IN THE CIRCUIT COURT FOR SEVIER COUNTY
AT SEVIERVILLE, TENNESSEE

ANDERSON COUNTY; BLEDSOE COUNTY; BRADLEY COUNTY; CLAIBORNE COUNTY; COCKE COUNTY; FRANKLIN COUNTY; GRAINGER COUNTY; GRUNDY COUNTY; KNOX COUNTY; LOUDON COUNTY; MARION COUNTY; MCMINN COUNTY; MEIGS COUNTY; MONROE COUNTY; POLK COUNTY; RHEA COUNTY; ROANE COUNTY; SEQUATCHIE COUNTY; SEVIER COUNTY; UNION COUNTY; CITY OF KNOXVILLE; and TOWN OF RUTLEDGE, Plaintiffs, v. BEARDEN HEALTHCARE ASSOCIATES, INC; CVS PHARMACY, INC; CVS TN DISTRIBUTION, LLC; CVS INDIANA, LLC; TENNESSEE CVS PHARMACY, LLC; ENDO HEALTH SOLUTIONS, INC.; ENDO PHARMACEUTICALS, INC.; ESTATE OF FRANK MCNIEL; FOOD CITY SUPERMARKETS, LLC; K-VA-T FOOD STORES, INC.; JANET MCNIEL; MCKINSEY & COMPANY, INC., WASHINGTON, D.C.; MORRIS & DICKSON CO., LLC; PAR PHARMACEUTICAL, INC.; PAR PHARMACEUTICAL COMPANIES, INC. f/k/a PAR PHARMACEUTICAL HOLDINGS, INC.; RITE AID HDQTRS. CORP.; RITE AID OF TENNESSEE, INC.; RITE AID OF MARYLAND, INC. d/b/a RITE AID MID-ATLANTIC CUSTOMER SUPPORT CENTER, INC.; TEVA PHARMACEUTICALS USA, INC.; WALGREEN CO.;	)	Case No. 22-CV-138-IV JURY DEMAND

WALMART INC.; and WAL-MART STORES EAST, L.P., Defendants.	)))))	

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1. This is an action brought by twenty-two Tennessee localities (the "Opioid Impacted Localities") that have been ravaged by the opioid epidemic against drug producers, drug distributors, pharmacy chains, and pill mill prescribers under the Tennessee Drug Dealer Liability Act ("DDLA"). This action seeks compensation for the damages inflicted by the opioid epidemic, and to halt the illegal flood of highly addictive and destructive drugs into these localities.

2. The opioid epidemic poses an ongoing crisis in Tennessee, particularly in areas rife with "pill mills." From 2012 to 2020 (the last year for which data has been reported), Tennessee set a new state record each year for the number of opioid overdose deaths, with 1,534 in 2019 and 2,388 in 2020.[1] According to IMS Health data, in 2015, there were also a staggering 7.8 million opioid painkiller prescriptions filled in the state – or 1.18 prescriptions for every man, woman, and child, placing Tennessee at number 2 in the nation among all states for the number of opioid prescriptions per capita. This trend continued, as evidenced by the CDC report, which showed that Tennessee providers wrote 68.5 opioid prescriptions per 100 persons in 2020, the third highest prescribing rate in the country and more than the average U.S. rate of 43.3 prescriptions.[2]

3. Along with overdose deaths, the number and rate of neonatal abstinence syndrome ("NAS")—a condition suffered by babies born to mothers addicted to opioids—has also increased dramatically in Tennessee. In 2020 alone, there were 824 NAS births in Tennessee.[3]

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4. The opioid epidemic did not appear overnight. It is the consequence of unconscionable greed perpetrated by Defendants ENDO HEALTH SOLUTIONS INC. and ENDO PHARMACEUTICALS, INC. (collectively "Endo"), PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC. f/k/a PAR PHARMACEUTICAL HOLDINGS, INC. (collectively "Par"), and TEVA PHARMACEUTICAL USA, INC. ("Teva") (collectively, "the Producer Defendants" or "the Drug Producer Defendants"); MORRIS & DICKSON CO., LLC ("M&D"); CVS PHARMACY, INC., CVS TN DISTRIBUTION LLC, CVS INDIANA, LLC, TENNESSEE CVS PHARMACY, LLC (collectively "CVS"), FOOD CITY SUPERMARKETS, LLC and K-VA-T FOOD STORES, INC. (collectively "Food City"), RITE AID HDQTRS CORPORATION, RITE AID OF TENNESSEE, INC., RITE AID OF MARYLAND, INC. d/b/a RITE AID MID-ATLANTIC CUSTOMER SUPPORT CENTER (collectively "Rite Aid"), WALGREEN CO. ("Walgreens") and WALMART INC. and WAL-MART STORES EAST, L.P. (collectively "Walmart") (collectively the "Pharmacy Chain Defendants"), and MCKINSEY & COMPANY, INC., WASHINGTON, D.C. ("McKinsey), who fueled the rampant addiction to opioid drugs that still ravages the general populations. Particularly egregious was (and remains) the opioid producers' unbridled distribution in pursuit of profit. Despite knowing about widespread diversion and illegal distribution by such actors as BEARDEN HEALTHCARE ASSOCIATES, INC. ("Bearden"), ESTATE OF FRANK MCNIEL, and JANET MCNIEL (collectively, the "McNeils") (collectively, the "Pill Mill Prescriber Defendants"), the opioid producers, distributors, and retailers continued to flood Tennessee with their highly addictive prescription drugs, which both perpetuated their multi-billion dollar drug empire and propelled opioid abuse to unprecedented levels. As described herein, the Producer Defendants, M&D, the Pharmacy Chain

Defendants, McKinsey and the Pill Mill Prescriber Defendants committed various acts that were intended to—and did—facilitate illegal diversion of their drugs.

5. Indeed, Defendants spent years pushing their drugs by selling drugs to illegitimate pill mills, convincing suspicious doctors that prescription opioids' addictive properties had been overblown, continuing to aggressively market opioids, and/or filling suspicious prescriptions even when these Defendants knew that millions of Americans and hundreds of thousands of Tennesseans were abusing and misusing prescription opioids and had no legitimate medical need for which prescription opioids should be consumed. The Drug Producer Defendants, Morris & Dickson, Pharmacy Chain Defendants, and Pill Mill Prescriber Defendants continue to knowingly participate in and profit from the illegal opioid drug market that they helped create and/or supply. Defendants knew that entire regions of the country were being devastated by addiction to prescription drugs that they distributed. They also recognized that prescribers were writing – and pharmacies filling – volumes of opioids that necessarily were both creating and supplying large volumes of drug addicts and pill seekers. Nevertheless, the Drug Producer Defendants, Morris & Dickson, Pharmacy Chain Defendants, and Pill Mill Prescriber Defendants persisted with distributing mind-boggling volumes of opioids into these same abuse-riddled communities, peddling the same misinformation to overcome prescribers' legitimate objections, urging suspect prescribers and pharmacies that supplied the illegal market to flood the market with even more opioids, and/or otherwise taking various measures to ensure that the flow of prescription opioids to feed drug addicts and pill seekers proceeded without impediment.

6. Under Tennessee law, prescription opioids are "Schedule II" controlled substances because they inherently have a "high potential for abuse" and that "may lead to severe psychic or

physical dependence."[4] For this reason, everyone who handles prescription opioids in Tennessee (from production to retail sales) must maintain appropriate safeguards against abuse and diversion, and must ensure that the drugs are only being distributed to serve legitimate medical purposes.[5] If either or both of these preconditions is not satisfied, it is unlawful to distribute prescription opioids in Tennessee. Indeed, entities holding a Tennessee license can be criminally prosecuted for violating their responsibilities in the distribution chain.[6] The Producer Defendants, M&D, and Pharmacy Chain Defendants did not lawfully distribute prescription opioids into or within Tennessee. Instead, using their licenses as a cover, they unlawfully distributed drugs without maintaining necessary controls (rendering the distribution unlawful), knowingly distributed those drugs into channels that they knew were resulting in diversion, knowingly encouraged high-volume pill mill prescribers to prescribe opioids without a legitimate medical purpose to feed drug abusers, pill seekers, and drug dealers, knowingly supplied pharmacies serving pill mills, and/or knowingly dispensed prescriptions that were not made for a legitimate medical purpose. Plaintiffs therefore assert that all drugs distributed in this manner (without appropriate controls, etc.) were unlawful and that defendants therefore knowingly participated in the illegal drug market in this fashion. Defendants also exceeded their lawful authority by taking actions that the federal government found were unlawful, that were not authorized by the FDA, the DEA, and Tennessee law or Tennessee authorities, and/or that specifically contradicted guidance from the FDA, the DEA, and Tennessee law or Tennessee authorities.

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[4] Tenn. Code Ann. § 39-17-407.

[5] *See, e.g.*, Tenn. Code Ann. § 53-11-302, -303, -312(c) *and* Rules of Tenn. Bd. Of Pharmacy, Ch. 1140-02.01.

[6] *See* Tenn. Code Ann. § 53-11-401.

7. The Producer Defendants and McKinsey also committed various other acts intended to facilitate diversion and illegal drug sales, from which they knowingly sought to profit. These acts include, inter alia: waging a public campaign of misinformation concerning opioids (including through "key opinion leaders" and front groups); encouraging prescribers to engage in prescription practices that the Producer Defendants knew and expected would drive up addiction rates; repeatedly calling on and targeting the highest volume prescribers to prescribe more opioids while knowing that those prescribers were or were likely operating pill mills (including high-volume prescribers in small, rural Tennessee communities who were prescribing at utterly unjustifiable levels); convincing naïve doctors willing to write prescriptions for powerful opioids to pill seekers and prescription drug abusers who sell the prescriptions wholesale; devising marketing strategies to overcome prescribers' legitimate objections to prescribing opioids for long-term use and in higher doses; convincing prescribers whom defendants knew were likely engaging in unlawful conduct and feeding the illegal drug market to prescribe even more opioids; incentivizing sales representatives to do business both with pill mills and with pharmacies supplying pill mills through volume-based compensation (and financially rewarding those sales associates for doing so); adding high-volume prescribers and pharmacies as customers without any due diligence, knowing that there was a strong likelihood that these high-volume businesses were running or supplying pill mills; filling suspicious orders despite knowing or reasonably suspecting that the orders reflected diversion; filling suspicious orders without any investigation; filling suspicious orders even where they met the Producer Defendants' own criteria for orders reflecting potential diversion; filling orders that they had subjectively identified as suspicious before undertaking or completing an investigation; continuing to do business with prescribers and pharmacies that had a history of suspicious prescribing or ordering practices; implementing sham

suspicious order monitoring programs that were structured to fail and to allow diversion to proceed unimpeded; continuing to target pill mill prescribers to prescribe more opioids and to target associated pharmacies that served them, even after being told by law enforcement that they were likely feeding the illegal drug market; supplying outlandish volumes of prescription opioids to rural Tennessee communities far exceeding any conceivable medical need; and over-supplying Tennessee with opioids while recognizing that doing so would create addicts and feed or expand the illegal drug market. Defendants' actions included encouraging higher volumes of prescriptions, supplying, and/or otherwise doing business with entities in Tennessee and the Opioid Impacted Localities patently engaging in diversion, such as Defendant Bearden and the other Pill Mill Prescriber Defendants.

8. M&D and Walmart similarly committed acts intended to facilitate the diversion of drugs into the illegal drug market in Tennessee. M&D and Walmart are or were major distributors of controlled substances. Like the Producer Defendants, M&D and Walmart were aware of (and helped cause) a growing epidemic from abuse, addiction, and diversion of the prescription opioids they supplied nationwide and in Tennessee. They were aware of the quantities and frequency with which those drugs were distributed in Tennessee and the Opioid Impacted Localities, and they knew with reasonable certainty which prescribers were operating pill mills (or otherwise over-prescribing) and which pharmacies were filling those prescriptions. Nevertheless, they chose to do business with pharmacies and dispensing physicians whom they knew or reasonably believed were feeding the illegal drug market. Furthermore, M&D and Walmart recognized that they had a responsibility not to fill suspicious orders, because filling those orders would foster diversion into the illegal drug market. They knew what types of orders were indicative of diversion, such as frequent and large orders by pharmacies in rural communities with low population, orders by

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[5] *See, e.g.*, Tenn. Code Ann. § 53-11-302, -303, -312(c) *and* Rules of Tenn. Bd. Of Pharmacy, Ch. 1140-02.01.

[6] *See* Tenn. Code Ann. § 53-11-401.

7. The Producer Defendants and McKinsey also committed various other acts intended to facilitate diversion and illegal drug sales, from which they knowingly sought to profit. These acts include, inter alia: waging a public campaign of misinformation concerning opioids (including through "key opinion leaders" and front groups); encouraging prescribers to engage in prescription practices that the Producer Defendants knew and expected would drive up addiction rates; repeatedly calling on and targeting the highest volume prescribers to prescribe more opioids while knowing that those prescribers were or were likely operating pill mills (including high-volume prescribers in small, rural Tennessee communities who were prescribing at utterly unjustifiable levels); convincing naïve doctors willing to write prescriptions for powerful opioids to pill seekers and prescription drug abusers who sell the prescriptions wholesale; devising marketing strategies to overcome prescribers' legitimate objections to prescribing opioids for long-term use and in higher doses; convincing prescribers whom defendants knew were likely engaging in unlawful conduct and feeding the illegal drug market to prescribe even more opioids; incentivizing sales representatives to do business both with pill mills and with pharmacies supplying pill mills through volume-based compensation (and financially rewarding those sales associates for doing so); adding high-volume prescribers and pharmacies as customers without any due diligence, knowing that there was a strong likelihood that these high-volume businesses were running or supplying pill mills; filling suspicious orders despite knowing or reasonably suspecting that the orders reflected diversion; filling suspicious orders without any investigation; filling suspicious orders even where they met the Producer Defendants' own criteria for orders reflecting potential diversion; filling orders that they had subjectively identified as suspicious before undertaking or completing an investigation; continuing to do business with prescribers and pharmacies that had a history of suspicious prescribing or ordering practices; implementing sham

suspicious order monitoring programs that were structured to fail and to allow diversion to proceed unimpeded; continuing to target pill mill prescribers to prescribe more opioids and to target associated pharmacies that served them, even after being told by law enforcement that they were likely feeding the illegal drug market; supplying outlandish volumes of prescription opioids to rural Tennessee communities far exceeding any conceivable medical need; and over-supplying Tennessee with opioids while recognizing that doing so would create addicts and feed or expand the illegal drug market. Defendants' actions included encouraging higher volumes of prescriptions, supplying, and/or otherwise doing business with entities in Tennessee and the Opioid Impacted Localities patently engaging in diversion, such as Defendant Bearden and the other Pill Mill Prescriber Defendants.

8. M&D and Walmart similarly committed acts intended to facilitate the diversion of drugs into the illegal drug market in Tennessee. M&D and Walmart are or were major distributors of controlled substances. Like the Producer Defendants, M&D and Walmart were aware of (and helped cause) a growing epidemic from abuse, addiction, and diversion of the prescription opioids they supplied nationwide and in Tennessee. They were aware of the quantities and frequency with which those drugs were distributed in Tennessee and the Opioid Impacted Localities, and they knew with reasonable certainty which prescribers were operating pill mills (or otherwise over-prescribing) and which pharmacies were filling those prescriptions. Nevertheless, they chose to do business with pharmacies and dispensing physicians whom they knew or reasonably believed were feeding the illegal drug market. Furthermore, M&D and Walmart recognized that they had a responsibility not to fill suspicious orders, because filling those orders would foster diversion into the illegal drug market. They knew what types of orders were indicative of diversion, such as frequent and large orders by pharmacies in rural communities with low population, orders by

pharmacies that they recognized were serving pill mill operators, sharp increases in order volume without justification, orders for tablets exceeding the number of people in a community, and orders by pharmacies that they knew were filling prescriptions from "patients" who traveled hundreds of miles to fill the prescriptions. Despite recognizing orders that reflected diversion, they processed and filled them anyway. Moreover, they intentionally ensured that they had no meaningful controls against diversion and intentionally structured their supposed suspicious order monitoring systems to fail.

9. Moreover, everyone in the distribution chain collaborated to get around whatever sham suspicious order monitoring systems that the drug producers may have put in place. They offered sham justifications for suspicious orders that everyone in the chain accepted without accepted without question, no matter how ludicrous – thereby giving the Producer Defendants, M&D, and the Pharmacy Chain Defendants a convenient pretense to make, fill, and ship orders that they knew would supply the illegal drug market. Through this symbiotic relationship, they persisted in filling suspicious orders for large volumes of products, calling on suspicious subscribers and pharmacies, filling suspicious prescriptions, and/or otherwise shipping drugs to rural Tennessee communities ravaged by the opioid epidemic at levels far exceeding any conceivable need. They knew that their actions would cause (and in fact did cause) increased abuse, addiction, and overdose rates in Tennessee and the Opioid Impacted Localities. They also knew that their actions facilitated illegal drug transactions in Tennessee and the Opioid Impacted Localities.

10. In their capacity as dispensers of pharmaceutical products, the Pharmacy Chain Defendants also committed various acts to facilitate diversion and illegal drug sales. These acts include but are not limited to: financially and professionally incentivizing pharmacists and other

pharmacy employees to fill suspicious orders, including pill mill prescriptions, without conducting due diligence; financially and professionally incentivizing pharmacists and other pharmacy employees to violate their professional obligation to withhold filling a prescription absent a legitimate medical purpose and without determining that the drugs were not likely to be abused or diverted; routinely filling suspicious prescriptions; filling prescriptions by Tennessee prescribers that the Pharmacy Chain Defendants knew were operating pill mills or knew otherwise were over-prescribing opioids that would supply the illegal drug market; filling prescriptions for individuals that the Pharmacy Chain Defendants recognized were pill seekers and drug addicts who would abuse and divert the drugs; filling prescriptions despite obvious signs of diversion and/or improper prescription practices, such as frequent prescriptions at an unrealistically high rate, frequent prescriptions at the highest allowable dosages, prescriptions filled by patients for years on end (who plainly were addicted), and prescriptions filled by individuals who engaged in suspect practices just outside the pharmacy immediately upon filling the prescriptions; and otherwise over-supplying Tennessee and the Opioid Impacted Localities, including rural Tennessee communities, with quantities of highly addictive opioids that far exceeded any conceivable medical need.

11. It is now beyond any reasonable question that defendants' actions caused thousands of Tennesseans to become addicted to opioids – an addiction that, as they well knew, was all but certain to occur. It is also beyond question that all defendants are aware that: opioids continue to be over-prescribed in Tennessee – including in the communities at issue in this lawsuit – at levels far beyond what could be medically justified; that a legion of addicts are obtaining pills on the black market or through "pill mills" to satisfy their addiction; that a significant share of the opioids market in Tennessee consists of illegal drug transactions; that they are doing business with pill mills; and that they are knowingly reaping profits from drug sales in the illegal drug market.

12. Defendants' misconduct garnered significant profits.[7] In 2010 alone, opioids generated $11 billion in revenue for drug companies. Opioids are now among the most prescribed class of drugs and the United States' opioid painkiller market is worth an estimated $10 billion annually.[8]

13. Plaintiffs now sue to recover damages for which Defendants are liable under the DDLA.

II. THE COURT HAS JURISDICTION AND VENUE IS APPROPRIATE

14. Jurisdiction is proper pursuant to Tenn. Code Ann. § 16-10-101, *et seq.*, and the DDLA, Tenn. Code Ann. § 29-38-101, *et seq.* Defendants directed their opioids to or into the Tennessee market, and more specifically to or into the Opioid Impacted Localities and the surrounding areas, with knowledge that the illegal opioids they diverted and sold would be used and/or resold within Tennessee illegally.

15. Venue is proper pursuant to Tenn. Code Ann. § 20-4-101 because Defendants participated in the illegal drug market that resulted in illegal opioids entering the Opioid Impacted Localities, and because the Opioid Impacted Localities are contiguous and operating through an agreement to bring this suit collectively pursuant to Tenn. Code Ann. § 5-1-114.

III. PARTIES

A. Plaintiffs

16. Plaintiffs Anderson County, Bledsoe County, Bradley County, Claiborne County, Cocke County, Franklin County, Grainger County, Grundy County, Knox County, Loudon

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[7] Katherine Eban, *OxyContin: Purdue Pharma's painful medicine*, Fortune.com, Nov. 9, 2011. Available at: http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/.

[8] Ariana Eunjung Cha, *The drug industry's answer to opioid addiction: More pills*, The Washington Post, Oct. 16, 2016. Available at: https://www.washingtonpost.com/national/the-drug-industrys-answer-to-opioid-addiction-more-pills/2016/10/15/181a529c-8ae4-11e6-bff0-d53f592f176e_story.-html?utm_term=.42e0328ca459.

County, Marion County, McMinn County, Meigs County, Monroe County, Polk County, Rhea County, Roane County, Sequatchie County, Sevier County, Union County, City of Knoxville, and Town of Rutledge are contiguous political subdivisions of the State of Tennessee. As described below, they have suffered damages for which Defendants are liable under the DDLA.

B. The Drug Producer Defendants

1. Endo

17. Defendant ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

18. Defendant ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of ENDO HEALTH SOLUTIONS INC., and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO HEALTH SOLUTIONS INC. and ENDO PHARMACEUTICALS INC. are referred to collectively as "Endo."

19. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and Tennessee. Endo also produces and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Tennessee, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Endo's flagship opioid product, Opana ER, yielded $1.15 billion in revenue from 2010 to 2013, and it accounted for 10% of Endo's total revenue in 2012. From 2012 through 2016, Endo continued to realize revenues on sales of Opana ER alone were over $1 billion. Endo eventually withdrew a reformulated version of Opana ER from the market in July 2017 at the FDA's behest because of widespread abuse and diversion of that product. Within months of that product coming off the market, Endo then entered into a profit-sharing agreement with Impax Laboratories, Inc. to share profits from a generic version of the prior formulation of Opana ER, which Endo had

represented in 2012 as so unsafe and subject to abuse and diversion that all sales of the product should be stopped to avert overdose deaths and other "predictable" public health hazards.

20. Endo transacts business in Tennessee, targeting the Tennessee market for its products, including the opioids at issue in this lawsuit. Endo hired employees to service the Tennessee market, including an extensive sales force. Endo also directed advertising and informational materials to impact Tennessee physicians and potential users of Endo products. Endo has a sales force that called on Tennessee prescribers to drive prescriptions and promote its products. Endo knowingly participates in the illegal drug market for opioids. The relevant illegal drug market included – and continues to include – Endo branded and generic opioids. Endo distributed its prescription opioids into Tennessee, the Opioid Impacted Localities, and the illegal drug market through M&D, and the Pharmacy Chain Defendants – and through prescriptions made by the Pill Mill Prescriber Defendants.

21. ENDO HEALTH SOLUTIONS, INC. can be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. ENDO PHARMACEUTICALS, INC. can be served through its registered agent: CT Corporation System, 300 Montvue Rd, Knoxville, TN 37919-5546 USA.

2. Par

22. Defendant PAR PHARMACEUTICAL, INC. is a Delaware Corporation with its principal place of business in Chestnut Ridge, New York and is a wholly owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. Defendant PAR PHARMACEUTICAL COMPANIES, INC. f/k/a PAR PHARMACEUTICAL HOLDINGS, INC. is a Delaware corporation with its principal place of business in Chestnut Ridge, New York. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively "Par") were acquired by Endo International plc in September 2015 and serve as operating companies of Endo

International plc. Subsequent to their acquisition, Par was merged with Qualitest, and serves as Endo's generic pharmaceutical manufacturer.

23. At all times relevant to this complaint, Par produced and sold generic opioids including, but not limited to, oxycodone, hydrocodone, and oxymorphone. Just like the other Drug Producer Defendants, Par flooded the illegal drug market with its opioid products by routinely filling suspicious orders for suspicious pharmacies and prescribers and failing to maintain effective controls on diversion. Following its acquisition by Endo and merger with Qualitest, it continued these same unlawful practices and distributed its prescription opioids into Tennessee, the Opioid Impacted Localities, and the illegal drug market through M&D and the Pharmacy Chain Defendants—and through prescriptions made by the Pill Mill Prescriber Defendants.

24. PAR PHARMACEUTICAL, INC. can be served through its registered agent: CT Corporation System, 28 Liberty St., New York, NY, 10005. PAR PHARMACEUTICAL COMPANIES, INC. f/k/a PAR PHARMACEUTICAL HOLDINGS, INC. can be served through its registered agent: CT Corporation System, 28 Liberty St., New York, NY, 10005.

3. <u>Teva</u>

25. TEVA PHARMACEUTICALS USA, INC. is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. TEVA PHARMACEUTICALS USA, INC. is a wholly owned subsidiary of Teva Pharmaceuticals Industries, Ltd., an Israeli corporation. Cephalon, Inc. is also a wholly owned subsidiary of Teva Pharmaceuticals Industries, Ltd. In August 2016, Teva Industries, Ltd. Bought Actavis Pharma, Inc. and Actavis LLC from Allergan Plc. Thus, since August 2016, Teva Industries, Ltd. Has owned the generic business that was formerly owned by Allergan. Hereinafter, TEVA PHARMACEUTICALS USA, INC., Teva Pharmaceuticals Industries, Ltd., Actavis Pharma, Inc., Actavis LLC, and Cephalon, Inc. are collectively referred to as "Teva."

26. Inclusive of companies and products lines it has acquired, Teva develops, markets, and sells prescription drugs, including opioids. In 2011, Teva purchased Cephalon, which was manufacturing a branded opioid called "Actiq" (a branded opioid containing fentanyl) and Fentora (an oral tablet form of fentanyl). Teva marketed and sold both Actiq and Fentora in Tennessee. In 2016, Teva purchased Actavis, which produces generic opioids. In Tennessee and nationally, Teva is engaged in the production, promotion, and distribution of generic opioids, including hydrocodone and oxycodone among other drugs. Teva transacts business in Tennessee, targeting the Tennessee market for its products, including the opioids at issue in this lawsuit. This includes producing generic opioids that filled millions of prescriptions per year in Tennessee. On its own and/or through front groups and key opinion leaders and otherwise, Teva directs advertising and/or informational materials to impact Tennessee physicians and potential users of opioids. Teva has employees who service the Tennessee market. Teva knowingly participates in the illegal drug market for opioids. The relevant illegal drug market included – and continues to include – Teva branded and generic opioids. Teva distributed its prescription opioids into Tennessee, the Opioid Impacted Localities, and the illegal drug market through M&D, and the Pharmacy Chain Defendants– and through prescriptions made by the Pill Mill Prescriber Defendants.

27. Teva can be served through its registered agent: Corporate Creations Network, Inc., 3411 Silverside Road, Tatnall Building, Ste. 104, Wilmington, DE 19810.

C. <u>Morris & Dickson</u>

28. Defendant MORRIS & DICKSON ("M&D") is a Louisiana business entity with its principal place of business in Louisiana. At all relevant times, M&D has distributed substantial amounts of opioids in Tennessee and in the Opioid Impacted Localities.

29. From 2006 through 2014, the last year for which ARCOS data is available, M&D shipped 110,221,071 dosage units of opioids into Tennessee, which amounted to 1,930,400,243 MME.[9]

30. M&D can be served through its registered agent, Wiener, Weiss & Madison, APC, c/o Russell R. Dickson, 330 Marshall St., Suite 1000, Shreveport, LA 71101. It can also be served through its registered agent in Tennessee, Incorp Services, Inc., 1585 Mallory Ln, Ste 104, Brentwood, TN 37027-3036 USA.

D. The Pill Mill Prescriber Defendants

31. Defendant BEARDEN HEALTHCARE ASSOCIATES, INC. ("Bearden") is a Tennessee company with a principal office and clinic in Knoxville, Tennessee. It can be served through its registered agent in Tennessee, Glenn Johnson, D.C., 10321 Kingston Pike, Knoxville, TN 37922-3224 USA.

32. Defendant FRANK MCNIEL, by and through his estate, formerly owned Bearden.

33. Defendant JANET MCNIEL is the wife of Frank McNiel and acted as a prescriber at Bearden until her license was suspended. She may be served at 4204 Holston Hills Rd, Knoxville, TN 37914 or wherever she may be found.

34. Endo called on the Pill Mill Prescriber Defendants, and M&D and Pharmacy Chain Defendants distributed and dispensed the opioids prescribed by them.

E. The Pharmacy Chain Defendants

1. CVS

35. CVS PHARMACY, INC. is a Rhode Island corporation with its headquarters and principal place of business in Woonsocket, Rhode Island, which can be served with process via its

[9] ARCOS Database.

registered agent in Tennessee, CT Corporation System at 300 Montvue Rd, Knoxville, TN 37919-5546 USA. TENNESSEE CVS PHARMACY, LLC is a Tennessee LLC with a principal office in Woonsocket, Rhode Island, which can also be served with process via its registered agent in Tennessee, CT Corporation System at 300 Montvue Rd, Knoxville, TN 37919-5546 USA. Upon information and belief, these entities have held that license at all relevant times, and, either directly or through related corporate entities, have maintained and operated various pharmacies that have dispensed (and continue to dispense) prescription opioids at all relevant times in Tennessee, including in the Opioid Impacted Localities.

36. CVS INDIANA, LLC is an Indiana corporation that was licensed with Tennessee as a wholesaler/distributor under License No. 00000920 from 1994 to 2019. It may be served with process via it's registered agent in Indiana, CT Corporation System, 334 North Senate Avenue, Indianapolis, IN, 46204, USA.

37. CVS TN DISTRIBUTION LLC, f/k/a CVS TN DISTRIBUTION, INC., is Tennessee LLC with a principal office in Woonsocket, Rhode Island, which may be served with process via its registered agent in Tennessee, CT Corporation System at 300 Montvue Rd, Knoxville, TN 37919-5546 USA. It has held wholesale/distributor license number 00000115 since 1976.

38. Plaintiffs refer to these entities and the associated retail pharmacy stores collectively as "CVS" herein.

2. <u>Food City</u>

39. 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. It may be served with process through its registered agent in Tennessee, K-VA-T Food Stores, Inc., 6305 Lonas Dr., Ste 201, Knoxville, TN 37909-2732 USA.

40. 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. It may be served with process through its registered agent in Tennessee, Northwest Registered Agent Inc., 5810 Shelby Oaks Dr., Ste B, Memphis, TN 38134-7315 USA.

41. K-VA-T FOOD STORES, INC. and FOOD CITY SUPERMARKETS, INC. (collectively "Food City") acted as principals and/or agents of one another and acted in concert with one another in connection with the actions attributed to Food City in the Complaint.

42. Food City operates seventy-five groceries with pharmacies in Tennessee, including pharmacies that serve the Opioid Impacted Localities and the surrounding area.

3. Rite Aid

43. RITE AID HDQTRS. CORP. is a Delaware corporation with a principal place of business in Camp Hill, Pennsylvania, that can be served with process through its registered agent in Tennessee, CT Corporation System at 300 Montvue Rd, Knoxville, TN 37919-5546 USA. Among other activities, employees of Rite Aid Hdqtrs. Corp. (1) reviewed and/or analyzed data regarding Rite Aid and its subsidiaries' distribution and dispensing of opioid products to its pharmacies, including those located in Tennessee and the Opioid Impacted Localities; (2) communicated with and analyzed data provided by district managers relating to the ordering of opioids from outside vendors, such as McKesson, and the dispensing of those products at Rite Aid pharmacies, including those located in Tennessee and the Opioid Impacted Localities; and (3) were responsible for approving and then submitting threshold increases for opioid orders for Rite Aid locations with outside vendors, such as McKesson, including for those located in Tennessee and the Opioid Impacted Localities.

44. Defendant RITE AID OF TENNESSEE, INC. is a Tennessee corporation with a principal place of business in Knoxville, TN, that can be served through its registered agent in Tennessee, CT Corporation System, 300 Montvue Rd., Knoxville, TN 37919-5546 USA.

45. Defendant RITE AID OF MARYLAND, INC. d/b/a RITE AID MID-ATLANTIC CUSTOMER SUPPORT CENTER, INC. is a Maryland corporation with its principal office located in Lutherville Timonium, Maryland, which is licensed with the Tennessee Department of Health as a manufacturer/wholesaler/distributor. It may be served with process through its registered agent in Maryland, The Corporation Trust, Incorporated, 2405 York Road, Suite 201, Lutherville Timonium, MD 21093-2264. Plaintiffs refer to these entities and the associated retail pharmacy stores collectively as "Rite Aid" herein.

46. Rite Aid pharmacies purchased (and continue to purchase) prescription opioids from M&D and other distributors that were/are in turn dispensed at Tennessee pharmacies.

4. Walgreens

47. WALGREEN CO. is a Delaware corporation with its principal headquarters and principal place of business located in Deerfield, Illinois ("Walgreens"). Walgreen Co. can be served through its registered agent in Tennessee, The Prentice-Hall Corporation System, Inc., 2908 Poston Ave, Nashville, TN 37203-1312 USA.

48. Walgreens has been registered in Tennessee as a wholesaler/distributor since 2008 under License Numbers 00002944 and 00002921.

49. Walgreens also owns and operates, either directly or through related corporate entities, various pharmacies that have dispensed (and continue to dispense) prescription opioids at all relevant times, including in the Opioid Impacted Localities. Walgreens is also the successor in interest to formerly Rite Aid-branded pharmacies that it acquired in 2018, including Rite Aid locations in Tennessee. Prior to that purchase (under Rite Aid) and after that purchase (under

Walgreens), the distribution chain to those pharmacies and those pharmacies themselves engaged in the same form of illegal market facilitation as the other Pharmacy Chain Defendants.

50. Walgreens pharmacies purchased (and continue to purchase) prescription opioids that were/are in turn dispensed at the Tennessee pharmacies.

5. Walmart

51. WALMART INC., formerly known as WAL-MART STORES, INC., ("Walmart") is a multinational retail corporation incorporated in the State of Delaware. It may be served with process through its registered agent in Tennessee, CT Corporation System, 300 Montvue Rd, Knoxville, TN 37919-5546 USA.

