Nos. 22-1819(L) & 22-1822

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

CITY OF HUNTINGTON, WEST VIRGINIA and
CABELL COUNTY COMMISSION,
Plaintiffs-Appellants,

v.

AMERISOURCEBERGEN DRUG CORPORATION, *et al.*,
Defendants-Appellees.

On Appeals from the United States District Court
for the Southern District of West Virginia
Case Nos. 3:17-cv-01362 and 3:17-cv-01665, Hon. David A. Faber

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DISCLOSURE STATEMENT

- In civil, agency, bankruptcy, and mandamus cases, a disclosure statement must be filed by **all** parties, with the following exceptions: (1) the United States is not required to file a disclosure statement; (2) an indigent party is not required to file a disclosure statement; and (3) a state or local government is not required to file a disclosure statement in pro se cases. (All parties to the action in the district court are considered parties to a mandamus case.)
- In criminal and post-conviction cases, a corporate defendant must file a disclosure statement.
- In criminal cases, the United States must file a disclosure statement if there was an organizational victim of the alleged criminal activity. (See question 7.)
- Any corporate amicus curiae must file a disclosure statement.
- Counsel has a continuing duty to update the disclosure statement.

No. 22-1819 Caption: City of Huntington, WV v. AmerisourceBergen Drug Corp, et al.

Pursuant to FRAP 26.1 and Local Rule 26.1,

City of Huntington, WV
(name of party/amicus)

who is Appellant, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☐ YES ☑ NO

2. Does party/amicus have any parent corporations? ☐ YES ☑ NO
If yes, identify all parent corporations, including all generations of parent corporations:

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☐ YES ☑ NO
If yes, identify all such owners:

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation? ☐YES ☑NO
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question) ☐YES ☑NO
If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:

6. Does this case arise out of a bankruptcy proceeding? ☐YES ☑NO
If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.

7. Is this a criminal case in which there was an organizational victim? ☐YES ☑NO
If yes, the United States, absent good cause shown, must list (1) each organizational victim of the criminal activity and (2) if an organizational victim is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of victim, to the extent that information can be obtained through due diligence.

Signature: /s David C. Frederick Date: April 17, 2023

Counsel for: Appellant City of Huntington, WV

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DISCLOSURE STATEMENT

- In civil, agency, bankruptcy, and mandamus cases, a disclosure statement must be filed by **all** parties, with the following exceptions: (1) the United States is not required to file a disclosure statement; (2) an indigent party is not required to file a disclosure statement; and (3) a state or local government is not required to file a disclosure statement in pro se cases. (All parties to the action in the district court are considered parties to a mandamus case.)
- In criminal and post-conviction cases, a corporate defendant must file a disclosure statement.
- In criminal cases, the United States must file a disclosure statement if there was an organizational victim of the alleged criminal activity. (See question 7.)
- Any corporate amicus curiae must file a disclosure statement.
- Counsel has a continuing duty to update the disclosure statement.

No. 22-1822 Caption: Cabell County Commission v. AmerisourceBergen Drug Corp, et al.

Pursuant to FRAP 26.1 and Local Rule 26.1,

Cabell County Commission
(name of party/amicus)

who is Appellant, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☐ YES ☑ NO

2. Does party/amicus have any parent corporations? ☐ YES ☑ NO
If yes, identify all parent corporations, including all generations of parent corporations:

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☐ YES ☑ NO
If yes, identify all such owners:

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation? ☐YES ☑NO
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question) ☐YES ☑NO
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6. Does this case arise out of a bankruptcy proceeding? ☐YES ☑NO
If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.

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If yes, the United States, absent good cause shown, must list (1) each organizational victim of the criminal activity and (2) if an organizational victim is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of victim, to the extent that information can be obtained through due diligence.

Signature: /s David C. Frederick Date: April 17, 2023

Counsel for: Appellant Cabell County Commission

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INTRODUCTION

Cabell County, West Virginia, and its largest city, Huntington, are in the grip of an opioid epidemic. Addiction is widespread, fracturing families and gutting neighborhoods. In a population of 100,000, more than a thousand people have died from opioid overdoses. From 2001 to 2015, the opioid oxycodone was the leading cause of overdose deaths in West Virginia. Three companies—AmerisourceBergen Drug Corp., Cardinal Health, Inc., and McKesson Corp., Appellees here—provided 89% of the oxycodone shipped to Cabell/Huntington.

At trial, Cabell/Huntington proved Appellees' role in causing the multifaceted crisis of public health that continues to ravage Cabell/Huntington. Year after year, Appellees shipped millions of opioids to Cabell/Huntington pharmacies, far beyond any medically justifiable need—averaging more than 40 opioid pills per person in Cabell/Huntington annually for 20 years.

Federal and state law strictly regulate the distribution of controlled substances, including opioids. They require wholesale distributors like Appellees to identify suspicious orders of unusual size, frequency, or pattern. Distributors must investigate these orders before shipping them, obtaining explanations for the orders' unusual features from the ordering pharmacy and verifying those explanations. Yet Appellees let area pharmacies order increasingly vast quantities of opioids with little scrutiny and little justification beyond the fact that the

pharmacies already were selling opioids in large volumes. Violating their federal and state duties, Appellees interfered unreasonably with public health and safety in Cabell/Huntington, making them liable for public nuisance.

The district court concluded Appellees were not liable because it decided—contrary to regulatory text, other courts' decisions, and the Drug Enforcement Administration's longstanding position—that drug distributors bear only minimal duties to prevent diversion of controlled substances. According to the court, a distributor need only ensure that it does not supply "pharmacies that are essentially acting as adjuncts of the illicit market." JA6503. As long as its pharmacy customers are not wholly illegitimate, the court held, a distributor has no obligation to scrutinize its customers' orders or the doctors and patients they serve.

The district court's mistaken narrowing of distributors' duties caused it to make numerous other errors. The court ignored significant evidence that Appellees did not investigate the massive orders placed by their Cabell/Huntington pharmacy customers, which were supplying area doctors who egregiously overprescribed opioids. The court also decided that doctors, pharmacies, and third parties were intervening causes—absolving Appellees of liability—notwithstanding its own findings that Appellees met doctors' and pharmacies' demand for opioids with "almost perfect[]" precision. JA6468.

The district court's conviction that drug distributors should bear few duties and no liability for the opioid epidemic also led it to make doctrinal missteps. Worrying about floodgates of litigation, the court ruled that public nuisance claims concerning the distribution and sale of products are impermissible. This holding contradicted West Virginia courts that consistently have permitted West Virginia government plaintiffs like Appellants to bring identical public nuisance claims against Appellees and other opioid defendants. And the district court imposed limits on abatement, the traditional equitable remedy for public nuisance, that have no foundation in West Virginia law.

The district court's multiple errors compel reversal.

JURISDICTIONAL STATEMENT

The district court had subject-matter jurisdiction under 28 U.S.C. § 1332 because Huntington and Cabell County are citizens of West Virginia, all Defendants are citizens of other States, and the amount in controversy exceeds $75,000 exclusive of interest and costs. This Court has jurisdiction under 28 U.S.C. § 1291. The district court entered final judgment on July 4, 2022. JA6522. Huntington and Cabell County timely filed a joint notice of appeal on August 2, 2022. JA6523-6525.

STATEMENT OF THE ISSUES

1. Whether the district court erred in holding that West Virginia law does not permit a public nuisance claim concerning the harms a community suffered resulting from the distribution and sale of prescription opioids.

2. Whether the district court erred in holding that Appellees did not violate their duties under the federal and West Virginia Controlled Substances Acts and that therefore Appellees' conduct was reasonable for purposes of determining their public nuisance liability.

3. Whether the district court erred in holding that Appellees did not proximately cause the opioid-related harms constituting the nuisance in Cabell/Huntington because other causes—including doctors, pharmacists, and other third parties—were intervening causes.

4. Whether the district court erred in holding that the abatement remedy for a public nuisance claim under West Virginia law is limited to an order directing the defendant to cease its wrongful conduct.

STATEMENT OF THE CASE

A. Opioids Are Controlled Substances With High Abuse Potential

Prescription opioids are highly addictive narcotics. JA6434; JA2021 (Waller). The Drug Enforcement Administration ("DEA") classifies oxycodone,

hydrocodone, and other opioids as Schedule II substances, *see* 21 C.F.R. § 1308.12(b)(1), which the Controlled Substances Act ("CSA") reserves for drugs with a "currently accepted medical use" but a "high potential for abuse" that "may lead to severe psychological or physical dependence," 21 U.S.C. § 812(b)(2).

The more opioids a person takes over a longer period of time, the greater the risk of developing "opioid use disorder," also called addiction. JA2444-2446 (Keyes). Opioid users become physically dependent, and painful withdrawal symptoms make it extremely difficult to stop using opioids. JA2617 (Deer); JA2359 (O'Connell). Opioids also depress breathing, so overdose can be fatal. JA2069, JA2071 (Priddy); JA2075, JA2078 (Rader).

Common prescription opioids include oxycodone and hydrocodone; illicit opioids include heroin. JA2037-2041 (Waller). Oxycodone is at least 1.5 times as potent as morphine, similar in potency to heroin. JA2949, JA2981; JA2024-2025, JA2034 (Waller). All opioids, including heroin, are chemically similar, with the same biological mechanism and similar effects. JA6434; JA2026-2027, JA2030-2031 (Waller); JA3017. Addiction to one opioid can be satisfied by another opioid. JA2030-2031 (Waller) ("the brain doesn't know" the difference between

prescription opioids and heroin); JA3014, JA3017; JA2440-2441 (Keyes) (heroin and prescription opioids have "similar pharmacological properties").

B. Distributors Of Controlled Substances Have Important Diversion-Control Duties

1. The controlled-substance supply chain starts with manufacturers that sell to distributors. JA2268-2269 (Rafalski); JA2124-2126 (Zimmerman); JA2621 (MacDonald). The largest opioid distributors in the United States are Appellees AmerisourceBergen Drug Corporation ("ABDC"), Cardinal Health, Inc., and McKesson Corporation, with a combined market share above 90%. JA3283; JA2103-2104 (Zimmerman). Distributors ship prescription opioids to pharmacies, which dispense them to consumers with prescriptions. JA3150; JA2103-2104 (Zimmerman); JA2269 (Appellants' expert, former DEA investigator James Rafalski).

