FILED CHARLES D. SUSANO III

SIXTH JUDICIAL DISTRICT AT KNOXVILLE 2021 FEB -4 AM 10: 21

STATE OF TENNESSEE, ex rel. HERBERT H. SLATERY III, ATTORNEY GENERAL and REPORTER,	NOX COLATY (L.f.J.) RNOX COLATY (L.f.J.) STRUCTURE SESSIONS PROXICE SESSIONS NOX COLATY (L.f.J.)
Plaintiff,)) JURY DEMAND
\mathbf{v}_{\star}) Case No. <u>3-32-24</u>
FOOD CITY SUPERMARKETS, LLC, and K-VA-T FOOD STORES, INC.,)))
Defendants.)

COMPLAINT AND PETITION FOR ABATEMENT

- 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), against Food City Supermarkets, LLC and K-VA-T Food Stores, Inc. (Food City or the Company) to protect the public, to abate and remedy Defendants' participation in an unlawful controlled substance selling scheme, and to preserve the integrity of the commercial marketplace.
- 2. The State brings suit pursuant to Tenn. Code Ann. § 29-3-103, part of Tennessee's public nuisance statute, Tenn. Code Ann. §§ 29-3-101 to -115, to abate and remedy a nuisance created from Defendants aiding and abetting the unlawful sale of narcotics and controlled substances including 30 milligram immediate release oxycodone, at Food City Pharmacy # 674 (5941 Kingston Pike, Knoxville, TN 37919), Food City Pharmacy # 694 (284 Morrell Road,

Knoxville, TN 37919), and Food City Pharmacy # 616 (11501 Hardin Valley Road, Knoxville, TN 37932).

- 3. The State also brings suit pursuant to the Attorney General's common law police power to abate and remedy the public nuisance created by Food City's interference with the commercial marketplace and endangerment of the public health through its actions and failures to act at the Food City pharmacies identified herein.
- 4. Finally, the State brings suit under Tenn. Code Ann. § 47-18-108 as sovereign under the Tennessee Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101 to -125, on the basis that Defendants' conduct concerning controlled substances, which was undertaken with the knowledge, actions, and directives of its corporate executives and managers, violates Tenn. Code Ann. § 47-18-104(b)(43) and constitutes an unfair practice that violates Tenn. Code Ann. § 47-18-104(a).
- 5. The State's enforcement action seeks injunctive relief, civil penalties for Food City's violations of law, disgorgement of its ill-gotten gains, abatement of the public nuisance Food City substantially helped to create, damages, and recoupment of the State's costs.

I. OVERVIEW

6. Food City is a regional supermarket chain that operates 75 stores with pharmacies in Tennessee. On the grocery side of its business, Food City exists within an industry that is highly competitive and that operates on tight margins. As part of an intentional, corporate-driven strategy to maximize profit centers *elsewhere*, Food City zeroed in on opioid sales at its in-store pharmacies and engaged in a series of unlawful acts that led it to become one of the biggest sellers of highly-diverted opioids in Tennessee.

- 7. Over the last 15 years, Food City has sold massive quantities of opioids, has continued to fail to maintain effective controls against diversion, and has taken affirmative steps to undermine its own opioid diversion controls and those of others. Among other things, Food City:
 - Purchased more oxycodone 30 mg (Oxy 30), one of the most diverted and potent immediate release opioids, ¹ from October 2011 to January 2012 from its primary distributor just for its one Food City # 674 location than were purchased by *all of the pharmacies in 38 entire states* and the District of Columbia; ²
 - Sold opioids with more morphine milligram equivalents (MMEs), a common unit to evaluate potency among different opioids, at Food City # 674 than *all* pharmacies in 81 Tennessee counties; and
 - Sold large quantities of opioids to individuals from foreign countries, including Poland, Australia, Venezuela, the UK, and Canada, and from faraway states within the United States, including Alaska, Arizona, California, Colorado, Hawaii, Montana, North Dakota, New Mexico, New Jersey, New York, Oklahoma, Pennsylvania, Texas, Utah, Washington (state), Wisconsin, and Wyoming.
- 8. Food City and its executives enacted policies and hired and retained employees to ensure that Food City's opioid sales pipeline continued to flow despite knowing that its pharmacies were acting as conduits for enormous amounts of diverted and illegitimate opioid prescriptions based on specific information and data they had collected about the providers and clinics who wrote the substantial majority of opioid prescriptions filled at its pharmacies.
- 9. Among thousands of different offerings ranging from ground beef to laundry detergent, Food City and its executives were fixated on maintaining high volume sales of Oxy 30 and other opioids.³

¹ TNAG-FC-CUST00013071 (e-mail from Food City's Mickey Blazer referencing oxycodone 30 mg as one of the four most commonly stolen/abused drugs).

² ABDCMDL00301692.

See, e.g., TNAG-FC-CUST00087781; TNAG-FC-CUST00092356; TNAG-FC-CUST0009456; TNAG-FC-CUST00010484.

10. Steve Smith, Food City's President and CEO, Mickey Blazer, its Director of Pharmacy Operations who has no pharmacy training, and other company executives were heavily involved in negotiations and efforts to maintain high opioids sales by securing the supply of Food City's opioids—especially Oxy 30.⁴ In a representative series of exchanges in 2013, Steve Smith and Mickey Blazer became increasingly upset when McKesson, facing its own probe from the Drug Enforcement Administration (DEA), reduced the supply of Oxy 30 at Food City's three highest volume stores # 674, # 694, and # 616.⁵ In one e-mail, Mr. Blazer reported to Mr. Smith that McKesson had assured him that Food City would not have any supply issues with Food City's three high volume stores and had known about Food City's high volume ordering history from AmerisourceBergen Drug Corporation, its former primary distributor, before McKesson became its primary distributor. Mr. Blazer said:⁶

---Original Message----From: Mickey Blazer

Sent: Friday, June 28, 2013 10:38 PM Eastern Standard Time

To: Steve Smith

Ce: Charlie Fugate; Jesse Lewis; 'Randy Skoda'

Subject: RE: McKesson meeting

Sam Thompson is the fellow that Curt and I met with in Denver and informed that I had 3 high volume control stores and I wanted to make sure I would not have any issues after the conversion. He assured me that they would take care of us based off of our ordering history with ABC. With that said, I don't have much confidence in him and I have not had any dealings with Jack Fragie. I have a feeling that these are the two guys that told us last Friday that we could get everything but the Oxy 30's and got over rode.

Mickey

In a related e-mail the next day discussing a potential meeting between Food City and McKesson to try to increase the supply of Oxy 30 to Food City's three high volume stores, Mickey Blazer told Steve Smith that a possible McKesson attendee "is a VP of Sales they sent to meet me in

⁴ TNAG-FC-CUST00122629; TC0321566.

⁵ TNAG-FC-CUST00026298; TNAG-FC-CUST00176227; TNAG-FC-CUST00237767; TNAG-FC-CUST00092407; TNAG-FC-CUST00027598; TNAG-FC-CUST00093245; TC0321879.

⁶ TNAG-FC-CUST00085708.

Abingdon after I went off on them for the limited thresholds the [sic] set after they told me they would base all my Stores on the ordering history from [Amerisource]. "That was a joke"!!"⁷

From: Mickey Blazer [blazermi@FoodCity.com] 6/29/2013 2:00:13 PM Sent: To: Steve Smith [smiths@FoodCity.com] Subject: RE: McKesson meeting The only people from McKesson that has come to me is: Bill Mahoney and Ned McKinney. Bill is their Compliance Officer that visited #616, #674, #694. Ned is a VP of Sales they sent to meet me in Abingdon after I went off on them for the limited thresholds the set after they told me they would base all my Stores on the ordering history from ABC. "That was a joke"!! I took him to visit the two Bristol Stores. Mickey Blazer Director of Pharmacy Operations K-VA-T Food Stores, ENC. 201 Trigg Street P.O. Box 1158 Abingdon, VA. 24212-1158 (276) 623-5100 Ext: 5737 azermi@foodcity.com

Similarly, in another e-mail sent to the head of Food City's buying group, CEO Steve Smith expressed his frustration with McKesson's position on supplying Oxy 30 to the three high volume stores saying among other things: "They are going through the motions and in my opinion will not turn us back on. I did tell him that every day that went by his liabilities got larger because of lost business. . . I also told him we make the change at great expense based on his companies [sic] FULL knowledge of our business."

⁷ TNAG-FC-CUST00093245 (emphasis added).

⁸ TNAG-FC-CUST00085710 (capitalized emphasis in original, italic emphasis added).

From: Steve Smith [smiths@FoodCity.com]
Sent: 6/29/2013 8:44:05 PM

To: 'Skoda, Randy' [rskoda@topco.com]

CC: Jesse Lewis [Lewisj@FoodCity.com]; Charlie Fugate [fugatec@FoodCity.com]; Mickey Blazer

[blazermi@FoodCity.com]

Subject: RE: McKesson meeting

He said they were complying with my request for a meeting and they would be gathering information to make a decision with. I told him if he would read the report his Chief Compliance Officer for the Southeast, Bill Mahoney wrote in November the only thing that had changed was we incorporated some of their suggestions and our Control volume was down. They are going through the motions and in my opinion will not turn us back on. I did tell him that every day that went by his liabilities got larger because of the lost business. I also explain to him my position at Topco when we made the decision to go with McKesson and my concern since they had snubbed their nose at Topco the first time around. I also told him we make the change at great expense based on his companies FULL knowledge of our business.

- 11. In a limited sense, the Company's and its executives' fixation on Oxy 30 and other opioids was unsurprising since the highly addictive opioids it sold were lucrative, had high margins, and, if continued, had to be refilled monthly—ensuring a reliable and profitable revenue stream. But in another sense, the Company's obsession with Oxy 30 and other opioids was more than surprising—it was shocking based on what the Company and its executives knew and continued to do.
- 12. Food City # 674 sold more Oxy 30 and other opioids than any other retail pharmacy in Tennessee from 2006 to 2014. Despite knowing of red flags for opioid diversion or abuse from opioids sold at Food City #674, the Company's sales of Oxy 30 and other opioids did not stop or slow down—they increased *exponentially*.
- 13. Food City's unlawful conduct was not limited to Food City # 674. With the full knowledge, direction, and/or participation by its executives, Food City:
 - Actively partnered with one of Tennessee's most notorious pill mills despite being told by its compliance auditors that the prescribing habits of the clinic's providers were "high risk" to Food City's business operations and its reputation, the clinic's providers "prescribe high levels of pain medication, often in 'cocktail combinations' that are sought by those who illicitly seek pain medications," knowing that the clinic's prescriptions were

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⁹ See, e.g., TNAG-FC-CUST00007651.

not being filled by competing pharmacies, the clinic had been sued at least twice as a result of opioid overdoses, the DEA was investigating the clinic, and the Tennessee Board of Medical Examiners had sanctioned some of its providers for opioid overprescribing; 10

- Directed its employees to host a party for the same pill mill when it changed locations so that its providers would keep referring lucrative opioid customers to Food City;
- Instructed each of its pharmacists that the legitimacy of each prescription
 "must be" evaluated patient by patient and prescription by prescription and
 that the refusal "to fill all prescriptions from duly licensed Prescriber,
 Clinic, or Practice Group is not an ethical practice, and could be
 considered defamatory to the Prescriber, Clinic, or Practice Group"
 (excerpt shown below);¹¹

While a pharmacist is empowered to exercise professional judgment in evaluating each prescription they are presented, this evaluation of the legitimacy of a prescription must be done patient by patient, and prescription by prescription. If there is any doubt regarding the legitimacy of a prescription, refusal to fill that prescription is appropriate.



To refuse to fill all prescriptions from duly licensed Prescriber, Clinic, or Practice Group is not an ethical practice, and could be considered defamatory to the Prescriber, Clinic, or Practice Group.

- Steeply discounted the price of its oxycodone to undercut competitors and maintain market share; 12
- Created a prescription savings card program that allowed customers to obtain additional price discounts on all opioids, including Oxy 30, which in combination with the Company's lax compliance policies, made Food City a desired location for drug diverters looking for the cheapest oxycodone in the area;¹³
- Allowed pharmacists to discount or match the price of opioids offered by competitors;¹⁴

^{# 73.1;} see also, TNAG-FC-CUST00007689-90 (showing that 95.85% of controls dispensed from Food City # 674 came from prescriptions from Bearden Health Care Associates in February 2012); TNAG-FC-CUST00122807 (showing 20.96% of all prescriptions (opioid and non-opioid) filled at Food City # 694 came from six Bearden pain clinic providers); TNAG-FC-CUST00123031 (showing between 50.37% and 65.23% of all opioid prescriptions written by seven Bearden providers were filled at Food City Pharmacies).

¹¹ TNAG-FC-CUST00002006 (bold emphasis in original).

¹² TNAG-FC-CUST00001617; see also, PCG-TN016133; PCG-TN016087.

See, e.g., #78.1, PCG-TN003879 (store audit referencing "VC cards are the primary payment method . . .").

¹⁴ See # 43.1.

- Established a policy of having its pharmacies try to order as many opioids and other controlled substances that its distributor would send to each store;¹⁵
- Worked with its pharmacists to help game (already high) thresholds imposed by its distributor for Oxy 30 by shifting prescriptions to Oxy 15s;¹⁶
- Allowed and/or directed pharmacists to also game thresholds by transferring Schedule II opioids between stores without filing the requisite paperwork;
- Entered into a special agreement with KVK/Masters Pharmaceutical solely for the purpose of supplying Food City with Oxy 30 and other immediate release oxycodone tablets to avoid the (already high) threshold limits from Food City's primary distributor;¹⁷
- Actively solicited secondary distributors of Oxy 30 when Food City's main distributor reduced thresholds to its highest volume pharmacies in Knoxville;¹⁸
- Created contingency plans to ensure supply when its main distributor would not increase thresholds as high as the CEO and company executives wanted;¹⁹
- Aggressively (and often successfully) lobbied its distributors to raise (already high) ordering thresholds for Food City's opioid orders, ²⁰ amounts it knew from distributor threshold warning reports triggered at 80% of the actual threshold; ²¹
- Pressured employees who worked in pharmacies that sold high volumes of opioids to increase sales;²²

¹⁹ TNAG-FC-CUST00093240.

TNAG-FC-CUST00092356 (Food City CEO Steve Smith stating in an e-mail, "[T]hey won't tell us what that is *so I guess we order until they won't ship and wait until the next month*. Still a Helluva way to run a railroad.") (emphasis added).

¹⁶ TNAG-FC-CUST00018036.

¹⁷ TNAG-FC-CUST00001968–69.

¹⁸ TC0322026.

TNAG-FC-CUST00093245 (Mickey Blazer e-mail stating "[N]ed is a VP of Sales they sent to meet me in Abingdon after I went off on them for the limited thresholds the [sic] set after they told me they would base all my Stores on the ordering history from ABC. 'That was a joke'!!'); TNAG-FC-CUST00094511; TNAG-FC-CUST0009456.

²¹ TNAG-FC-CUST00018029; TNAG-FC-CUST51390; TNAG-FC-CUST00026380; TC0367329; TC0367327; TC0326555; TC0326546; TC0318793; TC0025241; TC0028161.

Phillips' EEOC Compl. April 14, 2012; *see also*, TNAG-FC-CUST00007636 (Food City # 674 Pharmacist stating, "I am just worried because I do not want to have to explain why my gross profit may be down in 3 months, since I have inventory tomorrow.").

- Emphasized sales in performance evaluations of employees who worked in pharmacies that sold high amounts of opioids;²³
- Threatened to fire pharmacy employees if the pharmacy's sales numbers did not improve; 24
- Retained pharmacy employees that operated its most lucrative opioidselling stores;
- Analyzed the financial hit that (modest) threshold decreases imposed by its distributor had on its highest volume stores;²⁵
- Sought to hoard opioids by instructing its pharmacists to order as much as they could even when they did not need additional supply;
- Stockpiled huge quantities of oxycodone in anticipation of shortages;²⁶
- Transferred numerous opioids between Food City pharmacy stores to ensure a steady supply;²⁷
- Regularly sold individual patients *thousands* of opioids at a time—prescriptions that were so large their only purpose could have been diversion or suicide; ²⁸
- Continued selling massive quantities of opioids even after multiple instances of overdoses in stores or in store parking lots;²⁹
- Allowed its pharmacies for an extended period to accept cash payments for controlled substances; and
- Pushed back forcefully against public and private reports that Food City had compliance issues concerning controlled substances.³⁰

²⁵ TNAG-FC-CUST00097303.

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Phillips' EEOC Compl. April 14, 2012 (alleging Food City pharmacist "was told she had 1 year to get sales up in her Pharmacy or she would lose her job").

²⁴ Phillips' EEOC Compl.

²⁶ TC0345056; TC0324866; TNAG-FC-CUST00005561.

²⁷ Consent Or., *In the Matter of: Food City Pharmacy # 611*, Case No. 2015035061 (stipulated facts stating, "Numbers C2 drugs were transferred without sending C222 forms to the DEA"); TNAG-FC-CUST00244410 (referencing transfer of OxyContin from Food City Pharmacy # 699 to # 694).

TNAG-FC-CUST00007690 (showing 1,200 Schedule II controlled substance pills at Food City # 616 for one prescription and 1,000 Schedule II controlled substance pills at Food City # 674 for one prescription); *See also*, TC000576.

TNAG-FC-CUST00215517 (referencing heroin overdose in Food City # 676 parking lot); TNAG-FC-CUST00185095 (referencing fatal overdose in Food City # 678 parking lot); Maryville Police Report Feb. 28, 2019 (referencing female passed out in women's restroom with syringes on the floor next to her); *see also*, # 82.1 (referencing Dr. Frank McNiel of Bearden Health Care Associates being sued twice for overdose deaths).

³⁰ TNAG-FC-CUST00093207; TNAG-FC-CUST00093208.

- 14. Food City's executives not only shaped how its pharmacies sold opioids and other controlled substances, they were also aware of clear signs of illegitimate prescriptions and diversion from the Company's opioid sales early on. Among other things, Food City and its executives knew that:
 - Food City was sued on November 16, 2005 by Cheryl Armstrong, who alleged that her husband died in 2002 from prescriptions, including oxycodone, benzodiazepine, and a muscle relaxer, among others, he received from Food City # 674 that were written by Bearden Health Care Associates' Dr. Frank McNiel. Food City later settled the lawsuit in an order entered in December 2008;³¹
 - Shortly after August 21, 2008, Steve Smith, Food City's CEO, wrote and published a forceful denial to a Knoxville Metro Pulse article that alleged that Food City's Bearden pharmacy was one of the largest sellers of opioids in the State and had attracted criminal activity, including muggings, armed robberies, and drug deals to the Bearden area surrounding Food City # 674:³²
 - At least by May 12, 2010, knew that East Tennessee had a disproportionately high number of individuals addicted to opioids and that the I-75 corridor in Knoxville had an issue with pill mills, and oxycodone and hydrocodone specifically;³³
 - The DEA had taken enforcement actions against other pharmacies for dispensing high volumes of oxycodone based on prescriptions that it knew or should have known were illegitimate at least by February 2012;³⁴
 - The owner of three pain clinics had been accused of running a pill mill had been featured in a negative television news story and yet continued to sell opioids to patients of the clinics as of April 2012;³⁵
 - The DEA was conducting an audit of Food City # 674 and had identified numerous unrelated customers who were using the same address by at least April 2012;

Armstrong v. Bearden Healthcare, Food City, et al., Case No. C-05-263005 (Knox Cty. Cir. Ct. Nov. 16, 2005), Compl. at ¶¶ 29–30, 41–62.

³² PTN000039873.

See TNAG-FC-CUST00123064; see also, PCG-TN0009011 (Food City Stores training identifying I-75 corridor as having an issue with pill mills and oxycodone and hydrocodone specifically); PCG-TN006763.

³⁴ TNAG-FC-CUST00007692.

³⁵ TNAG-FC-CUST00007633.

- Food City # 694 was filling prescriptions of Oxy 15s to avoid (high) threshold limits on Oxy 30s at least by May 2012;³⁶
- As of July 10, 2012, Food City # 667 in Sevierville (as shown below in its answer to Food City's auditor question number 72) continued to sell opioids to individuals whose prescribers "write prescriptions that would be considered a 'lethal cocktail' on a daily basis[,]" including holy trinity combinations;³⁷

7,

Does Pharmacy fill high percentage of prescriptions that are considered "high risk"? Are commonly prescribed drugs considered a cocktail combination? If yes, then identify name of prescriber, drugs prescribed and frequency.

[break]

72. stated that the said prescribers above write prescriptions that would be considered a "lethal cocktail" on a daily basis. She has received prescriptions containing narcotics, benzodiazepines and muscle relaxers all on one prescription (Oxycodone/xanax-alprazolam/somazolpidem)

- Approximately 75% of its Food City # 674 customers from Bearden Health Care Associates received the "holy trinity," an extremely dangerous combination prescription coveted by drug seekers consisting of an opioid, an anti-anxiety benzodiazepine (e.g., Xanax), and a muscle relaxer (e.g., Soma) on or before July 11, 2012.³⁸ These drugs taken in combination produce an amplified euphoric effect, have an increased risk of causing fatal overdoses, are highly sought by drug seekers, are rarely legitimately prescribed together; and are very clear indicators of diversion;
- Food City continued to regularly sell illegitimate prescription combinations of the "holy trinity" in November 2016 from its own compliance auditors and employees;³⁹
- Food City was acting as a conduit for highly suspect providers whose high risk prescriptions comprised between 50 to 79%⁴⁰ of all their controlled substance prescriptions; [and]
- Food City had experienced significant diversion from within its own stores, including two separate instances at Food City # 673, located in Knoxville,

³⁶ TNAG-FC-CUST00018036.

³⁷ # 168.1.

^{# 165.1 (&}quot;Julie stated that she estimates at least 75% of the customer from Bearden receive prescriptions from all three groups (Narc/Benzo/Muscle Relaxant)."); see also, FC00000426 (stating Bearden Health Care practitioners "prescribe high levels of pain medications, often in "cocktail combinations" that are sought by those who illicitly seek pain medications.").

^{# 187.1 (&}quot;Rachel stated that Bearden physicians do fill prescription that she considers "high risk". Prescriptions filled usually contain a Narc, Benzo and muscle relaxant.").

^{40 # 84.1; # 187.1; # 58.1;} PCG-TN003510; PCG-TN003749; PCG-TN005532; PCG-TN005444; PCG-TN006032.

and # 667, located in Sevierville, in which approximately 5,000 hydrocodone pills were regularly diverted from the pharmacy over an extended period of time.⁴¹

- 15. Food City and its executives knew that the high volumes of opioids it was selling from its pharmacies, including but not limited to # 674, # 694, and # 616, were deeply suspect and were being diverted and abused in large quantities. Food City and its executives had access to dispensing and inventory information from all its stores and knew that # 674, # 694, and # 616 were outliers for opioid sales—even among its high-volume stores.
- 16. For instance, through a single spreadsheet Food City specially created, ⁴² Food City and its executives knew the following facts about # 674, # 694, and #616's opioid sales from January and February 2012 in April 2012:
 - # 674's *average* number of opioid pills per prescription was 267, which is just under *nine pills per day* for a 30-day prescription and over twice the 120 pills per prescription that the Company defined as a "large quantity[;]"⁴³
 - 95.85% of # 674's Schedule II controlled substances came from Bearden Health Care Associates:
 - # 616 had a single 30-day prescription for 1,200 opioid pills, which equals 40 pills a day and fills approximately 12 regular-sized prescription bottles;
 - # 674 had a single 30-day prescription for 1,000 opioid pills, which equals over 33 pills a day and fills approximately 10 regular-sized prescription bottles; and
 - # 616 allowed 41 patients with the same address to purchase Schedule II controlled substances.

⁴¹ TNAG-FC-CUST00013078–79.

⁴² TNAG-FC-CUST00007689–90.

⁴³ See # 198.1.

Despite these diversion red flags, Food City continued to work to supply opioids to those pharmacies in huge numbers and pressured pharmacists to keep dispensing.

		Con	trol S	ubsi	tance F	Reviev	V					
Store		616				674				6:	94	
Month		Jan-12	12-Feb T	otal		12-Jan	12-Feb 7	Total	T.	12-Jan	12-Feb T	otal
# of Clls in:		861	903	1764		1369	1348	2717		593	609	12
# of Pt. filled Cils:		453	468			730	650			347	351	
# of Pts with same address that get Clis:		41	28			42	43			25	22	
# of Cash customers that get Clls:		18	22	40		67	35	152		18	15	
# of VC Club customers that get Clls:												
% of Cash and VC Club of Clls vs. private ins:												
# of Rxs from Bearden Healthcare:		358	356	714		1205	1292	2497		368	357	1.
% of CIIs from Bearden HealthCare:		41.58%	39.42%	40.48%		88.02%	95.85%	91.90%		62.06%	58,62%	60.32
				Prescri	ptions							
Oxycodone 15mg:		Jan-12	12-Feb T	otal		12-Jan	12-Feb 7	Total		12-Jan	12-Feb T	otal
Total Number of Oxycodone 15mg Rxs.	# of Rxs	93	100	193	# of Rxs	96	91	187	# of Rxs	37	42	
Total Number of Oxycodone 15mg doses:	# of Doses	12,350	13.260	25,610	# of Doses	18.963	16,803	35,756	# of Doses	5.137	5.974	11,1
The lowest prescribed quantity	Lowest	10	10		Lowest	28	40		Lowest	10	10	
The highest prescribed quantity	Highest	330	525		Highest	600	540		Highest	540	540	
The averaged quantity prescribed	Average	113	133		Average	159	184		Average	139	150	
The most common quantity prescribed	Mode	180	90		Mode	180	180		Mode	180	120/180/300	
Oxycodone 30mg:		Jan-12	12.Feb T	otal		12-Jan	12-Feb	Total		12-Jan	12 Feb T	otal
Total Number of Oxycodone 30 mg Rxs;	# of Rxs	356	395	751	# of Rxs	579	583	1152	# of Rxs	214	213	4
Total Number of Oxycodone 30 mg doses:	# of Doses	72,312	78,441	150,753	# of Doses	154,820	155,060	309,880	# of Doses	51,207	51.977	103.1
The lowest prescribed quantity	Lowest	12	30		Lowest	10	20		Lowest	10	30	
The highest prescribed quantity	Highest	1200	1200		Highest	1000	1000		Highest	810	810	
The averaged quantity prescribed	Average	203	199		Average	267	203		Average	150	150	
The most common quantity prescribed	Mode	120	180		Mode	240	180		Mode	180	180	-
% of Oxycodone Rxs vs all other Clls		52.15%	54.82%			49.31%	50.00%			42.33%	41.87%	
Total CII Rx		861	903			1369	1348			593	609	
Total CII-V Rx		1501	1580			2281	2258			1275	1259	
Total Rx		3525	3580			3717	3753			4119	3951	
% CII Rx of Total Rx		24.43%	25.22%			36.83%	35.92%			14.40%	15.41%	
I-V Rx of Total Rx		42.58%	44.13%			61.37%	60.17%			30.95%	31.87%	

- 17. Food City and its executives knew of other red flags for diversion including that:
 - Opioid pharmacy customers were paying in cash so frequently that the cash registers at its high-volume locations would have to be emptied up to twice a day;
 - The Company, which usually had one small under-the-counter safe for controlled substances in most pharmacies, had to install up to two person sized safes approximately five feet tall and at least at one time two other safes about half that size to store the controlled substances at its highest volume store (shown below);⁴⁴

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See also, # 166.1 ("25. CII's are retained and secured within three separate safes. Two being a combination safe and another that has a key pad.").



- The Company had to hire armed guards to monitor and protect some of their pharmacies with the highest opioid sales and its customers;⁴⁵
- Food City was selling extremely high quantities of opioids that could have only been for diversion. For example, on November 2, 2010, Food City # 674 purchased 168,000 Oxy 30 pills and 12,000 Oxy 15 pills in one order. The Food City # 674 Oxy 30 order was submitted with orders from 11 other stores and yet the Food City # 674 still accounted for 96% of the total oxycodone that day, which was 187,700 tablets; and
- Food City was selling large quantities of opioids to individuals from foreign countries, and from far-away states within the United States.
- 18. There were other red flags Food City should have known about including that:
 - The pill mill Food City actively partnered with was subject to lawsuits and highly visible and publicized protests, such as a widely-covered demonstration outside of the Bearden Healthcare Associates offices on September 22, 2011.
- 19. The highly suspect nature of Food City's opioid ordering was readily apparent to others who knew about quantities of opioids Food City was selling. In one exchange, at Food City's request, its buying group asked Anda, an opioid distributor, to supply Food City with Oxy

⁴⁵ TNAG-FC-CUST00180788; see also, TNAG-FC-CUST00122412.

30 because the Company was having supply problems. Will Fan, who worked for Topco, Food City's buying group, stated:

Michelie,

As a follow-up to our conversation regarding orders for control drugs, specifically the member I eluded to was KVAT Food City. They have three stores that have an interest in placing orders with Anda.

Is there any reason Anda would not accept the orders for controls?

Thanks,

Will

Anda's sales representative responded:

KVAT Food City was actually the one chain pharmacy I was referring to yesterday as one of the only chains we have turned down. It basically comes down to our compliance team had great concerns regarding their product mix as having the highest top dispensed problem items that we look for. Our compliance director actually said it was the highest quantities he had seen for any Anda customer (and he has been here for like 15 years). 46

⁴⁶ TC0321575.

From: Michelle K Fleischhauer [mailto: Michelle, Fleischhauer@Andanet.com]

Sent: Thursday, June 20, 2013 2:14 PM

To: Fan, William

Subject: RE: Control Orders



Hi Will, sorry I got in a bit late today and have been in back to back meetings since but I will call you in a bit. KVAT Food City was actually the one chain pharmacy I was referring to yesterday as one of the only chains we have turned down. It basically comes down to our compliance team had great concerns regarding their product mix as having the highest top dispensed problem items that we look for. Our compliance director actually said it was the highest quantities he had seen from any Arida customer (and he has been here for like 15 years)

Having said that, they order from us regardless and have been for over a year. This is definitely something we can re-visit especially now that we are rolling this program out.

I will call you in a bit

Thanks!

Michelle Fleischhauer

Senior National Account Manager

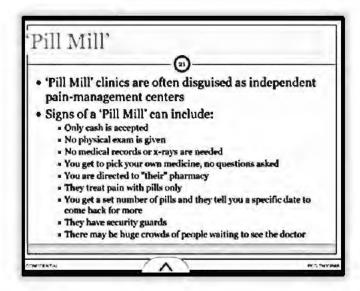
20. Similarly, Actavis, another opioid manufacturer of oxycodone, held a meeting with Food City's primary distributor, Amerisource, on October 22, 2012 in which Actavis conveyed that it knew Food City's Oxy 30 was being diverted based on the massive amounts of Oxy 30 that Food City was purchasing for sale. Notes from the meeting, stated "we know this stuff [is[being diverted" (excerpted below) and showed that Food City # 674, # 694, and # 616 ordered 1,912,000 opioid dosage units of Oxy 30, which is *nine times the national average* of Oxy 30 opioid dosage units ordered for three pharmacies. Food City, which had even better access to information about its own Oxy 30 and other opioid ordering habits, knew or should have known that its Oxy 30 was being diverted in massive numbers as well.

⁴⁷ MULTI3537759.

⁴⁸ ABC-MSAGC00008982; MULTI3537758.

we know this striff bury arrolled

21. Food City prioritized⁴⁹ and incentivized opioid sales⁵⁰ over compliance, instituted weak or ineffectual policies,⁵¹ and routinely ignored red flags for abuse and diversion at or near its pharmacies that the Company and its executives had learned from its own compliance auditors. Food City and its executives were told of hallmarks of pill mills, including:



22. Food City and its executives knew of these and other red flags⁵² and knowingly disregarded strong evidence that massive diversion of Oxy 30 and other opioids was occurring

See, e.g., TNAG-FC-CUST00010484 (Food City executive referencing a Walgreens program in the Knoxville district that limited pain medication to only 120 pills at a time and stating "This is a pilot program for this area and was initiated due to our local Walgreen Pharmacist complaining to corporate. They plan to lose a substantial amount of scripts.").

⁵⁰ See, e.g., TNAG-FC-CUST00010484.

^{# 73.1 (}stating "The PCG investigation has revealed that the current Food City Store Pharmacy policy lacks a mechanism the business practices of the practitioners and specifically their employers."); TNAG-FC-CUST00082246 (Food City employee stating in part, "I have a list of pts who can no longer come here but they end up coming in when I am not here.").

⁵² PCG-TN012259.

from its pharmacies while implementing policies to ensure that its opioid sales pipeline was not disrupted. Among others, Food City ignored the following red flags for opioid abuse and diversion at its pharmacies:

- The Company accepted post-dated prescriptions;⁵³
- The Company had the incorrect prescriber, incorrect patient, and incorrect labeling on vials;⁵⁴
- The Company stipulated that its staff at # 687 "admitted to never refusing to fill a prescription unless it was extremely early;"55
- A high percentage of the Company's controlled substance prescriptions were paid for by customers in cash;⁵⁶
- Many Food City opioid customers were from distant places, including outof-state or out-of-the-country;⁵⁷
- Patients were abusing or selling drugs in the pharmacy parking lot;
- The Company purchased disproportionate ratios of controlled substances to noncontrolled substances:
- The Company purchased disproportionate rates of one family or sub-family of controlled substances compared to other families;⁵⁸
- The Company purchased controlled substances from multiple distributors at once;⁵⁹ and

In Matter of Food City # 674, Consent Or., Case No. 2014000801 (Aug. 7, 2016) (p. 2).

⁵⁴

⁵⁵ Consent Or., In the Matter of Food City #611 [sic – should be 687 based on 2712 Loves Creek Rd address], Case No. 2015035061 (Jan. 12, 2016) (p. 2).

^{#166.1 (}Line 78 – Audit of Food City # 674 stating cash sales were 40%); #174.1 (Line 78 – Audit of Food City # 687 referencing pharmacist-in-charge's estimate for cash payment for prescriptions being 40%).

See Consent Or., In the Matter of Food City # 611 [sic - should be 687 based on 2712 Loves Creek Rd address], Case No. 2015035061 (Jan. 12, 2016) (Stipulated facts stating "Staff would early refill for cash and admitted to filling out of state prescriptions without question);" Consent Or., In Matter of Food City # 674, Case No. 2014000801 (Aug. 7, 2016) (p. 2) (referencing patients driving long distances to pharmacy).

^{# 95.1 (}Showing prescriptions for oxycodone constituted 40% of controlled substances prescriptions filled at Food City # 616 from July 1, 2011 to Nov. 22, 2011); #73.1(showing 5 Bearden Health Care Associates Providers who wrote over 70% of their Schedule II controlled substances prescriptions for oxycodone).

See TNAG-FC-CUST00001968: TC0028665.

- The Company sold huge amounts of dangerous combinations of controlled substances, such as "holy trinity" prescriptions consisting of an opioid, an anti-anxiety medication, and a muscle relaxer sought by drug seekers.
- 23. Not only did the Company and its executives fail to institute effective controls against this diversion, Food City ignored or actively subverted its own internal controls and knowingly exploited weaknesses in controls it instituted as well as those applied to it by its distributors and the others. This failure to maintain adequate controls against diversion has had devastating consequences.
- 24. Diversion from opioids that Food City sold fueled criminal drug rings in East Tennessee. From January 2008 to approximately October 2012, Gregory Rhea along with 11 codefendants, "obtained oxycodone from numerous physicians in the Eastern District of Tennessee and in the state of Florida for the purpose of distributing oxycodone in the Eastern District of Tennessee." Mr. Rhea, who lived in Morristown, which is about an hour away from Food City # 694, pled guilty to federal drug, firearm, and money laundering charges. In 2011 alone, Food City # 694 filled at least 27 opioid prescriptions for Criminal 1 of his oxycodone ring, each of

^{#73.1 (}stating Bearden Health Care Associates providers "prescribe high levels of pain medications, often in 'cocktail combinations' that are sought by those who illicitly seek pain medications."); # 187.1; # 165.1.

United States v. Rhea, No. 2:12-cr-105, No. 2:16cv323 (E.D. Tenn. May 25, 2018) ("Petitioner stipulated to the following facts ... Through the testimony of several witnesses, including law enforcement officers, the United States would demonstrate, beyond a reasonable doubt, that beginning from approximately December 1, 2003, to December 14, 2004, and from approximately January 1, 2008, continuing to on or about October 10, 2012, in the Eastern District of Tennessee, and elsewhere, the defendant did knowingly and intentionally conspire with at least one other person to distribute oxycodone, a Schedule II controlled substance . . . During the time period of the conspiracy, the defendant admits that he entered into an agreement with [at least 12 others] to distribute oxycodone, a Schedule II controlled substance. . . . On August 13, 2011, the defendant admits that he sold ten (10) dose units of thirty (30) milligram oxycodone pills to a confidential informant at the defendant's residence, located at 412 Hayter Drive, Morristown, Tennessee. During the transaction, the defendant admits that he attempted to recruit the confidential informant to travel to a pain clinic in Bearden, Tennessee, for the purpose of obtaining oxycodone. The defendant further admits that he offered to 'sponsor' the confidential informant to go to this pain clinic, which means that the defendant agreed to provide money for travel to the clinic and the payment of medical and prescription bills in exchange for half of the prescription pills obtained as a result of the pain clinic appointment.").

which was written by a Bearden Health Care Associates provider. Food City # 694 filled the following high volume prescriptions for Criminal 1:

Date	Rx
3/15/11	180 hydrocodone
3/29/11	210 Oxy 30s and 60 OxyContin 80mg
4/28/11	210 Oxy 30s and 60 OxyContin 80mg
5/26/11	210 Oxy 30s and 60 OxyContin 80mg
6/28/11	210 Oxy 30s and 60 OxyContin 80mg
7/27/11	210 Oxy 30s and 60 Opana 40mg
8/25/11	210 Oxy 30s and 60 Opana 40mg
9/27/11	210 Oxy 30s and 60 Opana 40mg

Between 2009 and September 2012, Food City # 694 also filled 42 opioid prescriptions totaling 12,390 pills (opioid dosage units or ODUs) for Criminal 2, one of Mr. Rhea's co-defendants, who also lived over an hour away from Food City # 694. Criminal 2's average Oxy 30 prescription from Food City # 694 was 314 pills, over 5 times higher MMEs than the CDC's recommended limit of 90 MMEs per day. The Rhea drug ring sold Oxy 30s from Bearden providers to the Department of Justice's confidential informant on or shortly after the date they were filled at Food City as shown below:

Date of Food City Rx Sale	Date of Undercover Sale	Rx Information				
July 27, 2011	July 29, 2011	# 694 sells Criminal 1 210 Oxy 30s prescribed by Teodora Neagu (Bearden)				
August 11, 2011	August 13, 2011	# 694 sells Criminal 2 360 Oxy 30s prescribed by Teodora Neagu (Bearden)				
August 25, 2011	August 27, 2011	# 694 sells Criminal 1 210 Oxy 30s prescribed by Donald Douglas (Bearden)				
October 11, 2011	October 11, 2011	#694 sells Criminal 2 360 Oxy 30s prescribed by Christina Collins (Bearden)				
November 11, 2011	November 23, 2011	# 694 sells Criminal 2 360 Oxy 30s prescribed by Donald Douglas (Bearden)				
September 11, 2012	September 18, 2012	# 694 sells Criminal 2 180 Oxy 30s prescribed by Donald Douglas (Bearden)				

- 25. Assuming the black-market rate for an oxycodone 30 mg pill is \$20-30,⁶² these undercover sales had a total of street value of approximately \$33,600 and \$50,400 on the low end. Notably, the highest volume of these prescriptions works out to a dozen pills per day, the equivalent of 540 MMEs per day—6 times higher than the CDC's recommended limit.
- 26. Food City sold opioids, particularly oxycodone, at such an incredibly alarming rate and volume that there could be no legitimate purpose associated with their use. The only possible explanation for the astronomical amount of opioids pouring into and out of Food City stores in Tennessee is that an extremely high and disproportionate portion of the drugs were being abused or diverted (i.e., stolen or otherwise obtained for illegal use).⁶³

II. PARTIES

27. The Plaintiff, State of Teunessee *ex rel*. Herbert H. Slatery III, Attorney General and Reporter, is charged with enforcing Tennessee's public nuisance statute, Tenn. Code Ann. §§ 29-3-102, -103, and the Tennessee Consumer Protection Act, Tenn. Code Ann. § 47-18-

https://www.dea.gov/press-releases/2019/07/02/doctor-who-operated-oxycodone-and-fentanyl-diversion-scheme-sentenced-5 (referring to \$20-\$30 per pill price of oxycodone 30 mg).

⁶³ See, e.g., TNAG-FC-CUST00007690.

- 108. 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).
- 28. Defendant Food City Supermarkets, LLC is a foreign limited liability company organized under the laws of Virginia with its principal place of business in Abingdon, Virginia. Food City's parent company, Defendant K-VA-T Food Stores, Inc., is a foreign corporation organized under the laws of Virginia with its principal place of business in Abingdon, Virginia. Defendants operate 13 pharmacies in Knox County and 62 other locations in Tennessee.
- 29. Defendants Food City and K-VA-T acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described in this Complaint. At all relevant times, Food City operated multiple pharmacies in Tennessee, including Food City # 674, # 694, and # 616 located in Knoxville, that are the subject of the State's statutory public nuisance claim.
- 30. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

III. STATE COURT JURISDICTION

- 31. The causes of action asserted and the remedies sought in this Complaint are based exclusively on Tennessee statutory, common, and decisional law.
- 32. 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. 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).

33. In this Complaint, the State occasionally references federal statutes, regulations, or actions, but does so only to establish Food City's knowledge, to explain how Food City'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).

IV. SUBJECT MATTER JURISDICTION

34. As a court of general jurisdiction, the Circuit Court is authorized to hear this matter, based on the statutory public nuisance, common law nuisance, and TCPA claims, the amount at issue, and the relief sought pursuant to Tenn. Code Ann. §§ 16-10-101 and -110, Tenn. Code Ann. § 29-3-102, Tenn. Code Ann. § 39-12-206(a), and Tenn. Code Ann. § 47-18-108.

V. PERSONAL JURISDICTION

35. As set forth below, this Court has personal jurisdiction over Defendants based on their contacts in Tennessee. Among other things, Food City is a supermarket chain with approximately 75 grocery stores in Tennessee with in-store pharmacies, including # 674, # 694, # 616, and all others referenced in this Complaint with a store number that begins with "6." Food City has transacted business in Tennessee including through sales of opioids at its pharmacies.

