30 sales and distribution.

**Dailey, Mike (ABDC)** was an Amerisource sales representative who is mentioned in PCG reports and emails from 2015 to 2017. He was ABDC's sales representative for Gray, Pardue's, Rippetoe's, Inc. (Howard's Pharmacy), and Belew Drug.

**Gundy, Bruce (ABDC)** is currently Amerisource's Director of Investigations and Security. Previously he was Amerisource's Director of Investigations and Manager of Investigations.

**Hazewski, Ed (ABDC)** is currently Amerisource's Director of Diversion Control and Security. Mr. Hazewski was hired by Amerisource in June 2007 as a Corporate Investigator. The next year, he was promoted to Manager of ABDC's diversion control program where he reported to Chris Zimmerman. Around 2014, Hazewski transitioned back into corporate investigations and later assumed his current role.

**May, David (ABDC)** is currently Amerisource's Vice President of Diversion Control and Security. Mr. May's previous role at Amerisource was Senior Director of Diversion Control.

**Mays, Steve (ABDC)** is currently Amerisource's Vice President of Corporate Security and Regulatory Affairs. Previously, he was Amerisource's Director of Regulatory Affairs.

**Miller, Mat (ABDC)** was an Amerisource Sales Account Manager as recently as 2015 and has also been referred to as a "Regional Representative" and "Sales Executive." Mr. Miller was the Amerisource sales representative for a number of Tennessee pharmacies including Jabo's Pharmacy, P & S Pharmacy, Blankenship Pharmacy, Brookside Pharmacy, and Rippetoe's, Inc. (Howard's Pharmacy).

**St. John, Kimberly (ABDC)** was an Administrative Assistant and employee in Amerisource's CSRA Department.

**Sullivan, Edward (PCG)** is currently a compliance consultant for Pharma Compliance Group. He prepared a number of reports for Amerisource regarding Tennessee pharmacies, including P & S, Blankenship, and Brookside pharmacies near the Kingsport, Tennessee area.

**Tomkiewicz, Joe (ABDC / Teva)** is currently Teva's Diversion Control Program DEA Compliance Manager. Previously he was Amerisource's Diversion Program Manager and a Corporate Investigator.

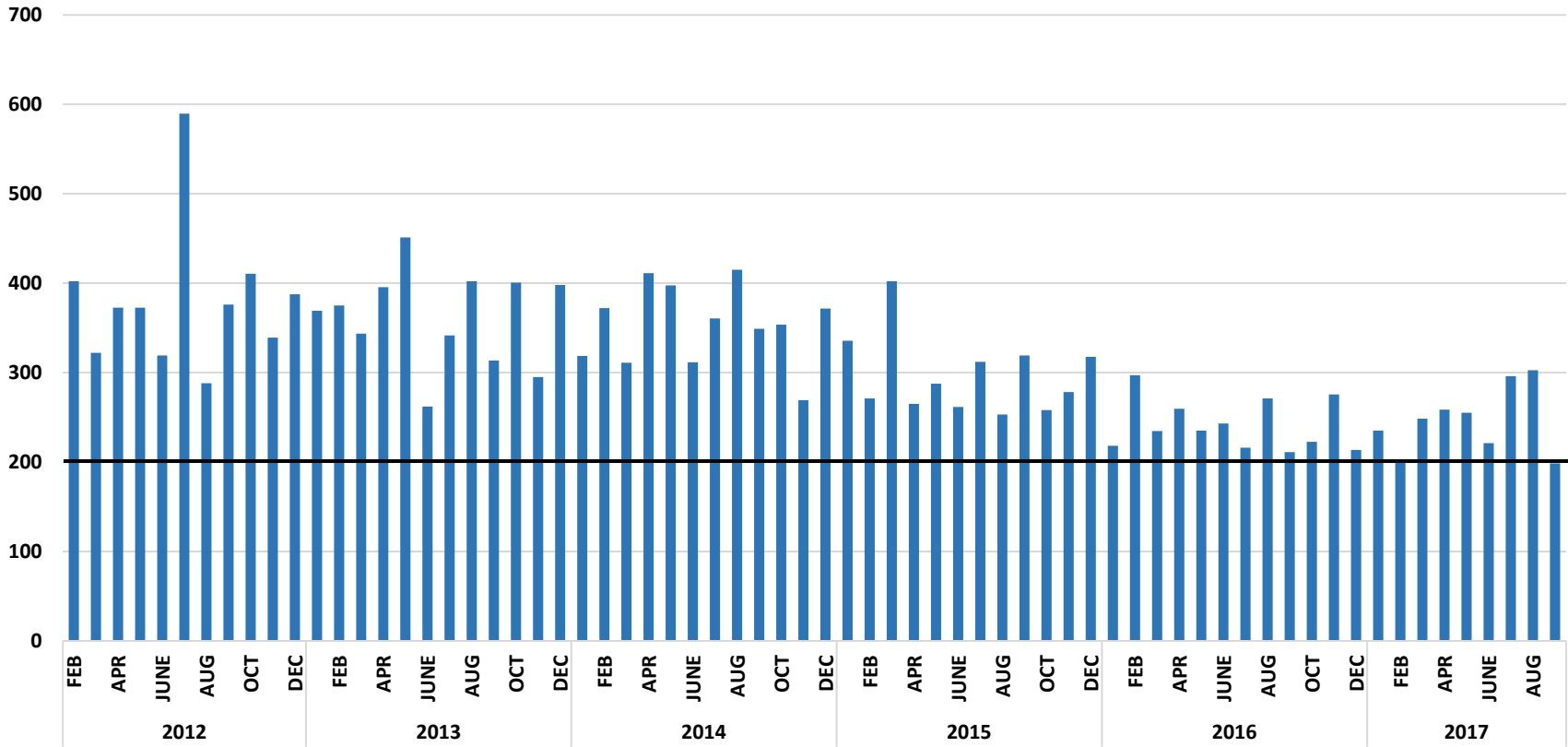
**Zimmerman, Chris (ABDC)** was Amerisource's Chief Compliance Officer and Senior Vice President of Corporate Security and Regulatory Affairs as of 2018.