Because the "improper use of controlled substances ha[s] a substantial and detrimental effect on the health and general welfare of the American people," 21 U.S.C. § 801(2), they are tightly regulated at all stages of the supply chain. The CSA creates a "closed system" of distribution requiring all who manufacture, distribute, prescribe, or dispense controlled substances to register with DEA. JA3209, JA3213; JA2366-2370 (former DEA head of Diversion Control Joseph

Rannazzisi); *see* 21 U.S.C. § 823(d)-(g). These regulated entities, known as "registrants," must "provide effective controls and procedures to guard against . . . diversion of controlled substances." 21 C.F.R. § 1301.71(a). "Diversion" means diversion of controlled substances "into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1). "[D]iversion is foreseeable if registrants fail to comply." JA1262-1263 (DEA Rule 30(b)(6) witness Thomas Prevoznik); JA2373 (Rannazzisi) ("A breakdown of the system will cause diversion.").

Diversion can take multiple forms: excessive prescribing; consumers "doctor shopping" for multiple prescriptions; forging prescriptions; consumers selling or giving away their medications; acquaintances stealing drugs (so-called "medicine cabinet" diversion); and illegal trafficking. JA1324-1325, JA1329-1330 (Prevoznik); JA2307 (Rafalski); JA2363, JA2397-2398 (Rannazzisi); JA2188 (Mone); JA3150; JA3070.

The controlled-substance supply chain is made up of millions of registrants and transactions, and DEA's investigative resources are limited. JA1258 (Prevoznik) (1,500 DEA staff to monitor 1.73 million registrants). The CSA's

regulatory scheme therefore relies on registrants to detect and prevent diversion. JA2370-2372 (Rannazzisi); JA1325-1326 (Prevoznik); JA3205-3216 (2012 DEA guidance letter). In 2008, the distributors' trade association recognized that, being "[a]t the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence . . . to help support the security of the controlled substances they deliver to their customers." JA3263. DEA agreed. JA1300-1301 (Prevoznik). As a "choke point" in the supply chain, JA3235, distributors efficiently could stop flows of controlled substances to suspicious purchasers.

2. The requirement to maintain "effective controls" against diversion, 21 C.F.R. § 1301.71(a), imposes three primary duties on distributors. The D.C. Circuit, interpreting the CSA and federal regulations, has held that distributors must identify, report, and investigate, or else decline to ship, suspicious orders placed by pharmacies for controlled substances. *See Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 212-13 (D.C. Cir. 2017). The court presiding over the opioid MDL adopted that interpretation. *See In re National Prescription Opiate Litig.*, 2019 WL 3917575, at *7 (N.D. Ohio Aug. 19, 2019) ("*MDL CSA Ruling*") (Polster, J.).

"Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).[1]

First, the duty to *identify* suspicious orders requires distributors to "design and operate a system to disclose to the [distributor] suspicious orders" of controlled substances. *Id.*; *see Masters*, 861 F.3d at 212; *MDL CSA Ruling*, 2019 WL 3917575, at *7. That duty requires "sorting suspicious from non-suspicious orders," *Masters*, 861 F.3d at 217, and identifying orders of unusual size, pattern, or frequency.

Second, the duty to *report* suspicious orders requires distributors to "inform [DEA] of suspicious orders *when discovered by the registrant*"—that is, when the distributor detects them. 21 C.F.R. § 1301.74(b) (emphasis added). These reports enable DEA investigators "to ferret out 'potential illegal activity.'" *Masters*, 861 F.3d at 212 (quoting *Southwood Pharms., Inc.*, 72 Fed. Reg. 36,487, 36,501 (DEA July 3, 2007)).

Third, the CSA's "basic requirement . . . not to ship a dubious order bearing indicia that the drugs could be diverted to illegal channels," *MDL CSA Ruling*, 2019 WL 3917575, at *9, requires a distributor that has identified a suspicious order to "make one of two choices: decline to ship the order, or conduct some

[1] The parallel West Virginia Controlled Substances Act and regulations impose the same duties. *See* W.Va. C.S.R. § 15-2-2 (2017), *superseded by* W.Va. C.S.R. § 15-2-3 (adopting federal regulations by reference).

'due diligence' . . . to determine that the order is not likely to be diverted into illegal channels," *Masters*, 861 F.3d at 212-13 (quoting *Southwood*, 72 Fed. Reg. at 36,500); *see also id.* at 222 (same); *City & Cnty. of San Francisco v. Purdue Pharma L.P.*, 491 F. Supp. 3d 610, 632 (N.D. Cal. 2020) (same). Distributors may not ship suspicious orders "unless due diligence reasonably dispels the suspicion." *MDL CSA Ruling*, 2019 WL 3917575, at *9.

Due diligence requires distributors to "investigate held orders," "obtain an[] explanation" from the ordering pharmacy, and "verif[y] that explanation." *Masters*, 861 F.3d at 217-19. All available information that "could [be] used . . . to identify suspicious orders is relevant," including information concerning "downstream transactions of its customers' customers"—that is, the prescriptions filled at the pharmacy. *MDL CSA Ruling*, 2019 WL 3917575, at *12 n.21. DEA told distributors in 2007 to consider "the patterns of the registrant's customer base." JA3462. Its Rule 30(b)(6) witness, Thomas Prevoznik, testified that distributors also should take into account "a geographic area's problem with controlled substance abuse." JA1322.

DEA enforces these duties by issuing orders to show cause to registrants, alleging facts supporting findings of violations. *See* 21 C.F.R. § 1301.37. It also may immediately suspend a registrant's operations if it finds that they pose "an imminent danger to the public health or safety." *Id.* § 1301.36(e).

C. Cabell/Huntington Are "Ground Zero" Of The Opioid Epidemic

1. West Virginia is "'ground zero,'" "the hardest-hit state in the country" for the nationwide opioid epidemic, and Cabell/Huntington are among the "hardest hit" West Virginia communities. JA6356.[2] "The opioid crisis has taken a considerable toll on the citizens of Cabell County and . . . Huntington." JA6520. As of 2017, more than 10% of Huntington residents had been or currently were addicted to opioids. JA6357. In 2017, Huntington's fatal overdose rate was 213.9 per 100,000 people per year, 14 times the national rate (15 per 100,000). JA3073; JA2449-2452 (Keyes). From 2001 to 2018, the opioid epidemic contributed to 1,002 deaths in Cabell/Huntington. JA2425 (Smith). Prescription opioids remain "an ongoing and significant cause" of Cabell/Huntington overdose deaths. JA6360.

The effects on Cabell/Huntington and its resources are wide-ranging. Up to 10% of newborns in Huntington are born with neonatal abstinence syndrome due to pregnant mothers' opioid use; Huntington hospitals must care for those newborns as they experience withdrawal. JA6357. In 2016, the rate for neonatal

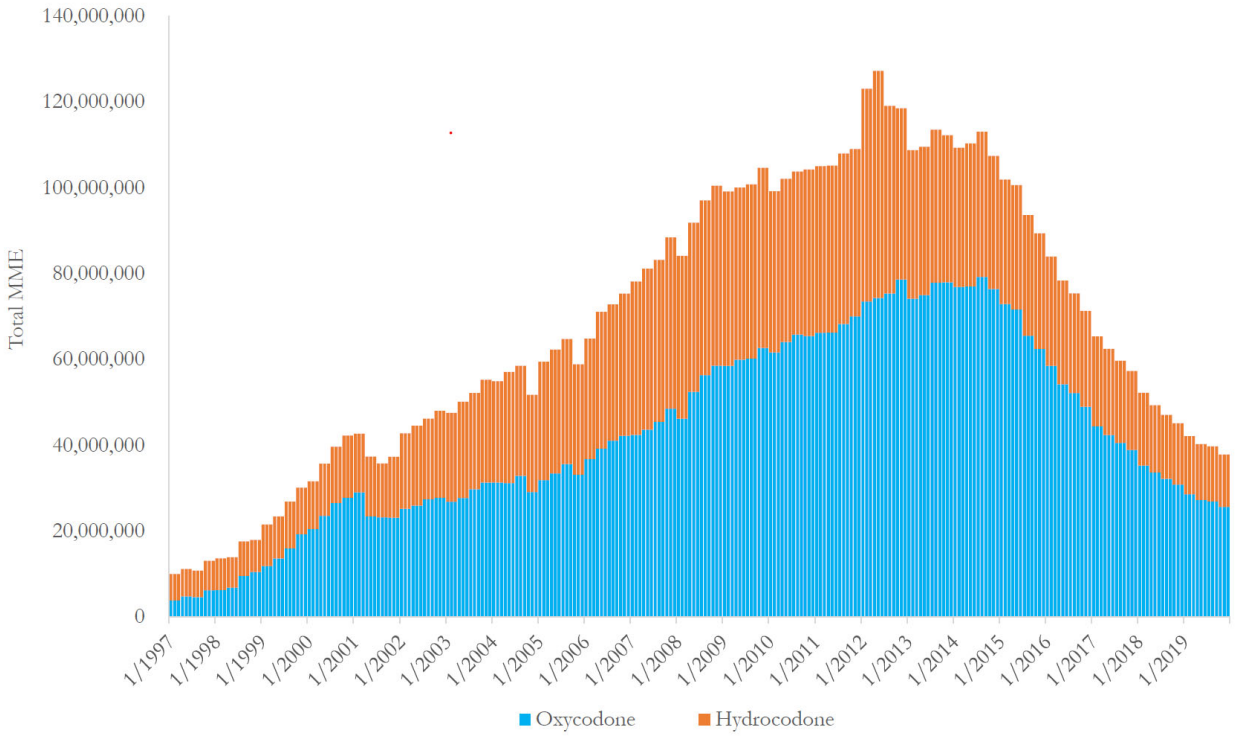
[2] Huntington is mostly within Cabell County. JA5476 (map). It is the second-largest city in West Virginia, with a population of approximately 50,000. The combined Cabell/Huntington population is approximately 100,000. JA2099 (McCann).

abstinence syndrome in Cabell was nine times the national rate. JA2452-2453 (Keyes).

Crime increased, with drug offenses that occurred in "only a small area of Huntington" in 2004 "engulf[ing] every neighborhood" by 2016. JA6360. Placements into foster care doubled, most due to parental substance abuse. JA6358. Infectious diseases—including HIV, Hepatitis B, and Hepatitis C—spread rapidly. JA6358-6359. Neighborhoods hollowed out. *See* JA2355 (Zerkle) ("[Y]ou drive through some of these neighborhoods and they're just burnt out, tore up houses."); *id.* (hundreds of abandoned houses in Huntington). At one time, Cabell/Huntington had "a great workforce"; now, they have "an addicted workforce" that "can't pass a drug test." JA2354 (Zerkle).