VI. VENUE

36. Venue is proper in Knox County pursuant to the public nuisance statute, Tenn. Code Ann. § 29-3-103 and the TCPA's specific state enforcement venue provision, Tenn. Code Ann. § 47-18-108(a)(3), because Food City # 674, # 694, and # 616 are located in Knoxville, it is a county where alleged violations took place, and is also a county in which Food City has conducted or transacted business.

VII. PRE-SUIT NOTICE

37. Consistent with Tenn. Code Ann. §§ 47-18-108(a)(2) and (3), the State certifies that it has provided Defendants with ten days' notice of its intention to initiate suit, an opportunity to respond or present reasons why suit should not be instituted, and the opportunity to present a resolution proposal.

VIII. SPECIFIC FACTUAL ALLEGATIONS

A. Background on Opioids

- 38. Opioids are narcotics that interact with specific receptors on nerve cells used to reduce the perception of pain. They include prescription pain relievers such as oxycodone, hydrocodone, morphine, and others and are closely related to heroin. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain.
- 39. Because of long-standing and well-founded fears about their potential for abuse and addiction, prescriptions opioids have usually been regulated at the state and federal level as Schedule II or III controlled substances.
- 40. Prescription opioids are classified as controlled substances and are unlawful to distribute under Tennessee law, absent limited exceptions. Schedule II opioids, including

oxycodone and, after 2014, hydrocodone, have the *highest* potential for abuse among any drug that has, in limited circumstances, a recognized medical use. *See* Tenn. Code Ann. § 39-17-407; § 39-17-408(b)(1)(O), (K); 21 U.S.C. § 812(b)(2). State law prohibits anyone, including a pharmacy, such as Food City, from knowingly participating in the diversion of opioids.

- 41. 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 opioids through pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes. For most people who abuse prescription opioids, the source of their drugs can typically be found in the excess supply of drugs in the community.
- 42. As known to Food City and its executives, oxycodone is one of the most diverted prescription opioids⁶⁴ that principally comes in two time-release formulations: immediate release and extended release. Extended release opioids are approved by the FDA for long-term pain in certain instances and, at least in theory, are supposed to be released over an extended period, while immediate release opioids are indicated for short-term pain and are released shortly after ingestion.
- 43. Immediate release oxycodone is either pure or combined with a non-opioid pain reliever such as acetaminophen, which can cause serious liver damage if abused. Pure immediate release oxycodone comes in different doses ranging from 5 mg to 30 mg with the most potent being 30 milligrams. Pure oxycodone has been abused and diverted in significant numbers and unlike oxycodone with acetaminophen does not cause liver damage if abused. More potent opioids

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TNAG-FC-CUST00013071 (e-mail from Food City's Mickey Blazer referencing oxycodone 30 mg as one of the four most commonly stolen/abused drugs).

generally command a higher price on the black market because of a purported increased euphoric effect among users.

44. Abuse and diversion of immediate release oxycodone, including Oxy 30, increased after Purdue Pharma took its highly potent extended relief oxycodone sold under the brand name OxyContin off the market and replaced it with a purportedly abuse deterrent formulation in August 2010.⁶⁵

B. The Role of Pharmacies in the Opioid Supply Chain

- 45. 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. The closed-system model contemplates manufacturers selling pharmaceuticals to distributors. Pharmacies, hospitals, nursing homes, palliative care facilities, and some dispensing physicians order pharmaceutical products from the distributors, who ship such products to them to be sold to the ultimate consumer. Participants in this closed system are registered under federal and state law. Registrants—including pharmacies that dispense controlled substances—must adhere to the specific security, recordkeeping, monitoring, and reporting requirement that are designed to identify or prevent diversion—and must maintain effective controls against diversion, among other things.
- 46. 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 sell prescription opioids to consumers.
- 47. 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

26

The State asserts that many of these manufacturers grossly misrepresented the extent of abuse deterrence.

prescription drugs. After production, many manufacturers sell their drugs to distributors for further dispersal.

- 48. After purchase, distributors inventory and sell pharmaceutical products to a variety of providers, including retail pharmacies, and are required to ensure their safe storage and distribution.
- 49. Pharmacies are the final, crucial step in the pharmaceutical supply chain before the drugs reach the consumer. Pharmacies purchase drugs from distributors, and occasionally directly from manufacturers, and then take physical possession of the drugs. Pharmacies are also required to ensure safe storage of controlled substances in their stores. Pharmacists then review prescriptions before dispensing and selling these drugs to consumers.

C. Regulatory Context for Pharmacies

- 50. Tennessee state law and its federal counterpart impose a series of overlapping and complementary restrictions on the distribution of controlled substances. 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 Controlled Substances Act giving DEA its authority). Pharmacies must first register with the Board of Pharmacy (and, under federal law, the DEA) to dispense controlled substances. 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).
- 51. Under Tennessee law, it is illegal for a pharmacist to dispense a controlled substance "for any purpose other than those authorized by and consistent with the person's

professional or occupational licensure or registration law, or to ... dispense any controlled substance in a manner prohibited by the person's professional or occupational licensure or registration law[.]" Tenn. Code Ann. § 53-11-401.

- 52. Tennessee and federal law requires pharmacies to recognize and act upon red flags indicative of addiction, abuse, and diversion, ⁶⁶ which the DEA has described as: (i) multiple customers receiving the same combination of prescriptions or drug cocktails; (ii) multiple customers receiving the same strength of controlled substances, no individualized dosing, and/or multiple prescriptions for the strongest dose of an opioid available; (iii) many customers paying cash for their controlled substance prescriptions; (iv) customers requesting early refills; (v) many customers with the same diagnosis codes written on their prescriptions; (vi) customers driving long distances to visit physicians and/or fill prescriptions; (vii) customers arriving in groups, with each customer presenting a prescription issued by the same physician; and (viii) customers with prescriptions for opioids written by physicians with specialties not associated with pain management, such as podiatry or gynecology. ⁶⁷
- 53. Pharmacies like Food City act as the last gatekeeper for diversion and observe many of these red flags first-hand, and often in real time. A majority, if not all, of these red flags were present at Food City pharmacies that sold opioids, yet Food City failed to act in response in any meaningful way.

See, e.g., East Main Street Pharmacy; Affirmance of Suspension Or., 75 F.R. 66149-01, 66163, 2010 WL 4218766 (Oct. 27, 2010).

⁶⁷ See Thomas Prevoznik, "Birmingham Pharmacy Division Awareness Conference," UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, available at https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2015/march_2015/prevoznik.pdf at 139–40.

D. Food City's Marketplace Position

- 54. The grocery store industry is highly competitive and generates thin profit margins for most products. Smaller grocery stores, such as Food City, must find ways to compete against much larger national chains, including Wal-Mart, Kroger, and Publix, and differentiate themselves from these and other competitors. The most obvious ways to compete, including offering a lower price, offering items that larger competitors do not sell, or being conveniently located, often prove the most difficult for smaller companies.
- 55. Smaller grocery stores do not have the purchasing power or sales volume to demand lower prices from wholesalers and have difficulty sustaining lower prices than larger competitors for most products. Offering products that larger competitors do not sell means investing in new supply chains and analytics to estimate consumer demand, which means more cost and risk. Securing the most desirable location for a grocery store may also prove challenging for smaller players. Larger chains may have more capital and be able to afford higher rents or may be able to secure more favorable lease terms from landlords because of their size and stability.
- 56. Despite these obstacles, Food City has managed to compete against larger market players not only in the grocery business, but in the pharmacy business as well where the competition is stiffer. In the pharmacy space, Food City must not only compete against in-store pharmacies at other grocery chains, but also against larger pharmacy chains, such as Walgreens and CVS, and independent pharmacies.
- 57. One of the ways that Food City has been able to compete against larger market players is with opioids. Other considerations aside, opioids offer money-making opportunities that other pharmaceutical products do not. While branded products generally sell for higher prices than generics, pharmacies may make more money off generics than branded products. For example, in

2011, Food City # 674's margin on Oxy 15 and 30 was over 10 times what its margin was for branded OxyContin. 68 Opioid prescriptions also have to be refilled every thirty days, whereas drugs that are not controlled substances can have prescriptions that can last for much longer durations. More trips to the pharmacy mean more dispensing fees for the pharmacy and additional foot traffic for the store. But larger competitors also saw this profit potential for opioids and controlled substances.

- 58. To help compete against larger chains on price, Food City joined Topco Associates, a co-operative of other regional supermarket chains from different areas of the country, to leverage greater buying power and demand lower prices for grocery items and pharmaceuticals, including opioids, from wholesalers based on the cooperative's collective sales volume. Food City CEO Steve Smith has served and currently serves on Topco's Board of Directors and, along with Food City itself, has been described as a "very influential member" of Topco. 69
- 59. Food City has used its buying group's contract with pharmaceutical distributors to help lower the wholesale cost of its opioids, including generic oxycodone and Oxy 30 specifically. But even with its buying group, Food City's pharmacies still have faced significant competitive headwinds.
- 60. Food City generally sold the same line of opioids that its competitors did, and its buying group would only partially help on its pricing. So, to find a way to compete against larger players, the Company often offered something different. Food City sold opioids by filling prescriptions written by high-volume providers and pill mills that most of its competitors would not sell. The Company also sold opioids in combinations (e.g., "holy trinity" of opioids, anti-

⁶⁸ TNAG-FC-CUST000007651.

⁶⁹ TC0321560.

anxiety medication, and muscle relaxers) that most of its competitors would not sell and that its own compliance auditors told Food City and its executives were sought by those who illicitly seek pain medications.⁷⁰

- 61. Food City actively partnered with known pill mills that directed their patients to have their prescription filled at Food City⁷¹—something that its larger competitors would not do or were reluctant to do. As a result of corporate directives that emphasized the profit potential of opioids, Food City quickly became known as the pharmacy where you could purchase massive quantities of opioids, especially Oxy 30, cheaply and with minimal hassle.
- 62. Food City used the trappings of legitimacy from its grocery store business, in part, to become an outlier of outliers even among high-volume opioid sellers. As a medium-sized regional supermarket chain, Food City found itself in an apparent sweet spot—smaller than major pharmacy chains that attracted attention and resources from the DEA and the Department of Justice (DOJ), but much larger than independent pharmacies, which often attracted the attention from local law enforcement.
- 63. Food City was also able to use its status as a supermarket chain to justify to distributors that it was less risky than independent pharmacies and should not be subject to (already high) opioid sales limits that its distributors applied to independent pharmacies.⁷²

E. Overview of Food City's Opioid Sales

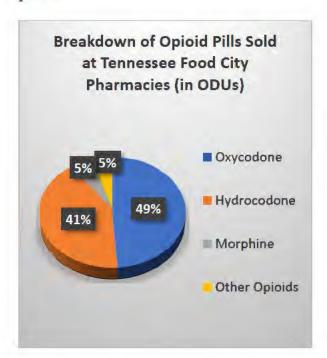
64. In Tennessee, Food City purchased over 103 million ODUs, usually in pill form, between January 1, 2006 and December 31, 2014, which equates to over 2.8 billion morphine

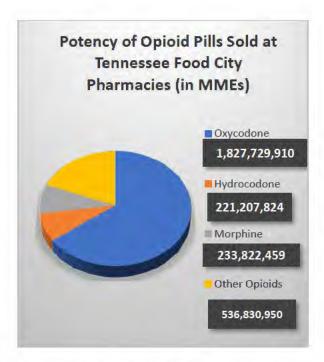
⁷⁰ # 73.1.

See, e.g., C2 Report (e-mail from Tom Geoghagan to Mickey Blazer, April 11, 2012) (showing that 95.85% of controls dispensed from Food City # 674 came from prescriptions from Bearden Health Care Associates in February 2012).

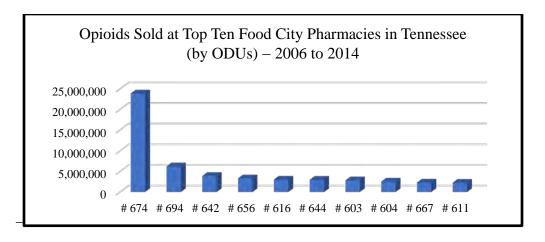
⁷² See, e.g., ABDCMDL00316920.

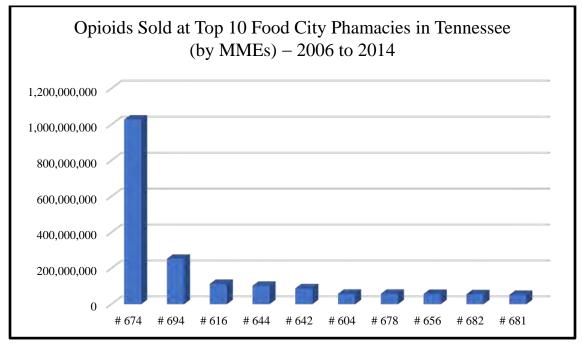
milligram equivalents, or MMEs, a standardized unit used to evaluate the relative potency of different opioids. As shown below, Food City sold more oxycodone than any other opioid and, based on the disproportionate MME for oxycodone compared to other opioids, more high dose oxycodone that is more desirable for diversion because higher potency opioids command higher prices.





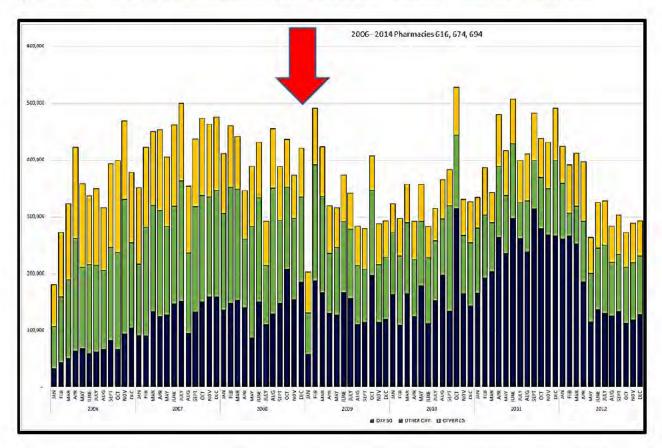
65. Food City's top ten opioid selling pharmacies all had high sales volume, but # 674 stood out. The charts below illustrate the number of pills (in ODUs) and potency (in morphine milligram equivalents) MMEs for the top ten Food City pharmacies from 2006 to 2014 and show how # 674 was an outlier among outliers.





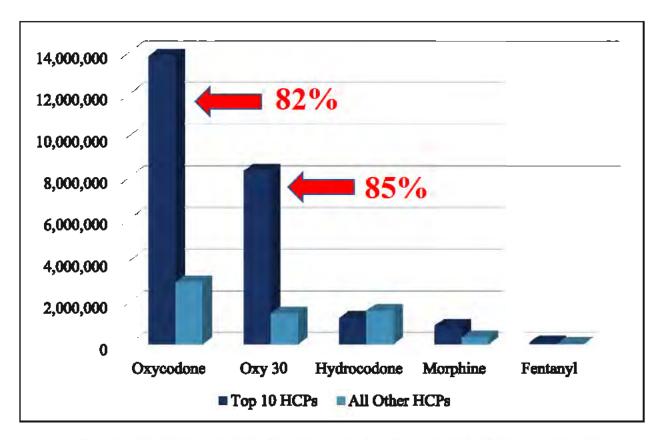
- 66. Food City # 674 made up the lion's share of the top ten pharmacies and accounted for over 23% of Food City's total pills ODUs and over 34% of its MMEs between 2006 and 2014.
- 67. The numbers are even more staggering if its limited to just oxycodone—Food City # 674 purchased over 18 million oxycodone pills, accounting for 36% of all of Food City's oxycodone. This was enough to give every single person living in Knoxville approximately 130 opioids each. In terms of relative potency, Pharmacy # 674 purchased 850 million MMEs of oxycodone, which accounted for 47% of Food City's overall oxycodone MMEs.

68. Food City # 674, # 694, and # 616 actively partnered with Bearden Health Care Associates and had a close relationship with its providers. In fact, a review of Oxy 30 (shown in blue), other oxycodone (shown in green), and other controlled substances (shown in yellow), at these pharmacies shows just how symbiotic the relationship was. The major dip in early 2009 in opioid sales was when DEA executed a search warrant on Bearden Health Care Associates. 73



69. The top ten prescribers at Food City # 674, # 694, and # 616 were all Bearden prescribers or former Bearden prescribers who wrote 82% of the oxycodone and 85% of the Oxy 30 that was sold at these Food City pharmacies, as shown by the chart below:

⁷³ See # 73.1.



70. Food City specially analyzed how much of Bearden's total prescriptions that were being sold at Food City. Unsurprisingly, Food City captured the overwhelming majority of prescriptions from Bearden providers. As shown by the chart below, from January 1 through March 31, 2012, Food City pharmacies were capturing over 75% of prescriptions from Bearden's most prolific prescribers.⁷⁴

⁷⁴ TNAG-FC-CUST00123048.

BHA Analysis					
1 Jan-31 Mar 2012					
Prescriber	Total Rx*	FC Rx	FC %	Other Pharm*	Avg/Pharm
F McNiel	1049	366	34.89%	80	8.54
B Burchell	2614	1971	75.40%	102	6.30
C Collins	2944	2232	75.82%	106	6.72
D Douglas	2081	1574	75.64%	88	5.76
T Neagu	2787	2127	76.32%	92	7.17
B Wilson	2879	2206	76.62%	86	7.83
NP total	13305	10110	75.99%		
total	14354	10476	72.98%		
*total taken from TN					
*total taken from TN Database					

71. The number of opioids being ordered and dispensed by Food City pharmacies was so large that there could not have been a legitimate use for the opioids, particularly when compared to the population being served. Food City knew, or should have known, that a substantial majority of the opioids it was selling to its customers in Tennessee were not based on legitimate prescriptions and were being diverted in huge numbers.

F. Emphasis on Opioid Sales

72. Food City devoted substantial attention to opioids because it was able to make a significantly bigger profit margin on opioids than it could most of its grocery and other products. Among opioids, Food City's profit margin was higher for generics than it was for branded products—especially when its ValuCard prescription savings card was used. As of August 2012, Food City could make up to eight times the average margin percentage for generic oxycodone

(Oxy 30 and Oxy 15) than it could for branded OxyContin. Food City's average margin percentage difference jumped to nearly 12 times when the ValuCard was used.⁷⁵

- 73. Food City and its executives placed enormous sales pressure on its pharmacies to generate profit. One of the principal ways that the Company did this was through opioids sales especially at Food City # 674, # 694, and # 616.
- 74. On October 1, 2010, Food City's Vice President of Operations followed up and again told Food City pharmacists to order oxycodone, including Oxy 30, from Masters "so that we can save money and generate additional revenue."

Subject: Copy of Food City New Approved Primary C-II Items From Masters.xls

Attachments: Copy of Food City New Approved Primary C-II Items From Masters.xls

Team,

On Thursday, September 23, 2010 we sent an email alerting you that Masters would be forwarding "UPS CII Air Express kits" to stores who currently do not order C-II items from Masters. That email also stated that have identified select C-II items which offer significant savings if they are ordered from Masters. Attached, please find the list of these identified items and their ordering information from Masters. Please begin ordering these items from Masters so that we can save money and generate additional revenue. If you have any questions regarding the procedures please follow instructions in the "Masters Rx UPS CII Air Express kits".

Sincerely,

Don Clark D. Ph.

Vice President of Pharmacy Operations

K-VA-T Food Stores, Inc. | (PH) 800-826-8451 Ext. 5737 | (F) 276-623-5440 | (Email) clarkd@foodcity.com "We will find a way, or make one!"

⁷⁵ TNAG-FC-CUST00007651.

⁷⁶ TNAG-FC-CUST00001974–75 (redaction of prices in the chart applied by the State).

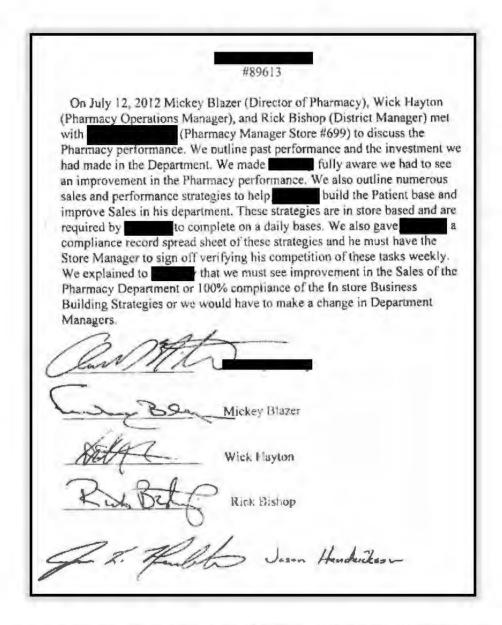
FOOD RETT	Masters Synergy* Vactors series - Marines rest:			
Masters Primary Approved New CII Items			(AIR EXPRESS-NEXT DAY UPS PRE -PRINTED UPS)	
Descritpion	OXYCODONE HCL 30MG TABS	Manufacturer	MALLINCKRO	
ItemNumber	399096	Product Size	100	
NDC	00406-8530-01	Case Quantity	12	
Brand Name	ROXICODONE	UOM	EACH	
OBR	AB	WAC		
Strength	30MG	AWP		
Color/Shape	LIGHT BLUE/ROUND/SCORED	Price		

75. Other examples abound. For instance, on April 21, 2011, the pharmacist at Food City # 674, the second highest volume opioid pharmacy in Tennessee, complained about the price of Oxy 30 from Food City's secondary distributor and stated, "I am just worried because I do not want to have to explain why my gross profit may be down in 3 months, since I have inventory tomorrow."

76. Food City's emphasis on sales can be seen from the Company's performance evaluations of its pharmacy managers, who oversaw the Company's pharmacists and other pharmacy employees. Food City's executives threatened to fire or demote pharmacy staff based on sales. In a representative example from July 12, 2012, Food City's executives, including its Director of Pharmacy, Pharmacy Operations Manager, and District Manager, memorialized a frank meeting they had with a Tennessee Pharmacy Manager. It states:

"We made [the Pharmacy Manager] fully aware we had to see an improvement in the Pharmacy performance. We also outline numerous sales and performance strategies to help [the Pharmacy Manager] build the Patient base and improve Sales in his department. . . . We explained to [the Pharmacy Manager] that we must see improvement in the Sales of the Pharmacy Department or 100% compliance of the In store Business Building Strategies or we would have to make a change in Department Managers."

⁷⁷ TNAG-FC-CUST00007636.



77. Food City executives including Pharmacy Operations Manager Ken Slagle expressly reprimanded pharmacists for detrimentally impacting sales or customer loyalty—including for opioids and controlled substances. As shown in the screen shot below, Food City reprimanded one of its pharmacists for, among other things, "[c]ontrolling the number of prescriptions he fills (Damages Company Financially)[;] "[p]rofiling patient scripts without filling them (Damages Patient Loyalty)[; and] "[n]ot filling C2 prescriptions unless the patient is there

(Damages Patient Loyalty)." Aside from identifying the reasons for the reprimand noted in parentheses, the Company stated:

These are a few of the *many concerns we have that are affecting our ability to grow and maintain our business*. If these issues cannot be remedied in a swift and efficient manner it can lead to disciplinary action up to and including discharge.⁷⁸

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⁷⁸ # 33.13 (redactions supplied by the State) (emphasis added).

K-VA-T FOOD STORES, INC.

EXECUTIVE & 201 Trigg Street ED, Fox 1158 langdon, VA 24212 276-023-5100



KARDY VILLE DIVISION OFFICE 6305 Lones Drive Suite 201 Knowlie, IN 37909 855-544-7061

8-17-18

#36670

and I met with Pharmacist concerning his demonstration of unusual On 5-23-18, behavior at work. At the time he stated he had started a new medicine and had a follow-up appointment coming up in June. He was instructed to explain our concerns to his treating physician and to share a copy of his job description that we supplied to him.

We have not heard anything back concerning any adjustments or accomplations that may need to be considered and the situation continues to deteriorate at work.

We have the following concerns that need to be addressed immediately:

- is staying late hours past our usual closing time (Security Issue)
- is having a tech stay over with him (Labor Expense Issue)
- is controlling the number of prescriptions he fills (Damages Company Financially)
- is leaving multiple prescriptions for the next RPh (Damages Patient Loyalty) (Morale Issue)
- is profiling patient scripts without filling them (Damages Patient Loyalty)
- is not filling C2 prescriptions unless the patient is there (Damages Patient Loyalty)

These are a few of the many concerns we have that are affecting our ability to grow and maintain our business. If these issues cannot be remedied in a swift and efficient manner it can lead to disciplinary action up to and including discharge.

Again, we encourage Pharmacistant to explain the severity of this situation with his medical expert and develop and plan to improve his own well-being. If we do not get any definitive guidelines from his doctor regarding what he can and cannot do while at work we will proceed within company guidelines to correct the shortcomings. The deadline for this is 8 344. He has been instructed to notify If on her cell phone when he has the appropriate documentation.

Pharmacist has been given the opportunity to ask questions for clarification.

8-31-18-Friday is Audin He has applion 8-30-18

KNOWNILLE DIVISION DIFFICE - 6005 LONAS DAIVE SUITE 201 - KNOWNILE TH 17909 - 865-584-7051

FC00002257

#33.13

78. In another example, Food City's Pharmacy Operations Manager, Ken Slagle, forwarded an e-mail he received from the pharmacist at # 674, the Company's most profitable pharmacy who stated that Walgreens, a direct competitor of # 674, was limiting sales of oxycodone, hydromorphone, and methadone to 120 pills at a time for insurance payors and 60 pills at a time for cash payors to prevent diversion. Mr. Slagle's response to Mr. Blazer, Director of Pharmacy Operations: "They plan to lose a substantial amount of scripts." ⁷⁹

From: Ken Slagle [slaglek@FoodCity.com]

Sent: 2/4/2013 2:21:47 PM

To: Mickey Blazer [blazermi@FoodCity.com]

Subject: FW: FYI

This is a pilot program for this area and was initiated due to our local Walgreen Pharmacist complaining to corporate. They plan to lose a substantial amount of scripts.

From: Ken Slagle

Sent: Monday, February 04, 2013 8:57 AM

To: Pharmacy Rx674

Cc: Mickey Blazer; Tom Geoghagan

Subject: RE: FYI

This is correct, but it is only oxycodone, hydromorphone and methadone.

From: Pharmacy Rx674

Sent: Monday, February 04, 2013 8:30 AM

To: Ken Slagle; Tom Geoghagan

Subject: FYI

Hey,

I found out this weekend that Walgreens instituted a new policy for the pharmacies in this district: they can only fill #120 of pain medication at a time if insurance and only #60 if cash paying. Do you know what is going on with this? Have you heard anything?

Thanks, Julie

Food City Pharmacy #674 5941 Kingston Pike Knoxville, TN 37919 865-588-0972

⁷⁹ TNAG-FC-CUST00010484.

G. Food City's Opioid Policies

- 79. Over the past 15 years, Food City and its executives have developed several broad policies about opioids. These policies, which generally applied to all pharmacies are described below, and are separate from specific responses to compliance audits at select stores that are discussed elsewhere.
- 80. While the exact contents have changed over the years, the Company's policies have always been calculated to prioritize opioid sales, including substantial amounts from pill mills and suspect providers, over efforts to maintain effective controls against diversion and abuse. Overall, Food City's opioid policies have been broadly written, provided limited concrete guidance, and have continued to have material omissions or limitations that prevent them from being effective. But even in the limited instances in which Food City created an actionable policy, such as checking Tennessee's Controlled Substances Monitoring Database (CSMD) before filling an opioid prescription, it far too often failed to follow its own policy (and state law). 80
- 81. And though the Company's opioid sales have decreased since their peak, this decrease is not attributable to Food City's policies, but rather to external factors beyond the Company's control. Food City still does not have effective controls against diversion and the effects of its actions and failures to act continue.
 - 82. Over the last 15 years, Food City has:
 - Generally required its pharmacists to review prescriptions prescription-byprescription and patient-by-patient, which ignores strong evidence of diversion

Consent Or., *In the Matter of Food City # 611* [sic – should be 687 based on 2712 Loves Creek Rd address], Case No. 2015035061 (Jan. 12, 2016) (Stipulated Facts stating "Investigators found the Pharmacist-in-Charge had been unable to log into the CSMD and admitted rarely checking the CSMD"); Consent Or., *In Matter of Food City # 674*, Case No. 2014000801 (Aug. 7, 2016) (p. 2); Agreed Or., *In Matter of Food City # 694*, Dkt. No. 17.56-127199A *available at* https://apps.health.tn.gov/FacilityListings/Home/ViewPDF/288 (May 13, 2015) (pp. 2–3); *see also*, # 3.1.

- or abuse from the provider, clinic, or practice group, such as uniform or near uniform diagnoses, pattern prescribing, and other red flags for diversion;
- Never implemented meaningful due diligence of its customers. Even today, the
 pharmacies have no internal mechanism to flag suspicious customers or
 providers among its stores;⁸¹Aside from one known instance initiated by the
 auditor, never conducted "on-site" prescriber reviews of significant opioid
 prescribers;⁸²
- Continued to employ or promote pharmacists and pharmacy employees at its high-volume opioid stores that generated more sales; and
- Not followed its own policies in many instances with repeat, serious violations occurring frequently.

2010

- 83. Before 2010 and even after more-detailed written policies concerning opioids were created, Food City's pharmacies did not act consistently and lacked infrastructure, protocols, and/or implementation of either to maintain effective controls against diversion.
- 84. In Spring 2010, Food City and its executives communicated about some aspects of the Company's position concerning opioids through group e-mails to its pharmacy staff.
- 85. On April 16, 2010, Food City's Vice President of Pharmacy Operations, Don Clark, sent an e-mail titled "Can a Pharmacy Refuse to Fill a Prescription from a particular Prescriber, Clinic, or Practice Group" to all Food City pharmacies with the instruction to review, print, and post in their pharmacies. 83
- 86. While the e-mail gave lip service to the idea of not filling illegitimate prescriptions, reminded pharmacists to act in the best interest of the patient, and provided basic advice, its central purpose was clear: Food City pharmacists should *not* refuse to fill all prescriptions from a licensed

See TNAG-FC-CUST00082246 (Food City # 682 pharmacist stating, "I have a list of patients who can no longer come here but they end up coming in when I am not here.").

⁸² # 89.1; see PCG-TN0008973.

⁸³ TNAG-FC-CUST00002006.

prescriber, clinic, or practice group, and to do so would be *unethical*. Food City emphasized that each prescription should be evaluated on a patient-by-patient and prescription-by-prescription basis.

87. The e-mail⁸⁴ stated the following:

Subject: Can a Pharmacy Refuse to Fill a Prescription from a particular Prescriber, Clinic, or Practice Group

Please review this email, Print and Post it for all Pharmacists that work at your locations:

Can a Pharmacy Refuse to Fill a Prescription from a particular Prescriber, Clinic, or Practice Group?

A Pharmacist is obligated to act in the best interest of their Patient. Therefore, evaluation of a prescription should always be done in the best interest of the patient.

While a pharmacist is empowered to exercise professional judgment in evaluating each prescription they are presented, this evaluation of the legitimacy of a prescription must be done patient by patient, and prescription by prescription. If there is any doubt regarding the legitimacy of a prescription, refusal to fill that prescription is appropriate.

To refuse to fill all prescriptions from duly licensed Prescriber, Clinic, or Practice Group is not an ethical practice, and could be considered defamatory to the Prescriber, Clinic, or Practice Group.

As Pharmacists we must take reasonable measures that assure that prescriptions we fill are:

 Generated as a result of a bona fide relationship between a licensed prescriber and a patient, pursuant to a physical examination.

⁻

⁸⁴ TNAG-FC-CUST00002006.

- The Prescription Standards for the licensed prescriber are those of the State in which the prescription is
 filled not those of the state in which the prescription is written. (i.e. if the prescription is from a Nurse
 Practitioner in Florida for a class of drugs that cannot be prescribed by a Nurse Practitioner in
 Tennessee, then the prescription is not valid in Tennessee).
- · The medication prescribed is within the prescriber's scope of practice.
- . In a dose and quantity that is within the guidelines indicated for the medication.
- We must make a reasonable effort identify suspicious behavior and take appropriate actions to assure
 that the medications are not going to be diverted or be used for illicit purposes

These standards of Professional Judgment apply to prescriptions, not Medications, Patients, or Prescribers. Therefore we must evaluate the prescriptions that we fill, not judge their Patients or Prescribers. A pharmacist presented with any prescription that they have doubts or reservations about, should exercise sound professional judgment, and determine the following:

- · Is the Prescriber Licensed
- Has the Prescriber actually has seen the Patient (at some point). More and more we are seeing prescribers that operate an internet site or do a telephone interview. The DEA has set a president that this does not constitute a "physical exam". Please understand this does not mean that the Prescriber has to see the patient every time they generate a prescription, simply that the prescriber must see the patient often enough to constitute a "bona fide relationship". To clarify, if the prescription is generated as the result of a telephone interview or internet questionnaire the prescription is not considered "legitimate" by the DEA.
- If this prescription was for a Narcotic drug, what are the other medications tried in Pain Management for
 this patient by the Prescriber. This information is necessary to allow for effective pharmaceutical care of
 the patient. If the office refuses to discuss this, then refusal to fill the prescription would be appropriate.
- Positive ID of the patient is required. Furthermore, performing a Corporate Patient Search of the
 EnterpriseRx System allows for the determination of existing clinical data for appropriate
 Pharmaceutical Care. Finally the use of the State Wide Controlled Substance Database to determine
 other kinds and types of medications which are currently being taken by the patient, would allow for
 Drug Utilization Review and additional information critical in exercising Professional Judgment in
 determining the appropriateness and legitimacy of these prescriptions.

Sincerely,

Don Clark D. Ph.

Vice President of Pharmacy Operations
K-VA-T Food Stores, Inc. | (PH) 800-825-8451 Ext. 5737 | (F) 276-623-5440 | (Email) clarkd@foodcity.com
"We will find a way, or make one!"

88. Though not phrased as starkly, Food City's message to its pharmacies was clear: do not cut off lucrative sales from pill mills or suspect providers, clinics, or practice groups automatically—no matter how bad. Instead, look at the prescription and patient in front of you and disregard other facts relating to your previous experience with a suspect provider, clinic, or practice group or other information, such as evidence of pattern prescribing or uniform or near uniform diagnoses, that would not be apparent from looking at a prescription in isolation.

- 89. Food City and its executives gave this directive because the Company knew that if major pill mills or other suspect providers, clinics, and practice groups were cut off, lucrative opioid sales would decrease exponentially overnight.
- 90. For example, as shown by the excerpt below, ⁸⁵ in January and February 2012, an average of 91.90% of the Schedule II controlled substances, which overwhelmingly were opioids, that were sold at Food City # 674 were from Bearden Health Care Associates. For Food City # 694, an average of 60.32% of the Schedule II controlled substances, which again were overwhelmingly opioids, were from Bearden Health Care Associates during the same time. For Food City # 616, an average of 40.48% of the Schedule II controlled substances, which also were overwhelmingly opioids, were from Bearden Health Care Associates from the same time. If all opioids from Bearden Health Care Associates were blocked, over 90% of opioid sales at Food City # 674, over 60% of the opioid sales at Food City # 694, and over 40% of the sales at Food City # 616 would disappear overnight.

Control Substance Review									
Store	616			674			694		
% of Clls from Bearden HealthCare	41,58%	39.42%	40.48%	88.02%	95 85%	91.90%	62.06%	58 62%	60.329

- 91. Food City's prescription-by-prescription directive also could not be carried out in any meaningful way at its high-volume pharmacies without significantly impacting sales and operations. There were just too many prescriptions being filled for too many opioids for Food City pharmacists to follow its own policy.
- 92. Even when specific resources, such as the "Controlled Substance Database" and the "Corporate Patient Search of the EnterpriseRx System" referenced in Food City's Vice

⁸⁵ TNAG-FC-CUST00007690.

President of Pharmacy Operations' e-mail, were mentioned, Food City on many occasions did not ensure that those resources were actually used or that its policies concerning those resources were followed.⁸⁶

- 93. By September 2010, Food City had created three opioid-related documents, which it distributed to its pharmacies. These included a one-page document titled "Pharmacy Rules," a one-page document titled "Handling of Prescriptions for Pain Management," and another document titled "Pain Management Procedure Manual."
- 94. The document titled "Pharmacy Rules" was not opioid-specific and stated five basic rules that applied to all prescriptions. These included requiring a picture identification to receive prescriptions, buying only prescriptions and no other items at the pharmacy, respecting wait times, and keeping away from the register when others were present.⁸⁸
- 95. Food City's document titled "Handling of Prescriptions for Pain Management," concerned opioids. 89 According to the document, Food City:
 - required the pharmacy to receive a signed contract between the physician and patient;
 - could refill prescriptions up to three days early or an entire prescription for lost or stolen medication with a police report or verification by the physician's office;
 - requested its pharmacies check the "Prescription Monitoring website" to obtain recent control medication activity, *but only for new patients*;
 - required the cashier or the pharmacist to inquire how the patient was doing for prescriptions that "were completely the same" as the previous visit, a category that constituted most opioid prescriptions sold; and

Consent Or., *In Matter of Food City # 674*, Case No. 2014000801 (Aug. 7, 2016); Dkt. *In Matter of Food City # 694*, Agreed Or., Dkt. No. 17.56-127199A, *available at* https://apps health.tn.gov/FacilityListings/Home/ViewPDF/288 (pp. 2-3); *see also*, FC0000028.

⁸⁷ TNAG-FC-CUST00001976; TNAG-FC-CUST00081459-61.

⁸⁸ TNAG-FC-CUST00081460.

⁸⁹ TNAG-FC-CUST00001977.

• required the pharmacy to check with the physician to determine prior prescriptions received by the patient from their office or other physicians and the prior pharmacy used by the patient, among other basic provisions that would apply to any prescription (e.g., "Physician is notified of problems/issues and works with pharmacy to resolve them."). 90

96. Food City's longer document titled "Pain Management Procedure Manual" likewise covered opioid practices and was divided into four topic areas: clinical responsibilities, legal responsibilities, procedural processes including inventory protocols, and associate procedures.⁹¹ Like all of Food City's policies, the Manual was not effective at preventing diversion. It relied heavily on paper documents like pain contracts and other forms for compliance⁹² that were easily gamed by suspect providers and customers.

97. For example, in addition to providing a pain contract, Food City stated that new patients were required to fill out a half-page "New Patient Form" at the pharmacy to keep on file.⁹³ Aside from contact or identification information, the New Patient Form, which is shown below in its entirety, asked only for pain diagnosis, medication history (on three lines), and drug allergies. The form provided little information that could be used by itself to evaluate the legitimacy of the prescription and was provided by the customer at the pharmacy.

⁹⁰ TNAG-FC-CUST00001977.

⁹¹ # 198.1.

⁹² TNAG-FC-CUST0001982, 84.

⁹³ # 196.1.

Name:			Phone: (
Address:		City	State:	
Zip code				
Date of Birth: mo	day	year	male	female
Drug Allergies if know				

- 98. And while Food City's Manual told pharmacists they "should use the PMP [prescription monitoring program] website to obtain previous medication usage and previous physician activity" for new patients during this time, Food City did not use the prescription monitoring program (also known as the CSMD) website frequently or at all and was later disciplined by the Board of Pharmacy for failing to check the CSMD.
- 99. But there were other significant problems with Food City's Manual. These included that:
 - Red flags for diversion or abuse or indications of suspicious behavior from providers, clinics, or pharmacies were not mentioned;
 - the pharmacist's duty to refuse to fill illegitimate or medically improper prescriptions was not mentioned; and

⁹⁴ TNAG-FC-CUST00001976.

Consent Or., In the Matter of Food City # 611 [sic – should be 687 based on 2712 Loves Creek Rd address], Case No. 2015035061 (Jan. 12, 2016) (Stipulated facts stating "Investigators found the Pharmacist-in-Charge had been unable to log into the CSMD and admitted rarely checking the CSMD;"); Consent Or., In Matter of Food City # 674, Case No. 2014000801 (Aug. 7, 2016); Dkt. In Matter of Food City # 694, Agreed Or., Dkt. No. 17.56-127199A, available at https://apps.health.tn.gov/FacilityListings/Home/ViewPDF/288 (pp. 2-3); Consent Or., In the Matter of Food City # 616, Dkt. No. 17.56-127200A (May 13, 2015); see also, # 3.1 (FC0000028-29).

- Many provisions were phrased as optional or discretionary instead of mandatory.
- 100. For example, when discussing access and storage of controlled substances, the Manual states that "CII medications should be kept in lockable cabinets or safes[,]" which is in contrast with other places where mandatory language appears, such as requiring job applicants to undergo a criminal background check and drug test ("Each applicant must...").
- 101. This was more than just semantics. It reflected Food City's lack of attention to and implementation of even basic compliance measures towards substances with the highest risk of abuse or diversion, which is reflected in later audits of its pharmacies.⁹⁷

2011

- 102. In 2011, Food City created a two-page document titled "Guidelines for Pain Management Clinic Prescriptions," which it gave to its pharmacists, including those in Tennessee. 98
- 103. Food City's 2011 Guidelines emphasized that each prescription was to be reviewed on a prescription-by-prescription basis—something that Food City had done in 2010 and would continue to do after 2011. Through this intentionally narrow focus, Food City again ignored other red flags with the provider, clinic, or practice group, including evidence about providers, clinics, or practice groups who gave the same or nearly uniform diagnoses and those who engaged in pattern prescribing.

This also leaves out a key requirement, which is that the safes should remain locked with the key secured when not in use.

⁹⁷ # 179.1; PCG-TN011078 (audit of # 674 stating "The CII substances are not locked until the end of the business day" and "The CII safes are kept open during business").

⁹⁸ TNAG-FC-CUST00007704.

- 104. The Guidelines stated that "[n]o prescriptions will be accepted from a practitioner not located in the K-VA-T/Food City operating area." But even if this was followed, it only meant that opioid prescriptions written by far away providers from out-of-state or within Tennessee, but still in the K-VA-T/Food City operating area could still be sold.
- 105. The limited guidance provided by Food City's Guidelines was often not followed. Aside from not performing a basic check of the CSMD, ¹⁰⁰ Food City routinely sold prescriptions to individuals who were from distant places and who had many other more convenient pharmacies between them and a given Food City pharmacy, including other Food City pharmacies. ¹⁰¹
- 106. Food City also used a document titled "Standard Operating Procedures for Controlled Drugs (CII CV)," which had much of the same language as the Guidelines. As before, Food City's Standard Operating Procedures emphasized that "[e]ach controlled prescription will be reviewed on a patient by patient basis." ¹⁰³
- 107. But Food City's Standard Operating Procedures regressed on certain points including allowing a controlled prescription from outside the already large Food City service area to be filled provided notice was given to the Pharmacy Professional Service Manager and contact

⁹⁹ *Id*.