# **COMPLAINT ATTACHMENT 1**

**PURE OXYCODONE SHIPPED TO  
JABO'S PHARMACY BY AMERISOURCE**

**(2/2/12 to 9/18/17)**

**PURE OXYCODONE SHIPPED TO JABO'S PHARMACY BY AMERISOURCE (in grams)**  
**February 2, 2012 to September 18, 2017**



**PURE OXYCODONE SHIPPED TO JABO'S PHARMACY BY AMERISOURCE (in grams)  
February 2, 2012 to September 18, 2017**

YEAR	MONTH	OXY ODUs	OXY MG	OXY Grams
2012	FEB	15,200	402,000	402
	MAR	10,800	322,000	322
	APR	14,100	372,500	373
	MAY	13,300	372,500	373
	JUNE	14,400	319,000	319
	JULY	20,100	589,500	590
	AUG	12,100	288,000	288
	SEPT	13,200	376,000	376
	OCT	16,400	410,500	411
	NOV	14,400	339,000	339
	DEC	15,400	387,500	388
	2013	JAN	14,400	369,000
FEB		13,400	375,000	375
MAR		16,900	343,500	344
APR		15,800	395,500	396
MAY		18,200	451,000	451
JUNE		12,600	262,000	262
JULY		14,100	341,500	342
AUG		16,900	402,000	402
SEPT		12,500	313,500	314
OCT		15,700	400,500	401
NOV		12,000	295,000	295
DEC		15,800	398,000	398
2014	JAN	14,600	318,500	319
	FEB	15,100	372,000	372
	MAR	11,800	311,000	311
	APR	18,420	411,100	411
	MAY	17,300	397,500	398
	JUNE	12,300	311,500	312
	JULY	15,100	360,500	361
	AUG	17,600	415,000	415
	SEPT	14,200	349,000	349
	OCT	15,900	353,500	354
	NOV	11,300	269,000	269
	DEC	16,400	371,500	372
2015	JAN	14,900	335,500	336
	FEB	12,500	271,000	271