52. Along with retail stores and other business unites, Walmart operates one of the largest pharmacy chains in the United States, consisting of more than 5,000 DEA-registered pharmacies located in Walmart and Sam's Club retail stores in the United States and its territories, including 141 in Tennessee.[10] As a pharmacy chain, Walmart dispenses controlled substances through its agents and employees.

53. Until 2018, Walmart also acted as a distributor of controlled substances for its pharmacies around the country. From 2000 to approximately May 2018, Walmart operated at least six distribution centers that distributed controlled substances to its pharmacies in the United States. The distribution centers were located in Bentonville, Arkansas; Rogers, Arkansas; Tifton, Georgia; Crawfordsville, Indiana; Hanford, California; and Williamsport, Maryland. The Rogers, Tifton, and Williamsport distribution centers are, and at all times relevant have been, licensed with the State of Tennessee as wholesalers/distributors with the respective Facility License Numbers

[10] Tennessee Department of Health, apps.health.tn.gov/facilityListings/ (Oct. 28, 2021).

00002526, 00000669, 00002224. Collectively, Walmart self-distributed to its pharmacies tens of millions of shipments of controlled substances.

54. The DEA registrant for those distribution centers was Defendant WAL-MART STORES EAST, L.P. is also incorporated in Delaware. It may be served with process through its registered agent in Tennessee, CT Corporation System, 300 Montvue Rd, Knoxville, TN 37919-5546 USA.

F. McKinsey

55. MCKINSEY & COMPANY, INC., WASHINGTON, D.C. ("McKinsey") is a privately owned entity headquartered in New York, New York. It may be served with process through its registered agent in Tennessee, Corporation Service Company, 2908 Poston Ave, Nashville, TN 37203-1312 USA. At all times relevant to this proceeding, McKinsey did business in Tennessee, including in the Opioid Impacted Localities.

56. McKinsey is one of the world's largest consulting companies. Its partners work worldwide for corporations and governments across a wide array of industries. Its influence is powerful because of its "best-in-class" reputation. McKinsey not only sells marketing strategies: it sells the notion that it can take whatever a company or government is doing and make them do it better.

57. McKinsey worked with entities involved in manufacturing and selling opioids and thereby contributed to the opioid crisis.

IV. SCIENTIFIC BACKGROUND

A. Opioids Have Never Been Proven Appropriate for Long-Term Chronic Pain and Other Non-Acute Medical Problems.

58. This case primarily, but not exclusively, concerns the following four types of opioids:

a. Oxycodone: Oxycodone is a powerful type of opioid. It can be prescribed as oxycodone or more specifically branded by a company, such as OxyContin or Roxicodone.

b. Hydrocodone: Hydrocodone is also a type of opioid. It can be prescribed as hydrocodone or more specifically branded by a company, such as Lortab or Vicodin.

c. Oxymorphone: Oxymorphone is also a type of opioid. It can be prescribed as oxymorphone or more specifically branded by a company, such as Opana and Opana ER.

d. Hydromorphone: Hydromorphone is also a type of opioid. It can be prescribed as hydromorphone or more specifically branded by a company, such as Exalgo.

59. The scientific consensus is that opioids such as these are dangerous, highly addictive, and inappropriate for long-term chronic pain – as opposed to cancer pain and pain associated with surgery and acute injuries. This opinion existed in the mid-1990s and has never been challenged in any meaningful way with new, valid scientific evidence.

60. The National Safety Council, a not-for-profit organization chartered by Congress to improve public health, has published a summary of research titled "Evidence for the Efficacy of Pain Medications."[11] The National Safety Council report concludes that "[d]espite the widespread use of opioid medications to treat chronic pain, there is no significant evidence to support this practice."[12]

61. Multiple researchers have found that "no evidence exists to support long term use—longer than four months—of opioids to treat chronic pain."[13]

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[11] Donald Teater, Nat'l Safety Counsel, *Evidence for the Efficacy of Pain Medications*, 3 (2014) (hereinafter Evidence for Efficacy).
[12] *Id.* at 6.
[13] *Id.* (citing multiple publications).

62. A 2013 review of existing literature by Dr. Igor Kissin of the Department of Anesthesiology, Perioperative, and Pain Medicine at Brigham and Women's Hospital, Harvard Medical School, concluded that "[n]ot a single randomized controlled trial with opioid treatment lasting [greater than] 3 months was found."[14]

63. The same review found that "[a]ll studies with a duration of opioid treatment [greater than or equal to] 6 months were conducted without a proper control group."[15]

64. Dr. Kissin further concluded that "[t]here is no strong evidence-based foundation for the conclusion that long-term opioid treatment of chronic malignant pain is effective."[16]

B. Opioids Carry a High Risk of Addiction, Serious Medical Problems, and Death.

65. Opioids have severe side effects, including: gastrointestinal bleeding, impaired recovery from injury or surgery, cognitive impairment, respiratory depression, endocrine abnormalities, hyperalgesia (increased sensitivity to pain), increased risk of fractures and hospitalization for the elderly, addiction, and death.[17]

66. Research based on actual patient interviews has found that, ***among patients who received four or more prescriptions in the prior year, 35% met the criteria for a lifetime opioid dependence, and 25.8% met the criteria for current opioid dependence.***[18]

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[14] Igor Kissin, *Long-term Opioid Treatment of Chronic Nonmalignant Pain: Unproven Efficacy and Neglected Safety?*, 2013:6 J. Pain Research 513, 513 (2013), available at: https://www.dovepress.com/long-term-opioid-treatment-of-chronic-nonmalignant-painnbspunproven-ef-peer-reviewed-article-JPR.

[15] *Id.*

[16] *Id.*

[17] Donald Teater, Nat'l Safety Council, *The Psychological and Physical Side Effects of Pain Medications*, 2-6 (2014) (summarizing side effect data). (hereinafter "*Side Effects*").

[18] Joseph A. Boscarino, *Opioid-Use Disorder Among Patients on Long-Term Opioid TherapyI*, 2015:6 Substance Abuse and Rehabilitation 87, 87-89 (2015), *available at:* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4548725/.

67. Dr. Nora D. Volkow and Dr. Wilson M. Compton, the Director and Deputy Director of the National Institute of Drug Abuse at the National Institute of Health, respectively, co-authored a 2006 study that concluded: "[t]hough the use of opioid analgesics for the treatment of acute pain appears to be generally benign, ***long-term administration of opioids has been associated with clinically meaningful rates of abuse or addiction***."[19]

68. Consistent with this finding, a 2011 review of medical and pharmacy claims records revealed that two thirds of patients who took opioids daily for ninety days were still taking opioids five years later.[20]

69. Researchers evaluating opioids for treatment following lumbar disc herniation likewise found that giving such patients opioids had no effect on treatment outcome, but significantly increased their risk for long term opioid addiction.[21]

70. Dr. Mitchell H. Katz, current director of the Los Angeles County Health Agency, has described how patients with nonmalignant conditions can end up as drug addicts because of the prescribing of opioids:

> A certain number of patients get better with NSAIDs [non-steroidal anti-inflammatory drugs, like Tylenol].... For those still complaining of pain, you next prescribe a short-acting opioid with a relatively low potency, such as acetaminophen with codeine. ...You tell them about the adverse effects of opioids and encourage them to use the lowest dose necessary. Not infrequently, at the next visit they tell you that the medicine works but that they are taking the pills more frequently than directed. At this point, you worry about liver damage from the acetaminophen and switch to a higher potency, longer acting agent. The patient returns for follow-up visits and tells you that the pills work but that they sometimes take an extra pill and could you please increase the number so they "don't run out before the next visit." Before you know it, the patient is on a high dose of an opioid,

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[19] Wilson M. Compton et al., *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies*, 81 Nat'l Inst. on Drug Abuse 103, 103-07 (2006) (emphasis added).
[20] Bradley C. Martin et al., *Long-term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, 26(12) J. Gen. Intern. Med. 1450, 1450-57 (2011).
[21] Evidence for Efficacy, at 5 (citing Radcliff et al., *Does Opioid Pain Medication Use Affect the Outcome of Patients with Lumbar Disk Herniation?*, 38(14) The Spine J. E849, E849-60 (2013)).

and you are unsure whether you have actually helped them. ***What you know is you have committed yourself to endless negotiations about increasing doses, lost pill bottles, calls from emergency departments, worries that your patient is selling the drugs, and the possibility that one day, your patient will take too many pills, perhaps with alcohol, and overdose.***[22]

V. MATERIAL FACTS

A. Overview: The Defendants Created the Illegal Drug Market Through Unlawful Distribution and Otherwise Knowingly Supplied and Knowingly Participated in the Illegal Drug Market in Tennessee.

71. The Drug Producer Defendants, Morris & Dickson, Pharmacy Chain Defendants, McKinsey, and Pill Mill Prescriber Defendants all participated in the illegal drug market in Tennessee and capitalized on it. Each played a knowing role in creating, perpetuating, and expanding the opioid crisis.

72. Controlled substances are, by definition, highly subject to abuse and diversion. For this reason, Tennessee regulates every participant in the chain of distribution. No one can distribute or dispense prescription opioids in Tennessee without maintaining effective controls against diversion and ensuring that the drugs are serving a lawful medical purpose. Indiscriminate distribution without sufficient controls is unlawful and can lead to criminal penalties in Tennessee.

73. The Drug Defendants, M&D, and Pharmacy Chain Defendants have used their registration certificates with Tennessee as cover for what is essentially a criminal enterprise. They knowingly distributed drugs into Tennessee without diversion controls, conscious that they were feeding pill mills and the black market rather than legitimate medical need. That conduct was unlawful. Even in isolation, it subjects them to liability under the DDLA.

74. But the problem was much, much worse than that. The Producer Defendants purposely created the illegal market for their own products by successfully convincing prescribers,

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[22] Mitchell H. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170(16) Arch Intern. Med. 1422, 1422-24 (2010) (emphasis added).

with the help of McKinsey, to prescribe opioids in high volumes, high dosages, and with such frequency that the patients quickly (and inevitably) would become addicted – as defendants knew would happen. They devised every way imaginable to guarantee this result. This included lying to prescribers about the risk profile of their opioids spreading disinformation about how addictive their drugs were, and targeting with surgical precision the highest-volume prescribers to convince them to prescribe more opioids – knowing that those prescribers were operating and were likely to be operating pill mills. They established direct relationships with pharmacies that supplied pill mills. They flooded small Tennessee communities with opioids at levels that their own experts determined was resulting in diversion – filling the very prescriptions that they convinced corrupt prescribers to make, to feed the addicts and pill seekers that they had addicted to their drugs. They hired large sales forces, rewarded them for doing business with pill mills, and penalized them for missing sales targets. When the government directed them to implement effective controls against diversion, they purposely created sham "suspicious order monitoring" programs that were structured to fail and structured to allow them to ship opioids into known diversion channels. This entire system was a criminal chain of distribution from start to finish. As the DEA determined relative to Mallinckrodt, this malfeasance made the Producer Defendants "kingpins" in a drug cartel.

75. M&D and Pharmacy Chain Defendants also participated in this enterprise and abused their authority. They knew who the pill mill operators were and knew when the level of drugs into these communities was feeding the illegal drug market. But like the Producer Defendants, they purposely did not implement meaningful diversion controls, incentivized their employees to service pill mills, and reaped handsome profits from the flow of drugs into the black

market. They distributed and dispensed these drugs unlawfully, and otherwise knowingly facilitated illegal prescription opioids sales.

76. The Pill Mill Prescriber Defendants also participated in the illegal drug market by issuing prescriptions for no legitimate medical purpose.

77. At every step, these Defendants sought to stream drugs into the illegal market, to continue over-supplying Tennessee communities at levels that were not medically justifiable, and enjoy profits derived from the illegal distribution of opioids. They continue to do so to this day.

B. The Drug Producer Defendants, M&D, and Pharmacy Chain Defendants Have All Participated in the Distribution Pipeline for Opioids in Tennessee and in the Opioid Impacted Localities.

1. The Drug Producer Defendants, M&D, and Pharmacy Chain Defendants Possessed Information Reflecting Diversion by Prescribers and Pharmacies but Facilitated that Diversion Anyway.

78. As described herein, the Drug Producer Defendants, M&D, and Pharmacy Chain Defendants did not maintain effective controls against diversion, rendering their actions illegal, and they otherwise engaged in many other acts to facilitate diversion of their drugs illegally. They also plainly undertook actions in Tennessee or directed at Tennessee that they knew were detrimental to public health and safety.

79. The related crises of abuse and illegal diversion of prescription opioids in Tennessee is well-documented in a variety of publicly available sources. Indeed, the prescription statistics reflect how the Producer Defendants, M&D, and Pharmacy Chain Defendants each are participating in the unconscionable flow opioids into East Tennessee.

80. Through their market research and extensive networks of sales representatives and face-to-face detailing of health care providers ("HCP"), The Drug Producer Defendants could, and

did, observe signs of illegal diversion. The Drug Producer Defendants could, and did, observe signs of diversion, including:

- an HCP who has a disproportionate number of patients who pay cash for office visits and dispensed medication;
- an HCP with a sudden unexplained change in prescribing or dispensing patterns that are not accounted for by changes in patient numbers or the practice type;
- an HCP's practice where unauthorized individuals are signing prescriptions or dispensing controlled substances;
- an HCP's practice where drugs or doses are not being individualized;
- an HCP with a lack of qualified staff, such as registered nurses or nurse practitioners;
- an HCP's practice with large numbers of patients who travel significant distances, for example across state lines, to obtain and/or fill their prescriptions without a rational explanation;
- an HCP's practice where there are reports that patients make frequent early requests for new prescriptions significantly in advance; and
- an HCP who moves his or her practice from one state to another on more than one occasion within a couple of years without rational explanation.

81. Upon information and belief, and as described further herein, the Drug Producer Defendants also received information from credible sources—including, but not limited to, pharmacists and law enforcement agencies—that an HCP or his or her patients were diverting prescription medications.

82. Upon information and belief, and as described further herein, the Drug Producer Defendants each maintained an internal database of HCPs suspected of inappropriately prescribing opioids. HCPs could be added to the database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills. In particular, the Drug Producer Defendants tracked

HCPs' prescribing practices using data obtained from IMS Health, which allowed them to identify HCPs writing excessively large numbers of prescriptions, particularly for high doses, which is a potential sign of diversion and drug dealing.[23]

83. The Drug Producer Defendants also possess information called "chargeback" data from their distributors. As reported in the Washington Post, there is an "industry-wide practice" whereby pharmaceutical drug producers pay their distributors rebates and/or "chargebacks" on prescription opioid sales.[24] In return, the distributors provide the Drug Producer Defendants with downstream purchasing information, which allows them to track their prescription opioids down the entire supply chain, all the way to the retail level.[25]

84. Using chargeback data, the Drug Producer Defendants knew – just as the prescription opioid distributors and pharmacy chains knew – the volume, frequency, and pattern of prescription opioid orders being placed and filled. From that data, they knew or recognized which orders were suspicious and indicative of diversion in Tennessee and elsewhere. However, they continued to fill orders relative to those accounts (including pharmacies and dispensing physicians) for their drugs, despite knowing that the orders were suspicious and indicative of diversion, that the pharmacies to whom the orders were shipped were engaging in suspicious practices indicative of diversion, and/or that the pharmacies were filling orders from pill mills and other high-volume prescribers engaged in suspicious prescribing practices. To make matters worse, the Producer Defendants used this chargeback data for sales purposes to identify the highest volume prescribers and highest-volume pharmacies as sales targets. Many of these targets were located in rural Tennessee communities with a thriving illegal drug market and an obvious over-

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[23] Ryan, *More than 1 million OxyContin pills.*
[24] *See* Berstein, *The government's struggle.*
[25] *Id.*

supply issue. In this way, the Producer Defendants knowingly facilitated the illegal diversion of prescriptions by (inter alia) suspicious prescribers and pharmacies, enabled the illegal diversion of prescription opioids, aided criminal activity, and otherwise facilitated the dissemination of massive quantities of prescription opioids into the black market.

85. Tennessee regulates the distribution of controlled substances. Under Tennessee law, prescription opioids are "Schedule II" controlled substances because they inherently have a "high potential for abuse" and that "may lead to severe psychic or physical dependence."[26] For this reason, everyone who handles prescription opioids in Tennessee (from production to retail sales) must maintain appropriate safeguards against abuse and diversion, and must register with the State and must ensure that the drugs are only being distributed to serve legitimate medical purposes.[27] If either or both of these preconditions is not satisfied, it is unlawful to distribute prescription opioids in Tennessee. Indeed, entities holding a Tennessee license can be criminally prosecuted for violating their responsibilities in the distribution chain.[28] Defendants violated these preconditions and acted unlawfully.

2. Endo's Misconduct has Contributed to the Opioid Epidemic Ravaging the Opioid Impacted Localities.

86. Endo continues to participate in an illegal drug market that it helped create.

87. The original version of Opana ER, which was known by the street names "stop signs," "the O bomb," and "new blues," is typically crushed by addicts and either snorted or

[26] Tenn. Code Ann. § 39-17-407.
[27] *See, e.g.*, Tenn. Code Ann. § 53-11-302, -303 *and* Rules of Tenn. Bd. Of Pharmacy, Ch. 1140-02.01 *et seq*, 1140-09.01 *et seq*.
[28] *See* Tenn. Code Ann. § 53-11-401(a).

injected.[29] "Crushing defeats the pill's 'extended release' design, releasing the drug all at once."[30] This type of Opana abuse is particularly dangerous "because [Opana] is more potent, per milligram, than OxyContin, and users who are not familiar with how strong it is may be vulnerable to overdosing."[31]

88. Endo introduced Opana ER in 2006. For the next several years, it endeavored to capture market share and cut into the OxyContin market. As with the other defendants, Endo actively marketed to the highest volume prescribers of extended release opioids.

89. In July 2012, USA Today reported that Original Opana ER had overtaken OxyContin as the drug of choice for prescription opioid addicts.[32]

90. The USA Today article began by recounting how, in 2012 alone, there had been 11 pharmacy robberies in Fort Wayne, Indiana (a city of only 250,000 people), and "[i]n almost every case, the robbers asked specifically for Opana."[33]

91. The article went on to explain that "the Opana problem grew swiftly and sharply, particularly in several states where prescription drug abuse is deeply engrained." Among the states experiencing a dramatic increase in Opana ER abuse, the article listed the following:

- "Nassau County, N.Y. issued a health alert in 2011 when the New York City suburb saw the first signs of an alarming spike in Opana use. Medicaid data for the county showed prescriptions for extended-release Opana had increased 45% in six months."[34]

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[29] Mary Wisniewski, *Painkiller Opana, new scourge of rural America*, Reuters (Mar. 26, 2012). Available at: https://www.reuters.com/article/us-drugs-abuse-opana/painkiller-opana-new-scourge-of-rural-america-idUSBRE82Q04120120327. (hereinafter "Wisniewski, Painkiller Opana, new scourge").
[30] *Id.*
[31] *Id.*
[32] Donna Leinwand Leger, Opana abuse in USA overtakes OxyContin, USA Today (July 11, 2012). Available at: http://usatoday30.usatoday.com/news/nation/story/2012-07-10/opana-painkiller-addiction/56137086/1. (hereinafter "Leger, Opana Abuse").
[33] *Id.*
[34] *Id.*

- "A DEA intelligence briefing noted increases in Opana [use] in Pennsylvania, including Philadelphia, and Delaware. In New Castle, Del., the DEA said, drug users had switched from uncrushable OxyContin to the crushable oxymorphone 'for ease of use,' pushing the price for a 40 mg tablet to $65. A tablet costs $4 to $8 when purchased legitimately at a pharmacy."[35]

- "In Ohio, authorities in Akron, Cincinnati and Athens noted surges in Opana as a replacement for OxyContin, the state's Substance Abuse Monitoring Network reported earlier [in 2012]. . . . Opana 40 mg tablets sell for $60 to $70 each, outpacing the once-popular old formulation OxyContin, which now sells for at least $1 a milligram, the report said."[36]

92. The spike in Opana ER abuse and diversion was particularly pronounced in Tennessee's neighbor to the north, Kentucky.[37] In 2010, toxicology tests identified oxymorphone, the key ingredient in Opana ER, in 2% of Kentucky's overdose death cases, according to the Kentucky Office of Drug Control Policy.[38] By 2011, oxymorphone was present in the blood of 23% of overdose victims in the state.[39]

93. In 2011, the drugs most frequently found in overdose victims in Kentucky broke down as follows: Alprazolam (Xanax) – found in 286 overdose victims; Oxycodone (OxyContin) – found in 213 overdose victims; Hydrocodone (Vicodin) – found in 187 overdose victims; and oxymorphone (Opana ER) – found in 154 overdose victims.[40]

94. Another 2012 news article, this one by Reuters, further highlighted the "Opana problem [that] has been reported by abuse experts around the country."[41] As evidence of the "Opana problem," the Reuters' article pointed to Florida, where "the number of oxymorphone-

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[35] *Id.*
[36] *Id.*
[37] *Id.*
[38] *Id.*
[39] *Id.*
[40] *Id.*
[41] Wisniewski, *Painkiller Opana New Scourge*.

related deaths rose to 493 in 2010, an increase of 109 percent from the previous year."[42] Additionally, the article specifically referenced the fact that "users and dealers get painkillers from so-called 'pill mills' – storefront pain clinics that sell drugs for cash up front, often to out-of-state buyers who take them for resale."[43]

95. Of particular note, the 2012 Reuters article also quoted Detective Michael Donaldson – a Nashville, Tennessee detective who saw an increase in Opana abuse in the state – who said that "many small towns have 'dirty doctors' willing to give out unneeded prescriptions."[44]

96. As seen across the country, diversion of reformulated Opana ER was rampant in Tennessee following its introduction to the market. In October 2012, the CDC issued a health alert, saying a "cluster of at least 12 patients" (later raised to 15 victims) in Tennessee had contracted thrombotic thrombocytopenic purpura, a rare blood-clotting disorder, after injecting reformulated Opana.[45] These incidents immediately provided a clear and unmistakable signal to Endo that the "abuse-deterrent" formulation of Opana ER in fact was highly susceptible to intravenous abuse, which both Endo and the FDA considered to be a far more dangerous form of abuse than insufflation.

97. Furthermore, following the release of reformulated Opana ER, Hawkins County law enforcement officials told Endo that they were "overwhelmed by Opana abuse in their area." They told Endo that local doctors were writing prescriptions to prescription drug abusers, that they

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[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] Tom Dreisbach, *How A Painkiller Designed To Deter Abuse Helped Spark An HIV Outbreak*, NPR – All Things Considered (Apr. 1, 2016). Available at: https://www.npr.org/sections/health-shots/2016/04/01/472538272/how-a-painkiller-designed-to-deter-abuse-helped-spark-an-hiv-outbreak.

had arrested and convicted multiple doctors for writing fraudulent prescriptions for drug traffickers, and that three people had died from a "suspect doctor" who opened a pain clinic in the area. Endo even interviewed one of the TTP victims, where it learned that abusing reformulated Opana ER by boiling and then injecting it was also occurring in nearby Johnson City and Kingsport. Despite receiving this clear safety signal, Endo nevertheless continued to call on Tennessee prescribers and distribute Opana ER not only in upper East Tennessee where the crisis erupted, but throughout the state.

98. During the same time frame, Endo commissioned an internal report which stated that, in light of the non-availability of original OxyContin, Opana ER had become the key drug of choice for abusers and addicts. Endo also quickly recognized that higher injection rates (i.e., intravenous abuse) were occurring in Tennessee. Indeed, in 2012, Endo acknowledged under oath that, following the introduction of reformulated OxyContin in August 2010, abuse of Opana ER spiked because drug users found that it was easier to snort or inject. This transfer of addicts and abusers from OxyContin to Opana ER was called the "squeezing the balloon" effect.[46] Endo nevertheless continued to detail Tennessee prescribers.

99. Indeed, when an "abuse-deterrent" form of OxyContin in 2012, Endo recognized that pill seekers and other drug abusers were finding OxyContin more difficult to abuse, and that those drug abusers were turning to Opana ER because it was easy to crush and snort. Perceiving this "squeeze the balloon" effect, Endo consciously endeavored to capture the market share that OxyContin was losing as addicts turned away from OxyContin and sought out an alternative to abuse.

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[46] Collins PI Declaration ¶ 9.

100. In connection with its unsuccessful petition to have reformulated Opana ER designated as tamper-resistant, Endo publicly advocated that its original formulation of Opana ER was so dangerous and susceptible to abuse and diversion that it should be taken off the market.[47] Endo represented, inter alia, that its own testing shows that "96% of research subjects were willing to snort the Original Formulation (which could be crushed into powder)."[48] It argued that allowing the Original Formulation onto the market "will result in increases in drug abuse, misuse and diversion," and that "[s]erious and predictable public harm would flow from entry and continued sale" of that product. Moreover, Endo acknowledged under oath that, following the introduction of reformulated OxyContin in August 2010, abusers turned to Opana ER as a drug that was easier to snort or inject.[49]

101. Thereafter, Endo sued the FDA, seeking a preliminary injunction to prevent generic versions of the original Opana ER from coming onto the market. It represented to a federal court as follows:

> Unless the Court intervenes and issues an injunction to preserve the status quo, on January 1, 2013, a generic version of the Original Formulation drug will be released. If this occurs . . . the public interest will be substantially and irreparably injured by release of generic versions of a drug which relies upon a drug that was withdrawn for safety reasons and that is subject to abuse and misuse that FDA acknowledges and against which it has long fought.
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> [***]
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> Unless the Court intervenes and issues a preliminary injunction, there is a significant risk that a readily crushable, and thus admittedly less safe, opioid drug

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[47] https://www.beckershospitalreview.com/opioids/endo-to-receive-royalties-from-generic-opioid-it-once-called-unsafe-7-things-to-know.html; *see also Endo Pharm. v. U.S. Food & Drug Admin., et al.,* Civil Action No. 1:12-cv-01936-RBW (Dkt. No. 5-1), Memo in Support of Motion for Preliminary Injunction, at 13 (stating that Endo represented to the FDA that permitting a generic manufacturer to introduce a generic equivalent to the original Opana ER "would allow abuse or diversion to continue . . . .").

[48] *Id.* at 14.

[49] Collins PI Declaration ¶ 9.

> will serve as the RLD for generic drugs that will then be subject to abuse and misuse. FDA inaction will have facilitated precisely the type of harm to the public interest against which it has fought for many years.[50]

Endo also argued that introducing the generic equivalent "***will result in drug abuse, misuse and diversion with a predictable upsurge in serious injuries and overdose deaths***."[51]

102. Thus, in 2012, Endo publicly acknowledged that it knew that original Opana ER was highly susceptible to abuse and diversion, that it was such a threat to public health and safety that neither it nor any equivalent should be allowed on the market, that diversion and adverse public health effects (including "serious injuries and overdose deaths") are "predictable" consequences of producing and distributing opioids that are subject to abuse. However, even as Endo was arguing that original Opana ER would harm people, it continued to distribute original Opana ER throughout the country for the next 9 months, including in Tennessee. Once the stores were exhausted, Endo then voluntarily removed that original formulation of Opana ER on the basis of those stated safety concerns.

103. In a conference call with investors on February 28, 2013, Endo officials were asked about the reports of injection abuse, specifically those in Tennessee.[52] On that call, Ivan P. Gergel, Endo's chief scientific officer at the time, said: "We've designed the Opana crush-resistant formulation to be crush-resistant, to avoid primarily the nasal root of abuse. . . . Clearly, we are looking at this data . . . but it's in a very, very distinct area of the country."[53] Endo clearly knew that addiction and abuse of Opana ER was centered in Tennessee. It could have stopped calling on doctors in Tennessee and stopped filling orders for Opana ER intended for distribution in

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[50] *Endo Pharm. v. U.S. Food & Drug Admin.*, et al., Civil Action No. 1:12-cv-01936-RBW (Dkt. No. 5-1), Memo in Support of Motion for Preliminary Injunction, at 3.
[51] *Id.* (emphasis added).
[52] *Id.*
[53] *Id.*

Tennessee to stop the abuse and diversion. Instead, it chose to continue to call on Tennessee prescribers, particularly its highest volume prescribers. And it continued to push pills on prescribers and market Opana ER in Tennessee the same way as the rest of the country: Tennessee representatives received the same instructions relative to Tennessee prescribers as everywhere else.

104. Endo's sales department received IMS Health data that identified the volume of Opana prescriptions written by particular providers in Tennessee. Endo reviewed these reports regularly. It used that data to target physicians to prescribe more Opana ER.

105. Later, in 2014, a case study from the University of Tennessee School of Medicine described the university-based hospital's experience of a series of ten patients with characteristic clinical and laboratory findings of Thrombotic Microangiopathy (TMA) and documented recent history of illicit intravenous Opana ER use.

106. Endo itself recognized abuse and diversion of Opana ER in Tennessee was especially acute in Tennessee. Endo collected information from multiple sources reflecting the incidence of abuse of Opana ER in Tennessee relative to other drugs and the source of those drugs. Based on that data, in March 2017, Endo's Chief Medical Officer, Neil Shusterman acknowledged to the FDA in March 2017 that ***75% of all abuse of reformulated Opana ER occurred in Tennessee*** over the post-monitoring period for reformulated Opana ER, even though Tennessee has just 2% of the nation's population. Shusterman also acknowledged that "while Endo was receiving quarterly surveillance reports in real-time, NAVIPPRO informed us ***that a continually increasing proportion of Opana ER cases was coming from Tennessee.***"[54] In fact, Tennessee's

[54]https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM553190.pdf, Transcript of March 13, 2017 FDA Hearing, at 71 (emphasis added).

abuse rates were so high that Endo chose to exclude them from its nationwide calculations. Dr. Shusterman presented an alarming picture of acute problems with Opana ER and other opioids in Tennessee:

a. Relative to the rest of the country, rates of Opana ER injections in Tennessee were exceptionally high for oxycodone immediate release, morphine extended release, and OxyContin before 2012. Endo stated that there was "clearly an intravenous abuse issue in Tennessee that goes beyond Opana ER[.]"

b. Intravenous abuse of Opana ER ***increased*** by approximately a factor of three after the reformulation in 2012.

c. Following the reformulation, injection abuse of Opana ER in Tennessee increased.

d. Tennessee had an "uncommonly high abuse" not only for Opana ER, but also for many other opioids.

e. The data indicated that Tennessee drug abusers who needed substance treatment "might be a more severe group of opioid abusers with more intravenous experience than those in other states."[55]

f. Endo therefore noted a special "effect of Tennessee," which "warrants that the two regions be looked at separately."[56]

g. Endo acknowledged that rates of IV abuse in northeast Tennessee "have been documented for a long time."[57]

h. Tennessee had "abuse prevalence an order of magnitude higher than in other parts of the United States, and increased intravenous abuse of all opioids, particularly Opana ER."[58]

i. Tennessee had a special "abuse psychology."[59]

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[55] *Id.* at 77.
[56] *Id.*
[57] *Id.* at 91.
[58] *Id.* at 100.
[59] *Id.* at 132.

j. When asked by the FDA whether Endo could "determine how many tablets of oxymorphone that you ship to a specific area in a given year," Endo responded: "Absolutely."[60]

107. Like the other defendants, Endo employed a sales force that specifically targeted high-volume opioid prescribers to convince them to prescribe more Opana ER or to prescribe it instead of OxyContin, as well as to prescribe Endocet and other branded Endo drugs. Endo identified these high-volume prescribers as the softest targets. Like other defendants, it compiled data showing which prescribers issued the most opioid prescriptions and detailed those prescribers repeatedly, including prescribers in Tennessee and in the Opioid Impacted Localities. As with the other producer defendants, Endo recognized that detailing doctors drives prescriptions, and it provided volume-based bonuses or commissions to sales representatives. Endo's detailing efforts were successful. Opana ER sales rose, and the vast majority of prescriptions for Opana ER came from doctors that Endo detailed. Upon information and belief, the same holds true as to Endo's other branded opioids.

108. Endo knew that supplying large quantities of opioids to a region necessarily correlates with increased rates of abuse and diversion. In other words, it knew that the more opioids are available in a given area, the more they will be abused. For example, in 2014, its Risk Management analyzed Inflexion data and determined that "[t]he number of prescriptions dispensed within a geographic region is related to a product's potential diversion and abuse."[61] Endo also determined that the level of prescriptions dispensed for reformulated Opana ER in Tennessee was among the highest among states within the dataset that Endo was analyzing.

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[60] *Id.* at 133.
[61] ENDO-OPIOID_MDL-01333144.

109. Endo also recognized that the vast majority of opioids that are abused originate with prescriptions from a healthcare provider, as opposed to another source (pharmacy theft, etc.). Endo recognized that there was an illegal market for its products and knew that supplying Opana ER and other prescription opioids would cause diversion to addicts. Endo knew that Opana ER became the opioid of choice for abusers in Tennessee. Nevertheless, it continued to push pills on the most dangerous, highest-volume prescribers and to encourage them to prescribe more Opana ER, knowing by doing so it would result in its drugs reaching the illegal drug market in increasing volumes.

110. In fact, Endo recognized that even legal, non-fraudulent opioid prescriptions constitute diversion when a naïve doctor willingly writes prescriptions for powerful opioids to pill seekers and prescription drug abusers who sell the prescriptions wholesale. In other words, even as to prescribers did not know any better, Endo recognized that writing scripts for pill seekers and abusers was a form of diversion. Endo knew that this form of diversion was occurring in Tennessee and in the Opioid Impacted Localities at alarming rates, and that any effort to convince those doctors to prescribe more opioids would cause increased diversion. It nevertheless continued to push pills on these prescribers, convincing them to prescribe more Opana ER despite knowing that this would result in further abuse and diversion in Tennessee – which had an acute abuse and diversion problem that Endo itself recognized.