2. West Virginia, Cabell, and Huntington did not always have an epidemic of opioid addiction. Historically, opioid abuse was far rarer. JA3016 (Appalachia "historically did not have much illicit opioid trade"); JA2428-2429 (Smith) (overdose rate grew 13-fold from 2001 to 2018). Before 2000, the fatal overdose rate was below the national average. JA2048 (Gupta); JA2065 (Gupta).

In the late 1990s, the volume of prescription opioids shipped to West Virginia increased dramatically:



JA5474.[3] By 2006, prescription opioids were the most abused prescription drug in Appalachia and the most common cause of drug overdoses. JA3026. Because oxycodone is so potent, and common forms could be snorted or injected, it became especially widely abused. JA2949, JA2954-2955; JA3070; JA3016. Oxycodone was the leading cause of overdose deaths in West Virginia from 2001 to 2015. JA4898.

[3] The chart shows the volume of oxycodone and hydrocodone in terms of the milligram morphine equivalent ("MME")—a measure that weights volume by potency compared to morphine—to account for oxycodone's greater potency.

Around 2014, under increasing DEA enforcement and public scrutiny, the prescription opioid supply began contracting, and people with opioid addiction turned to illicit opioids like heroin. JA2044 (Waller); JA3017; JA2525-2526 (Holbrook); JA4926. The portion of drug abuse cases in Huntington due to heroin and fentanyl soon grew from 10% to 60-70%. JA2350-2351 (Zerkle). But prescription opioids remained the primary driver of addiction: in 2018, more than 7,100 cases of opioid use disorder in Cabell/Huntington were due to prescription opioids. JA2479 (Keyes); *see also* JA2433-2438 (Keyes) ("prescription opioid use was by far the strongest risk factor for transition to heroin").

D. Appellees Shipped Significant Quantities Of Opioids To Cabell/Huntington Without Identifying Or Blocking Suspicious Orders

1. Appellees shipped more than 80 million opioid pills to Cabell/Huntington between 1997 and 2018

From 1997 to 2018, Appellees shipped at least 81.2 million dosage units of opioids to Cabell/Huntington. JA2082-2085 (McCann); JA5485, JA5488, JA5491. That is more than 40 pills per person every year for 20 years. The true number likely is higher, because ABDC and McKesson produced data going back to only 2002 and 2004, respectively. JA2084 (McCann); JA5485, JA5491.

Cabell/Huntington were inundated with opioids, out of proportion to the rest of the country. From 2006 to 2014—when data is complete—all distributors combined shipped 109.8 million dosage units of oxycodone and hydrocodone to Cabell/Huntington, triple the per-capita rate of shipments to the United States as a whole. JA5470 (122.1 units per person per year in Cabell/Huntington, versus 39.9 nationwide). Appellees—not other distributors—shipped most of these opioids: 51% of all the hydrocodone and 89% of all the oxycodone. JA5494. Appellees thus sold nearly all the oxycodone to Cabell/Huntington that was the State's leading cause of overdose death from 2001 to 2015.

2. Appellees did not identify or block shipments of suspicious orders of opioids, leading to DEA enforcement

Throughout the 2000s and 2010s, Appellees identified suspicious orders by applying numerical thresholds to their pharmacy customers' orders of controlled substances, flagging orders as suspicious that exceeded the thresholds. For years, these thresholds were multipliers of ordering averages that increased as opioid sales grew, allowing pharmacies to order increasing quantities without being flagged.

Before 2007, ABDC's default thresholds permitted a pharmacy to order up to three times the average amount of a drug it had ordered over the prior four months. JA6371. A pharmacy averaging 10,000 oxycodone units per month could

order up to 30,000 units the next month without the order being flagged as suspicious. JA2114-2118 (Zimmerman). Cardinal's thresholds were four times the average order of pharmacies served by the same distribution center. JA3616-3941; JA2272-2274 (Rafalski). McKesson's thresholds were three times the customer's monthly average. JA6390-6391; JA2670-2671.

When Appellees' systems flagged orders as suspicious, Appellees did not investigate before shipping them. ABDC admitted that "from '98 to '07 we would identify a suspicious order and ship it." JA2131 (Zimmerman); JA2149 (Mays). Cardinal and McKesson did the same. JA1215-1217 (Reardon); JA2231, JA2240 (Oriente); JA1197 (Hartle). Appellees also shipped orders before reporting them, only later submitting bulk reports to DEA. JA2114, JA2121 (Zimmerman) (ABDC); JA1215-1217 (Reardon) (Cardinal); JA3341, JA3346 (McKesson).

In 2005, DEA met with Appellees to convey the rising problem of opioid diversion. JA2375-2376, JA2379 (Rannazzisi); JA3544-3561. DEA reminded Appellees that federal law required them not only to *report* suspicious orders but also to "make a sales decision" about each order. JA3552-3553. DEA also sent letters reiterating these duties. JA3460-3471. The first, in September 2006, highlighted the "serious and growing health problem" of prescription drug abuse,

stressing distributors' "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate . . . channels." JA3468-3469.

DEA subsequently took enforcement action against Appellees. In 2006 and 2007, DEA issued show-cause orders alleging that McKesson failed to maintain effective diversion controls at its Florida and Maryland distribution centers, JA4852, and alleged violations at McKesson facilities in Texas and Colorado, JA4852-4853. In 2007, DEA issued an order immediately suspending an ABDC distribution center in Florida. JA3217; JA2386 (Rannazzisi). DEA alleged that ABDC knew or should have known its pharmacy customers were diverting opioids because their orders "far exceeded what an average pharmacy orders to meet the legitimate needs of its customers." JA3217-3218. In 2007 and 2008, DEA issued immediate suspension orders to four Cardinal distribution centers across the country, alleging Cardinal had supplied significant quantities of hydrocodone to pharmacies that it knew or should have known were diverting them. JA3506-3526.

Appellees used consistent policies and practices at their distribution centers, including those supplying Cabell/Huntington. JA2107 (Zimmerman); JA1220-1221 (Reardon); JA1229-1230 (Walker); JA2216-2217 (Oriente). Appellees

resolved the enforcement actions by settlement, agreeing to improve diversion controls throughout their nationwide operations. ABDC pledged to review orders flagged as suspicious and ship them only if it determined they were "legitimate following diligent review." JA3280; JA3194. McKesson agreed to pay $13.25 million. JA4854-4856. Establishing new monthly limits for oxycodone and hydrocodone, McKesson pledged to ship orders exceeding those limits only after completing "a due diligence review." JA4877-4878. Cardinal agreed to pay $34 million, JA3491-3504, and committed to ship orders flagged as suspicious only if investigation first cleared the suspicion, JA2183-2185 (Mone).

Following the settlements, each Appellee adopted new policies and changed its methods for setting thresholds that flagged orders for further review. JA6376-6377, JA6384-6387, JA6393-6394; JA2135-2136, JA2139-2141 (Mays) (ABDC); JA2181-2182 (Mone) (Cardinal); JA2243-2245 (Oriente) (McKesson).

Yet under the revised policies, Appellees could—and did—increase thresholds for specific customers, allowing them to order more and more opioids without triggering review. *See infra* Part II.A.2. McKesson employees, for instance, described threshold increases as "almost automatic," "too easily accept[ed]," and sometimes done without even a customer's request. JA3568;

JA3222; JA5448-5451. ABDC used *sales staff* to report problems with the pharmacy customers they served, while compensating those employees based on how many opioids they sold. JA2145 (Mays); JA1210-1213 (Elkins); JA2153-2154 (Perry). Cardinal assigned diligence responsibilities to sales staff, typically hired "right out of college" with their "real duty" being sales. JA4723-4726; JA2206 (Kave); JA1225-1227 (Lawrence).

Appellees warned customers when they were nearing their thresholds, enabling them to avoid triggering review. ABDC gave threshold warnings to Walgreens "to prevent having a bunch of orders reported to the DEA and held." JA1205-1208 (Hazewski). McKesson did the same from 2008 to 2013, so that "work could begin on justifying an increase in threshold prior to any lost sales." JA3226; JA2249-2251 (Oriente); JA3454; JA3607.

McKesson also applied special policies to chain-pharmacy customers, the bulk of its business. JA1202-1203 (Hartle); JA2226-2227 (Oriente); JA5489. McKesson did not assess threshold increases or perform due diligence on those customers, instead letting the chains police themselves, without asking many questions. JA3569; JA3564; *Huntington* ECF No. 1490-30, at 65-66, 73-74

(Walker) (McKesson generally did not conduct site visits at chain pharmacies and was "never made privy to the specifics of their [diversion-control] programs").

After several years, DEA took enforcement action again. In 2012, it issued an immediate suspension order alleging that Cardinal's Lakeland, Florida distribution center distributed "egregious quantities" of opioids while "fail[ing] to conduct meaningful due diligence." JA3485-3487; JA2389-2390 (Rannazzisi). Joseph Rannazzisi, who signed the order as head of DEA's Office of Diversion Control, testified that the allegations reflected "systemic failure," with the same problems "happening elsewhere as well." JA2390-2394. Cardinal settled, admitting that "its due diligence efforts" were "inadequate." JA3474.[4]

In 2014, DEA warned McKesson that it "remain[ed] concerned that McKesson fail[ed] to appreciate the serious and systemic nature of the CSA-related problems that DEA has observed in its several investigations into [McKesson's] operations." JA3229. In 2017, McKesson agreed to pay $150 million to resolve alleged CSA violations at 12 of its distribution centers, including its facility supplying Cabell/Huntington. JA5434-5447.

[4] In 2016, Cardinal admitted additional failures to identify and report suspicious orders at its Florida distribution center between 2009 and 2012, agreeing to pay $34 million. JA3305, JA3307.

E. Evidence That Cabell/Huntington Can Abate The Opioid Epidemic

The oversupply of opioids causes widespread addiction, diversion, and related effects such as opioid-related crime and overdoses. JA1263 (Prevoznik); JA2373 (Rannazzisi). Existing measures are insufficient to address these harms in Cabell/Huntington, but they can be addressed with additional measures. JA2540-2544, JA2574-2575 (Alexander). Epidemiologist Dr. Caleb Alexander, Cabell/Huntington's expert on abating the opioid epidemic, testified it would take 15 years to do so using four measures. JA2530, JA2533-2534, JA2571, JA2585-2601 (Alexander):

Prevention. Preventing new cases of opioid use disorder and further diversion is a key step. JA2544-2546, JA2549-2550 (Alexander). Prevention programs have proven effective at reducing opioid-related harms. JA2550 (Alexander).