	MAR	18,300	402,000	402
	APR	13,500	265,000	265
	MAY	12,000	287,500	288
	JUNE	13,500	261,500	262
	JULY	14,600	312,000	312
	AUG	13,100	253,000	253
	SEPT	15,100	319,000	319
	OCT	13,100	258,000	258
	NOV	14,520	278,100	278
	DEC	16,600	317,500	318
2016	JAN	10,800	218,000	218
	FEB	15,600	297,000	297
	MAR	13,200	234,500	235
	APR	12,600	259,500	260
	MAY	12,800	235,000	235
	JUNE	12,600	243,000	243
	JULY	11,200	216,000	216
	AUG	15,300	271,000	271
	SEPT	11,800	211,000	211
	OCT	13,200	222,500	223
	NOV	15,000	275,500	276
	DEC	12,400	213,500	214
2017	JAN	12,900	235,000	235
	FEB	12,140	202,100	202
	MAR	14,500	248,500	249
	APR	14,800	258,500	259
	MAY	14,600	255,000	255
	JUNE	12,500	221,000	221
	JULY	17,200	296,000	296
	AUG	17,600	302,500	303
	SEPT	11,500	198,500	199
TOTAL		973,680	21,438,800	21,453

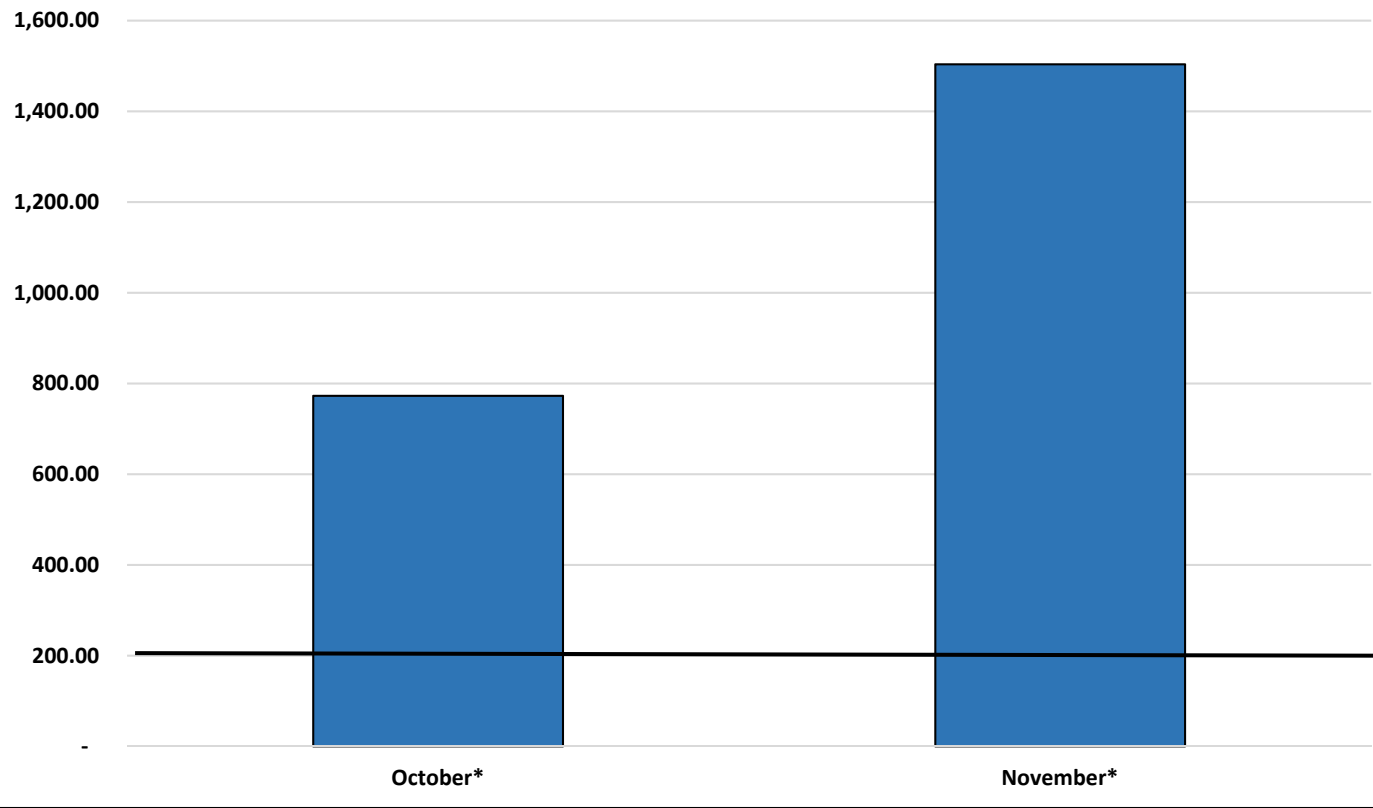
# **COMPLAINT ATTACHMENT 2**

**PURE OXYCODONE SHIPPED TO  
FOOD CITY # 674 BY AMERISOURCE**

**(10/23/12 to 11/15/12)**



**OXYCODONE WITHOUT ACETAMINOPHEN SHIPPED TO FOOD CITY PHARMACY # 674**  
**(in grams)**  
**October 23, 2012 to November 15, 2012**



**PURE OXYCODONE SHIPPED TO FOOD CITY PHARMACY # 674 BY AMERISOURCE (in grams)**

**October 23, 2012 to November 15, 2012**

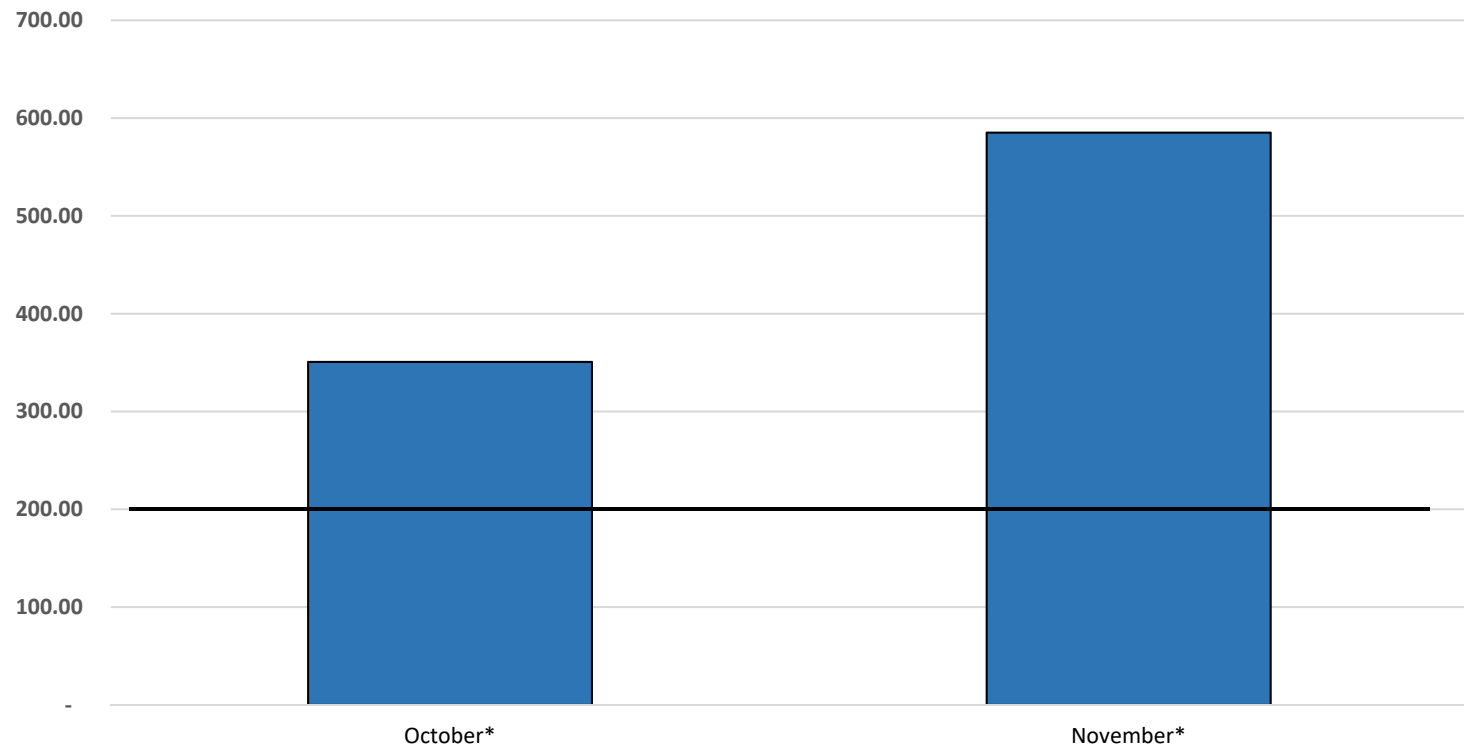
MONTH	OXY ODUs	OXY MG	OXY Grams
October*	27,100	773,000	773.00
November*	47,970	1,503,800	1,503.80
* indicates incomplete month			