111. Both before and after the reformulation of Opana ER, Endo pushed Opana ER to Tennessee prescribers who were operating pill mills, some of whom eventually were indicted. Endo actively pushed Opana ER on these prescribers even after receiving reports of suspected criminal activity.

a. For instance, in 2007, Endo received word from a district manager questioning whether Dr. Frank McNeil's practice was legitimate. The

district manager indicated that Dr. McNeil was prescribing 80-100 scripts per week for extend release opioids, that 90% of his scripts were for OxyContin (i.e., one product), that he was not actually seeing patients regularly, had physicians' assistants who rotated through the office every 6 months, that he was receiving cash for OxyContin from "a lot" of his patients, and was prescribing OxyContin at a level that "seems almost impossible even for a pain clinic." Endo nevertheless told the district manager that Endo could continue to call on that prescriber, noting internally that Dr. McNeil was responsible for 20% of the sales volume within one of Endo's sales territories. As described herein, in 2018 Tennessee ultimately stripped Dr. McNeil's medical license.

b. Endo also facilitated diversion by Dr. Mohamed in Morristown. After successfully courting Dr. Mohamed and convincing him to prescribe more Opana ER, Dr. Mohamed informed him that his "patients" could not fill their Opana ER prescriptions because the pharmacies had run out. Essentially, he had written so many scripts that local pharmacies ran out of sufficiently supply to meet them. Endo then contacted numerous other local pharmacies and Endo's distributors in an effort to stock those pharmacies to fill Dr. Mohamed's prescription and make up for the shortage. Dr. Mohamed was Endo's highest prescriber in Tennessee. Endo never formally identified Dr. Mohamed as a suspicious subscriber.

These are just representative examples.

112. Endo sales representatives also called on pharmacies to ensure that the pharmacies stocked Endo products.

113. In 2011, the FDA directed Endo to conduct a post-marketing epidemiological study concerning the abuse deterrence potential of reformulated Opana ER. Endo conducted a study and learned through NAVIPPRO reports that Opana ER reformulated during the study period was procured for abuse primarily nationwide through ***drug dealers***, at a rate 12 to 15 times higher than the national average for prescription drug abuse. As Endo later acknowledged to the FDA in March 2017, the same reports showed that abuse of Opana ER in Tennessee was multiple orders of magnitude higher than the rest of the country.

114. Endo tried to convince the FDA that patterns of abuse would be different and lower with the reformulated version. However, it turned out that reformulated Opana ER resulted in

higher rates of intravenous abuse because of the specific chemical properties of the drug. This led to outbreaks of Thrombotic Microangiopathy, Hepatitis C, and HIV. Within three months of the reformulation hitting the market in 2012, Endo learned about the spike in intravenous and the associated outbreaks. Despite such troubling reports of its newly-reformulated Opana ER product being abused intravenously, internally Endo's sales team was being told with respect to their detailing that it was "business as normal." Indeed, four years after first receiving reports of TTP from abuse of the newly-formulated Opana ER in Tennessee, Endo executives were discussing the fact that they had not yet solved "the intravenous issue."

115. Endo had evidence that 10% of prescriptions nationwide were coming from East Tennessee, even though that region has less than 0.7% of the nationwide population. This disproportionately included small communities, such as those in the larger the Opioid Impacted Localities area, where there were far more prescriptions than people, a pervasive illegal drug network for prescription opioids (which included both pharmacies and prescribers who were engaged in criminal conduct and unlawful practices concerning prescription opioids), and high rates of addiction, NAS deaths, and overdose deaths.

116. During the same time frame that Endo reformulated Opana ER was being acutely abused and diverted in Tennessee, Endo engaged in a lobbying campaign to have Tennessee exclude a competing generic version of the drug (which was not "tamper resistant") from the market, and characterized Tennessee as a "critical" state for sales and marketing purposes that Endo needed to "win" in order for Opana ER to be successful. Essentially, at the same time that Endo identified that reformulated Opana ER was being abused intravenously in Tennessee at exceptionally high rates relative to the rest of the country, Endo simultaneously was targeting Tennessee as a "critical" and "key" state where it needed to drive more sales. In service of that

goal, it engaged in a multi-pronged effort to drive sales of reformulated Opana ER, including targeting high-volume prescribers, including physicians, nurse practitioners, and physicians assistants, and "selling" the benefits of reformulated Opana.

117. Indeed, by 2014, the problem with Opana ER abuse and diversion in Tennessee had gotten so bad that Endo's President internally considered whether to close off distribution of Opana ER entirely. Endo recognized that its drugs were being abused and diverted at such volumes that stopping distribution entirely was warranted. However, Endo never took that step. Instead, it continued to flood Tennessee with Opana ER so as not to lose sales revenue. Indeed, during the same time frame, Endo was actively pushing Opana ER on the highest volume Tennessee prescribers who were pushing pills into the illegal drug market in alarming quantities. As of early 2014, 7 of Endo's top 20 prescribers were located in Tennessee, including prescribers in Knoxville (Dr. Mohamed among them), Nashville, and Memphis. Endo also identified the top OxyContin prescribers (including Dr. Mohamed) and directed its sales force to target them to prescribe a larger share of Opana ER.

118. Endo knew that it had a responsibility to monitor and report suspicious orders. Nevertheless, it implemented a system for detecting and reporting that was designed to fail. Endo utilized a structure that encouraged sales representatives to call on pill mill prescribers or over-prescribers and that, by the same token, disincentivized those representatives from reporting suspicious practices. Sales representatives had an inherent conflict of interest because reporting their customers would reduce their compensation. By the same token, Endo did not penalize any sales representatives for having supplied a suspicious prescriber. Furthermore, Endo's Chief Medical Liaison believed that sales personnel were not qualified to detect and report signs of abuse and diversion, and should not have been involved in that important function. Nevertheless, Endo

entrusted the sales force to be only source of abuse detection and reporting for Endo. Not surprisingly, sales representatives did not report a single instance or abuse or diversion by a Tennessee prescriber. Nor, for that matter, did Endo classify an order from a distributor as suspicious.

119. Relative to Tennessee, ***it filled every single order ever submitted to it*** and continued to push Opana ER and other dangerously addictive pills on the highest-volume prescribers essentially no matter what information it learned.

120. Endo knowingly facilitated downstream diversion of its products and participated in Tennessee's illegal drug market for opioids. Its effort resulted in rampant abuse and diversion of Opana ER nationwide, in Tennessee, and in the Opioid Impacted Localities.

121. The ongoing, and excessive, abuse of Opana ER reached such a critical level that, on June 8, 2017, the FDA took the unprecedented step of demanding that Endo permanently remove the drug from the marketplace.[62] According to a FDA press release, the agency's "decision [was] based on a review of all available post marketing data, which demonstrated a significant shift in the route of abuse of Opana ER from nasal to injection following the product's reformulation."[63] The FDA further stated that its decision to remove the opioid from the marketplace followed a March 2017 FDA advisory committee meeting where a group of independent experts voted that "the benefits of reformulated Opana ER no longer outweigh its risks."[64]

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[62] FDA Press Release. FDA requests removal of Opana ER for risks related to abuse. June 8, 2017. Available at:
https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.
[63] *Id.*
[64] *Id.*

122. On July 6, 2017, Endo announced that it would voluntarily remove Opana ER from the market, citing the FDA's concerns of diversion.[65]

123. Despite evidence of widespread abuse, Endo continued to push its drug into the addiction pipeline in Tennessee, including the Opioid Impacted Localities, with its highly addictive, and deadly, prescription opioid, all the while knowing that it was being diverted into the illicit market. From September 2015 through August 2017, Endo's Opana ER and Endocet were the second and third most-prescribed branded opioids throughout Tennessee, respectively, following only OxyContin.[66]

124. Furthermore, after the new Opana ER formulation was removed from the market at the FDA's request in July 2017, Endo pivoted and entered into a contract with Impax to share profits from sales of a generic equivalent to the original Opana ER sold under the "Impax" name. The agreement allows for profit-sharing for the next 11 years, starting January 1, 2018. As numerous observers have pointed out, "Endo is profiting off of the very drug it said was unsafe to stay on the market."[67] By Endo's own admission, continuing to distribute this product "will result in increases in drug abuse, misuse and diversion," along with "serious and predictable public harm." Accordingly, Endo has known all along that streaming its opioid products into communities "predictably" results in high levels of addiction, overdose death, and illegal diversion – but it does not care, so long as it continues to turn a profit.

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[65] CBS News online. Opana ER opioid painkiller pulled from the market by FDA request. July 7, 2017. Available at: https://www.cbsnews.com/news/drug-opana-er-opioid-painkiller-pulled-from-the-market-by-fda/ (last visited Dec. 1, 2021).
[66] Quintiles IMS Data.
[67] https://www.beckershospitalreview.com/opioids/endo-to-receive-royalties-from-generic-opioid-it-once-called-unsafe-7-things-to-know.html.

125. Endo knowingly entered and participated in the illegal drug market in Tennessee and the Opioid Impacted Localities. Endo is aware of the extraordinary and unjustifiable volume of opioid prescriptions in Tennessee in relation to other states. Endo knew that such inflated prescribing necessarily reflects improper prescribing and diversion of opioids, including Endo's products. Endo also knowingly participated in the illegal drug market in the Opioid Impacted Localities by supplying quantities of its products to physicians and pharmacies whose prescribing habits necessarily or likely reflected unlawful diversion, and by engaging in the other acts referenced herein.

126. Also, Endo knowingly instituted internal procedures designed to fail to identify potential abuse, diversion, and/or inappropriate prescribing of opioids in Tennessee and the Opioid Impacted Localities, including: (i) incentivizing sales representatives not to report signs of abuse, diversion, and inappropriate prescribing of prescription opioids; (ii) paying bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing of prescription opioids; and (iii) permitting and directing sales representatives to visit prescribers whose were engaging in suspicious conduct.

3. Teva's Misconduct is Contributing to the Opioid Epidemic Ravaging the Opioid Impacted Localities and the State of Tennessee.

127. Teva continues to flood East Tennessee with opioids in an amount that clearly contributes to the illegal opioid drug market.

128. Teva's generic oxycodone and hydrocodone products both represent the largest market share for either product throughout Tennessee according to IMS Health Data. These quantities of opioid pills clearly exceed the number that would be appropriate for normally prescribed therapeutic use and contribute to the illegal Tennessee opioid market.

129. Teva also knowingly participated in the illegal drug market in Tennessee by supplying suspicious quantities of its products to suspect physicians and pharmacies in Tennessee, without disclosing suspicious orders as required by applicable regulations.

130. According to IMS data, from September 2015 to August 2016, Teva accounted for 33.5% of the hydrocodone prescribed in Tennessee, 28.8% of the oxycodone prescribed in Tennessee, 16.8% of the oxymorphone, and 1.6% of the hydromorphone. This amounted to 1,913,712 Tennessee opioid prescriptions filled by Teva in one year. On average, this means Teva filled an opioid prescription for one out of every 3.5 Tennesseans during that year.

131. During the same timeframe of September 2016 through August 2017, Teva accounted for 32.3% of Tennessee hydrocodone prescriptions, 25.1% of its oxycodone prescriptions, 1.8% of its oxymorphone prescriptions, and 1.8% of its hydromorphone prescriptions. This amounted to 1,619,143 Tennessee opioid prescriptions filled by Teva in one year. On average, this means Teva filled an opioid prescription for one out of every 4.1 Tennesseans during that year.

132. Teva's role relative to branded drugs involved knowing participation in the illegal drug market. Cephalon, a pharmaceutical company purchased by Teva in 2011, sold two opioid drugs, Actiq and Fentora. As part of the approval process for Actiq the FDA required a risk management program (RMP) for the marketing of the drug. The RMP for Actiq in 1998 specifically included special adverse event reporting for adverse events related to "unintended pediatric exposure," "diversion (i.e., use by an individual other than for whom it was prescribed)," or "in the context of 'off label use'". As of 2001, the FDA further informed Cephalon that it had concerns that its fentanyl based drug, Actiq, might be used by patients who were not indicated for its use and that there was potential for diversion and abuse of the drug. In 2006 *The Wall Street*

Journal reported that Actiq, a fast acting lollipop like oral analgesic that contained fentanyl, was reportedly being called "perc-a-pop" on the street.[68]

133. In 2005, Cephalon knew that 90% of Actiq prescriptions were for off-label use, and 55% of that total were for chronic back pain. From 2000 to 2006, sales of Actiq grew from $15 million to over $400 million a year.[69] *The Wall Street Journal* further reported that surveys from research firm ImpactRx from June 2005-October 2006 found that more that 80% of patients who use the drug don't have cancer.[70]

134. In 2006, as Actiq was losing its patent protection as a branded drug, Cephalon began marking a new fentanyl based drug to replace it, called Fentora. Fentora, like Actiq, was only ever approved by the FDA for the treatment of breakthrough cancer pain. As part of the FDA approval of Fentora, Cephalon again was required to agree to a risk management program or RiskMAP, including a plan to monitor, evaluate and determine the incidence of use of Fentora by opioid intolerant individuals, misuse of Fentora, and unintended (accidental) exposure to Fentora.

135. In November 2007, Cephalon submitted a supplemental New Drug Application (sNDA) to the FDA requesting that the FDA approve Fentora for use in non-cancer opioid tolerant patients with breakthrough pain. The FDA denied Cephalon's request, explaining that "[i]n the face of a national crisis of prescription opioid abuse and misuse, it is critical that you provide a risk management program with established efficacy [and] adequate restrictions to avoid widespread abuse and misuse."[71] The FDA's letter to Cephalon denying its request addressed the

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[68] John Carreyrou, *Narcotic 'Lollipop Becomes Big Seller Despite FDA Curbs*, Wall Street Journal, Nov. 3, 2006, available at: https://www.wsj.com/articles/SB116252463810112292.
[69] *Id.*
[70] *Id.*
[71] Ex. 29 to Condodina Dep. (Sept. 12, 2008 letter from the FDA).

complete failure of the company to address the abuse and misuse of both its potential and its existing products:

> [Y]ou have not adequately addressed the public health concern of increased abuse, misuse, overdose and addiction that is to be expected with more widespread availability of this product in the community. Your proposed plan to mitigate these risks has not been adequately tested to assure that it will, indeed, achieve this outcome for your currently approved indication, let alone the proposed expanded indication.[72]

These problems were never resolved by Cephalon in an amended application and the FDA never approved Fentora for expanded use beyond cancer pain.

136. Teva expanded its opioid business beyond Actiq and Fentora when it bought pharmaceutical company Activis, which produces several generic opioids, mainly hydrocodone-acetaminophen and oxycodone-acetaminophen. Those types of opioids are prevalent in Tennessee.

137. After the FDA in 2012 required all opioid manufactures to adopt a strategy to combat opioid abuse, Teva began developing a new branded opioid called Vantrela. In seeking FDA approval of the drug, Teva presented Vantrela as an "abuse-deterrent" form of hydrocodone. Teva then developed a marketing plan to target managed care organizations in the hopes they would add this new drug to their formulary. The opioids that Teva sold were the generic versions of these same opioids. In fact, Teva sold millions of those same opioids in Tennessee from 2015 – 2018, as part of its pitch, Teva cited to publicly available documents that demonstrated that the U.S. was in the midst of an opioid abuse and addiction crisis.

138. In 2015 and 2016, Teva was reviewing and sharing publicly available information and studies about opioid addiction in preparation for Teva's third-party payer marketing strategy

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[72] *Id.*

for Vantrela, planning to promote Vantrela as an abuse deterrent product. One such publicly available source was a Time Magazine article in June 2015, highlighting the public health crisis of opioid addiction, including specifically in Tennessee. The Time story highlighted, among other things, that patients often buy the pills on the black market after becoming addicted, and approximately 1/5 of Americans who take opioids are estimated by the National Institutes of Health to be in danger of turning to the black market for more pills.

139. In June 2016 Actavis prepared a managed care overview to be provided to payers outlining why the misuse, abuse and diversion of opioids is a major public health concern, including the fact that in 2010 1 in 20 Americans over 12 abused opioids, in 2011 1 in 3 ER visits were opioid related, and in 2014 there were 18,000 opioid overdose deaths, a 300% increase in deaths from 1999. Teva recognized that between 9-28% of misusers of pain relievers get their drugs through a doctor's prescription. Teva also recognized the substantial economic burden of opioid abuse on healthcare, workplace, criminal justice, and societal costs. Teva even cited studies showing that approximately 27% of chronic pain patients prescribed opioids for non-cancer pain are likely to abuse the drugs. Teva positioned its branded Vantrela as a cost savings for managed care payers compared to its generic opioids because generic opioids have a "high rate of abuse and generate enormous costs," lead to high levels of addiction, are responsible for around 2/3 of overdose deaths, contribute to increased healthcare costs and other indirect costs.

140. Despite now having clear knowledge of the risks of abuse of opioids, including its own opioid products, Teva continued to send its generic opioid products into Tennessee and throughout the United States in large numbers. Vantrela was approved by the FDA in January

2017, yet Teva continues to promote its generic, less abuse-deterrent drugs.[73] From 2015-2017, IMS data shows that over 2 million Teva produced opioids prescriptions were filled in Tennessee.

141. Like the other Drug Producer Defendants, Teva received chargeback data from its distributors that told Teva precisely where its pills were going, in what amount, and to whom. It had the ability to deny chargebacks relative to pharmacies and dispensing physicians supplied by its distributors, which effectively amounted to controlling whether its pills would reach those pharmacies or not. And like other defendants, it recognized when orders were manifestly suspicious (because of the size of the order, the size of the community served, and other indicators) and likely to be diverted. However, it rarely, if ever, denied chargebacks relative to pharmacies anywhere in the country, let alone in Tennessee. Instead, it chose to fill those suspicious orders anyway, including in Tennessee, recognizing that the shipments were likely being dispensed to fill pill mill prescriptions or otherwise to be diverted into the black market.

142. Teva recognized that prescription rates per capita are an indicator of potential abuse of prescription opioids. Nevertheless, Teva continued to fill orders in the Opioid Impacted Localities where the per capita prescription rates were high and that Teva knew or should have known had no legitimate medical need for the opioids being sold there. Instead of recognizing these orders as suspicious and reporting them to the DEA, Teva simply continued on with business as usual in filling millions of prescriptions for its generic opioids that Teva knew were being widely abused and misused.

143. As with the other defendants, Teva's suspicious order monitoring system did not actually detect suspicious orders. Upon information and belief, Teva placed primary responsibility for detecting and reporting suspicious orders with its sales personnel, who were financially

[73] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/207975Orig1s000Approv.pdf.

incentivized to call on customers who made suspicious prescriptions or submitted suspicious orders rather than report them, and to come up with sham justifications to "clear" suspicious orders or to justify calling on them further. From 2002 to 2011, Teva did not report a single one of its prescription orders as suspicious. In fact, prior to being named in numerous opioid-related lawsuits, Teva's SOM system has only flagged – and Teva only reported to the DEA – 6 TOTAL suspicious orders total for the entire country. The included just one in 2013, one in 2014, 4 in 2015, and none in 2016. Otherwise, Teva supplied essentially anyone and everyone who submitted an order for its drugs. This included filling orders that it recognized were being dispensed, in large volumes, to fill prescriptions relative to prescribers under circumstances that Teva recognized were suspicious and indicative of diversion.

144. Teva shipped orders of opioids in frequencies and in volumes that were inherently suspicious. For example, in April 2015 alone, Teva shipped nearly 5 million pills of hydrocodone into Tennessee. The multitude of orders comprising this volume necessarily were suspicious. Yet Teva filled them. Upon information and belief, Teva filled large volumes of orders from M&D for pharmacies and dispensing physicians within Tennessee, under circumstances demonstrating that each order was suspicious.

145. Other than its so-called suspicious order monitoring program, Teva does nothing to prevent the illegal diversion of its prescription opioid products once the products leave the individual manufacturing facilities, even though it knows that some customers of prescription opioids obtain them expressly for nonmedical purposes. Teva is also aware that Appalachia, in the area in or adjacent to TN, is a hotspot for opioid abuse and that that the opioid drug diversion problem is particularly large and problematic in Tennessee.

146. Upon information and belief, as with the other Defendants:

a. Teva's suspicious order monitoring program was structured to be ineffective;

b. Teva, like the other Producer Defendants, utilized a sales force to sell its branded opioids who called on prescribers directly and on pharmacies and dispensing physicians – nationwide and in Tennessee;

c. Teva, like the other Producer Defendants, paid sales representatives of its branded opioids bonuses or commissions based on sales volume relative to Tennessee (as elsewhere);

d. relative to branded sales, Teva financially incentivized its sales force to call on high-volume prescribers and targeted those high-volume prescribers to prescribe more opioids; and

e. relative to its relationship with pharmacies and dispensing physicians, Teva financially incentive its sales personnel to process and fill suspicious orders.

147. Furthermore, like other Producer Defendants, Teva received chargeback data from its distributors that told Teva precisely where its pills were going, in what amount, and to whom. It had the ability to deny chargebacks relative to pharmacies and dispensing physicians supplied by its distributors, which effectively amounted to controlling whether its pills would reach those pharmacies or not. And like other defendants, it recognized when orders were manifestly suspicious (because of the size of the order, the size of the community served, and other indicators) and likely to be diverted. It rarely, if ever, denied chargebacks relative to pharmacies anywhere in the country, let alone in Tennessee. It chose to fill those suspicious orders anyway, including in Tennessee.

C. M&D Participated in the Illegal Drug Market.

1. M&D's Business Model is Unlawful or Otherwise Facilitates Diversion.

148. M&D facilitated illegal drug transactions in Tennessee by submitting suspicious orders, having them filled, and stocking suspect pharmacies and dispensing physicians with opioids destined for the illegal drug market. They had a choice when faced with suspicious orders: submit them or impound them and investigate until they actually cleared the suspicion. They

consistently chose to ship opioids to downstream buyers who were likely – and in many instances were criminally convicted for – diverting prescription opioids. They also acted by promoting their services to suspect pharmacies and dispensing physicians to drive sales volumes, knowing that doing so would encourage diversion. Furthermore, to avoid reporting their own customers, they provided sham justifications for suspicious orders to the Producer Defendants, as part of a "nod, nod, wink, wink" collaboration between M&D and the Producer Defendants. Essentially, M&D recognized that the Producer Defendants would accept essentially any purported justification for an inherently suspicious order. Through this "nod nod, wink wink" arrangement, M&D and the Drug Producers collaborated to put prescription drugs into the illegal market without alerting law enforcement or losing their best customers.

149. Through these depraved acts and schemes, the Producer Defendants and M&D helped each other get rich from the devastation that they wrought on Tennessee communities, including the Opioid Impacted Localities. This included causing increasing numbers of opioid overdose abuse deaths each year – including 1,543 deaths in 2019 and 2,388 deaths in 2020 – and staggering rates of NAS births, including over 1,600 babies born with NAS in Tennessee over the last two years. The Producer Defendants and M&D did not care about the human and economic toll on Tennesseans that their misconduct caused – all they cared about was profit.

150. M&D know that they have an important responsibility to monitor their customers' practices and that they are not supposed to fill suspicious orders.

151. M&D knew they should monitor, detect, and halt suspicious orders. For example, industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due

diligence in order to help support the security of the controlled substances they deliver to their customers."[74] The guidelines set forth recommended steps in the "due diligence" process, and note in particular "[i]f an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest."[75]

152. M&D sold prescription opioids in and around the Opioid Impacted Localities, which Defendants knew were likely to be diverted into the illegal drug market.

153. DEA Agent Joseph Rannazzisi has emphasized the importance of drug distributors in preventing opioid diversion: "[b]ecause distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances . . . from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system created by the [Controlled Substances Act] collapses."[76]

154. The sheer volume of prescription opioids distributed to pharmacies in the Opioid Impacted Localities and/or to pharmacies from which M&D knew the opioids were likely to be diverted into the Opioid Impacted Localities, is excessive for the medical need of the community

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[74] Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061, Doc. No. 1362415 (App'x B) (D.C. Cir. Mar. 7, 2012).
[75] *Id.*
[76] Declaration of Joseph Rannazzisi, ¶ 10 (filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-2 (D.D.C. February 10, 2012).

and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.

155. M&D filled inherently suspicious orders originating from the Opioid Impacted Localities or which M&D knew were likely to be diverted to or within the Opioid Impacted Localities.

156. M&D filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in the Opioid Impacted Localities, and/or orders which Defendants knew or should have known were likely to be delivered and/or diverted into the Opioid Impacted Localities.

157. M&D possessed direct knowledge of obvious signs of diversion by their customers. They knew that Tennessee pharmacies were receiving prescription opioids in volumes grossly disproportionate to the population and any conceivable medical need. They knew that local prescribers near those pharmacies were prescribing at levels that were not medically justifiable and that the pharmacies were filling prescriptions for suspect prescribers.

158. Rather than seek to stop pharmacies from supplying pills or to stop dispensing physicians who were operating pill mills, M&D targeted these entities and competed for their business. In other words, M&D targeted high-volume dispensing pharmacies (including independent or locally owned pharmacies in small rural communities) to compete for their business. Effectively, they competed for pill mill market share.

159. M&D also provided sham justifications for certain suspicious orders to have them filled. M&D and the Producer Defendants tacitly understood that any purported justification (no matter how false, ludicrous, or insufficient) would suffice for the Producer Defendants to clear and ship an inherently suspicious order. Through this "nod nod, wink wink" arrangement, M&D and

the Drug Producers collaborated to put prescription drugs into the illegal market without alerting law enforcement or losing their best customers.

160. M&D has been cited failing to report suspicious orders of opioids. M&D knew that it had a responsibility to safeguard against diversion.

161. For example on September 27, 2006, the DEA sent a letter to "every commercial entity in the United States registered with the [DEA] to distribute controlled substances."[77] The letter stated that manufacturers and distributors "share responsibility for maintaining appropriate safeguards against diversion" and "given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, ***even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.***"[78] The letter advised that "DEA will use its authority to revoke and suspend registrations in appropriate cases."[79] The letter also provides that "in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[80] The letter further discusses that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[81]

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[77] 2006 Rannazzisi Letter at 1.
[78] *Id.* at 2 (emphasis added).
[79] *Id.*
[80] *Id.*
[81] *Id.* at 1.

162. The DEA sent another letter on December 27, 2007 to "reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders."[82] This letter reminded manufacturers and distributors of their obligation to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[83]

163. The letter states that in terms of reporting suspicious orders:

> Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.
>
> When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."[84]

The 2007 letter also said that "[f]ailure to maintain effective controls against diversion is inconsistent with the public interest . . . and may result in the revocation of the registrant's DEA Certificate of Registration."[85]

164. The 2007 letter also references the final order issued in Southwood Pharmaceuticals, Inc., 72 FR 36487 (2007), which "[i]n addition to discussing the obligation to

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[82] 2007 Rannazzisi Letter at 1.
[83] *Id.*
[84] *Id.* at 2.
[85] *Id.* at 1-2.

report suspicious orders when discovered" and "some criteria to use when determining whether an order is suspicious," the order "also specifically discusses your obligation to maintain effective controls against the diversion of controlled substances."[86]

165. M&D knew which pharmacies and dispensing physicians were filling prescriptions, including the amount and type of drug. M&D maintained direct relationships with pharmacies and dispensing physicians, including those plainly engaging in filling pill mill prescriptions *en masse*.

166. All of these allegations concerning M&D are also applicable to the Pharmacy Chain Defendants that self-distributed controlled substances to their own pharmacies.

167. The illegal market for prescription opioids exists because distributors, like M&D, choose to submit suspicious orders to manufacturers, manufacturers choose to fill them, and the distributors distribute them to pill mills and other recognized sources of diversion. In American Overdose, Mr. Rannazzisi summed up the role of distributors: To Rannazzisi, distributing highly addictive and potentially lethal drugs wasn't the same as delivering chocolate bars. He regarded the lucrative licenses the wholesalers held as carrying particular responsibilities: "These companies have one task, and that is the safe and secure distribution of drugs, particularly prescription drugs. Otherwise FedEx or UPS could do this role. This isn't a compliance challenge, like gender discrimination at a tech company, which is horrific, but it's not fundamental to their operation. This is the equivalent of a tech company failing on cybersecurity. If these companies were doing their job right, you shouldn't be seeing black-market prescription painkillers."

2. Morris & Dickson Has Facilitated Illegal Drug Transactions.

168. M&D flooded Tennessee communities with amounts of opioids that would have put a law-abiding distributor on notice to investigate diversion. For example, M&D distributed

[86] *Id.* at 2.

234,990 dosage units of opioids, representing 4,590,342 MME, in 2014 to Garrett's Pharmacy, which operates in Pickett County, the least populated county in Tennessee.

169. M&D had a duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opioids originating from Tennessee and the Opioid Impacted Localities, as well as a duty to maintain reasonable controls against diversion of prescription opioids.

170. M&D received guidance from the DEA, including letters outlining its obligations with respect to reporting suspicious orders and implementing controls to prevent diversion sent on September 27, 2006 and December 27, 2007.

171. Since 2014, M&D has distributed controlled substances to approximately 800 retail pharmacies in 17 states, including Tennessee.

172. On May 24, 2019 M&D paid $22 million in civil penalties to settle U.S. government charges that it failed to report thousands of suspicious orders of opioids.

173. M&D had, in the period after January 2014, failed to report thousands of retail pharmacy orders that it should have reported to the DEA as suspicious, as required by law.

174. Referring to his company's failure to report the pharmacy orders, the company publicly stated: "We acknowledge we made mistakes."

175. In reference to M&D's 2019 settlement, DEA Special Agent in Charge Brad L. Byerly confirmed that "[t]he failure to report suspicious orders as required by federal regulations contributes to the opioid epidemic, which has caused devastating harm to individuals and our communities."

176. M&D's failure to properly report suspicious orders shipped to Tennessee and the Opioid Impacted Localities was knowing and facilitated the illegal drug market in the Opioid Impacted Localities.

177. M&D knowingly operated systems that failed to meet its obligation to properly track and report suspicious orders and prevent diversion for the period covered by this complaint, at minimum from September 27, 2006 through the present.

D. Walmart's Self-Distribution of Opioids Followed a Similarly Unlawful Business Model as Morris & Dickson that Facilitated Illegal Drug Transactions.

178. Walmart, in addition to purchasing opioid medications from third-party distributors, primarily self-distributed opioid medications until 2018.

179. Walmart had the same obligations under Tennessee law to monitor, detect, and halt suspicious orders as M&D. Similarly, Walmart repeatedly failed to identify, investigate, report, and/or halt hundreds of thousands of suspicious opioid orders across the country, including orders going to Tennessee.

180. The numbers that Walmart distributed into the state of Tennessee were staggering. From just 2006 to 2014, Walmart distributed 251,048.435 dosage units of opioids into Tennessee.

181. Walmart did not implement effective diversion control measures when shipping these pills. Instead, they put in place policies and protocols that ensured that the flow of drugs into the illegal market would continue.

182. From 2000 to approximately May 2018, Walmart self-distributed tens of millions of shipments of controlled substances to Walmart-branded and Sam's Club-branded pharmacies. Throughout the period from 2012 to 2018, Walmart was the largest self-distributor in the country for oxycodone, hydromorphone, and hydrocodone in terms of both dosage units and grams.

183. Because Walmart acted as its own distributor, it had access to extensive data and other information that independent distributors would not ordinarily have. In particular, Walmart had a wealth of dispensing information that gave it the ability to investigate the circumstances

underlying orders for controlled substances. Walmart had data about individuals who filled controlled-substance prescriptions at its pharmacies, the identities of medical providers who were prescribing controlled substances for those individuals, and reports from its own pharmacists raising concerns.

184. Despite having information about how often and how much Walmart-branded pharmacies and Sam's Club-branded pharmacies ordered from third-party distributors, Walmart did not account for these orders and shipments in its SOM program.

185. In November 2010, Walmart adopted Pharmacy Manual 21-402 ("Controlled Substance Monitoring"). This policy simply required certain Walmart employees to review a monthly report, known as a "control drug stock exception report," after the controlled substances had been shipped to the pharmacies and identify any controlled substances that constituted more than 3.99% of a pharmacy's total controlled and non-controlled substance purchases during the prior month.

186. Under Pharmacy Manual 21-402 (November 2010), Walmart failed to detect many unusual orders. First, the monthly reports did not identify specific controlled substance orders that were unusually large. Instead, the reports aggregated all shipments of particular controlled substances and then compared those aggregated totals to see if they exceeded 3.99% of a pharmacy's total shipments that month. As a result, many unusually large orders were not flagged because they were not subsumed in the aggregated totals. Second, the policy did not require Walmart to flag any orders that were otherwise suspicious (e.g., exhibiting an unusual frequency or unusual pattern).

187. Pharmacy Manual 21-402 (November 2010) did not describe these aggregated totals as "suspicious orders" or even state that Walmart was required to detect and report suspicious orders to DEA.

188. In a June 12, 2014 email, Walmart attached a risk assessment in which it observed that its system for monitoring suspicious orders was an "existing risk" and "emerging risk" for which it had "no processes in place." Walmart's own assessment was that the risk that its pharmacies would place suspicious orders with its own distribution centers was "likely," the second-highest of five levels on Walmart's scale of likelihood of risks.

189. In July 2014, Walmart revised Pharmacy Manual 21-402 and titled the revised policy "Evaluating Orders of Interest and Suspicious Order Reporting." Unlike the 2010 version of the policy, Pharmacy Manual 21-402 (July 2014) instructed compliance unit personnel to evaluate individual orders as they were placed—rather than monthly aggregated totals after Walmart's distribution centers had already shipped the controlled substances—and report any suspicious orders to DEA.

190. Pharmacy Manual 21-402 (July 2014) called for Walmart first to identify "orders of interest" from among all controlled substance orders, and then to investigate those "orders of interest" to determine whether they were indeed "suspicious orders" subject to reporting to DEA.

191. Both steps of this system failed. The criteria Walmart adopted for flagging "orders of interest in the first instance were plainly inadequate, allowing many suspicious orders to evade any scrutiny. And Walmart routinely failed to investigate orders that were flagged as "orders of interest" to ascertain whether they were suspicious, prioritizing expeditious distribution of controlled substances to meet its pharmacies' and pharmacists' demands over compliance with state and DEA regulations.