Treatment. Treating people with opioid use disorder reduces the risk of death, homelessness, unemployment, and other harms. JA2552-2553, JA2555-2556 Alexander). Treatment includes inpatient and outpatient models and connecting individuals with opioid use disorder to treatment. JA2551-2556 (Alexander). Such measures can decrease mortality risks by as much as 50%. JA2557 (Alexander).

Recovery. Drug courts, vocational training, and mental health counseling reduce opioid-related crime. JA2537, JA2550 (Alexander). Dr. Alexander testified to their effectiveness: for example, 82% of Cabell drug-court graduates did not re-offend in the next 12 months. JA2560-2561 (Alexander).

Special Populations. Interventions aimed at pregnant women, new mothers, post-incarcerated individuals, and children and families affected by the epidemic are necessary. The efficacy of these interventions is "well supported by the scientific and public health evidence." JA2561, JA2564-2565 (Alexander).

Abating the opioid epidemic in Cabell/Huntington will cost $2,544,446,548 in future value, or $1,890,000,000 in present value (as of September 1, 2021). JA2609, JA2612-2613 (Barrett).

F. Procedural History

1. Huntington and Cabell filed these suits on January 19, 2017, and March 9, 2017, respectively. JA836-919; JA920-1179. The Judicial Panel on Multidistrict Litigation transferred both suits to the Northern District of Ohio under 28 U.S.C. § 1407(a), along with thousands of suits brought by municipalities against manufacturers, distributors, and dispensers of opioids. *See In re National*

Prescription Opiate Litig., MDL No. 2804 (N.D. Ohio); JA1180-1187; JA1188-1195. On December 31, 2018, the MDL court designated the Cabell/Huntington suits as "Track Two" bellwether cases. JA1222-1223. On August 19, 2019, the MDL court issued its decision determining distributors' duties under the CSA. *See MDL CSA Ruling*, 2019 WL 3917575, at *7; *supra* pp. 9-10.

The "Track One" bellwether cases, brought by two Ohio counties against Appellees and opioid manufacturers, settled on the eve of trial in 2019. JA1872. The MDL court then directed Cabell and Huntington to streamline their cases to serve as bellwethers with "a practicable, triable number of defendants" and limited legal theories. JA1873-1875. Cabell/Huntington pursued only public nuisance claims against Appellees. JA1878-1881, JA1882, JA1883-1886. The suits were remanded on January 14, 2020, JA1887-1888, and consolidated for trial on February 7, 2020, JA1900-1902.

Before trial, Appellants twice sought rulings from the district court confirming it would adhere to the MDL court's interpretation of distributors' CSA duties. JA1903-1904 (Mar. 3, 2020); JA1958-1960 (Sept. 22, 2020). The court summarily denied the motions before trial, stating that the "reasons [would] be

placed on the record forthwith." JA2001-2002, JA2011. It did not subsequently provide reasoning for either ruling.

2. Trial ran from May 3, 2021, to July 28, 2021.[5] The district court issued its decision on July 4, 2022. It found there was a two-decade-long opioid epidemic in Cabell/Huntington that caused widespread harms. JA6356-6360; *see supra* pp. 11-14. The court nevertheless ruled for Appellees on four grounds at issue here.

Applicability of public nuisance. The court held that "the sale, distribution, and manufacture of opioids" is not actionable under public nuisance law. JA6488-6496. It held that public nuisance claims are limited to "conduct that interferes with public property or resources" and cannot address "distribution or sale of a product." JA6490-6491.

Interference with a public right. The court held that Appellees complied with their CSA duties. It limited the "diversion" that distributors must "guard against" to "handing over pills to pharmacies that are essentially acting as adjuncts of the illicit market" and found no evidence that Appellees' pharmacy customers in Cabell/Huntington were such wholly illegitimate operations. JA6502-6503, JA6508-6509. Weighing "the gravity and avoidability of the harm" to

[5] The month after trial, Appellees entered into a nationwide settlement (excluding West Virginia). JA5670-5689.

Cabell/Huntington against "the social utility of the defendants' conduct" in distributing opioids, the court held Appellees had not unreasonably interfered with a public right. JA6496-6498.

Causation. The court reasoned that "overprescribing by doctors, dispensing by pharmacists of the excessive prescriptions, and diversion of the drugs to illegal usage" were "intervening causes beyond the control of defendants," and therefore "oversupply" by Appellees did not proximately cause the opioid epidemic. JA6515.

Abatement. The court held that an abatement remedy was unavailable because the nuisance subject to abatement was only the wrongful "conduct," not the resulting harmful "condition," JA6515-6516, JA6519-6520, and the remedy Appellants sought constituted damages, not abatement, JA6518.

Cabell County and Huntington timely appealed. JA6523-6525.

SUMMARY OF ARGUMENT

I. Under West Virginia law, public nuisance is a claim that can address various conditions harmful to public health and safety. Even otherwise-lawful business activities can create nuisances when conducted in a manner that harms the public. West Virginia courts have permitted governmental plaintiffs to bring public nuisance claims just like these, including against Appellees.

The district court departed from those cases and held that a public nuisance claim is unavailable, violating the rule that, when federal courts sit in diversity, the outcome "'should be substantially the same, so far as legal rules determine the outcome of a litigation, as it would be if tried in a State court.'" *Ferens v. John Deere Co.*, 494 U.S. 516, 524 (1990) (quoting *Guarantee Tr. Co. v. York*, 326 U.S. 99, 109 (1945)). Holding that West Virginia law does not allow public nuisance claims concerning the distribution and sale of products, the court imposed limits that West Virginia precedent does not recognize; rejected or ignored West Virginia decisions allowing equivalent public nuisance claims; and followed a minority of out-of-state cases.

Under the correct law, Appellants proved a public nuisance: the undisputed opioid epidemic in Cabell/Huntington, involving addiction, death, infectious disease, and other harms that resemble—indeed, exceed—the harms held to constitute public nuisances.

II. West Virginia's test of a public nuisance is an act's or condition's "reasonableness or unreasonableness . . . in relation to the particular locality involved." *Duff v. Morgantown Energy Assocs.*, 421 S.E.2d 253, 257 (W.Va. 1992). Unlawful conduct harming the general public can be unreasonable and give rise to a nuisance claim.

A. The evidence established that Appellees violated their duties under the federal and West Virginia Controlled Substances Acts by failing to identify and investigate suspicious orders from their Cabell/Huntington customers. For years, Appellees concededly did not investigate any order flagged as suspicious before shipping it. Following DEA enforcement in 2007-2008, Appellees pledged to comply. But they shipped ever-larger orders of opioids to Cabell/Huntington without conducting the due diligence necessary to dispel suspicion from these orders. Appellees kept raising thresholds, allowing pharmacies to order vast quantities without triggering review. As a result, Appellees supplied opioids to Cabell/Huntington pharmacies that served doctors engaged in egregious overprescribing.

B. The district court's conclusion that Appellees complied with their duties was error. Contrary to regulations and precedent focusing on suspicious *orders*, the court held that distributors need only ensure they do not supply wholly illegitimate *pharmacies* acting as adjuncts to the illicit market. Beyond that low

bar, the court held that distributors have no obligation to scrutinize or block their customers' orders.

That erroneous holding led the district court to err further in concluding that Appellees complied with those duties. It ignored or dismissed extensive evidence that Appellees repeatedly increased thresholds for their top Cabell/Huntington customers and failed to investigate their orders. The court ignored DEA enforcement actions against Appellees and their admissions of wrongdoing.

C. Because the district court misinterpreted the CSA, its attempt to assess the reasonableness of Appellees' conduct necessarily fails. The court also mistakenly applied West Virginia's *private* nuisance test; incorrectly held that lawful conduct cannot constitute a nuisance; and considered only the good-faith prescribing decisions of doctors, ignoring the outlier overprescribers Appellees enabled.

III. West Virginia law imposes liability on "all persons who join or participate in the creation or maintenance of a nuisance." *West v. National Mines Corp.*, 285 S.E.2d 670, 678 (W.Va. 1981). The record evidence established that Appellees supplied extreme quantities of opioids to Cabell/Huntington and failed to maintain diversion controls despite knowing that diversion was the foreseeable result of their failures. That makes Appellees a proximate cause of the nuisance:

"one of the efficient causes thereof, without which the injury would not have resulted." *Wehner v. Weinstein*, 444 S.E.2d 27, 33 (W.Va. 1994).

Concluding otherwise, the district court misapplied West Virginia's intervening-cause standard, never considering whether the purported intervening causes—overprescribing, overdispensing, and diversion—were *concurrent* causes together with Appellees' oversupply of opioids. It also failed to consider whether the purported intervening causes were foreseeable, despite extensive evidence that they were.

IV. Finally, the district court erred by rejecting Appellants' requested remedy of abatement. West Virginia law authorizes ordering defendants to remediate harmful conditions constituting the nuisance, including by paying money to abate the nuisance. The court erroneously held that nuisances consist of conduct, not conditions, limiting abatement remedies to orders directing defendants to cease wrongful conduct. And it mischaracterized Appellants' requested remedy as damages. Appellants seek money for future services to eliminate the present harmful conditions in their communities, not compensation for their expenditures.

STANDARD OF REVIEW

This Court reviews the district court's conclusions of law following a bench trial de novo and its factual findings for clear error. *See Butts v. United States*, 930 F.3d 234, 238 (4th Cir. 2019). This Court may reverse factual findings that are "derived under an incorrect legal standard" or that are unsupported by substantial evidence, ignore substantial evidence, or are contrary to the clear weight of the evidence. *Heyer v. U.S. Bureau of Prisons*, 984 F.3d 347, 355 (4th Cir. 2021). This Court "owe[s] no deference" to findings "derived as a result of the court's misapplication of the law." *Sara Lee Corp. v. Kayser-Roth Corp.*, 81 F.3d 455, 460 (4th Cir. 1996). When the factual record is sufficiently clear under the correct legal standard, this Court can resolve issues without remand to the district court. *See Pullman-Standard v. Swint*, 456 U.S. 273, 292 (1982); *North Carolina State Conf. of NAACP v. McCrory*, 831 F.3d 204, 234-35 (4th Cir. 2016).