Consent Or., *In the Matter of Food City # 611* [sic – should be 687 based on 2712 Loves Creek Rd address], Case No. 2015035061 (Jan. 12, 2016) (Stipulated Facts stating "Investigators found the Pharmacist-in-Charge had been unable to log into the CSMD and admitted rarely checking the CSMD"); Consent Or., *In Matter of Food City # 674*, Case No. 2014000801 (Aug. 7, 2016); Dkt. *In Matter of Food City # 694*, Agreed Or., Dkt. No. 17.56-127199A, *available at* https://apps health.tn.gov/FacilityListings/Home/ViewPDF/288 (pp. 2–3); Consent Or., *In the Matter of Food City # 616*, Dkt. No. 17.56-127200A (May 13, 2015); *see also*, FC0000028.

See Consent Or., In the Matter of Food City # 611 [sic – should be 687 based on 2712 Loves Creek Rd address], Case No. 2015035061 (Jan. 12, 2016) (Stipulated Facts stating "Staff would early refill for cash and admitted to filling out of state prescriptions without question"); In Matter of Food City # 674, Consent Or., Case No. 2014000801 (Aug. 7, 2016) (p. 2) (referencing patients driving long distances to pharmacy).

¹⁰² # 198.1.

¹⁰³ # 198.1.

was made the prescriber's office to verify a provider/patient relationship. ¹⁰⁴ In addition, Food City gave pharmacists the green light to fill prescriptions early, which is an indicator of diversion, based on the very broad exception "an increase in dosage frequency[,]" among other things. ¹⁰⁵

108. Food City also continued to use the same "Pain Management Procedures" Manual from 2010. 106

2013

109. By July 2013, the Company had switched primary distributors from AmerisourceBergen to McKesson and had had its supply of Oxy 30 cut off for its highest volume pharmacies for Oxy 30, # 674, # 694, and # 616. 107 As Food City and McKesson continued heated discussions throughout that summer, Food City updated its Manual 108 once its Oxy 30 had been cut off at the three stores.

110. Food City's July 2013 Manual reflected new legal requirements related to the CSMD and contained additional provisions concerning controlled substance inventory and invoices. More importantly, the update also created a new classification for Food City pharmacies—"Pharmacies with above average dispensing of Controlled Substances will be classified as 'Pain Management Specialty Pharmacies' and will be determined by the Director of Pharmacy."

¹⁰⁴ # 198.1.

¹⁰⁵ # 198.1.

¹⁰⁶ # 198.4; # 198.76 (FC00000228–30).

¹⁰⁷ TNAG-FC-CUST00085708; TNAG-FC-CUST00085710.

¹⁰⁸ TNAG-FC-CUST00087893.

- 111. Notably, Food City's Director of Pharmacy Operations—then and now—Mickey Blazer, has never been a pharmacist or a compliance specialist. Nor does Mr. Blazer have any certification or formal training in pharmacy.
- 112. The purpose of the re-classification of Food City's highest volume pharmacies for opioid sales into "Specialty Pharmacies" was purportedly to keep a more watchful eye on the controlled substance dispensing. But the real reason was because McKesson, Food City's primary opioid distributor, which itself was feeling pressure from the DEA, forced Food City's hand. With a newly aggressive DEA, Food City's high-volume oxycodone stores had become a potential liability for McKesson.
- 113. The July 2013 Manual had many of the same core components and flaws as previous versions. Like previous versions, Food City's policy emphasized that "[e]ach controlled prescription will be reviewed on a patient by patient basis." Food City also continued to authorize filling controlled prescriptions outside of the K-VA-T operating area under certain circumstances and still gave pharmacists the green light to fill prescriptions early, a strong indicator of diversion, based on "an increase in dosage frequency[,]" among other things. ¹⁰⁹
- 114. And though the Manual did make some positive changes, at least on paper, such as the prohibition against pharmacies accepting cash for controlled substances from patients with insurance, 110 its high-volume stores continued to have significant problems and failed to implement key provisions.
- 115. In other places, the July 2013 Manual tacitly recognized that its Specialty Pharmacies were selling large quantities of illegitimate "holy trinity" combination prescriptions of

¹⁰⁹ TNAG-FC-CUST00087893.

¹¹⁰ PCG-TN011078.

an opioid, benzodiazepine (anti-anxiety medication), and a muscle relaxer. As part of the Manual, excerpted below, Food City's Specialty Pharmacies were supposed to inventory alprazolam (a benzodiazepine), diazepam (another benzodiazepine) and carisoprodol (a muscle relaxer), 111 but this only highlights the fact that its Specialty Pharmacies were selling substantial amounts of illegitimate holy trinity combination prescriptions. And regardless of the policy, numerous Food City pharmacies did not conduct regular monthly inventories at all.

- Pharmacies classified as Pain Management Specialty Pharmacies will inventory the drugs listed below monthly:
 - Alprazolam.
 - ii. Carisoprodol (350 mg strength only).
 - iii. Diazepam.
 - iv. Hydrocodone.
 - v. Tramadol.

116. Under the July 2013 Manual "Specialty Pharmacies" were required to check the CSMD on all controlled prescriptions, could not have more than two pain contract patients from the same address, were required to inventory five specific additional controlled substances per month, and the pharmacists were not permitted to fill controlled prescriptions for patients who lived beyond the county or county-adjacent without their manager's prior approval. Of course, there was no logical reason that these requirements should only apply to the pharmacies with "above average dispensing." Furthermore, these requirements did nothing to address other well-known problematic red flags, such as unusual prescriber specialties, multiple patients presenting with the same or similar prescriptions, or practitioners located far away.

PCG-TN011078; TNAG-FC-CUST00007571.

117. As the heated discussions between Food City, McKesson, and Topco continued, the Manual was updated yet again in August 2013.¹¹² The August 2013 version of the Manual was substantially the same as the July version, but included a draft generic letter to a prescriber asking him or her to complete a "treatment plan certification."¹¹³

2014

- 118. Food City's Manual was revised again in February 2014.¹¹⁴ With a few notable exceptions, the February 2014 Manual was largely the same as previous years including the Company's constant emphasis on reviewing prescriptions on a patient-by-patient basis¹¹⁵ and allowance of early-fill prescription for "increase in dosage frequency."¹¹⁶
- 119. And while Food City's adherence to its own policies remained a significant issue, its internal policies, while forcefully stated in parts, had huge loopholes.
- 120. For example, the Company's February 2014 Manual, as shown by the excerpts below, required a pharmacist to request a diagnostic code and purpose for prescriptions of large quantities of controlled substances and to "maintain such documentation in the patient's file" to check that it is being used properly. But in the very next provision, Food City provided a huge loophole. Instead of obtaining this documentation, the pharmacist could simply dispense the prescription anyway by filling out this basic form stating that he or she tried to get documentation about the patient's diagnosis codes and treatment plan: 117

¹¹² # 198.1.

¹¹³ # 198.1.

¹¹⁴ TNAG-FC-CUST00007554.

¹¹⁵ # 198.1.

¹¹⁶ # 198.1.

¹¹⁷ # 198.1.

	FOOD GCITY
	PHARMACY
	Value Service Convenience
	Food City Pharmacy #
	Pharmacist's certificate of due diligence
Potient na	frie
Date of Sh	th
Prescriber	
documenta provided to appropriat	t to contact this prescriber's office was made on this date () to obtain additional ation about this patient's treatment plan and diagnosis codes. This information has not been a the pharmacy at this time, but through my professional judgment, I believe that it is a to fill this prescription based on my knowledge of the patient, prescriber, and verification of rescription monitoring program.

but had significant gaps that made them ineffective. For example, the Manual extended the default policy of not filling for individuals who lived outside of the pharmacy's county or surrounding counties to all pharmacies, not just to Food City's Specialty Pharmacies. The Manual stated "Pharmacist will not be allowed to accept prescriptions to accept prescriptions from patients outside their 'Immediate Operating Area'[,]" which it defined as the pharmacy's county or a surrounding county. This meant that a pharmacy anywhere in Knox County could sell opioids to individuals who lived anywhere in Knox, Anderson, Union, Grainger, Jefferson, Sevier, Blount,

¹¹⁸ # 198.1 (emphasis added).

Loudon, and Roane Counties. But the Manual makes clear that "will not be allowed" was not true because the pharmacist *could* sell opioids to an individual who lived outside of this area no matter how far away if he or she simply notified the Pharmacy Professional Services Manager. And regardless of the policy, Food City pharmacies regularly sold opioids to individuals who lived outside of a contiguous county from the pharmacy.

122. Food City's Manual was slightly revised again several months later in November 2014. This version of the Food City's Manual also tacitly acknowledged that Food City was filling substantial numbers of illegitimate "holy trinity" combination prescriptions because it, like previous versions, required that the pharmacy conduct an exact count of benzodiazepines (anti-anxiety medications) and muscle relaxers. ¹²¹ And regardless of the policy, numerous Food City pharmacies continued to not conduct regular inventories of controlled substances.

2018

123. Food City waited to update its Manual again until June 2018¹²² despite five of its stores being disciplined by the Board of Pharmacy in 2015 and 2016.¹²³ The 2018 Manual differed only slightly from the previous 2014 version. It still allowed a pharmacist to sell opioids to individuals for whom the pharmacist did not have a diagnosis code or treatment plan, allowed early fills for an increase in dosage frequency, and allowed a pharmacist to sell opioids to individuals

¹²⁰ # 198.1.

¹¹⁹ # 198.1.

¹²¹ # 198.1.

¹²² # 198.1.

See Consent Or., In the Matter of Food City # 611 [sic – should be 687 based on 2712 Loves Creek Rd address], Case No. 2015035061 (Jan. 12, 2016); Agreed Or., In the Matter of: Food City Pharmacy # 616, Dkt. No. 17.56-127200A (May 13, 2015); Consent Or., In Matter of Food City # 674, Case No. 2014000801 (Aug. 7, 2016); Consent Or., In the Matter of Food City Pharmacy # 667, Case No. L12-PHR-RBS-2012000931 (July 30, 2015); Agreed Or., In Matter of Food City # 694, Dkt. No. 17.56-127199A, available at https://apps.health.tn.gov/FacilityListings/Home/ViewPDF/288 (May 13, 2015) (pp. 2–3).

from outside the county where the pharmacy was located or a surrounding county if the Pharmacy Professional Service Manager was notified though it purported to prohibit "out-of-area" maintenance prescription. 124

<u>2019</u>

- 124. Food City's most recent Manual was revised in May 2019. This version had a few notable changes including:
 - "Pharmacists are required to review logbooks, perpetual inventory, invoices, receipts, and other pharmacy distribution records to flag excessive ordering or dispensing, recognizing that the DEA and law enforcement do not simply focus on prescriptions, but also on controlled substance ordering practices by pharmacies and Pharmacists[;]" 126

But Food City's 2019 Manual still suffered from many of the same defects as the Company's previous policies.

- 125. Throughout each version of the Manual, pharmacists were instructed to review each controlled prescription "on a patient-by-patient basis." Food City's narrow focus was self-imposed. Other pharmacies including Walgreens, CVS, Wal-Mart, and others refused to fill opioid prescriptions from Dr. Frank McNiel and Bearden Health Care Associates years ago. As evidenced by e-mail traffic and statements by former pharmacists, the purpose of Food City's seemingly innocuous requirement was to avoid blanket prohibitions on filling for potentially suspicious practitioners or clinics that remained lucrative for the Company.
- 126. This policy, which is still in place, allowed and still allows Food City to continue to sell opioids to pill mills and other suspect providers, clinics, and practice groups, like Bearden Health Care Associates, and is evidence of Food City prioritizing opioid sales over compliance.

¹²⁴ # 198.1.

¹²⁵ # 198.1.

¹²⁶ # 198.1.

Moreover, Food City continues to not have an established mechanism or common database to inform its pharmacies about suspicious practices or providers.

G. Food City's Corporate Knowledge and Actions Concerning Opioids

- 127. In evaluating Food City's history with opioids, two strong themes emerge. First, the Company prioritized opioid sales above everything else, including compliance. Second, the Company knew early on that a substantial amount of its opioid sales were being diverted, abused, or otherwise leading to harm in the communities it served.
- Associates, its owner Dr. Frank McNiel, and others by Cheryl Armstrong on behalf of herself, her late husband Gerald, and their children in Knox County Circuit Court. The Armstrong Plaintiffs alleged that Ms. Armstrong and her husband had been patients at Bearden Health Care Associates and Food City # 674 dating back to 2002 and had been prescribed a host of drugs, including oxycodone, a benzodiazepine, and a muscle relaxer, as well as other opioids, which were filled at Food City # 674. Ms. Armstrong alleged in her lawsuit that she and her husband both became addicted to their prescription medications, particularly OxyContin, which resulted in Cheryl suffering two nonfatal overdoses, both undergoing rehabilitation, both of them losing their jobs, Cheryl being arrested three times, Gerald being prosecuted for driving under the influence, the repossession of their vehicles, their home being foreclosed, and in Gerald ultimately suffering a fatal overdose from oxycodone.
- 129. Food City of course knew of these allegations. It filed an Answer to the original Complaint on April 28, 2006 and ultimately settled with no admission of liability through an order entered December 31, 2008.

- 130. Earlier that year on August 27, 2008, Food City CEO Steve Smith wrote an open letter titled "WESTWOOD HOMEOWNERS ASSOCIATION STORY RECKLESS" responding to a KNOXVILLE METRO Pulse story reporting on a four-paragraph news item in a seasonal bulletin published by a Bearden-area homeowners association about Food City # 674.
 - 131. The Westwood Homeowners Association's news story stated the following: 127

Concerns about Narcotic Trade at Food City Pharmacy

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

According to eyewitnesses and police reports, during the spring of 2008, some pharmacy customers were inugged 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 Folice Officers to guard the store during pharmacy hours. (Continued on Page 2)

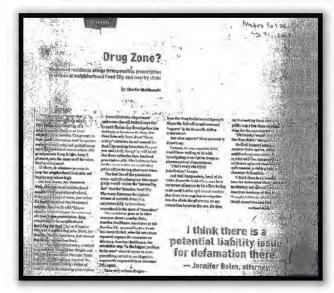
Westwood . (continued from page 1) Just around the corner from Food City, at 420 Bearden Road, is Dates to Remember Bearden Healthcare Associates, a clinic operated by Drs. Frank and Janet McNiel. According to one local Drug Enforcement Agency (DEA) - Park Clean-up Day: Saturday official, this clinic, when it comes to overprescribing narcotics, is "the Sept. 27th, 9-11 a.m. Let's spruce up Westwood Park biggest problem in the state." for its 15th Birthdayl Bring gloves, rakes, pruners, loppers, According to Knoxville Police and the DEA, Bearden Food City chain saws, etc. The rain date is September 28. Pharmacy is the only pharmacy in town still accepting prescriptions from the Drs. McNeil. A group of concerned neighbors has begun * Fall Picnic: Sunday, October meeting to address this issue. Their goal is to persuade Food City to 5th, 4:30 p.m. put neighbors first and stop honoring the Drs. McNiel's narcotic prescriptions at any of the Knoxville Food City pharmacies. For more information, contact Westwood nebbie Moo neighbor David Stewart at 898-2307

¹²⁷ PTN000039868.

- 132. Knoxville's alternative newspaper, the METRO PULSE, picked up on Westwood Homeowners' Association's newsletter and published a more detailed article titled "Drug Zone?" (image shown below) that interviewed more witnesses and built on the bulletin on August 21, 2008. Among other things, the article stated:
 - "Knoxville Police Department spokesman Darrell DeBusk says that he can't discuss any investigation into incidents at the store. He says that there have only been about 'three or four' robberies in and around the Food City parking lot within the past year and a half, though he will admit that those robberies have involved prescription pills. The incidents have led the store to hire an off-duty police officer during pharmacy hours[;]"
 - "The newsletter goes on to raise concerns about a nearby clinic, Bearden Healthcare Associates at 420 Bearden Rd, operated by Drs. Frank and Janet McNeil [sic], who did not return repeated requests for comment on this story. Bearden Healthcare, the newsletter says, 'is the biggest problem in the state' when it comes to overprescribing narcotics, an allegation supposedly supported by an unnamed DEA agent... And Neil Morgenstern, head of the DEA's Knoxville field office, says he is not aware of anyone in his office having made such a claim and cannot confirm that there is an ongoing investigation into this clinic, the pharmacy, or any connection between the two. He does say that making these concerns so public was a less-than-responsible thing for the organization to do. 'Obviously, I would have preferred that they didn't,' Morgenstern says[;]"
 - "[W]estwood Homeowners Association president Jean Bonnyman says she's pretty sure there is an illicit connection between the two, and she'd like to see it severed. 'With the knowledge that transactions with any businesses dealing heavily with narcotics—either prescribing or dispensing—attract criminal elements, our goal is to persuade Food City to stop honoring the Drs. McNiels' narcotic prescriptions at any of the Knoxville Food City pharmacies,' she wrote in an e-mail statement earlier this month. Westwood homeowner Joni Caldwell agrees. A 12-year resident of the area, Caldwell says she feels reluctant to go to the store, the closest to her house, anymore. She says she's been talking to Food City president Steve Smith who has been polite but 'did not seem to truly care' about the concerns of someone, like herself, 'who's been his customer for 13 years,' she writes in an e-mail . . ."
 - For the past three years, attorney Robert Vogel has been representing the family of Gerald Armstrong. Armstrong, formerly of Hamblen County died in 2005 from an overdose of OxyContin. He received the prescription at Bearden Healthcare, then located on Kingston Pike . . . According to court

documents between 2002 and 2005 Armstrong was prescribed more than 20 different types of pills, including OxyContin, Diazepam, Xanax, and Paxil, from the clinic. And he picked them all up the Bearden Food City Pharmacy, a pharmacy strongly recommended by Bearden Healthcare doctors, says Vogel. Basically, they told him that there were only a few pharmacies that would take the prescription," says Vogel. But was it the large number of prescriptions he was taking that made other local pharmacies reluctant to honor them? Not according to Vogel, who says that it was the clinic's signature on the prescriptions. 'I haven't checked every pharmacy in town, obviously, but it does seem that this is one of the only a couple that will deal with that clinic,' he says. The \$5 million lawsuit is yet to go to trial, but just last month Knox County Circuit Judge Howard Winberley denied the defense's final motion for dismissal. The next step, says Vogel, is a jury trial[;]"

• "Westwood resident David Stewart says he's had suspicions about the clinic, which has been operating out of this Bearden Road office for just under three years, for quite a while now. What drew Stewart's attention, along with the robberies around Food City, is the high volume of cars coming in and out of the business' parking lots. 'Just go there on any weekday and watch that parking lot,' says Stewart. 'There's an obscene number of cars there, both at the clinic and the Food City with license plates from counties all over the state, even a lot of out-of-state ones." 128





133. The Metro Pulse article also included statements from an attorney and special counsel for the American Academy of Pain Medicine who is quoted as saying, "I would definitely

¹²⁸ PTN000039870-71.

advise Bearden and Food City to seek out legal counsel with someone well-versed in defamation law." Elsewhere in the piece the same attorney is reported to have said that "[t]here's really nothing unusual about a pain clinic with a high volume of out-of-town patients" and that "ironically, it's often groups like the Westwood Homeowners Association that are responsible for the phenomenon. They do this, [the attorney] says, by harassing pain clinics—whose doctors often prescribe narcotics—with these types of allegations, forcing them to leave town or shut down." 129

- 134. The American Academy of Pain Medicine was an interest group that promoted opioid use, which was funded by opioid manufacturers like Purdue Pharma L.P., the maker of OxyContin and others. A 2018 Minority Staff Report from the United States Senate Homeland Security & Governmental Affairs Committee found that five manufacturers, Purdue Pharma L.P., Janssen Pharmaceuticals, Inc., Mylan N.V., Depomed, Inc., and Insys Therapeutics, Inc., paid the American Academy of Pain Medicine \$1,199,409.95 between 2012 and 2017. 130
- 135. Bearden and Food City both responded forcefully to the METRO PULSE article after its publication. Bearden and Dr. Frank McNiel, consistent with the recommendation from the special counsel to the AAPM, filed a libel suit against members of the Westwood Homeowners Association based on the four paragraphs contained in the neighborhood news bulletin. The lawsuit was later dismissed.
- 136. Food City, through CEO Steve Smith, threatened to pull future advertising by Food City in the KNOXVILLE NEWS SENTINEL, which through its parent company, E.W. Scripps Company, owned the METRO PULSE at the time.

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¹²⁹ PTN00039870-71.

https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Part y%20Advocacy%20Groups.pdf.

Food City CEO Steve Smith responded to the METRO PULSE with the open letter published in the METRO PULSE on August 27, 2008 referenced above, which stated in relevant part:

"I am writing in response to the August 21, 2008 article which allowed certain residents of Westwood subdivision to publicize reckless comments about the Food City Pharmacy located close to their community. Many in my position would not step forward to respond to such unfounded comments, but I cannot let the libelous publication of unsubstantiated rumors go without an appropriate response. . ."

"We are all very proud of our Food City Pharmacies. Food City Pharmacy associates are truly healthcare professionals – not only because of the certification and licenses they hold, but also because of their commitment to providing quality service to every individual they serve. To attempt to brand any one of our pharmacies any other way simply because of their service to patients of any particular doctor or clinic is patently unfair."

"I am concerned that it was deemed acceptable to print rumor and innuendo based upon only one source of record – a plaintiff's attorney with an active lawsuit seeking money through broad and baseless (in my opinion) allegations. I think most would agree this is not an objective source. For example, the plaintiff's attorney is quoted as stating that 'this [pharmacy] is one of only a couple that will deal with that clinic.' In fact, however, a statewide controlled substance database indicates that since July 1, 2008, more than 150 pharmacies in the greater Knoxville area have filled prescriptions and serviced patients from the clinic in question. More specifically, eight of these pharmacies are in the 37919 zip code (Bearden) . . ."

"I am also very disappointed with the story's implication that I personally have not satisfied some of the residents that have directly spoken with me. I have spent significant time in these communications, but I'm at a loss to know how to completely satisfy someone who expresses dislike for any pharmacy operating close to their home because 'it might attract undesirables' (as suggested by the resident). Food City is in the business to serve all Knoxville area customers – not judge them."

"There are times when the display of negative and reckless behavior propels others into positive actions and I am heartened by some contacts I have received from other Westwood residents. The called, after publication of the story, to express their support and patronage of Food City and to make sure we knew that the actions of a very few did not represent all. I appreciate those sentiments and am resolved to follow that example by moving forward in a positive manner by continuing to provide the best products, service and community support that all of us at Food City can offer."131

PTN000039873.

WESTWOOD HOMEOWNERS ASSOCIATION STORY RECKLESS

i are writing to response to the August 21, 2008 article which officered custoin recidents of Westweed subdivision to publicize recklass comments about the Food City Phormacy located close to their community. Many is my position would not step forward to responsi to much sufficientled comments, but I cannot let the libelous publication of unsubstantiated runters go without an appropriate response.

I am primarily disappointed with the article's irresponsible attempt to improge the reputation of Feed City and all its hard-working, associates. Our inscess at Food City results from a combination of factors. These factors include our commitment to hise good and competent people who will serve our customers to the best of their ability. Food City also strives to be a responsible and productive member of the community by its work for, and contributions to, organizations that benefit our customers and their communities. Is exponsible publication of the narrow generated by a few individuals can easily case years of involvement and land work by so many of our associates, and it is simply and eight.

We are all very proud of our Food City Pharmedes. Food City Pharmedy associates are truly healthcare professionals—not only because of the certifications and licenses they hold, but also because of their convolutes and providing quality service to every individual they serve. To attempt to bound any one of our pharmacies any other way simply because of their service to patients of any particular doctor or clinic is patently unfeir.

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I am also very disappointed with the story's implication that I personally have not satisfied some of the residents that have directly spoken with me. I have spent significant time in these communications, but I'm at a less to know how to completely satisfy conserve who expresses distilke for any pharmacy operating close to their home because "it might attract undesirables" (as suggested by one resident). Found City is in business to serve all Know area customers – not judge from.

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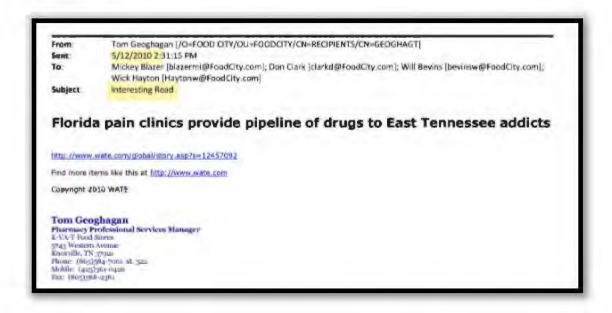
Sincerely,

Steven C. Smith Food City President & CEO

Angest 31, 2005 / METRIC FRIEZ / J

138. Food City's executives knew that East Tennessee had a high and disproportionate number of individuals addicted to opioids. While Food City's executives undoubtedly knew sooner, on May 12, 2010, Food City's Pharmacy Professional Services Manager sent his fellow Food City executives an e-mail, shown below, with the subject "Interesting Read" with a link to

an article from Knoxville's ABC affiliate, WATE, titled "Florida pain clinics provide pipeline of drugs to East Tennessee addicts." ¹³²



139. Food City executives were not only aware of East Tennessee's opioid addiction problem, they were aware that many of the Company's stores were filling holy trinity prescription combinations of an opioid, a benzodiazepine, and a muscle relaxer. On August 3, 2010, then Director of Pharmacy Operations Don Clark sent an e-mail to Mickey Blazer without comment with a spreadsheet that showed holy trinity prescription combinations were being sold from one provider, who was later indicted for illegal distribution of narcotics, at multiple Food City locations throughout East Tennessee, including # 609, # 615, #616, #626, #630, # 647, # 650, # 654, # 655, # 661, # 667, # 672, # 673, #676, #679, and # 694. **

139.

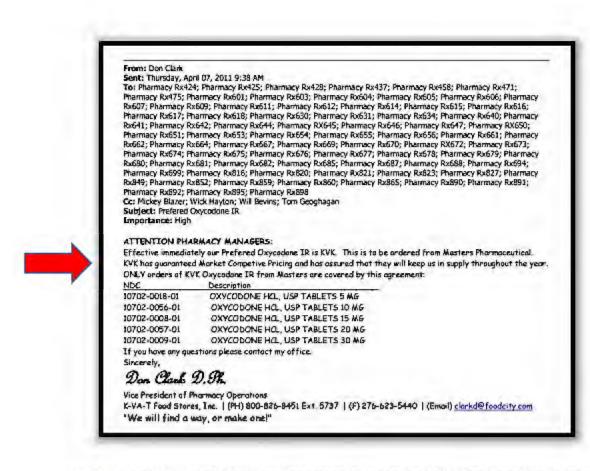
¹³² TNAG-FC-CUST00123064 (highlight emphasis added)...

¹³³ TNAG-FC-CUST00001989-90.

- 140. On September 23 and again on October 1, 2010, Food City's Vice President of Pharmacy Operations Don Clark told all pharmacies that they needed to order Oxy 30 and other controlled substances from a secondary distributor, Masters Pharmacy.¹³⁴
- 141. Food City and its executives continued to work to make sure that Food City had a distributor that would supply the Company with the growing supply of Oxy 30 and other immediate release oxycodone it would need.
- 142. Food City's executives had knowledge of red flags for diversion or abuse just based on distributor invoices it received for extremely high purchases of opioids, like oxycodone, that they knew were highly abused and diverted. As examples, on November 1, 2010, Food City # 694 purchased 72,000 Oxy 30 pills and 30,000 Oxy 15 pills for a total of 102,000 in one order. On November 2, 2010, Food City # 674 purchased 168,000 Oxy 30 pills and 12,000 Oxy 15 pills. The Food City # 674 Oxy 30 order was submitted with orders from 11 other stores and yet the Food City # 674 *still accounted for 96%* of the oxycodone that day, which was 187,700 tablets. Food City had to pay these outsized invoices for oxycodone and were aware of the extremely high opioid sales at certain based on dispensing records.
- 143. On April 7, 2011, Food City's Don Clark sent another e-mail to Food City's pharmacists announcing that he had secured a special agreement with Masters Pharmaceutical for Oxy 30 and other immediate release oxycodone after Masters assured Food City that it "will keep [them] in supply throughout the year." The e-mail read:

¹³⁴ TNAG-FC-CUST00001974–75.

¹³⁵ TNAG-FC-CUST00001967-68.



- 144. Food City and its executives used a secondary distributor not only because they thought they could (purportedly) get a better price than ordering all of Food City's opioids from the Company's primary distributor, but also because a secondary distributor would help Food City avoid already high opioid thresholds imposed on the Company by its primary distributor.
- 145. But to Food City's top opioid sales performer, Food City # 674, any change, including more reliance on secondary distributors for supply, was risky for sales. In two e-mails on April 7 and 21, 2011, Julie Varnum, the pharmacist at Food City # 674, expressed concern. First, she was concerned that Masters would not be able to supply *enough* oxycodone to her pharmacy. She stated in part, "[I]t may be difficult for me to order all of the Oxycodone from Masters *due to the sheer quantity I order* (240 bottles of 15 mg and 1224 bottles of Oxycodone were ordered from ABC in March 2011). Can I continue to order my Oxycodone from

Amerisource[?]"¹³⁶ Second, she complained about the price of immediate release oxycodone from Masters, wanted to be assured Masters would provide Food City a rebate off the cost, and stated in part, "I do not want to have to explain why my gross profit may be down in 3 months, since I have inventory tomorrow."¹³⁷

- 146. Food City continued with Masters for oxycodone. According to ARCOS data, Masters sent Food City # 674, # 694, and # 616 a total of 318,395 opioid pills in May 2011. Eighty-one percent of this was oxycodone, and 81% of the oxycodone was Oxy 30.
- 147. During this time, Food City executives worked with Food City's buying group, Topco Associates, to secure cashback payments known as volume incentive rebates from opioid manufacturers. As proposed, Food City, as a Topco member, could receive money back from an opioid manufacturer based on purchasing volume—with more cash back from more volume.
- 148. By June 2011, Food City had developed the reputation as the go-to place where you could get cheap Oxy 30 and other opioids with minimal hassle. Food City priced its Oxy 30 aggressively and used steep discounts on opioids from its prescription savings cards to gain market share. By June 2011, Food City through its prescription savings card was selling oxycodone nearly *fifty percent cheaper* than its major competitors. ¹³⁸
- 149. But while opioid sales climbed after June 2011, Food City was not receiving the rebates it was purportedly promised for oxycodone sales. By August 2011, Don Clark was in the hot seat at the Company because the rebates from Masters for Oxy never materialized. 139

¹³⁶ TNAG-FC-CUST00001967 (emphasis added).

TNAG-FC-CUST00007636 (emphasis added).

¹³⁸ TNAG-FC-CUST00001616.

¹³⁹ TNAG-FC-CUST00094698.

- 150. On August 15, 2011, then-Food City Pharmacy Operations Manager Mickey Blazer sent Food City's Knoxville pharmacies the directive to purchase Oxy 30 and other immediate release oxycodone from Amerisource and to discontinue ordering from Masters. 140
- and other opioids in huge numbers overall, but also in huge numbers at one time. One Food City customer drove half an hour to Food City # 616 on September 1, 2011 where he purchased 720 Oxy 30s, 180 Oxy 15s, and 120 OxyContin 80 mg written by Bearden prescribers. The customer would fill the same prescriptions again on September 29, 2011. In September 2011 alone, the Food City customer received prescription opioids worth around \$67,800, assuming \$1/mg on the black market. Over time, Food City sold this customer 24,810 total Oxy 30s, which averaged around 450 Oxy 30 pills per prescription.
- 152. Other Food City pharmacies continued to sell extremely high volumes of oxycodone in September 2011. For example, Food City # 674 sold one customer, who lived approximately 67 miles away from the store, 720 Oxy 30s and 600 Oxy 15s on September 6, 2011.
- 153. Another Food City # 674 customer, who lived over 100 miles away from the pharmacy, purchased 240 OxyContin 80 mg, 240 OxyContin 60 mg, and 650 Roxicodone 30 mg, totaling 1,130 opioid dosage units equal to 79,650 MMEs, in one pharmacy visit. Assuming a street value of \$1/mg, the opioids from this one visit had a street value of \$53,100.
- 154. By September 13, 2011, Mickey Blazer had replaced Don Clark as Director of Pharmacy Operations at Food City. On that date he sent an e-mail to all pharmacies that all product had to be ordered from Amerisource or the Food City Distribution Centers and that pharmacists should only order through secondary distributors if they could not get it from Food City's primary

¹⁴⁰ TNAG-FC-CUST00094698.

distributors.¹⁴¹ On the same day, Mr. Blazer forwarded his e-mail and a question from a pharmacist about whether Amerisource was really cheaper with the message:

From: Mickey Blazer

Sent: Tuesday, September 13, 2011 06:53 PM

To: Wick Hayton; Will Bevins; Tom Geoghagan; Chris Ashby; Christian Darnell; Connie Reed

Cc: Jody Helms; Steve Smith; Jesse Lewis Subject: FW: Ordering Pharmacy Product

Guys,

I need your guys full support on helping our Folks understand this. My directive pretty much goes against everything they have been told in the past. I want to make sure we are all sending the same message.

Your phones are going to light up in the morning, so be ready.

Mickey Blazer Food City Director of Pharmacy Operations (276) 623-6100

Ext. 5737

155. In a response the next day, Food City CEO Steve Smith stated:

From: Steve Smith [smiths@FoodCity.com]

Sent: 9/14/2011 12:03:38 AM

To: Mickey Blazer [blazermi@FoodCity.com]

Subject: Re: Ordering Pharmacy Product

Hang tight we will find a secondary supplier to use or even get a better deal from ASB! Steve

156. The exchange showed that Food City had used secondary distributors extensively to supply its high-volume stores and to escape from threshold limits imposed by distributors. After Food City's directive to use only Amerisource, Amerisource's distribution of oxycodone, and Oxy 30 specifically, increased significantly.

¹⁴¹ TNAG-FC-CUST00122629.

November and December 2011 based on September sales that it shared with Topco and Amerisource. But the projections were so large that they made Amerisource nervous and Amerisource floated the idea of not filling Food City's complete projection. In a response with the subject "RE: Oxycodone Projections," Amerisource told Food City through Topco that "there is a shortage of product that may have an impact on KVAT getting product even once we figure out their allocation." In an internal e-mail from Topco, shown below, Topco President and CEO Randy Skoda asked, "Do we have any backup sources?", trying to secure more oxycodone. 142

From: Skoda, Randy [/O=SKOKIE, ILLINOIS/OU=SKOKIE/CN=RECIPIENTS/CN=RSKODA]

Sent:

10/21/2011 2:58:44 PM

Subject:

Maki, Curt [cmaki@topco.com] Re: Oxycodone Projections

Do we have any backup sources?

From: Maki, Curt

Sent: Friday, October 21, 2011 02:55 PM

To: Skoda, Randy

Subject: RE: Oxycodone Projections

OK

I have been on the phone with Mickey twice and exchanged several emails with Mickey and ABC. And I have been on the phone with Rita. Since you and I talked ABC said that there is a shortage of product that may have an impact on KVAT getting product even once we figure out their allocation. We will stay on top of it.

Curt

158. Ultimately, sales were too tempting and Amerisource ended up supplying Food City with extremely high amounts of oxycodone. Between October 2011 and January 2012, Amerisource distributed more Oxy 30 to Food City # 674 and Food City # 694 than it did to its pharmacy customers in 42 states. These 42 states are set forth in the graphic below. Blue

¹⁴² TC0345048.

¹⁴³ See ABDCMDL00301692.

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.

States with Fewer IR Oxycodone 30 mg Tablets from Amerisource than Food City # 674 and # 694 Oct. 2011 to Jan. 2012



159. Around November 2011, Amerisource forced Food City to hire a third-party compliance consultant, Pharma Compliance Group (PCG), to audit its Special 3 stores in Knoxville, due to concerns regarding the levels of controlled substances dispensed from the pharmacies. The investigators spent November 29 and 30 conducting an in-depth regulatory compliance inspection and then submitted a report to Mickey Blazer, Food City's Director of Pharmacy. The investigators' findings were alarming. They stated in relevant part (shown in gray below):

-

Acquired_Actavis_00761942.

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 [sic] Healthcare Associates pain clinics to Food City Store Pharmacies 616, 674, and 694:

- Practitioners employed by the Beardon [sic] Healthcare Associates are the *highest prescribers of total controlled substance prescriptions* fulfilled and dispensed by pharmacies 616,674 [sic], *and* 694
- Practitioners employed by Beardon [sic] Healthcare Associates prescribe 21% of controlled substances dispensed by pharmacies 616,674 [sic] and 694
- Practitioners employed by Beardon [sic] 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* [sic], Medical Director, Beardon [sic] 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 [sic] 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 [sic] Healthcare Associates
- Beardon [sic] Healthcare Associates vs. Westwood Homeowners Association

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 the possible adverse action against Food City Store pharmaceutical drug distributor, AmerisourceBergen Corp. ... The PCG findings are not a repudiation of the pain management philosophy of Dr. McNeil or the practitioners he employs. However, it is the finding of the Pharma Compliance Group that the prescribing habits of 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. ... PCG determined it was necessary to provide this analysis because of the unique relationship between volume of controlled substance prescriptions issued by Beardon [sic] Healthcare Associates that are subsequently dispensed by Food City Pharmacies 616,674 [sic], 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 that certain benchmarks measured by PCG Investigators considered "High Risk" metrics has determined that the Beardon [sic] Healthcare Associates practitioners are a risk in most categories, specifically as it relates to the dispensing 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 ssignificant [sic] concern is the pharmacies filling prescriptions for practitioners located in Georgia and North Carolina. ...

Food City Store Pharmacy management has instituted pro-active corporate policies to prevent the 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 Pharma Compliance Group recommends that Food City Store implement safeguards to prevent fulfilling an excessive amount of controlled substances from individual prescribers. The Code of Federal Regulations (CFR) mandates that a pharmacist ensure that a prescription was written for a legitimate medical purpose. 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.

Dr. FRANK McNEIL [SIC] INTERVIEW

On November 30, 2011 Pharma Compliance Investigators Matthew Murphy and Carlos Aquino conducted an in-depth interview with Dr. Frank McNeil, Medical Director, Beardon [sic] Healthcare Associates (BHCA). The meeting took place at the BHCA offices located at 10321 Kingston Pike, Knoxville, TN.

. . . .

Dr. McNeil said that the practitioners at BHCA examine about one hundred patients per day and the patients are examined every thirty days. The BHCA has *thousands* of patients; however, Dr. McNeil does not know the exact number.

. . . .

Dr. McNeil said he is concerned that practitioners that legitimately practice pain management often become the target of law enforcement and regulatory agencies. Dr. McNeil 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. McNeil told the investigators that in either 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. McNeil was not present during the execution of the warrant. Dr. McNeil told the investigators that he has not received a status relative to the investigation that is apparently ongoing. His attorney told him that there is a five year [sic] statute of limitations for charges to be filed.

Dr. McNeil said he has been *subject to two wrongful death suits involving overdose deaths*. One case alleged that *he caused a patient to become addicted to controlled substances*. Dr. McNeil 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 trial. The family of the plaintiff was awarded \$250,000.00. Dr. McNeil said that his *malpractice insurance has tripled* and that he pays approximately \$85,000.00 per year for coverage.

Dr. McNeil said that this DEA registration is in restricted states 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).

Dr. McNeil told the 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. McNeil told the 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.* ¹⁴⁵

160. The PCG investigators also wrote separate reports for each of the three Food City pharmacies they investigated. They performed their in-store audit of Pharmacy # 674 on November 29, 2011 and wrote the following, in relevant part: 146

[T]he Investigators spoke with Registered Pharmacist Julie Varnum] regarding Food City Store pharmacy operations, specifically store 674. Pharmacist Varnum told the investigators that she has been an employee of Food City Store Company for approximately ten years. During that time, she was a supervisory pharmacist for approximately five and a half to six years and has been assigned to store 674 for the past four years. ...

During her tenure with Food City Store Corp., Pharmacist Varnum has provided training to pharmacists regarding Food City Pharmacy company policies and procedures. She also provides the pharmacist(s) with guidance and direction relative to specific company policies when fulfilling prescriptions for practitioners that are high prescribers of pain medications or specialize in pain management.

Pharmacist Varnum said that the pharmacy fulfills a high volume of prescriptions of drugs of concern than most of the other stores because of the close proximity to the Beardon [sic] Healthcare Associates, (BHCA), a pain clinic operated by Dr. Frank McNeil that specializes in chronic pain management. ... It is her professional opinion that Beardon [sic] Healthcare Associates legitimately provides pain management to patients and that Dr. McNeil and his staff prescribe controlled substances appropriately. Although she also said that when the Beardon [sic] clinic was nearby, the DEA and other law enforcement agencies would visit the pharmacy periodically in conjunction with an investigation that concerned a

¹⁴⁵ # 82.1 (italic emphasis added, bold emphasis in original).

^{# 104.1 (}italic emphasis added).

patient of the clinic or a prescription written by a practitioner employed at Beardon [sic] Healthcare Associates.

. . . .

Schedule III to V controlled substances are dispersed throughout the pharmacy. ...

Food City Pharmacy # 674 has an armed City of Knoxville police officer, contracted through the City of Knoxville. Pharmacist Varnum stated that the purpose of the armed guard is to act as a deterrent to a robbery while the pharmacy is open. Several robberies have occurred during business hours.

161. After the disastrous results of the PCG audits, Tom Geoghagan e-mailed Mickey Blazer and Ken Slagle on January 13, 2012 with an updated "Action Plan in response to Pharma Compliance Group." The one-page Action Plan stated:

¹⁴⁷ TNAG-FC-CUST00007696.