# **COMPLAINT ATTACHMENT 3**

**PURE OXYCODONE SHIPPED TO  
FOOD CITY # 694 BY AMERISOURCE**

**(10/23/12 to 11/15/12)**

**PURE OXYCODONE SHIPPED TO FOOD CITY PHARMACY # 694 BY  
AMERISOURCE (in grams)  
October 23, 2012 to November 15, 2012**



**PURE OXYCODONE SHIPPED TO FOOD CITY PHARMACY # 694 BY AMERISOURCE  
(in grams)**

**October 23, 2012 to November 15, 2012**

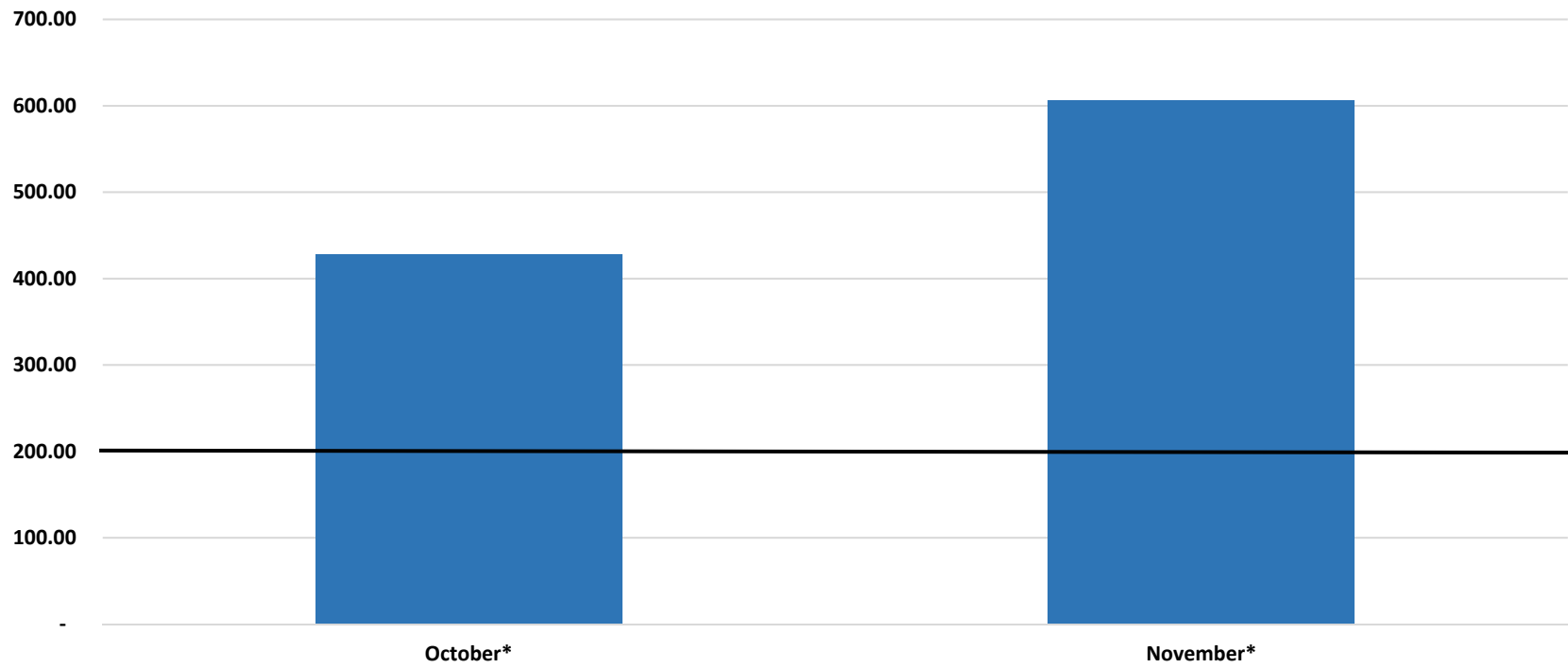
MONTH	OXY ODUs	OXY MG	OXY Grams
October*	11,315	350,750	350.75
November*	16,640	585,200	585.20
* indicates incomplete month			