ARGUMENT

I. THE DISTRICT COURT ERRED IN HOLDING THAT WEST VIRGINIA PUBLIC NUISANCE LAW DOES NOT APPLY TO THE DISTRIBUTION AND SALE OF OPIOIDS

A. West Virginia Permits Public Nuisance Claims Concerning Opioids

1. Public nuisance addresses conditions that harm public health and safety

West Virginia defines a public nuisance as "'an act or condition that unlawfully operates to hurt or inconvenience an indefinite number of persons.'" *State ex rel. Smith v. Kermit Lumber Co.*, 488 S.E.2d 901, 921 (W.Va. 1997) (quoting *Sharon Steel Corp. v. City of Fairmont*, 334 S.E.2d 616, 620 (W.Va. 1985)). The Restatement (Second) of Torts (1979) ("Restatement (Second)") similarly defines a public nuisance as "'an unreasonable interference with a right common to the general public.'" *Duff*, 421 S.E.2d at 257 n.6 (quoting Restatement (Second) § 821B(1)); *accord* W. Page Keeton et al., *Prosser and Keeton on the Law of Torts* § 90 (5th ed. 1984) (*cited in Sharon Steel*); 58 Am. Jur. 2d *Nuisances* § 26 (2012) (same). "A public nuisance action usually seeks to have some harm which affects the public health and safety abated." *Kermit Lumber*, 488 S.E.2d at 925. Whether an act or condition constitutes a public nuisance depends on its "'reasonableness or unreasonableness'" in "'relation to the particular locality involved.'" *Duff*, 421 S.E.2d at 257 (quoting *Sharon Steel*, 334 S.E.2d at 626).

"[A] business lawful in itself" may be a nuisance. *Id.* "Even in as useful and important industry as the mining of coal, an incidental consequence . . . cannot be justified or permitted unqualifiedly, if the health of the public is impaired thereby." *Board of Comm'rs of Ohio Cnty. v. Elm Grove Mining Co.*, 9 S.E.2d 813, 817 (W.Va. 1940) (affirming abatement decree); *see also Taylor v. Culloden Pub. Serv. Dist.*, 591 S.E.2d 197, 207 (W.Va. 2003) ("providing a service that has societal benefits does not give a corporate entity license to freely pollute the waters of this State").

Understanding nuisance as "a flexible area of the law that is adaptable to a wide variety of factual situations," the West Virginia Supreme Court of Appeals ("WVSCA") has applied it to the manufacture and distribution of products. *See Sharon Steel*, 334 S.E.2d at 621 (hazardous waste generated at a coking plant); *see also Kermit Lumber*, 488 S.E.2d at 921-22 (hazards generated in the process of treating lumber). The WVSCA applied public nuisance law to "commodities of essential, if not primary, importance"—powder and nitroglycerine—because their manufacture was "dangerous" to a nearby town and railroads. *Wilson v. Phoenix Powder*, 21 S.E. 1035, 1035-36 (W.Va. 1895).

2. West Virginia courts allow public nuisance claims concerning opioids

When ruling on state law in a diversity case, "'the outcome of the litigation in the federal court should be substantially the same, so far as legal rules determine

the outcome of a litigation, as it would be if tried in a State court.'" *Ferens*, 494 U.S. at 524 (quoting *Guarantee Tr.*, 326 U.S. at 109). West Virginia courts repeatedly allowed government entities to bring public nuisance claims concerning opioids, and the WVSCA declined petitions for writs regarding those rulings.[6] These decisions guide the federal court's analysis. *See Wells v. Liddy*, 186 F.3d 505, 528 (4th Cir. 1999) ("To forecast a decision of the state's highest court we can consider . . . the state's trial court decisions.").

In 2014, a West Virginia court refused to dismiss the State's public nuisance claims against Appellees for their role in the opioid epidemic. *See State ex rel. Morrisey v. AmerisourceBergen Drug Corp.*, 2014 WL 12814021, at *8-9 & n.9 (W.Va. Cir. Ct. Dec. 12, 2014). The WVSCA declined review. *See State ex rel. AmerisourceBergen Drug Corp. v. Thompson*, No. 15-1026 (W.Va. Jan. 5, 2016) (Add.215-216). In 2018, another West Virginia court followed *Morrisey*, denying opioid defendants' motion to dismiss public nuisance claims. *See Brooke Cnty. Comm'n v. Purdue Pharma L.P.*, 2018 WL 11242293 (W.Va. Cir. Ct. Dec. 28, 2018) (Hummel, J.). The WVSCA again denied review. *See State ex rel. Cardinal Health, Inc. v. Hummel*, No. 19-0210 (W.Va. June 4, 2019) (Add.217-218).

[6] West Virginia permits parties in pending cases to petition for writs of prohibition when a trial court "exceeds its legitimate powers." *State ex rel. AmerisourceBergen Drug Corp. v. Moats*, 859 S.E.2d 374, 382 (W.Va. 2021) (citing W.Va. Code § 53-1-1).

The West Virginia Mass Litigation Panel ("MLP"), composed of seven judges appointed by the Chief Justice, is handling more than 80 opioid cases brought by West Virginia government entities. *See Moats*, 859 S.E.2d at 379. Calling *Brooke County* "well-founded," it denied opioid manufacturers' motion to dismiss public nuisance claims, and the WVSCA declined review. Order at 3, *Monongalia Cnty. Comm'n v. Purdue Pharma L.P.* (W.Va. M.L.P. Oct. 31, 2019) (Add.219-222), *writ denied*, *State ex rel. AmerisourceBergen Drug Corp. v. Moats*, No. 19-1051 (W.Va. Jan. 30, 2020) (Add.223); *see also* Am. Order Regarding Pretrial Rulings at 4, *In re Opioid Litig.* (W.Va. M.L.P. May 23, 2022) (Add.224-261) (denying summary judgment on public nuisance).

The MLP denied opioid distributors' similar summary-judgment motions. *See* Order Denying Defs.' MSJ re "Factual Issue #2," *In re Opioid Litig.* (W.Va. M.L.P. July 1, 2022) (Add.262-270) ("*MLP SJ Opinion*"). It held that "West Virginia public nuisance law encompasses [governmental plaintiffs'] opioid claims," citing West Virginia decisions, the WVSCA's repeated writ denials, the MDL court's rulings, and rulings in 22 other States. *See id.* at 2 & n.1, 6.

After the decision in this case, the MLP again declined to dismiss public nuisance claims. *See* Order Denying Pharmacy Defs.' Mots. To Dismiss at 26-35, *In re Opioid Litig.* (W.Va. M.L.P. Aug. 3, 2022) (Add.271-309) ("*MLP Pharm MTD Order*"). It declined to follow the district court, explaining that the

"placement of an artificial external constraint on the common law cause of action for public nuisance is inconsistent" with the WVSCA's flexible conception of public nuisance. *Id.* ¶ 70. The WVSCA denied review. *See State ex rel. CVS Pharmacy, Inc. v. Moats*, No. 22-635 (W.Va. Sept. 8, 2022) (Add.310-311); *see also* Order Denying Defs.' Mots. To Dismiss ¶ 21, *City of Beckley v. Allergan PLC*, No. 20-C-34 MSH (W.Va. Cir. Ct. Oct. 18, 2022) (Moats, J.) (Add.312-322) (denying pharmacies' motions to dismiss and characterizing decision in this case as "neither predictive nor consistent with West Virginia law on public nuisance").

West Virginia's public nuisance decisions accord with most other jurisdictions. Courts in 24 States have held that public nuisance law reaches the distribution and sale of opioids.[7] Many, like West Virginia's courts, grounded

[7] *See Alabama v. Purdue Pharma*, slip op. 11-12 (Ala. Cir. Ct. 2019) (Add.1-25); *Alaska v. McKesson*, slip op. 4-7 (Alaska Super. Ct. 2019) (Add.26-41); *City of Surprise v. Allergan*, slip op. 34-36 (Ariz. Super. Ct. 2020) (Add.42-89); *Arkansas v. Purdue Pharma*, 2019 WL 1590064, at *3-4 (Ark. Cir. Ct.); *San Francisco v. Purdue Pharma*, 2022 WL 3224463, at *50 (N.D. Cal.); *Florida v. Purdue Pharma*, slip op. 3 (Fla. Cir. Ct. 2022) (Add.90-94) (denying summary judgment on nuisance); *In re National Prescription Opiate Litig.*, 452 F. Supp. 3d 745, 773-75 (N.D. Ohio 2020) (Florida law); *Kentucky v. Walgreens Boots All.*, slip op. 2-4 (Ky. Cir. Ct. 2019) (Add.95-113); *City of Boston v. Purdue Pharma*, 2020 WL 416406, at *8 (Mass. Super. Ct.); *Michigan v. Cardinal Health*, slip op. 2 (Mich. Cir. Ct. 2021) (Add.114-116), *rev'g on recons.* (Mich. Cir. Ct. Nov. 17, 2020); *Minnesota v. Purdue Pharma*, 2019 WL 11729023, at *4 (Minn. Dist. Ct.); *Mississippi v. Cardinal Health*, slip op. 2-3 (Miss. Cir. Ct. 2021) (Add.117-123); *Missouri v. Purdue Pharma*, slip op. 6-8 (Mo. Cir. Ct. 2020) (Add.124-140); *Nevada v. McKesson*, slip order (Nev. Dist. Ct. 2020) (Add.141-148); *New Hampshire v. Purdue Pharma*, 2018 WL 4566129, at *13 (N.H. Super. Ct.);

their holdings in public nuisance's traditional scope, citing the Restatement (Second).[8]

B. The District Court Misapplied West Virginia Law

The district court held that West Virginia public nuisance law does not permit nuisance claims based on the distribution and sale of opioids and applies only "in the context of conduct that interferes with public property or resources." JA6490. It reached this errant conclusion by misreading West Virginia cases; erroneously relying on the Restatement (Third) of Torts: Liability for Economic Harm (2020) ("Restatement (Third)"), which West Virginia has not adopted;

New Mexico v. Purdue Pharma, 2022 WL 6822694, at *1-2 (N.M. Dist. Ct.) (summary judgment); *In re Opioid Litig.*, 2018 WL 3115102, at *27-28 (N.Y. Sup. Ct.) ("*New York Opioids*"); *Cnty. of Delaware v. Purdue Pharma* (Pa. Ct. Com. Pl. Oct. 25, 2019, Dec. 4, 2019, and Mar. 13, 2020) (Add.149-183); *Rhode Island v. Purdue Pharma*, 2019 WL 3991963, at *7-9 (R.I. Super. Ct.), *nuisance decision aff'd on summary judgment*, 2022 WL 577874 (R.I. Super. Ct.); *South Carolina v. Purdue Pharma* (S.C. Ct. Com. Pl. 2018) (Add.184-186); *Tennessee v. AmerisourceBergen*, slip op. 7-9 (Tenn. Cir. Ct. 2020) (Add.187-197); *In re Texas Opioid Litig. (Cnty. of Dallas)* (Tex. Dist. Ct. 2019) (Add.198); *Vermont v. Cardinal Health*, slip op. 5-10 (Vt. Super. Ct. 2020) (Add.199-214); *Washington v. Purdue Pharma*, 2018 WL 7892618, at *2 (Wash. Super. Ct.).