192. Walmart failed to detect and report at least hundreds of thousands of suspicious orders of controlled substances. Over an approximately four-year period from 2013 to 2018, a time during which Walmart shipped an estimated 37.5 million controlled-substance orders to its pharmacies, it reported only 204 suspicious orders to the DEA—in other words, almost none. By comparison, during the same time period, Walmart's back-up distributor McKesson Corporation, which filled orders only when Walmart could not, reported to the DEA more than 13,000 suspicious orders from Walmart pharmacies.[87]

E. The Pharmacy Chain Defendants' Dispensing Model Violated Tennessee Law and Otherwise Facilitated Diversion.

193. The Pharmacy Chain Defendants knowingly filled prescriptions for obviously suspect prescribers and pill mills. Upon information and belief, the Pharmacy Chain Defendants filled prescriptions for Pill Mill Prescriber Defendants in this action, the pill mill operators and other suspect prescribers specifically identified above, and pill operators and other suspect prescribers in Tennessee and the Opioid Impacted Localities.

194. The Pharmacy Chain Defendants also over-supplied Tennessee and the Opioid Impacted Localities with opioids at levels far exceeding any conceivable medical need.

195. Pharmacies are the final step on the pharmaceutical supply chain before drugs reach a patient. Pharmacies purchase drugs from wholesalers, including M&D, and occasionally from manufactures directly (upon information and belief, including the Producer Defendants here). Pharmacies are required to maintain accurate, detailed data concerning the prescribing habits of individual prescribers. Upon information and belief, the Pharmacy Chain Defendants maintained

[87] Despite even reporting that many (and that is just for the single customer Walmart), in 2017, McKesson was fined $150,000,000 by the DEA for its systemic failure to report suspicious orders during roughly the same period that Walmart reported only 204.

this data relative to Tennessee prescribers (including those in or serving the Opioid Impacted Localities) and provided that data to the Producer Defendants in return for rebates or other forms of consideration.

196. Pharmacies, like those operated by the Pharmacy Chain Defendants, are the last line of defense in keeping drugs out of the illegal market. Under Tennessee law, pharmacies have heightened obligations to ensure that illegitimate prescriptions are not filled.[88] Pharmacies and its employees must "observe the law…[and] shall expose, without fear or favor, illegal or unethical conduct,"[89] which includes "mak[ing] every reasonable effort to prevent the abuse of drugs which [its] pharmacist dispenses."[90] Simply, Tennessee law requires the Pharmacy Chain Defendants' pharmacies to operate and manage its pharmacies in manner which will minimize diversion.

197. As acknowledged in an article CVS published in the New England Journal of Medicine, "[p]harmacies have a role to play in the oversight of prescriptions for controlled substances, and opioid analgesics in particular." The DEA has identified "both pharmaceutical distributors and chain pharmacies as part of the problem" contributing to opioid abuse and related deaths.[91] The Pharmacy Chain Defendants have a particular "advantage" in meeting their obligations under the CSA because these entities can use "aggregated information on all prescriptions filled at the chain" in order to examine "patterns" of opioids and other "high-risk drugs" and target "inappropriate prescribing." For example, a chain pharmacy should properly use its chainwide dispensing data to identify "high risk prescribers" by "benchmarking" prescription data based on "several parameters," including "volume of prescriptions for high-risk drugs," "the

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[88] Rules of Tn. Bd of Pharmacy, Chapter 1140-02.01(2).
[89] *Id.* § 1140-02.01(4).
[90] *Id.* § 1140-02.01(10).
[91] Mitch Betses, R.Ph., and Troyen Brennan, M.D., M.P.H., *Abusive Prescribing of Controlled Substances – A Pharmacy View*, N. ENGL. J. MED. 369;11, Sept. 12, 2013, at 989-991.

proportion of the prescriber's prescriptions that were for such [high-risk] drugs, as compared with the volume and proportion for others in the same specialty and region," cash payment, ages of patients, and the prescriber's ratio of "prescriptions for noncontrolled substances with prescriptions for controlled substances. This "[a]nalysis of aggregated data" from chain pharmacies can "target patterns of abuse," in the face of "the growing use of controlled substances and resulting illnesses and deaths." Accordingly, as CVS touts in the article, "innovative use of transparent data is only prudent."

198. Tennessee pharmacies must also maintain detailed data for everyone who fills prescriptions at the pharmacy, including where that person is from, their age, and their individual prescribing history.[92] They must also record and maintain records of all prescriptions dispensed, including the type of medication, the amount, and the prescriber.[93] Pharmacists are also limited to dispensing prescriptions only "[a]t a rate, based on the actual number of medical and prescriptions order compounded and dispensed per hour or per day, that does not pose a danger to the public health, safety or welfare."[94] Pharmacies also may not dispense medications unless they determine that it will not be subject to "clinical abuse/misuse."[95]

199. Pharmacies, including the Pharmacy Chain Defendants, also must register for Tennessee's Controlled Substance Monitoring Database ("CSMD"), to which they must periodically submit specific information that includes, *inter alia*, the date of each prescription, the

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[92] Rules of Tn. Bd of Pharmacy, Chapter 1140-03.01(2).
[93] *Id.* § 1140-03-03.
[94] *Id.* at § 1140-03.01(6).
[95] *Id.* at § 1140-03-01(7).

amount, the strength, the patient name, and the prescriber.[96] Law enforcement officials can access this database to use the information.[97]

200. Violation of any of these duties is a basis for civil penalties.[98]

201. The Pharmacy Chain Defendants have no obligation to dispense a prescription that is suspicious or indicative of diversion. To the contrary, they are not supposed to fill any order absent a determination that the order is lawful and/or will not be abused. In other words, the Pharmacy Chain Defendants are not automatons in the supply chain. Every prescription they fill reflects a conscious, affirmative act that Tennessee regulates.

202. The Pharmacy Chain Defendants adopted policies, including performance metrics and quotes, that facilitated diversion of their drugs.

203. Upon information and belief, the Pharmacy Chain Defendants ignored similar calls from their staff to change dispensing policies and practices to give the locations a shot at being complaint with the law and likewise knowingly filled prescriptions issued by pill mill operators and other over-prescribers in Tennessee and the Opioid Impacted Localities, including but not limited to the Pill Mill Prescriber Defendants in this action.

204. In an addition to these financial incentives, the Pharmacy Chain Defendants otherwise structured their operations to minimize the likelihood that any pharmacy would refuse to fill suspicious orders or report suspicious practices to law enforcement. Upon information and belief, they avoided reviewing any information that might cut off high-volume dispensing practices, such as media and journal publications regarding the risks of prescribing opioids in high volumes and dosages, reports from government agencies regarding suspicious practices, questions

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[96] *See id.* § 1140-11-.01 *et seq.*
[97] *See id.* § 1140-11-.02.
[98] *Id.* at § 1140-08-.01.

posed by their own employees regarding suspicious practices, news reports regarding the illegal drug market and pill mills whose prescriptions they were filling, and other communications from the DEA and others regarding suspicious practices.

205. Upon information and belief, the Pharmacy Chain Defendants knew that their pharmacies serving the Opioid Impacted Localities were feeding the illegal drug market. The Pharmacy Chain Defendants knew about the illegal drug market. They knew which prescribers were rampantly over-prescribing opioids, including prescriptions that were plainly inappropriate. They knew that they were over-supplying Tennessee communities with highly addictive prescription opioids at levels and in dosages that necessarily were being abused and diverted.

206. Upon information and belief, like the other defendants, they recognized that dispensing opioids at these volumes and in these dosages to Tennessee communities necessarily was feeding and/or expanding the illegal drug market. They also knew when patients were submitting prescriptions under obviously suspicious circumstances, such as large volumes, frequently filling prescriptions for high volumes and/or high dosages, filling prescriptions for long-term supply, filling prescriptions from out-of-state or out-of-county prescribers, and filling prescription for notorious pill mill operators such as the Pill Mill Prescriber Defendants. They also knew when their daily prescription volumes far exceeded any conceivable medical need.

207. Upon information and belief, the Pharmacy Chain Defendants also paid productivity-based bonuses to their pharmacists, providing additional incentives to fill suspicious prescriptions.

208. By the same token, upon information and belief, the Pharmacy Chain Defendants did not routinely measure their employees' performance relative to pharmacy accuracy, customer safety, or processing only non-suspicious orders for a legitimate medical purpose.

209. In these ways, the Pharmacy Chain Defendants financially incentivized their pharmacies and pharmacists to make suspicious orders, fill suspicious prescriptions, and/or to fill orders without adequate due diligence.

210. Upon information and belief, the Pharmacy Chain Defendants did not adequately train their pharmacists and pharmacy technicians on how to identify prescription drug abuse and illegitimate orders.

211. Indeed, the Pharmacy Chain Defendants over-supplied rural Tennessee communities at rates that far exceeded any conceivable medical need, plainly without conducting the requisite due diligence.

212. For example, CVS adopted a policy called The Metrics System, which rates its retail stores' pharmacists and employees based solely on productivity – namely, how many and how quickly those stores filled prescription each day based on store volume. These requirements placed significant and unrealistic time pressures on pharmacists. This created a perverse incentive for their retail stores to fill orders (including suspicious orders and pill mill prescriptions) without regard to whether the orders themselves were legitimate. Upon information and belief, the Pharmacy Chain Defendants required pharmacists to fill one prescription every three minutes. Upon information and belief, the targets set in these types of programs effectively required pharmacists to fill prescriptions in violation of their professional responsibilities, including filling prescriptions at volumes that plainly exceeded any conceivable medical need or legitimate purpose, filling prescriptions in large volumes from out-of-state or out-of-county residents, and filling prescriptions for individuals that the Pharmacy Chain Defendants knew were drug addicts or pill seekers.

1. CVS's Dispensing Model Has Facilitated Diversion.

213. In 2013, CVS paid $11 million in fines for allegations by the DEA that they violated the CSA. According to the DEA press release:

> The United States has alleged that from October 6, 2005 to October 5, 2011, CVS pharmacy retail stores violated the CSA and the record-keeping regulations by:
>
> "Creating, entering and maintaining invalid "dummy" DEA registration numbers or numbers other than the valid DEA registration number of the prescribing practitioner on dispensing records, which were at times provided to state prescription drug monitoring programs; b) Filling prescriptions for certain prescribers whose DEA registration numbers were not current or valid; and c) Entering and maintaining CVS dispensing records, including prescription vial labels, in which the DEA registration numbers of non-prescribing practitioners were substituted for the DEA registration numbers of the prescribing practitioners."

214. CVS's unlawful practices have made it a frequent target for other state and federal enforcement actions. For instance:

a. in 2013, the Oklahoma Board of Pharmacy fined CVS $350,000 for improperly selling prescription drugs at five locations in or around Oklahoma City;

b. in 2015, it (1) paid $450,000 to resolve allegations that it violated the federal CSA by filling invalid prescriptions and maintained deficient records at its Rhode Island stores; (2) paid $22 million to the federal government followed a DEA investigation that found that two pharmacies in Florida had filled prescriptions for which there was no legitimate medical need;

c. in 2016, it paid $8 million to settle allegations made by the DEA and DOH that, from 2008 to 2012, CVS stores and pharmacists in Maryland filled prescriptions with no legitimate medical purpose. That year, it also paid $600,00 to settle allegations by the DOJ that Connecticut CVS stores failed to maintain proper records, entered into a $795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs, and paid $3.5 million to the DOJ to resolve allegations that 50 of its stores had filled forced prescriptions for control substances – mainly painkillers – more than 500 times between 2011 and 2014;

d. in 2017, it entered into a $5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its

pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances;

e. in 2018, CVS paid a civil penalty of $1.5 million for its failure to timely report the loss or theft of controlled substances in New York. It also paid a civil penalty of $1 million concerning its record keeping violations at certain Alabama stores; and

f. in 2019, CVS paid $535,000 for filling invalid opioid prescriptions in Rhode Island pharmacies.

215. Upon information and belief, the same practices that these state and federal agencies discovered with regard to CVS occurred in Tennessee, including stores that served Tennessee. CVS knew that its drugs were being diverted in Tennessee. These investigations put CVS on notice that it was violating its obligations under Tennessee law as a registrant and others committed acts in Tennessee that facilitated diversion of opioids into the illegal market. CVS was also aware of various read flags for diversion in Tennessee but chose to ignore them.

216. Upon information and belief, the same practices that the DEA discovered in its investigations of CVS occurred in Tennessee, including the Pharmacy Chain Defendants' stores that served the Opioid Impacted Localities.

2. Food City's Dispensing Model Has Facilitated Diversion.

217. Food City was for many years the "go to" pharmacy for patients of pill mills and corrupt prescribers throughout Tennessee. Food City recognized opioids as a profit center and adopted corporate policies to ensure that its opioid sales were maximized. Food City drove its pharmacists to prescribe high volumes of controlled substances. Food City coordinated with notorious pill mills to ensure continuous supply of opioids to addicts. Food City ignored signs of diversion as blatant as jailed prescribers and addicts dying in its parking lots. Food City routinely ignored its own compliance audits. Food City was from at least 2010 through 2018 a major conduit of opioids into the illegal drug market.

218. From at least 2010 through at least 2019, Food City's top executives were personally and intimately involved in maximizing sales of opioids, which generated profit margins many times greater than most products sold by the company. They aggressively worked to keep Food City's pharmacies supplied with opioids while discounting and disregarding red flags and warnings about diversion that came in, year after year, from multiple credible sources.

219. Certain Food City pharmacies were among the highest volume opioid sellers in the nation. Food City # 674, located in the Bearden Shopping Center in Knoxville, Tennessee, sold more opioids than any other retail pharmacy in Tennessee from 2006 to 2014. As reported in the Wall Street Journal, store #674 bought nearly one million OxyContin pills in 2008, the third-most in the United States.

220. To put Food City's opioid dealing in proper perspective, Food City bought more oxycodone 30mg pills between October 2011 and January 2012 from AmerisourceBergen Drug Corporation ("ABC), its primary distributor during that period, for one location – Food City #674 – than were purchased by all of the pharmacies in each of thirty-eight states and the District of Columbia.

221. Effectively, Food City operated, from at least 2010 through at least 2019, with pill mills and disreputable providers in an integrated, illegal, and highly profitable drug dealing operation that fueled East Tennessee's opioid crisis for many years despite warnings, administrative sanctions and, ultimately, arrests.

a. ***Food City's Highest Volume Stores Worked Closely with Pill Mills to Maximize Opioid Sales.***

222. Three Food City Stores in the Knoxville area – those that sold its highest volumes of opioids, #674, #694 and #616 – were closely aligned with a notorious pill mill, Bearden Healthcare Associates, Inc. ("Bearden").

223. Bearden was independently identified as a pill mill by representatives of at least three opioid manufacturers – including Endo Pharmaceuticals, Inc. ("Endo"), among many others.

224. Numerous Bearden providers were subject to administrative sanction or arrest over the years, including its owner, Dr. Frank McNiel, who pled guilty to felony drug charges in October 2019.

225. Food City store #674, around the corner from the Bearden pill mill, purchased 18 million oxycodone pills between 2006 and 2014. That was an amount sufficient to give 130 pills each to every citizen of Knoxville.

226. The top ten prescribers at Food City stores #674, #694 and #616 were all prescribers who worked at Bearden Healthcare or had worked there in the past. These prescribers in and of themselves accounted for over 82% of the oxycodone sold at those pharmacies.

227. Food City Stores #674, #694 and #616 saw their sales drop sharply, albeit temporarily, in early 2009; that was the month that the DEA executed a search warrant at Bearden Healthcare.

228. The Bearden prescribers worked closely with Food City to ensure that their mutually profitable operation was not impacted by temporary supply problems. For example, when 30mg oxycodone supplies were running low at Food City #694, Bearden Healthcare prescribers switched their prescriptions to 15mg pills. As noted by the pharmacist at the store in a May 30, 2012 email: "Since the cut backs on the oxy30's, they have been writing increasing amounts of oxy 15's … 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 mid-month. Next month we aren't going to be able to keep up it they keep writing it like they have along with the 30's. I just wanted to let you know that this is probably going to create a problem soon."

229. A spreadsheet created in April 2012 by Food City confirmed the following facts about opioid sales at Food City stores #674, #694 and #616 between January and February 2012:

a. Bearden Healthcare accounted for over 90% of opioid sales at Food City #674, over 60% of opioid sales at Food City #694 and 40% of sales at Food City #616.

b. Store #616 had a single 30-day prescription for 1200 opioid pills, which equals 40 pills a day and is enough to fill about twelve standard prescription bottles.

c. Store # 616 allowed 41 patients at the same address to purchase Schedule II controlled substances.

d. Store # 674 had a single 30-day prescription for 1,000 opioid pills, which equals over 33 pills a day and is enough to fill about ten standard prescription bottles.

230. Food City had ample warning of Bearden Healthcare's improper prescribing practices. Food City was sued along with Bearden Healthcare and its owner, Dr. Frank McNiel, on November 16, 2005 by a husband and wife over improper prescribing and dispensing of opioids. Food City settled the lawsuit on December 31, 2008.

231. On August 21, 2008, the Knoxville Metro Pulse newspaper published a lengthy article entitled "Drug Zone?" which reported on a neighborhood association's complaints about the drug trade at the Bearden Food City store #674.

232. The neighborhood association had published a newsletter in which it detailed "[c]oncerns about Narcotic Trade at Food City Pharmacy" and stated that "[a]ccording to eyewitnesses and police reports, during the spring of 2008, some pharmacy customers were mugged as they left the store and their prescriptions stolen, some at gunpoint. Several shoppers have observed drug deals taking place in the parking lot. These crimes prompted Food City to hire armed Knoxville Police Officers to guard the store during pharmacy hours."

233. The article quoted one resident, David Stewart, noting that "What drew Stewart's attention, along with the robberies around Food City, is the high volume of cars coming 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."

234. Food City was aware of the allegations in the Metro Pulse article. Its CEO Steve Smith wrote an open letter in response on August 27, 2008, entitled "Westwood Homeowner's Association Story Reckless," in which he dismissed the reports as "rumor and innuendo." As noted herein, Food City's own outside compliance auditors later confirmed that they were in fact highly accurate.

b. ***Food City Pressured Prescribers to Over-Prescribe and Ignore Sound Practices.***

235. Food City's senior executives put relentless pressure on pharmacy employees to sell opioids, threatening them with dismissal if they did not meet volume goals. For example, on July 12, 2012, Mickey Blazer, the Director of Pharmacy, and other executives, gave the pharmacy manager of store # 699 the following directive: "We made [him] fully aware we had to see an improvement in the Pharmacy performance ... We explained to [him] 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."

236. On August 17, 2018, Food City Operations Manager Ken Slagle chastised a pharmacist in his for the following failings, among others: (1) "controlling the number of prescriptions he fills (Damages Company Financially"; (2) "profiling patient scripts without filling them (Damages Patient Loyalty"; and (3) "not filling C2 prescriptions until the patient is there (Damages Patient Loyalty."

237. Thus, decades into Tennessee's severe opioid crisis, a top Food City executive was formally criticizing a company pharmacist for acting responsibly with respect to controlled substance prescriptions, making it clear that company policy continued to require that opioid prescriptions be maximized and that efforts to prevent diversion, such as "profiling patient scripts without filling them" be actively discouraged.

238. On April 16, 2010, Don Clark, Vice President of Pharmacy Operations, sent an email to all pharmacists in which he gave the following guidance, highlighted in bold: "***To refuse to fill all prescriptions from a duly licensed Prescriber, Clinic, or Practice Group is not an ethical practice and could be considered defamatory to the Prescriber, Clinic or Practice Group.***" He directed that this guidance be reviewed, printed and posted in the pharmacies. Upon information and belief, this continues to be Food City policy to this day.

c. ***Food City Executives Scrambled to Maintain the Extraordinary Volumes of Opioids its Stores Needed in the Face of Diversion Concerns Raised by Numerous Distributors.***

239. On October 1. 2010, Don Clark, Food City's Vice President of Pharmacy Operations, alerted company pharmacists about "select C-II [Schedule II opioids] items which offer significant savings if they are ordered from [distributor] Masters" and directed "Please begin ordering these items from Masters so that we can save money and generate additional revenue."

240. The pharmacist at Food City store # 674 reacted to a distributor's price hike on 30mg oxycodone pills by noting, on April 21, 2011, "I am just worried because I do not want to have to explain why my gross profits may be down in 3 months."

241. The pharmacist at Food City Store # 674 also raised the concern that Masters would not meet the enormous volume needs of the Bearden store: "it 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)."

242. ARCOS data reveals that Masters sent three Food City Stores - #674, #694 and #616 - 318,395 opioid pills in May 2011, over eighty percent of which were oxycodone.

243. ABC was Food City's primary distributor. On September 31, 2011, Pharmacy Director Mickey Blazer emailed his CEO and other top executives to warn them that because of his directive to pharmacies to now order opioids from ABC "your phones are going to light up in the morning, so be ready." In response, CEO Steve Smith assured him: "Hang tight we will find a secondary supplier to use or even get a better deal from ASB! Steve."

244. In an October 21, 2012 email exchange under the subject line "RE: Oxycodone Projections", ABC warned Randy Skoda, the President and CEO of Topco, Food City's buying group, that "there is a shortage of product and that may impact KVAT getting product," to which Skoda responded "Do we have any backup sources?"

245. On October 22, 2012, oxycodone manufacturer Activas met with ABC and noted that Food City stores #674, 694 and 616 were the highest sellers of Activas oxycodone in the United States. Activas's Director of Customer Service and Controlled Substances Compliance, Nancy Baran, made a handwritten note documenting the meeting in which she recorded that Activas told ABC that it was "showing you these slides because there is a prob[lem] that needs to be rectified" and "we know this stuff is being diverted."

246. Shortly thereafter, ABC ceased distributing to Food City, and was replaced with McKesson.

247. On November 19, 2012, Mickey Blazer emailed buying group executives about "McKesson Control Orders," noting that he had "spoken with Sheri at McKesson about an hour

ago to see what progress they were making getting the Control Threshold issues resolved." He warned that "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 that there were no surprises with this conversation."

248. The next day, Randy Skoda at the buying group emailed Food City CEO Steve Smith to assure him that Food City #674 would get its opioids: "My understanding 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."

249. On December 6, 2012, the pharmacist at Food City store #694 alerted Mickey Blazer: "Hey Guys, I just unloaded my mckesson cII order and I did not receive the oxycodone 30 I ordered. I have ordered 1 box of 15's and 1 box of 30's so far this month 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 30's when we ordered them. Please help."

250. The next day, Karen Martindale at McKesson informed Blazer that other stores "had controlled omits today," explaining that "For store 616 ... 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."

251. Blazer responded by chastising Martindale in an email copied to numerous other McKesson executives: "Unbelievable!!!! #616 ??????????? #616 will be out of product over the weekend. I know you asked me not to involve anyone but you and Denise ... but I don't seem to be making any progress this way."

252. Martindale responded in less than an hour, confirming that "I've arranged for a special delivery to store 616 for the oxycodone."

253. When McKesson, which was under investigation by the DEA, told Food City, on June 19th, 2013, it would not ship oxycodone 30mg pills to Food City stores #674, #694 and # 616, Food City reached out to its former supplier, ABC. ABC responded on June 20, 2013, that "they have no interest in serving those KVAT stores."

254. On June 20, 2013, Michelle Fleischhauer, Senior National Account Manager at Anda, an independent drug distributor, emailed Will Fan, who worked Topco, Food City's buying group, in response to Fan's email in which he mentioned that "KVAT Food City ... ha[d] three stores that have an interest in placing orders with Anda." Fleischhauer responded that "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)."

255. On June 28, 2013, Mickey Blazer, Food City's Director of Pharmacy Operations, reported to the company's President and CEO, Steve Smith, regarding his conversations with representatives of McKesson Corp. ("McKesson"), in which he discussed the need to maintain supplies of opioids to three "high volume stores" as McKesson took over as primary distributor from ABC. Blazer noted that "Sam Thompson [of McKesson] is the guy Curt and I met with in Denver and informed that I had 3 high volume control [controlled substance] stores and I wanted to make sure I would not have any issues after the conversion. He assured me that he would take care of us based off 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 overrode."

256. The next day, June 29th, 2013, Blazer added in another email to CEO Smith, "[t]he only people from McKesson that has come to see me is: Bill Mahoney and Ned McKinney ... Ned is a VP of Sales they sent to meet me in Abingdon after I went off on them for the limited thresholds the[y] set after they told me they would base all my Stores on the ordering history from ABS. 'That was a joke!'"

257. On the same day, Smith wrote Blazer: "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."

258. On the Fourth of July, Food City CEO Smith emailed Randy Skoda at Topco and remarked "I called Mark W [at McKesson] 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!"

259. The next day, Skoda emailed Dave Picarillo, President of Food City's buying group, to describe a conversation in which he told Smith that McKesson would not change its oxycodone limits: "Spoke with Smith, not happy obviously. Wants to know at what level they would be comfortable or what if they reduced Bearden etc."

260. That same day, July 5, 2013, another Topco executive noted that he had asked McKesson "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)."

261. That same day, July 5, 2013, another Topco executive noted that he had asked McKesson "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)."

262. On July 9th, 2013, Topco executive Dave Picarillo emailed Randy Skoda to confirm that Anda had refused to supply oxycodone for Food City: "No, will not ship. Way too much risk for them."

263. Reflecting the integrated relationship between Bearden and Food City, during the period that Bearden Food City #674 was cut off by McKesson for oxycodone 30 mg tablets, Bearden Healthcare prescribers shifted their patients' prescriptions to other opioids that were available, such as morphine and oxymorphone.

264. On October 29, 2014, Mickey Blazer pushed McKesson to increase thresholds for hydrocodone at stores #674, #496 and #616. McKesson relented, effectively supplying Food City the drugs it desired.

265. On January 21, 2014, Michael Lockhard emailed CEO Steve Smith to inform him about company accountants' analysis of the financial impact of McKesson's temporary stoppage of certain controlled substances for two months during the previous year. He noted: "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 $__ to $__ for just the last six months) for both the Pharmacy operation and store overall since the June 19, 2013 decision. I put a hard copy of the reports in your mail slot."

266. After learning of the 60 Minutes episode featuring DEA Deputy Assistant Administrator Joe Rannazzisi, CEO Steve Smith noted "I think we found the guy who put us in

such a bind. He was threatening the distributor [McKesson] and really wanted some of their blood as well as jail time. I still believe that the whole situation would have been handled better if everyone had had an adult conversation."

267. ABC directed Food City to hire Pharma Compliance Group ("PCG") to audit its stores in Knoxville. The audit occurred on November 29 and 30, 2011.

268. The audit set out concerns about Bearden Healthcare in meticulous detail. Select findings include:

> 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 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;
> - Beardon [sic] Healthcare Associates vs. Westwood Homeowners Association
>
> ***
>
> 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 significant [sic] concern is the pharmacies filling prescriptions for practitioners located in Georgia and North Carolina. ...

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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.

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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 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.

269. Following receipt of the audit report, Food City made no significant changes in the management that had fostered Food City's high volume opioid business and did not meaningfully alter its profitable business relationship with Bearden Health. Instead, Food City created an

"Action Plan" that dictated cosmetic changes to business operations, such as "An additional security camera will be installed in store 694 to observe activity in the safe in the rear store area."

270. Following receipt of the audit report, Food City sold millions of opioid dosage units prescribed by providers at Bearden Healthcare, including its owner, Dr. Frank McNeil.

271. Even today, according to the Bearden Healthcare website, it continues to employ nurse practitioner James Santella, who has been identified by Food City's outside compliance auditor as "a prescriber with 'unusual' or excessive prescribing habits" and one who the DEA reported as prescribing a "disproportionate share" of controlled substances.

272. Throughout the period that Bearden Healthcare has employed providers engaged in pill mill practices, Food City has aggressively worked to supply the opioids prescribed by those providers and thereby maintain its longstanding, mutually profitable relationship with one of Tennessee's most notorious pill mills.

273. Follow-up store audits by PCG in April, 2012, confirmed that Food City had not significantly altered its profitable opioid business or its relationship with local pill mills. Among other findings:

a. "The pharmacy is filling a high percentage of pain management prescriptions."

b. "[Pharmacist] estimated that 40% of the prescriptions filled would be considered high risk."

c. "[Pharmacist] stated that the practitioners ar[e] Bearden Healthcare Associates have the majority of prescriptions they fill. She estimated that 40% would come from there."

d. "[Pharmacist] roughly estimated that 85% of the prescriptions for pain management she would consider of 'high risk.'"

e. "[Pharmacist] estimates that Oxycodone owns at least 40% of the total of controlled substances filled."

f. "[Pharmacist] estimated that cash would be the primary payment at 60%."

274. Throughout the period that Food City senior executives were scrambling to obtain more opioids, PCG continued to send the company audit reports showing that its pharmacies were continuing their relations with pill mills and disregarding red flags for diversion. For example, an audit of Bearden store #674 revealed that "[t]he 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 Healthcare Associates, totaling 42.1% for the clinic]." The audit also noted that "[t]he total number of scripts listed for 'pain management' was 1346 compared to the total number of scripts of 2914. The average comes to 46%."

275. In December 2014, another PCG audit noted that store # 694 was filling prescriptions written by numerous prescribers who were writing excessive numbers of "high risk" prescriptions. In September, 2015, an audit of store 687 reported, among other findings, that "the Pharmacist-in-Charge had been unable to log in to the CSMD and admitted rarely checking the CSMD [and that] 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." Another audit alerted Food City to the fact that store #616 had issued 59 prescriptions to one couple involving "Trinity Cocktails" to one married couple between June 5th, 2015 and November 4th, 2015.

276. Food City represented to McKesson, in an August 9, 2013 email, as a condition of getting resumed opioid shipments, that it would limit sales of controlled substances to ten percent of total sales, but it routinely ignored this limitation. For example, an October 10, 2018 PCG audit of Food City #650 confirmed that controlled substances represented 17.2% of total prescriptions.

277. Food City's own compliance auditor had given presentations to the company emphasizing that a high percentage of controlled versus non-controlled substances dispensed was a red flag for diversion. Yet Food City, having committed to its distributor to enforce a 10% ceiling on controlled substance prescriptions, was continuing to disregard that commitment in 2018.

278. In the same vein, the auditor found that Food City store #630 in Dandridge, Tennessee was still filling what it believed to be "high risk" opioid prescriptions on April 20, 2018, knowing that the prescriptions were at a substantial risk of being diverted.

279. On April 27, 2018, another Food City store, #705 in Chattanooga, Tennessee, filled a "pre-dated" prescription for opioids for an individual who was already dead. Mickey Blazer was made aware of this, and conceded in an email that filling a "pre-dated" prescription was a "questionable" practice while complaining "how are we supposed to know they died?"

280. An audit confirmed that as late as November 2018, a Food City pharmacist did not even know how to access the Emdeon system for evaluating prescribers to confirm their DEA status and alert the company to prescribers that might be involved in diversion and other improper practices. Even at that late date, Food City was not equipping its prescribers to perform even the most elemental actions needed to prevent diversion of opioids and other controlled substances.

281. On May 23, 2013, Mickey Blazer received emails from separate pharmacists identifying more red flags for diversion and raising safety concerns. The pharmacist from store #682 raised a concern that a customer who was told he could not get his opioids "come back in with na [sic] guy wearing a gang hat … [t]his was way before the news about the shooting." The pharmacist for store #682 reported that "pain customers … refuse to take no for an answer," adding "the pain customers will hang around the store and we have had to have someone walk us to our cars on several occasions."

282. On April 29th, 2015, Food City store #676 reported that a woman had died of an apparent overdose in its parking lot on the previous day.

d. *Food City Sold Pills Prescribed by Numerous Suspicious Providers, Ignoring Clear Evidence of Diversion.*

283. Bearden was only one of a number of pill mills that Food City facilitated. Food City stores dispensed hundreds of thousands of pills prescribed by providers at pill mills supplying East Tennessee – providers who's record of improper practices should have been readily apparent to an organization that was interested in preventing diversion.

284. For example, between December 7, 2010, when Breakthrough Pain Therapy was raided by federal agents, and October 7, 2014, when nine of its medical professionals were indicted for illegal prescribing, Food City stores sold over a quarter million opioid tablets, over 60% of which were 30mg oxycodone tablets, prescribed by prescribers at the clinic.

285. In another example, Food City stores filled prescriptions from a pill mill in Atlanta, Georgia. On July 2, 2010, a pharmacist at Food City store #688 in Knoxville alerted the company to suspicious prescriptions from Dr. James Earl Chapman at Atlanta Medical Group: "The prescriptions were all EXACTLY the same: each patient had 3 scripts, Oxycodone 20mg #200, Oxycodone 15mg #40 and 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!! … this doctor is under investigation by the D.E.A."

286. Food City stores continued to fill prescriptions from Dr. Chapman, even though the stores were located hundreds of miles from his office.

287. Dr. Chapman was indicted in July 2011 for unlawful prescribing, and was eventually sentenced to ten years in federal prison.

288. In the same vein, Dr. Andrew Seguntheraj was the owner of two clinics that were raided in 2013 as part of an investigation by the DEA, the TBI and the U.S. Department of Health Office of the Inspector General. The raid was reported extensively in the Knoxville News Sentinel.

289. Nevertheless, over a year after the raid, a December, 2014 PCG audit reported that Seguntheraj was among the top prescribers of controlled substances sold at Food City stores #694 and #679.

290. Food City's practice of studiously ignoring red flags of diversion in the face of profitable opioid sales was perhaps most glaringly illustrated by its relationship with Dr. Robert Moughan.

291. A September 18, 2013 PCG audit of First Med Family Center in Gatlinburg identified Dr. Moughan as a provider accounting for 20% of the controlled substances dispensed by Food City #611. Dr. Maughan had had his license suspended by the Board of Medical Examiners for improper prescribing, but Food City did not conduct due diligence to uncover such information and on information and belief was unaware of it.