# **COMPLAINT ATTACHMENT 4**

**PURE OXYCODONE SHIPPED TO  
FOOD CITY # 616 BY AMERISOURCE**

**(10/23/12 to 11/15/12)**

**PURE OXYCODONE SHIPPED TO FOOD CITY # 616 BY AMERISOURCE (in grams)**  
**October 23, 2012 to November 15, 2012**



**PURE OXYCODONE SHIPPED TO FOOD CITY # 616 BY AMERISOURCE (in grams)**

**October 23, 2012 to November 15, 2012**

MONTH	OXY ODUs	OXY MG	OXY Grams
October*	12,900	428,000	428.00
November*	21,300	606,500	606.50
* indicates incomplete month			

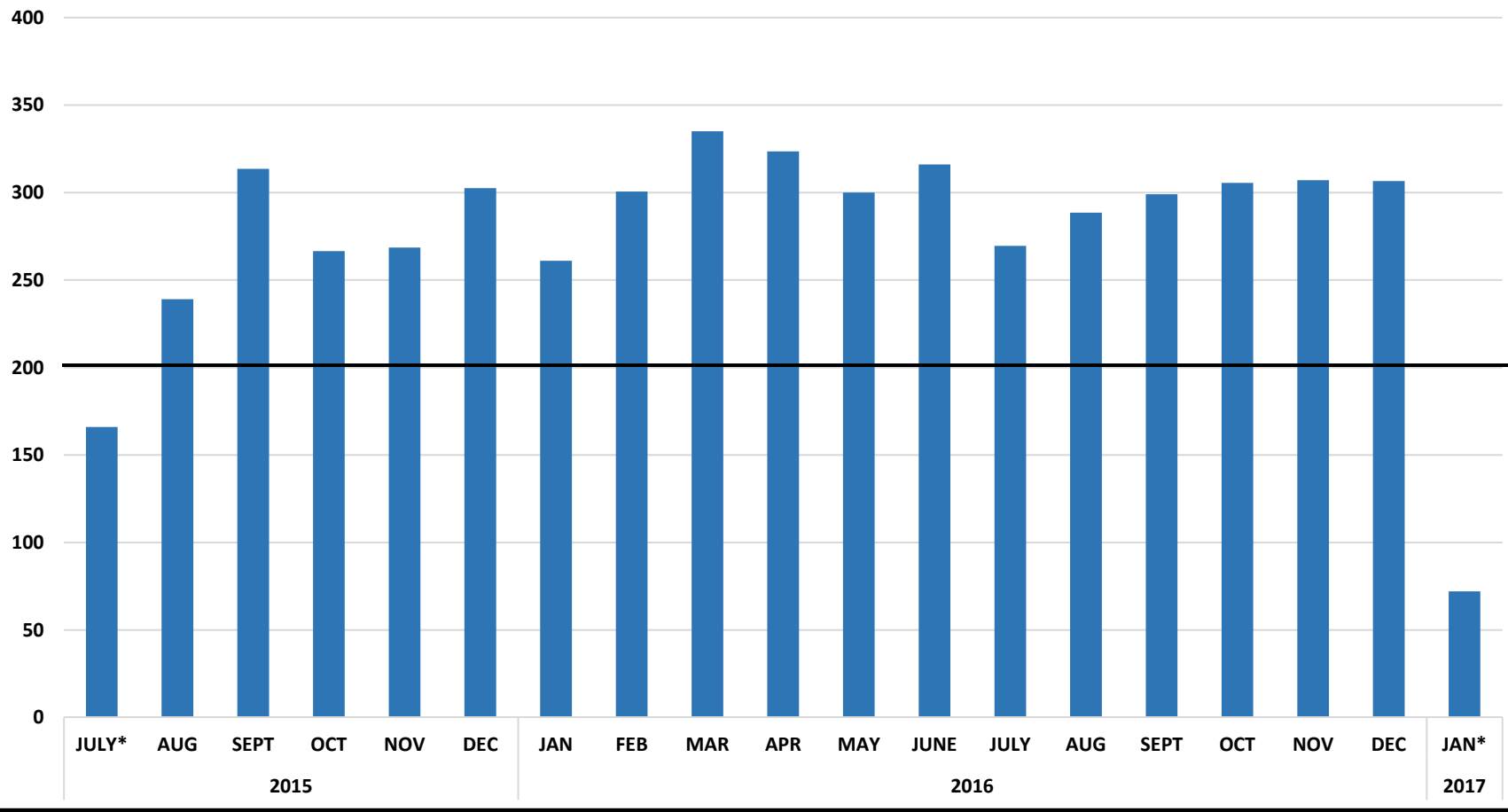


# **COMPLAINT ATTACHMENT 5**

**PURE OXYCODONE SHIPPED TO  
PARDUE'S PHARMACY BY AMERISOURCE**

**(7/16/15 to 1/6/17)**

**PURE OXYCODONE SHIPPED TO PARDUE'S PHARMACY BY AMERISOURCE (in grams)  
July 16, 2015 to September 18, 2017**