Action Plan in response to Pharma Compliance Group

- 1. All stores will conduct an additional exact count inventory audit on all solid products containing the following (this inventory count is in addition to our annual controlled substance inventory and will be completed annually during the month of December)
 - a. Alprazolam
 - b. Carisoprodol (350mg strength only)
 - c. Diazepam
 - d. Hydrocodone
 - e. Tramadol
- 2. All invoices for schedule III-V substances will be maintained and filed separately by month. In addition, the Pharmacist receiving the order will verify and notate by either circling or checking beside the quantity of each item received along with signing and dating the invoice.
- 3. All invoices for schedule II substances will be maintained and filed separately by month. The department will maintain the invoices as above and attach the appropriately executed DEA-222 form to the invoice.
 - **a.** The DEA-222 form will either be in the form of the traditional "blue" copy or a printed copy from the CSOS application.
- 4. Changes have been made to the Pharmacy Checklist (to be completed by the Pharmacy Operations Manager or Pharmacy Professional Services Manager) to ensure the enacted policy changes are being adhered to. Changes are listed below.
 - a. Verification of both the annual and additional inventory
 - b. Verification of CIII-V invoices and filing procedure
 - c. Verification of CII invoices and filing procedure
- **5.** An additional security camera will be installed in store 694 to observe activity near the safe in the rear storage area.
- **6.** Stores may refuse to honor controlled substance prescriptions written by "Pain Management Clinics" not certified by the state of Tennessee.
 - a. The above applies to Pain Management Clinics located in the state of Tennessee only.
 - b. Pain Management Clinic is defined in Tennessee Public Chapter No. 340
 - **c.** Not all pain management clinics are required to be certified (these clinics are exempt from the above)
 - i. Exemptions can be found in Tennessee Public Chapter No. 340 (63-1-302)
- 162. Despite PCG's finding that "the prescribing habits of Beardon [sic] Healthcare Associates practitioners are a "High Risk" to the business operations and the reputational image of Food City Store pharmacies" and numerous other "high risk" factors, ¹⁴⁸ which effectively

¹⁴⁸ # 73.1 (italic emphasis added, bold emphasis in original).

recommended that Food City cease honoring Bearden prescriptions, the Action Plan did not address Food City's core underlying problems and allowed for Bearden opioid sales to continue at its three pharmacies. Instead, the Plan was designed to make modest changes that would not disrupt Food City's high opioid sales.

- 163. After December 5, 2011, Food City sold just over 5 million opioid dosage units prescribed by Bearden Health Care Associates providers at its eight highest volume pharmacies. After December 5, 2011, Food City sold nearly 150,000 opioids prescribed by Dr. Frank McNiel.
- 164. Food City's Action Plan did not address the massive diversion that was occurring from these pharmacies in any meaningful or serious way. It did not even suggest creating an inventory for oxycodone—the biggest opioid seller at these stores. The Action Plan referenced inventory counts, invoices, transfer forms, and a new security camera at # 694 over the controlled substances safe. Aside from this, the Action Plan only stated that Food City pharmacies "may" refuse to honor controlled substance prescription written by "Pain Management Clinics" that were not registered with the State. As stated, Food City authorized its pharmacies to continue selling opioids based on prescriptions from pain management clinics that were operating unlawfully in Tennessee.
- 165. During this time, Food City executives continued to monitor DEA opioids enforcement. On February 7, 2012, Tom Geoghagan, the Pharmacy Professional Services Manager, sent an e-mail to other Food City executives with an excerpt and a link to a WALL STREET JOURNAL article about a DEA enforcement action against the distributor Cardinal. As shown below, Mr. Geoghagan's excerpt stated, "The DEA said the Cardinal facility 'failed to maintain effective controls' while noting a similar DEA move there, and at other Cardinal locations, in

81

¹⁴⁹ TNAG-FC-CUST00007692.

2007" and highlighted in hold, red font the statement: "The drug agency also noted the heavy flow of Oxycodone doses through the CVS pharmacies and alleged those outlets either knew, or should have known, 'a large number' of prescriptions weren't for legitimate purposes."



- 166. Likewise, Food City and its executives not only knew specifically about their duty to maintain effective controls against diversion, they knew or should have known based on the heavy flow of oxycodone doses through its pharmacies that a large number of oxycodone prescriptions were not for legitimate purposes—especially given the high numbers of combination prescriptions in which oxycodone was combined with a benzodiazepine (e.g., Xanax) and a muscle relaxer (e.g., Soma).
- 167. Eye-popping opioid sales continued at the end of Winter 2012. As one example, on March 16, 2012, Food City # 674 sold 950 Oxy 30 mg tablets in one prescription from Bearden provider Dr. Donald Douglas to an individual from Kingsport, which is over an hour and a half away.

- 168. Two months later, on April 5, 2012, PCG audited Pharmacy # 674 again and other troubling discrepancies reappeared, such as:
 - The CII substances are not locked until the end of the business day;
 - The CII safes are kept open during business;
 - The [Pharmacy Manager] has not completed a random count on the CII drug quantities;
 - The initials of the dispensing pharmacist *were not noted* on the prescriptions;
 - The pharmacy is filling a high percentage of pain management prescriptions;
 - The pharmacy is filling a high percentage of out of state / area prescriptions;
 - Patient prescription information is not stored in a secure location;
 - The security monitor *does not have* a time or date posted;
 - There was insufficient video on-hand from the previous day's activities; and
 - The 24-Hour Post-filling Audit was not being completed. 150
- 169. On April 6, 2012, PCG audited Pharmacy # 616 in Hardin Valley and reported the following, in addition to various record-keeping deficiencies:
 - A DEA 106 form was completed on 3/26/12 for employee pilferage in the amount of \$1,147 for Buprenorphine and Suboxone.
 - The last Pharmacy Visit Checklist was completed on 1/12/11 by Tom Geoghagan. 151
- 170. On April 17, 2012, PCG audited Pharmacy # 682 in Knoxville and reported the following, in addition to various record-keeping deficiencies:
 - Physical inventories are not completed on a consistent basis when shipment received or product dispensed.

¹⁵⁰ # 179.1 (emphasis added).

¹⁵¹ # 180.1.

- There is no inventory count to update within the system.
- [PIC] is unaware of any time her PPSM came in for a visit and verified VII quantities.
- [PIC] is unaware of where the [Food City standard operating procedure for controlled drugs] is located.
- [PIC] estimated that 40% of the prescriptions filled would be considered high risk. 152
- 171. That same day, PCG also audited Food City # 644, located in Seymour, and reported the following, in addition to various record-keeping deficiencies:
 - [PIC] stated that last documented incident for theft/loss occurred in October of 2009. Completed 106 on file dated 10/19/09. There was no documentation or fax indicating the form had been submitted.
 - The cabinet containing all the invoices and other records was found unsecured upon inspection.
 - The way the pharmacy is set up they would have to open up a door to access
 the register area each time a customer is present. For this reason, the door
 to the pharmacy remains open at all times leaving the scripts and drugs
 accessible.
 - [Inventory e]xceptions found are as follows: Oxycontin 10mg -25 units, Alprazolam .25mg -36 units, Hydrocodone 10/650 +533 units. An error was found within the perpetual binder for the Oxycontin around the date range of 2/10 through 3/10 involving a miscount of 25 units.
 - [PIC] stated that *only large discrepancies* would be reported to Tom when they occur. Example would be a missing bottle. Anything less would *just get adjustment in the book*.
 - [PIC] stated that *Tom has not visited the pharmacy within the current year*. It is unknown as to when the last random inventory count check was completed.

84

¹⁵² # 176.1.

- [At least one part-time pharmacist was *unfamiliar with the PMP inquiry process*.] 153
- 172. On April 18, 2012, PCG audited Pharmacy # 687 in Knoxville and reported the following, in addition to various record-keeping deficiencies:
 - [PIC] stated that the practitioners ar [sic] Bearden Healthcare Associates have the majority of the prescriptions that they fill. She estimated that around 40% would come from there. Other clinics identified [as writing a disproportionate share of the prescriptions for controlled substances]: Pain Management Center and Comprehensive Healthcare Systems.
 - [PIC] roughly estimated that 85% of the prescriptions for pain management she would consider of "high risk".
 - [PIC] estimates that *Oxycodone owns at least 40% of the total* of controlled substances filled.
 - [PIC] estimated insurance being the primary method of payment with 60% compared to *cash at 40%*. ¹⁵⁴
- 173. That same day, PCG audited Food City # 672 in Knoxville and reported the following, in addition to various record-keeping deficiencies:
 - [Most recent inventory was retained within an *unsecured drawer* and conducting pharmacist's signature was not present.]
 - Completed POA on file for Tom Geoghagan and [former staff pharmacist]. *There was not one found for* [current PIC, who had been PIC since 2005.]
 - [Cabinet containing filed CII invoices was *unlocked*].
 - Most recent returns to Medturn, dated 4/16, did not have a completed 222 attached.
 - Record cabinet is always kept *unsecured*.
 - Perpetual binders were kept on top of the counter. These were left *unsecured* throughout the day.

¹⁵³ # 177.1 (emphasis added).

¹⁵⁴ # 174.1 (emphasis added).

- Door to the pharmacy *remained open* during the course of the audit. Scripts are kept in an *unlocked* drawer.
- [PIC] does *not* keep his wallet card on his person.
- Cabinet contained [CII] pain medications was found unsecured with key in place. In speaking with [PIC], he stated that he usually keeps it unlocked as he frequently fills from the cabinet.
- Existing inventory of CII's are only verified when dispensing and not when shipment is received.
- Several shipment entries found for CII's where the *pharmacist did not sign/initial*.
- [PIC] was unaware that monthly audits are required to be documented. There was a random audit completed this year on 4/4/12. No other documented inventories found for the current year.
- [PIC] is *unaware of any random counts* being conducted by the PPSM.
- There are *no cameras* within the pharmacy itself.
- Barry Rosemand [sic] (Knoxville Algiatry) was identified as having excessive prescribing habits.
- [PIC] estimated that *cash would be the primary payment at 60%* [for controlled substance prescriptions]. 155

174. By May 11, 2012, Food City and its executives were responding to a DEA audit of Food City # 674, # 694, and # 616. Food City's executives prepared spreadsheets to respond to the audit. These spreadsheets not only showed that a number of its customers, most of whom received oxycodone from a Bearden Health Care Associates provider, had the same or similar address, 156 but also showed that individual patients were receiving huge dosages of oxycodone and other opioids in monthly prescriptions, including:

¹⁵⁵ # 175.1 (emphasis added).

¹⁵⁶ TNAG-FC-CUST00007670–73.

- 500 Oxy 30 pills, 420 OxyContin 80 mg pills, <u>and</u> 300 methadone 10 mg pills issued to the same person on the same date based on a prescription from a Bearden provider; ¹⁵⁷
- 420 Oxy 30 pills, 180 hydromorphone 8 mg pills, <u>and</u> 30 OxyContin 60 mg pills sold by # 674 to the same person on the same date based on a prescription from a Bearden provider; ¹⁵⁸
- 428 Oxy 30 pills and 150 OxyContin 60 mg pills sold at # 674 to the same person on the same date based on a prescription from a Bearden provider;¹⁵⁹
- 375 Oxy 30 pills sold to an individual at # 674 with a prescription from Dr. Frank McNiel of Bearden Health Care Associates; 160
- 360 Oxy 30 pills <u>and</u> 270 methadone 10 mg pills sold to the same person on the same date at # 694 based on a prescription from a Bearden provider; ¹⁶¹
- 540 Oxy 15 pills <u>and</u> 60 morphine sulfate 60 mg pills sold to the same person on the same date at # 694 based on a prescription from a Bearden provider; ¹⁶² and
- 400 Oxy 30 pills <u>and</u> another 100 Oxy 30 pills on April 10, 2012, another 400 Oxy 30 pills <u>and</u> still another 100 Oxy 30 pills two days later on April 12, 2012, and 120 OxyContin 80 mg <u>and</u> 360 methadone 10 mg on April 14, 2012 sold to the same person based on a prescription from Dr. Frank McNiel of Bearden Health Care Associates. 163
- 175. In April 2012, Amerisource's compliance department made a special trip to Knoxville to conduct site visits of the Food City # 674, # 694, and # 616 stores along with PCG, which was conducting a quarterly audit.
- 176. Despite the DEA audit, the PCG audit findings, and stated concerns from Amerisource, Food City refused to take compliance seriously. On April 20, 2012, Food City's Director of Pharmacy sent an e-mail to other Food City executives, including its CEO Steve Smith,

¹⁵⁷ TNAG-FC-CUST00007672.

¹⁵⁸ *Id*.

¹⁵⁹ *Id*.

¹⁶⁰ *Id*.

¹⁶¹ TNAG-FC-CUST00007671.

¹⁶² *Id*.

¹⁶³ TNAG-FC-CUST00007673.

dismissing concerns about a purported pill mill, whose prescriptions Food City continued to fill.

The e-mail stated:

From: Mickey Blazer [/O=FOOD CITY/OU=FOODCITY/CN=RECIPIENTS/CN=BLAZERMI]

Sent: 4/20/2012 12:51:09 PM

To: Lou Scudere [scuderel@FoodCity.com]

CC: John Jones [jonesj@foodcity.com]; Steve Smith [smiths@FoodCity.com]

Subject: RE: Prodigal Primary Care

Lou

David Brickhouse does not have any pending investigation or disciplinary action or attached to his DEA license. He was previously involved with a Dr. Rodenberg that got him a lot of attention with the media. "Don Dare" did a segment on Rodenburg and interviewed Brickhouse about his association with him. There are a couple of Blogs indicating Brickhouse is running a pill mill but I don't put much stock in Blogs. Please note: Prodigal Primary Care is registered with the State of Tennessee as a Pain Clinic in the following three locations. (This requirement of registration become mandatory January 2012 with a grace period until April, 2012.)

Prodigal Primary Care, PC 2911 Essary Road Knoxville, TN 37918

Prodigal Primary Care, PC 10904 Kingston Pike Knoxville, TN 37934

Prodigal Primary Care, PC 901 Merchants Drive Knoxville, TN 37912

The State requires you to register as a Pain Clinic when:
"Pain management clinic" means a privately-owned facility in which a
medical doctor, an osteopathic physician, an advanced practice nurse, and/or a
physician assistant provides pain management services to patients, a majority of
whom are issued a prescription for, or are dispensed, opioids, benzodiazepine,
barbiturates, or carisoprodol, but not including suboxone, for more than ninety (90)
days in a twelve-month period; and

Please let me know if I need to provide any further information.

Thanks,

Mickey Blazer

Food City

Director of Pharmacy Operations

177. For years, Food City and Bearden Health Care Associates have had a symbiotic and close relationship, including in May 2012. When Food City had some of its Oxy 30 cut back, Bearden began writing Oxy 15s to help Food City avoid its (already high) Oxy 30 threshold with its distributor, and in turn caused Food City to hit thresholds for Oxy 15. An e-mail from Food City's pharmacist at # 694 that was passed along to other executives at Food City described the dynamic. It stated:

From:

Tom Geoghagan [geoghagt@FoodCity.com]

Sent:

5/30/2012 8:27:48 PM

To:

Mickey Blazer [blazermi@FoodCity.com]

Subject:

see below

Tom Geoghagan

Pharmacy Professional Services Manager K-VA-T Food Stores 6305 Lonas Drive Suite 201

Knoxville, TN 37909 Phone: (865)584-7061 xt 522 Mobile: (423)361-0426 Fax: (865)588-2381

From: Pharmacy Rx694

Sent: Wednesday, May 30, 2012 4:27 PM

To: Tom Geoghagan; Ken Slagle

Subject:

Hey Guys, just wanted to give you a heads up. Since the cut backs on the oxy30s, they have been writing increasing amounts of oxy15s. I went through and did a tally of what we've used to so far this month. We just skirting the line on the 30's, but for the 15's even though we are fine this month because they didn't start writing it for everyone until midmonth. Next month we aren't going to be able to keep up if they keep writing it like they have along with the 30s. I just wanted to let you know that this is probably going to create a problem soon.

Rachel, 694

- 178. In yet another sign that Food City was an outlier even among high volume pharmacies, Purdue Pharma's Executive Director of Compliance conducted a site visit of Food City's # 674 location in June 2012, like Amerisource's Compliance team had done in April. While visits from sales representatives from distributors and manufacturers, including Purdue, were relatively commonplace, it was extremely unusual for compliance directors to visit pharmacies *in person*, especially more than one within a two-month period.
- 179. On July 10, 2012, PCG audited Food City # 667 in Sevierville and reported the following, in addition to various record-keeping deficiencies:
 - [Investigator] tried to reconcile the perpetual inventory entries to the shipment report and activity report for the Oxycodone discrepancy, however, was unable to due to a pharmacist dispensing a partial quantity, but entered the full quantity as dispensed on the log leaving a negative on hand count. ... Large discrepancies found for each drug.

- The main two clinics that own the majority of the prescriptions are Affordable Healthcare Medical Clinic and Skyview Medical Center. Charles Weckesser, MD (Affordable Healthcare Medical Clinic), Valeria [sic] Sawicki, ARNP (writing under Charles' supervision). Larry Sims, PAC, Portia Hutchinson, Jerome Sherard MD (Skyview Medical Center). Robert Maughon (General Practitioner).
- Per the DEA Report ran by Tom G, the following prescribers own the majority of the prescriptions written: Valerie Sawicki (7.71%), Rodney C (3.91%), Larry Sting (2.09%)[,] Courtney Newman (2.09%).
- [PIC] stated that the said prescribers above write prescriptions that would be considered a "lethal cocktail" on a daily basis. She has received prescriptions containing narcotics, benzodiazepines and muscle relaxers all on one prescription (Oxycodone/Xanax-alprazolam/soma-zolpidem).
- [Does the Pharmacy purchase an amount of controlled substances associated with pain management that are greater than 20% of the total controlled substance purchases?] yes. [PIC] stated that their shipment of Oxycodone (regular) was cut off by the DEA due to over purchasing as a percentage of controlled substances.
- [PIC] identified the Dr. McNeil (General Practitioner[)] as one who has excessive prescribing habits. [PIC] stated she stopped filling his prescriptions as soon as she started as RX Manager. 164
- 180. Food City's problematic audits continued that month. On July 11, 2012, PCG again audited Food City # 674 in Knoxville and reported the following, in addition to various record-keeping deficiencies:
 - [CII's are retained in *four* safes, which all have a locking feature.]
 - Two of the CII safes were found unsecured.
 - Julie stated that the remaining inventory is *only* verified upon dispensing for a prescription.
 - Julie stated that she is *unaware of any* routine or random counts on CII drug quantities by the PSM.

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^{# 168.1 (}emphasis added) (Note: "cut off by the DEA" could be imprecise reference to threshold limits).

- The majority of the prescriptions filled for pain management are from Bearden Healthcare, Tennova/St. Mary's and Active Pain Treatment (Dr. Fox).
- Julie stated that the amount of prescriptions are somewhat equal from the prescribers from the three facilities noted above (Bearden Dr. McNeil / Teodora Neagu / Barbara Wilson / Christina Collins / Brandy Burchell / Don Douglas, Tennova Pamela Pullin / James Wike, Julie Bliss / Mark Nelson / Christopher Vinsant / Krista Cutshaw, Active Pain Clinic Dr. Fox / Rachel Payne.
- Julie stated that she estimates at least 75% of the customer from Bearden receive prescriptions from all three groups (Narc/Benzo/Muscle Relaxant). The other two, Tennova/St. Mary's/Active Pain Treatment do prescribe for both Narcotics and Muscle Relaxants. They usually let the patient's general practitioner or psychiatrist prescribe the benzodiazepines.
- Julie estimates that the pain management purchases are around 60% of the total controlled substance purchased.
- Julie stated that she does not consider any prescriber to be excessive or unusual. Based on the patient's history and diagnosis they are prescribed the appropriate amounts.
- Julie estimates that 75% of the total prescriptions filled are controlled substances. 165
- 181. Notably, Julie Varnum was not disciplined despite the repeated problems (e.g., leaving CII safes unlocked), not following Food City policy (e.g., early refills), and questionable judgment (e.g., identified no prescriber as excessive yet said 75% of Bearden patients were receiving highly suspect, lethal prescription combinations). Instead, Varnum continued training other Food City pharmacists on how to dispense controlled substances.
- 182. That same day, PCG also audited Food City # 694 in Knoxville and reported the following, in addition to various record-keeping deficiencies:
 - Bearden Healthcare and Chilhowee Pain Center are the two main facilities that own the majority of the prescriptions. [PIC] stated that all prescribers

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¹⁶⁵ # 165.1 (emphasis added).

- from these facilities are equal in [controlled substance] prescriptions written.
- [PIC] stated she believes the quantity of prescriptions seem equal across the board for Bearden Healthcare. As far as Chilhowee Pain Center, Donna Smith (Nurse Practitioner) writes the majority of the prescriptions (85% of the scripts are estimated to be from Donna[)].
- [PIC] stated that most of the prescriptions from Bearden contain several drugs for one patient that would be considered high risk. (Oxycodone/Xanax/Soma).

72. Rachel stated that most of prescriptions from Bearden contain several drugs for one patient that would be considered high risk. (Oxycodone/Xanax/Soma)

- Bearden is the only facility with what would be considered "excessive" prescribing habits.
- [PIC] estimated at least 40% of the total prescriptions filled would be controlled substances. 166
- 183. Aside from the other obvious issues with this report, it is worth noting that Donna Smith alone should have been a red flag. She was a nurse practitioner with Breakthrough Pain Therapy, the pill mill run by Sandy and Randy Kincaid in 2009 and 2010, and she later pled guilty to federal drug conspiracy charges.
- 184. On July 18, 2012, PCG audited Food City # 609 in Kodak and reported the following, in addition to various record-keeping deficiencies:
 - [At least eleven] CII invoices found without an executed 222 attached.
 - Completed DEA 106 form [for theft or loss] on file dated 7/9/12 for "Employee Pilferage." There was no documentation attached showing submission to State Board/Pharmacy Director.
 - The latest [state board of pharmacy] inspection on file was dated 4/23/12.
 One deficiency noted, which was the inability of the pharmacist to access the CSMD due to not having a login/password. In speaking with [RPh], it

^{166 # 172.1 (}emphasis added).

- was identified that she has never had access to this system to complete PMP inquiries.
- Both the CII cabinet and drawer were found unsecured. In speaking with [RPh], this was common practice to leave both unsecured during and outside of business hours.
- Keys to the pharmacy were retained on [RPh's] person. *The keys to the CII lock up were found in the unsecured CII drawer*.
- Other than the documented annual inventory from June, there were no entries found for the monthly inventory. In speaking with [RPh], she stated that to her knowledge there have been no monthly inventories completed for the CII's.
- Monthly accountability inventories were not conducted to identify discrepancy. [RPh] stated that the occasionally discrepancy of a pill would be noted in the book, but not communicated due to the insignificance.
- [RPh] was without a [CSMD] login ID since she has been RPH, so PMP inquiries were not being done.
- [Inspector] figured the percentage being close to 50% for the total purchases of controlled substances associated with pain management compared to the total number of controlled substances purchased by the pharmacy. This number is skewed due to the recent incident involving employee pilferage of Hydrocodone. Excessive ordering of the Hydro 10/325 was occurring.
- Three practitioners identified as owning a disproportion share of [controlled substance] prescriptions. They are as follows: Roger Barnes (6.38%), Gary Gribble (3.37%) and Valerie Sawickie (1.55%).
- [RPh] stated that the only prescriber she would consider high risk would be Dr. Weckesser (Oxy, Xanax, Zanaflex). 167
- 185. On September 18, 2012, PCG audited Food City # 674 in Knoxville and reported the following, in addition to various record-keeping deficiencies:
 - Two of the CII lock ups remained open during the entire course of the audit. Julie stated that they usually stay open during the day due to the frequency (Julie confirmed that 72 CII's were filled on 9/19).

¹⁶⁷ # 169.1 (emphasis added).

- [Oxy, hydro, and alprazolam variances found during accountability inventory.]
- [Does Pharmacy service pain management and clinics / physicians?] Yes. *Bearden, St. Mary's, Jackson Family Health, R. Allen Rice*.
- The DEA Audit report was not supplied to the auditor to determine accurate numbers. Based on discussion and review of CII scripts, it was determined that *Bearden Healthcare associates* [sic] own the majority share of CII prescriptions filled.
- Julie stated that both Bearden and St. Mary's writes prescriptions that would be considered high risk (Narc/Benzo/Anti-Depressant[).]
- Julie estimates that 75% of the purchases of controlled substances would be associated with pain management. Review of the prescriptions confirmed more than half were associated with pain management.
- Julie stated that she does not service anyone that she feels would be considered as an unusual or excessive prescriber.
- Julie estimates that the *controlled substance prescriptions filled would account for around* **50%** *of the total prescriptions* filled at the pharmacy.
- In review of the Sales Data Report ran from 6/15 to 9/15 the amount contributed to cash sales listed as 40%. 168
- 186. Again, as with the earlier audits, Ms. Varnum's claim that she filled for no "unusual or excessive" prescribers is directly belied by the report itself, specifically that she was filling high risk combinations prescribed by Bearden and St. Mary's.
- 187. Food City pharmacies, in many cases, did not act upon PCG findings despite being told about them repeatedly. Most notably, almost a year after PCG told them that Bearden posed a substantial risk to the Company, Bearden Health Care Associates still had the majority of Schedule II controlled substances sold at Food City # 674.
- 188. But there were others. For example, PCG had notified Food City's executives that Food City # 674's CII safes stayed open during business hours in back-to-back audits in April and

1

¹⁶⁸ # 166.1 (emphasis added).

September 2012.¹⁶⁹ Moreover, Food City's executive team had been notified of this CII security problem before April 2012 in other audits of 674 and in audits of other Food City pharmacies.

- 189. On September 19, 2012, PCG audited Food City # 616 in Knoxville and reported the following, in addition to various record-keeping deficiencies:
 - All three cabinets that are accessed throughout the day to fill CII scripts are kept unsecured until close of business.
 - Bearden Healthcare, Comprehensive Healthcare and Clinic for Productive Living are the three pain clinics serviced.
 - Per the EDA Audit Report ran from 6/1, Bearden Healthcare writes 58% of the total controlled substance scripts filled at the pharmacy. Individual prescriber percentages from Bearden are as follows: Christina Collins 9%, Brandy Burchell 10%, Don Douglas 9%, Teodora Neagu 9%, Barbara Wilson 13%. (Total controlled scripts filled was 4211, which Bearden wrote 2,455).
 - 37% is the total amount of controlled substance prescriptions filled compared to the total prescriptions filled at the pharmacy. 170
- 190. On September 20, 2012, PCG audited Food City # 694 in Knoxville and reported the following, in addition to various record-keeping deficiencies:
 - [998 units of Alprazolam 1mg and 91 units of Alprazolam 0.5mg were missing.]
 - [Does Pharmacy service pain management and clinics / physicians?] Bearden, Chilhowee and Preferred Pain Management are the three major clinics that the pharmacy fills for.
 - The DEA Audit Report was run from 6/1 to 9/19 to obtain statistical information. Bearden Healthcare wrote [52.1%, or] 2,214 prescriptions out of the 4,360 control substance prescriptions filled at the pharmacy since 6/1. Individual prescriber totals are as follows: Brandy Burchell 373 scripts @ 8.5%, Christina Collins 541 scripts @ 12.5%, Donald Douglas 455 scripts at 10.5%, Teodora Neagu 471 scripts @ 10.8%, Barbara Wilson 428 scripts @ 9.8%.

¹⁶⁹ # 179.1.

¹⁷⁰ # 160.1 (emphasis added).

- [PIC] is still seeing prescriptions frequently patients [sic] consisting of Narcotics, Benzos and Muscle Relaxants. The common drugs written for these "cocktails" were explained as Oxycodone 30/15, Soma and Xanax.
- Controlled substance purchases associated with pain management was 34% of the total controlled substance purchases since 6/1.
- Other than **Bearden writing half the number of controlled prescriptions**, there are no others that are excessive. Christina Collins writes the most prescriptions with 541, but her patient load is unknown.
- Controlled substance prescription filled factor 28% of the total number of prescriptions filled since 6/1. 171
- 191. On September 21, 2012, PCG audited Food City # 650 in Lenoir City and reported the following, in addition to various record-keeping deficiencies:
 - [F]rom May through September 2012, there were 8 CIII-V invoices that were not signed by an authorized person.
 - The Accountability Audit revealed that there was a deviation of 864 dosage units short of the Oxycodone 15mg, which resulted in a difference of 8.95%. During the reconciliation process the DEA Audit Report, the Drug Usage Summary Report, and a count of each dispensation located in the perpetual inventory log book resulted in different totals; however, none of the methods used accounted for all dispensations.
 - ... The Oxycontin 80mg was physically inventoried resulting in 150 dosage units; however, the perpetual inventory indicated that 136 dosage units should be on-hand. The Oxycodone/APAP 5/325mg was physically inventoried resulting in 147 dosage units; however, the perpetual inventory indicated that 197 dosage units should be on-hand. The Morphine Sulfate ER 15mg was physically inventoried resulting in 196 dosage units; however, the perpetual inventory indicated that 218 dosage units should be on-hand. ...
 - [RPh] stated that *she does not consistently conduct monthly inventories as required*.
 - During the duration of the inspection the entry door into the pharmacy was open. This could pose a possible risk for pharmacy personnel and theft.
 - Per the DEA Report from 6/29/2012 to 9/21/2012 and RpH, there are several pain doctors who prescribed a high percentage of controlled

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¹⁷¹ # 90.1 (emphasis added).

substances compared to other drugs prescribed. Dr [sic] Christina Collins wrote 19 prescriptions and 14 of them were for controlled substances. Dr Clara Cobb wrote 19 prescriptions and 14 of them were for controlled substances. Dr Lindsay Stubblefield wrote 19 prescriptions and 15 were for controlled substances. Dr Richard Larson wrote 14 prescriptions and 11 of them were for controlled substances. According to [RpH], the last three doctors are associated with Comprehensive Healthcare Systems, which is a pain clinic that raises suspicion. 172

192. Signs of massive diversion from Food City pharmacies was apparent to the manufacturers and distributors that were supplying Food City with Oxy 30 and other oxycodone. On October 22, 2012, Actavis, an Oxy 30 manufacturer, met with AmerisourceBergen (Food City's primary distributor) to discuss suspicious order monitoring and review of ARCOS data specific to Oxy 15 and Oxy 30.

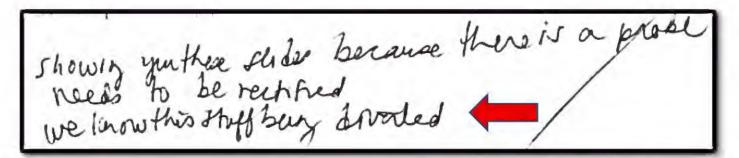
193. At the meeting, which Food City was not invited to, Actavis showed Amerisource data slides and relayed its serious concerns about Food City and other Tennessee pharmacies. The first of the slides showed 15 problematic Actavis pharmacy customers out of its top 50 customers for Oxy 30 that used Amerisource as a distributor. The top three pharmacies in the country that dispensed the most Actavis Oxy 30 were Knoxville's Food City # 674, # 694, and # 616.

194. 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. 173

¹⁷² # 173.1 (emphasis added).

¹⁷³ MULTI3537738.

195. 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." 174



- 196. However, Amerisource was soon replaced by McKesson as the primary distributor for Food City. McKesson had entered a contract with Food City's buying group, which became effective around November 15, 2012.
- 197. Food City's transition to McKesson was rocky from the start. Food City wanted McKesson to supply Oxy 30 and other opioids in the same manner and the same quantities that Amerisource had. So while the contract was in its infancy, Food City and its executives became livid when McKesson refused to supply Oxy 30. They demanded that Topco get McKesson to raise its threshold for the stores, stating that McKesson knew what Food City's Oxy 30 high volume supply needs were when it signed the primary distributor contract with Topco.
- 198. In the first of a series of related e-mails, Food City Director of Pharmacy Operations

 Mickey Blazer relayed this message to Topco and copied Food City CEO Steve Smith: 175

¹⁷⁴ MULTI3537759.

¹⁷⁵ TNAG-FC-CUST00094526.

From: Mickey Blazer [mailto:blazermi@FoodCity.com]

Sent: Monday, November 19, 2012 11:47 AM

To: Fan, William; Maki, Curt Cc: Jody Helms; Steve Smith Subject: McKesson Control Orders

Will and Curt.

I spoke with Sheri at McKesson about an hour ago to see what progress they were making getting the Control Threshold issues resolved.

She told me she was contacting their Regulatory Manager and they were working on it.

I have not heard back from her.

Are there any other Members that went live last week experiencing these problems?

We are going to be out of business at Pharmacy #674 after today if we don't get some resolve on this.

This is very disappointing, after the effort Will, Curt, and myself made to communicate to McKesson there were no surprises with this conversion.

Mickey Blazer
Director of Pharmacy Operations
K-VA-T Food Stores, INC.
201 Trigg Street
P.O. Box 1158
Abingdon, VA. 24212-1158
(276) 623-5100 Ext: 5737
blazermi@foodcity.com

199. After Topco assured Food City that it was "working very closely with McKesson to try and get [it] product today at #674" and that obtaining a supply of Oxy 30 was a high priority, Steve Smith, who also sat on Topco's Board of Directors, personally intervened and forwarded the exchange to Topco's President and CEO, Randy Skoda, to express his displeasure. He stated: 176

From: Steve Smith [mailto:smiths@FoodCity.com] Sent: Monday, November 19, 2012 2:09 PM

To: Skoda, Randy

Subject: FW: McKesson Control Orders

I was afraid this would happen. We were quite clear on our situation and how we needed to be serviced. Hopefully we will now have to revert back to ABC for service. Steve

200. Ultimately, Topco was able to get McKesson to ship the Oxy 30 to # 674 by November 21, which Topco's President conveyed to Steve Smith through this e-mail: 177

From: Skoda, Randy [rskoda@topco.com]

Sent: 11/20/2012 4:45:57 AM

To: Steve Smith [smiths@FoodCity.com]
Subject: RE: McKesson Control Orders

Was able to catch up with Curt on this earlier today and while I understand what happened, its inexcusable.

My understanding is that is that #674 was able to "make it" through the day and that they should be receiving the appropriate shipment by 9 tomorrow. Again, apologize for the issue and I believe the team is on it.

201. Despite the Oxy 30 shipment though, McKesson was still reluctant to raise thresholds. Increasingly desperate, Food City's Mickey Blazer met with McKesson's Bill Mahoney on November 27, 2012 and they toured # 674, # 694, and # 616, and Mr. Mahoney later separately toured the Bearden Health Care clinic. Topco's President told other Topco executives to keep pushing McKesson on thresholds after receiving an e-mail summarizing Food City's current status. 178

¹⁷⁷ TNAG-FC-CUST00094526.

¹⁷⁸ TC0318793.

---- Original Message ----

From: Skoda, Randy

Sent: Tuesday, November 27, 2012 08:13 PM

To: Maki, Curt; Broccolo, Andy

Subject: Re: KVAT

Need to stay on McKesson on this...push them don't walt for it to happen to us.

---- Original Message -----

From: Maki, Curt

Sent: Tuesday, November 27, 2012 08:10 PM

To: Skoda, Randy; Broccolo, Andy

Subject: KVAT

I just spoke to Mickey Blazer at KVAT. He toured three stores with Bill Mahoney from McKesson today and Mickey said that it seemed to go well. They are touring another two stores tomorrow and Bill is going to visit on his own the Bearden (sp?) clinic that is writing most of the oxycodone scripts. We have a conference call with Bill, Mickey, and others from McKesson at 8:30 AM Central tomorrow to discuss the results of the tour and the next steps. Sam Thompson is scheduled to be on the call which will be very helpful. We are hopeful that Bill has seen enough to increase the thresholds for those key stores to the appropriate levels.

Curt

- 202. Meanwhile, Food City continued to engage in problematic conduct outside of the three largest Knoxville stores. In November 2012, PCG audited Food City # 601 in Johnson City and reported the following, in addition to various record-keeping deficiencies:
 - After a review of the invoices for CIII to CV from May 2012 through November 2012 there were 15 invoices that were not dated [sic] by an authorized person.
 - Per the DEA Audit Report ... [t]here were 555 prescriptions were filled for controlled substances associated with pain management. These controlled substances include Oxycodone 15mg (37), Oxycodone 30mg (23), Hydrocodone 10-325mg (58), Alprazolam 2mg (28), Hydrocodone 10-500mg (255), Hydrocodone 5-500mg (154). These quantities reflect a 22% of controlled substances being filled for drugs typically associated with pain management and are highly abused. According to Will Bevins the Hydrocodone 10-500mg and the Hydrocodone 5-500mg are more likely to be diverted and abused in this region. In counting only the quantities for Hydrocodone 10-500mg and 5-500mg it resulted in 16% of these drugs being filled.
 - The pharmacy currently does not have CCTV cameras monitoring the activities within the pharmacy[.]
 - During the duration of the inspection the entry door to the pharmacy was open. This could pose a possible risk for pharmacy personnel and theft.

- Per the DEA Report from 6/5/2012 to 11/15/2012 there are several doctors who prescribed a higher than 20% of controlled substances compared to other drugs prescribed. Dr Dana Allen wrote 153 prescriptions and 89 of them were for controlled substances or 58%. Dr Sherry Barrett wrote 245 prescriptions and 66 of them were for controlled substances or 27%. Dr William Clever wrote 516 prescriptions and 145 were for controlled substance or 28%. Dr Debra Uncapher wrote 251 prescriptions and 107 were for controlled substances or 43%.
- After a review of the DEA Audit Report from 6/5/2012 to 11/15/2012 it revealed that PA Dana Allen consistently prescribed a cocktail combination of controlled substances to all the patients who have filled prescriptions at this location. After [RpH] queried the PMP on 2 individuals with the same last name it was found that both of these patients utilized multiple same addresses when trying to fill a prescription; however, the Food City system indicated a different address for each of these two patients. The PMP query also indicated that these patients in particular had prescriptions written by PA Allen for controlled substances that were filled at several different pharmacies in the area. 179
- 203. Food City's supply problems persisted. On December 6, 2012, Food City # 694's pharmacist informed the Company's executives that the store had not received the Oxy 30 it ordered because it had already hit its limit, despite only being six days into the month: 180

From: Pharmacy Rx694 [rx694@FoodCity.com]

Sent: 12/6/2012 4:26:08 PM

To: Tom Geoghagan [geoghagt@FoodCity.com]; Ken Slagle [slaglek@FoodCity.com]

CC: Mickey Blazer [blazermi@FoodCity.com]

Subject: oxycodone

Hey Guys, I just unloaded my mckesson cll order and I did not receive the oxycodone 30 I ordered. I have ordered 1 box of 15s and 1 box of 30s so far this month and they denied them because it says that I have already met my monthly allotment. This is going to be a problem if I cannot order anymore for the rest of the month as we are already low on the stock of 30s when we ordered them. Please help!

Rachel, 694

¹⁷⁹ # 158.1 (emphasis added).

¹⁸⁰ TNAG-FC-CUST00018036.

204. The next day, on December 7, 2012, Mickey Blazer received a message from McKesson that it was not filling an alprazolam order from # 682 and that it had increased the threshold for Oxy 30 for # 616 but not before the order was placed. According to the e-mail, # 616 had ordered 2,400 doses of Oxy 30 on the 5th, followed by an order for an additional 4,800 doses of Oxy 30 the next day.¹⁸¹

From: Martindale, Karen [mailto:Karen.Martindale@McKesson.com]

Sent: Friday, December 07, 2012 10:20 AM

To: Mickey Blazer

Cc: McKenna, Ned; Joslyn, Denise; de Gutierrez-Mahoney, Bill

Subject: KVAT Controlled Omits

Hi Mickey,

I wanted to give you a heads up on 2 stores that had controlled omits today. Below are the stores and items omitted and the reason for the omits. For store 616, they did receive 24x100 Oxycod 30mg yesterday for an order placed Wednesday. As indicated below, the order they placed yesterday came in before Bill made a threshold increase in the system. For store 682, they're threshold for Alprazolam is 8000 doses per month. If there is a need to increase their threshold, let me know. I'm filling in for Denise today so feel free to call me if you have any questions.

Customer #	Customer Name	Material #	Material Des.	Omit Code	Qty Ord.
75851	FOOD CITY PHCY #616	2124527	OXYCOD HCL TAB 30MG	V	48
450086	FOOD CITY PHCY #682	2146538	ALPRAZOL TAB 1MG CAR	V	2.4

Oxycodone threshold for #616 was addressed yesterday. They ordered before change; have plenty of capacity now.

Alprazolam issue for #682—they averaged less than 7K doses/month in three month data period; ordered 24X500=12000 last night.

Thanks,

205. Food City's Mickey Blazer was furious and sent the following response including to senior executives at McKesson who were not part of the original e-mail thread: 182

¹⁸¹ TNAG-FC-CUST00018037.

¹⁸² TNAG-FC-CUST00018037.

From: Mickey Blazer [/O=FOOD CITY/OU=FOODCITY/CN=RECIPIENTS/CN=BLAZERMI] Sent 12/7/2012 3:49:26 PM 'McKenna, Ned (Ned,McKenna@McKesson.com)' [Ned,McKenna@McKesson.com]; 'Joslyn, Denise To: (Denise Joslyn@McKesson.com)* [Denise.Joslyn@McKesson.com] Subject FW: KVAT Controlled Omits Unbelievable!!!! #616 ????????????? #616 will be out of product over the week end. I know you asked me to not involve anyone else but you and Denise so that issues can be resolved in a more timely manner but I don't seem to be making any progress this way. The #682 ALPRAZOL TAB 1MG CAR was a miss key but the threshold may need to be reset so they can get the 4 they need for Monday. Mickey Blazer Director of Pharmacy Operations K-VA-T Food Stores, INC 201 Trigg Street P.O. Bax 1158 Abingdon, VA. 24212-1158

206. In response, McKesson "arranged a special delivery to store 616 for the Oxycodone" and told Food City that Food City # 682 still had "6000 doses [of Alprazolam] available on their thresholds so if they key an order under that amount it will get filled for Monday delivery," as shown below:

Martindale, Karen [Karen.Martindale@McKesson.com] 12/7/2012 4:40:18 PM Sent Martindale, Karen (Karen Martindale@McKesson.com); Mickey Blazer | blazermi@FoodCity.com | CC McKerna, Ned [Ned.McKerna@McKesson.com]; Joslyn, Denise [Denise.Joslyn@McKesson.com]; de Gutierrez-Mahoney, Bill [Bill.Mahoney@McKesson.com] **RE: KVAT Controlled Omits** Subject Mickey, Per my voicemail, I've arranged a special delivery to store 616 for the Oxycodone. Store will receive later today. I spoke with Ellen (pharmacist) at the store. She has keyed her order and the DC is picking it now. As for store 682, Alprazolam, they still have 6000 doses available on their threshold so if they key an order under that amount it will get filled for a Monday delivery. Thanks, Karen

(276) 623-5100 Ext: 5737 blazermi@foodcity.com

¹⁸³ TNAG-FC-CUST00018029.