[8] *See Alabama*, *supra*, at 11-12; *Alaska*, *supra*, at 4 n.10; *Arizona*, *supra*, at 34-35; *Arkansas*, 2019 WL 1590064, at *3; *National Prescription Opiate Litig.*, 452 F. Supp. 2d at 773-74 (Florida law); *Kentucky*, *supra*, at 3; *Mississippi*, *supra*, at 2-3; *New Hampshire*, 2018 WL 4566129, at *13; *New Mexico*, 2022 WL 6822694, at *2; *New York Opioids*, 2018 WL 3115102, at *27; *Rhode Island*, 2019 WL 3991963, at *9; *Tennessee*, *supra*, at 7; *Vermont*, *supra*, at 5-8.

rejecting West Virginia decisions permitting public nuisance claims against opioid defendants; and following outlier out-of-state authority.

1. The district court erroneously precluded a public nuisance claim based on distribution and sale of a product

The district court held that applying public nuisance to opioids would impermissibly "exten[d] . . . the law of nuisance." JA6491. It misread *Sharon Steel*'s discussion of prior public nuisance decisions, incorrectly holding that the cited decisions involved misuse of or interference with public property or resources, but not distribution and sale of products. JA6490-6491 (citing *Sharon Steel*, 334 S.E.2d at 621). Two of those prior cases—*Mahoney v. Walter*, 205 S.E.2d 692 (W.Va. 1974), and *Martin v. Williams*, 93 S.E.2d 835 (W.Va. 1956)—concerned a salvage yard for used automotive parts and a used car lot, respectively. The WVSCA emphasized that such "lawful business[es]" "may become a nuisance" depending on "circumstances" including "location and operation." *Martin*, 93 S.E.2d at 838; *accord Mahoney*, 205 S.E.2d at 699-700 (manner in which automobiles were stored presented a "danger" justifying nuisance finding). Far from adopting the district court's limitations, *Sharon Steel* listed cases to illustrate that "nuisance is a flexible area of the law that is adaptable to a wide variety of factual situations." 334 S.E.2d at 621.

Excluding products from public nuisance law would be unworkable. Pollution, a classic nuisance, frequently attends the manufacture or distribution of

products such as aluminum, wood pulp, and textiles. *See id.* When "essential" commodities are manufactured in a dangerous way, their production is a nuisance. *See Wilson*, 21 S.E. at 1035 (explosive powder). There is no principled distinction between harms to public health that occur during production and that occur as a result of use.

West Virginia courts criticized the district court's deviation from West Virginia law. *See City of Beckley* ¶ 21 (district court imposed "an artificial external constraint on the common law cause of action for public nuisance [that] is inconsistent with" West Virginia law). The MLP called it "inconsistent with the [WVSCA's] longstanding recognition that a public nuisance is *any* act or condition that 'operates to hurt or inconvenience an indefinite number of persons' and that 'nuisance is a flexible area of the law adaptable to a wide variety of situations.'" *MLP Pharm MTD Order* ¶¶ 69-70 (quoting *Duff*, 421 S.E.2d at 257; *Sharon Steel*, 334 S.E.2d at 621).

2. The district court mistakenly cited the Restatement (Third)

The district court erroneously relied on the Restatement (Third)'s comment that "most courts" have rejected "public nuisance based on the sale and distribution of a product." JA6490 (citing Restatement (Third) § 8 cmt. g).[9] It reasoned that

[9] The Restatement (Third)'s comment is inaccurate with respect to opioids: "most courts" to consider the issue have allowed those public nuisance claims to proceed. *See supra* p. 35 n.7.

the WVSCA "followed the Restatement of Torts" in "discussing the scope of public nuisance under West Virginia law." *Id.* (citing *Duff*, 421 S.E.2d at 257 n.6). This analysis contains multiple errors.

First, *Duff* (1992) did not cite (indeed, predated) the Restatement (Third). Instead, *Duff*, like other WVSCA decisions, quoted the Restatement (*Second*)'s definition of a public nuisance: "'an unreasonable interference with a right common to the general public.'" 421 S.E.2d at 257 n.6 (quoting Restatement (Second) § 821B(1)); *see also Bansbach v. Harbin*, 728 S.E.2d 533, 537-38 (W.Va. 2012) (citing Restatement (Second)); *Hendricks v. Stalnaker*, 380 S.E.2d 198, 201-02 (W.Va. 1989) (same). The Restatement (Second) recognizes public nuisance cases involving the sale of products.[10]

Second, like other jurisdictions, "Section 8 of the Third Restatement has not been adopted by any court in West Virginia." *MLP SJ Opinion* at 4.[11] And the

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[10] *See* Restatement (Second) § 821B reporter's note (citing *Ileto v. Glock Inc.*, 349 F.3d 1191, 1209-12, 1214, 1224 (9th Cir. 2003) (guns); *San Francisco*, 491 F. Supp. 3d at 669, 672 (opioids); *In re StarLink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d 828, 844, 848 (N.D. Ill. 2002) (genetically modified corn); *California v. ConAgra Grocery Prods. Co.*, 227 Cal. Rptr. 3d 499, 593, 594 (Cal. Ct. App. 2017) (lead paint); and *City of Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136, 1142-43, 1157, 1158 (Ohio 2002) (guns)).

[11] *Accord*, *e.g.*, *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 394-99 (Pa. 2014) (rejecting product-liability portion of Restatement (Third) and discussing other courts that have done the same); *Delaney v. Deere & Co.*, 999 P.2d 930, 946 (Kan. 2000) (Restatement (Third) "goes beyond the law"); *Potter v. Chicago*

district court cited an inapplicable section addressing public nuisance claims by *private parties*, which acknowledges that the definition of nuisance for claims brought by "public officials" is "broader" than in the context of "private suit[s]." Restatement (Third) § 8 & cmt. a.

The district court miscast "[t]he original legal character of nuisance" as related only to "real property" or "land." JA6491. But "[u]nlike a private nuisance, a public nuisance does not necessarily involve interference with use and enjoyment of land." Restatement (Second) § 821B cmt. h.

3. The district court erroneously rejected West Virginia nuisance decisions

The district court created a rift on questions of West Virginia law. It held that neither *Brooke County* nor *Morrisey* contained an "in-depth consideration of the question," JA6492, and ignored the MLP decisions predating its ruling and the WVSCA's refusals to intervene. *See supra* Part I.A.2 (discussing MLP rulings).

Ignoring the MLP—which issued most relevant West Virginia trial court decisions—is error. And *Morrisey* and *Brooke County* were not summary rulings. In *Morrisey*—the State's opioid suit against Appellees—the court explained the

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Pneumatic Tool Co., 694 A.2d 1319, 1331 (Conn. 1997) (calling a provision of the Draft Restatement (Third) "a source of substantial controversy among commentators" that is inconsistent with the court's "independent review of the prevailing common law").

governing law and its reasons for rejecting defense arguments. *See* 2014 WL 12814021, at *8-10 & nn.9-11. In *Brooke County*—another suit against Appellees—the court reasoned that public nuisance is not limited to property disputes. *See* 2018 WL 11242293, at *7. It cited *Sharon Steel* and *Lemongello v. Will Co.*, 2003 WL 21488208 (W.Va. Cir. Ct. June 19, 2003), which permitted public nuisance claims concerning sale of another lawful product (firearms).

The district court erred in calling *Brooke County* "inconsistent with the Restatement of Torts that has been favorably commented upon by the [WVSCA]." JA6492. *See supra* pp. 38-40. And it ignored *Lemongello*, cited in both *Brooke County* and Appellants' briefing, JA6242-6243 (¶¶ 25 n.1110, 26 n.1112). Instead, it cited out-of-state decisions reaching the opposite conclusion. JA6495-6496 (citing *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099 (Ill. 2004); *New York ex rel. Spitzer v. Sturm, Ruger & Co.*, 761 N.Y.S.2d 192 (App. Div. 2003)).

The district court's duty under the *Erie* doctrine is to ensure "conformity in result" between equivalent proceedings in state and federal court. *McLeod v. Stevens*, 617 F.2d 1038, 1041 (4th Cir. 1980). *Morrisey* and *Brooke County* permitted nuisance claims on virtually identical facts against the same defendants. The MLP permitted equivalent claims by West Virginia cities and counties. Yet

the district court erroneously rejected or ignored these decisions, diverging from the state courts and creating dissimilar outcomes for the same claims.

4. The district court erroneously followed a minority of out-of-state decisions

The district court improperly rested on out-of-state cases when West Virginia has numerous opioid decisions. *See supra* pp. 33-35. The court's *Erie* authority for looking out-of-state—*St. Paul Fire & Marine Insurance Co. v. American International Specialty Lines Ins. Co.*—involved a scenario with "no Virginia precedents" on point. 365 F.3d 263, 272 (4th Cir. 2004). To the extent out-of-state authority is relevant, it favors recognizing a public nuisance claim.

The district court followed the minority of cases rejecting nuisance liability in opioid litigation. JA6492-6495; *Oklahoma ex rel. Hunter v. Johnson & Johnson*, 499 P.3d 719, 730 (Okla. 2021); *City of New Haven v. Purdue Pharma, L.P.*, 2019 WL 423990 (Conn. Super. Ct. Jan. 8, 2019); *North Dakota ex rel. Stenehjem v. Purdue Pharma L.P.*, 2019 WL 2245743 (N.D. Dist. Ct. May 10, 2019).

These decisions are outliers. *See supra* p. 35 n.7 (collecting cases allowing nuisance claims). Most courts, including the others with MDL bellwether trials, permitted public nuisance claims. *See In re National Prescription Opiate Litig.*, 589 F. Supp. 3d 790, 815 (N.D. Ohio 2022) (denying post-trial motion challenging public nuisance claim); *San Francisco*, 2022 WL 3224463, at *50 (finding opioid

dispenser liable for public nuisance); *MLP SJ Opinion* at 2 & n.4, 5 n.8 ("courts in 22 other states . . . have recognized public nuisance claims in the opioid litigation").