292. Food City received a report from the pharmacist at Dr. Robert Maughon's office who warned that "I just wanted to let you know that I had Dr. Maughon's office lie to me again today … the patient told me they were only taking it [Phentermine 38.5 mg.] once daily and the office wrote it that way so she could get a 2-month supply. 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."

293. An April 13, 2016 PCG audit warned that the pharmacist in charge at Food City #611, located in Seymour Tennessee, "reported concerns of prescribing habits with Robert Maughon due to frequence [sic] of script for patients."

294. Food City #611 and #644, also located in Seymour, sold one customer 92,713 opioid dosage units over time, much of it prescribed by Dr. Moughan.

295. As of June 1, 2018, Food City executives had become aware that Dr. Maughon was in jail. Yet as of June 6, 2018, Food City # 611 was filling prescriptions for controlled substances written by Dr. Maughon.

296. On August 1, 2018, Dr. Maughon was disciplined by the Board of Medical Examiners. He stipulated, among other things, that "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."

297. Despite reported excess prescribing, reports of lying, concerns about improper prescribing reported by its pharmacists, Dr, Moughan's known presence in jail and formal discipline, Food City continued to fill prescriptions written by Dr. Moughan through August 15, 2018 .

e. ***Food City Supplied Criminal Organizations.***

298. Food City supplied criminal organizations that took advantage of its corporate policy of aggressive, unrestrained prescribing.

299. For example, from January 2008 to approximately October 2012 Gregory Rhea and eleven co-defendants "obtained oxycodone from numerous physicians in the Eastern District of Tennessee ... for the purpose of distributing oxycodone in the Eastern District of Tennessee." In 2011, Food City store #694 filled at least 27 opioid prescriptions for one member of Rhea's oxycodone ring, each of which was written by providers at Bearden Healthcare.

300. On August 13, 2011, Rhea sold oxycodone to a confidential informant and "attempted to recruit the confidential informant to travel to a pian clinic in Bearden, Tennessee, for the purpose of obtaining oxycodone."

301. Between 2009 and September 2012, Food City #694 also filled 42 opioid prescriptions totaling 12,390 pills for another of Mr. Rhea's co-defendants, with the average prescription being for 314 pills, as compared to the CDC recommended limit of 90.

f. ***Food City's Inadequate Controls Facilitated Diversion.***

302. Food City also fed drugs into the illegal drug market by recklessly allowing pilfering by employees.

303. Food City repeatedly received PCG audits finding lax controls with respect to controlled substances at numerous pharmacies. Food City's inadequate controls led to extensive illegal pilferage, which often went undiscovered for lengthy periods. For example, Food City reported an employee, reported a pharmacy technician for stealing hydrocodone pills from store #673 in Knoxville after catching her with a hidden camera. She "stated that whs had been stealing it daily for months and giving it to her husband and brother for resale." The hidden camera was only installed after Food City executive Ken Slagle realized that the store was short nearly 5000 hydrocodone pills.

304. Thousands of opioid pills turned up missing at other Food City stores as well. For example, Food City #667 was unable to account for 5,406 hydrocodone with APAP pills from the period June 26, 2012 through February 20, 2013.

305. Food City's conduct from at least 2010 through the present constituted knowing participation in the illegal drug market, including but not limited to:

a. knowingly supplying quantities of opioids to suspect patients who were showing signs of addiction or participation in diversion;

b. knowingly supplying suspicious quantities of opioids prescribed by physicians, physician assistants, and nurse practitioners working at Bearden Healthcare and other pill mills;

c. failing to cut off prescriptions issued by suspicious providers and in fact taking active steps to ensure ready availability of opioids to those prescriptions;

d. failing to report suspicious providers, activities, or orders to law enforcement even in the face of internal audits identifying those suspicious providers, activities, and orders;

e. knowingly failing to implement effective controls and procedures to guard against diversion of opioids;

f. flooding the communities in which Food City stores operated with excessive volumes of opioids knowing that those volumes necessarily reflected improper prescribing; and

g. creating perverse incentives for pharmacists and other employees to not impose or follow procedures to prevent diversion of opioids.

3. Walgreens' Dispensing Model Has Facilitated Diversion.

306. Walgreens also knew the patterns and instances of improper distribution and use of prescription opioids in Tennessee. It also had data concerning the individual prescribing habits of Tennessee doctors, the percentage of a prescriber's subscriptions that were controlled substances, individual prescriber's activity across all Walgreens stores, and the percentages of prescription purchased in cash.

307. Walgreens combined its purposeful shipping of suspicious orders with policies, practices, and incentives at the pharmacy level that facilitated the dispensing of drugs into the illegal market.

308. In November 2012, Teva-owned drug distributor Anda analyzed nearly 1.3 billion pills, including oxycodone, handled by Walgreens, and flagged 3,768 of the chain's pharmacies

for dispensing high numbers of controlled substances,[99] including Walgreens locations in Tennessee. In 2013, Cardinal conducted an audit of Walgreens' Perrysburg, Ohio distribution center and identified 372 locations the DC shipped to as requiring a site and/or surveillance visit before Cardinal would ship controlled substances to the stores,[100] including stores in Tennessee.

309. Walgreens' own attorneys appeared to discourage the company from identifying inappropriate prescriptions, noting, "***If these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance.***"[101]

310. This "blind eye" approach was encouraged even when pharmacists informed their supervisors of observing numerous red flags associated with opioid prescriptions, including instances where patients were travelling from Tennessee to other states to have large oxycodone prescriptions filled.

311. Walgreens also encouraged its pharmacists to dispense opioids to customers and for prescribers in Tennessee who exhibited red flags, even situations in which Walgreens was aware that drug charges had been brought or the prescriptions were clearly in contravention to Tennessee law and regulations.

312. Walgreens unlawful dispensing practices have frequently made it a target for state and federal enforcement actions. For instance:

a. on April 7, 2011, Walgreens entered into a Settlement Agreement with the DEA regarding allegations of non-compliance with the Controlled

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[99] Jenn Abelson, Aaron Williams, Andrew Ba Tran, & Meryl Kornfield, *At Height of Crisis, Walgreens Handled Nearly One in Five of the Most Addictive Opioids*, Wash. Post, Nov. 7, 2019, https://www.washingtonpost.com/investigations/2019/11/07/height-crisis-walgreens-handled-nearly-one-five-most-addictive-opioids/.

[100] *Id.*

[101] *Id.*(emphasis added).

Substance Act wherein Walgreens had agreed to "maintain a compliance program to detect and prevent diversion of controlled substances[;]"

b. on July 17, 2013, Walgreens agreed to pay $80 Million in civil penalties related to allegations that Walgreens was filling numerous prescriptions that Walgreens employees knew, or should have known, were not issued for a legitimate medical purpose; and

c. on January 18, 2017, Walgreens agreed to pay $200,000 following an investigation by the Massachusetts Attorney General's Office, which found that Walgreens failed to track the opioid use of high-risk patients in the state's Medicaid program.

4. Walmart's Dispensing Model Has Facilitated Diversion.

313. Walmart's pharmacy compliance policies and procedures were likewise secondary to Walmart's business interests. Retailers like Walmart operate pharmacies primarily to draw customers into their stores with the expectation that those customers will buy other, non-pharmacy goods. For example, Walmart observed in its fiscal year 2017 annual report that risks to its pharmacy business could "result in the loss of cross-store or -club selling opportunities and, in turn, adversely affect our overall net sales, other results of operations, cash flows and liquidity." In another example, Sam's Club at times offered drastic discounts on opioids that helped drive customer traffic to its stores.

314. To retain customers, Walmart managers repeatedly told pharmacists to fill prescriptions as quickly as possible. For example, a December 17, 2014 email to certain pharmacists stated that "shorter wait times keep patients in store." Other emails urged that if prescriptions were not filled quickly, customers would shop elsewhere.

315. Even though Walmart pharmacists had legal requirements to satisfy before they could fill controlled substance prescriptions, Walmart managers told pharmacists to "[h]ustle to the customer, hustle from station to station" because filling prescriptions is a "battle of seconds."

316. In various emails, Walmart Health and Wellness Directors set a goal for pharmacists to fill prescriptions in less than 20 minutes—a goal that they later shortened to less than 15 minutes. When pharmacists pointed out the steps required to fill prescriptions, the directors stated that pharmacists should complete all the necessary procedures in 15 minutes or less.

317. Walmart pharmacists reported feeling unable to do their jobs properly because Walmart pharmacies lacked sufficient staff and the company added resources only when the situation became unmanageable.

318. Walmart conducted surveys of many of its pharmacy employees in June 2012, July 2014, and October 2014, which showed that a substantial number of pharmacy employees reported that their pharmacy lacked sufficient staff to handle the workload.

319. The following are specific comments these pharmacy employees made to Walmart corporate about the lack of staffing and the company's over-emphasis of speed over compliance:

- "We are not adequately staffed for safely filling the volume of prescriptions that are brought to this pharmacy. We spread too thin[.]"
- "[W]e do not have enough pharmacist help. I feel overwhelmed and like we are being asked to do more and more....We are being forced to not focus on the patients in front of us[.]"
- "More bodies in the pharmacy are required to adequately serve our patients, both in a timely and safe manner."
- "[Staffing] is too low for a pharmacy and is dangerous for patients if the staff always feels overwhelmed or rushed while working on patients' prescriptions."
- "Since...new Control Class II Change for Hydrocodone we have been added more responsibility and time consuming tasks, but our allotted hours for pharmacy staff has not changed....[T]his can add to pharmacy staff being more rushed to fill Rx, therefore more change of mistakes happening in the pharmacy." ways feels overwhelmed or rushed while working on patients' prescriptions."
- "We are always under staff[.] [sic] This pharmacy is in [a] busy location, we do a lot of CII and we do have drive thru which takes longer time and needs more staff."

- "I feel that corporately we are expected to get things too quickly. The expectation times seem unrealistic with the lack of staffing and amount of work we are expected to get done[.]"

- "I think someone should come in on a busy day when we do the most scripts...and just see how we really need man power to ensure safety and accuracy as opposed to not having enough technicians and feeling rushed and behind all the time to save money. One mistake could potentially cost more than it would to have an extra body to keep everything safer and feel less overwhelmed."

- "[Need to] have upper management understand the time constraints with the new cii hydrocodone issues."

- "I have worked at Walmart for 10 years and generally feel that pharmacist staffing is generally inadequate to provide an environment for a pharmacist to perform tasks in a manner that is truly safe."

- "We don't have enough staff to keep each station caught up at all times. And that is a huge red flag for possible errors."

- "Our [District Manager] continually sends our pharmacy nasty emails and chastises us for not having high enough numbers in our input and fill accuracy and times. We are therefore instructed to cheat the system[.]"

- "[B]ecause of the constant harassment from our market manager about us not getting rx's done in 20 min, we often take shortcuts in filling and counseling rx's that could lead to patient safety issues."

- "Us being criticized by our health and wellness director about not getting prescriptions out in 20 minutes causes the pharmacy to take short cuts and affects patient safety."

As a result of these systemic issues, and upon information and belief, Walmart knowingly filled prescriptions issued by pill mill operators and other over-prescribers in Tennessee and the Opioid Impacted Localities, including but not limited to the Pill Mill Prescriber Defendants in this action.

320. Walmart recognized that its monitoring system for dispensing controlled substances around the country, and specifically in Tennessee, were insufficient.

321. Walmart's compliance policies, maintained in a Pharmacy Operations Manual ("POM"), acknowledged that it had to comply with important legal requirements when dispensing controlled substances.

322. In March 2009, Walmart added to its POM a policy ("POM 1311") entitled "Practitioner/Patient Relationship. According to a Senior Director of Pharmacy Professional Services and Government Relations, POM 1311 "provides guidance on the pharmacist's responsibility to ensure that a prescription has been issued for a valid purpose...." The policy thus would serve as a "reference for pharmacists regarding," among other things, "prescription-mills."

323. From its inception, POM 1311 provided a non-exhaustive list of factors indicating when a proper prescriber-patient relationship may not exist. For example, these factors included prescriptions for a large quantity of certain medications or prescriptions with markings suggesting the prescription had been rejected by another pharmacy. The policy also stated that "[i]f the pharmacist does not reasonably believe that a valid prescriber-patient relationship exists, the pharmacist may not dispense the prescription."

324. Walmart issued an amended version of POM 1311 in or about March 2011 that remained in effect at least through January 2014. POM 1311 (2011) identified the same red flags as the prior version and added two more: prescriptions written by an out-of-state prescriber and prescriptions "written by a doctor or for a patient for whom the pharmacy has rejected other prescriptions for a failure to have an appropriate doctor-patient relationship." This list was "by no means all inclusive." POM 1311 (2011).

325. Walmart's POM 1311 (2011) recognized that "federal rules and the laws of many states" require a proper prescriber-patient relationship for a prescription to be valid. The policy acknowledged that pharmacists should not blindly accept a prescriber's assurances: "Simply

because the prescriber verifies that he or she has seen the patient does not mean that an 'appropriate' patient prescriber relationship exists; if other signs of an inappropriate relationship are present, the pharmacist can still exercise his or her judgment and not fill the prescription at issue." Similarly, the policy stated that "pharmacists must consider whether the patient and the doctor have a relationship, but the relationship is not valid because it is being used for abuse or diversion."

326. POM 1311 (2011) recognized that a pharmacist should dispense a controlled-substance prescription only if the pharmacist was able to resolve any red flags, and that the pharmacist should document the resolution of those red flags. Under the policy, if a pharmacist had concerns about a prescription, the pharmacist was permitted to fill the prescription only if the pharmacist "reasonably believe[d]" after speaking with the prescriber that the prescription was valid. In such circumstances, pharmacists still were directed to "make a notation on the prescription specifying" the pharmacist's name, the name of the prescriber, the date of the conversation, and the notation "proper relationship verified."

327. However, Walmart failed to comply with both federal law and its own internal policies, and intervention by the DEA was required. In March 2011, DEA and Walmart entered into a nationwide memorandum of agreement ("MOA") to resolve an administrative action predicated upon a California Walmart pharmacy's alleged failure to comply with its dispensing obligations when filling controlled-substance prescriptions, including filling such prescriptions where the prescription was not issued for legitimate medical purpose or by a prescriber acting within the usual course of professional practice.

328. The MOA was in effect from March 2011 through March 2015. In the MOA, Walmart committed to, among other things, "maintain a compliance program, updated as

necessary, designed to detect and prevent diversion of controlled substances as required by the Controlled Substances Act."

329. In the MOA, Walmart recognized that in order to comply with its regulatory obligation not to dispense controlled substances based on prescriptions "issued by physicians for other than a legitimate medical purpose and/or outside the usual course of professional practice...," Walmart needed to create a process that would ensure that its pharmacists were identifying common signs of diversion. Specifically, the MOA required that Walmart's compliance program would include procedures to ensure that pharmacists identified red flags: The program shall include procedures to identify the common signs associated with the diversion of controlled substances including but not limited to, doctor-shopping, requests for early refills, altered or forged prescriptions, prescriptions written by doctors not licensed to practice medicine in the jurisdiction where the patient is located, and prescriptions written for other than a legitimate medical purpose by an individual acting outside the usual course of his professional practice.

330. In the MOA, Walmart also agreed that if one of its pharmacists did conclude that a prescription was not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice, was forged, or had been altered, and refused to fill that prescription, Walmart would notify the local DEA field office within seven business days of the refusal to fill.

331. Following the expiration of the MOA, in or about April 2015, as prescription drug abuse continued to ravage the United States, including and especially in Tennessee and the Opioid Impacted Localities, Walmart again revised POM 1311 to specifically address a pharmacist's obligations with respect to controlled-substance prescriptions, explaining that the CSA imposed a "corresponding responsibility" on pharmacists to dispense controlled-substance prescriptions only if they were written for a legitimate medical purpose and based on a proper prescriber-patient

relationship. POM 1311 (2015) quoted directly from 21 C.F.R. § 1306.04 and explained that this regulation was the basis for nearly all criminal actions taken by DEA against pharmacies and pharmacists.

332. POM 1311 (2015) listed several red flags that DEA had identified as signs that a prescription was not issued for a legitimate medical purpose. Walmart acknowledged that red flags could relate to concerns about a prescriber, the prescription itself, or a patient. The red flags Walmart identified included the following:

Prescriber Red Flags

- Prescription is written by a prescriber outside of the pharmacy's trade area;
- Prescriber routinely prescribes a large number (or percentage) of prescriptions for controlled substances relative to prescriptions for non-controlled substances;
- Prescriber prescribes the same medication, with the same directions, for the same quantity for a large number of individuals;
- Prescriber routinely writes for large doses of controlled substances;
- Prescriber provides the same diagnosis for the majority of individuals; and
- Prescriber engages in the unauthorized practice of medicine, including writing prescriptions outside the scope of practice and/or not having a proper relationship with the patient.

Patient Red Flags

- Individual insists on paying cash, or insists on paying cash for controlled substances even though insurance is on file;
- Evidence of "doctor shopping" exists;
- Evidence of "pharmacy shopping" exists;
- Individual resides outside of the area of [the] pharmacy;
- The individual's statements and conduct or behavior suggest abuse of controlled substances;
- Individual asks for certain drugs prone to abuse by color, trade name or markings and/or uses "street names";
- Individual routinely attempts to obtain an early refill on controlled substances; and
- Individuals have suspicious relationships with each other. For example: multiple patients filling prescriptions from one address; prescriptions being presented by someone other than the patient; groups of patients arriving all with prescriptions for the same medication from the same doctor.

Prescription Red Flags

- Prescriptions presented represent a "cocktail" of commonly abused drugs or are presented in a combination that can cause medical complications;
- Prescription presented is for an unusually large quantity or high starting dose;
- Prescription appears to be altered or duplicated; and
- Prescription has an electronically generated or rubber-stamped signature.

333. POM 1311 (2015) stated that, before a pharmacists filled a controlled-substance prescription with any of these red flags, the red flags "should be evaluated, resolved, and documented." Thus, POM 1311 (2015) shows Walmart's recognition of its legal obligations under the CSA and Tennessee law to identify and resolve any red flags, and document the resolution of those red flags, when deciding whether to fill prescriptions for controlled substances.

334. Despite these explicit policies patterned on state and federal law and intervention from the DEA, Walmart's internal records show that it was constantly breaching its MOA with the DEA, violating federal and state law, and abused its own policies whenever they conflicted with Walmart's avaricious interests.

335. Tennessee state and law enforcement officials complained directly to Walmart that their pharmacists were using the POM as a means to obfuscate law enforcement investigations into and/or conceal information they should have reported regarding suspicious prescribers and suspicious prescriptions.

336. Even when its pharmacists were reporting red flags to corporate compliance, Walmart's default position was that if a suspicious prescription was not filled, it would negatively affect Walmart's business. When pharmacists would contact corporate compliance about prescriptions that had multiple red flags, compliance would not recommend that they refuse to fill the prescription; rather, corporate would simply remind them that, if they decided not to fill the prescription, their only obligation was to internally document the reasons to protect Walmart from potential retribution from the patient and/or prescriber.

337. Despite repeated "red flags" of suspect prescribing in the region and the State of Tennessee, Walmart blocked only a handful of Tennessee prescribers, and a *de minimus* amount nationally.

338. However, even when a prescriber is centrally blocked, Walmart's system will still allow the prescription to be filled, including suspect prescribers in Tennessee.

339. On December 22, 2020, the United States Department of Justice filed a nationwide lawsuit against Walmart alleging that it unlawfully dispensed and distributed prescription opioids. The Complaint alleged, among other things, that "from June 26, 2013, to the present [the date of filing], Walmart filled thousands upon thousands of invalid prescriptions and, in doing so, repeatedly violated the CSA [Controlled Substances Act] dispensing requirements identified in 21 C.F.R. § 1306.04(a) and § 1306.06." Walmart filled prescriptions that it knew were not issued for a legitimate medical purpose, or were not issued by a medical practitioner acting in the course of his professional practice, or both, in violation of section 1306.04(a). And by filling these prescriptions despite the red flags, Walmart pharmacists failed to adhere to the usual course of professional pharmacy practice, in violation of section 1306.06. These illegal practices by Walmart reflected nationwide company practices impacting Tennessee, including Plaintiff localities.

F. Pill Mill Prescribers, like Frank and Janet McNiel and the Other Practitioners at Bearden Healthcare Associates, Illegally Trafficked Prescription Opioids in and Around the Opioid Impacted Localities, Aided by the Producer Defendants, Morris & Dickson, and Pharmacy Chain Defendants.

340. Bearden Healthcare Associates, Inc. was founded and, for many years, owned and operated by Dr. Frank McNeil (who was forced to surrender his medical license in 2018 and has been convicted on felony drug charges) and his wife, Dr. Janet McNiel (who was forced to surrender her medical license in November 2020).

341. Bearden Healthcare prescribers routinely engaged in improper prescribing practices. For example, at Food City store #674, the pharmacy located near Bearden Healthcare which filled thousands of prescriptions issued by its doctors, approximately 75% of its customers from Bearden Healthcare received the "holy trinity" cocktail used by drug addicts, which includes an opioid, an anti-anxiety benzodiazepine like Xanax and a muscle relaxer such as Soma.

342. An internal audit conducted by Food City in 2012 documented multiple pages of concerns about the "High Risk" prescribing practices of Bearden Healthcare prescribers.

343. Food City store #674 sold more opioids than any other retail pharmacy in Tennessee from 2006 to 2014, and Bearden Healthcare prescribers accounted for a far greater share of those prescriptions than prescribers with any other organization.

344. Multiple Bearden Healthcare prescribers have been subjected to professional discipline because of over-prescribing and mis-prescribing of opioids.

345. For example, the Tennessee Department of Health has initiation actions to discipline or revoke the licenses of nurse practitioners Lisa Adams, Brandy Burchell, Cynthia Collins, Donald Douglas, and Teadora Neagu, for improper prescribing while working for Bearden.

346. Sales representatives from multiple companies, including Endo, identified Bearden Healthcare as a pill mill yet continued to prioritize it and its prescribers as targets and call on them.

347. As early as 2007, an Endo District Sales Manager took note of McNiel's improper prescribing at Bearden Healthcare: "He has a full staff and his office is always packed. I spoke to the local pharmacist and he stated that a lot of Dr. McNiel's patients pay cash....Dr. McNiel prescribes almost three times what the average (primary care physician) writes and I am not sure

how legitimate his practice appears to be. AS an example. Dr. McNiel has written 3,800 scripts of OxyContin through September of this year, which seems almost impossible even for a pain clinic."

348. As noted in orders issued by the Tennessee Board of Medical Examiners, providers at the Bearden Clinic routinely worked in concert to provide opioids to patients, with providers typically providing opioids to patients who had received care from multiple providers at the Bearden Healthcare Clinic.

349. For example, the Board of Medical Examiners found that PA Donald Douglas "routinely prescribed controlled substances, primarily large quantities of opioids, for treatment of patients with chronic pain complaints at Bearden Healthcare," that Douglas's "prescribing was non-therapeutic in nature, neither justified nor medically necessary," and that Douglas "often prescribed monthly prescriptions to individual patients which included combinations of long-acting and short-acting opioids often combined with benzodiazepine." The board of Medical Examiners further found that he typically "treated patients that had been receiving care from multiple providers at Bearden Healthcare prior to his encounter with the patient."

350. One provider at Bearden Healthcare, nurse practitioner Cynthia Collins, issued a prescription to a patient for 51 pills a day.

351. After arriving at Bearden Healthcare in 2010, Collins prescribed between 275,000 and 470,000 pills over the next two years.

352. According to Collins, her overprescribing reflected the prescribing policies of Bearden Healthcare.

353. Many of Collins' prescriptions tracked prescriptions issued to the same patients previously by Dr. McNeil, according to her testimony.

354. For example, Dr. McNeil prescribed opioids to a patient who had implausibly claimed to have recovered after being paralyzed from the waist down in a snowboarding accident. Collins later increased his dose of opioids, which he claimed to require for the constant pain that miraculously replaced his paralysis.

355. Collins also upped the prescription of opioids for a patient with a history of illegal drug use. When the patient initially came to the Bearden clinic, his medical record reflected a negative drug test with the handwritten warning: "Cocaine – not good." Nevertheless, he received a prescription for Xanax, Soma and a large dosage of morphine.

356. In June 2021, Evamay Noor, wife of physician Sidi Noor, pled guilty to distributing oxycodone that she had been prescribed by Dr. McNeil. McNeil received and filled prescriptions in July 2010 for 450 oxycodone 30mg tablets, 240 OxyContin 80mg tablets, 90 fentanyl transdermal patches, 360 diazepam 10 mg tablets and 600 carisoprodol 350 mg tablets.

357. McNiel supervised numerous providers who were subject to disciplinary action for improperly over-prescribing controlled substances.

358. For example, McNiel supervised Lisa Adams, who the Tennessee Board of Medical Examiners reprimanded on January 10, 2014, for prescribing "controlled substances in higher amounts and for longer durations than the board believes were necessary" and that she "routinely prescribed controlled substances, primarily large quantities of opioids, for treatment of patients at Bearden Healthcare."

359. In the same vein, McNiel supervised Teadora Neagu, an advanced practice nurse. The Tennessee Board of Medical Examiners found that under McNiel's supervision, Neagu's "prescribing was non-therapeutic in nature, neither justified nor medically necessary for patients' diagnosis, and not for a legitimate purpose."

360. Dr. Frank McNiel worked at Bearden Healthcare through 2012. During that period, McNiel supervised numerous medical providers who were subsequently disciplined for improperly prescribing opioids under his training and direction, including Lisa Adams, P.A. (Complaint No. 2011002521), Brand Burchell, APN (Complaint No. 2011002521), and Teodora Neagu (Docket No. 17.19.-138051A).

361. In disciplinary actions, the State Board of Medical Examiners repeatedly observed that providers at Bearden Healthcare overprescribed opioids as part of a company practice, in which patients would be served by multiple prescribers and prescribers would simply repeat the treatment decisions of other providers without exercising independent judgment. For example, the Agreed Order disciplining Dr. Teodora Neagu, observed: "Respondent typically treated patients that had been receiving care from multiple providers at Bearden Healthcare prior to her encounter with the patient. As opposed to treating patients based upon her own medical judgment. Respondent often mimicked the previous treatment provided. This regularly included prescribing large amounts of controlled substances for which patient charts did not prescribe sufficient justification."

362. McNiel continued seeing patients at his home after leaving Bearden Healthcare, and claimed that he only saw approximately 15 patients while seeking to find them new providers. Yet, from 2015 through March 2018, McNiel prescribed 59,712 pain pills.

363. In 2018, the Tennessee Board of Medical Examiners voted to discipline Frank McNiel, finding that he had repeatedly "prescribed controlled substances in amounts not medically necessary, advisable, or justified."

364. The Board also found that McNiel did not use the state-mandated CSMD to confirm that his patients were not doctor shopping or otherwise seeking multiple prescriptions.

365. The Board also found that McNiel was supervising physician for multiple NPs and PAs who also prescribed opioids "excessively."

366. Dr. Frank McNiel pled guilty to unlawful distribution of controlled substances in October 2019, which is prima facie evidence of participation in the illegal drug market.[102]

367. As set out in his guilty plea, McNiel prescribed opioids out of his home without performing drug screens or checking the state-mandated database.

368. As set out in his guilty plea, McNiel "prescribed opioids at double or above the national guidelines promulgated by the Center for Disease Control."

369. As set out in his guilty plea, these practices were all "red flags in the professional practice of medicine."

370. As set out in his guilty plea, McNiel also prescribed opioids to a patient without seeing the patient or making a diagnosis.

371. Frank McNiel's conduct, including illegally prescribing opioids for which there was no medical justification, prescribing excessive quantities of opioids, and facilitation diversion violated federal laws governing prescribing and violated the DDLA.

372. After Dr. Frank McNiel left Bearden Healthcare, his wife, Dr. Janet McNiel, continued to practice there and continued the pill mill practices that led to her husband's conviction and the disciplining of multiple Bearden Healthcare providers.

373. Janet McNiel, who was continuing to practice at Bearden Healthcare as late as June 2019, according to reporting by the Knoxville News Sentinel, was herself determined to be "guilty of overprescribing controlled substances" in an action taken by the Board of Medical Examiners in November 2020. She had her license "permanently voluntarily suspended," which the Board

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[102] *See* Tenn. Code Ann. § 29-38-113.

noted was the "same as permanently revoked." Her continued management of the clinic ensured ensuring Frank McNiel continued to financially benefit from the drug dealing operation he founded even after pleading guilty to felony drug charges.

374. During the period that Janet McNiel operated Bearden Healthcare, numerous prescribers were disciplined by the Tennessee Board of medical examiners for overprescribing and/or improperly prescribing opioids.

375. During the period that Janet McNiel operated Bearden Healthcare, she oversaw a classic pill mill operation in which multiple providers saw each patient at different times and prescribed large amounts of opioids without conducting meaningful medical examinations.

376. Janet McNiel's conduct violated the DDLA.

377. Bearden Healthcare has continued the practice of overprescribing opioids through a shifting group of medical professionals who have been disciplined or prosecuted by state and federal medical authorities. Some were practicing at Bearden as recently as 2021, according to its website, including James Santella, who has been identified by Food City's compliance auditor as a "provider with 'unusual' or excessive prescribing habits" and who the DEA identified as prescribing a "disproportionate share" of controlled substances.

378. Bearden Healthcare's conduct constituted knowing participation in the illegal drug market, including but not limited to: knowingly supplying suspicious quantities of opioids to suspect patients who were showing signs of addiction or participation in diversion; knowingly supplying suspicious quantities of opioids which were not medically justified; knowingly supplying suspicious quantities of opioids which quantities necessarily reflected diversion; and knowingly failing to implement effective controls and procedures to guard against diversion of opioids.

G. **The Producer Defendants Helped Create the Illegal Drug Market.**

1. **In the 1990s, the Producer Defendants Knew that Using Opioids for Non-Malignant Pain Creates a Serious Risk of Abuse and Diversion, Yet Encouraged Opioid Sales and Distribution Practices that it Knew Have Those Effects.**

379. As stated by Tennessee's Commissioner of Health Dr. John Dreyzehener, "***in the 1990's, MDs started prescribing opioids in large volume to treat [nonmalignant] pain which has caused an opioid addiction problem.***"[103] Douglas Varney, Commissioner of the Tennessee Department of Mental Health, speaking at a meeting of the Governor's Working Group, similarly concluded that "***[b]asically we are dealing with the fallout from the medical profession overprescribing opioids.***"[104]

380. Up until the mid-1990s, physicians prescribed opioids primarily to cancer patients and persons recovering from surgery. Fearful of the addictive qualities of opioids, physicians would not generally prescribe them for long term chronic pain. As detailed in a review of the development of the opioid crisis published in the 2015 Annual Review of Public Health, "[p]rior to the introduction of OxyContin [by Purdue in 1995], many physicians were reluctant to prescribe OPRs [opioid pain relievers] on a long-term basis for common chronic conditions because of their concerns about addiction, tolerance, and physiological dependence."[105]

381. This research confirmed the mid-1990s consensus of medical providers regarding the dangers of opioids. According to the Agreed Statement of Facts signed by Purdue in connection with its 2007 guilty plea to federal criminal charges for misbranding OxyContin: "During the period February through March 1995, Purdue supervisors and employees obtained market research

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[103] Tenn. Dep't of Mental Health and Substance Abuse Services, *Opioid Abuse Reduction Act Working Group*, at 22 (Nov. 10, 2015) (hereinafter "*Working Group Report*") (emphasis added).
[104] *Id.* (emphasis added).
[105] Andrew Kolodny, et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 Ann. Rev. Pub. Health 559, 562. (2015).

that included focus groups of forty primary care physicians, rheumatologists, and surgeons to determine their receptivity to using OxyContin for non-cancer pain... '***[t]he biggest negative of [OxyContin] was the abuse potential.***'"[106]

382. When branded opioids were introduced to the U.S. market, including Tennessee, the Producer Defendants carefully evaluated physicians' concerns about the risks of addiction associated with opioids and embarked on a highly successful campaign to convince physicians that opioids created minimal risk of addiction. Upon information and belief, the Producer Defendants knew that, if its efforts were successful, many people would become addicted to prescription opioids and that, as a consequence, abuse and illegal diversion would follow.

383. As the Producer Defendants' efforts demonstrated success in the form of rapid increases in opioid prescribing, other opioid producers joined in their efforts to expand the market for opioids.

2. The Drug Producer Defendants Funded "Key Opinion Leaders" to Spread Misinformation Regarding Opioids.

384. The Producer Defendants engaged "key opinion leaders" to promote the use of their opioids in a variety of ways. Each Producer Defendant would pay a key opinion leader an honorarium each time he or she agreed to attend a variety of functions, from intimate meals with a single pain management clinic's staff to presenting at huge national and international symposia. Key opinion leaders were selected based on a number of criteria such as the prestige of their affiliated hospitals and the quantity of their published articles, but most importantly their willingness to promote the prescription of opioids.

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[106] Information as to Purdue Frederick Co., Inc., *U.S.A v. Purdue Frederick Co., Inc.*, No. 1:07-cr-00029 W.D. Va. May 10, 2007, ECF No. 5-2 at ¶19 (emphasis in original).

3. The Drug Producer Defendants Funded Dr. Russell Portenoy, Who Facilitated the Widespread Distribution and Abuse of Opioids by Acting as a Vocal Proponent of Opioid Use.