Associates, and in particular Dr. Frank McNiel, because so much of its pharmacy business—especially at # 674, # 694, and # 616—was tied to the clinic. On December 21, 2012 Food City Pharmacy Operations Manager Ken Slagle forwarded a message from Julie Varnum, the pharmacist at # 674, to Mickey Blazer expressing uncertainty about the future of Bearden. The e-mails stated: 184

From: Ken Slagle [slaglek@FoodCity.com] 12/21/2012 5:24:12 PM Sent: Mickey Blazer [blazermi@FoodCity.com] To: CC: Randy Williams [williamsr@FoodCity.com] Subject: FW: BHCA Not sure how this will work out. Ken From: Pharmacy Rx674 Sent: Friday, December 21, 2012 12:01 PM To: Tom Geoghagan; Ken Slagle Subject: BHCA FYI.... Dr. Barry Roseman will be the new medical director at Bearden HealthCare Associates. He is starting Wednesday, December 26, 2012. Dr. Frank McNiel is "retiring". Thanks, Julie Rx674

208. But Food City's Ken Slagle had other problems besides uncertainty at Bearden or the new medical director with pill mill ties. On December 26, 2012, he sent an e-mail, which is shown below, to the Knox pharmacy division, as well as store managers and district managers in the Knoxville division, that outlined significant compliance problems, including 12 stores that had not filed their Schedule II controlled substance invoices properly, 2 stores that had "significant discrepancies when we counted their CII safes," and "2 stores were not performing CII inventories monthly!"

¹⁸⁴ TNAG-FC-CUST00122922.

From: Ken Stagle

Lent: Wednesday, December 26, 2012 3:16 PM

To: <Knox Pharmacy Division>; <KnoxDiv Store Mgrs>
Cc: <KnoxDiv District Mgrs>; John Jones; Jody Helms

Subject: 2012 Rx Checklists for 2nd half

Follow Up Flag: Follow up Flag Status: Flagged

To all:

Tom and I have now completed the 2nd half checklists for the Knoxville Division for 2012. Below is a brief recap of the opportunities uncovered:



15 stores had incomplete temp logs - Equipment needs to be checked and recorded 3x a day!

13 stores had not completed their DMEPOS quarterly self-audits!

12 stores had not filed their Cli Invoices properly - Physically separated by month, placed in order, each drug circled/checked and each page signed.

istores had an excessive amount of Return to Stocks as recorded from the Enterprise system.

2 Fibres had rotation issues.

2 stores had dress code violations.



2 stores were not up to date on their Technician Registries

2 states had significant discrepancies when we counted their CII safes.

2 stores were not performing Cit inventories monthly!

Pext step is to review the problem areas of the 2^{nd} half-checklists and compare them with the 1^{nt} half-checklists. If the having repeat issues at the same store, we will need to get some involvement from the store management team asist in follow-up.

have made significant headway in our pharmacies, but we want to make sure all issues are addressed in a ressive manner. Our goal is for you to feel totally confident that if you have a state inspection, insurance audit, there will be no areas of concern.

n Slagle

macy Operations Manages ville Division sk@foodcity.com Lonas Drive Suite 201 ville, TN 37909 a: 865-584-7061 Ext. 520 365-588-2381 865-806-3156

- 209. On February 4, 2013, the PIC at Food City # 674 told Ken Slagle and Tom Geoghagan that she had heard that due to the city's dire opioid crisis Walgreens had adopted a new policy specifically for its Knoxville stores in which they could only fill 120 pain medication pills at a time for patients with insurance and only 60 pills for individuals paying in cash. Mr. Slagle responded that he had heard about Walgreens' local policy and that it applied to oxycodone, hydromorphone, and methadone. Mr. Slagle then forwarded the exchange to Mickey Blazer and noted, "They plan to lose a substantial amount of scripts." With its eye ever on sales, Food City declined to adopt the measures.
- 210. As testament to the scale and obviousness of Food City's diversion problem, on February 11, 2013, unbeknownst to Food City, a senior compliance employee at Actavis, an Oxy 30 manufacturer, told his counterpart at Amerisource that "[w]e were very pleased to hear [that] you no longer distribute the before mentioned Actavis products [Oxy 15 and Oxy 30] to the Food City pharmacy chain located in Knoxville, TN[.]" 186
- 211. Problematic audit findings continued in 2013 and in stores other than # 674, # 694, and # 616, which is unsurprising because Food City rarely, if ever, disciplined pharmacists following receipt of negative PCG audits and failed to provide training on red flags for diversion or abuse until 2014. This was despite the fact that these problems spanned across multiple stores, extended for years, and contributed to consequences such as armed robberies; even issues as basic as leaving the safes where Schedule II drugs were stored unsecured were given a pass.
- 212. On March 12, 2013, PCG audited Pharmacy # 604 in Newport and reported the following, in addition to various record-keeping deficiencies:

¹⁸⁵ TNAG-FC-CUST00010484.

¹⁸⁶ ACQUIRED_ACTAVIS_1675185.

- A set of **CII lock up keys were found unsecured** at the pharmacist's work station. The pharmacist was not present at the counter on **multiple** occasions leaving them unattended.
- [PIC] stated that a back fill count is completed when a CII is dispensed, but not done when received.
- The perpetual inventory sheets do not contain any documentation showing monthly audits are being conducted.
- [PIC] stated that the patients he fills for are not associated with pain management clinics or physicians. 95-99% of the prescriptions are prescribed by family practitioners.
- ... The total number of controlled substance prescriptions filled was 6,854. The following prescribers owned the majority of the prescription [sic] written. Thomas Conway 301 @ 4.3%, Michael Hood 136 @ 1.9% and David Kickliter 179 @ 2.6%.
- Based off of the McKesson shipment report supplied with the time frame of 12/1/12 through 3/11, controlled substance purchases associated with pain management factor at 52% of the total amount of controlled substance purchased.
- [Since 12/1/12, **42**% of prescriptions filled were for controlled substances.]
- [Cash payments were 12%]¹⁸⁷
- 213. On March 13, 2013, PCG audited Pharmacy # 630 in Dandridge and reported that, in addition to various record-keeping deficiencies, such as incorrect dates on at least 15 prescriptions for controlled substances, the pharmacy was filling prescriptions from Bearden Healthcare and Advance Pain Therapeutic, and 45% of the controlled substance purchases were associated with pain management, over double the national average. ¹⁸⁸
- 214. On March 22, 2012, PCG audited Pharmacy # 617 in Bristol and reported the following, in addition to various record-keeping deficiencies:

¹⁸⁷ # 96.1 (emphasis added).

¹⁸⁸ # 90.1.

- Keys were not kept in pharmacist's possession. Keys were left near the back computer for the technician to use.
- [PIC] reported counts are completed upon dispense to patients. *She stated counts are not done upon receipt of shipments.*
- [Lyrica 200mg variance was -22% and Diazepam [a benzodiazepine] variance was +38%.]
- [At least a dozen prescriptions had the date of issuance recorded incorrectly.]
- [PIC] reported the pharmacists rarely fill out of state scripts. *She reported several prescriptions come from the Knoxville, Tennessee area* [which is not in a surrounding county to Sullivan] These have their filling history reviewed prior to issuing a prescription.
- [PIC] stated that the pharmacy fills prescriptions for approximately 15 pain management centers in the area. 189
- 215. Food City and its executives continued to receive updates about DEA enforcement actions against large retail pharmacy chains. On April 4, 2013, the pharmacist for Food City # 664 in Kingsport forwarded an e-mail to Food City pharmacy managers containing a DEA press release titled "CVS TO PAY \$11 MILLION TO SETTLE CIVIL PENALTY CLAIMS INVOLVING VIOLATIONS OF THE CONTROLLED SUBSTANCES ACT[,]" which resolved CSA recordkeeping violations, saying "Here is another reason for us to clean up our MD files....." 190

¹⁸⁹ # 97.1 (emphasis added).

¹⁹⁰ TNAG-FC-CUST00013974 (excerpt of e-mail thread shown).

	Pharmacy Rx664 [rx664@FoodCity.com]
Sent:	4/4/2013 1:23:18 PM
To:	Will Bevins [bevinsw@FoodCity.com]; Wick Hayton [Haytonw@FoodCity.com]
CC	Mickey Blazer (blazermi@FoodCity.com)
Subject:	FW: CVS TO PAY \$11 MILLION TO SETTLE CIVIL PENALTY CLAIMS INVOLVING VIOLATIONS OF CONTROLLED SUBSTANCES ACT
Here is an	other reason for us to clean up our MD tiles.
Loni	
Sent: We To: Pharm	ni Garca [mailto:lonilg@charter.net] dnesday, April 03, 2013 10:03 PM lacy Rx664 PW: CYS TO PAY \$11 MILLION TO SETTLE CIVIL PENALTY CLAIMS INVOLVING VIOLATIONS OF CONTROLLED LES ACT
Sent: We	5. Drug Enforcement Administration [mailto:dea@govdelivery.com] dnesday, April 03, 2013 5:16 PM
To: lonita Subject:	dnescay. April 03, 2013 5:16 PM @alumni.unc.edu CVS TO PAY \$11 MILLION TO SETTLE CIVIL PENALTY CLAIMS INVOLVING VIOLATIONS OF CONTROLLED
To: lonita Subject:	dnesday, April 03, 2013 5:16 PM @elumni, unc., edu CVS TO PAY \$11 MILLION TO SETTLE CIVIL PENALTY CLAIMS INVOLVING VIOLATIONS OF CONTROLLED TES ACT
To: lonita Subject:	dnesday, Adril 03, 2013 5:16 PM @alumni, unc., edu CVS TO PAY \$11 MILLION TO SETTLE CIVIL PENALTY CLAIMS INVOLVING VIOLATIONS OF CONTROLLED CES ACT FOR IMMEDIATE RELEASE
To: lonita Subject:	dnesday, April 03, 2013 5:16 PM @elumni, unc., edu CVS TO PAY \$11 MILLION TO SETTLE CIVIL PENALTY CLAIMS INVOLVING VIOLATIONS OF CONTROLLED TES ACT
To: lonita	dnesday, Adril 03, 2013 5:16 PM @alumni, unc., edu CVS TO PAY \$11 MILLION TO SETTLE CIVIL PENALTY CLAIMS INVOLVING VIOLATIONS OF CONTROLLED CES ACT FOR IMMEDIATE RELEASE
ro: lonita Subject:	Inescay, April 03, 2013 5:16 PM @alumni, unc.edu VS TO PAY \$11 MILLION TO SETTLE CIVIL PENALTY CLAIMS INVOLVING VIOLATIONS OF CONTROLLED ES ACT FOR IMMEDIATE RELEASE Contact: DEA Public Affairs
To: lonita Subject:	Inescay, April 03, 2013 5:16 PM @alumi, unc.edu CVS TO PAY \$11 MILLION TO SETTLE CIVIL PENALTY CLAIMS INVOLVING VIOLATIONS OF CONTROLLED ES ACT FOR IMMEDIATE RELEASE Contact: DEA Public Affairs (202) 307-7977
To: lonita Subject:	diesosy, April 03, 2013 5:16 PM @alumi, unc., edu CVS TO PAY \$11 MILLION TO SETTLE CIVIL PENALTY CLAIMS INVOLVING VIOLATIONS OF CONTROLLED TES ACT FOR IMMEDIATE RELEASE Contact: DEA Public Affairs (202) 307-7977 Press Release

216. Food City had direct knowledge of clear, ongoing indicators of diversion and abuse at its other pharmacy locations in Knoxville besides # 674, # 694, and # 616. On May 23, 2013, the pharmacist at Food City # 682, located at 7608 Mountain Grove Drive in Knoxville, sent Mickey Blazer 2 e-mails stating that she had serious concerns about some of its pain customers. At 11:00 p.m. ET, she sent this message:

From: Pharmacy Rx682 [rx682@FoodCity.com]

Sent: 5/23/2013 11:00:05 PM

To: Mickey Blazer [blazermi@FoodCity.com]

Subject: RE: Control Substance Monitoring Data Base Requirements

I am concerned about the safety of pour pharmacy. The people we say no to will not leave. My techs have noticed they are pushier. One man was hanging on the swinging gate when I came back from the bathroom. I had said no the insurance would not cover etc. and he had come back in with na guy wearing a gang hat whom I had never seen. I ask him what's going on you are too close to the door. This was way before the news about the shooting. I just wanted you to know I am concerned. My techs are somewhat naïve.

Sixteen minutes later she sent another e-mail to Food City's Director of Pharmacy Operations that stated:

From: Pharmacy Rx682 [rx682@FoodCity.com]

Sent: 5/23/2013 11:16:35 PM

To: Mickey Blazer [blazermi@FoodCity.com]

Subject: RE: Control Substance Monitoring Data Base Requirements

Dear Mr. Blazer,

I just wanted to send you a note about some of our pain customer and the problems we are having with some of them. If there is a problem or question about their Rx. They refuse to take no we cannot fill your prescription as an answer. They hang around the pharmacy or come back repeatedly during the day. They take up our time and this prevents us from taking care of our regular customer in a timely fashion. Some of our regular monthly customer have left and gone to other pharmacies because of our "problem pain customers". Sometimes the pain customers will hang around the store and we have had to have someone walk us to our cars on several occasions. We would appreciate any help you can give us regarding this problem and our safety.

217. But Mickey Blazer and Food City were about to have larger problems. McKesson, facing a DEA probe of its own, had mounting concerns about the sales of oxycodone at Food City # 674, # 694, and # 616 and planned to once again cut off shipments of oxycodone and other controlled substances to those stores on or around June 19, 2013. A subsequent analysis of this time period by Topco concluded, among other things, that McKesson already had high thresholds

¹⁹¹ TC000571.

to begin with and that Food City's "Oxy usage was way out of line compared to other [Topco] member typical thresholds."

Observations:

1. In June 2013, it looks like McKesson may have already had high thresholds on the Oxy since they did not create alerts at 2 of the 3 stores before shutdown.

2. Their Oxy usage was way out of line compared to other member typical thresholds.

- 218. On June 20, 2013, Topco, at Food City's behest, contacted McKesson to get more information about the oxycodone stoppage. The day before, June 19, Topco, again on behalf of and with Food City's knowledge, reached out to Anda, an Oxy 30 manufacturer and distributor, to try to obtain a backup supply of Oxy 30 for the three stores. 192
- 219. An Anda sales executive responded to Topco on June 20, 2013, 193 stating, among other things:

KVAT Food City was actually the one chain pharmacy I was referring to yesterday as one of the only chains we have turned down. It basically comes down to our compliance team had great concerns regarding their product mix as having the highest top dispensed problem items that we look for. Our compliance director actually said it was the highest quantities he had seen from any Anda customer (and he has been here for like 15 years)[.]

¹⁹² TC0321575-76; TC0321560.

¹⁹³ TC0321575 (emphasis added).

From: Michelle K Fleischhauer [mailto:Michelle.Fleischhauer@Andanet.com]

Sent: Thursday, June 20, 2013 2:14 PM

To: Fan, William

Subject: RE: Control Orders



Hi Will, sorry I got in a bit late today and have been in back to back meetings since but I will call you in a bit. KVAT Food City was actually the one chain pharmacy I was referring to yesterday as one of the only chains we have turned down. It basically comes down to our compliance team had great concerns regarding their product mix as having the highest top dispensed problem items that we look for. Our compliance director actually said it was the highest quantities he had seen from any Anda customer (and he has been here for like 15 years)

Having said that, they order from us regardless and have been for over a year. This is definitely something we can re-visit especially now that we are rolling this program out.

I will call you in a bit

Thanks

Michelle Fleischhauer

Senior National Account Manager

220. By the next day, McKesson had already agreed to ship everything *but* the Oxy 30 to the three Food City stores. Meanwhile, as shown in the e-mail below, Topco asked its former distributor, Amerisource, to supply Oxy 30 to the three stores while it also continued to pursue Anda.

From: Maki, Curt [/O=SKOKIE, ILLINOIS/OU=SKOKIE/CN=RECIPIENTS/CN=CURT MAKI]

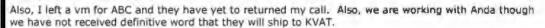
Sent: 6/21/2013 1:23:48 PM

To: Picarillo, Dave [dpicarillo@topsourcellc.com]

Subject: FW: KVAT

This message has been archived. View the original item

See note below to Sam.



Curt

From: Maki, Curt

Sent: Friday, June 21, 2013 1:07 PM

To: 'Thompson, Sam' (Sam.Thompson@McKesson.com)

Subject: KVAT

Sam,

I just spoke to Randy and he said that Jack called him to say that McKesson will resume shipping all but 30mg.

As we discussed we would really like to have this shipment arrive on Saturday. Please let me know if that is not possible and why.

And does the store need to transmit new orders and who is going to work with KVAT to get it done?

Curt

Curtis Makl

Vice President Pharmacy

Topco Associates LLC

221. The same day, Topco received word that Amerisource had "no interest in serving those three KVAT stores[,]" (though they expressed "interest[] in pursuing a broader arrangement") and, with increasing desperation, Topco continued to pursue Anda for more oxycodone for Food City. 194

¹⁹⁴ TC321625.

Picarillo, Dave [/O=SKOKIE, ILLINOIS/OU=SKOKIE/CN=RECIPIENTS/CN=DPICARI] Sent: 6/21/2013 6:11:01 PM Maki, Curt [cmaki@topco.com] Ta: Subject: This message has been archived. View the original item Anda? From: Maki, Curt Sent: Friday, June 21, 2013 03:48 PM To: Picarillo, Dave Subject: KVAT Dave. I just got off the line with AmerisourceBergen and they have no interest in serving those three KVAT stores. They said they may be interested in pursuing a broader arrangement with KVAT but I said that is not an option. Curt Curtis Maki Vice President Pharmacy Topco Associates LLC

- 222. By June 25, 2013, Topco, on Food City's behalf and with its knowledge, had gotten Anda's compliance committee to at least consider supplying the three stores so Mickey Blazer then sent data to Anda as part of the committee's review. 195
- 223. But Topco's own analysis, sent internally the same day, showed why Food City continued to be such a risky prospect. Topco's analysis, which was sent to Randy Skoda, its President and CEO, stated, "[W]hile the 3 store totals are down about 50% over last year, it appears the store 674 may have taken up the slack as their usage increased by 13%." 196
- 224. Anda was hesitant and, two days later, requested additional information. Food City and its executives were becoming more and more anxious. At the same time it was trying to secure

¹⁹⁵ TC0321857; TC0321774.

¹⁹⁶ TC0348009 (emphasis added).

Anda as a secondary Oxy 30 distributor for the Big 3, Food City tried its hand with yet a third distributor, Harvard Drug Group. In an e-mail to onboard Harvard as a new vendor, Food City CEO and President Steve Smith expressed the urgency in four simple words: 197

From: Steve Smith [/O=FOOD CITY/OU=FOODCITY/CN=RECIPIENTS/CN=SMITHS]

Sent: 6/27/2013 7:46:23 PM

To: Michael Lockard [lockardm@FoodCity.com]
CC: Mickey Blazer [blazermi@FoodCity.com]

Subject: FW: New Vendor Attachments: Credit Application.pdf

We need this today. Steve

225. During Food City's ongoing Oxy 30 supply crisis, PCG continue to audit its pharmacies, the results of which only further underscored why distributors were hesitant to open themselves up to such clear liability. Food City # 674 was audited by PCG on June 27, 2013, the same day Mr. Smith's email was sent, and the investigator noted the following:

- The total number of scripts listed for "pain management" was 1346 compared to the total number of scripts of 2914. The average came to 46%.
- Julie stated that the patients that she fills the majority of pain management scripts for Bearden Healthcare.
- ... The following prescribers owned the majority of the prescriptions written. James Santella had 651 scripts or 22.40%; Teodora Neagu had 336 scripts or 12.30%; and Donald Douglas had 216 scripts or 7.40% [All of whom were at Bearden Health Care Associates, totaling 42.1% for the clinic.]
- The pharmacy prescribes 27% of prescriptions that would be considered pain management
- Julie stated that she would consider James Santella as being a prescriber who has "unusual" or excessive prescribing habits.

¹⁹⁷ TNAG-FC-CUST00026298.

Prescriptions filled as controlled substances totaled 2914 of the [7499] total scripts, or 38%. 198

226. The next morning Food City CEO Steve Smith was still trying to convince McKesson to change its mind about the three stores. Mr. Smith sent an e-mail to Topco's President and CEO the morning of June 28, 2013 to express his frustration about being unable to schedule a meeting with a "decision maker" from McKesson and wanted the number for the CEO: 199

From: Steve Smith [/O=FOOD CITY/OU=FOODCITY/CN=RECIPIENTS/CN=SMITHS]

Sent: 6/28/2013 12:52:24 PM To: rskoda@topco.com

CC: Mickey Blazer [blazermi@FoodCity.com]; Charlle Fugate [fugatec@FoodCity.com]

Subject: McKesson

Randy, I have still had NO luck with getting a meeting scheduled for McKesson to come and talk. I have talked to Mark Walehirk both Wen, and Thur, with promises that he would schedule someone in the regulatory and legal departments to come and talk. I have explained to him that this is fine but we need a decision maker on that trip, I was promised an email last night but did not receive one with potential dates for a meeting. I will give him to noon but feel I need to try my last resort, a call to the CEO. Can you relay his number to me. Steve

227. Topco continued to work on behalf of Food City to convince Anda to supply Oxy 30 to Food City's three highest volume stores. In an internal Topco e-mail dated June 28, 2013, Dave Picarillo, Senior Vice President at Topco, said the following about the efforts to secure Oxy 30 supply from Anda:

¹⁹⁸ # 99.1 (emphasis added).

¹⁹⁹ TNAG-FC-CUST00092408; TC321840.

From: Picarillo, Dave

Sent: Friday, June 28, 2013 11:20 AM

To: Maki, Curt

Subject: RE: Anda Update

We need to put greater pressure. I am not getting the sense of URGENCY from these notes. WHEN WILL

WE GET AN ANSWER

David Picarillo

from:

Senior Vice President - TopSource IIc

228. In response, another Topco executive stressed the urgency of the situation with Anda and his understanding of the importance of the task, stating:

Maki, Curt [/O=SKOKIE, ILLINOIS/OU=SKOKIE/CN=RECIPIENTS/CN=CURT MAKI]

Sent: 6/28/2013 11:31:27 AM

To Picarillo, Dave (dpicarillo@topsourcellc.com)

Subject: RE: Anda Update

This message has been archived. View the original item

I had called Bill Versosky the VP some time ago and have not heard back from him. I again stressed the urgency of getting product to KVAT. Unfortunately we are up against a situation where Anda is getting swamped with requests. I also called Michelle and left a vm and stressed the urgency to move this along and give me a call. I also just talked to Mickey and confirmed that Anda needs additional numbers.

I will stay on top of this.

229. Later that day, Topco and Food City upped their joint effort to obtain Oxy 30 for the three Knoxville stores. In addition to asking Harvard, Anda, and Amerisource, Topco also reached out to a subsidiary of Cardinal Health, one of the nation's three largest distributors. But this was a dead end because the subsidiary said it would take up to 90 days to make a decision and might be reluctant because "[C]ardinal was hit real hard by the DEA several years ago." 200

²⁰⁰ TC321876.

230. Still later that same Friday evening, June 28, 2013, Food City thought it had solved the Oxy 30 supply crisis for # 674 and the other two stores. Mickey Blazer e-mailed Topco shortly after 9 p.m. ET, copying Steve Smith, to say that Food City had secured an arrangement with Harvard and was still waiting to hear back from Anda: ²⁰¹

From: Mickey Blazer [blazermi@FoodCity.com]

Sent: 6/28/2013 9:08:57 PM

To: Curt Maki (CMaki@topco.com) [CMaki@topco.com]; Will Fann (wfan@topco.com) [wfan@topco.com]

CC: Steve Smith [smiths@FoodCity.com]; Jesse Lewis [Lewisj@FoodCity.com]

Subject: KVAT Pharmacy

Curt and Will,

I wanted to give you a quick update as to where I am with our current situation.

thave submitted the latest greatest data requested by Anda to Robert Brown of their Compliance Department. I got a message back that he was out of the Office until July 9th, I copied Michelle, so hopefully if there is someone else she can get to review the Data she will forward it on.

I have secured the arrangement with Harvard and should be able to get the first control order on Tuesday. I will keep you posted as we proceed with secondary suppliers.

Mickey Blazer
Director of Pharmacy Operations
K-VA-T Food Stores, ENC
201 Trigg Street
P.O. Gaz 1158
Abingson, VA. 24212-1158
(276) 623-5100 Ext-5737

(276) 623-3100 955:373 blazermi@foodcity.com

231. By this time, CEO Steve Smith, who remained active in these discussions, was becoming increasingly upset with McKesson for cutting off the supply of Oxy 30 to the Big 3 pharmacies. He e-mailed Topco's President at 10:35 p.m. ET that Friday night, copying Mickey Blazer, and expressed his frustration with his contacts at McKesson while also stating, "On a positive note *Mickey says Harvard will ship controls to us next Tuesday*. Still no answer from Anda? When this is over I will need some control drugs myself!! Steve." 202

²⁰¹ TNAG-FC-CUST00176227.

²⁰² TNAG-FC-CUST00092407 (emphasis added).

From: Steve Smith [/O=FOOD CITY/OU=FOODCITY/CN=RECIPIENTS/CN=SMITHS]

Sent: 6/28/2013 10:35:36 PM To: rskoda@topco.com

CC: Mickey Blazer [blazermi@FoodCity.com]

Subject: FW: Mckesson

I talked to Diane, Hammergrens Admin told her who I was and requested to speak to him. Was told he was out but she would relay my message to him. Told her I had attempted to resolve my issue with Mark walchirk but wasn't getting return calls. She ask if Mark could help and I told her he hadn't so far!! This message is what I got at 426 EDT. Damnest thing I've ever seen. On a positive note Mickey says Harvard will ship controls to us next Tuesday. Still no answer from Anda? When this is over I will need some control drugs myself!! Steve

Mr. Skoda responded just to Mr. Smith at 11:12 p.m. ET that evening and echoed his frustration with McKesson, stating:²⁰³

From: Skoda, Randy [rskoda@topco.com]

Sent: 6/28/2013 11:12:21 PM

To Steve Smith [smiths@FoodCity.com]

Subject: Re: Mckesson

Good news on Harvard! Thing are moving forward, albeit way too slow, on Anda. Hopefully we will at least have options soon.

On MCK, agreed, never seen anything like this in my career. I get if they have DEA issues, but the communications and how to deal with customers is the worst I've EVER seen. I haven't heard from anyone at MCK since Tuesday....head in the sand.

Unbelievable.

232. Separate from this discussion, Food City's Mickey Blazer sent another e-mail late that evening at 10:39 p.m. ET to Food City CEO Steve Smith, copying other Food City executives and Randy Skoda, complaining about McKesson's treatment of Food City. Among other things, Mr. Blazer stated "Sam Thompson [a McKesson employee] is the fellow that Curt [Maki] and I met with in Denver and informed that I had 3 high volume control stores and wanted to make sure I would not have any issues after the conversion. He assured me that they would take care of us

²⁰³ TNAG-FC-CUST00027598.

based off of our ordering history with ABC [Amerisource]. . . . I have a feeling that these are the two guys that told us last Friday that we could get everything but the Oxy 30's and got over rode."²⁰⁴

From: Mickey Blazer

Sent: Friday, June 28, 2013 10:39 PM

To: Steve Smith

Cc: Charlie Fugate; Jesse Lewis; 'Randy Skoda'

Subject: RE: McKesson meeting

Sam Thompson is the fellow that Curt and I met with in Denver and informed that I had 3 high volume control stores and I wanted to make sure I would not have any issues after the conversion. He assured me that they would take care of us based off of our ordering history with ABC. With that said, I don't have much confidence in him and I have not had any dealings with Jack Fragie. I have a feeling that these are the two guys that told us last Friday that we could get everything but the Oxy 30's and got over rode.

Mickey

233. The next day, on Saturday, June 29, 2013, Steve Smith responded to Mr. Blazer's e-mail and stated that he was going to talk with another contact at McKesson. In his response, Mr. Blazer referenced a previous incident with a McKesson sales executive in which Mr. Blazer "went off on them for the limited thresholds the [sic] set after they told me they would base all my Stores on the ordering history from ABC. 'That was a joke'!!" 205

²⁰⁴ TNAG-FC-CUST00093245.

²⁰⁵ TNAG-FC-CUST00093245.

From: Mickey Blazer [blazermi@FoodCity.com]

Sent: 6/29/2013 2:00:13 PM

To: Steve Smith [smiths@FoodCity.com]

Subject: RE: McKesson meeting

Nope,

The only people from McKesson that has come to me is: Bill Mahoney and Ned McKinney.

Bill is their Compliance Officer that visited #616, #674, #694.

Ned is a VP of Sales they sent to meet me in Abingdon after I went off on them for the limited thresholds the set after they told me they would base all my Stores on the ordering history from ABC. "That was a joke"!!

I took him to visit the two Bristol Stores.

Mickey Blazer

Director of Charmacy Operations

X-VAT Food Stores, DVC.

234. Later that same Saturday night at 8:44 p.m. ET, Steve Smith expressed more frustration with McKesson's efforts and with the junior status of the McKesson representatives who were planning to meet with Food City the next week in another e-mail to Randy Skoda. Among other things, Mr. Smith stated:

I told [the McKesson contact] if he would read the report his Chief Compliance Officer for the Southeast, Bill Mahoney wrote in November the only thing that had changed was we incorporated some of their suggestions and our Control volume was down. They are going through the motions and in my opinion will not turn us back on. I did tell him that every day that went by his liabilities got larger because of the lost business. I also explain to him my position at Topco when we made the decision to go with McKesson and my concern since they had snubbed their noses at Topco the first time around. I also told him we make the change at great expense based on his companies [sic] FULL knowledge of our business. ²⁰⁶

²⁰⁶ TNAG-FC-CUST00085710 (emphasis added).

From: Steve Smith [smiths@FoodCity.com]

Sent: 6/29/2013 8:44:05 PM

To: 'Skoda, Randy' [rskoda@topco.com]

CC: Jesse Lewis [Lewis]@FoodCity.com]; Charlie Fugate (fugatec@FoodCity.com); Mickey Blazer

[blazermi@FoodClty.com]

Subject: RE: McKesson meeting

He said they were complying with my request for a meeting and they would be gathering information to make a decision with. I told him if he would read the report his Chief Compliance Officer for the Southeast, Bill Mahoney wrote in November the only thing that had changed was we incorporated some of their suggestions and our Control volume was down. They are going through the motions and in my opinion will not turn us back on. I did tell him that every day that went by his liabilities got larger because of the lost business. I also explain to him my position at Topco when we made the decision to go with McKesson and my concern since they had snubbed their nose at Topco the first time around. I also told him we make the change at great expense based on his companies FULL knowledge of our business.



235. By July 1, 2013, Topco and Food City were still trying to convince Anda to become a secondary distributor for the three stores. Topco prepared a letter to send to Anda and sent it to Food City for their input.²⁰⁷ Mickey Blazer, copying Steve Smith, responded with concerns about the letter, including that he did not want to make it appear as if Food City was only interested in obtaining Anda's controlled substance business for the three stores. The e-mail stated:

²⁰⁷ TC321915.

From: Mickey Blazer [mailto:blazermi@FoodCity.com] Sent: Monday, July 01, 2013 12:51 PM To: Picarillo, Dave Cc: Maki, Curt; Steve Smith; Charlie Fugate Subject: RE: draft letter to Anda re: Pharmacy Compliance with CS Distribution While much of the content of this letter is appropriate there are a couple of statements that I think would do us more harm with Anda than good. Parts of the letter that concern me are displayed in red. K-VA-T has asked that we communicate with Anda, Inc. ("Anda") for purposes of establishing Anda as a distributor of controlled substances to its Food City locations #616, #674, and #694, all located in Knoxville, Tennessee (the "Knoxville Stores"). If I were Anda, I would not consider to just supply these 3 Stores with Control Substances as the letter indicates. We want them to open up our entire Chain to be able to order Controls along with the Legend Drugs we are already ordering. Let's not make it appear that we are only wanting them for a source of Control Substances. Because of my experience in this area, K-VA-T has asked that I assist them with establishing Anda as the source for wholesale distribution of controlled substances for K-VA-T's Knowille Stores. We have many more Stores in Knooville than these 3 and many more Stores in locations other than Knooville. in December of 2012, K-VA-T engaged Pharma Compliance Group ("PCG"), a third-party pharmacy compliance auditor formed and operated by former agents from the federal Drug Enforcement Agency ("DEA"), to complete a due-diligence investigation of its Knaxville Stores. Following the deep-dive review of the Knaxville Stores, PCG submitted to K-VA-T its Executive Summary and Findings and Recommendations related to each Knoxville Store (the "PCG Report"). This Statement makes it appear that we did not engage "PCG" until November of 2012, when in fact we had engaged them in 2011. A "Deep Dive" Audit was performed in November 2012 which was the second "Deep Dive" Audit. That's why the Audit states that KVAT Has made significant progress in lowering the number of Controls being dispensed at these 3 locations. Again, I am fine with furnishing Anda a letter from Kevin on our behalf but it needs to be pertinent to what we are wanting to accomplish as well as factual.

[page break]

Can I get a final copy of what Kevin set McKesson?

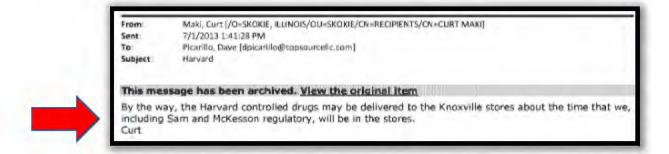
Thanks,

Mickey Glazer

Orienter of Phannecy Operations
X-V/A-T Food Stores, IMC

236. Meanwhile, Topco worried internally that the controlled substances it was going to receive from Harvard would be delivered during the exact time that Topco, Food City, and

McKesson regulatory would be conducting a site visit to the three stores, as shown below in an email sent the same day:²⁰⁸



237. On July 2, 2013, Food City, Topco, and McKesson met in Knoxville to discuss McKesson's refusal to deliver Oxy 30 to the 3 Knoxville pharmacies. Food City attendees included Steve Smith, Jesse Lewis (COO and Senior Vice President), Mickey Blazer, John Jones (Executive Vice President of the Knoxville Division), and Charlie Fugate (Food City's General Counsel). Topco's Vice President for Pharmacy, Curt Maki, attended on its behalf. McKesson attendees included Sam Thompson and Joe Lumpkin. And at least some representatives from the three companies also conducted a site visit to Pharmacy # 674.

238. McKesson did not provide any immediate answers for Food City or Topco at the July 2, 2013 meeting. The next day, Randy Skoda sent an e-mail to only Steve Smith, outlining his efforts to reach McKesson executives and an update on Topco's communication with Anda. Mr. Skoda stated:²⁰⁹

²⁰⁸ TC0321926.

²⁰⁹ TNAG-FC-CUST00092394.

----Original Message----

From: Skoda, Randy [rskoda@topco.com]

Sent: Wednesday, July 03, 2013 05:53 PM Eastern Standard Time

To: Steve Smith Subject: McKesson

Steve,

I reached out today, several times, to Jack Fragie (the EVP of Sales) to get an update as well as tell him we wanted to schedule a call with Mark. Dave Picarillo has also been working to get ahold of Don Walker to discuss yesterday's visit. Not surprisingly, neither of us received any return calls or notes. You just can't make this stuff up. I will continue to pursue them and keep you in the loop.

On a related note, we continue to push with Anda and the latest update we received this afternoon from their compliance officer was, and I quote "I understand the urgency. We are currently in the final stage of the review and are working diligently to get it finalized. I will follow up with you as soon as possible." Perhaps there's something in the water.

On an unrelated note, hopefully your business is picking up and will be strong through the long weekend. Hope you, Debbie and the girls have a happy and safe fourth of July.

Talk to you soon.

Randy

Early on the Fourth of July, Steve Smith replied and expressed his continued frustration with McKesson. Food City's CEO stated, among other things, "I sent Joe and Sam a Thank You for their time yesterday *OMG I'm tired of puckering*!"²¹⁰

From: Steve Smith [/O=FOOD CITY/OU=FOODCITY/CN=RECIPIENTS/CN=SMITHS]

Sent: 7/4/2013 12:24:54 AM

To: 'Skoda, Randy' [rskoda@topco.com]

Subject: RE: McKesson

I called Mark W and guess what Voice Mail! Surprise Surprise. I sent Joe and Sam a Thank You for their time yesterday OMG I'm tired of puckering! Hopefully soon we can move on one way or the other. Rain Rain and more rain here! Sales soft. Happy 4th to you guys.

²¹⁰ TNAG-FC-CUST00092394 (emphasis added).

239. The following day, Food City received two pieces of bad news: the in-person meeting had not changed McKesson's mind and Harvard did not even carry the oxycodone Food City needed. In an internal Topco e-mail, Randy Skoda stated:²¹¹

---- Original Message -----

From: Skoda, Randy

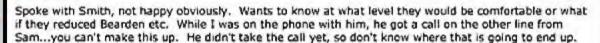
Sent: Friday, July 05, 2013 01:24 PM

To: Picarillo, Dave Cc: Broccolo, Andy

Subject: RE: Call when you have a chance

Dave,

Call me at 815-



Also on Harvard, turns out they don't carry any of the Oxy products so they are getting all controlled except the Oxy's.

Need to keep pushing on Anda, and I will fill you in on his request for next steps.

- 240. Notably, even at this moment, Food City was unwilling to cut off Bearden entirely. The Company wanted to negotiate and, at most, possibly "reduce Bearden." Not only was obtaining Oxy 30 for three of its 72 pharmacies such an integral part of Food City's business that it required the full attention of the Company's CEO, but it was so integral to Food City's business that it required the full attention of the President and CEO of Food City's buying group.
- 241. Topco and Food City were also worried about other, larger potential implications of McKesson's decision to cut off Oxy 30 and controlled substance shipments to the three stores. Later that day, Topco's Curt Maki, who had attended the Knoxville meeting a few days before summarized a call with McKesson in which he "also asked [McKesson] about any requirement

²¹¹ TC0322029.

that McKesson would have regarding notifying the DEA if McKesson took action toward one of their customers." ²¹²

From: Maki, Curt

Sent: Friday, July 05, 2013 03:19 PM

To: Picarillo, Dave Subject: KVAT

Dave,

I spoke with Sam just after you and I talked. I shared with him the information you and I talked about with regard to McKesson calling KVAT and he understood though he had not yet talked with Jack (though he cut our call short as Jack was calling him).

I also asked him about any requirement that McKesson would have regarding notifying the DEA if McKesson took action toward one of their customers. Sam said he did not know the requirements of if McKesson notified the DEA (no surprise).

Curt

Curtis Maki

Vice President Pharmacy

Topco Associates LLC

242. Because of this, both Food City and Topco redoubled their efforts to secure Anda as an oxycodone distributor. To help this effort, Topco sent Mickey Blazer a proposed letter to Anda that he edited on the evening of July 5, 2013, stating:²¹³

²¹² TC0322031 (emphasis added).

²¹³ TNAG-FC-CUST00093219.

From: Mickey Blazer [blazermi@FoodCity.com]

Sent: 7/5/2013 5:51:21 PM

To: 'Picarillo, Dave' [dpicarillo@topsourcellc.com]

CC: Steve Smith [smiths@FoodCity.com]; Charlie Fugate [fugatec@FoodCity.com]

Subject: RE: Letter to Anda re K-VA-T
Attachments: Letter to Anda re K-VA-T II.docx

Dave

The content of this letter is much better to assist with engaging Anda than the previous one. Original second version attached.

I do have a couple of things, that in my opinion still need to be changed.

Current Statement in Letter displayed in red, suggested changes displayed in dark blue:

K-VA-T has asked that we communicate with Anda, Inc. ("Anda") for purposes of establishing Anda as a distributor of prescription drugs to its Food City pharmacies (the "Food City Pharmacies").

K-VA-T has asked that we communicate with Anda, Inc. ("Anda") for purposes of expanding Anda's and KVAT's business relationship to include the distribution of Control Substances to its Food City pharmacies (the "Food City Pharmacies").

The Audited Stores and pharmacy employees therein comply with all applicable federal and state inventory requirements relating to controlled substances, including the DEA biennial inventory, annual Tennessee Board of Pharmacy inventory, and Change in Pharmacist-in-Charge inventory for Schedule II controlled substances.

K-VA-T retail pharmacy locations, including the Audited Stores and pharmacy employees therein comply with all applicable federal and state inventory requirements relating to controlled substances, including the DEA biennial inventory, Tennessee Board of Pharmacy inventory, and Change in Pharmacist-in-Charge inventory for Schedule II controlled substances.

K-VA-T is dedicated to the safety of its customers and the general public. It has in place at the Audited Stores CCTV systems with range and quality sufficient to assist law enforcement with the identification of a person attempting to commit a crime within the pharmacy. The PCG Report found that the security systems meet and exceed all DEA security requirements associated with the handling and storage of Schedules II through V controlled substances. Further, the exteriors of the pharmacies, including front and rear doors of each of the Audited Stores, are well secured and provide an effective deterrent to theft. Finally, the Audited Stores each have an alarm system that provides effective controls to guard against crimes involving the theft and diversion of controlled substances, including a back-up alarm system in the event of a power failure or willful destruction of the system, and panic buttons in the event of a robbery.

K-VA-T is dedicated to the safety of its customers and the general public. K-VA-T retail pharmacy locations, including the Audited Stores have in place CCTV systems with range and quality sufficient to assist law enforcement with the identification of a person attempting to commit a crime within the pharmacy. The PCG Report found that the security systems meet and exceed all DEA security requirements associated with the handling and storage of Schedules II through V controlled substances. Further, the exteriors of the pharmacies, including front and rear doors of each of the Audited Stores, are well secured and provide an effective deterrent to theft. Finally, K-VA-T retail pharmacy locations, including the Audited Stores each have an alarm system that provides effective controls to guard against crimes involving the theft and diversion of controlled substances, including a back-up alarm system in the event of a power failure or willful destruction of the system, and panic buttons in the event of a robbery.