Hunter is inapplicable too. It rested on the Oklahoma Supreme Court's historical interpretation of its statute limiting public nuisance to criminal nuisances and those "causing physical injury to property" or rendering it "uninhabitable." 499 P.3d at 724; *see* Okla. Stat. tit. 50, §§ 1, 2. By contrast, the WVSCA has emphasized the adaptability of West Virginia nuisance law and has followed the Restatement (Second), which makes clear that public nuisance is not limited to cases involving injury to real property. *See supra* pp. 38-40.

The district court cited "policy considerations" favoring following Oklahoma, including that "the manufacture, marketing and sale of opioids" were "public policy matters that should be dealt with by the legislative and executive branches." JA6492-6493. But policy preference cannot justify a federal court sitting in diversity disregarding a consistent line of applicable state-court decisions. *See supra* pp. 33-35. If West Virginia's legislature opposed public nuisance claims about opioids, it could have acted to preclude them. Opioid litigation has been ongoing at least since *Morrisey*, filed more than eight years ago, and the legislature has not stepped in. It was inappropriate for the district court to do so.

C. Appellants Proved A Public Nuisance

When viewed through the proper legal frame, the evidentiary record more than amply establishes public nuisance. The district court identified an "opioid epidemic" in Cabell/Huntington, presenting "an extraordinary public health crisis" devastating West Virginia—"the hardest-hit state in the country"—"for more than a decade." JA6356. More than 10% of Cabell/Huntington residents are or have been addicted to opioids, including more than 600 pregnant women in 2018. JA6357. Cabell County has the highest incidence in the country of babies with neonatal abstinence syndrome. *Id.* Overdose deaths exceed the national average. *Id.*

These facts state a "condition" that "hurt[s] or inconvenience[s] an indefinite number of persons," *Kermit Lumber*, 488 S.E.2d at 921, like others the WVSCA has called a nuisance. *See*, *e.g.*, *Elm Grove*, 9 S.E.2d at 814-18 (coal production fumes affecting community health); *Wilson*, 21 S.E. at 1035 (explosive powder endangering residential area); *accord Martin*, 93 S.E.2d at 844 (business selling used cars harming neighborhood is private nuisance).

Even if public nuisance were limited to impairment of public resources and property, Cabell/Huntington proved such impairment: an immense strain on public resources, including health, law enforcement, emergency response, judiciary, jails, foster care, and other services. JA6358. The court found the opioid epidemic

increased crime rates. JA6360. And echoing cases collected in *Sharon Steel*, it concluded the opioid epidemic "decreased property values" and "adversely affected neighborhoods" throughout Cabell/Huntington, reducing the tax base and leaving Huntington with many "abandoned homes." *Id.* As the MLP stated, even under the district court's "reformulation of public nuisance to require 'conduct that interferes with public property or resources,'" governmental plaintiffs can "sufficiently allege[]" such interference. *MLP Pharm MTD Order* ¶ 71; *see also Morrisey*, 2014 WL 12814021, at *10 ("[p]ublic resources are being unreasonably consumed in efforts to address the prescription drug abuse epidemic," "[j]ails and prisons suffer from overcrowding," and "[l]aw enforcement and prosecutorial resources are being exhausted and consumed by having to address prescription drug abuse issues to the exclusion of other matters").

II. THE DISTRICT COURT ERRED IN HOLDING THAT APPELLEES DID NOT UNREASONABLY INTERFERE WITH A PUBLIC RIGHT

The test of whether an act or condition hurting the general public constitutes a public nuisance is its "'reasonableness or unreasonableness . . . in relation to the particular locality involved.'" *Duff*, 421 S.E.2d at 257 (quoting *Sticklen v. Kittle*, 287 S.E.2d 148, 160-61 (W.Va. 1981)). Appellees' interference with public rights in Cabell/Huntington was unreasonable because, as Appellees shipped massive quantities of opioids to Cabell/Huntington, they failed to comply with their duties under the CSA and its West Virginia equivalent. Conduct is unreasonable for

nuisance purposes if it is unlawful. *See* Restatement (Second) § 821B(2)(b) (conduct unreasonable if "proscribed by a statute, ordinance or administrative regulation"); *West*, 285 S.E.2d at 677 (nuisance may arise from "unlawful" conduct).

The district court's holding that Appellees' conduct was reasonable, *see* JA6498, was rooted in its erroneous legal conclusion that the CSA requires distributors to maintain effective controls only against extreme cases of pharmacies "essentially acting as adjuncts of the illicit market." JA6503. This overly narrow interpretation of the CSA conflicts with the regulations' text and decisions including *Masters*, where the D.C. Circuit affirmed DEA's broader interpretation of distributors' duties. These legal errors infected the district court's factual review, which overlooked Appellees' failures to identify and investigate suspicious orders. The court likewise ignored DEA's allegations that Appellees violated the CSA and Appellees' own admissions of wrongdoing.

The court's misinterpretation and misapplication of Appellees' CSA duties fatally undermine its assessment of Appellees' conduct.

A. Appellees Violated Their Duties Under The CSA

Appellees violated their duty to investigate or else block suspicious orders for controlled substances. *See Masters*, 861 F.3d at 212-13; *MDL CSA Ruling*, 2019 WL 3917575, at *7-9. It is a "basic requirement . . . not to ship a dubious

order bearing indicia that the drugs could be diverted to illegal channels." *Id.* at *9. Distributors thus must "exercise 'due diligence' before shipping any suspicious order." *Masters*, 861 F.3d at 221-22 (quoting *Southwood*, 72 Fed. Reg. at 36,500). "[M]eaningful investigations" of suspicious orders entail contacting the ordering pharmacy "to request an explanation" for the order's unusual characteristics and then "verif[ying] that explanation." *Id.* at 218-19.

For years, Appellees concededly did not investigate any order flagged as suspicious prior to shipping it. After DEA took action against them in 2007-2008, Appellees pledged to comply. But they shipped ever-larger orders of opioids to Cabell/Huntington pharmacies and failed to conduct the due diligence necessary to dispel suspicion from those orders. Appellees performed so little diligence because they repeatedly increased ordering thresholds for their top Cabell/Huntington customers, allowing them to order vast quantities without triggering any review at all.

1. Appellees violated the CSA by shipping suspicious orders without investigating them

Before DEA's enforcement actions in 2007-2008, Appellees shipped suspicious orders of opioids without any investigation. ABDC admitted it "would identify a suspicious order and ship it." JA2131 (Zimmerman). Cardinal and

McKesson admitted doing the same. JA1218-1219 (Reardon); JA2237-2240 (Oriente); JA1197 (Hartle).

Those actions violated Appellees' duties under the CSA and occurred repeatedly as Appellees shipped increasingly vast quantities of opioids to Cabell/Huntington pharmacies. JA5493. In 2006, ABDC's monthly oxycodone shipments to its top customer in the area, SafeScript, were 11 to 15 times the average amount that ABDC shipped to pharmacies nationwide. JA5452 (38,100 dosage units versus 3,424 in January 2006; 56,700 versus 3,649 in November 2006). The same year, Cardinal shipped oxycodone to its top Cabell/Huntington customers, Medicine Shoppe and CVS, at triple or quadruple Cardinal's nationwide per-pharmacy average; McKesson routinely doubled its nationwide per-pharmacy average in shipping oxycodone to Rite Aid, its top customer in the area. JA5458, JA5464.

Appellees exacerbated their failure to investigate suspicious orders by ineffectually flagging orders as suspicious in the first place, violating their duty to identify suspicious orders. *See* 21 C.F.R. § 1301.74(b). Their systems used simple multipliers of ordering averages, *see supra* pp. 15-16, so as average opioid dispensing increased, ordering thresholds did too, thereby enabling pharmacies to order more without being flagged. *See Masters Pharm., Inc.*, 80 Fed. Reg. 55,418, 55,483 (DEA Sept. 15, 2015) (distributor violated CSA where increasing

thresholds "allow[ed] the customer to order even larger quantities of controlled substances without even triggering . . . further review").

2. Appellees continued to not investigate suspicious orders even after DEA actions

Following DEA's enforcement actions, Appellees vowed to comply with their duties. For instance, ABDC pledged in 2007 to ship orders that its system flagged as suspicious only after a "diligent review" determined the orders were not suspicious. JA3280; *see supra* pp. 17-18. But this led only to cosmetic changes. Appellees sold even more opioids to Cabell/Huntington than before, while failing to conduct due diligence to justify increasingly massive sales. They continually raised thresholds for their highest-volume customers, subjecting fewer and fewer orders to review.

a) ABDC

After its settlement with DEA, ABDC shipped oxycodone to Cabell/Huntington at even greater rates. Its per-capita oxycodone shipments to Cabell/Huntington doubled over the next three years. JA5452-5453 (7,238 to 11,523 oxycodone units per month in 2007; 13,486 to 21,280 per month in 2010). ABDC shipped oxycodone to SafeScript at 10 times its average per-pharmacy rate; it supplied its other top customers, McCloud Family Pharmacy and Drug Emporium #1, at three to six times its average and two to four times its average, respectively. JA5452.

The district court required Appellees to produce and specifically identify their due diligence for their Cabell/Huntington customers. JA1944-1945. Yet ABDC provided no evidence that it conducted anywhere near the due diligence necessary to dispel suspicion that these opioids would be diverted, and the evidence indicates it did not. In 2015, DEA requested due-diligence files for McCloud and Drug Emporium, but both files were "empty." JA4847-4851. Despite selling opioids to them at exceedingly high rates for years, ABDC had *no* due-diligence records for these pharmacies.

ABDC avoided conducting due diligence by increasing the pharmacies' ordering thresholds so the thresholds would not flag orders as suspicious in the first place. Take SafeScript. ABDC sold it opioids until February 2012, when DEA raided it and the police arrested its owner for drug-related crimes. JA2160 (Perry); JA4839. From 2007 to 2009, ABDC more than quadrupled SafeScript's threshold for ordering oxycodone without any due diligence to justify the increases; by 2009, SafeScript could—and did—order up to 45,000 dosage units of oxycodone every month without triggering review. JA6070-6071 (¶¶ 148, 150 & nn.200-201); JA5668-5669; JA5452. The justification for these increases that ABDC's local sales representative provided was circular: SafeScript has "always purchased a

high volume" of opioids, so ABDC increased opioid thresholds "due to this being the primary business at this account." JA4845.