385. The Drug Producer Defendants funded and worked closely with Dr. Russell Portenoy, a physician who emerged as one of the industry's most vocal proponents of long-term opioid use.[107] According to a Wall Street Journal article, Portenoy essentially made it "his life's work" to campaign for the movement to increase use of prescription opioids.[108] To this end, speaking on Good Morning America in 2010, Portenoy stated categorically that "[a]ddiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted." This program was broadcasted across the country and, upon information and belief, was widely watched, including within Tennessee and in the Opioid Impacted Localities. Portenoy, who himself is facing lawsuits for his work as a paid opioid pitchman, has now conceded that this promotion of opioids for chronic pain was "clearly the wrong thing to do."[109] He is on record stating: "I gave innumerable lectures in the late 1980s and 90's about addiction that weren't true."[110]

386. The Drug Producer Defendants paid Dr. Portenoy millions of dollars from 1997 to 2007 to continue publicizing information that they knew would continue to create opioid addicts and would fuel the secondary illegal market for opioids. For example, in approximately 2004,

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[107] Thomas Catan & Evan Perez, *A Pain Champion has Second Thoughts*, wsj.com (Dec. 17, 2012). Available at: https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.
[108] *Id.*
[109] *Id.*
[110] *Id.*

Endo published an education pamphlet edited by Dr. Portenoy, called Understanding Your Pain: Taking Oral Opioid Analgesics, which claimed that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems."[111] In funding Dr. Portenoy, the Drug Producer Defendants yet again knowingly helped foster the growing population of opioids addicts and perpetuated the illegal opioids market that serviced them and which would carry forward into the late 2010's.

387. Endo and Teva listed Dr. Portenoy as a "Key Opinion Leader" at various times.

4. In December 2009, Endo Funded the Publication of Medical Education Materials Stating, *inter alia*, That "Addiction is Rare in Patients Who Have Become Psychologically Dependent on Opioids."

388. Aside from funding a pro-opioid pitchman, in December 2009, Endo also paid for medical education materials which: (1) reiterated the claim that "addiction is rare in patients who become psychologically dependent on opioids while using them for pain control"; (2) emphasized the need to individually evaluate each patient "as clinical trials [rejecting opioid treatment] are not designed to identify the best treatment regimen in a given situation to manage chronic pain"; and (3) urged use of opioids even for patients engaging in "aberrant behaviors" while setting the following extreme standard to be used to identify individual patients with addiction problems: "a patient exhibiting egregious behaviors that persist, despite repeated warnings and that require significant time and resources to manage, is likely to have a problem with abuse and possibly addiction." The materials further stated that "[a]n opioid trial is the only way a clinician can determine the efficacy and tolerability of a particular agent in a particular person."[112] In other

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[111] http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf.

[112] Anderson et al, "Opioid Prescribing: Clinical Tools and Risk Management Strategies, available at: https://mn.gov/boards/assets/Opioid_Prsecibing_Clinical_Tools_and_Risk_Management_Strategies.pdf_tcm21-366993.pdf.

words, the only way to rule out opioids for any given chronic pain patient was to give opioids a try. Upon information and belief, these materials were available to and/or were distributed to Tennessee physicians.

389. Upon information and belief, Endo funded the publication of these materials knowing that doing so would result in more opioid addicts and would promote the significant illegal market for opioids on which those addicts depended – and that precisely those effects were occurring nationwide, in Tennessee, and in the communities at issue in this case.

5. The Drug Producer Defendants Funded the American Pain Foundation, Which Claimed (Among Other Things) That the Belief That "Opioid Pain Medicines are Universally Addictive" was a Common Misconception.

390. The Drug Producer Defendants also funded the American Pain Foundation ("APF"), which has been described by the President of Physicians for Responsible Opioid Prescribing as "a front for opioid manufacturers."[113] The APF's 2010 annual report details thousands of pro-opioid advertisements, public statements, letters, Facebook Posts, and similar communications. It states that: "Through online, print, radio, and television outlets, APF's local and national media outreach efforts secured 1,600 media stories on pain in 2010 – an increase of 1,255% from 2009. Reaching more than 600 million people with important pain-related messages, APF spokespeople and advocates provided education, information and assistance to people with pain and combated the negative stereotypes and stigmas associated with pain."[114] Upon

[113] Charles Ornstein and Tracy Weber, *Patient Advocacy Group Funded by Success of Painkiller Drugs, Probe Fins*, washingtonpost.com, Dec. 23, 2011. Available at: https://www.washingtonpost.com/national/health-science-/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probe-finds/2011/12/20/gIQAgvczDP_story.html.
[114] American Pain Fund 2010 Annual Report. Available at: https://archive.org/stream/277604-apf-2010-annual-report/277604-apf-2010-annual-report_djvu.txt.

information and belief, APF distributed the types of messages referenced in its 2010 Annual Report to physicians within Tennessee.

391. For example, in or around 2011, the APF published "Policymaker's Guide," which characterized the notion that "strong pain medication leads to addiction" as a "common misconception[]":

> Many people living with pain, and even some health care practitioners, falsely believe that opioid pain medicines are universally addictive. As with any medication, there are risks, but these risks can be managed when these medicines are properly prescribed and taken as directed. For more information about safety issues related to opioids and other pain therapies, visit http://www.painsafe.org.[115]

The guide describes "pain in America" as "an evolving public health crisis" and characterizes concerns about opioid addiction as misconceptions: "Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include: . . . ***Misconceptions about opioid addiction***."[116] It even characterizes as a "***myth***" that "***[c]hildren can easily become addicted to pain medications***."[117] This message is just one example of the types of messages that APF published with substantial financial support from the Drug Producer Defendants.

392. Upon information and belief, the Drug Producer Defendants funded the APF and supported it with the intention and expectation that APF's messaging would continue to create more opioid addicts and necessarily result in more illegal abuse and distribution of opioids – and knowing that precisely those effects were occurring nationwide, in Tennessee, and in the communities at issue in this case.

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[115] *A Policymaker's Guide to Understanding Pain & Its Management*, American Pain Foundation at 5. Available at: http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last visited Dec 1, 2021).
[116] *Id.* at 6 (emphasis added).
[117] *Id.* at 40 (emphasis added).

H. Endo also Independently Contributed to the Creation and Expansion of the Market for Prescription Opioids Across the Country, Including Tennessee.

1. Endo Operated and/or Sponsored Websites and Other Publications Stating, *inter alia*, That "Most Healthcare Providers Who Treat Patients With Pain Agree That Patients Treated With Prolonged Opioid Medications Usually Do Not Become Addicted."

393. Upon information and belief, on its website, www.opana.com, Endo included a claim that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medications usually do not become addicted."

394. In other materials, Endo further claimed that the risk of addiction is low and unlikely to develop when opioids are prescribed, as opposed to being obtained through the illicit market. For example:

a. Endo sponsored a facially unaffiliated website, Painknowledge.com, available in Tennessee and elsewhere, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." The website further promised that, on opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Painknowledge.com was run by the National Institute on Pain Control ("NPIC"), an APF initiative, and Endo's involvement was not disclosed on the website, by the NPIC, or by Endo; and

b. similarly, *Exit Wounds*, a 2009 publication sponsored by Purdue and distributed by APF with grants from Endo, describes opioids as "under-used" and the "gold standard of pain medications" without referencing the risk of addiction, overdose, or injury. It notes that opioid medications "increase your level of functioning" and that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." The book also asserts that "denying a person opioid pain medications because he or she has a history of substance abuse or addiction is invalid and contrary to the guidelines for the prescription of opioids published by the U.S. Federation of State Medical Boards."

395. Upon information and belief, these websites and publications were available to physicians in Tennessee and to end users of opioids.

396. The guidelines of the U.S. Federation of State Medical Boards ("FSMB") referenced in Exit Wounds were actually created and published during a time that the FSMB itself received significant financial support from The Drug Producer Defendants. In a June 8, 2012 letter to the Senate Finance Committee, the FSMB disclosed the following payments it had received: Defendant Endo paid FSMB a total of $371,620.00 from 2007 to 2009 and 2011 to 2012; and Defendant Teva paid FSMB a total of $180,000 from 2007-2008 and in 2011.[118]

397. The drug producer-sponsored FSMB guidelines warned physicians to "[b]e aware of the distinction between pseudoaddiction and addiction" and taught that behaviors such as "[r]equesting [drugs] by name," "[d]emanding or manipulative behavior," "[o]btaining opioid drugs from more than one physician" and "[h]oarding opioids" – which are, in fact, signs of genuine addiction – are all really just signs of "pseudoaddiction."[119] The FSMB guidelines defined "Physical Dependence" as an acceptable result of opioid therapy not to be equated with addiction and states that while "[i]t may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications," there could be other acceptable reasons for non-adherence.[120] The guide became the seminal authority on opioid prescribing for the medical profession.

2. In 2012 and 2013, Endo Directed its Sales Associates to Claim That Reformulated Opana ER was Less Subject to Tampering Despite Knowing that Use of Opana ER was Still Likely to Foster Addiction.

398. Endo further sought to minimize the perceived risk of abuse and addiction of its opioid product by downplaying the abuse-potential of a new version of Opana ER. In 2012, Endo

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[118] June 8, 2012 Letter from Federation of State Medical Boards to U.S. Senators Max Baucus and Charles Grassley.
[119] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide*, at 62 (Waterford Life Sciences 2007).
[120] *Id.*

replaced the original formulation of Opana ER with a new formulation ostensibly intended to make the drug resistant to physical and chemical manipulation for abuse by snorting or injecting. At that time, Endo asked the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, meaning that it was protected against manipulation that would allow users to snort or inject it. It also sought permission to withdraw its previous approval for Opana ER in favor of its newer, purportedly safer version. Endo announced that it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse deterrence), which (if true) would have prevented generic copies of the original Opana ER.

399. While Endo's new version of Opana ER met the regulatory standards for approval, the FDA determined that the data did not show that the reformulation could be expected to meaningfully reduce abuse and declined the company's request to include labeling describing potentially abuse-deterrent properties for Opana ER.

400. Nevertheless, upon information and belief, Endo advised its sales representatives to market reformulated Opana ER as the only oxymorphone extended release tablets that are "designed to be" crush resistant. Endo did so to falsely imply that Opana ER actually was crush-resistant and that the crush-resistant quality would make Opana less likely to be abused.

401. Upon information and belief, in an internal Endo document from February 2013, an Endo consultant, after reviewing national data from substance abuse treatment facilities, reported that "[t]he initial data presented do not necessarily establish that the reformulated Opana ER is tamper resistant," and that there were reports of higher levels of abuse of reformulated Opana ER via injection.[121]

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[121] *See, e.g., In re: Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No.: 15-228 (March 2016). Available at: https://ag.ny.gov/press-release/ag-schneiderman-announces-

402. The Endo consultant's finding was consistent with the CDC's "Guideline for Prescribing Opioids for Chronic Pain – United States, 2016," which states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse."[122] The CDC further notes that the "abuse-deterrent" technologies, even when they work, "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[123]

3. In 2016, Endo Entered Into an Agreement with the State of New York to Cease Touting that Opana ER is Less Likely to Result in Addiction.

403. Endo's conduct drew the attention of the Attorney General of the State of New York ("NY AG"), who opened an investigation into the company's promotional practices. In March 2016, the NY AG and Endo reached an agreement ending the investigation.[124] As part of that agreement, Endo agreed not to:

a. make statements that Opana ER or opioids generally are non-addictive;

b. make statements that most patients who take opioids do not become addicted, unless such statements are supported by competent and reliable evidence. If Endo believes that such evidence exists, it shall provide such evidence to the OAG at the time of initial dissemination of the statement, along with a copy of such statement;

c. make statements describing what most HCPs believe, unless such statements are supported by competent and reliable evidence. If Endo believes that such evidence exists, it shall provide such evidence to the OAG at the time of initial dissemination of the statement, along with a copy of such statement;

d. make statements that Reformulated Opana ER is, is designed to be, or is crush resistant, unless such statements are supported by the FDA-approved product labeling; and

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settlement-endo-health-solutions-inc-endo-pharmaceuticals. (Hereinafter "NY AG Settlement"), ¶ 16 (quoting from an Endo document).

[122] Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, at 22, March 18, 2016. Available at: https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.

[123] *Id.*

[124] *See, e.g.*, NY AG Settlement.

e. use the term "pseudoaddiction" in any training or marketing.

I. Teva Also Contributed to Tennessee's Opioid Epidemic.

1. Teva Pushed Opioid Drugs for Unapproved Purposes.

404. As described herein, Teva is knowingly participating in the distribution chain of illegal opioids in Tennessee and in the Opioid Impacted Localities by various means. Among other acts alleged herein, its prodigious supply of opioids into East Tennessee far exceeds the quantity of drugs that could be used legally and for medically necessary purposes, and necessarily reflects knowing participation in the widespread and notorious illegal opioids market in the Opioid Impacted Localities. These facts alone establish knowing participation in the chain of distribution of illegal drugs in East Tennessee. Teva's knowing participation in this illegal drug market is reinforced by its own historic efforts to increase the size of that market and/or to capture an increasing share of it from year to year.

405. According to a DOJ press release that summarizes Teva's guilty plea for criminal violations of the Food and Drug Act, Teva trained its sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of Teva opioids and funded Continuing Medical Education ("CME") Courses to promote off-label uses. Specifically, the DOJ stated:

> From 2001 through at least 2006, ***[Teva] was allegedly promoting [Actiq] for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy. [Teva] also promoted Actiq for use in patients who were not yet opioid-tolerant, and for whom it could have life-threatening results.***[125]

[125] Press Release, U.S. Department of Justice, Pharmaceutical Company Teva To Pay $425 Million for Off-Label Drug Marketing (Sept. 29, 2008). Available at: https://www.justice.gov/sites/default/files/civil/legacy/2014/01/09/Cephalon%20Press%20Release.pdf (emphasis added).

406. As a result of this unlawful marketing of Actiq, almost 90% of Actiq prescriptions were to patients for off-label, non-cancer use.

407. Then-acting U.S. Attorney Laurie Magid commented on the dangers of Teva's unlawful practices:

> This company subverted the very process put in place to protect the public from harm, and put patients' health at risk for nothing more than boosting its bottom line. People have an absolute right to their doctors' best medical judgment. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved.[126]

2. Teva Funded Pro-Opioid Publications and Presentations.

408. In addition to its direct marketing, Teva indirectly marketed through third parties to change the way doctors viewed and prescribed opioids - disseminating the messages that opioids were safe for the treatment of chronic, long-term pain, that they were non-addictive, and that they were under-prescribed to the detriment of patients who were needlessly suffering. Teva did so by sponsoring pro-opioid front groups, prescription guidelines, articles, and CMEs, and Teva paid physicians thousands of dollars every year to publicly opine that opioids were safe, effective and non-addictive for a wide variety of uses.

409. Through its sponsorship of the FSMB's "Responsible Opioid Prescribing: A Physician's Guide," Teva continued to encourage the prescribing of opioid medication to "reverse ... and improve" patient function, attributing patients' displays of traditional drug- seeking behaviors as merely "pseudoaddiction."

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[126] *Id.*

410. Teva sponsored APF's guide, which warned against the purported under-prescribing of opioids, taught that addiction is rare and suggested that opioids have "***no ceiling dose***" and are therefore the most appropriate treatment for severe pain.

411. A summary of the February 12-16, 2008 AAPM annual meeting reinforced the message, promoted both by the AAPM and the APS, that "the undertreatment of pain is unjustified." It continues:

> ***Pain management is a fundamental human right*** in all patients not only with acute postoperative pain but also ***in patients suffering from chronic pain***. Treating the underlying cause of pain does not usually treat all of the ongoing pain. Minimal pathology with maximum dysfunction remains the enigma of chronic pain. Chronic pain is only recently being explored as a complex condition that requires individual treatment and a multidisciplinary approach. It is considered to be a disease entity.[127]

412. Teva also sponsored, through an educational grant, the regularly published journal Advances in Pain Management. In a single 2008 issue of the journal, there are numerous articles from Portenoy, Dr. Steven Passik, Dr. Kenneth L. Kirsh, and Webster, all advancing the safety and efficacy of opioids. In an article titled "Screening and Stratification Methods to Minimize Opioid Abuse in Cancer Patients," Webster expresses disdain for the prior 20 years of opioid phobia.

413. In another article from the same issue, "Appropriate Prescribing of Opioids and Associated Risk Minimization," Passik and Kirsh state: "[c]hronic pain, currently experienced by approximately 75 million Americans, is becoming one of the biggest public health problems in the US." They assert that addiction is rare, that "[m]ost pain specialists have prescribed opioids for long periods of time with success demonstrated by an improvement in function" and that then-

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[127] Mohamed A. Elkersh & Zahid H. Bajwa, *Highlights From the American Academy of Pain Medicine 24th Annual Meeting*, 2(1) Advances in Pain Management 50-52 (2008) (emphasis added).

recent work had shown "that opioids do have efficacy for subsets of patients who can remain on them long term and have very little risk of addiction."[128]

414. In November 2010, Fine and others published an article presenting the results of another Teva-sponsored study, concluding that: (a) "[t]here has been a steady increase in the use of opioids for the management of chronic non-cancer pain over the past two decades"; (b) the "widespread acceptance" had led to the publishing of practice guidelines "to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain"; and (c) those guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain."[129] They also conclude that the number of abuse-related events was "small."[130]

415. From 2000 forward, Teva has paid doctors nationwide millions of dollars for programs relating to its opioids, many of whom were not oncologists and did not treat cancer pain. These doctors included Portenoy, Fine, Passik, Kirsh, and others.

J. From 2012-2017, the Drug Producer Defendants Helped Funnel Millions of Dollars to Advocacy Groups That Promoted Opioid Use.

416. On February 13, 2018, Senator Claire McCaskill, released a report showing that Purdue and other producers funneled over $10 million to 14 advocacy groups and affiliated doctors who took "industry friendly positions," which included issuing medical guidelines promoting opioids for chronic pain, lobbying to defeat or include exceptions to state limits on opioid

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[128] Steven D. Passik & Kenneth L. Kirsh, *Appropriate Prescribing of Opioids and Associated Risk Minimization,* 2(1) Advances in Pain Management 9-16 (2008).
[129] Perry G. Fine, et al., Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study, 40(5) J. Pain & Symptom Management 747-60 (Nov. 2010).
[130] *Id.*

prescribing, and criticizing prescribing guidelines from the U.S. Centers for Disease Control and Prevention.[131] The Report states that as these industry-funded entities and affiliated physicians:

> [o]ften echoed and amplified messages favorable to increased opioid use -- and ultimately the financial interest of opioid manufacturers. These groups have issued guidelines and policy minimizing the risk of opioid addiction and promoting opioids for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for over-prescription and misbranding. Notably, a majority of these groups also strongly criticized 2016 guidelines from the Centers for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain – the first national standards for prescription opioids and a key federal response to the ongoing epidemic.
>
> The fact that these same manufacturers provided millions of dollars to the group described [in this report] suggests, at the very least, a direct link between corporate donations and the advancement of opioids-friendly messaging. By aligning medical culture with industry goals this way, the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic.[132]

K. The Drug Producer Defendants Knowingly Fostered Opioid Addiction and Fueled the Illegal Opioids Market in Which They are Now Knowingly Participating.

417. The Drug Producer Defendants' promotion of opioids gave rise to and fueled the illegal drug market that existed in the Opioid Impacted Localities during all periods relevant to this suit. Each company's representations regarding the risks of opioids and actions taken to push opioids through aggressive marketing of their collective message contributed to the market for both illegally prescribed opioids and for diverted opioids (and heroin for those addicts who could no longer obtain or afford prescription opioids).

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[131] http://www.wjhl.com/news/national/opioid-makers-gave-10m-to-advocacy-groups-amid-epidemic-1/971172541.

[132] Fueling an Epidemic, Report Two: *Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Group*, U.S. Homeland Security & Governmental Affairs Committee, Ranking Member's Office, https://www.publicintegrity.org/2018/02/12/21568/021218-mccaskill-report.

418. As set forth in the examples above, the Drug Producer Defendants operated websites and/or funded third party physicians, organizations, and websites that all pushed the message that opioids were not highly addictive and/or were appropriate for long-term use to treat chronic pain. The Drug Producer Defendants chose not to fund any organizations and third parties who promoted the contrary (and scientifically supported) message that opioids were highly addictive and not suitable for long-term use to treat chronic pain. It also chose not to pull funding from the pro-opioids organizations. The Drug Producer Defendants made these choices knowing and expecting that by doing so, the opioids market would continue to expand and continue to create more opioid addicts dependent on the illegal diversion of their products.

419. Each of the Drug Producer Defendants' actions benefitted the other by creating legions of opioid addicts desperate to obtain opioids from any producer's line. The dramatic rise in opioid prescriptions, and associated overdoses, other related health problems, and NAS births (as detailed below) since the commencement of the Drug Producer Defendants' campaign in the mid-1990's shows the scope of the illegal drug market knowingly created by those defendants.

420. Speaking before the House Opioid Task Force in 2017, Dr. Michael Baron of the Tennessee Board of Medical Examiners summed up the cumulative effect of the opioid producers' multi-year campaign:

> We came out with what I call 'Generation O.' A whole generation of physicians that were taught it's ok to prescribe opiates, that they're safe, and that it's what the patient wants. But we bypassed evidence-based medicine. The whole medical system was hijacked by industry and really agreed.
>
> ***
>
> The triggers of the opioid epidemic were really the pharmaceutical industry and pain experts that were on the payroll of the pharmaceutical industry. And they preached that opioids are safe and effective for chronic, non-cancer pain, the risk

of addiction is rare, and opioid therapy can be easily discontinued, all of which is nonsense.[133]

L. **McKinsey's Consulting Services Contributed to Tennessee's Opioid Epidemic.**

421. McKinsey provided consulting services to opioid producers in connection with designing the companies' marketing plans and programs that knowingly facilitated the illegal drug market in Tennessee and the Opioid Impacted Localities.

422. McKinsey advised opioid producers to target prescribers who write the most prescriptions, for the most patients, and thereby make the most money for McKinsey's clients.

423. In 2008, McKinsey with worked with an opioid producer client to develop its FDA mandated risk evaluation and mitigation strategy ("REMS"). McKinsey advised this client to "band together" with other opioid manufacturers toward a class REMS to "formulate arguments to defend against strict treatment by the FDA." Ultimately, the FDA adopted a class-wide REMS that resulted in high-dose extended-release opioids remaining subject to the same oversight as lower-dose opioids.

424. In 2013, McKinsey laid out new plans to increase the sales of one client's branded opioids, which included the following key components:

a. focus sales calls on high-volume opioid prescribers, including those who wrote as many as 25 times as many scripts for the client's branded opioid as the lower volume counterparts;

b. remove sales representative discretion in target prescribers;

c. focus the client's marketing messaging to titrate to higher, more lucrative dosages;

d. significantly increase the number of sales visits to high0volume prescribers; and

[133] House Opioid Task Force, February 23, 2017.

e. create an "alternative model for how patients receive" the branded opioid, including direct distribution to patients and pharmacies, to help address the "product access" problem.

425. McKinsey also partnered with an opioid manufacturer client to test a program called FieldGuide, a proprietary software that McKinsey sought to license to other opioid manufacturer clients. This software would enable other opioid manufacturers to target and aggressively pursue high-volume prescribers.

426. McKinsey continued to design and develop ways that opioid producer clients could increase sales of branded opioids well after the opioid epidemic peaked. One proposal McKinsey recommended was for a client to pay "additional rebates on any new [branded opioid] related overdose or opioid use disorder diagnosis." McKinsey advised this client on its strategies to obtain and maintain broad formulary coverage for its branded opioid with insurers and pharmacy benefit managers, even as payors began reducing coverage for it as the opioid crisis mounted.

427. Subsequently, in the wake of hundreds of thousands of opioid deaths and thousands of lawsuits, McKinsey proposed a plan for this client's exit from the opioid business whereby the client would continue selling opioids as a way to fund new ventures. According to McKinsey, this change was necessary because of negative events that materially compromised the client's brand.

428. McKinsey collected millions of dollars designing and implementing marketing programs for the country's largest opioid manufacturers, such as Endo, increasing the sale and use of opioids in Tennessee. McKinsey designed and implemented for other opioid producers marketing plans like the ones discussed above.

429. At the same time McKinsey was working for opioid producers, McKinsey also consulted with governments and non-profits working to abate the raging opioid crisis—a crisis that McKinsey's own research showed was caused in large part by prescription opioids.

430. Upon information and belief, individuals at McKinsey considered destroying or deleting documents related to their work for certain opioid producers' clients.

431. McKinsey's clients, such as Purdue, have been found criminally liable for their role in the creating and exacerbating the opioid epidemic, which included implemented the marketing strategies advocated for by McKinsey. McKinsey client Johnson & Johnson was found civilly liable by an Oklahoma state court for helping cause the opioid epidemic in Oklahoma.

432. In February 2021, McKinsey itself reached a settlement with 49 states attorneys general, five U.S. territories, and the District of Columbia, for its role in the opioid epidemic, agreeing to pay nearly $600 million to settle investigations into its role in promoting the sales of branded opioids.

433. While McKinsey announced in 2019 that it would no longer with opioid producers, the harm created by McKinsey's marketing plans for opioid producers has not stopped, including the creation, expansion, and facilitation of the illegal opioid market in Tennessee and the Opioid Impacted Localities.

M. The Drug Producer Defendants, M&D and Other Distributors, the Pharmacy Chain Defendants, McKinsey Engaged in a Conspiracy to Profit from the Opioid Market by Any Means Necessary Which Exacerbated the Opioid Epidemic.

434. The Drug Producer Defendants, the M&D and other distributors, and the Pharmacy Chain Defendants were engaged in a conspiracy to circumvent state and federal laws intended to minimize the diversion of opioids.

435. Through chargeback data, the Drug Producer Defendants had visibility into the extravagant opioid orders being placed by retail pharmacies, including those owned and operated by the Pharmacy Chain Defendants. Instead of reporting these orders to law enforcement and refusing to honor these rebates, the Drug Producer Defendants almost always continued to supply

the Pharmacy Chain Defendants and others with opioids at a discounted rate to maximize their profits.

436. When a large pharmacy chain took steps to scrutinize suspicious opioid orders, McKinsey stressed to one of its opioid producer clients that they "need[ed] to take action" on this "urgent" issues affecting their branded opioid, telling their client to engage in senior level discussions with the pharmacy chain, increase efforts with patient advocacy groups to clamor against dispensing limits, and accelerate considerations of an alternative distribution channel, such as delivering the branded opioid directly to patients through mail-order pharmacies.

437. M&D and other distributors were in regular contact with the Drug Producer Defendants about potentially suspicious pharmacies; but as long as the Drug Producer Defendants continued to honor chargebacks, M&D and other distributors continued to fill these pharmacies' suspicious orders, especially if the pharmacy at issue was one of the Pharmacy Chain Defendants.

438. The Pharmacy Chain Defendants knew that M&D and other distributors fiercely competed with one another for their substantial books of business. As a prerequisite to gifting the Distributors their accounts, the Pharmacy Chain Defendants would demand that all of their locations be exempted from the Distributor's SOM system until their exorbitant monthly orders of opioids would not be identified as "suspicious" by the Distributors. Even when an order for a Pharmacy Chain Defendant was identified by a Distributor's SOM system, the Distributors would expediate a threshold increase to clear the order. The Distributors were so worried about losing the Pharmacy Chain Defendants' business that they would proactively reach out to the Pharmacy Chain Defendants when their SOM team saw a Pharmacy Chain Defendant location nearing its threshold for opioids.

439. As self-distributors of opioids themselves at certain points, the Pharmacy Chain Defendants understood that the Distributors had obligations to monitor for suspicious orders, but nevertheless demanded (and received) threshold increases for what the Pharmacy Chain Defendants clearly knew were suspicious orders for opioids. The Drug Producer Defendants witnessed and enabled these unlawful ordering tactics by continuing to grant chargebacks for the Pharmacy Chain Defendants, and encouraged the Distributors to keep the opioids flowing to these suspicious pharmacies.

440. The Drug Producer Defendants, the Distributors, the Pharmacy Chain Defendants, and McKinsey knew that their concerted and coordinated effort to subvert state and federal law resulted in the diversion of opioids into the illegal drug market, including the illegal drug markets in Tennessee and the Opioid Impacted Localities.

N. The United States, and Tennessee in Particular, is Plagued by Rampant Opioid Abuse.

1. Opioids are Abused and Diverted at Alarming Rates.

441. The increasing demand, and high availability, of prescription opioids correlates with increased addiction, abuse, and diversion (a term used to describe redistribution of prescription drugs for illegal uses) throughout the country, including Tennessee and Opioid Impacted Localities. According to the Centers for Medicare & Medicaid Services, "'[d]rug diversion' is best defined as the diversion of licit drugs for illicit purposes. It involves the diversion of drugs from legal and medically necessary uses towards uses that are illegal and typically not medically authorized or necessary."[134]

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[134] "Drug Diversion in the Medicaid Program: State Strategies for Reducing Prescription Drug Diversion in Medicaid," Centers for Medicare & Medicaid Services (Baltimore, MD: January 2012), p. 1., available at:

442. Opioid misuse is a national epidemic. For example, the federal government estimated that ***11.5 million people*** had abused opioid pain relievers in 2016, including approximately ***4.4% of all people in the United States aged 12 or older.***[135] These statistics are disturbing, indicating that about 1 in 20 people in the U.S. are abusing opioids.

443. Unfortunately, the situation in Tennessee is no better, and indeed may be worse. During 2013 – 2014, the State of Tennessee estimated that nearly 5% (221,000) of adults in Tennessee used pain relievers for non-medical purposes. Of these, the State estimated that 69,100 Tennesseans were addicted to prescription opioids and required treatment for prescription opioid abuse. The other 151,900 were using prescription opioids in ways that could be harmful and may benefit from early intervention strategies.[136] Not surprisingly, opioids abuse continues to go hand in hand with an illegal drug market from which the Defendants are knowingly deriving substantial profits.

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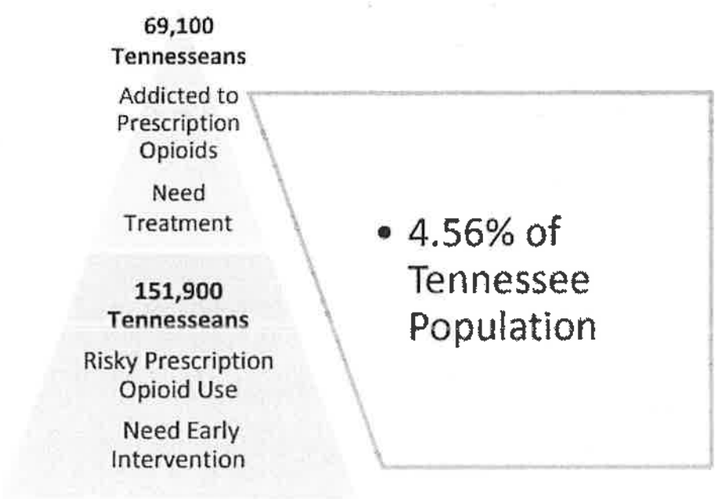
https://www.cms.gov/Medicare-Medicaid-Coordination/FraudPrevention/MedicaidIntegrityProgram/downloads/drugdiversion.pdf.

[135] https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.htm#opioid.

[136] "Prescription for Success: Statewide Strategies to Prevent and Treat the Prescription Drug Abuse Epidemic in Tennessee," Tennessee Department of Mental Health and Substance Abuse Services et al., (Summer, 2014), pg. 9, available at: https://web.archive.org/web/20160414040557/https://www.tn.gov/assets/entities/behavioral-health/sa/attachments/Prescription_For_Success_Full_Report.pdf ("Prescription for Success").



2. **The Defendants are Aware of a Nationwide Problem.**

444. Trends in opioid production, prescriptions, and usage over the last decade put drug producers and distributors on notice of a heightened risk of abuse and diversion nationwide. For example:

a. according to the Working Group Report, "[s]ince 1999, there has been no overall change in the amount of pain experienced by Americans, yet the number of prescriptions for opioids has quadrupled[;]"[137]

b. in the past two decades, the rate of opioid prescribing in the United States has increased 600%.[138] The United States accounts for 4.6% of the world population but its citizens, by 2011, were consuming 80% of the world's opioid production;[139]

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[137] *Working Group Report* at 3.
[138] *Side Effects* at 2 (citing Leonard Paulozzi et al., Ctr. For Disease Control and Prevention, *CDC Grand Rounds: Prescription Drug Overdoses- A U.S. Epidemic*, *in* 61 Morbidity & Mortality Weekly Rept. 774, 774-76 (2012)).
[139] *Id.* (citing Daneshvari R. Solanki et al., *Monitoring Opioid Adherence in Chronic Pain Patients: Assessment of Risk of Substance Misuse*, 14 Pain Physician J. 119, 120 (2011)).

c. between 2009 and 2013, both the number of prescriptions filled per patient and the number of days of medication per prescription increased by approximately 8.4%;[140]

d. nearly half (46.9%) of new opioid users who take these medications for more than 30 days in the first year continue using them for three years or longer. Signaling a particularly alarming trend, nearly 50% of these patients are only taking short-acting opioids — which can make them more prone to addiction — rather than long-acting formulations, which are designed for extended pain relief;[141]

e. on average, the patients who chronically used these medications filled 56 short-acting opioid prescriptions over three years — nearly 19 prescriptions each year;[142] and

f. prescription opioid overdose deaths quadrupled in parallel with prescription opioid sales in the United States between 1999 and 2010.[143]

445. Defendants know that production volumes of opioids skyrocketed in the last twenty-five years. In 1993, the DEA allowed pharmaceutical companies to produce 3,520 kilograms of oxycodone. In 2015, the DEA authorized production of 137,500 kilograms of oxycodone. That's a 39-fold increase in 22 years.

446. Defendants are also well-aware that for 2018, the DEA proposed a 20% reduction in the number of prescribed schedule II opioid painkillers that can be produced in the United States, with Acting Administrator Chuck Rosenberg warning that "Physicians, pharmacists, and patients must recognize the inherent risks of these powerful medications, especially for long-term use."