Thanks,

Mickey Blazer Director of Pharmacy Operations R-VA-T Food Storus, ENC 201 Trigg Street 243. Food City's edits to the letter, as well as its compliance audits more generally, tried to highlight its supposed inventory and physical security controls and intentionally did not address the immense volume of oxycodone at the three stores or the Company's closely-guarded relationship with problematic prescribers. But even those statements about inventory and physical security from Food City were grossly misleading because PCG had already found *numerous* examples of serious issues—inventory discrepancies, pharmacies not conducting monthly inventories for controlled substances at all, problems with the storage of Schedule II medications, and even problems with how Food City was running its video security system.²¹⁴

244. Food City and Topco became progressively more frantic to get a supply of Oxy 30. On July 9, 2013, Topco found out that Anda, Food City's last hope, would not supply it with any Schedule II controls, including oxycodone. Topco executive Dave Picarillo sent Randy Skoda an e-mail that day, breaking the news that it was because it would place way too much risk on Anda: 215

See, e.g., # 175.1; # 176.1; # 177.1; 179.1; and # 180.1.

²¹⁵ TC0322076.

From: Picarillo, Dave [/O+SKOKIE, ILLINOIS/OU+SKOKIE/CN+RECIPIENTS/CN+DPICARI]

Sent: 7/9/2013 2:31:30 PM

To: Skoda, Randy [rekoda@topco.com]

Subject: Anda

This message has been archived. View the original Item

NO, will not ship any C2 In. Way too much risk for them



I know you are in mtg, let me know if you want to step out and I will come down

Mickey will know in 15 minutes

David Picarillo

Senior Vice President - TopSource IIc

245. Meanwhile, PCG continued to report problematic audit findings to Food City. For example, PCG audited Food City # 694 again on July 12, 2013 and the investigator noted the following:

- Chilhowee Pain Management, Bearden Healthcare, Pain Consultants of East TN, Active Pain, Pain Management Center are the main clinics that the pharmacy services.
- Per the DEA Audit Report, he [sic] following prescribers own the disproportioned share of the prescriptions written: James Santella (189 @ 8%), Teodora Neagu (130 @ 5.5%), Kim Satterfield (125 @ 5.3%), Don Douglas (101 @ 4.3%).
- [PIC] identified Donald Douglas at Bearden Healthcare as the only prescriber that once in a while prescribes Clonazepam with Oxycodone/Oxycontin/Opana.
- [44% of the controlled substances purchased were associated with pain management.]
- [Despite this, PIC] did not identify any of the prescribers as having unusual or excessive prescribing habits.²¹⁶

²¹⁶ # 107.1 (emphasis added).

246. In this audit, the pharmacist "confirmed that they do not fill for anyone outside of their filling market." But this was not true. Pharmacy # 694 had in fact sold opioids to out-of-state patients, including ones from North Carolina, Texas, Virginia, and Colorado, within the previous six months.

247. On July 19, 2013, eight days after its PCG audit, the pharmacist for Food City # 694 sent a message to Mickey Blazer asking him when the pharmacy would get shipments of controls. Because it was so reliant on opioid sales, Food City was feeling the financial impact of the McKesson decision. The # 694 pharmacist reported that Food City was losing business, which she estimated at 60 prescriptions worth approximately \$6,000 to \$8,000, because other pharmacies that had controls in stock would not fill them until the individual switched all of their prescriptions, including non-controls to the competing pharmacy. The pharmacist stated: ²¹⁸

From: Pharmacy Rx694

Sent: Friday, July 19, 2013 9:36 AM

To: Tom Geoghagan; Ken Slagle; Mickey Blazer

Subject: percentage of controls

Hey, I was just wondering if there has been any word regarding if the percentage of the business that is pain management falls below their critical level that we might be able to get anything again? I have in the last week lost 4 of my biggest customers, ones that get either expensive non control medication or a bunch of non-control medication because the other pharmacies are holding the controls they've brought them until they transfer all their other medications. Between all of them, I would say that we've at least lost 60 rx's and probably 6000-8000 worth of business and we many of these was have lost to Chad at Volunteer. None of these rx's are related Bearden Health Care, they are either PCP's or other smaller clinics they we don't see many rx's from.

I don't mean to be a pain, I was just hoping that maybe we can eventually salvage some of the rest of our business and stop the bleeding

Thanks Rachel, 694

248. Mickey Blazer forwarded the # 694 pharmacist's e-mail to Steve Smith and Jesse Lewis, the Company's Senior Vice President, later that day. Notably Mr. Blazer acknowledged

²¹⁷ Id

²¹⁸ TNAG-FC-CUST0081880.

that Food City was directing many of its customers who would fill controlled prescriptions at #674, #694, and #616 to other Food City pharmacies as much as possible but that the other pharmacies were fearful. Mr. Blazer stated:²¹⁹

From: Mickey Blazer

Sent: Friday, July 19, 2013 12:04 PM

To: Steve Smith; Jesse Lewis

Cc: Jody Helms

Subject: FW: percentage of controls

Steve and Jessie,

Please bear with me on all of the communication I am forwarding you but I want to make sure that you are hearing the whole impact of the McKesson issue.

Please see the email below.

I know this is old news, but I think it is important to understand what these Pharmacist are dealing with and how it is impacting the rest of our business.

We are directing as many of these type Patients to other Food City Pharmacies as possible but the other Food City Pharmacist are terrified to take on a new Patient with Controls because they are afraid they will get cut off. They are concerned with the stigma it brings to a Pharmacist when a Pharmacy that they work in or manage gets cut off.

Thanks,

Mickey Blazer

Director of Pharmacy Operations

K-VA-T Food Stores, INC.

249. By August 9, 2013, Food City had hired Kutak Rock as outside counsel to help convince McKesson to start supplying Oxy 30 and other controlled substances to Food City # 674, # 694, and # 616 again. As part of a lengthy exchange that Steve Smith ultimately forwarded to Topco's Randy Skoda, Food City's counsel told McKesson the following: 220

From: Burr, Kevin E.

Sent: Friday, August 09, 2013 2:32 PM

To: Peck, Krista (Krista.Peck@McKesson.com); 'Larry.Cote@quarles.com' (Larry.Cote@quarles.com)

CONFIDENTIAL

TNAG-FC-CUST00092372

²¹⁹ Id

²²⁰ TNAG-FC-CUST00092373.

Subject: K-VA-T Importance: High

Hi Krista & Larry:

Heft a message earlier today for Krista – I'm wondering if I can follow-up on just a couple of issues that were discussed on yesterday afternoon's call with Mickey and Don.

In our initial communication to you from last week (outlining the K-VA-T policy enhancements), we discussed, generally, the changes that were made to existing K-VA-T policies for dispensing controlled substances. We did not, in that communication, provide every single policy enhancement that was actually undertaken.

Don's questions yesterday made me wonder if we should not be more specific with respect to those changes. In particular, we want to express to Don K-VA-T's <u>overall commitment</u> to drive controlled substance prescription volumes to a level commensurate with similarly-situated pharmacy chain controlled substance volumes.

With regard to C-II's, K-VA-T recognizes that its volumes must come down commensurately and has committed to keeping C-II prescriptions to a level of 10% or less of total prescription volume. We understand the point that Don made with regard to "high dosage" C-II prescriptions for opioids (and other frequently abused drugs) and believe that those kinds of "high dosage" prescriptions will be additionally regulated within the affected stores by new policies specifically addressing prescriptions that have dosages for more than 120 tablets/month.

As an example, here are some of the policies that have already been implemented that are intended to address dosage issues over and above the controls that K-VA-T has implemented to keep controlled prescriptions (as a percentage of overall prescriptions) down:

- Pharmacists will ensure that prescriptions were written in the usual course of professional treatment
 considering the prescriber's professional practice, field of medicine, specialty and their board certifications,
 particularly for the prescription of opioids as a part of a pain management treatment;
- For prescriptions for opioids prescribed as a part of a pain management treatment, pharmacists will be
 required to contact prescribers to confirm the existence of a physician/patient relationship, must confirm
 with the patient and through the Tennessee CSMD when they last saw the prescriber, and should ask other
 general questions related to the interaction with the prescriber;
- Any prescription exceeding 120 dosage units of an opioid will only be accepted for pain relating to cancer, intractable pain or hospice. Pharmacists will be required to contact the prescriber when such information is not noted on the prescription or provided by the physician to the pharmacist as part of the customer's treatment plan;
- If customers are submitting prescriptions for large quantities of controlled substances (defined as more than 120 dosage units per prescription or multiple controlled substance prescriptions), pharmacists shall request a diagnostic code and purpose for such prescriptions, a copy of the customer's treatment plan and/or the patient contract from the prescribing physician and shall maintain such documentation in the customer's file so that the pharmacists can ensure that the pain medication is being utilized to treat a valid medical condition in coordination with other protocols (i.e., physical therapy, etc.), and;
- Pharmacists must access information related to the prescriber and the patient within the Tennessee
 Controlled Substance Monitoring Database. Impacted Pharmacies are required access the CMSD (or other
 relevant Prescription Monitoring Program) on <u>all</u> prescriptions for C-II and "commonly abused" controlled
 substances.

I'd also like to talk a bit about Don's reference in the conversation yesterday about "refusing to fill prescriptions" from certain physicians and/or clinics (which I interpret to be a reference to the Beardon Clinics). We want to make it clear that the reference is not lost on K-VA-T and that we recognize the issues. Again, the manner in which the policies have been implemented at the affected pharmacies is intended to address these concerns - allowing pharmacists, in the exercise of their professional discretion, only after receiving appropriate documentation regarding physician orders or



the physician approved treatment plan, to accept or reject the prescription (on a case-by-case basis) without implementation of a system-wide ban on any physician or practice group.

In any event, I'd like to take a few minutes to discuss these matters if you have a chance. Can you (or you and Larry) give me a call at your earliest convenience?

Thanks, in advance, for your attention! I'm looking forward to hearing from you soon!

Kevin E. Burr Partner Kutak Rock LLP

- 250. But Food City's proposed solutions would do little to impact Food City's opioid business. By the terms of the letter, Food City's commitment to keep C-II prescriptions to a level of 10% or less of total prescription volume was not for the three stores and appeared to be for all of Food City's 75 pharmacies—meaning that it could offset high percentages at stores like # 674, # 694, and # 616 through non-controlled sales at its other pharmacies. In addition, Food City's commitment to not accept any prescription exceeding 120 dosage units except for cancer, hospice, or intractable pain would do nothing to stop business from pill mills that wrote illegitimate prescriptions in bulk purportedly for intractable pain. And Food City's refusal to terminate the relationship with Bearden was telling. Bearden had made and would continue to make Food City substantial amounts of money.
- 251. Moreover, Food City's reliance on policies that "already have been implemented" were only made effective the month before, only applied to "specialty" pharmacies Mickey Blazer picked out, and were disregarded in the policies revised in August.
- 252. On August 13, 2013, McKesson finally caved and sent a letter offering to reinstate the three Food City stores the next day, on the condition that Food City apply its controlled

substance compliance program to *all* pharmacies and that it administer an auditing plan to all pharmacies. ²²¹

253. Three days later, Steve Smith sent Randy Skoda an e-mail acknowledging that McKesson had delivered the Schedule II controlled substances to the three stores and stated that these three would be subject to thresholds set at the national average. He went on to say, "They won't tell us what that is so I guess we order until they won't ship and wait until the next month. Still a Helluva way to run a railroad. We work worth with this and see." The full e-mail read:

From: Steve Smith [mailto:smiths@FoodCity.com]

Sent: Friday, August 16, 2013 7:40 AM

To: Skoda, Randy Cc: Charlie Fugate Subject: Rx is Jinxed!!

Well the CIIs were delivered as promised to the 3 stores that were restricted by McKesson. Very good day to move forward, however they have put some very strong restrictions on these stores which we are told equate to the CII s at the national average. They won't tell us what that is so I guess we order until they won't ship and wait until the next month. Still a Helluva way to run a railroad. We will work with this and see. On another bizarre note we had one of our Kingsport stores robbed at gunpoint yesterday and guess what they wanted, yep you guessed CIIs. No one hurt just scared and shook up. We have pictores of robber and the car he drove. Should be able to catch this guy. Another day in the Rx business. Thanks again for your help!! And I mean that!! Steve

254. However, *during* these intense negotiations surrounding McKesson's June 19, 2013 to August 16, 2013 cut off, Food City *did* sell Oxy 30, including at the three affected stores. At least at Food City # 674, many of the Bearden providers who had prescribed high amounts of Oxy 30 or oxycodone started prescribing more hydrocodone, morphine, tramadol, and oxymorphone during this time. ²²³ The shift, especially to other Schedule II and III opioids is a strong indicator of coordination between providers at Bearden and its preferred pharmacy.

²²¹ TNAG-FC-CUST00093178.

²²² TNAG-FC-CUST00093171 (emphasis added).

²²³ TNAG-FC-CUST00007672.

255. And while Food City and Topco were fixated on Oxy 30, they soon began lobbying for threshold increases from McKesson for other opioids at the three stores, including for hydrocodone. On October 29, 2013, Mickey Blazer, with Food City CEO Steve Smith's knowledge, lobbied McKesson to increase the hydrocodone thresholds at # 674, # 694, and # 616, which Mr. Blazer said "appears to be set extremely low at 4000.²²⁴

256. Food City had detailed knowledge not just about the threshold for hydrocodone, but also for oxycodone, despite the DEA instruction to distributors not to tell pharmacy customers the threshold levels so that they would not game the system. In a separate e-mail titled "Threshold" on November 4, 2013, Mickey Blazer told Topco that "[1]% dose units of Oxycodone 30's of total dose units is a red flag."²²⁵

257. Food City's executives continued to receive disturbing reminders that a substantial portion of its customer base was suffering from opioid use disorder. In an e-mail sent on November 5, 2013, the Food City # 617 pharmacist in Bristol, Tennessee responded by not only comparing shortages of pain killers to the zombie apocalypse, but also mocking individuals struggling with addiction:²²⁶

²²⁴ TNAG-FC-CUST00094511.

²²⁵ TC0367329; TC0324866.

²²⁶ TNAG-FC-CUST00007623.

From: Pharmacy Rx617 [rx617@FoodCity.com]

Sent: 11/5/2013 4:12:46 PM

To: Mickey Blazer [blazermi@FoodCity.com]

Subject: RE: Mallinckrodt Oxycodone

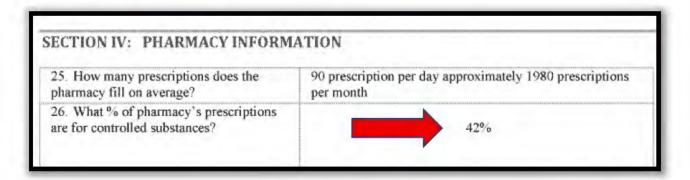
I just noticed that our SGX1-A generic Lortab 10/500mg is unavailable in 500 count (manufacturing issues). The 100s are available, but the SGX1-ac product is much more expensive.

So, we have manufacturing problems for oxycodone and hydrocodone. This is phase one of the zombie apocalypse. Phase two is increased pharmacy robberies and other violent crimes. Drug addicts move to whatever other drug is available. The ones who shift to bath salts become temporary zombies (super-strong, incoherent, etc). If you haven't seen bath salt highs, watch one or two on youtube. All this time, we thought the movies were fantasy. Get prepared, and have a nice day.

-Jamie

PS: You may not know me well enough to know my sense of humor.

258. Despite Food City's experience earlier in the year with McKesson, problematic audits continued—including at the three stores in Knoxville. For example, on November 15, 2013, PCG reported that 42% of all prescriptions that Food City # 616 sold were controlled substances—well above Food City's commitment to limit the amount of controls to 10% of total prescriptions.²²⁷



259. In December 2013, Food City continued to have knowledge that it was operating pharmacies whose controlled substance policies "may raise some concerns." In an e-mail to other executives including Food City President and CEO Steve Smith, Mickey Blazer stated:²²⁸

²²⁷ PCG-TN003531.

²²⁸ TNAG-FC-CUST00087778.

From: Mickey Blazer [/O=FOOD CITY/OU=FOODCITY/CN=RECIPIENTS/CN=BLAZERMI]

Sent: 12/19/2013 12:38:22 AM

To: Jody Helms [helms]@FoodCity.com]; Jesse Lewis [Lewisj@FoodCity.com]; Steve Smith [smiths@FoodCity.com]

Subject: Todays Topco Conference Call

Just FYI

I had a conference call with Topco today. One topic discussed I want to share.

They said they had received notification from McKesson that they had completed reviewing their Control
Policies and they would be reaching out to each Member in January requesting 90 days of dispensing data for
review

(Not sure where this will go, but bases on the criteria they have discussed with me, we could have a couple of other Stores that may raise some concerns)

They also said they will require a copy of each Members Control SOP. (They already have ours)

 They would require knowledge of what Members were doing corporately to prevent diversion and what each Member was doing to monitor suspicious ordering habits. (I feel good with the process we have in place).

 They will be requiring Members to go through some sort of process (I took it as watching some kind of video or listening to someone either hired by McKesson or someone from McKesson but that was not what was said exactly), to make sure we understood the Pharmacy's role in deterring diversion.

 They said we would continue to get the Threshold Reports that I currently get daily. (Any Store that gets within 80% of their limit)

They said they would address threshold increase request on a case by case bases and they would be considered
per their guidelines set forth in their new Control Policies.



Mickey Blazer
Director of Pharmacy Operations
K-VA-T Food Stores, INC.

260. In 2013, Food City continued to have significant problems with compliance and with diversion including at the three stores that had caused it so many problems. At Food City # 674 in 2013:

- "An audit of patients who filled prescriptions at the pharmacy during this time revealed that individuals were driving long distances to the pharmacy[;]"
- "[P]rescriptions dispensed in 2013 had the incorrect prescriber, incorrect
 patient and incorrect labeling on the vials. Incomplete information occurred
 on transferred prescriptions and Respondent was found to be accepting postdated prescriptions[; and]"

• "During the Respondent's period of operation as a pharmacy in 2013, Respondent's staff failed to check the Controlled Substance Monitoring Data base prior to filling prescriptions for controlled substances." 229

261. Notably, the findings conflicted with PCG reports that stated that Food City customers at # 674 were limited to Knox County and surrounding counties.

262. As evidence of its prioritization of profits over compliance, Food City executives asked the Company's accountants to calculate the financial impact of McKesson cutting off controlled substances to three stores for just under two months and its other policies. An excerpt from an e-mail sent by one of these accountants to Steve Smith stated:²³⁰

From: Michael Lockard [lockardm@FoodGty.com]

Sent:

1/21/2014 12:53:43 AM

To:

Steve Smith [smiths@FoodCity.com]

CC:

Laura Mullins [MullinsL@FoodCity.com]; Mickey Blazer [blazermi@FoodCity.com]; Paul Cox [coxp@FoodCity.com]

Subject:

FW: 616-674-694 Comparison

Attachments: 616-674-694 Pharmacy Comparisons Combined.xlsx

Steve,

Laura and Mickey worked together to analyze the impact of McKesson's allocation on stores 616, 674, and 694. As you know, it is significant (unfavorable impact of \$ 100 to \$

263. Despite its ongoing compliance problems, Food City continued to lobby McKesson to increase its threshold limits on controlled substances, directly and through Topco. On February 17, 2014, Food City's Mickey Blazer received a threshold warning report from McKesson about the Oxy 30s and enlisted Topco's to help convince McKesson's account manager to raise the threshold, which McKesson ultimately did at least temporarily. Mr. Blazer, who stated he had a separate conversation about the threshold issue with CEO Steve Smith, stated that the justification

Consent Or., In the Matter of Food City Pharmacy #674, Case No. 2014000801 (Tenn. Bd. of Phmcy.) (emphasis added).

²³⁰ TNAG-FC-CUST0097303 (excerpt; redactions over dollar figures supplied by State).

for the increase was that # 694 was receiving the patient files from # 675, which closed. Mr. Blazer's e-mail stated:²³¹

From: Mickey Blazer [mailto:blazermi@FoodCity.com]

Sent: Monday, February 17, 2014 8:18 AM

To: Picarillo, Dave Cc: Maki, Curt

Subject: FW: CSMP Report: Follow-Up with Account Manager

[page break]

Dave,

I wanted to give you a heads up on this.

I had a conversation with Steve this morning and we discussed how things were going at our #694 Pharmacy.

I know you will be seeing him later today and I didn't want you to get caught off guard.

We were told that the Thresholds at #694 would be adjusted by McKesson due to us closing the Store #675 and moving the Patient files to #694.

I was even told by Meg Mitchell from McKesson that they had adjusted the Thresholds on Oxycodone, Hydrocodone, and Alprazolam for this Store.

I have attached the latest Threshold Warning Report.

Pharmacy #694 is on the list, showing Oxycodone 30's at a Threshold of 2000.

This is the same number they set it at when they turned the 3 Stores back on.

It is evident that the Oxy 30's has not been change. I can't tell yet about anything else yet.

I will try to follow up with you via a phone call as well.

<image001.jpg>

Mickey Blazer

Director of Pharmacy Operations

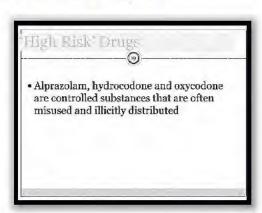
K-VA-T Food Stores, INC.

264. Food City and its executives were all too aware of strong indicators of pill mills and suspect prescribers, clinics, and practice groups—it just chose and continues to choose to

²³¹ TC0326551.

ignore them. For example, on March 9, 2014, PCG delivered a presentation to Food City pharmacy employees about pill mills, abuse, and diversion. This was the first such training Food City provided to its employees. Among other things, Food City was expressly told:

- "Alprazolam, hydrocodone and oxycodone are controlled substances that are often misused and illicitly distributed [under the header "'High Risk' Drugs]"²³²
- "Pill Mill' Clinics are often disguised as independent pain-management centers[;]"²³³
- "Signs of a 'Pill Mill' can include:
 - Only cash is accepted
 - No physical exam is given
 - No medical records or xrays are needed





- You get to pack your own medicine, no questions asked
- o You are directed to "their" pharmacy
- o They treat pain with pills only
- You get a set number of pills and they tell you a specific date to come back for more
- o They have security guards
- There may be huge crowds of people waiting to see the doctor²³⁴
- "Six Key Components to Analysis"

²³² PCG-TN008963.

²³³ PCG-TN008965.

²³⁴ PCG-TN008965.

- Due diligence analysis seeks the six critical points of review
 - Percent of Schedule III distribution to Schedule III through V
 - High risk narcotic distribution
 - Cash and insurance payment trends
 - Monthly trends in distribution for specific drugs
 - Top 10 prescriber analysis
 - Individual analysis of prescribers of interest[.]²³⁵



- 265. In spite of this knowledge, Food City continued to sell prescription opioids written by prescribers, clinics, and practice groups that met many of the signs of a pill mill and despite having PCG reports that identified suspicious prescribers, clinics, and practice groups as high risk for opioid diversion or abuse.
- 266. Notably, in the presentation, PCG listed "on-site prescriber reviews" as being a "critical element of understanding to a 'know your customer' program."

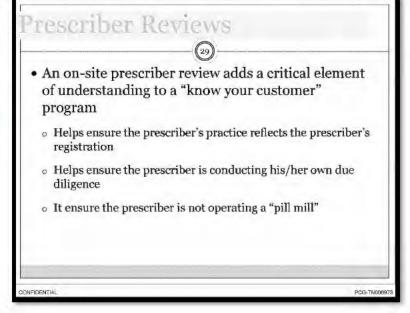
 But aside from one interview with Dr.

 Frank McNiel in 2011 as part of a compliance audit that PCG

 Prescriber Reviews

 An on-site prescriber review adds a critical element of understanding to a "know your customer" program

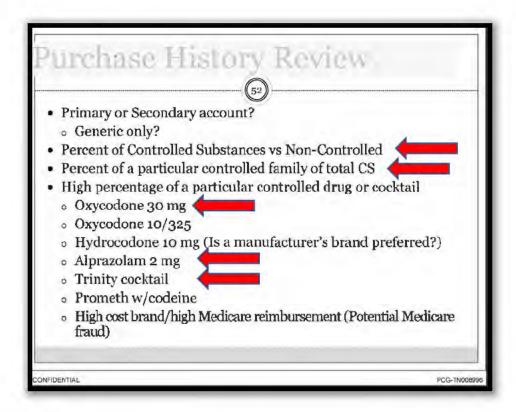
 Helps ensure the prescriber's practice reflects the prescriber's registration



²³⁵ PCG-TN008969.

initiated, ²³⁶ Food City did not ask PCG to perform on-site prescriber reviews and PCG often only had responses from Food City pharmacists about certain prescribers. Nor did Food City itself did not conduct such reviews. Food City intentionally did not want to know the answers.

267. Other parts of the PCG presentation focused on recognizing suspect pharmacies, and the red flags described Food City. Under the slide titled "Purchase History Review," PCG listed multiple factors, all of which described Food City, with the possible exception of two (Prometh w/codeine and High cost brand/high Medicare reimbursement (Potential Medicare fraud)). 237



268. On one slide titled "Red Flag Indicators of Suspect Pharmacies" shown below, PCG referenced armed guards, demographic of customers, abundance of out of state license plates,

²³⁶ PCG-TN008973.

²³⁷ PCG-TN008996.

customers lining walkway prior to business opening, and proximity to pain clinics.²³⁸ Food City had armed guards at several stores, had customers who did not fit the demographics of the area, had individuals from across the country and even the world, and, in many instances, their pharmacies were located very close to pain clinics. For years, Bearden Health Care Associates was located a half of a block from Food City # 674 and even after it moved, it was less than 10 miles from the Big 3 Food City pharmacies.



Red Flag Indicators of Suspect Pharmacies



- Environmental Scan
 - o Armed guards
 - Demographic of customers
 - Abundance of out of state license plates
 - Customers lining walkway prior to business opening
 - Proximity to Pain Clinics

CONFIDENTIAL

PCG-TN008987

²³⁸ PCG-TN008987.

269. As Food City well knew before this, PCG's March 9, 2014 presentation also highlighted that the pill mills were a known problem in the I-75 corridor especially with oxycodone and hydrocodone.²³⁹



- 270. Notably, Pharmacy # 674 is located about half of a mile from an I-75 on-ramp, as well as other interstates. It could not have been easier for out of state patients to stop at Bearden for a prescription, fill it at # 674 next door, and then be back on the interstate without traveling more than 2 miles.
- 271. In March 2014, Mickey Blazer submitted due diligence documents to McKesson, per its request, and to Topco "regarding the highlighted Pharmacy locations on the KVAT Control Data Report." The pharmacies identified were # 437 (Pikeville, KY), # 611 (Gatlinburg), # 620 (Vonore), and # 632 (Loudon).

²³⁹ PCG-TN009011.

- 272. Each due diligence review began by describing the town where the pharmacy was located, then evaluated three months of dispensing information, and concluded with an analysis of the main practices or pain clinics it serviced. Food City's due diligence research showed both its awareness of certain red flags, but also exclusion of certain key analyses.
- 273. For example, the dispensing analysis for Food City # 611, which was in Gatlinburg, read:

During the time period ranging from December 1, 2013 to February 28, 2014, Food City Pharmacy # 611 filled 11,629 prescriptions with a total of 652,376.3 dosage units. During that same time frame 2620 prescriptions were for a controlled substance equaling 187,889 dosage units. This equates to 22.53% prescriptions and 28.80% dosage units of the total dispensed. Of those controlled substance prescriptions filled, 537 prescriptions were for a form of hydrocodone totaling 42,735 dosage units. Of the hydrocodone prescriptions, 350 prescriptions and 33,221 dosage units were for a form that contained 10mg of hydrocodone. The pharmacy filled 203 prescriptions for oxycodone 30mg totaling 22,774 dosage units. ²⁴⁰

- 274. This means that 65% of the prescriptions and 78% of the dosage units of hydrocodone that were dispensed were the 10mg, *the highest available and most diverted dose*.
- 275. What was not disclosed to McKesson or Topco was that during this time period, Food City # 611 was selling these opioids to patients from as far as Alabama, Florida, Georgia, Kentucky, Michigan, Mississippi, North Carolina, North Dakota, and Ohio, as well as across Virginia and Tennessee. It was accepting prescriptions written by HCPs in Alabama, Georgia, Kentucky, Maryland, Montana, North Carolina, New York, South Carolina, and West Virginia.
- 276. The review of practices and pain clinics Food City # 611 serviced only included First Med, the highly suspicious clinic run by Dr. Robert Maughon, and showed where most of the

²⁴⁰ TC0371246.

high dose immediate release hydrocodone was coming from at the pharmacy. It stated in relevant part:

[F]irst Med is an Urgent Care and Primary Care facility offering a full range of medical services. During the stated time frame Food City Pharmacy #611 filled 3768 total prescriptions and 214,772.25 total dosage units that were prescribed by the staff at First Med. This equates to 32.40% of their total prescription volume and 32.92% of their total dosage units. Food City Pharmacy filled 1178 controlled substance prescriptions equaling 98,741 dosage units. This is 44.96% of their total controlled prescription percentage and 52.41% of the controlled dosage units dispensed. A form of hydrocodone accounted for 268 prescriptions and 28,414 dosage units with a product containing 10mg being 240 prescriptions and 24,742 dosage units. First Med prescribed 49.9% of all hydrocodone prescriptions accounting for 66.49% of the dosage units. They also account for 68.57% of the prescriptions and 74.48% of the dosage units for hydrocodone 10mg product. Oxycodone 30mg accounted for 64 prescriptions and 7503 dosage units. This amounts to 31.53% of the prescriptions and 32.95% of the dosage units.

277. The dispensing analysis for Food City # 620, located in Vonore showed a similarly high controlled substance percentage versus total prescriptions, but continued high sales of Oxy 30 instead of hydrocodone. It read:

During the time period ranging from December 1, 2013 to February 28, 2014, Food City Pharmacy #620 filled 3783 prescriptions with a total of 213,894.1 dosage units. During that same time frame 916 prescriptions were for a controlled substance equaling 62,824 dosage units. This equates to 24.21% prescriptions and 29.37% dosage units of the total dispensed. Of those controlled substance prescriptions filled 268 prescriptions were for a form of oxycodone totaling 26,960 dosage units. Of the oxycodone prescriptions, 139 prescriptions and 14,982 dosage units were for oxycodone 30mg. 242

278. According to this, 43% of the controlled substance dosage units sold were oxycodone tablets and of that oxycodone, 52% of the prescriptions for oxycodone were for Oxy 30 and 56% of the oxycodone dosage units were Oxy 30. Such unbalanced ratios should have been a red flag.

²⁴¹ TC0371246 (emphasis added).

²⁴² TC0371248.

279. The review continued:

During the above time frame, 44 different prescribers wrote a prescription for a form of oxycodone with 18 of those prescribes writing for oxycodone 30mg. Of those prescribers, there are 7 prescribers that account for 150 prescriptions and 16,176 dosage units of a form of oxycodone with 111 prescriptions and 11,854 dosage units being oxycodone 30mg.²⁴³

280. This means that those seven prescribers accounted for 56% of the oxycodone prescriptions and 60% of the oxycodone dosage units, despite only accounting for 16% of the total oxycodone prescribers. They also accounted for 80% of the Oxy 30 prescriptions and 79% of the Oxy 30 dosage units.

281. The review then analyzed the dispensing for pain clinics, starting with Chilhowee Pain Center, located about half an hour away:

Chilhowee Pain Center in Maryville, TN is located 23 miles via Hwy 411 from Food City Pharmacy #620. Located in Chilhowee Professional Park, the clinic is the neighbor of five medical practices (2 dentists, 2 internal medicine doctors, and Blount Memorial Hospital's outpatient lab). Chilhowee Pain Center is registered with state of Tennessee as a pain management clinic listing *Elizabeth LeBrun as the medical director*. Food City Pharmacy #620 has filled prescriptions for four of their prescribers, *Elizabeth LeBrun, Thomas McDonald, Donna Smith and Martha Burnett*. Licensure search via the Tennessee Department of Health website showed no listed disciplinary actions for any of the prescribers. A search was conducted to validate each prescriber's DEA on the DEA website, which showed all registrations as active. Between Dec. 1, 2013 and Feb. 28, 2014, the pharmacy filled a total of 250 prescriptions equaling 19,408 dosage units. 112 prescriptions and 12,064 dosage units were for a form of oxycodone with 86 prescriptions and 9304 dosage units being for oxycodone 30mg.²⁴⁴

282. Both Elizabeth LeBrun and Thomas McDonald are gynecologists, a specialty which is commonly used as an *example* of an unusual specialty for pain management. Donna Smith, who was also referenced in the review, had also previously worked at Breakthrough Pain Therapy prior to the DEA shutting it down. According to the above analysis, 45% of the

²⁴³ TC0371248.

²⁴⁴ *Id*.

prescriptions the pharmacy filled were for oxycodone, 77% were for Oxy 30. However, when analyzed by dosage unit, the issue becomes clearer—62% of the dosage units sold were oxycodone and 48% of the overall dosage units were Oxy 30.²⁴⁵

283. The next clinic was East Knoxville Healthcare Services:

East Knoxville Healthcare Services in Knoxville, TN is located 35 miles via I-75 from Food City Pharmacy #620. East Knoxville Healthcare Services is registered with the state of Tennessee as a pain management clinic listing Richard Larson as the medical director. Food City Pharmacy #620 has filled prescriptions for three of their prescribers, *Richard Larson, Courtney Newman, and Cynthia Clemmons* [sic]. Licensure search via the Tennessee Department of Health showed no listed disciplinary actions for any of the prescribers. A search was conducted to validate each prescriber's DEA on the DEA website, which showed all registrations as active. Between Dec. 1, 2013 and Feb. 28, 2014, the pharmacy filled a total of 111 prescriptions equaling 7925 dosage units. 38 prescriptions and 4112 dosage units were for a form of oxycodone with 25 prescriptions and 2550 dosage units being for oxycodone 30mg. ²⁴⁶

284. This means that that while only 34% of the prescriptions were for oxycodone, that drug made up 52% of the dosage units which were sold, 62% of which was Oxy 30. Just over a year later, this clinic was raided, and its prescribers later indicted as "garden-variety drug dealers" in the massive \$21 million Sylvia Hofstetter pill mill case. The indictments alleged that medical professionals, including Larson, Clemons, and Newman, were paid to write prescriptions without examining patients and were accused of being responsible for the oxycodone overdose deaths of patients.²⁴⁷ The clinics run by Hofstetter were allegedly responsible for at least 700 overdose deaths in Florida and East Tennessee. Dr. Larson, who had also run "feeder-clinics" for PA David Brickhouse prior to working with Hofstetter and "was medical director for nearly half a dozen

²⁴⁵ *Id*.

²⁴⁶ *Id*.

²⁴⁷ "Moment of Decision," WBIR, available at https://www.wbir.com/article/news/crime/moment-of-decision-jury-about-to-get-lengthy-case-against-alleged-pill-mill-boss-former-staff/51-0e8ace77-19a2-41a4-98e4-1f04a8e91e30.

clinics all tied to the medical dispensing of opiates to addicts," died before he could be prosecuted.²⁴⁸ Nurses Cynthia Clemons and Courtney Newman were both convicted of maintaining a drug-involved premises.

285. PCG also reviewed Food City # 632, located in Loudon, including its relevant dispensing information:

During the time period ranging from December 1, 2013 to February 28, 2014, Food City Pharmacy #632 filled 4719 prescriptions with a total of 276,953.7 dosage units. During that same time frame 1173 prescriptions were for a controlled substance equaling 79,819 dosage units. This equates to 24.86% prescriptions and 28.82% dosage units of the total dispensed. Of those controlled substance prescriptions filled 298 prescriptions were for a form of oxycodone totaling 28,800 dosage units. Of the oxycodone prescriptions, 141 prescriptions and 15,848 dosage units were for oxycodone 30mg. ²⁴⁹

- 286. According to this, 36% of the controlled substance dosage units sold were oxycodone, 55% of which was Oxy 30—disproportionate ratios which were also red flags.
- 287. Food City # 632 in Loudon also sold prescriptions for Chilhowee Pain Center, located about 40 minutes away and run by two gynecologists:
 - ... Food City Pharmacy #632 has filled prescriptions for four of their prescribers, Elizabeth LeBrun, Thomas McDonald, Donna Smith and Martha Burnett. Licensure search via the Tennessee Department of Health website showed no listed disciplinary actions for any of the prescribers. A search was conducted to validate each prescriber's DEA on the DEA website, which showed all registrations as active. Between Dec. 1, 2013 and Feb. 28, 2014, the pharmacy filled a total of 130 prescriptions equaling 9955 dosage units. 48 prescriptions and 5748 dosage units were for a form of oxycodone *all of which were for oxycodone 30mg*. ²⁵⁰
- 288. This means that 58% of the dosage units sold were oxycodone, astoundingly "all of which were ... oxycodone 30mg."

Jamie Satterfield, "Rare Medical RICO Conspiracy with Italian Ties Had its Roots in Meeting in a "Medical Spa," KNOX NEWS SENTINEL, *available at* https://www.knoxnews.com/story/news/crime/2018/01/23/rare-medical-rico-conspiracy-italian-ties-had-its-roots-meeting-medical-spa/1052559001/.

²⁴⁹ TC0371250.

²⁵⁰ TNAG-FC-CUST00056579 (italic emphasis added).

- 289. Food City # 632 also filled for East Knoxville Healthcare Services, a pill mill located a half an hour away:
 - ... Food City Pharmacy #632 has filled prescriptions for three of their prescribers, Richard Larson, Courtney Newman, and Cynthia Clemmons. ... Between Dec. 1, 2013 and Feb. 28, 2014, the pharmacy filled a total of 106 prescriptions equaling 9422.5 dosage units. 35 prescriptions and 3905 dosage units were for a form of oxycodone with 26 prescriptions and 2915 dosage units being for oxycodone 30mg.²⁵¹
 - 290. This means that 75% of the oxycodone sold was Oxy 30.
- 291. As of May 20, 2014, Food City knew that it continued to have major compliance problems at its pharmacies, including # 694. As of that date, Food City had:
 - "[P]harmacists employed by Respondent failed to perform satisfactory Drug Utilization Review (DUR) prior to dispensing controlled substance prescriptions to patients[;]"
 - "Pharmacists employed by Respondent *filled and refilled controlled substance prescriptions early*, prior to the exhaustion of the prescribed supply of medication[;]"
 - "Pharmacists employed by Respondent *dispensed Schedule II prescriptions* which were written on the same date, instead of requiring new prescriptions written subsequent to a contemporaneous examination[; and]"
 - "Pharmacists employed by Respondent dispensed controlled substance prescriptions to at least 4 patients who received those prescriptions from multiple providers with fewer than 30 days between each visit." ²⁵²
- 292. On June 5, 2014, Topco conducted a post-mortem on the anniversary of the stoppage of controlled substances to Food City's three Knoxville stores. In an e-mail titled "KVAT 3 store CS follow-up one year later ..." sent that day to Topco's Vice President of Pharmacy, Curt Maki, an analyst stated the following:

²⁵¹ TC0371250.

Agreed Or., In the Matter of Food City Pharmacy # 694, Dkt. No. 17.56-127199A (Tenn. Bd. of Phmcy.).

From: Smeele, Roger [/O=SKOKIE, ILLINOIS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=SMEELE, ROGER40C)

Sent:

6/5/2014 1:20:50 PM

To:

Maki, Curt [cmaki@topco.com]

Subject:

Charter, Andrew (acharter@topco.com)
KVAT 3 store CS follow-up one year later

This message has been archived. View the original item

Curt,

Attached are numbers that I extracted on KVAT following your request this morning. The data looks at 2 general areas—1) threshold alerts for the period immediately during and after the June shutdown (plus general non-KVAT member thresholds for comparison) and 2) actual purchase usage for alerted items.

Below is a reprint of the observations from that data.

Let me know if you need anything else.

Observations:

- In June 2013, it looks like McKesson may have already had high thresholds on the Oxy since they did not create alerts at 2 of the 3 stores before shutdown.
- 2. Their Oxy usage was way out of line compared to other member typical thresholds.
- 3. It looks like some CS monitoring categories were initially brought back at about half the typical threshold.
- 4. It looks like although the initial lowered has not changed in most cases, each of the location looks to be operating within guidelines.
- 5. McKesson will not share thresholds by I was able to extract from daily CSMP reporting.
- 6. It looks like some thresholds may have been adjusted recently (noted by their absence from alert report (e.g. store 694 using more Hydrocodone and Oxy 30 than alerts noted in January but are not appearing on current threshold report).
- Initial cutoff in June 2013 appears to have only been Oxy and not all C2s since other c2s continued to create alerts.

293. By June 2014, Food City Director of Pharmacy Operations Mickey Blazer was continuing to send Food City CEO Steve Smith reports on high prescribers.²⁵³

294. In December 2014, Food City continued to receive audits that showed that recurring problems had not been fixed and that red flags from prescribers continued. For example, PCG notified Food City in December 2014 that Pharmacy # 694 was selling opioids prescribed by providers who were identified as writing "high risk" prescriptions *up to 66%* of the times that they prescribed a controlled substance, such as:²⁵⁴

Practitioner Name	:	LEE A SIMMONS
Percent of High Risk	to Total:	66%
Practitioner Name:	:	WILLIAM B ROBINSON
Percent of High Risk	to Total:	48%
Practitioner Name	:	CHEN, CHANGWEN
Descriptions:	Prescriber specializes in Family Medicine	e .
Percent of High Risk	to Total:	61%
Practitioner Name	:	OTIS, MICHAEL
Descriptions:	Prescriber specializes in Family Medicine	e.
Percent of High Risk	to Total:	46%

295. In another PCG report from December 2014, Food City was notified that Pharmacy # 616 had sold 589 prescriptions for high risk controlled substances, including oxycodone, hydrocodone, and alprazolam from June 1, 2014 to November 30, 2014.²⁵⁵

²⁵³ TNAG-FC-CUST00094830 (referencing Food City # 839).

²⁵⁴ PCG-TN005575; PCG-TN005580.

²⁵⁵ PCG-TN005934.

296. Food City and its executives continued to receive red flags about opioid diversion and abuse in April 2015. On April 29, 2015, one of Food City's loss prevention specialists at Food City # 676, located in Knoxville, e-mailed Steve Smith and Mickey Blazer, among other Food City executives, and notified them that a woman had died in the parking lot the previous day from an apparent drug overdose and was found with a syringe in her hand. The e-mail stated:²⁵⁶

From: David Edwards [edwardsd@FoodCity.com]

Sent: 4/29/2015 2:07:56 AM

To: Steve Smith [smiths@FoodCity.com]; Jesse Lewis [Lewisj@FoodCity.com]; John Jones [jonesj@foodcity.com]; Mickey

Blazer [blazermi@FoodCity.com]; Randy Williams [williamr@FoodCity.com]

CC: Haskel Bledsoe [Bledsoeh@FoodCity.com]; Robby Gosnell [gosnellr@FoodCity.com]

Subject: 676 Incident



On 4/28/15, I received a phone call, from Assistant Manager Barry Horn at Food City #676, at approximately 6:00pm stating that he believed there was a dead body in the parking lot. Mr. Horn stated that the police were at the store and were wanting to review video. I immediately went to the store and met with the Knoxville Police Department. I was informed that a female was deceased from an apparent drug overdose in a white Chevrolet Blazer in our parking lot. A male was also found in the vehicle alive but heavily under the influence of narcotics. I reviewed video and found the vehicle enter the parking lot at 4:11pm and park outside of camera view. At approximately 5:30pm, a customer notified the Gas N Go attendant that someone needed to check on the woman in the Chevrolet Blazer. The paramedics were notified and then alerted the police. The woman was found deceased with a syringe in her hand. The police are investigating a rash of recent overdoses believing there to be a bad batch of heroin in the area. The body as well as the vehicle was removed from the premises. The male subject was taken into custody for further questioning. All relevant video was burned for the police. As more information becomes available, follow up reports will be submitted.