\* indicates incomplete month

**PURE OXYCODONE SHIPPED TO PARDUE'S PHARMACY BY AMERISOURCE  
(in grams)**

**July 16, 2015 to September 18, 2017**

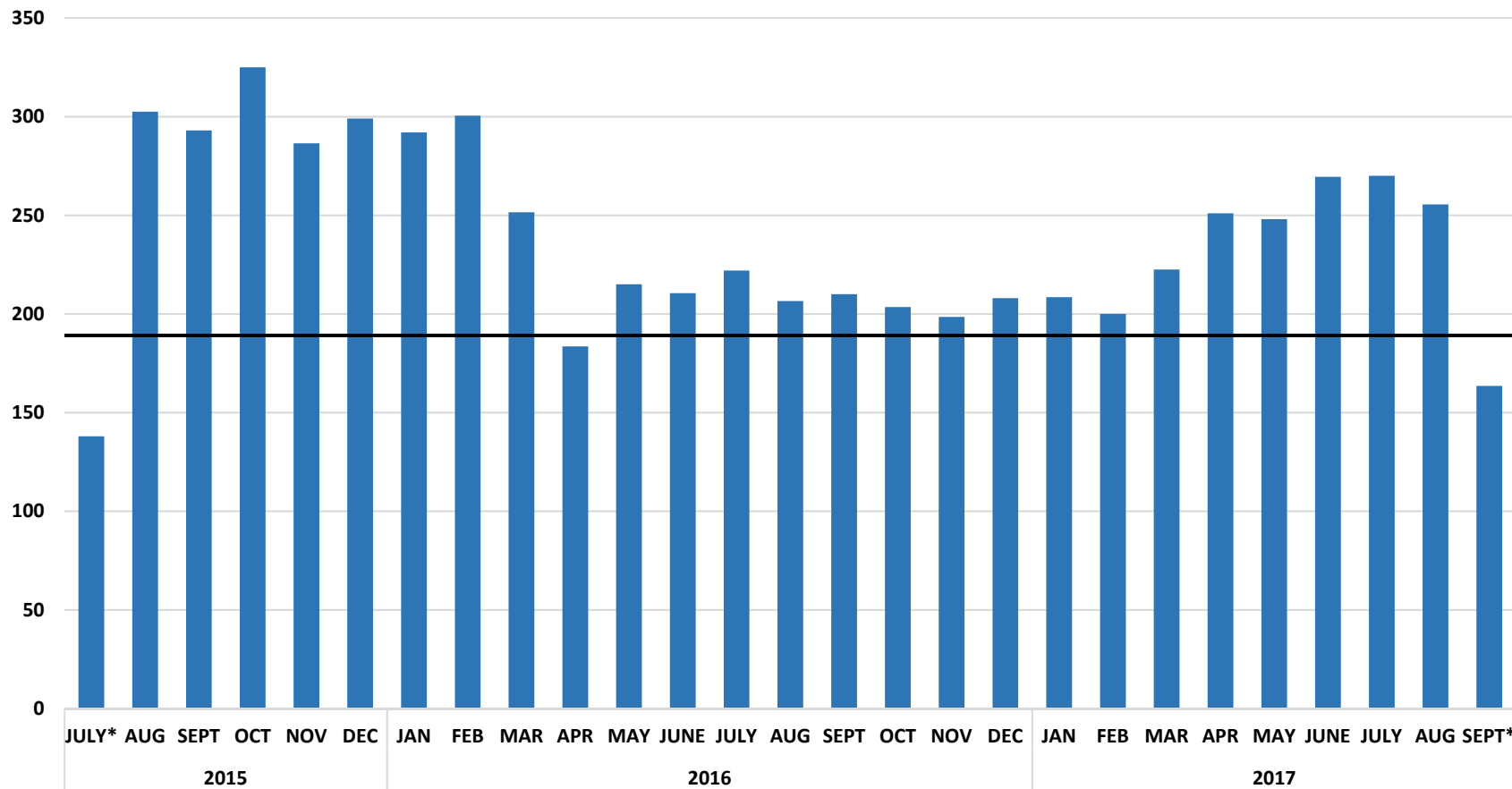
YEAR	MONTH	ODUs	OXY MG	OXY Grams
2015	JULY *	6,500	166,000	166
	AUG	9,700	239,000	239.0
	SEPT	13,200	313,500	313.5
	OCT	13,000	266,500	266.5
	NOV	11,400	268,500	268.5
	DEC	12,800	302,500	302.5
2016	JAN	11,600	261,000	261.0
	FEB	12,500	300,500	300.5
	MAR	14,500	335,000	335.0
	APR	14,200	323,500	323.5
	MAY	13,100	300,000	300.0
	JUNE	13,200	316,000	316.0
	JULY	11,500	269,500	269.5
	AUG	12,800	288,500	288.5
	SEPT	13,200	299,000	299.0
	OCT	13,100	305,500	305.5
	NOV	14,300	307,000	307.0
	DEC	13,100	306,500	306.5
2017	JAN *	3,300	72,000	72.0
* = incomplete months				