3. The Stream of Opioids into Tennessee is Alarmingly High and Put Defendants on Notice of Abuse and Diversion.

[140] "A Nation in Pain" by Express Scripts, 2015.
[141] *Id.*
[142] *Id.*
[143] *Id.*

447. Patients in small cities, particularly in the Southeast, are among the highest users of longer-term narcotic pain medications across the United States.[144]

448. Tennessee currently has the third highest statewide opioid prescription rate in the nation.[145] Indeed, Tennessee doctors in 2015 wrote more than 7.8 million opioid prescriptions — or ***1.18 prescriptions for every man, woman and child in the State***, placing Tennessee number 2 in the nation among all States for the number of opioid prescriptions per capita according to IMS Health data. By contrast, California with its population of 38.8 million people only had 0.48 prescriptions per capita in 2015. As reported by the CDC, Tennessee's oxycodone prescription rate is twenty-two times that of Minnesota's. As reported by Commissioner of Health Dreyzehner in 2016 his presentation "Neonatal Abstinence Syndrome, a Tennessee Perspective," ***51 hydrocodone pills and 21 oxycodone pills were prescribed for every Tennessean*** during the period covered by that report. The same report details the dramatic, multi-fold increase in opioid prescriptions since 1999, in the absence of any meaningful increase in patients experiencing chronic pain.

449. According to the Tennessee Department of Health's Drug Overdose Dashboard, there were 7,636,112 opioid prescriptions written in Tennessee in 2016 alone.[146] The State is currently dispensing opioids at rate of 68.5 opioid prescriptions per 100 persons.[147]

450. The following map assembled by the State of Tennessee indicates the rate of controlled substances dispensed across Tennessee counties adjusted by population as reported in 2012. As the map shows, more than half of Tennessee had dispensing rates between 3.1 to 3.5 (or

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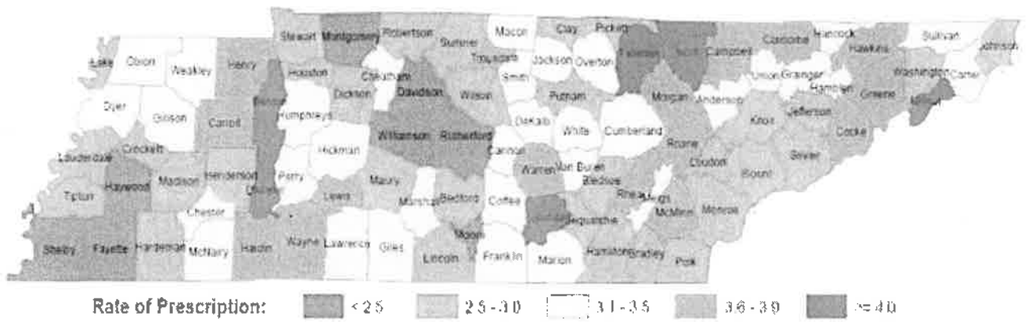
[144] *Id.*
[145] *See* https://www.cdc.gov/drugoverdose/rxrate-maps/state2020.html.
[146] Tennessee Drug Overdose Dashboard.
[147] Center for Disease Control, *U.S. State Opioid Dispensing Rates, 2020*, https://www.cdc.gov/drugoverdose/rxrate-maps/state2020.html.

greater) prescriptions for opioids or benzodiazepines per resident, with, for example, Grundy County falling into the 4.0:[148]

Map I-1. Rate of Prescriptions Dispensed (per capita) in Tennessee Among Tennessee Residents Reported to CSMD, 2012



Source: Tennessee Department of Health

As the map indicates, the problem of opioid over-prescription is acute in East Tennessee.

451. According to IMS Health Data, the number of prescriptions of popular branded and generic opioid products containing hydromorphone, oxymorphone, oxycodone, and hydrocodone in the State of Tennessee totaled 6,148,823 for the 12-month period of September 2015 through August 2016, and 5,639,429 for the 12-month period of September 2016 through August 2017. This means in just over a two-year period, Tennesseans received more than 11.7 million of these prescriptions.

4. <u>The Opioids Pipeline Involves Substantial Diversion and the Presence of an Illegal Market.</u>

[148] "Prescription for Success" at 14-15.

452. The U.S. Department of Justice's ("DOJ") yearly drug market analysis of the Appalachia High Intensity Drug Trafficking Area ("Appalachia HIDTA") – which, as of July 2017, includes 32 counties in Tennessee,– provides an overview of opioid-related abuse and diversion in and around Tennessee.[149] The "Appalachia HIDTA uses a 'multi-disciplinary' approach to deal with the ongoing threats to public health and safety, particularly as it regards prescription drug diversion" and also addresses, among other things, "the emerging threat of heroin."[150]

453. As the DOJ explained in its 2008 drug market analysis:

> The diversion, distribution, and abuse of controlled prescription drugs (CPDs) such as OxyContin (oxycodone), Vicodin (hydrocodone), and Valium (diazepam), are significant threats in the Appalachia HIDTA region. Traffickers and abusers illicitly obtain CPDs through traditional diversion methods (primarily doctor-shopping, theft, forged prescriptions, and unscrupulous physicians and pharmacists working alone or in association). Prescription drug traffickers and abusers increasingly circumvent law enforcement efforts to prevent CPD diversion in the region by obtaining drugs in Florida, Pennsylvania, and Tennessee.[151]

454. The DOJ's drug market analyses of the Appalachia HIDTA for the years 2008 through 2011 detail a steady rise in the availability and law enforcement seizures of oxycodone (primarily OxyContin) in the Tennessee illegal drug market: 1,069 dosage units of oxycodone

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[149] Appalachia HIDTA Counties, 2017 Revised. Available at: http://ahidta.org/sites/all/themes/ahidta/img/ahidta-map-2017.jpg.; *see also* U.S. Dep't of Justice, Appalachia High Intensity Drug Trafficking Area, Drug Market Analysis, 1-2 (June 2007) (explaining that, at the time, the AHIDTA region "has a combined population of approximately 2.5 million" and "Knoxville, Tennessee, is the largest metropolitan area").

[150] News Channel 11 Staff, Sullivan Co. designated as member of Appalachia High Intensity Drug Trafficking Area, wjhl.com (Aug. 24, 2017). Available at: http://wjhl.com/2017/08/24/live-2p-federal-local-authorities-hold-news-conference-to-reveal-about-drug-trafficking-in-region/.

[151] U.S. Dep't of Justice, Appalachia High Intensity Drug Trafficking Area, Drug Market Analysis, 2 (Mar. 2009).

seized in Tennessee in 2007;[152] 2,679 dosage units of oxycodone seized in Tennessee in 2008;[153] 3,016 dosage units of oxycodone seized in Tennessee in 2009;[154] and 4,142 dosage units of oxycodone seized in Tennessee in 2010.[155]

455. In its 2015 Appalachia HIDTA Annual Report, the DOJ reiterated that "[p]rescription drug diversion and abuse has been a consistent and tenacious obstacle for both the law enforcement community and the citizens of Appalachia."[156] According to the DOJ, Tennessee had the highest number of painkiller prescriptions in the United States, with 143 prescriptions per 100 people, followed by West Virginia (138 prescriptions per 100 people), and then Kentucky (128 prescriptions per 100 people).[157] Relying on treatment data, the DOJ also found that "prescription opioids rank as the number one abused drug among individuals receiving state-funded services" in Tennessee.[158]

456. The 2015 Appalachia HIDTA report also highlighted the fact that cities in Tennessee in particular are a significant source of prescription drug diversion:

> Over the past few years, the number of Appalachian residents traveling out-of-state for prescription drugs has been drastically reduced, yet does remain an issue....Locations inside the AHIDTA itself have also become sources for CPDs [controlled prescription drugs]. Cities within Tennessee and Kentucky are listed by law enforcement as locations for obtaining prescription drugs for diversion. In response to the prescription drug problem that has plagued the region for several years, members of Appalachia HIDTA task force initiatives removed nearly 80,000

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[152] U.S. Dep't of Justice, Appalachia High Intensity Drug Trafficking Area, Drug Market Analysis, 4 (June 2008).
[153] U.S. Dep't of Justice, Appalachia High Intensity Drug Trafficking Area, Drug Market Analysis, 4 (March 2009).
[154] U.S. Dep't of Justice, Appalachia High Intensity Drug Trafficking Area, Drug Market Analysis, 3 (May 2010).
[155] U.S. Dep't of Justice, Appalachia High Intensity Drug Trafficking Area, Drug Market Analysis, 11 (Sept. 2011).
[156] U.S. Dep't of Justice, Appalachia High Intensity Drug Trafficking Area, CY2015 Annual Report, at 4 (2015).
[157] *Id.*
[158] *Id.* at 30.

dosage units of diverted prescription drugs during CTY 2015, valued at over $1.3 million.[159]

457. The DOJ's 2016 Threat Assessment indicates that the situation has not improved in the AHIDTA region:

> Diverted pharmaceuticals have traditionally posed a significant threat to the AHIDTA region and show no signs of a change to the trend in upcoming years. Trafficking of CPDs [controlled prescription drugs] continues to originate from Michigan, Ohio, Georgia, North Carolina and areas within Tennessee.[160]

458. The 2016 Threat Assessment goes on to explain that "[t]he most commonly diverted, abused, and illicitly obtained pharmaceuticals in the [AHIDTA] region are narcotic analgesics such as oxycodone, hydrocodone, methadone, and depressants such as alprazolam and diazepam."[161]

459. Over the period 2008 through 2012, between 2% to 3% of morphine-equivalent milligrams of opioids were diverted in the state of Tennessee, which is elevated on a national scale, but comparable to the rates of diversion in neighboring Alabama, Mississippi, Georgia, and Virginia:[162]

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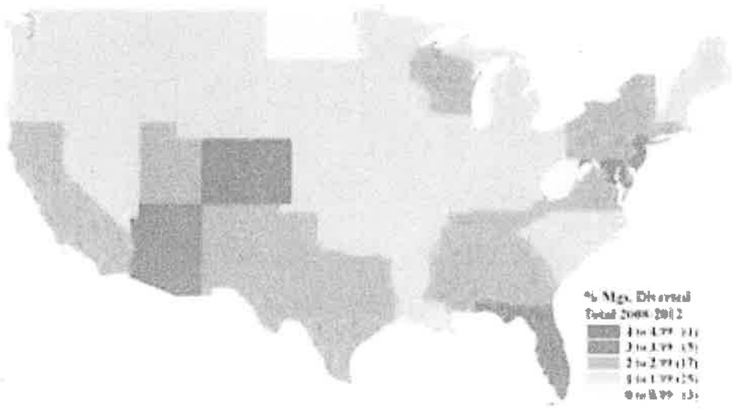
[159] *Id.* at 5.
[160] U.S. Dep't of Justice, *Appalachia High Intensity Drug Trafficking Area,* 2016 Threat Assessment, at 8 (2016).
[161] *Id.* at 20.
[162] "Doctor Shopping Behavior and the Diversion of Prescription Opioids," Ronald Simeone, *Substance Abuse: Research and Treatment Volume 11: 1–10,* by Sage Journals (April 11, 2017), available at: http://journals.sagepub.com/doi/full/10.1177/1178221817696077.



5. **The Opioid Epidemic has Devastated Tennessee Communities.**

460. It is difficult to overstate the human, economic, and societal toll that the opioid epidemic and associated abuse and diversion have wrought in Tennessee. The levels of opioid abuse in Tennessee are staggering: Tennessee and the Opioid Impacted Localities in particular are awash in opioids, plagued by high levels of opioid-induced deaths and babies born with NAS, and racked by an illegal opioids market. The flood of opioids has had – and continues to have – predictably devastating effects on Tennessee communities, including the Opioid Impacted Localities. This includes staggering rates of addiction, opioid-related deaths, and babies born with NAS, along with the presence of criminal drug trafficking rings.

461. "Opioid overdoses, mainly from prescription drugs, are … the leading cause of the recent unexpected rise in the mortality rate of middle-aged white Americans, particularly women in rural areas, after decades of steady decline."[163]

[163] Lenny Bernstein, et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: 'No One Was Doing Their Job'*, washingtonpost.com, Oct. 22, 2016, available at:

462. As recently as 2016, the preeminent medical journal in the United States concluded that "[t][wo major facts can no longer be questioned. First, opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.... Second, the major source of diverted opioids is physician prescriptions."[164] Overdose deaths increased in Tennessee from 342 in 1999 to 2,388 in 2020, the last year for which overdoses have been calculated.[165] That represents a nearly 600% increase. Tragically, the rates of opioid deaths in Tennessee outpace the national average by a wide margin. The vast majority of overdose deaths in Tennessee – nearly 72% in 2015 – involved opioids.[166] From 2012 to 2020 (the last year for which data has been reported), Tennessee set a new record each year for the number of opioid overdose deaths, with 2,388 in 2020 alone.[167] The rate in 2020 equated to more than 6 opioid overdose deaths in Tennessee every single day.

Rates of Opioid Related Overdose Death (rate per 100,000 Population)
Tennessee and United States, 1999-2010

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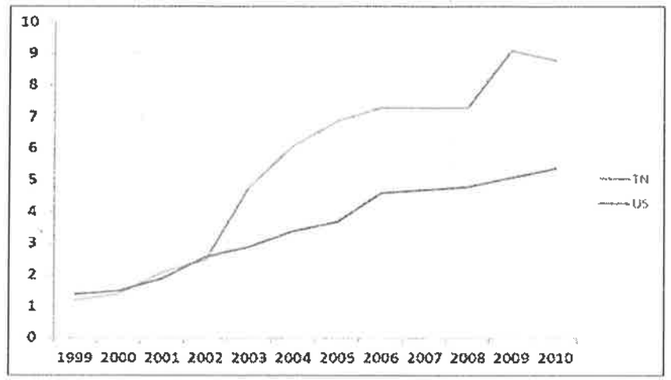
https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html.

[164] "Opioid Abuse in Chronic Pain — Misconceptions and Mitigation Strategies," Nora D. Volkow, M.D., and A. Thomas McLellan, Ph.D., N Engl J Med 2016; 374:1253-1263 (March 31, 2016), available at: http://www.nejm.org/doi/full/10.1056/NEJMra1507771.

[165] Tennessee Drug Overdose Dashboard.

[166] *Id.*

[167] *Id.*



Between 2005 and 2015, just one decade, unintentional overdose deaths in Tennessee increased over 250%. Unintentional overdose deaths now account for more early deaths in Tennessee than automobile accidents, suicides, or homicides.[168]

463. Defendants also contributed to NAS deaths in Tennessee. NAS is a clinical diagnosis, and "a consequence of the abrupt discontinuation of chronic fetal exposure to substances that were used or abused by the mother during pregnancy."[169]

464. According to a report produced by Governor Bill Haslam's Opioid Abuse Working Group pursuant to 2015 Tenn. Pub. Acts Ch. 389 ("Governor's Working Group Report"), "***[t]he number of babies born with Neonatal Abstinence Syndrome (NAS). . . increased tenfold from 2000 to 2010.***"[170] Since 2010, the problem has only gotten worse.

465. Along with overdose deaths, the number and rate of NAS – a condition suffered by babies born to mothers addicted to opioids – has also increased dramatically in Tennessee since 2007:

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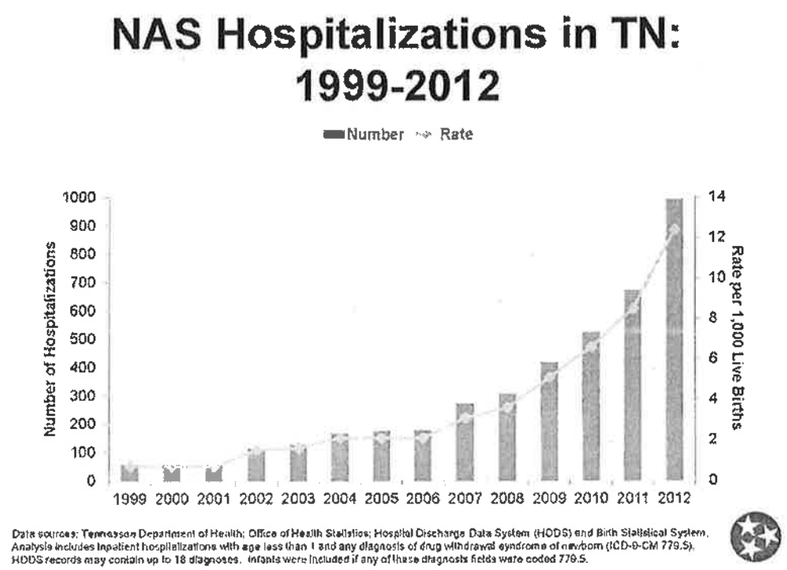
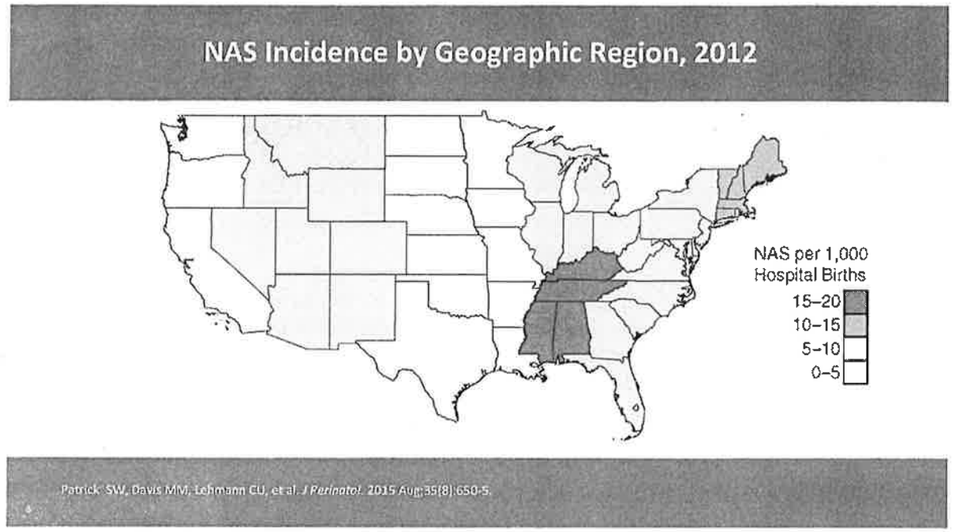
[168] *Working Group Report* at 4.
[169] Prabhakar Kocherlakota, *Neonatal Abstinence Syndrome*, 134(2) Pediatrics 547, 547-48 (2014), available at: http://pediatrics.aappublications.org/content/pediatrics/134/2/e547.full.pdf.
[170] *Working Group Report* at 4 (emphasis added).



466. As illustrated by the following map, researchers analyzing hospital discharge data have determined that Tennessee, along with its border states Kentucky, Alabama, and Mississippi, have the highest rates of NAS births in the nation.[171]

[171] Stephen W. Patrick et al., *Increasing Incidence of Neonatal Abstinence Syndrome: United States 2009-2012*, 35(8) J. Peronatol. 650, 650-55.



467. The percentage of pregnant women served by the Tennessee Department of Mental Health & Substance Abuse Services – 42.3% in 2012 – listing prescription opioids as their primary substance of abuse was over twice the percentage in the United States overall (18.4% in 2012).

468. NAS births in Tennessee are further concentrated in Northeast Tennessee with many counties in that region reporting at least 10 and some more than 30 NAS babies per 1,000 live births during 2014.

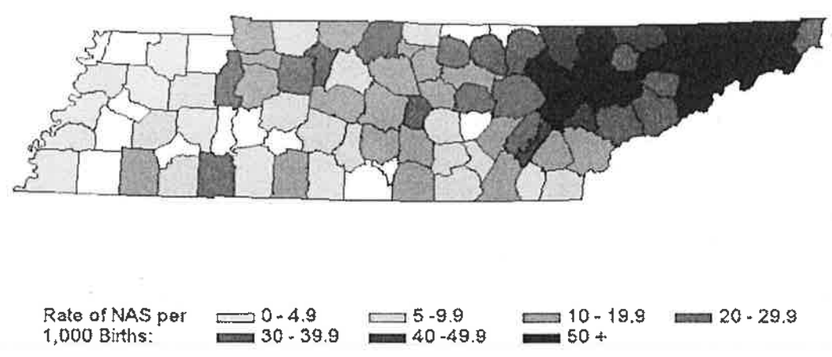


Figure 198. Incidence of NAS among TennCare recipients, 2014

Source: Bureau of TennCare Division of Health Care Finance and Administration (Provisional Data)

469. TennCare eligibility records establish that 24.3% of babies born with NAS in 2012 were placed in the Department of Children's Services' custody within one year of birth.[172]

470. The epidemic of NAS babies is an outgrowth of the explosion in the amount of opioids in Tennessee since the mid-1990s. As the Appalachia HIDTA recognized in its 2015 Annual Report:

> [T]he state of Tennessee and east Tennessee in particular, is plagued by an epidemic of opioid abuse, which has unfortunately now resulted in a resurgence of heroin as a growing threat. A consequence of this opioid abuse is the alarming number of children being born dependent on opioids, afflicted with Neonatal Abstinence Syndrome (NAS). Children born with NAS suffer extreme physical symptoms of withdrawal and require specialized care in the neonatal wards of hospitals. This treatment often consists of children being given smaller doses of methadone or similar drugs, over time, to break their addiction to opioids.[173]

471. The direct link between the flood of prescription opioid and the NAS baby crisis in Tennessee has been clearly stated by Tennessee's Commissioner of Health Dr. John Dreyzehner. In a 2015 presentation entitled "Neonatal Abstinence Syndrome: A Tennessee Perspective," Commissioner Dreyzehner addressed "***the Substance Abuse Epidemic and resulting NAS epidemic***."[174]

472. In his NAS presentation, Commissioner Dreyzehner identified the obvious link between opioid sales and opioid related health problems, noting "the incredible correlation between sales and supply and availability [of opioids] and opioid related deaths and opioid treatment admissions."[175]

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[172] *Working Group Report* at 4.
[173] U.S. Dep't of Justice, Appalachia High Intensity Drug Trafficking Area, CY2015 Annual Report, at 4 (2015).
[174] National DEC, "Neonatal Abstinence Syndrome A Tennessee Perspective," Vimeo, May 4, 2015. Available at: https://vimeo.com/126839454 (emphasis added).
[175] *Id.*

473. Additionally, Dr. Stephen Loyd, Medical Director of the Tennessee Department of Mental Health and Substance Abuse Services, recently testified before the Tennessee House of Representatives' Opioid Task Force ("House Opioid Task Force") that: "[m]arketing of opioids as having a low addictive potential when used for the treatment of chronic pain" resulted in "opioids prescribed more freely by practitioners," and, in turn, an "increase in number of babies born drug dependent."[176]

474. The nationwide epidemic of NAS has a focal point in Tennessee.[177] The statistics are alarming:[178]

a. in 2015, 12.1 of every 1,000 babies were born with NAS in Tennessee;

b. in 2016, 12.2 of every 1,000 babies were born with NAS in Tennessee;

c. in 2017, 13.5 of every 1,000 babies were born with NAS in Tennessee;

d. in 2018, 11.7 of every 1,000 babies were born with NAS in Tennessee;

e. in 2019, 10.0 of every 1,000 babies were born with NAS in Tennessee; and

f. in 2020, 10.2 of every 1,000 babies were born with NAS in Tennessee.

475. Among other issues, NAS babies experience long-term difficulties, including but not limited to the following types of effects: poor performance in school;[179] higher risk of

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[176] House Opioid Task Force, February 23, 2017.

[177] The TN Department of Health has tracked statistics related to babies with NAS from which the following statistical data has been gathered. Available at: https://www.tn.gov/health/article/nas-update-archive.html.

[178] *Id.*

[179] *Neonatal Abstinence Syndrome and High School Performance* (Jan. 16, 2017), available at: http://i2.cdn.turner.com/cnn/2017/images/01/16/neonatal.abstinence.syndrome.and.high.school.performance.pdf.

developmental disabilities and the accompanying need for special needs services;[180] and lower cognitive function.[181]

O. In Addition to Death and NAS, Opioid Abuse and Diversion has Other Deleterious Economic and Societal Consequences.

476. In addition to these health effects, the flood of opioids into Tennessee corresponds to lost productivity and increases in crime, children in State custody, and treatment and healthcare costs.[182] In a 2013 report, the State of Tennessee itself identified prescription drug as the cause of these deleterious effects:[183]

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[180] https://consumer.healthday.com/pregnancy-information-29/pregnancy-drugs-news-545/babies-born-addicted-to-opioids-often-struggle-with-learning-722293.html (summarizing results of CDC study of NAS-born babies in Tennessee).

[181] Nygaard, Egil, et al., *Longitudinal Cognitive Development of Children Born to Mothers with Opioids and Polysubstance Abuse*, Pediatric RESEARCH, Vol. 28 No. 3 (Sept. 2015).

[182] "Prescription for Success" at p. 9.

[183] *Id.*

SUMMARY OF THE PRESCRIPTION DRUG EPIDEMIC IN TENNESSEE

Who Abuses Prescription Drugs?

- In 2012, prescription opioids became the primary substance of abuse for people in Department of Mental Health and Substance Abuse Services-funded treatment, overtaking alcohol for the first time.
- Almost 5% of Tennesseans have used pain relievers in the past year for non-medical purposes.
- Young adults (18-25-year-olds) in Tennessee are using prescription opioids at a 30% higher rate than the national average.

Access to Prescription Drugs

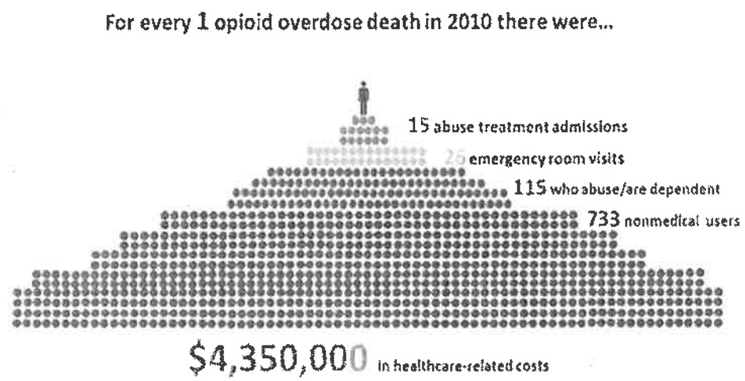
- **High Number of Prescriptions Dispensed**
  - There were 25% more controlled substances dispensed in Tennessee in 2012 than in 2010.
- **Doctor Shopping**
  - In March 2013, 2,010 people received prescriptions for opioids or benzodiazepines from four or more prescribers.
- **Prescribing Practices**
  - As of August 1, 2013, 25 physicians had been prosecuted for overprescribing during 2013.
- **Sources of Prescription Drugs**
  - More than 70% of people who use prescription drugs for non-medical reasons got them from a friend or relative.

Consequences of Prescription Drug Abuse

- **Healthcare Costs**
  - The number of emergency department visits for prescription drug poisoning has increased by approximately 40% from 2005 to 2010.
- **Overdose Deaths**
  - There has been a 220% increase in the number of drug overdose deaths from 1999 to 2012 (342 in 1999 to 1,094 in 2012).
- **Criminal Justice System Involvement**
  - Drug-related crimes against property, people and society have increased by 33% from 2005 to 2012.
- **Lost Productivity**
  - The cost of lost productivity due to prescription drug abuse in Tennessee was $142.9 million in 2008. This number adjusted for 2013 inflation is $155.2 million.
- **Children in State Custody**
  - About 50% of the youth taken into Department of Children's Services custody resulted from parental drug use.
- **Neonatal Abstinence Syndrome**
  - Over the past decade, we have seen a nearly ten-fold rise in the incidence of babies born with Neonatal Abstinence Syndrome in Tennessee.
- **Treatment Costs**
  - It is estimated that the cost of providing state-funded treatment services to individuals that abuse prescription drugs and live below the poverty level would cost $27,933,600.

477. As the graphic below reflects, opioid overdose deaths represent only the "tip of the iceberg of the human and societal cots of the opioid epidemic:[184]

[184] Benjamin Schachtman, *'Closer to Home' – The Cost of the Opioid Epidemic May be the Tip of the Iceberg*, portcitydaily.com, Apr. 3, 2017 (attributing graphic chart to the N.C. Public Health Department). Available at: http://portcitydaily.com/2017/04/03/closer-to-home-the-cost-of-the-opioid-epidemic-may-be-the-tip-of-the-iceberg/.



478. According to a recent article by the Tennessean, the "substance abuse epidemic – most notably involving opioids" -- costs Tennessee more than $2 billion annually.[185] That $2 billion annual price tag includes $46 million for babies born in Tennessee with NAS; $422.5 million for hospitalizations associated with opioid abuse; and another $372,440 in emergency room visits associated with opioid abuse.[186] However, the largest component of the substantial yearly costs is the $1.29 billion in "lost income from having an estimated 31,000 people, or 1 percent of the workforce, out of jobs.[187] As the article further explains:

> Teresa Waters, the chair of preventive medicine at the University of Tennessee Health Sciences Center and person responsible for compiling the data used in the Tennessean article, said she "took a conservative approach to the analysis so the overall economic impact and state spending is likely higher." In particular, Waters noted that "she didn't include costs associated with substance abuse overdoses because of debate over how to estimate economic impact from early loss of life."[188]

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[185] Holly Fletcher, *Drug, alcohol abuse saps $2 billion from Tennessee annually – an under-the-radar impact of the opioid epidemic*, USA TODAY NETWORK – Tennessee (Dec. 3, 2017). Available at: https://www.tennessean.com/story/money/industries/health-care/2017/12/04/drug-alcohol-abuse-saps-2-billion-tennessee-annually-under-the-radar-impac.
[186] *Id.*
[187] *Id.*
[188] *Id.*

479. Defendants' creation and/or expansion of the opioid market has given rise to a market for heroin in Tennessee, made up largely of addicts who can no longer afford diverted prescription opioids available on the black market. There is a relationship between opioid pain reliever use and heroin use. According to the federal government's National Survey on Drug Use and Health, four out of five heroin addictions begin with opioid prescription pain relievers.[189]

480. On November 13, 2015, E. Douglas Varney, Commissioner of the Tennessee Department of Mental Health, issued a message detailing the recent rise of heroin abuse in Tennessee.[190] In the message, Varney explained that, as the state "forged efforts to reduce availability of opioid based pain remedies, in the shadows, heroin arrived on the scene. It arrived like a tidal wave in Tennessee. It's a far more potent form of opioids, cheaper, more dangerous and more lethal."[191] Varney referenced data from multiple sources showing heroin, and heroin-related criminal activity, sharply on the rise, and said: "I'm saddened to see our friends and neighbors that have been struggling with opioid addiction now transitioning to heroin which is coming from the criminal underground street dealer."[192]

481. In a December 2016 publication of the Tennessee Medical Association titled "No Easy Fix: Tennessee's Doctors Take on The Opioid Abuse Epidemic," Dr. Roland W. Gray

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[189] Pradip K. Muhuri et al., Substance Abuse and Mental Health Services Administration, *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States* (August 2013), *available at*: http://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm.

[190] TN Dep't of Mental Health and Substance Abuse Services, *Message from Commissioner E. Douglas Varney on Heroin's Grip in our Cities and Suburbs* (Nov. 13, 2015), *available at:* https://www.tn.gov/behavioral-health/news/20176.

[191] *Id.*

[192] *Id.*

described the opioid epidemic as the "worst and deadliest drug epidemic in our nation's history."[193] He went on to say that "[t]here's good news in that we are prescribing significantly fewer opiates in Tennessee; the bad news is they are being replaced by a heroin epidemic. Tennesseans are rapidly turning to those drugs – they're available on the street and are cheaper and far more powerful than prescription opiates."[194]

482. According to the Tennessee Department of Health, heroin-associated overdose deaths are also on the rise, increasing from 147 in 2014 to 205 in 2015.[195]

483. Commissioner Dreyzehner has determined that "[t]here is a direct correlation between opioid addiction and heroin use."[196]

484. As set forth in a September 2016 report by the Tennessee Department of Mental Health and Substance Abuse Services, people with prior treatment admissions, people who inject opioids, people ages 25-34, and people who started opioid use after age 18 are all at increased risk for switching from prescription opioids to heroin.[197]

P. Tennessee and the Opioid Impacted Localities are at the Epicenter of the Opioid Crisis Caused by Defendants' Unlawful Conduct in Creating and/or Supplying the Illegal Secondary Market.

485. The Opioid Impacted Localities have experienced, even more acutely, the same "ring of abuse" stemming from the Drug Producer Defendants', M&D's, and the Pharmacy Chain Defendants' unabated distribution of opioids into their communities, including the associated rates

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[193] Roland W. Gray, *The Good News/Bad News About Tennessee's Opioid Epidemic*, 109 Tenn. Med., 4, 23 (2016), *available at:* https://www.tnmed.org/Documents/TennMed-Qtr4-05FINAL.pdf.
[194] *Id.*
[195] Tenn. Dep't of Health, *1,451 Tennesseans Die from Drug Overdoses in 2015*, tn.gov (Nov. 15, 2016). Available at: http://tn.gov/health/news/46773.
[196] *Working Group Report.*
[197] K. Edwards, Tennessee Department of Mental Health & Substance Abuse Services, *Turning the Curve on Opioid and Heroin Abuse in Tennessee*, 14 (September 14, 2016).

of addiction, death, opioid dependent babies, criminality, and economic and social devastation. The Opioid Impacted Localities have suffered and will continue to suffer damages on behalf of individual drug users who live in their communities. These damages include, but are not limited to, the cost of treatment and rehabilitation, medical expenses, loss of economic or educational potential, loss of productivity, absenteeism, support expenses, accidents or injury, prosecution, law enforcement costs, and other pecuniary and nonpecuniary losses proximately caused by the illegal drug use.

486. In the Opioid Impacted Localities, there were 1,052,302 opioid prescriptions filled in 2020 alone.[198] During that year, the average per capita rate of opioid prescriptions in the Localities ranged from 625.41 to 1474.72 opioid prescriptions filled per 1,000 residents.[199] From 2017 to 2020, there were a staggering 1,548 opioid overdose deaths in the Opioid Impacted Localities, including 516 in 2020 alone.[200] The number of opioid overdose deaths rose 58.7% over that time period.