David Edwards Loss Prevention

297. In May 2015, nearly two years after McKesson stopped controlled substance shipments to Food City # 674, # 694, and # 616, Mickey Blazer sent an e-mail to CEO Steve Smith and other Food City executives indicating that McKesson stopped the shipments to the three stores because it was under investigation by the DEA. Mr. Blazer's e-mail stated:

²⁵⁶ TNAG-FC-CUST00215517.

----Original Message-----From: Mickey Blazer

Sent: Friday, May 01, 2015 06:33 AM Eastern Standard Time

To: Steve Smith; Jesse Lewis; Charlie Fugate; John Jones; Will Bevins

Cc: Ken Slagle; Tom Geoghagan

Subject: McKesson

Here you go!!

Not a lot of details but this does explain a lot about June of 2013.

The Cardinal issue a couple of years ago was strictly with the DEA, if I remember correctly.

This article indicates that there were several government agencies involved in the McKesson investigation.

McKesson settles investigation on controlled substances

Reuters - 13 hours ago

Mickey Blazer
Executive Vice President of Operations
Knoxville Division
K-VA-T Food Stores Inc.

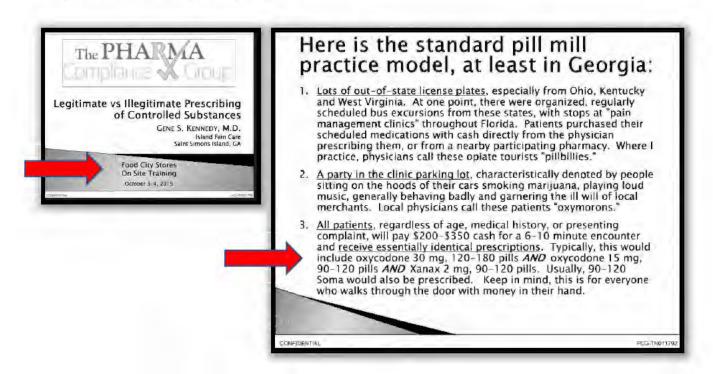
298. As of September 11, 2015, Food City's major compliance problems persisted. At

Knoxville's Food City # 687, among other things:

- "Investigators also found that there were pharmacy technicians without registrations or affidavits, C2 were not signed and dated and the C2 perpetual inventory was incorrect[;]"
- "Incomplete invoices were found by the investigators, as well as incomplete
 or missing C222 forms. [DEA required forms to transfer controlled
 substances] Numerous C2 drugs were transferred without sending C222
 forms to the DEA[;]"
- "Investigators found the Pharmacist-In-Charge had been unable to log into the CSMD and admitted rarely checking the CSMD[;]"
- "Respondent's staff admitted to never refusing to fill a prescription unless
 it was extremely early. Staff would early refill for cash and admitted to
 filling out of state prescriptions without question."²⁵⁷

²⁵⁷ In the Matter of Food City Pharmacy # 611 [sic should be # 687 based on Lovell Road address], Case No. 201503561 (Tenn. Bd. of Phmcy.) (emphasis added).

299. On October 3 through 4, 2015, Food City was again taught red flags for pill mills in a presentation during an on-site training titled "Legitimate vs. Illegitimate Prescribing of Controlled Substances." As shown in the slides below, the training referenced the "standard pill practice model" from Georgia and described customers with out-of-state license plates, customers receiving essentially identical prescriptions, and holy trinity prescription combinations of an opioid, Xanax, and muscle relaxer. 258



300. Food City continued to be aware that holy trinity prescription combinations were signs of pills mills and of diversion and abuse, including through these trainings, but it persisted selling holy trinity combination prescriptions and opioids prescribed by suspect providers who met these factors. Food City also continued to be aware of and ignore other red flags for diversion and abuse referenced in the trainings.

²⁵⁸ PCG-TN0011759, -92.

301. And despite previously committing to restrict sales of under 10% of its total prescriptions as controlled substances, Food City continued to have stores that had much higher percentages of controlled substances compared to total prescriptions. A PCG audit of Food City # 687, located in Knoxville, on November 19, 2015, stated that 16% of its total prescriptions were controlled substances.²⁵⁹

302. Food City received still more news that its policies were not being implemented based on audit findings from PCG in December 2015. On December 2nd, PCG reported to Food City, as shown below, that its consultant "had identified two family members, possibly husband and wife, who were filling prescriptions for "Trinity Cocktails" . . . Collectively this couple filled approximately # 59 prescriptions at Food City # 616 between June, 5, and November 2015 of the above mentioned combination medications from those five prescribers listed above." ²⁶⁰

²⁵⁹ PCG-TN003879 (Response No. 79, line 238).

²⁶⁰ PCG-TN004023.

ELEMENT 3: DUE DILIGENCE -- PRESCRIPTIONS

Consultant Sullivan had the opportunity to review some of the patients/customers prescriptions randomly who were receiving controlled substances for pain management. The prescriptions were then queried by Consultant Sullivan on the pharmacy's McKesson Enterprise system patient profiles.

Consultant Sullivan identified two family members, possibly husband and wife, who were filling prescriptions for "Trinity Cocktails" written by the following practitioners:

MA2903830
MG0541587
AM5434117
MM0125989
BR6963816
A STATE OF THE PARTY OF THE PAR

RX #4019655	Flurazepam 30mg	#30 du
RX #4019556	Alprazolam 1 mg	#120 du
RX #4019501	Carisoprodol 350 mg	#84 du
RX #2027163	Oxycodone 15 mg	# 90 du
RX #2027162	Oxycontin 40 mg	# 60 du

Collectively, this couple filled approximately # 59 prescriptions at Food City #616 between June 5, 2015 and November 04, 2015 of the above mentioned combination medications from those top five prescribers listed above.

- 303. In addition, PCG told Food City, "There were multiple controlled substance prescriptions with no documentation in some of the patient profiles." ²⁶¹
- 304. In 2016, Food City continued to sell high risk opioids. On July 8, 2016, PCG conducted an audit of Food City # 616 in which the pharmacist-in-charge stated that 5–10% of the prescriptions "could be considered high risk." While 5–10% is smaller than estimated percentage at other stores, the figure is still high given the likelihood of diversion and/or abuse.
- 305. In October 2017, Food City continued to follow news of DEA enforcement actions.

 On October 16, 2017, Executive Vice President Mickey Blazer sent an e-mail to other executives, including CEO Steve Smith and his subordinates, summarizing a 60 MINUTES news story about the origins of the opioid epidemic that featured Former DEA Deputy Assistant Administrator Joe

²⁶¹ PCG-TN004024.

²⁶² # 87.1.

Rannazzisi. Mr. Blazer noted that the story was "why we have to be so diligent with our policies when it comes to filling Controls" while also noting: "The first question that a Pharmacist is asked during a Board of Pharmacy inspection for over the past two years is 'are you getting pressure from your Supervisor or Company" to fill Prescriptions you are not comfortable with.' Every inspection!!!!"²⁶³

From: Mickey Blazer Sent: Monday, October 16, 2017 8:27:08 AM To: Mark Hubbard; Les McSwain; Brandon Mowell; David Robinson; Brady Parvin; Steve Trout; Randy Williams; Joe Greene; Rodney Dillard: Daryl Massey; John Cecil; Ron Tacker; Rick Bishop; John Jones; Greg Sparks; Steve Smith; Charlie Cc: Wick Hayton; Ken Slagle; Tom Geoghagan; Melissa McCall; Amanda McCall; Chrissy Darnell Subject: 60 Minutes Opioid Addition If you did not get an opportunity to watch "60 Minutes" last right, I encourage you to google "60 Minutes Opioid Addiction". This is the rest of the Story on "Operation Choke" All though I don't agree with Joe Rannazzisi stance on the Distributors being untouched it is an interesting story. McKesson paid 13,2ml in fines and Cardinal paid 34ml, He also talks about Pain Clinics, Pharmacist, and Chain Pharmacies that used the Opioid Epidemic to get rich. They interviewed "Matt Murphy" former DEA Agent. Matt is my direct contact with Pharma Compliance, the Third Party we use to audit our Pharmacies. He basically tried to confirm that Rannazzisi got railroaded. This Story will give some idea of our Pharmacist face every day and why we have to be so diligent with our policies when it comes to filling Controls. The first question that a Pharmacist is asked during a Board of Pharmacy Inspection for over the past two years is "are you getting pressure from your Supervisor or Company" to III Prescriptions you are not comfortable with". Every Inspection!!! I encourage you to read or listen to the clips of the article when you have a minute. Thanks, Mickey Blazer Executive Vice President Tharmacy and Fuel Operations K-VA-T Food Stores Inc.

306. Steve Smith responded later that day just to Mr. Blazer and indicated that he thought Mr. Rannazzisi was the DEA agent who caused them so many problems because he placed pressure on McKesson, which caused the distributor to place pressure on Food City, albeit temporarily. Mr. Smith stated:²⁶⁴

²⁶³ TNAG-FC-CUST00092600 (highlighted emphasis added).

²⁶⁴ TNAG-FC-CUST00092600 (highlighted emphasis added).

From: Steve Smith I/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0315D447D4E34FECA4A6C312735CE2C9-STEVE SMITH)

Sent: 10/16/2017 2:27:47 PM

To: Mickey Blazer [blazermi@FoodCity.com]

Subject: Re: 60 Minutes Opioid Addition

I think we found the guy that put us in such a bind. He was threatening the distributor and really wanted some of their blood as well as jail time. I still believe that whole situation could have been handled better if everybody had had a adult conversation

Steve Smith

307. Food City executives did place pressure on its pharmacists to fill opioid prescriptions to increase profits from the pharmacy. In one case, after hearing that a Food City pharmacist was uncomfortable with filling suspect opioid prescriptions from Bearden Health Care Associates after the DEA's raid, the executive got in his car and drove almost two hours to Knoxville from Abingdon, Virginia to personally tell the pharmacist that the pharmacist had to keep filling these Bearden opioid prescriptions.

308. As of April 2018, Food City had knowledge of signs that diversion was occurring from Food City # 705, located in Chattanooga. Food City sold Endocet based on a "pre-dated" prescription to an individual who had died before the sale occurred. Mickey Blazer was sent the following e-mail:²⁶⁵

²⁶⁵ TNAG-FC-CUST00107679.

From: Rebecca Blackstone [blackstone@FoodCity.com]

Sent: 4/27/2018 9:02:18 PM

To: Mickey Blazer [blazermi@FoodCity.com]

Subject: Audit we need to discuss

Attachments: 3098_001.pdf

Mickey,

Attached is a notice I received from Humana this afternoon. It states that we need to reverse a claim, because the patient had already died prior to fill. I looked at this before I sent it to the store, and I don't think this is our issue. The only thing that we did that was questionable was accept "pre-dated" prescriptions for a control. If a family member presented us with a prescription for a patient (who was probably sick), how are we supposed to know they died? I think Humana needs to take this up with the patient's family. I don't see how we are going to be out \$73 for someone else's criminal act. You can call me if you wish. I will not send this to 705 until I hear from you or Amanda.

Becky

- 309. Food City continued to sell opioids that its own pharmacist considered high risk in April 20, 2018. In a PCG audit for Food City # 630, located in Dandridge, the pharmacist-in-charge reported that "less than 10% of the scripts that could be considered high risk." ²⁶⁶
- 310. And again, despite previously committing to restrict sales of under 10% of its total prescriptions as controlled substances, Food City continued to have stores that had much higher percentages of controlled substances compared to total prescriptions. A PCG audit of Food City # 650, located in Harriman, on October 10, 2018 stated that 17.2% of its total prescriptions were controlled substances.²⁶⁷
- 311. Food City has continued to intentionally avoid extremely basic steps to perform due diligence on prescribers. For example, as known to Food City executives, a November 28, 2018 PCG audit showed that the pharmacist at Food City # 601 in Johnson City was not able to

^{266 # 125.1.}

²⁶⁷ # 132.1 (Response No. 79, line 229).

access the "Emdeon²⁶⁸ system" and reported "not using the system very often."²⁶⁹ The Emdeon system is a basic tool that, among other things, provides realtime basic information on prescribers including DEA registration status. The PCG report, excerpted below, stated:

56	Does the pharmacist understand how a prescriber's DEA registration is ran through Emdeon? Is the Pharmacist verifying unknown prescribers thru the DEA website? Document their response.	1.	0

- 312. In 2019, Food City continued to receive notices of opioid overdoses at its locations. For instance, on March 1, 2019, the loss prevention specialist at Food City # 647, located in Maryville, notified CEO Steve Smith and others that a woman, who later admitted to injecting heroin in the bathroom, and had suffered a non-fatal overdose.²⁷⁰
- 313. By March 2019, Food City wanted to change the way that its audits would be conducted because they were costing the Company too much money. In a discussion Mr. Blazer had with PCG, which PCG summarized in a subsequent e-mail, Mr. Blazer told PCG that "he thought the return on investment might not be worth it on the audits and he feels the current checklist should be updated relative to DEA and State Regulations." According to the e-mail:
 - "Mickey also stated that the last year's inspections resulted in scores that are consistent among Food City Pharmacies and there is no significant difference."

The Company rebranded in 2015 and changed its name to Change Healthcare.

²⁶⁹ # 136.1 (Resp. No. 56, line 165).

²⁷⁰ TNAG-FC-CUST00135253.

- "Mickey stated that there might not be a need for the Deep Dive, and to start fresh with revising the checklist and conducting fewer audits but a more detailed audit."
- "There was a discussion that the inspection should be unannounced, and DQIT [another compliance company] should coordinate with Food City Pharmacy Professional Pharmacy [sic] Managers by the 15th of the month before the next month in which the inspection is going to take place due to Pharmacist-in-Charge schedules."
- "Mickey stated that he didn't want the inspection to be an 'I got you thing' instead he wanted it to be a *teaching event* for the pharmacist." ²⁷¹
- 314. The e-mail highlights the inherent and continuing flaws of Food City's compliance program. From December 2011 until today, Food City, as noted by distributors, has limited inhouse compliance enforcement and has relied *almost exclusively* on its outside consultants to conduct and police controlled substance policies designed to prevent diversion and abuse of opioids, among other things—and has only done so at the insistence of its distributors. Conducting fewer audits, no matter how detailed, especially given Food City's history and the lack of a meaningful internal compliance infrastructure, invites the diversion and abuse of opioids. Moreover, having the Company shape the contours of the audit demonstrates the inherent conflict of interest with the process. If a consultant group becomes too diligent with audits, the Company can simply fire it and hire a replacement that will not.
- 315. In too many instances, Food City received an adverse audit finding and did not attempt to correct or address the problem. Food City's audits, which its distributors required to reduce their own liability, were largely a means to an end—to keep the supply of opioids coming.

164

PCG-TN001959.

H. Food City Opioid Sales from Specific Suspect Providers, Clinics, or Practice Groups

316. Aside from Bearden Health Care Associates, Food City had years of actionable intelligence and information about opioid diversion and abuse from pill mills or other highly suspect prescribers, clinics, or practice groups, but saw them as less of a liability and more as a business opportunity.

i. Breakthrough Pain Therapy Center

- 317. Breakthrough Pain Therapy was a clinic owned and operated by Sandy and Randy Kincaid, both non-health care providers, that was raided by federal authorities on December 14, 2010. Mr. and Mrs. Kincaid were indicted for money laundering and conspiracy to distribute oxycodone, morphine, oxymorphone, and alprazolam based on illegitimate controlled substance prescriptions.
- 318. Before the December 14, 2010, Food City had knowledge of red flags for abuse and diversion at the clinic, including high percentages of cash payors, and distributed over 272,500 opioid dosage units before the raid. During the week after the December 14, 2010 raid, Food City dispensed over 4,000 Schedule II controlled substances, 77% of which were Oxy 30 and 76% of which paid in cash.
- 319. Food City's executives, including Mickey Blazer, also knew by April 2012 of reports that David Brickhouse, who was affiliated with both Breakthrough Pain Center and Prodigal Primary Care, was running a pill mill.²⁷²
- 320. Between the December 7, 2010 raid, which was highly publicized by the DEA through a press release and known in Knoxville, and the October 7, 2014 indictments, Food City

²⁷² TNAG-FC-CUST00007633.

603, 611, 616, 644, 656, 674, and 694 sold approximately 268,000 opioid prescribed by Breakthrough prescribers. Roughly 63% of this amount was Oxy 30.

ii. Prodigal Primary Care

321. On April 18, 2012, Lou Scudere sent an e-mail to Mickey Blazer regarding Prodigal Primary care which read, "The follow's name is David Brickhouse, I have no indication of a middle name. Let me know what else you might need." Mr. Blazer sent the following response, in which he states that "a couple of Blogs" claim that Brickhouse is running a pill mill, but Mr. Blazer said that he "doesn't put much stock in Blogs": ²⁷³

²⁷³ TNAG-FC-CUST00007633.

Mickey Blazer [/O=FOOD CITY/OU=FOODCITY/CN=RECIPIENTS/CN=BLAZERMI] 4/20/2012 12:51:09 PM Sent: Lou Scudere [scuderel@FoodCity.com] To: John Jones [jones]@foodcity.com]; Steve Smith [smiths@FoodCity.com] CC: Subject: RE: Prodigal Primary Care David Brickhouse does not have any pending investigation or disciplinary action or attached to his DEA license. He was previously involved with a Dr. Rodenberg that got him a lot of attention with the media. "Don Dare" did a segment on Rodenburg and interviewed Brickhouse about his association with him. There are a couple of Blogs indicating Brickhouse is running a pill mill but I don't put much stock in Blogs. Please note: Prodigal Primary Care is registered with the State of Tennessee as a Pain Clinic in the following three locations. (This requirement of registration become mandatory January 2012 with a grace period until April, 2012.) Prodigal Primary Care, PC 2911 Essary Road Knoxville, TN 37918 Prodigal Primary Care, PC 10904 Kingston Pike Knoxville, TN 37934 Prodigal Primary Care, PC 901 Merchants Drive Knoxville, TN 37912 The State requires you to register as a Pain Clinic when: "Pain management clinic" means a privately-owned facility in which a medical doctor, an osteopathic physician, an advanced practice nurse, and/or a physician assistant provides pain management services to patients, a majority of whom are issued a prescription for, or are dispensed, opioids, benzodiazepine, barbiturates, or carisoprodol, but not including suboxone, for more than ninety (90) days in a twelve-month period; and Please let me know if I need to provide any further information. Thanks, Mickey Blazer Food City Director of Pharmacy Operations

322. Food City and Mickey Blazer were dismissive of internal information they possessed suggesting that Prodigal Primary care was operating as a pill mill and did not bother even doing a cursory review of his prescriptions or with whom Mr. Brickhouse was currently working. Prodigal and Brickhouse were part of a vast pill mill operation led by Sylvia Hofstetter, who federal prosecutors have called "the largest drug dealer to ever set foot in a courtroom in East Tennessee."

[&]quot;New Trial Set for Hofstetter in Federal Pill Mill Case," WBIR, available at https://www.wbir.com/article/news/new-trial-set-for-hofstetter-in-federal-pill-mill-case/229753444.

- 323. Food City's pharmacies, including Food City # 674, filled opioid prescriptions for Mr. Brickhouse and other Prodigal Providers even *after* April 18, 2012, the date of Mr. Scudere's email, in part because no information about Brickhouse was shared with the pharmacists. ²⁷⁵
- 324. On May 28, 2015, PCG sent Food City's Mickey Blazer and Will Bevins an e-mail with information that confirmed what Food City was told about three years earlier—that the Prodigal clinics were pill mills.²⁷⁶
- 325. On May 29, 2015, Mickey Blazer forwarded PCG's e-mail, shown below, to Food City executives including CEO Steve Smith with the message: "Lots and Lots of activity from the FED's in Knoxville and surrounding area on Pain Clinics. See attached articles: Tough time to be a Pharmacist in Knoxville." 277

Mickey Blazer [blazerni@FoodCity.com] From: Sent: 5/29/2015 1:07:50 PM John Jones [Jonesj@foodcity.com]; Jesse Lewis [Lewis]@FoodCity.com]; Steve Smith [smiths@FoodCity.com] CC: Will Bevirss [bevinsw@FoodCity.com]; Charlle Fugate [fugatec@FoodCity.com] Subject: FW: Information received in Knoxville TN Judge Alleged pill mill operator must stay in jall htm; How did officials miss pill-mill operation - News Sentinel Attachments: John, Jesse, and Steve, Lots and Lots of activity from the FED's in Knoxville and surrounding area on Pain Clinics. See attached articles: Tough time to be a Pharmacist in Knoxville. Mickey Blazer Executive Vice President of Operations Knowille Division K-VA-T Food Stores Inc.

326. Mr. Blazer's statement, "Tough time to be a Pharmacist in Knoxville" was notable because the federal indictments and news coverage did not reference any federal actions against pharmacists—only actions against prescribers and owners of pill mills.

²⁷⁵ 674 DEA Report(a) (Franklin).

²⁷⁶ PCG-TN006274.

²⁷⁷ TNAG-FC-CUST00093770.

- 327. Food City pharmacies, including # 674 and # 616, continued to sell prescriptions from Prodigal providers well *after* Mr. Blazer's May 29, 2015 e-mail, ²⁷⁸ and would continue to sell numerous high-dose, high-volume opioid prescriptions from Prodigal providers who Food City knew transferred to Bearden Health Care Associates until at least 2018 in some cases. At Food City # 674 alone, the Company sold opioid prescriptions to patients of three different providers still working at Prodigal *after* May 29, 2015 and as late as 2017. Food City # 616 also sold prescriptions from Prodigal providers and from those who quickly transferred to Bearden Health Care Associates well after the federal action was announced in 2015. ²⁸⁰
- 328. All told, Food City sold approximately 4,500 doses of oxycodone and other opioids prescribed by Prodigal Primary Care HCPs *after* May 29, 2015 from Food City # 694, # 674, # 616, and # 644, which was located in Seymour.

iii. James Earl Chapman and Atlanta Medical Group

- 329. Food City had actionable information about Dr. James Earl Chapman, who operated a pill mill in Atlanta, Georgia, and disregarded the direct warning.
- 330. On July 2, 2010, the pharmacist in charge at Food City # 688 in Knoxville, reported valid, grave concerns regarding the Atlanta Medical Group, a clinic located three hours away in the heart of Georgia, and the clinic's primary doctor, a cardiologist named Dr. James Earl Chapman:²⁸¹

²⁷⁸ 674 DEA Report(a) (Bartlett).

²⁷⁹ 674 DEA Report(a) (Bartlett, Chen, Nations, search of 2911 Essary Rd, 3221 Middlebrook Pike, 598 John Deere Dr, 901 Merchant Dr., 901 Merchants Dr.)

²⁸⁰ 616 DEA Report(a) (Bartlett, McCormick, search of 2911 Essary Rd, 3221 Middlebrook Pike).

²⁸¹ TNAG-FC-CUST00001992.

From: Pharmacy Rx688 [/O=FOOD CITY/OU=FOODCITY/CN=RECIPIENTS/CN=RX688]

Sent: 7/2/2010 9:07:53 PM

To: Mickey Blazer [blazermi@FoodCity.com]; Tom Geoghagan [geoghagt@FoodCity.com]; Don Clark

[clarkd@FoodCity.com]; Connie Reed [reedc@FoodCity.com]

Subject: question prescriptions from GA

received 3 separate requests for prescriptions to be filled from:

Dr. James Earl Chapman The Atlanta Medical Group, Inc. Cartersville, GA 30120

The prescriptions were all EXACTLY the same: each patient had 3 scripts, Oxycodone 30mg #200, Oxycodone 15mg #40, Xanax 2mg #50

The office will verify that the prescriptions are valid; however, each person said they'd had a difficult time getting a pharmacy to fill them...yet another red flag!! So, I called 2 pharmacies in Cartersville, GA and one Walgreen's in a nearby town. They told me that this doctor is under investigation by the D.E.A. and they were no longer filling for him. The D.E.A. has requested all his prescriptions from one of the pharmacies (Rite-Aid) be gathered and they will be in that pharmacy soon to pick them up... Walgreen's has this doctor flagged in their system as "under investigation by the D.E.A."

I don't feel good about these prescriptions because I don't think there's a valid situation backing them up! One pharmacist told me that you can call very lete...after hours...and someone will verify the prescriptions as valid but there's no doctor present at that time...WOW!!!

Just wanted you to be aware so you can decide how to handle this. I think all the pharmecies need to know these details, and again, I do not feet this is a legitimate patient/doctor relationship. It's sounds like a..."you pay me an office fee—I give you prescriptions" racket.

Thanks

Rx688

331. Half an hour later, Don Clark, Food City's then-Director of Pharmacy, forwarded a modified version of the e-mail, despite the pharmacists statement "I think all the pharmacies need to know these details," which excluded some of the most damning facts, including that the pharmacist explicitly stated that she did "not feel this is a legitimate patient/doctor relationship," Dr. Chapman was under investigation, and multiple pharmacies in his area would not fill his prescriptions: ²⁸²

²⁸² TNAG-FC-CUST00001993.

CC: Wick Hayton [Haytonw@FoodCity.com]; Will Bevins [bevinsw@FoodCity.com]; Mickey Blazer

[blazermi@FoodCity.com]; Tom Geoghagan [geoghagt@FoodCity.com]; Don Clark [clarkd@FoodCity.com]; Connie

Reed [reedc@FoodCity.com]

Subject: Questionable prescriptions from GA - Message from Don Clark

FROM DON CLARK

Several Stores have called regarding Questionable Prescriptions coming from a Clinic in Atlanta GA.

Dr. James Earl Chapman The Atlanta Medical Group, Inc. Cartersville, GA 30120

Many of the prescriptions appear to be EXACTLY the same: the patients had 3 scripts, Oxycodone 30mg, Oxycodone 15mg, Xanax 2mg

The office will verify that the prescriptions are valid; however, it is virtually impossible to validate a Bona Fide Prescriber Patient relationship for an out of state prescriber.

Exercise extreme caution with these Prescriptions and unless you know the patient, and in your professional judgment can feel assured that there is a Bone Fide relationship between this Prescriber and the Patient refuse to fill these prescription. Simply tell the Patient you "Do not have everything you need to fill these prescriptions"

If you have any questions, please contact your Pharmacy Operations Manager, Professional Services Manager, or the KVAT Pharmacy Office.

- 332. Unsurprisingly, Food City continued to sell opioids based on Dr. Chapman's prescriptions despite the clear evidence that this was an illegal pill mill. For example, within the next thirty days, Pharmacy # 611, located three and a half hours away in Gatlinburg, filled at least five prescriptions totaling 720 pills for patients from his office, all for immediate release oxycodone and all paid for in cash. Notably, to get to Food City # 611 in Gatlinburg, customers from the Atlanta Medical Group had to bypass numerous pharmacies, including other Food City pharmacies, in Northern Georgia, near Chattanooga, and outside of Knoxville.
- 333. Dr. Chapman was indicted in July 2011²⁸³ and tried on 49 counts of drug trafficking for prescribing and dispensing controlled narcotics. He was ultimately convicted and sentenced to 10 years in federal prison. According to the U.S. Attorney's Office's press release, the Atlanta

Amy Womack, "Macon Doctor Indicted in 'Pill Mill' Case, THE TELEGRAPH, available at https://www.macon.com/news/article28613215 html (July 13, 2011).

Medical Group was just "a front for the mass distribution of addictive pain killers." The clinic owners told an obliging Dr. Chapman "to see as many patients as possible, and to prescribe as many oxycodone pills as possible." According to federal prosecutors:

In May 2010, using information from the FBI/NW Georgia Criminal Enterprise Safe Streets Task Force, federal, state and local law enforcement agents joined together in investigation of Atlanta Medical Group ("AMG") after learning that the clinic, located in Cartersville, Georgia, was prescribing pain pills outside the bounds of legitimate medical practice. ...

Chapman, while serving in his role at AMG, failed to fulfill a doctor's basic obligations to conduct physical examinations of patients and verify medical histories before prescribing astronomical quantities of controlled substances. Significantly, in the first year the clinic opened, Chapman received the highest number of oxycodone pills of any doctor in the State of Georgia. Chapman continued to prescribe controlled substances in dangerous amounts and combinations even after he received notice that many pharmacies in the area were refusing to fill the prescriptions and that the medical board had subpoenaed his records to determine the propriety of his prescribing practices. Those patient records revealed that Chapman knew that at least some of his patients were drug addicts: the records contained information (from a nurse or the "patients" themselves) that those patients had previously purchased the drugs illegally.

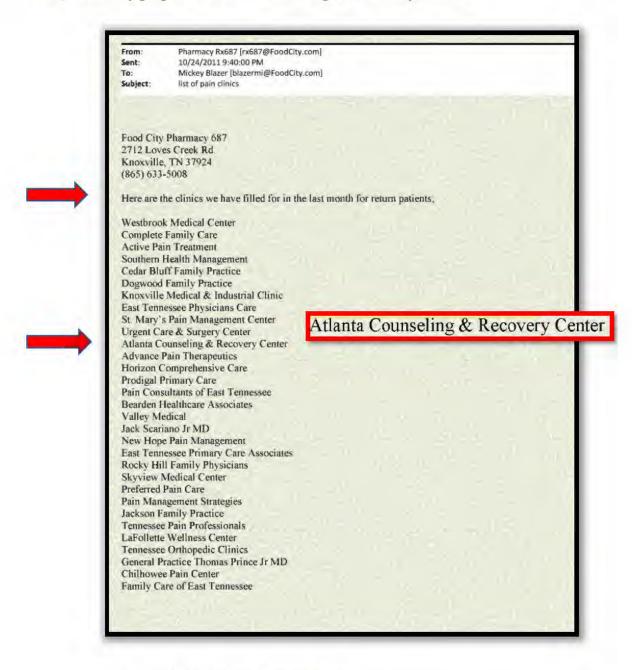
In fact, more than 98% of the patients traveled to AMG from surrounding states in order to receive prescriptions for controlled substances. Furthermore, the evidence showed that Chapman was a drug user himself, and that he asked clinic employees to assist him in illegally obtaining narcotics for his own use. For example, on one day in particular, Chapman had another clinic employee fill out narcotics prescriptions for him to sign, as he was too intoxicated to do so himself. Still, his own drug use did not stop him from seeing "patients.²⁸⁴

334. Even after news of Dr. Chapman's indictment broke in July, as of October 24, 2011, Knoxville Food City # 687 still listed the Atlanta Counseling & Recovery Center on its list of "clinics we have filled for *in the last month for return patients*" in an e-mail to Food City Director of Pharmacy Operations Mickey Blazer as part of Amerisource's required due diligence.²⁸⁵

[&]quot;Former Heart Surgeon Convicted of Unlawfully Prescribing and Dispensing Oxycodone," UNITED STATES DEPARTMENT OF JUSTICE, *available at* https://www.justice.gov/usao-ndga/pr/former-heart-surgeon-convicted-unlawfully-prescribing-and-dispensing-oxycodone (September 28, 2015) (emphasis added).

²⁸⁵ TNAG-FC-CUST00121495 (emphasis added).

Notably, the name alone should have been a red flag. Not only did it specify that it was out of state, but clearly purported to be a "counseling and recovery" center.



iv. Dr. Andrew Sugantharaj

335. Similarly, Food City had specific knowledge about Dr. Andrew Sugantharaj and continued to sell opioids based on prescriptions he wrote anyway. 336. Dr. Sugantharaj was listed as one of the top ten prescribers of controlled substances in the PCG report for Pharmacy # 674 for July to November 2011. The report also stated that 57% of his prescriptions for controlled substances that Pharmacy # 674 filled were *high risk*. ²⁸⁶

337. He was still in Pharmacy # 674's top ten prescribers for July to October 2013.²⁸⁷

338. In September 2011 alone, patients of Dr. Sugantharaj were filling his prescriptions for oxycodone at 21 different Food City pharmacies.

339. Dr. Sugantharaj, an internist, was also the registered owner of a weight loss clinic and Complete Family Care, a registered pain management clinic. As reported by the Knoxville News Sentinel, both of his clinics were raided in May 2013 pursuant to a federal search warrant as part of a joint investigation conducted by the TBI, DEA, and the U.S. Department of Health and Human Services Office of the Inspector General.

340. In the December 2014 PCG report for Food City # 694, Dr. Sugantharaj was tied as the practitioner responsible for the most controlled substance prescriptions that the pharmacy filled. The report also noted that a quarter of his controlled substance prescriptions were high risk.²⁸⁸

341. That same month, PCG submitted a report for Pharmacy # 679, located in Powell, where Dr. Sugantharaj was also in the top ten highest prescribers of controlled substances. However, this report noted that 67% of his control prescriptions were high risk.²⁸⁹

²⁸⁶ # 104.1.

²⁸⁷ PCG-TN003024; # 138.1.

²⁸⁸ PCG-TN005974; # 54.1.

²⁸⁹ # 64.1; FC00001285.

v. Dr. Robert Maughon

- 342. Dr. Robert Maughon was a general practitioner who worked at an urgent care and primary care facility called First Med Family Center in Gatlinburg along with five other practitioners.
- 343. Food City was first alerted about Dr. Maughon in a PCG report from a September 18, 2013 audit of Food City # 611 which revealed that he accounted for 20% of the controlled substance prescriptions it dispensed. The other two most prolific writers also worked at First Med and collectively they wrote 41% of the controlled substance prescriptions filled by Pharmacy # 611.²⁹⁰
- 344. The PIC of Food City # 611 also revealed that 40% of the controlled substance prescriptions she filled were "high risk" combinations.
- 345. In the 90 days prior to this report, Food City # 611 dispensed nearly 60,000 CIIs written by First Med, including massive doses such as a 2-day prescription for 180 hydrocodone pills.
- 346. A few months later, First Med resurfaced in a March 7, 2014 e-mail Mickey Blazer sent to McKesson's compliance department and Topco which had "information gathered as part of [K-VA-T's] due diligence regarding" Food City # 611:²⁹¹

²⁹⁰ # 114.1.

²⁹¹ TNAG-FC-CUST00056571.

First Med Family Center located on 1015 East Parkway in Gatlinburg is the major medical office in the community. There are six practitioners at the Gatlinburg location, Robert Maughon, Craig Benson, Melvin Willis, L. Glenn Adkison, R.G. Hamm, and James Womack. First Med is an Urgent Care and Primary Care facility offering a full range of medical services. During the stated time frame Food City Pharmacy #611 filled 3768 total prescriptions and 214,772.25 total dosage units that were prescribed by the staff at First Med. This equates to 32.40% of their total prescription volume and 32.92% of their total dosage units. Food City Pharmacy filled 1178 controlled substance prescriptions equaling 98,741 dosage units. This is 44.96% of their total controlled prescription percentage and 52.41% of the controlled dosage units dispensed. A form of hydrocodone accounted for 268 prescriptions and 28,414 dosage units with a product containing 10mg being 240 prescriptions and 24,742 dosage units. First Med prescribed 49.9% of all hydrocodone prescriptions accounting for 66.49% of the dosage units. They also account for 68.57% of the prescriptions and 74.48% of the dosage units for hydrocodone 10mg product. Oxycodone 30mg accounted for 64 prescriptions and 7503 dosage units. This amounts to 31.53% of the prescriptions and 32.95% of the dosage units.

- 347. Typical due diligence would have included seeing whether disciplinary action had been taken against the prescriber. Had that been done here, Food City would have found that the Board of Medical Examiners previously suspended Dr. Maughon's license due to his unlawful controlled substance prescribing, including prescribing controlled substances to addicts without trying to cure their addiction. Regardless of its due diligence, Food City affirmatively knew of red flags for abuse and diversion at Dr. Maughon's practice. Again, Food City chose to focus on profits and continued selling opioids.
- 348. Food City # 611 was audited again by PCG on April 13, 2016, and it was reported back to Food City that the prescriber they filled the most controlled substance prescriptions for was again Robert Maughon, at 22%. The report also specifically stated that the PIC "reported concerns of prescribing habits with Robert Maughon due to frequence [sic] of script for patients."

²⁹² # 72.1.

349. Another glaring red flag emerged on February 13, 2018 when the PIC at Food City # 611 e-mailed Food City's Tom Geoghagan to report that Dr. Maughon's office had lied to him again to get him to fill a prescription: ²⁹³

From: Tom Geoghagan [geoghagt@FoodCity.com]

Sent: 2/14/2018 12:56:32 AM

To: Mickey Blazer [blazermi@FoodCity.com]
CC: Ken Slagle [slaglek@FoodCity.com]

Subject: FW: First Med

FYI

----Original Message----From: Pharmacy Rx611

Sent: Tuesday, February 13, 2018 05:49 PM Fastern Standard Time

To: Tom Geoghagan Subject: First Med

Tom-

I just wanted to let you know I had Dr. Maughon's office lie to me again today. I got an rx from there for Phentermine 37.5 mg 1 bid #60. I called to verify that it was supposed to be bid dosing instead of once daily. They came back and told me it was correct and they wanted the increased dose because it wasn't working for the patient. I went out to counsel the patient when they came on the signs of an overdose or toxicity. The patient told me they were only taking it once daily and the office wrote it that way so she could get a 2 month supply of the medication. Now, I don't know what I can believe from them since that is the second time they have lied to me to get me to fill an rx.

- 350. Food City sent no warnings to the other pharmacists and Food City stores, including Food City # 611, continued filling prescription after prescription from his office.
- 351. By June 1, 2018, Food City executives knew that Dr. Maughon was in jail and knew that Food City # 611 was continuing to accept prescriptions from his office, except for his handwritten prescriptions, knowing this on the basis that his license was still active. ²⁹⁴
- 352. By June 6, 2018, five days later, Food City # 611 resumed filling prescriptions for controlled substances written by Dr. Maughon.

²⁹³ TNAG-FC-CUST00103368 (redacted by the State).

²⁹⁴ TNAG-FC-CUST00104502.

- 353. Just over one month later, on August 1, 2018, the Board of Medical Examiners disciplined Dr. Maughon. In the resulting Consent Order, he stipulated that from at least May 2011 to July 2015 to the present:
 - he provided treatment for chronic pain to numerous patients, which included prescribing large doses of narcotics and other controlled substances in amounts and/or for durations not medically necessary;
 - he failed to refer patients to a licensed pain management clinic for continued long term pain management treatment;
 - his medical records provided scant details, which included repetitive computerized documentation of physical examinations, a diagnosis based largely on a patient's complaint, and a treatment plan that prescribed drugs, often indefinitely, with unspecified goals for the treatment;
 - he failed to adequately inform his patients of the harmful effects of certain medication combinations, and failed to adequately inform his patients about the potential risk and benefits of the prescribed medications;
 - he prescribed narcotics and/or other controlled substances to his patients when the quantity, duration and method was such that the patients could potentially become addicted to the habit of taking said medications;
 - he failed to consistently perform pill counts; and
 - he routinely failed to consistently provide alternative modalities of treatment other than the prescription of controlled substances. ²⁹⁵
- 354. Despite verifiable reports of his arrest, warnings from pharmacists, and the Board of Medical Examiners order, Food City # 611 was *still* honoring huge CII prescriptions written by Dr. Maughon, frequently in the same amounts, for oxycodone, fentanyl, morphine, and hydrocodone up *until August 15*, 2018, even after his disciplinary action.²⁹⁶
- 355. While he was practicing, Food City sold a significant quantity of Dr. Maughon's opioid prescriptions. Food City # 611 and # 644, located in Seymour, sold one customer 92,713

In the Matter of Robert Maughon, M.D., Docket No. 17.18-150855A (Tenn. Bd. of Med. Exam. Aug. 1, 2018) available at https://apps health.tn.gov/DisciplinaryExclusion/boardorder/display/1606 16795 080118.

²⁹⁶ 611 DEA Report(a).

opioid dosage units over time—the vast majority of which were written by Dr. Maughon or his office.

vi. Dr. Peter Stimpson

356. Dr. Stimpson is a family practitioner located in Loudon, who is also licensed to prescribe Suboxone. As with others, there were multiple red flags about Dr. Peter Stimpson's opioid prescribing.

357. On March 18, 2014, PCG audited Food City # 632 in Loudon, a town about forty miles southwest of Knoxville. According to the investigator, the PIC reported that the prescribers with the highest percentage of scripts included Peter Stimpson at 8%, Donna Smith at 6%, and Irina Lavrik at 5%. The PIC also reported that her pharmacy filled prescriptions for Chilhowee Pain Center, Spinal Pain Solutions, and Serenity Health; that approximately 10% of the prescriptions they filled were high risk; and that Frank McNeil and Clary Foote had "unusual prescribing habits." ²⁹⁷

358. Dr. Stimpson was disciplined by the Board of Medical Examiners on September 14, 2016 after it reviewed 45 of his patient records and found that:

- from at least March 1999 to present, [he] provided treatment chronic pain to numerous patients which included prescribing doses of narcotics and other controlled substances without documenting sufficient justification for such prescribing in the patients' charts[;]
- [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 his treatment plans[;]
- [he] prescribed controlled substances and other medication without documenting a written treatment plan with regard to the use of controlled substances and other medications[;]

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²⁹⁷ # 75.1.