# **COMPLAINT ATTACHMENT 6**

**PURE OXYCODONE SHIPPED TO  
P & S PHARMACY BY AMERISOURCE**

**(7/17/15 to 9/18/17)**

**PURE OXYCODONE SHIPPED TO P & S PHARMACY BY AMERISOURCE (in grams)**  
**July 17, 2015 to September 18, 2017**



\*indicates incomplete month

**PURE OXYCODONE SHIPPED TO P & S PHARMACY BY AMERISOURCE (in grams)**

**July 17, 2015 to September 18, 2017**

<b>YEAR</b>	<b>MONTH</b>	<b>OXY ODUs</b>	<b>OXY MG</b>	<b>OXY GRAMS</b>
2015	JULY*	8,000	138,000	138
	AUG	17,200	302,500	303
	SEPT	16,400	293,000	293
	OCT	18,100	325,000	325
	NOV	15,700	286,500	287
	DEC	16,800	299,000	299
2016	JAN	16,600	292,000	292
	FEB	16,300	300,500	301
	MAR	14,400	251,500	252
	APR	10,800	183,500	184
	MAY	12,200	215,000	215
	JUNE	12,800	210,500	211
	JULY	12,800	222,000	222
	AUG	12,600	206,500	207
	SEPT	12,600	210,000	210
	OCT	12,100	203,500	204
	NOV	12,400	198,500	199
	DEC	12,500	208,000	208
2017	JAN	12,200	208,500	209
	FEB	11,500	200,000	200
	MAR	12,700	222,500	223
	APR	14,100	251,000	251
	MAY	14,300	248,000	248
	JUNE	15,100	269,500	270
	JULY	15,100	270,000	270
	AUG	15,000	255,500	256
	SEPT*	8,700	163,500	164
* indicates incomplete month				