1. **Anderson County**

487. According to the most recent census data, Anderson County, Tennessee had a population of 77,123.[201] 13.1% of Anderson County residents live below the poverty line. The median household income is $35,483.[202]

488. In 2020, the per capita rate of opioid prescriptions in Anderson County was 924.28 prescriptions per 1,000 persons.[203]

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[198] Tennessee Overdose Dashboard.
[199] *Id.*
[200] *Id.*
[201] U.S. Census Bureau (2019), *Census Reporter Profile Page for Anderson County, TN*, http://censusreporter.org/profiles/05000US47001-anderson-county-tn.
[202] *Id.*
[203] Tennessee Drug Overdose Dashboard.

2. Bledsoe County

489. According to the most recent census data, Bledsoe County, Tennessee had a population of 14,913.[204] 18.1% of Bledsoe County residents live below the poverty line. The median household income is $28,982.[205]

490. In 2020, the per capita rate of opioid prescriptions in Bledsoe County was 1,089.82 prescriptions per 1,000 persons.[206]

3. Bradley County

491. According to the most recent census data, Bradley County, Tennessee had a population of 108,620.[207] 16.0% of Bradley County residents live below the poverty line.[208] The median household income is $40,032.[209]

492. In 2020, the per capita rate of opioid prescriptions in Bradley County was 844.78 prescriptions per 1,000 persons.[210]

4. Claiborne County

493. According to the most recent census data, Claiborne County, Tennessee had a population of 31,732.[211] 22.4% of Claiborne County residents live below the poverty line.[212] The median household income is $46,835.

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[204] U.S. Census Bureau (2019), *Census Reporter Profile Page for Bledsoe County, TN*, https://censusreporter.org/profiles/05000US47007-bledsoe-county-tn/.
[205] *Id.*
[206] Tennessee Drug Overdose Dashboard.
[207] U.S. Census Bureau (2019), *Census Reporter Profile Page for Bradley County, TN*, https://censusreporter.org/profiles/05000US47011-bradley-county-tn/.
[208] *Id.*
[209] *Id.*
[210] Tennessee Drug Overdose Dashboard.
[211] U.S. Census Bureau (2019), *Census Reporter Profile Page for Claiborne County, TN*, https://censusreporter.org/profiles/05000US47025-claiborne-county-tn/.
[212] *Id.*

494. In 2020, the per capita rate of opioid prescriptions in Claiborne County was 1,159.42 prescriptions per 1,000 persons.[213]

5. **Cocke County**

495. According to the most recent census data, Cocke County, Tennessee had a population of 35,552.[214] 23.5% of Cocke County residents live below the poverty line.[215] The median household income is $36,716.[216]

496. In 2020, the per capita rate of opioid prescriptions in Cocke County was 1,252.89 prescriptions per 1,000 persons.[217]

6. **Franklin County**

497. According to the most recent census data, Franklin County, Tennessee had a population of 41,725.[218] 14.4% of Franklin County residents live below the poverty line.[219] The median household income is $51,585.[220]

498. In 2020, the per capita rate of opioid prescriptions in Franklin County was 956.55 prescriptions per 1,000 persons.[221]

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[213] Tennessee Drug Overdose Dashboard

[214] U.S. Census Bureau (2019), *Census Reporter Profile Page for Cocke County, TN*, https://censusreporter.org/profiles/05000US47029-cocke-county-tn/.

[215] *Id.*

[216] *Id.*

[217] Tennessee Drug Overdose Dashboard.

[218] U.S. Census Bureau (2019), *Census Reporter Profile Page for Franklin County, TN*, https://censusreporter.org/profiles/05000US47051-franklin-county-tn/.

[219] *Id.*

[220] *Id.*

[221] Tennessee Drug Overdose Dashboard.

7. **Grainger County/Town of Rutledge**

499. According to the most recent census data, Grainger County, Tennessee had a population of 23,101.[222] 18.1% of Grainger County residents live below the poverty line.[223] The median household income is $44,064.[224] Plaintiff Town of Rutledge is located in Grainger County.

500. In 2020, the per capita rate of opioid prescriptions in Grainger County was 1,018.44 prescriptions per 1,000 persons.[225]

8. **Grundy County**

501. According to the most recent census data, Grundy County, Tennessee had a population of 13,344.[226] 22.7% of Grundy County residents live below the poverty line.[227] The median household income is $40,516.[228]

502. In 2020, the per capita rate of opioid prescriptions in Grundy County was 1,474.72 prescriptions per 1,000 persons.[229]

9. **Knox County/City of Knoxville**

503. According to the most recent census data, Knox County, Tennessee had a population of 470,313.[230] 13.5% of Knox County residents live below the poverty line.[231] The median household income is $60,283.[232] Plaintiff City of Knoxville is located in Knox County.

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[222] U.S. Census Bureau (2019), *Census Reporter Profile Page for Grainger County, TN*, https://censusreporter.org/profiles/05000US47057-grainger-county-tn/.
[223] *Id.*
[224] *Id.*
[225] Tennessee Drug Overdose Dashboard.
[226] U.S. Census Bureau (2019), *Census Reporter Profile Page for Grundy County, TN*, https://censusreporter.org/profiles/05000US47061-grundy-county-tn/.
[227] *Id.*
[228] *Id.*
[229] Tennessee Drug Overdose Dashboard.
[230] U.S. Census Bureau (2019), *Census Reporter Profile Page for Knox County, TN*, https://censusreporter.org/profiles/05000US47093-knox-county-tn/.
[231] *Id.*
[232] *Id.*

504. In 2020, the per capita rate of opioid prescriptions in Knox County was 625.41 prescriptions per 1,000 persons.[233]

10. Loudon County

505. According to the most recent census data, Loudon County, Tennessee had a population of 52,340.[234] 11.3% of Loudon County residents live below the poverty line.[235] The median household income is $58,065.[236]

506. In 2020, the per capita rate of opioid prescriptions in Loudon County was 706.92 prescriptions per 1,000 persons.[237]

11. Marion County

507. According to the most recent census data, Marion County, Tennessee had a population of 28,538.[238] 15.4% of Marion County residents live below the poverty line.[239] The median household income is $49,432.[240]

508. In 2020, the per capita rate of opioid prescriptions in Marion County was 1,188.99 prescriptions per 1,000 persons.[241]

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[233] Tennessee Drug Overdose Dashboard.
[234] U.S. Census Bureau (2019), *Census Reporter Profile Page for Loudon County, TN*, https://censusreporter.org/profiles/05000US47105-loudon-county-tn/.
[235] *Id.*
[236] *Id.*
[237] Tennessee Drug Overdose Dashboard.
[238] U.S. Census Bureau (2019), *Census Reporter Profile Page for Marion County, TN*, https://censusreporter.org/profiles/05000US47115-marion-county-tn/.
[239] *Id.*
[240] *Id.*
[241] Tennessee Drug Overdose Dashboard.

12. McMinn County

509. According to the most recent census data, McMinn County, Tennessee had a population of 53,053.[242] 19.3% of McMinn County residents live below the poverty line.[243] The median household income is $43,285.[244]

510. In 2020, the per capita rate of opioid prescriptions in McMinn County was 1,095.23 prescriptions per 1,000 persons.[245]

13. Meigs County

511. According to the most recent census data, Meigs County, Tennessee had a population of 12,104.[246] 16.9% of Meigs County residents live below the poverty line.[247] The median household income is $49,167.[248]

512. In 2020, the per capita rate of opioid prescriptions in Meigs County was 1,224.52 prescriptions per 1,000 persons.[249]

14. Monroe County

513. According to the most recent census data, Monroe County, Tennessee had a population of 46,064.[250] 18.4% of Monroe County residents live below the poverty line.[251] The median household income is $42,429.[252]

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[242] U.S. Census Bureau (2019), *Census Reporter Profile Page for McMinn County, TN*, https://censusreporter.org/profiles/05000US47107-mcminn-county-tn/.
[243] *Id.*
[244] *Id.*
[245] Tennessee Drug Overdose Dashboard.
[246] U.S. Census Bureau (2019), *Census Reporter Profile Page for Meigs County, TN*, https://censusreporter.org/profiles/05000US47121-meigs-county-tn/.
[247] *Id.*
[248] *Id.*
[249] Tennessee Drug Overdose Dashboard.
[250] U.S. Census Bureau (2019), *Census Reporter Profile Page for Monroe County, TN*, https://censusreporter.org/profiles/05000US47123-monroe-county-tn/.
[251] *Id.*
[252] *Id.*

514. In 2020, the per capita rate of opioid prescriptions in Monroe County was 1,087.39 prescriptions per 1,000 persons.[253]

15. Polk County

515. According to the most recent census data, Polk County, Tennessee had a population of 16,814.[254] 15.0% of Polk County residents live below the poverty line.[255] The median household income is $43,306.[256]

516. In 2020, the per capita rate of opioid prescriptions in Polk County was 1,173.36 prescriptions per 1,000 persons.[257]

16. Rhea County

517. According to the most recent census data, Rhea County, Tennessee had a population of 32,719.[258] 19.3% of Rhea County Residents live below the poverty line.[259] The median household income is $42,206.[260]

518. In 2020, the per capita rate of opioid prescriptions in Rhea County was 1204.21 prescriptions per 100,000 persons.[261]

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[253] Tennessee Drug Overdose Dashboard.
[254] U.S. Census Bureau (2019), *Census Reporter Profile Page for Polk County, TN*, https://censusreporter.org/profiles/05000US47139-polk-county-tn/.
[255] *Id.*
[256] *Id.*
[257] Tennessee Drug Overdose Dashboard.
[258] U.S. Census Bureau (2019), *Census Reporter Profile Page for Rhea County, TN*, https://censusreporter.org/profiles/05000US47143-rhea-county-tn/.
[259] *Id.*
[260] *Id.*
[261] Tennessee Drug Overdose Dashboard.

17. Roane County

519. According to the most recent census data, Roane County, Tennessee had a population of 53,075.[262] 13.9% of Roane County residents live below the poverty line.[263] The median household income is $53,367.[264]

520. In 2020, the per capita rate of opioid prescriptions in Roane County was 1,014.09 prescriptions per 1,000 persons.[265]

18. Sequatchie County

521. According to the most recent census data, Sequatchie County, Tennessee had a population of 14,861.[266] 19.7% of Sequatchie County residents live below the poverty line.[267] The median household income is $49,370.[268]

522. In 2020, the per capita rate of opioid prescriptions in Sequatchie County was 1,137.36 prescriptions per 1,000 persons.[269]

19. Sevier County

523. According to the most recent census data, Sevier County, Tennessee had a population of 98,250.[270] 13.6% of Sevier County residents live below the poverty line.[271] The median household income is $57,741.[272]

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[262] U.S. Census Bureau (2019), *Census Reporter Profile Page for Roane County, TN*, https://censusreporter.org/profiles/05000US47145-roane-county-tn/.
[263] *Id.*
[264] *Id.*
[265] Tennessee Drug Overdose Dashboard.
[266] U.S. Census Bureau (2019), *Census Reporter Profile Page for Sequatchie County, TN*, https://censusreporter.org/profiles/05000US47153-sequatchie-county-tn/.
[267] *Id.*
[268] *Id.*
[269] Tennessee Drug Overdose Dashboard.
[270] U.S. Census Bureau (2019), *Census Reporter Profile Page for Sevier County, TN*, https://censusreporter.org/profiles/05000US47155-sevier-county-tn/.
[271] *Id.*
[272] *Id.*

524. In 2020, the per capita rate of opioid prescriptions in Sevier County was 700.89 prescriptions per 1,000 persons.[273]

20. Union County

525. According to the most recent census data, Union County, Tennessee had a population of 19,488.[274] 22.0% of Union County residents live below the poverty line.[275] The median household income is $44,671.[276]

526. In 2020, the per capita rate of opioid prescriptions in Union County was 944.52 prescriptions per 1,000 persons.[277]

527. Recoverable damages that the Opioid Impacted Localities have suffered or will suffer from Defendants' participation in the illegal drug market includes, but is not limited to, any costs that have been or will be incurred for:

a. increased law enforcement costs;

b. costs borne by the political subdivisions to care for, house, rehabilitate, and/or foster opioid addicts and opioid-dependent babies and children;

c. costs associated with early childhood intervention;

d. special needs education costs and the political subdivisions with respect to babies born with NAS because of opioid abuse, who require special education costs when they attend local schools;

e. prosecution-related costs, including hiring additional prosecutors, investigators, or staff, as well as additional courtroom-related expenses borne by prosecutor's offices, the political subdivisions, and local courts;

f. costs for additional jail space and other costs associated with incarceration;

g. drug treatment program costs; and

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[273] Tennessee Drug Overdose Dashboard.
[274] U.S. Census Bureau (2019), *Census Reporter Profile Page for Anderson County, TN*, https://censusreporter.org/profiles/05000US47173-union-county-tn/.
[275] *Id.*
[276] *Id.*
[277] Tennessee Drug Overdose Dashboard.

h. any other pecuniary loss proximately caused by the illegal drug use at issue.

VI. THE THCLA DOES NOT APPLY

528. Tennessee's Healthcare Liability Act does not apply to this DDLA action or any other claims made in this lawsuit. Plaintiffs are not seeking damages resulting from injuries caused by "a health care provider or providers .... provision of, or failure to provide, health care services to a person," Tenn. Code Ann. § 29-26-101(a)(1). Plaintiffs seek damages under the DDLA that are a result of "an individual's use of an illegal drug." Tenn. Code Ann. § 29-38-105(a). Plaintiffs must demonstrate that "[t]he defendant's participation in the illegal drug market was connected with the same type of illegal drug used by the individual drug user." Tenn. Code Ann. § 29-38-106(b)(2)(B). Defendants' conduct does not fall under the umbrella of the THCLA.

VII. CAUSES OF ACTION

COUNT I
TENNESSEE DRUG DEALER LIABILITY ACT

529. Plaintiffs incorporate all preceding paragraphs by reference.

530. Tennessee's Drug Dealer Liability Act ("DDLA"), Tenn. Code Ann. § 29-38-101 et seq., provides a civil remedy for "damages to persons in a community as a result of illegal drug use." Tenn. Code Ann. § 29-38-102.

531. Among the persons to whom the DDLA provides a remedy are "[a] medical facility, insurer, governmental entity, employer, or other entity that funds a drug treatment program or employee assistance program for the individual drug user, or that otherwise expended money on behalf of the individual drug user." Tenn. Code Ann. § 29-38-106.

532. The Opioid Impacted Localities are governmental entities that fund drug treatment, employee assistance programs for individual drug users, and/or that have otherwise expended

money as a result of the illegal distribution of opioids in the Opioid Impacted Localities and the surrounding area.

533. The DDLA makes anyone who "knowingly participates in the illegal drug market within this state ... liable for civil damages." Tenn. Code Ann. § 29-38-105(a).

534. "A person may recover damages under [the DDLA] ... for injury resulting from an individual's use of an illegal drug." Tenn. Code Ann. § 29-38-105(b).

535. Under Tennessee criminal laws, such as Tenn. Code Ann § 39-17-417 and Tenn. Code Ann § 39-17-418, oxycodone, Opana, and other opioids are "illegal drugs" if possessed, sold, and distributed without a valid prescription. They are also illegal if distributed without diversion control and other obligations under Tennessee law.

536. An "illegal drug" under the DDLA is "a drug, the distribution of which is a violation of state law." (Tenn. Code Ann. § 29-38-104(1).) Under clearly established Tennessee law, illegally diverted opioids are "illegal drugs." Drugs distributed without diversion control are also illegal. (*See* Tenn. Code Ann. §§ 53-10-312; 53-11-301 *et seq.*, 53-11-401 *et seq.*)

537. The DDLA makes anyone who "knowingly participates in the illegal drug market within this state ... liable for civil damages." Tenn. Code Ann. § 29-38-105(a). a person participates in an illegal drug market if that person, inter alia, "commit[s] an act intended to facilitate the marketing or distribution of an illegal drug." Tenn. Code Ann. § 29-38-104(9).

538. For purposes of the DDLA, an "'individual drug user' means the individual whose illegal drug use is the basis of an action brought under [that statute]," Tenn. Code Ann. § 29-38-104(4).

539. Residents of the Localities who acquired oxycodone, hydrocodone, hydromorphone, oxymorphone, Opana ER, morphine and/or another drugs produced by the Drug

Producer Defendants (or distributed, dispensed, or prescribed by the other defendants) from unlicensed drug dealers illegally distributing the prescription opioids in the Opioid Impacted Localities are "individual drug user[s]" under the DDLA. Under Tennessee criminal laws, such as Tenn. Code Ann § 39-17-417 and Tenn. Code Ann § 39-17-418, hydrocodone, oxycodone, hydromorphone, oxymorphone, Opana ER, morphine and other opioids are illegal drugs if possessed, sold, and distributed without a valid prescription.

540. Those purchases of hydrocodone, oxycodone, hydromorphone, oxymorphone, Opana ER, morphine and any other drugs produced by the Drug Producer Defendants (or distributed, dispensed or prescribed by the other defendants) were illegal in that they were made without a valid prescription as required by Tenn. Code Ann. § 53-11-308(a).

541. The DDLA imposes liability on those who directly participate in the distribution of an illegal drug that causes damages. Damages may be recovered under the DDLA from a "person who knowingly distributed, or knowingly participated in the chain of distribution of, an illegal drug that was actually used by the individual drug user." Tenn. Code Ann. § 29-38-106(5)(b)(1).

542. The DDLA also imposes market liability on those who participate in the unlawful distribution of drugs in the area where illegal drugs cause damages. Damages may be recovered under the DDLA from a "person who knowingly participated in the illegal drug market, if (A) [t]he place of illegal drug activity by the individual drug user is within the illegal drug market target community of the defendant; (B) the defendant's participation in the illegal drug market was connected with the same type of illegal drug used by the individual drug user; and (C) [t]he defendant participated in the illegal drug market at any time during the individual user's period of illegal drug use." Tenn. Code Ann. § 29-38-106(5)(b)(2)(A)-(C). A "person" is defined to include an "individual" as well as any "corporation[s] . . . partnership[s], or incorporated or unincorporated

association[s] existing under or authorized by the law of [Tennessee], another state, or foreign country." Tenn. Code Ann. § 29-38-104(11).

543. By statute, the DDLA declares that "[t]hose involved in the illegal drug market in a community are necessarily interrelated and interdependent, even if their identity is unknown to one another." Tenn. Code Ann. § 29-38-103(8).

544. The DDLA "expressly adopts a legislatively crafted form of liability for those who intentionally join the illegal drug market." *Id.* § 29-38-103(9). The DDLA is intended to be "destructive of market initiative and product development" with regard to illegal drug markets. *Id.*

545. With respect to causation, the DDLA is specifically intended to supplant traditional common law causation doctrines, because those doctrines may impose unnecessary "barriers" to recovery. Tenn. Code Ann. § 29-38-103(7). Accordingly, a plaintiff may recover regardless of whether the plaintiff in the "actual chain of distribution." Tenn. Code Ann. § 29-38-103(7).

546. An "illegal drug market" under the DDLA is "the support system of illegal drug related operations, ***from production to retail sales***, through which an illegal drug reaches the user." Tenn. Code Ann. § 29-38-104(2) (emphasis added).

547. The DDLA imposes market liability on those who participate in the unlawful distribution of drugs in the area where illegal drugs cause damages. Damages may be recovered under the DDLA from a "person who knowingly participated in the illegal drug market, if (A) [t]he place of illegal drug activity by the individual drug user is within the illegal drug market target community of the defendant; (B) the defendant's participation in the illegal drug market was connected with the same type of illegal drug used by the individual drug user; and (C) [t]he defendant participated in the illegal drug market at any time during the individual user's period of illegal drug use." Tenn. Code Ann. § 29-38-106(5)(b)(2)(A)-(C). By statute, the DDLA declares

that "[t]hose involved in the illegal drug market in a community are necessarily interrelated and interdependent, even if their identity is unknown to one another." Tenn. Code Ann. § 29-38-103(8). The DDLA "expressly adopts a legislatively crafted form of liability for those who intentionally join the illegal drug market." *Id.* § 29-38-103(9). The DDLA is intended to be "destructive of market initiative and product development" with regard to illegal drug markets. *Id.*

548. The DDLA is intended "to shift, to the extent possible, the cost of the damage caused by the existence of the illegal drug market in a community to those who profit from that market." Tenn. Code Ann. § 29-38-102; *see also* Tenn. Code Ann. § 29-38-103(2) ("The persons who have joined the illegal drug market should bear the cost of the harm caused by the market in the community.")

549. The Drug Producer Defendants, Morris & Dickson, and the Pharmacy Chain Defendants knowingly participated in the production, procurement of the originally diverted prescription, and/or distribution of prescription opioids into the illegal market that reached the Opioid Impacted Localities during all times relevant to this complaint. For purposes of the DDLA, Defendants' "illegal drug market target community" is the entire state of Tennessee, because Defendants participated in the illegal drug market by distributing 4 ounces or more of a "specified illegal drug." Tenn. Code Ann §§ 29-38-104(8), 29-38-109(4). As noted by the Tennessee Department of Health in a 2015 presentation, the Tennessee market for hydrocodone and oxycodone pills comprised of 51 hydrocodone pills and 21 oxycodone pills for every Tennessean. Commissioner of Health Dreyzehner noted that 50% of mothers of NAS babies obtained their pills, in whole or in part, from diverted pills (28.7% solely from diverted drugs). Given that a single oxycodone tablet, on information and belief, weighs approximately 135 mg and contains at least

10 mg of opioid, there can be no question that each of the Defendants' production, distribution, dispensing, and prescribing far exceeded the four-ounce level.

550. With regard to distribution and dispensing, the Drug Producer Defendants, M&D, and the Pharmacy Chain Defendants, all recognized that they had a responsibility not to procure or fill suspicious orders, not to convince prescribers to write scripts without a valid medical purpose, and not to supply channels of distribution that they knew or reasonably expected would result in diversion. Nevertheless, they violated these responsibilities through the various acts referenced herein.

551. Under Tennessee law, prescription opioids are "Schedule II" controlled substances because they inherently have a "high potential for abuse" and that "may lead to severe psychic or physical dependence."[278] For this reason, everyone who handles prescription opioids in Tennessee (from production to retail sales) must maintain appropriate safeguards against abuse and diversion, and must ensure that the drugs are only being distributed to serve legitimate medical purposes.[279] If either or both of these preconditions is not satisfied, it is unlawful to distribute prescription opioids in Tennessee.[280] Indeed, entities holding a Tennessee license can be criminally prosecuted for violating their responsibilities in the distribution chain. The Producer Defendants, M&D, and Pharmacy Chain Defendants did not lawfully distribute prescription opioids into or within Tennessee. Instead, using their licenses as a cover, they unlawfully distributed drugs without maintaining necessary controls (rendering the distribution unlawful), knowingly distributed those drugs into channels that they knew were resulting in diversion, knowingly encouraged high-

[278] Tenn. Code Ann. § 39-17-407.
[279] *See, e.g.*, Tenn. Code Ann. § 53-11-302 and -303; Rules of Tn Bd. of Pharmacy, Ch. 1140-02.01 *et seq.* and Ch. 1140-09.01 *et seq.*
[280] *See* Tenn. Code Ann. § 53-11-401(a).

volume pill mill prescribers to prescribe opioids without a legitimate medical purpose to feed drug abusers, pill seekers, and drug dealers, knowingly supplied pharmacies serving pill mills, and/or knowingly dispensed prescriptions that were not made for a legitimate medical purpose. Plaintiffs therefore assert that all drugs distributed in this manner (without appropriate controls, etc.) were unlawful and that defendants therefore knowingly participated in the illegal drug market in this fashion. They also exceeded their lawful authority by taking actions that the federal government found were unlawful, that were not authorized under Tennessee law and/or Tennessee authorities, and/or that specifically contradicted what they knew their responsibilities to be.

552. The Drug Producer Defendants and McKinsey also committed various other acts intended to facilitate the marketing or distribution of illegal opioids for purposes of Tenn. Code Ann. § 29-38-104(9). These acts are detailed in the preceding paragraphs, which are incorporated by reference. Those acts include, but are not limited to:

a. engaging in a mass marketing campaign to downplay the risks of addiction from long-term use of opioids of non-cancer pain;

b. taking actions that violated DEA and FDA requirement or guidelines regarding the marketing and promotion of their drugs and/or suspicious order monitoring;

c. utilizing front groups and key opinion leaders to spread misinformation regarding the risks of addiction and the signs of addiction;

d. utilizing marketing teams to devise ways to overcome the legitimate concerns of Tennessee prescribers regarding long-term use of opioids;

e. successfully encouraging Tennessee prescribers to engage in prescription practices that defendants knew and expected would drive up addiction rates;

f. oversupplying Tennessee and the Opioid Impacted Localities with opioids, knowing that the oversupply would necessarily feed and expand the black market;

g. targeting the highest-volume Tennessee prescribers for sales efforts and calling on these prescribers repeatedly to convince them to prescribe more opioids;

h. using volume-based bonuses and commissions for sales representatives with respect to a highly addictive and widely abused narcotic, and otherwise encouraging and rewarding sales representatives for doing business with Tennessee pill mills and other over-prescribers;

i. knowingly establishing business relationships with Tennessee pill mills and over-prescribers to compete for their business by convincing them to prescribe more opioids, including high-volume prescribers in small, rural Tennessee communities who were prescribing opioids at unjustifiable levels;

j. directly pushing Tennessee prescribers (through frequent calls, in-person visits, and promotions) to prescribe more opioids after it was clear, even by the Drug Producer Defendants' own stated criteria, that those prescribers were engaging in highly suspicious prescribing practices or criminal conduct;

k. directly pushing Tennessee prescribers (through frequent calls, in-person visits, and promotions) to prescribe more opioids after receiving reports from law enforcement that the prescribers and pharmacies were supplying drug addicts and the illegal market;

l. establishing new accounts with high-volume opioid prescribers without due diligence, knowing that the new account may be a pill mill;

m. providing patients or Tennessee prescribers incentives to prescribe more opioids;

n. convincing naïve Tennessee doctors willingly to write prescriptions for powerful opioids to pill seekers and prescription drug abusers who sell the prescriptions wholesale;

o. directly pushing Tennessee prescribers (through frequent calls, in-person visits, and promotions) to prescribe more opioids when defendants that those prescribers knew were likely engaging in unlawful conduct and feeding the illegal drug market;

p. incentivizing sales representatives to do business both with Tennessee pill mills and with pharmacies supplying pill mills (and financially rewarding those sales associates for doing so);

q. filling suspicious orders intended for distribution in Tennessee despite knowing that the orders reflected diversion;

r. implementing sham suspicious order monitoring programs that were structured to fail and to allow diversion to proceed unimpeded in Tennessee and elsewhere;

s. filling orders that the Drug Producer Defendants had subjectively identified as suspicious before undertaking or completing an investigation into those orders;

t. permitting sales representatives to call on or prescriber or pharmacy even after internally recommending that the entity be reported to the DEA;

u. in the case of Endo, knowingly selling a product for 9 months after Endo told the FDA that the product was so rampantly abused and diverted that it had to be removed from the market to avoid addiction, diversion, and overdose deaths, then returning to profit-share from sales of that product from 2017 forward;

v. continuing to call on pill mill prescribers and associated pharmacies even after being told by law enforcement that they were likely feeding the illegal drug market;

w. collaborating with the Drug Distributors to provide sham justifications to fill suspicious orders;

x. placing primary or sole responsibility for suspicious order monitoring in the hands of a commission/volume bonus-based sales force with an inherent conflict of interest;

y. allowing inherently conflicted sales representatives to "clear" suspicious orders without any independent investigation;

z. allowing sales associate to determine whether to self-report their best customers even where the stated criteria for reporting diversion are met; and

aa. supplying outlandish volumes of prescription opioids to rural Tennessee communities far exceeding any conceivable medical need.

553. M&D and Walmart also committed acts intended to facilitate the marketing or distribution of illegal opioids for purposes of Tenn. Code Ann. § 29-38-104(9). These acts are

detailed in the preceding paragraphs, which are incorporated by reference. Those acts include, but are not limited to:

a. providing volume-based bonuses or commissions to sales representatives relating to shipment of a highly addictive and widely abused narcotic;

b. incentivizing or otherwise rewarding sales personnel who did business with pharmacies that supply pill mills and other over-prescribers;

c. routinely filling suspicious orders, including that should have been flagged as suspicious and impounded based on the Drug Distributors' and Pharmacy Chain's own stated criteria (such as orders of unusual size or frequency);

d. routinely filling orders, including plainly suspicious orders, without due diligence;

e. establishing new accounts without due diligence;

f. implementing a suspicious order marketing program that was designed to fail;

g. making adjustments to the suspicious order monitoring program to make it less effective on purpose, such as changing thresholds for customers that initially exceeded them;

h. providing sham justifications to "clear" orders from being impounded or accounts from being frozen through chargeback restrictions;

i. intentionally seeking out relationships with pain clinics or pharmacies that serve pain clinics;

j. shipping excessive amounts of opioids to pharmacies and dispensing physicians in Tennessee at levels far exceeding any conceivable legitimate need, where the volume of pills far exceeded the number of people, and where the prescription per capita rate was exceedingly high; and

k. shipping excessive amounts of opioids to pharmacies and dispensing physicians in Tennessee, despite reports from law enforcement, firsthand observations, or other knowledge that the pharmacy was honoring pill mill prescriptions *en masse*.

554. The Pharmacy Chain Defendants further committed acts intended to facilitate the marketing or distribution of illegal opioids that reached the Opioid Impacted Localities for

purposes of Tenn. Code Ann. § 29-38-104(9). These acts are detailed in the preceding paragraphs, which are incorporated by reference. Those acts include, but are not limited to:

a. financially and professionally incentivizing pharmacists and other pharmacy employees to fill suspicious orders, including pill mill prescriptions, without conducting due diligence;

b. financially and professionally incentivizing pharmacists and other pharmacy employees to violate their professional obligation to withhold filling a prescription absent a legitimate medical purpose and without determining that the drugs were not likely to be abused or diverted;

c. routinely filling suspicious prescriptions;

d. filling prescriptions by Tennessee prescribers that the Pharmacy Chain Defendants knew were operating pill mills or knew otherwise were over-prescribing opioids that would supply the illegal drug market;

e. filling prescriptions for individuals the Pharmacy Chain Defendants recognized were pill seekers and drug addicts who would abuse and divert the drugs;

f. filling prescriptions despite obvious signs of diversion and/or improper prescription practices, such as frequent prescriptions at an unrealistically high rate, frequent prescriptions at the highest allowable dosages, prescriptions filled by patients for years on end (who plainly were addicted), and prescriptions filled by individuals who engaged in suspect practices just outside the pharmacy upon filling the prescriptions; and

g. otherwise over-supplying Tennessee and the Opioid Impacted Localities, including rural Tennessee communities, with quantities of highly addictive opioids that far exceeded any conceivable medical need.

555. As a result, the Drug Producer Defendants, M&D, and Pharmacy Chain Defendants knowingly produced, distributed, disseminated, and dispensed massive quantities of prescription opioids to suspect physicians, pharmacies, and patients and into the black market, including as to "pill mills" such as the Pill Mill Prescriber Defendants. They also committed other acts that also were intended to facilitate the illegal diversion of prescription opioids into the black market, knowing that such opioids would be illegally trafficked and abused.

556. The Pill Mill Prescriber Defendants and McKinsey also committed acts intended to facilitate the marketing or distribution of illegal opioids that reached the Opioid Impacted Localities for purposes of Tenn. Code Ann. § 29-38-104(9), as described elsewhere in this complaint.

557. The diversion of prescription opioids into the secondary, criminal market and the increase in the number of individuals who abuse or are addicted to opioids has placed unnecessary and excessive demands on the medical, public health, law enforcement, and financial resources of the Opioid Impacted Localities.

558. Having knowingly participated in the illegal distribution of the prescription opioids purchased by residents of the Opioid Impacted Localities in the "place of illegal drug activity," Defendants are liable to the Opioid Impacted Localities under the DDLA for damages caused by opioids that were acquired from distribution channels in which Defendants were a market participant. Plaintiffs have one or more places of illegal drug activity in common where the period of illegal drug use overlaps with other Plaintiffs.

559. The Opioid Impacted Localities bring this action under the DDLA to hold the Defendants civilly liable for the devastation that their facilitation of the illegal opioids market in Tennessee has wrought. In so doing, they are vindicating the stated purpose of the DDLA to undermine the sprawling illegal opioids market in their communities using civil liability.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment as follows:

1. Against the Defendants and in favor of the Plaintiffs for the amount of damages sustained by the Plaintiffs as a result of Defendants' breaches of law as described more fully in this Complaint;

2. Punitive damages against the Defendants, including, but not limited to, punitive damages for those acts or omissions which resulted in the Defendants, or any one of them, being convicted of a felony under state or federal law, and which acts or omissions caused the Plaintiffs' damages or injuries;

3. Under the DDLA, "[e]conomic damages, including, but not limited to: the cost of treatment and rehabilitation, medical expenses, loss of economic or educational potential, loss of productivity, absenteeism, support expenses, accidents or injury, and any other pecuniary loss proximately caused by the illegal drug use" described in this Complaint. Tenn. Code Ann. § 29-38-106(c)(1). In this case, in addition to these expenses, the Opioid Impacted Localities have incurred numerous structural costs, including, but not limited to, increased healthcare costs, the cost of increased police services, and the cost of increased incarceration services;

4. Under the DDLA, Plaintiffs are entitled to recover awards from all Defendants, including but not limited to the costs and disbursements of this action, reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses as provided by the common fund doctrine and other applicable law pursuant to Tenn. Code Ann. §29-38-106(c)(3) (4)-(5);

5. A permanent injunction against all Defendants prohibiting them from flooding the Tennessee markets, specifically those located in the Opioid Impacted Localities with illegal opioids;

6. Declaratory relief;

7. All other remedies and relief available under law;

8. Such other and further relief as the Court deems just and proper; and

9. As an *ad damnum*, Plaintiffs demand $25,000,000,000.00.

The Plaintiffs demand a trial by jury on all issues <u>except</u> attorney's fees and costs.

Filed on this the 11th day of March, 2022.

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