- [his] patient charts frequently involved handwritten notes with scant medical details and multiple office visits on one page[;]
- [he] failed to adequately document consultations with patients regarding anomalous urine drug screens and of the harmful effects of medication combinations[;]
- [he] failed to document few modalities of treatment other than the prescription of controlled substances provided to his patients[;]
- [a]s an example of [his] overprescribing behavior, [he] prescribed patient RH dangerously high levels of controlled substances from 2007 through 2014, including prescribing Xanax, Oxycodone Hydrochloride, and Oxycontin, at one point prescribing patient RH a combined total of approximately 900 morphine equivalent daily dosage. [He] failed to counsel patient RH regarding the dangerous interaction of opiates and benzodiazepines, failed to suggest an alternative treatment, and failed to document in patient RH's charts the variances in dosages, vitals, and plan of care[;] and
- [he] was among the top fifty (50) prescribers of controlled substances in the State of Tennessee in 2014 and 2015. 298
- 359. In response, the Board placed his license on probation for five years, required him to decrease the volume of opioids he prescribed by at least 30%, to document such decrease, to obtain practice monitoring by a third party for five years, and to receive training in controlled substance prescribing.
- 360. On October 10, 2018, PCG gave two reports to Food City referencing Dr. Stimpson: one based on Food City # 650 in Harriman, located about 40 miles from Loudon, and the other Food City # 662 in Crossville, over 60 miles from Loudon. PCG also audited Pharmacy # 650 in Harriman, a town about 40 miles from Loudon. PCG told Food City that the Food City # 662 pharmacist "reported concerns with combinations prescribed by Dr. Stimpson." ²⁹⁹ PCG told

In the Matter of Peter G. Stimpson, M.D., Case No. 2013-020951 (Tenn. Bd. Med. Exam. Sept. 14, 2016), available at https://apps health.tn.gov/DisciplinaryExclusion/boardorder/display/1606 8483 091416.

²⁹⁹ # 119.1.

Food City that the PIC in Harriman "reported concerns with combinations prescribed by Dr. Stimpson" and *identified him as a practitioner who wrote 4.4% of the controlled substances* prescriptions sold at the pharmacy.³⁰⁰

viii. Dr. Steven J. Jackson

361. Food City's executives, including Mickey Blazer, knew that the Company's pharmacies were selling opioids based on prescriptions from Dr. Steven Jackson and others within his practice group, Jackson Family Practice, as early as October 2011.³⁰¹ Opioids based on the prescriptions of Dr. Jackson and Jackson Family Practice were sold at Food City # 674, # 616, and # 644.

362. In the July 8, 2014 PCG audit of Pharmacy # 678 in Knoxville, the pharmacist "identified Steven Jackson as the one doctor that stands out with filling multiple scripts which she considers a 'cocktail.' One patient receives methadone 10, Oxycodone 30, and Soma 350."³⁰²

363. The pharmacist also "stated that the majority of prescriptions that Steven Jackson prescribes is for immediate release. This does not fall in line with the majority of the pain clinic/prescribers [sic] practice of prescribing extended release drugs for patients with chronic pain."³⁰³

364. Yet despite the pharmacist's concerns, Jackson Family Practice was still one of the primary pain clinics Food City # 678 serviced, along with Bearden Healthcare, Preferred Pain Care, and Chilhowee Pain.

³⁰⁰ # 132.1.

³⁰¹ TNAG-FC-CUST00121491.

³⁰² # 53.1.

³⁰³ # 53.1.

- 365. PCG audited Pharmacy # 687, also in Knoxville, on November 19, 2015, where the pharmacist stated that "[p]rescribers with the highest percentage of scripts included: Tonya Warwick (Jackson Family Medical)" and "reported concerns of prescribing habits [of] prescribers at Jackson Family Medical. Her concerns were with dosages over 120 for Morphine [Equivalent]." 304
- 366. In December 2015, Pharmacy # 687 was again surveyed by PCG but this time, the pharmacist told the PCG investigators that it refused to fill prescriptions from Steven Jackson's clinic:³⁰⁵

40 .Are there any physicians the pharmacy will not fill prescriptions for?		NO	
--	--	----	--

367. However, this was untrue because the investigators found patients being prescribed dangerous and highly diverted combinations of drugs by Dr. Jackson that the pharmacy was indeed filling: 306

³⁰⁴ PCG-TN003879.

³⁰⁵ PCG-TN003909.

³⁰⁶ PCG-TN007939.

ELEMENT 3: DUE DILIGENCE -- PRESCRIPTIONS

Consultant Sullivan had the opportunity to review some of the patients/customers prescriptions randomly who were receiving controlled substances for pain management. The prescriptions were then queried by Consultant Sullivan on the pharmacy's McKesson Enterprise system patient profiles.

Dr. Steven Jackson Trinity Cocktails

Rx#2016986 oxycodone 30mg #120 07/22/15

RX# 4020386 Alprazolam 1mg #120 07/22/15

RX#4020387 Carisoprodol 350mg # 60 07/22/15

Tonya Warwick, PA Trinity Cocktails

Rx# 2017379 Oxymorphone 10mg #180 09/09/15

Rx# 4020579 Carisoprodol 350 mg #60 09/09/15

Rx# 4020490 Alprazolam 1 mg # 120 09/09/15

A patient who is paying by cash and by insurance. This patient received the same regiment of controlled substances again on 08/05/15.

Dr. Steven Jackson

RX# 4020370 Alprazolam 1 mg # 60 cash 07/06/15

Rx# 2016958 Oxycodone 30mg # 80 cash 07/06/15

Rx# 2016957 Oxymorphone 15 mg # 90 cash 07/06/15

Rx # 2016956 Oxycodone 30 mg # 40 insurance 07/06/15

368. Indeed, he and Tonya Warwick were listed as the top two of the "Top Ten Prescribers of High Risk Controlled Substances" for Pharmacy # 687 for June 1, 2015 through November 13, 2015:³⁰⁷

³⁰⁷ PCG-TN003945.

Top Ten Prescribers of High Risk* Controlled Substances June 1, 2015 through November 13, 2015				
Prescriber	# RX	# DU	% Group RX	% Group DU
IACKSON, STEVEN				
HYDROCODONE	3	90	1&	<1%
OXYCODONE	31	2,365	7%	7%
ALPRAZOLAM	15	1,260	6%	7%
WARWICK, TONYA				
HYDROCODONE	3	120	196	<1%
OXYCODONE	25	2,160	6%	9%
ALPRAZOLAM	14	1,200	5%	6%

Prescriber Name	June	July	August	September	October
JACKSON, STEVEN	29	29	17	2	1
WARWICK, TONYA	0	0	11	30	26
SHUTT, ROBERT	8	11	10	10	9
BROOME, WILLIAM	9	6	10	11	7
PAYNE, RACHEL	6	9	8	5	9
MCNIEL, JANET	9	6	6	6	5
MIRE, A	6	6	6	6	6
LETT, ANGELA	5	6	7	5	7
PARAHOO, SHASTINA	6	6	6	5	5
AMBLER, TONYA	7	- 6	5	2	5
ntrolled Substance Do					
		July	August	September	October
ntrolled Substance Do	osage Units				
ntrolled Substance Do	osage Units	July	August	September	October
ntrolled Substance Do Prescriber Name JACKSON, STEVEN	June 2,310	July 2,430	August 1,310	September 80	October 120
ntrolled Substance Do Prescriber Name JACKSON, STEVEN WARWICK, TONYA	June 2,310	July 2,430 0	August 1,310 1,050	September 80 2,440	October 120 2,110
ntrolled Substance Do Prescriber Name JACKSON, STEVEN WARWICK, TONYA SHUTT, ROBERT	June 2,310 0 414	July 2,430 0 445	August 1,310 1,050 510	September 80 2,440 460	October 120 2,110 420
Prescriber Name JACKSON, STEVEN WARWICK, TONYA SHUTT, ROBERT BROOME, WILLIAM	June 2,310 0 414 300	July 2,430 0 445 242	August 1,310 1,050 510 538	September 80 2,440 460 388	October 120 2,110 420 318
Prescriber Name JACKSON, STEVEN WARWICK, TONYA SHUTT, ROBERT BROOME, WILLIAM PAYNE, RACHEL	June 2,310 0 414 300 250	July 2,430 0 445 242 520	August 1,310 1,050 510 538 460	September 80 2,440 460 388 340	October 120 2,110 420 318 640
Prescriber Name JACKSON, STEVEN WARWICK, TONYA SHUTT, ROBERT BROOME, WILLIAM PAYNE, RACHEL MCNIEL, JANET	June 2,310 0 414 300 250 930	July 2,430 0 445 242 520 540	August 1,310 1,050 510 538 460 540	September 80 2,440 460 388 340 540	October 120 2,110 420 318 640 480
Prescriber Name JACKSON, STEVEN WARWICK, TONYA SHUTT, ROBERT BROOME, WILLIAM PAYNE, RACHEL MCNIEL, JANET MIRE, A	June 2,310 0 414 300 250 930 480	July 2,430 0 445 242 520 540	August 1,310 1,050 510 538 460 540 510	September 80 2,440 460 388 340 540 510	October 120 2,110 420 318 640 480 510

369. The report even identified that 63% of Dr. Jackson's prescriptions were "high risk": 308

³⁰⁸ PCG-TN003950.

High Risk* Dispensing Habits:	
Hydrocodone:	3
Alprazolam:	15
Oxycodone:	
Total of High Risk:	
Percent of High Risk to Total:	
• • • • • • • • • • • • • • • • • • •	

370. The report also identified that 58% of Tonya Warwick's prescriptions were "high risk" as well:³⁰⁹

High Risk* Dispensing Habits:	
Hydrocodone:	
Alprazolam: Oxycodone:	14
Total of High Risk:	42
Percent of High Risk to Total:	58%

- 371. In fact, Pharmacy # 687 continued filling prescriptions for that practice *despite telling the auditors otherwise and despite the auditor's clear expressed concerns*. In May 2016, PCG auditors returned to # 687, where the pharmacist reported that "[p]rescribers with the highest percentage of scripts included: Steven Jackson at 6%" and "reported concerns of prescribing habits with Jackson Family Practice due to Morphine equivilents [sic]."³¹⁰
- 372. Other red flags for Dr. Jackson's prescribing included 27% of his patients paid for their CII opioid prescriptions in cash.
- 373. As an illustrative example, one of his patients purchased nearly 50,000 doses of CII opioids including methadone, oxycodone, oxymorphone, morphine, and hydromorphone, from Food City # 644 that had been prescribed by Dr. Jackson, 60% of which was paid for in cash. She was driving from over forty minutes from Sevierville to Knoxville to see Dr. Jackson, and then another 20 minutes to Seymour to fill her prescription at # 644.

³⁰⁹ PCG-TN003951.

³¹⁰ # 78.1.

374. This was not the only example. Another one of Dr. Jackson's patients drove long distances to Food City to get opioid prescriptions written by Dr. Jackson. One individual received approximately 16,373 doses of Schedule II opioids, including over 10,000 doses of methadone 10mg and over 6,000 tablets of Oxy 30 and 15.

I. Food City's Ties to Criminal Oxycodone Diversion Rings

375. Apart from having active partnerships with known pill mills and other suspect providers, Food City, which was known for selling the cheapest oxycodone with minimal hassle or questions, was the source of Oxy 30 and other opioids for criminal drug rings.

i. Gregory Allen Rhea's Oxycodone Ring

- 376. Gregory Allen Rhea was convicted and sentenced in 2014 for federal drug trafficking crimes. During court proceedings, he and members of his oxycodone ring, which consisted of 11 other people, admitted to selling Oxy 30 to a confidential informant on several specific occasions. Many of these sales to the confidential informant correspond directly to when the Rhea oxycodone ring member purchased thousands of Oxy 30 at Food City # 694—prescriptions all written by Bearden Healthcare providers.
- 377. For example, Food City # 694 sold a prescription to Criminal 1 of Greg Rhea's oxycodone ring consisting of 210 Oxy 30s and 60 Opana 40mg on July 27, 2011. According to court records, two days later "[o]n July 29, 2011, [Criminal 1] admitted that he sold ten (10) dose units of thirty (30) milligram oxycodone pills to a confidential informant in Morristown, Tennessee."
 - 378. The court records state that less than a month later,

On August 13, 2011, the defendant admits that he sold ten (10) dose units of thirty (30) milligram oxycodone pills to a confidential informant at the defendant's residence. During the transaction, the defendant admits that he attempted to recruit the confidential informant to travel to a pain clinic in Bearden, Tennessee, for the

- purpose of obtaining oxycodone. The defendant further admits he offered to "sponsor" the confidential informant to go to this pain clinic, which means that the defendant agreed to provide money for the travel to the clinic and the payment of medical and prescription bills in exchange for half of the prescription pills obtained as a result of the pain clinic appointment.
- 379. Food City # 694 sold 360 Oxy 30s on August 11, 2011 to Criminal 2 again two days prior to the drug deal to the informant.
- 380. Food City # 694 sold Criminal 1 another prescription for 210 oxy 30s and 60 Opana 40s on August 25 at # 694. According to the court's order, "On August 27, 2011, the defendant admits that he and [his co-defendant] sold ten (10) dose units of thirty (30) milligram oxycodone pills to a confidential informant at the defendant's residence."
- 381. Again, on October 11, 2011, Food City # 694 sold Criminal 2 a prescription for 360 oxy 30s. "On October 11, 2011, the defendant admits that he and co-defendants Criminals 2 and 3 sold nine (9) dose units of thirty (30) milligram oxycodone pills to a confidential informant at the defendant's residence."
- 382. In all, Pharmacy # 694 sold Criminal 1 over 2,000 pills (all either Oxy 30s, OxyContin 80s, or Opana 40mg—each the strongest dosage available for that drug) in the span of 6 months.
- 383. Between November 2009 and October 2012, Criminals 2 and 3 received 12,570 pain pills.
- 384. Each one of the Criminals 1, 2, and 3 prescriptions referenced above came from Bearden Health Care Associates and each one was sold at Food City # 694.

ii. Ralph Teague's Oxycodone Ring

385. Aside from the Gregory Rhea oxycodone ring, Food City was the source of Oxy 30 and other others for other criminal drug rings. In February 2013, 10 people were arrested and

charged in another oxycodone ring led by Ralph Teague. Criminal 4, who lived almost an hour away from # 616, had 29 opioid prescriptions filled at Food City # 616, totaling 4,196 pills. The prescriptions were mostly for Oxy 30 and OxyContin 80, but also hydrocodone. Criminal 5, who also lived almost an hour away from # 616, had two oxycodone and methadone prescriptions filled at Food City # 616 each month from March to September 2012.

iii. James Light's Oxycodone and Other Opioid Ring

386. On April 25, 2013, the U.S. Attorney's Office for the Eastern District of Tennessee announced the arrest of James Light of Rogersville and sentenced him to 150 months in prison, followed by four years of supervised release. As a result of the Light investigation, the U.S. Attorney's Office announced that several other individuals had been convicted and sentenced for their involvement in drug conspiracies.

387. Food City # 616 sold two prescriptions for 180 Oxy 30 pills each from Dr. Samuel Mintlow of Norcross, Georgia to Criminal 6, who lived about an hour and a half from Food City # 616, on July 1, 2011 and August 8, 2011. Dr. Mintlow had his DEA registration revoked by the DEA in an order referencing that the patients at his Georgia clinic were overwhelmingly from Rogersville, Tennessee, which is located over four and a half hours away.³¹¹

388. Similarly, Food City # 616 also sold Criminal 7, who also lived an hour and a half from the pharmacy, 180 Oxy 30 pills on July 15, 2011 and August 16, 2011 from prescriptions written by Georgia's Dr. Mintlow.

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Samuel Mintlow, M.D.; Decision and Or., 80 Fed. Reg. 15, 3630-3653, (Jan. 23, 2015), available at https://www.deadiversion.usdoj.gov/fed_regs/actions/2015/fr0123_2 htm.

- 389. Overall, Food City # 616 filled 239 Dr. Mintlow prescriptions for 35,607 ODUs (35,167 were oxycodone, 94% of which was Oxy 30) between June 27 and August 30, 2011—including to patients from Florida, North Carolina, Virginia, and West Virginia.
- 390. Food City's executives were specifically told that Dr. Mintlow was one of the highest opioid prescribers for Food City # 616 in 2011 by the Company's auditors³¹² and had 73% of his controlled substance prescriptions were high risk.³¹³

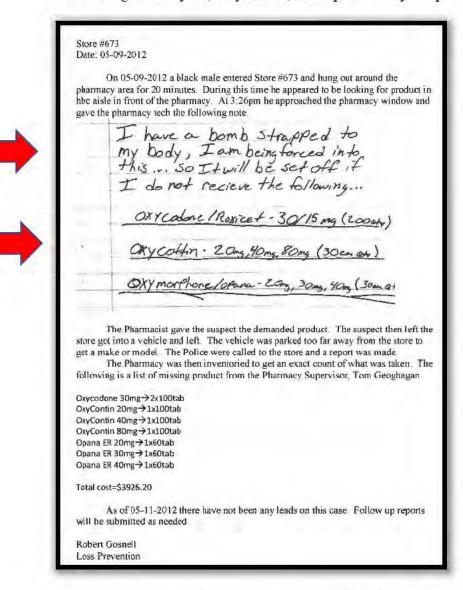
iv. Other Likely Oxycodone and Opioid Rings

- 391. Food City's records provide other evidence of likely drug rings that Food City knew or should have known about and, like the others, were completely foreseeable. For example, between January 19, 2009 and September 14, 2012, Food City Customer A received 31,151 dosage units, 27,860 of which were Oxy 30 pills, amounting to 1,566,360 MMEs based on prescriptions written by Bearden or former Bearden prescribers. Over three and a half years, he received opioids with an estimated street value of approximately \$1,500,000.
- 392. Between February 2, 2009 and June 20, 2014, Food City Customer B, whose diagnostic codes were largely not recorded, received 189 prescriptions, mostly methadone, morphine, and oxycodone, from 11 different practices, including Bearden, totaling 69,782 opioid dosage units and 3,014,660 MMEs.
- 393. Aside from this, Food City knew or should have known that diversion was taking place on Food City premises and that individuals were coming to Food City for the purpose of diverting or abusing opioids. Among other things:
 - On May 9, 2012, a loss prevention specialist at Food City # 673 reported that an unidentified male approached the pharmacy, handed the pharmacy

³¹² # 95.1.

³¹³ *Id*.

technician a note (shown below) that said he had a bomb strapped to his body that would go off if he did not receive oxycodone and oxymorphone, and was given Oxy 30, OxyContin, and Opana ER by the pharmacist;³¹⁴



 In 2013, the pharmacist-in-charge at Food City # 682 informed Mickey Blazer that she and the pharmacy team felt so unsafe they had to be escorted to their cars. She stated that: new "problem pain" pharmacy customers were so 'pushy' that longstanding regular customers had fled to other pharmacies; these new "problem pain" customers refused to take 'no' for an answer when prescriptions were denied and would return several times a day;

³¹⁴ TN-FC-CUST00027922.

- In August 2009, police came to Food City # 674 because an individual was causing a disturbance and refused to leave – it was discovered the individual had clonazepam;
- In February 2009, a patient called Food City # 674 and pretended to be a doctor in order to get Lortab;
- In January 2008, there was a robbery at # 674 in the parking lot: a customer's bag containing oxycodone, Oxycontin, and Alprazolam as snatched from the customer...who had paid \$1,955.86 out-of-pocket for the pills; and
- In September 2007, there were two robberies at Food City # 674 in the
 parking lot on different days: on September 14 a man with a gun demanded
 customers' hydrocodone pills; and on September 8 a man stole a woman's
 pain medication from her and took off running.

J. Diversion of Opioids within Food City Pharmacies

- 394. Aside from aiding and abetting the unlawful sale of opioids and other controlled substances through sales from its pharmacies despite its specific knowledge of red flags that massive abuse and diversion was occurring, Food City has had significant indicators of opioid diversion and internal inventory problems from behind its counters and through its lax enforcement and policies has aided and abetted this diversion.
- 395. On July 18, 2012, PCG conducted an audit of Food City # 609, located in Kodak, which showed that:
 - the pharmacy had had a recent incident of "employee pilferage of hydrocodone," which it had no records to show was ever reported to the State Board or Pharmacy Director;³¹⁵

 Completed DEA 106 form on file dated 7/9/12 for 'Employee Pilferage'. There was no documentation attached showing submission to State Board/Pharmacy Director.

the pharmacy was ordering excessive amounts of hydrocodone;³¹⁶

^{315 # 169.1 (}Resp. No. 10, line 51).

³¹⁶ # 169.1 (Resp. No. 74, line 74).

74 figured the percentage being close to 50% for the total of purchases of controlled substances associated with pain management compared to the total number of controlled substance purchased by the pharmacy. This number is skewed due to the recent incident involving employee pilferage of Hydrocodone. Excessive ordering of the Hydro 10/325 was occurring.

 the pharmacy was not conducting monthly inventories of Schedule II controlled substances;³¹⁷

36. Other than the documented annual inventory from June, there were no entries found for the monthly inventory. In speaking with stated that to her knowledge there have been no monthly inventories completed for the CII's.

she

 the pharmacy had at least 11 transfers of controlled substances that were not documented with the proper DEA transfer form;³¹⁸

5. CII invoices found without an executed 222 attached. They are as follows: Invoice #052-360127 (4/30), #052-360127 (4/30), #702230272 (5/25), 702202635 (5/23), #702463788 (6/4), #702656616 (6/14), #702684404 (6/14), #702685323 (6/14, 3702849092 (6/21), 702850740 (6/21), #702982359 (6/29).

 at the pharmacy, "occasionally [the] discrepancy of a pill would be noted in the book, but not communicated due to insignificance[:]"³¹⁹

 Monthly accountability inventories were not conducted to identify discrepancy I be noted in the book, but not communicated due to the insignificance. stated that the occasional discrepancy of a pill would

the pharmacy was selling holy trinity combination prescriptions;³²⁰

72. stated that the only prescriber she would consider high risk would be Dr. W

(Oxy, Xanax, Zanaflex)

the pharmacist did not even have a login to access the CSMD;³²¹

13. The latest inspection on file was dated 4/23/12 One deficiency noted, which was the inability of the pharmacist to access the CSMD due to not having a login/password. In speaking with (current RPH), it was identified that she has never had access to this system to complete PMP inquiries.

³¹⁷ # 169.1 (Resp. No. 36, line 114).

^{318 # 169.1 (}Resp. No. 5. line 47).

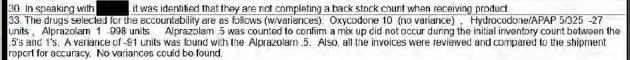
^{319 # 169.1 (}Resp. No. 38, line 115).

^{320 # 169.1 (}Resp. No. 72, line 206).

³²¹ # 169.1 (Resp. No. 13, line 54).

396. On September 20, 2012, PCG conducted an audit of Food City # 694, which stated that it was missing almost 1,000 units of alprazolam, a benzodiazepine more commonly known by its branded name Xanax, that Food City # 694 was selling in large quantities in "holy trinity" combination prescriptions. 322 The report stated, among other things:

Narrative Reponses to Record Keeping Questions:



397. On September 21, 2012, PCG conducted an audit of Food City # 650, located in Lenoir City, which stated that the pharmacy could not account for around 864 Oxy 15 pills and could not account for other opioids including oxycodone. 323 The report stated, among other things:

Narrative Reponses to Record Keeping Questions:

33. The Accountability Audit revealed that there was a deviation of 864 dosage units short of the Oxycodone 15mg, which resulted in a difference of 8.95%. During the reconciliation process the DEA Audit Report, the Drug Usage Summary Report, and a count of each dispensation located in the perpetual inventory log book resulted in different totals; however, none of the methods used accounted for all dispensations.

34. The Oxycodone 20mg was physically inventoried resulting in 483 dosage units and the perpetual inventory indicated 483 dosage units were on-hand. The Oxycontin 80mg was physically inventoried resulting in 150 dosage units; however, the perpetual inventory indicated that 136 dosage units should be on-hand. The Oxycodone/APAP 5/325mg was physically inventoried resulting in 147 dosage units; however, the perpetual inventory indicated that 197 dosage units should be on-hand. The Morphine Sulfate ER 15mg was physically inventoried resulting in 196 dosage units; however, the perpetual inventory indicated that 218 dosage units should be on-hand. The Fentanyl 25mg patch was physically inventoried resulting in 20 dosage units and the perpetual inventory indicated that 20 dosage units were on-hand.

36. RpH stated that she does not consistantly conduct monthly inventories as required.

³²² # 167.1 (Resp. Nos. 30, 33, lines 109–10).

³²³ # 173.1 (Resp. Nos. 33, 34, 36, lines 110–12).

398. Food City and its executives knew that the Company's lax establishment of and policing of internal protocols against diversion at the pharmacy allowed for massive diversion to occur. And Food City's problems with diversion from its pharmacies continued after its executives had knowledge of internal deficiencies.

399. In a representative example, Food City's loss prevention specialist sent a report to its CEO and President Steve Smith, Vice President Jesse Lewis, and Director of Pharmacy Operations Mickey Blazer on December 4, 2012 notifying them that a pharmacy technician at Food City # 673 in Knoxville had been stealing hydrocodone-APAP 10mg/500 mg, was terminated, and had been turned over to the Knoxville Police Department.³²⁴

400. If the report showed that a pharmacy tech was promptly fired after it was *quickly* discovered that she was stealing controlled substances, it would be evidence that Food City's anti-diversion policies were working. But that is not what the report showed.

401. Instead, the report stated that the technician by her own admission "had been *stealing it daily for months* and giving it to her husband and his brother for resale" (emphasis added). Food City had only discovered it when Ken Slagle, Food City's Pharmacy Operations, realized that the pharmacy was short *nearly 5000* pills of hydrocodone 10 mg/500mg after an internal review that went back to June 2012. After the 5,000-pill hydrocodone shortage was discovered, Food City's loss prevention placed a covert camera in the ceiling that caught the pharmacy tech. ³²⁵ The report is shown below:

³²⁴ TNAG-FC-CUST00013078–79.

³²⁵ Id.

Store #673

Date: 12-03-2012

On 11-28-2012 I received a phone call from Ken Slagle, Pharmacy Operations Manager. Mr. Slagle informed me that Store #673's pharmacy was showing a shortage of nearly 5000 pills of hydrocodone 10mg/500mg. This shortage was found by running Back Door / Front Door movement reports going back to June of this year. On 11-29-2012 I met with Tom Geoghagan, pharmacy supervisor, after midnight at the store to install a covert camera in the ceiling.

On 12-02-2012 I reviewed the CCTV footage and found that Lori King, pharmacy tech, selected hydrocodone 10mg/500mg from the shelf and dumped it into her hand and then into her pocket on 11-30 and on 12-01. On 11-30 Ms. King took one hand full (30 to 40 pills) and then on 12-01 Ms. King took twice as much.



On 12-03-2012 I went to Store #673 with Todd Brengle and David Edwards in order to catch Ms. King red handed with product. At 11:30am Ms. King selected the product and dumped it into her pocket. At this time Mr. Brengle and I went into the pharmacy. As we entered the department Ms. King stepped into an aisle and emptied her pocket into a trash can. We then collected the evidence from the can (30 pills) and escorted Ms.

[page break]

King from the department and to the back office. During the interview Ms. King gave both a verbal and written confession to stealing hydrocodone. She stated that she had been stealing it daily for months and giving it to her husband and his brother for resale. Ms. King was terminated and handed over to two undercover KPD narcotics officers. Ms. King will be charged with felony theft of \$1,175 worth of product among other possible charges. Follow up reports will be submitted as needed.

Robert Gosnell Loss Prevention D5/6

402. On December 26, 2012, Food City's Pharmacy Operations Manager sent an e-mail, shown below, to the Knoxville Pharmacy Division, store managers for the Knoxville Division, and district managers for the Knoxville Division that stated, among other things:

Tom and I have now completed the 2nd half checklists for the Knoxville Division for 2012. Below is a brief recap of the opportunities uncovered:

. . . .

- 2 stores had significant discrepancies when we counted their CII safes
- 2 stores were not performing CII inventories monthly!
- 403. Food City's significant controlled substance inventory problems continued in 2013. On March 4, 2013, Tom Geoghagan, Food City's Pharmacy Professional Services Manager in an e-mail to Mickey Blazer, among others, noted huge discrepancies in the store's hydrocodone inventory at Food City # 667, located in Sevierville from 2012 as shown below. In one calculation from June 26, 2012 to February 20, 2013, Food City # 667 could not account for 5,406 hydrocodone with APAP (10/325) pills. In another calculation from December 28, 2012 to

February 20, 2013, Food City could not account for 2,395 hydrocodone with acetaminophen (10/325) pills.³²⁶

From:	Tom Geoghagan [geoghagt@FoodCity.com]	
Sent:	3/4/2013 7:12:16 PM	
To:	David Edwards [edwardsd@FoodCity.com]	
CC: Subject:	Ken Slagle [slaglek@FoodCity.com]; Mickey Blazer [blazermi@FoodCity.com] RE: 667	
Amount on	Hand 26June2012 (8PM)	2523
Amount Re	ceived (Amerisource)	18000
Amount Re	ceived (McKesson)	15000
Amount Di	spensed	29256
Theoretical	on Hand	6267
Actual on H	land 20Feb2013 (7:30PM)	861
Difference		(5406)
Amount on	Hand 28Dec2012 (8AM)	1256
Amount Re	ceived (Amerisource)	0
Amount Re	ceived (McKesson)	9000
Amount Di	spensed	7000
Theoretical	on Hand	3256
Actual on F	land 20Feb2013 (7:30PM)	861
Difference		(2395)
The produc	ct in question is Hydrocodone w APAP- 10/325	
Let me kno	ow if you have any questions	
Tom Geogl	hagan	
Pharmacy	Professional Services Manager	
K-VA-T Foo	od Stores	

404. Other examples abound. On June 6, 2013, Tom Geoghagan, Food City's Pharmacy Professional Services Manager, notified Mickey Blazer, among others, that Food City # 687 was short 60 tablets of Oxymorphone ER 15 mg tablets.³²⁷

³²⁶ TNAG-FC-CUST00013074 (emphasis added).

³²⁷ TNAG-FC-CUST00122411.

687 informed me Tuesday (6/4/2013) that they are short 60 tablets of Oxymorphone ER 15mg tablets.

405. Despite rarely taking follow-up action, Food City executives received and regularly reviewed PCG reports that were prepared. Food City's executives also knew specifically that the controlled substances that could not be accounted for or that were taken by employees were some of the "most commonly stolen/Abused drugs." In an e-mail asking whether controlled substance bottles should be marked to potentially help law enforcement track diversion sources, Food City's Director of Pharmacy Operations Mickey Blazer stated:

From: Mickey Blazer [/O=FOOD CITY/OU=FOODCITY/CN=RECIPIENTS/CN=BLAZERMI]

Sent: 8/21/2013 4:29:14 PM

To: Joe Fryar [fryar]@FoodCity.com]
Subject: FW: marking narcotics in pharmacy

After the Race, lets revisit this.

I think that we can mark 4 of the most commonly Stolen/Abused Drugs and not run into an issue with returning product.

Oxycodone 30mg
Alprazolam 2mg
Carisoprodol 350mg

Thanks,

Hydrocodone 10/325

Mickey Blazer Director of Pharmacy Operations K-VA-T Food Stores, INC.

406. Food City has also continued to have internal security issues with controlled substances. On November 28, 2018, PCG conducted an audit of Food City # 601, located in Johnson City, which stated, among other things that "outdated/adulterated" controlled substances that could not be sold were left unsecured in a top drawer about the Schedule II cabinet and that five controlled substances prescription either did not have a prescriber DEA number or had DEA

numbers that did not match.³²⁸ In the same audit, the pharmacist also admitted to filling opioid prescriptions early, which is another red flag for diversion. The pharmacist stated:

that he had two 'IOUs' to adjust when the shipment came in during the review. He stated they were CII product. He stated he owed 108 pills of Hydrocodone 10/325."³²⁹

stated that he had two "IOUs" to adjust when the shipment came in during the review. He stated they were CII product. He stated he owed 108 pills of Hydrocodone 10/325.

COUNT I: PUBLIC NUISANCE STATUTE

Violation of Tennessee's Public Nuisance Statute

Tenn. Code Ann. § 29-3-103

- 407. Plaintiff incorporates by reference and re-alleges all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:
- 408. Through their substantial assistance, Defendants aided and abetted the unlawful sale of narcotics and controlled substances, including 30 milligram immediate release oxycodone and hydrocodone at Food City Pharmacy # 674 (5941 Kingston Pike, Knoxville, TN 37919), Food City Pharmacy # 694 (284 Morrell Road, Knoxville, TN 37919), and Food City Pharmacy # 616 (11501 Hardin Valley Road, Knoxville, TN 37932) and have created or maintained nuisances at those places as provided in Tenn. Code Ann. §§ 29-3-101(a)(2)(A), (b).
- 409. By ignoring indicators of diversion and abuse that they knew about, failing to maintain effective controls against diversion, enacting insufficient polices or those that seek to undermine opioid diversion or abuse, and hiring and retaining employees to increase sales of opioids, including Oxy 30 and hydrocodone, that they knew or should have known were being

³²⁸ # 136.1 (Resp. Nos. 27, 48, lines 93, 157).

³²⁹ # 136.1 (Resp. No. 60, line 169).

diverted based on specific information and data they had collected about the providers and clinics who wrote the substantial majority of opioid prescriptions filled at Food City pharmacies # 674, # 694, and # 616 as well as at these stores, Defendants have aided and abetted a nuisance.

- 410. Food City, through its executives, knew that sales of opioids not for a legitimate purpose were illegal. By failing to maintain effective controls against diversion and by knowingly selling diverted opioids, Defendants have aided and abetted a nuisance and have substantially assisted.
- 411. Among other things, Food City knew or should have known substantial diversion was occurring based on its own pharmacy ordering invoices, its own sales data, direct reports from its compliance auditors who analyzed these pharmacies, reports from its employees, sales of massive quantities of combination "holy trinity" prescriptions (an opioid, a benzodiazepine, and a muscle relaxer) sold at the same time to the same patient, reports of diversion within its pharmacies, and its failure to maintain accurate inventories at its own pharmacies.
- 412. Further, by owning, leasing, and/or otherwise controlling the pharmacies and nearby premises at Food City Pharmacies # 674, # 694, and # 616, Defendants are liable for maintaining a nuisance consistent with Tenn. Code Ann. §§ 29-3-101(a)(4), (b).
 - 413. Defendants constitute "person[s]" as defined in Tenn. Code Ann. § 29-3-101(a)(3).
- 414. Food City pharmacies # 674, # 694, and # 616 are buildings and/or a part or portion thereof of the larger grocery store and constitute "place[s]" as defined in Tenn. Code Ann. § 29-3-101(a)(4).
- 415. Public services, including costs associated with opioid use disorder prevention, treatment, and recovery as well as law enforcement costs, have been incurred and are required to abate or manage the nuisance the Defendants have aided and abetted.

COUNT II: COMMON LAW NUISANCE

- 416. Plaintiff incorporates by reference and re-alleges all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:
- 417. Through the actions described above, Defendants have 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.
- 418. By ignoring indicators of diversion and abuse, failing to maintain effective controls against diversion, enacting insufficient polices or those that seek to undermine opioid diversion or abuse, and hiring and retaining employees to increase sales of opioids, including Oxy 30 and hydrocodone, that Defendants knew or should have known were being diverted based on specific information and data they had collected about the providers and clinics who wrote the substantial majority of opioid prescriptions sold as identified herein, Defendants have aided, abetted a nuisance through their conduct at the pharmacies identified herein.
- 419. Defendants sold opioids, including through the extensive sale of "holy trinity" prescriptions that lacked any legitimate purpose and despite knowing that the combination were highly sought out by drug seekers and diverters. Defendants unlawfully sold these prescription opioids that they possessed and controlled until the point of sale, when they knew, or reasonably should have known, these would be diverted and/or used illegally.
- 420. Through Defendants' conduct, Defendants intentionally and/or unlawfully failed to maintain effective controls against diversion. Such actions were inherently dangerous to the health and welfare of residents of Tennessee.

- 421. Both the Tennessee Drug Control Act, similar state law, and the federal Controlled Substances Act create a broad duty on the part of registered pharmacies to maintain effective controls against diversion. Defendants violated this duty as set forth above.
- 422. Defendants have 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). Defendants violated this duty as set forth above.
- 423. While Defendants' degree of care is not relevant in a common law nuisance suit brought by the sovereign State, Defendants behaved knowingly or intentionally as set forth above.
- 424. Through the actions described above, Defendants have 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.
- 425. Defendants' actions have created an abundance of opioids available for criminal use and fueled a wave of addiction, abuse, injury, and death.
- 426. Defendants' actions and failures to act as described above were a substantial factor in numerous unlawful sales of opioids.
- 427. Defendants' actions have and will continue to injure and harm many residents throughout Tennessee for many years to come.
- 428. While tort-based standards are not applicable to a public nuisance suit brought by the sovereign State, the public nuisance was foreseeable to Defendants, which knew or should have known that their conduct was creating a public nuisance.
- 429. A reasonable person in Defendants' position would foresee diversion and abuse from the opioids Defendants sold based on their knowledge of red flags for abuse and diversion.

- 430. But for Defendants' conduct, an abundance of opioids would not have been accessible for diversion to the black market or for abuse.
- 431. Defendants acted without express authority of a statute in their conduct referenced above.
- 432. The health and safety of Tennessee residents, including those who use, have used, or will use opioids, as well as those affected by abusers or diverters 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. Defendants' conduct interfered in the enjoyment of these public rights.
- 433. Public services, including costs associated with opioid use disorder prevention, treatment, and recovery as well as law enforcement costs, have been incurred and are required to abate or manage the nuisance the Defendants have aided and abetted.
- 434. As part of its nuisance action, the State does not seek monetary relief attributable to TennCare, Medicaid, or Medicare.

COUNT III: TENNESSEE CONSUMER PROTECTION ACT Violations of Tenn. Code Ann. § 47-18-104(a) and (b)(43)(C)

- 435. Concerning its TCPA claim, Plaintiff incorporates by reference and re-alleges all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:
- 436. Defendants selling and offering of opioid products to individuals, as alleged herein, are things of value and constitute and affect "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.

- 437. The opioids Defendants sold 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.
- 438. Oxycodone is a Schedule II controlled substance that is unlawful to sell or possess in Tennessee absent limited exceptions. *See* Tenn. Code Ann. §§ 39-17-417(a)(3) and (4).
- 439. To fit within an exception, licensed pharmacies 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 licensed pharmacy to sell or possess a narcotic, including a Schedule II as oxycodone, that it knows or should reasonably know will be diverted.
- 440. In fact, it is unlawful for licensed pharmacies, such as those operated by Food City, 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 license is based, among other things, on "[m]maintenance 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), and "[t]he existence in the applicant's establishment of effective controls against diversion." *See* Tenn. Code Ann. § 53-11-303(a)(4).
- 441. Dispensing a controlled substance in a manner inconsistent with the pharmacy's or pharmacist's licensure law precludes a party from relying on the exception in Tenn. Code Ann. § 39-17-427 and renders the underlying controlled substances unlawful or illegal.
- 442. Among other things, Defendants' failure to maintain effective controls against opioid diversion, predominantly through the corporate policies and directives, coupled with the

continued sale of opioids despite specific knowledge that diversion of these opioids would occur or was highly likely to occur or that the underlying prescriptions, including "holy trinity" combination prescriptions consisting of an opioid, a benzodiazepine, and muscle relaxer, were illegitimate, renders the opioids (and benzodiazepines and muscle relaxers) unlawful for purposes of the TCPA.

- 443. Knowingly selling or offering to sell opioids to individuals that will be diverted or abused, 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.
- 444. By engaging in the above conduct concerning highly-addictive and potentially deadly pharmaceutical drugs that affect consumer health and safety, Defendants have also caused or are 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, Defendants have violated Tenn. Code Ann. § 47-18-104(a) in each instance.
- 445. As alleged herein, Defendants knew specific information and had actionable intelligence about downstream diversion and abuse of the opioids at Food City pharmacies and actively enabled it and participated in it for the sake of profit.
- 446. Through this action, the State does not seek removal of any opioid or other product from the market, does not seek recovery for personal injury, death, or property damage, or injury to a specific person.

PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiff, the State of Tennessee, *ex rel*. Herbert H. Slatery III, Attorney General and Reporter, pursuant to Tennessee's public nuisance statute, 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, 29-3-104, and 47-18-116;
- 2. That process issue and be served upon Defendants requiring them to appear and answer;
- 3. That an order be entered that provides for abatement of the public nuisance Defendants aided and abetted, the costs of abating or managing this nuisance, an award to the State for damages in an amount to be determined at trial, as provided in Tenn. Code Ann. §§ 29-3-101(b), (d), 29-3-110, 29-3-114, and any other relief or remedy allowable under state law;
- 4. That, in addition to the above, an order be entered that directs the removal from the Food City Pharmacies # 674, # 694, and # 616 of all means, appliances, fixtures, appurtenances, materials, supplies and instrumentalities used for the purpose of conducting, maintaining or carrying on the unlawful practice constituting the nuisance and directing the sale of thereof consistent with Tenn. Code Ann. § 29-3-110(a);
- 5. That an order be entered that provides for abatement of the public nuisance Defendants have 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;

6. That this Court adjudge and decree that Defendants engaged in the aforementioned

acts or practices that violate the TCPA;

7. That pursuant to Tenn. Code Ann. §§ 47-18-108(a)(1), (a)(4), and (a)(5), this Court

permanently enjoin and restrain Defendants from engaging in the aforementioned acts or practices

which violate the TCPA;

8. That this Court make such orders or render such judgments as may be necessary to

disgorge the net-profits and ill-gotten gains Defendants realized by reason of the alleged violations

of law;

9. That this Court adjudge and decree that Defendants pay 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);

10. That this Court enter judgment against Defendants 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;

11. That all costs, including discretionary costs, in this case be taxed against

Defendants;

12. That a jury be empaneled to hear and decide all appropriate matters; and

13. That this Court grant the State such other and further relief as this Court deems

just and proper.

Respectfully submitted,

H**ERBERT H. SLATERY III/**B.P.R.

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GLOSSARY

ABC / ABDC – acronym for Amerisource

Benzo or Benzodiazepine – an anti-anxiety medication (e.g., Xanax)

C2 or CII – shorthand for Schedule II Controlled Substances

CSMD – acronym for the Controlled Substances Monitoring Database, the specific name of Tennessee's prescription monitoring program that pharmacists and prescribers can access

DEA – Drug Enforcement Administration

Holy Trinity – a combination prescription consisting of an opioid, a benzodiazepine, and a muscle relaxer

MME – Morphine Milligram Equivalents, a standard unit of measurement to assess potency among opioids

ODU – Opioid Dosage Unit, usually though not exclusively a pill or tablet, but it can be a patch or other medication delivery mechanism

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 which Food City, and others, contracted with to audit pharmacies

PIC – Pharmacist-in-Charge

PMP – acronym for prescription monitoring program, a generic name used to signify a state database for pharmacists and prescribers to use with controlled substances. In Tennessee, the specific name is the Controlled Substances Monitoring Database.

Rph – Registered Pharmacist