Despite repeatedly raising SafeScript's ordering limits, ABDC still flagged 775 SafeScript orders as suspicious from 2007 to 2011. JA6074 (¶ 157); JA5502-5667. Yet ABDC provided no evidence that it "request[ed] an explanation" from SafeScript for these orders' unusual characteristics or that it "verified that explanation." *Masters*, 861 F.3d at 218-19.

Instead, ABDC simply allowed SafeScript to order *even more* opioids without triggering review. In one month in 2011, ABDC flagged 24 SafeScript oxycodone orders as suspicious, despite already raising SafeScript's ordering threshold numerous times. JA6072 (¶ 152); JA5502-5667; JA5668-5669. ABDC's sales representative requested another threshold increase, citing SafeScript's "issues" with "exceeding the thresholds." JA4842. ABDC approved the request even though its policy stated that "[e]xceeding the established threshold does not in itself justify a threshold increase in all cases." *Id.*; *see* JA4831-4832. ABDC also approved the request despite 86% of SafeScript's orders from ABDC being for controlled substances, whereas ABDC policy considered 30% to be sufficiently "high" that thresholds should not be increased. JA4831-4832; JA3258-3259.

b) Cardinal

After settling with DEA in 2008, Cardinal continued to ship increasingly significant quantities of opioids to Cabell/Huntington pharmacies, routinely shipping oxycodone at five to six times Cardinal's national per-pharmacy average to Medicine Shoppe and two to four times its national per-pharmacy average to CVS locations in Cabell/Huntington. JA5458-5459. Cardinal gained four Fruth pharmacies in Cabell/Huntington as customers in 2010. It regularly shipped hydrocodone to each of them at more than four times its national per-pharmacy average, and it exceeded 10 times its national per-pharmacy average for Fruth #5 and #12. JA5462-5463.

Cardinal failed to produce documentation to justify these vast opioid shipments. From November 2012 to 2018, Cardinal's due-diligence file for Medicine Shoppe had just five documents, totaling only 18 pages, despite Cardinal flagging more than 100 orders as suspicious in that period and Medicine Shoppe inheriting SafeScript's customers after DEA raided it in 2012. JA6106, JA6108 (¶¶ 232, 236); JA4994-5379. Cardinal's file for CVS stores in Cabell/Huntington contained no indication that it ever reviewed a single suspicious order. JA5380-5433.

Cardinal had scant due-diligence records because it raised these customers' thresholds so their orders were not flagged or scrutinized. Cardinal repeatedly

increased the ordering limits for Medicine Shoppe, its largest Cabell/Huntington customer, with no due diligence to justify the increases. JA6106 (¶ 232); JA2199 (Kave). Such steps allowed Cardinal to more than triple its monthly shipments of oxycodone to Medicine Shoppe—from 10,000 in 2006 to more than 30,000 in 2012—without flagging or investigating the staggering volumes. JA2088 (McCann).

Cardinal likewise increased ordering limits for the Fruth stores. Between 2010 and 2012, it raised Fruth #5's hydrocodone limit from 10,000 units per month to 113,900 per month—more than 11 times higher—without due diligence to justify the increase. JA6104-6105 (¶ 229); Trial Ex. P-44275 (rows 13, 47), *Huntington* ECF No. 1519 (see JA Digital Media Volume); JA4967-4993.

c) McKesson

After McKesson's 2008 DEA settlement, its per-capita oxycodone shipments to Cabell/Huntington grew steadily. JA5464-5465. It supplied oxycodone to its top Cabell/Huntington customers—three Rite Aid stores—at rates exceeding its national per-pharmacy average, often at more than double that level. *Id.* In 2010 and 2011, it supplied oxycodone at *triple* its national per-pharmacy average to Custom Script in Cabell. JA2091-2092 (McCann); JA5500-5501.

McKesson conducted no due diligence on Rite Aid orders at all: it let Rite Aid police itself. If McKesson raised concerns about a store or an order, Rite Aid "review[ed] those stores that McKesson identified and Rite Aid would report back their findings" and it was "resolved with the additional information that Rite Aid would provide." JA2259-2260 (Oriente). This violates the CSA. *See Masters*, 861 F.3d at 219 (faulting defendant because "it accepted, without seeking to verify," its customers' explanations).

McKesson likewise delegated to Rite Aid the investigation needed to justify threshold increases, rather than investigating itself, as the CSA requires. JA1232-1233, JA1235-1238 (Walker). McKesson repeatedly raised thresholds for Rite Aids in Cabell/Huntington based on nothing more than Rite Aid's own say-so about needing more opioids. JA6135 (¶ 334).

McKesson increased the ordering thresholds for Custom Script too, enabling it to order up to 30,500 dosage units of oxycodone per month in 2010, nearly four times McKesson's standard threshold of 8,000, without triggering review. JA3595-3596; JA2210-2213 (Oriente). McKesson produced no due diligence justifying this decision. Its only recorded justification was that Custom Script had started "aggressiv[e]ly marketing" to local pain clinics and expected a "surge in

usage of product containing oxycodone." JA3597. Aggressive marketing of opioids to pain doctors should have been cause for *more* scrutiny, not less. *See Masters*, 80 Fed. Reg. at 55,485 (rejecting "actively marketing to nearby pain clinics" as justification for treating pharmacy's orders as non-suspicious).

3. Appellees supplied Cabell/Huntington's highest overprescribers of opioids

Appellees' failure to identify and investigate suspicious orders meant they did not scrutinize the doctors served by their pharmacy customers. JA3462; *see Masters*, 80 Fed. Reg. at 55,485 (faulting distributor for taking "no further steps to verify the credentials of the physicians" its pharmacy customers cited to justify dispensing high opioid volumes). They supplied vast quantities of opioids to the pharmacies serving Cabell/Huntington's two highest overprescribers of opioids: Dr. Deleno Webb and Dr. Philip Fisher.

"High volume, unprincipled prescribers . . . writ[ing] opioid prescriptions that are not medically necessary" is one of the "main" ways diversion occurs. *San Francisco*, 2022 WL 3224463, at *46. Drs. Webb and Fisher ranked in the top 0.02% and 0.03%, respectively, of opioid prescribers nationwide. JA2486 (Keller). Dr. Webb surrendered his medical license in 2017 after a state investigation into his excessive prescribing, while Dr. Fisher's license was suspended in 2011 following state investigations related to the deaths of at least

seven patients. JA2499, JA2505-2507 (Keller). Before losing their licenses, Drs. Webb and Fisher combined to prescribe more than 24 million dosage units of opioids in Cabell/Huntington. JA2493-2494, JA2496 (Keller); JA6188 (¶ 543).

Appellees supplied most of these pills. Drs. Webb and Fisher were two of the top three prescribers at SafeScript, as ABDC learned when it increased SafeScript's ordering threshold in mid-2011. JA2157 (Perry); JA4831-4832. Likewise, McKesson knew that Custom Script aggressively marketed to Dr. Fisher and included Dr. Webb among its top prescribers. JA3597; JA3580. More than 70% of Dr. Webb's prescriptions filled at Drug Emporium #1 were for opioids, JA2502 (Keller), for which ABDC had no due-diligence files in 2015. Dr. Webb also accounted for by far the largest share of opioid prescriptions at Cardinal's customer, Medicine Shoppe. JA2489-2490 (Keller).

Appellees' failures to identify and investigate suspicious orders led them to supply huge quantities of opioids to the highest-volume pharmacies serving the highest-prescribing doctors in Cabell/Huntington, including pharmacies and doctors that authorities eventually shut down. Neither medical evidence about the high relative prevalence of health conditions in West Virginia, JA6461-6462, nor the changing standard of care for prescription opioids, JA6440-6463, justified the volume of Appellees' opioid shipments into Cabell/Huntington that facilitated

these doctors' overprescribing. Appellees' misconduct unreasonably interfered with a public right in Cabell/Huntington.

B. The District Court Misinterpreted And Misapplied The CSA

1. The district court incorrectly narrowed Appellees' CSA duties

The district court cast its holding that Appellees complied with their CSA duties as a finding of fact, JA6369, but its holding followed from its legally erroneous interpretation of distributors' duties under the CSA. The court erred by narrowing the diversion for which regulated distributors are responsible in two respects. *First*, it construed the duty to prevent diversion under 21 C.F.R. § 1301.71(a) as requiring only that distributors not sell to "pharmacies that are essentially acting as adjuncts of the illicit market." JA6503. It therefore reviewed Appellees' due-diligence efforts only to see if they cleared that low bar. *See infra* Part II.B.2. It held distributors need not investigate or block orders placed by "legitimate pharmacies." JA6510.

Second, the district court ruled that distributors could be liable only for opioids "diverted while in defendants' custody or under their control" or by their direct pharmacy customers, excusing them from responsibility to guard against "diversion that occurred downstream from their pharmacy customers." JA6510-6511. The court considered it irrelevant whether a distributor supplied pharmacies that filled prescriptions for "doctor shopping" customers, JA6506, pharmacies with

"suspicious customers," JA6504-6505, or pharmacies filling prescriptions from "doctors who may be intentionally or unintentionally violating medical standards," JA6509.

These limitations have no basis in law. They depart from the CSA and its regulations as interpreted by the D.C. Circuit in *Masters*, the MDL court, and DEA. Despite Appellants seeking confirmation before trial that the district court would adhere to the MDL court's CSA interpretation, JA1903-1904 (Mar. 3, 2020); JA1958-1960 (Sept. 22, 2020), the district court announced its novel interpretations of the CSA only after trial.

CSA regulations require registrants to monitor *orders* for suspicious attributes, not merely to decide whether a customer's operations, judged as a whole, indicate legitimacy or illegitimacy. *See* 21 C.F.R. § 1301.74(b) (registrant must operate system to identify "suspicious orders" and inform DEA of same); *Masters*, 861 F.3d at 217-19 (focusing on registrant's failure to report and investigate specific orders).

The regulations do not relax distributors' obligations based on the district court's spurious distinction between legitimate and illegitimate pharmacies. The duties exist regardless of how many suspicious orders a given pharmacy generated. *See Masters*, 861 F.3d at 221-22 ("[T]he Shipping Requirement mandates that

pharmaceutical companies exercise 'due diligence' before shipping *any* suspicious order.") (emphasis added). A distributor cannot declare a customer "legitimate" and be done with it; "the obligation to perform due diligence is ongoing throughout the course of a distributor's relationship with its customer." *Masters*, 80 Fed. Reg. at 55,477.

Likewise, nothing in the CSA confines a distributor's duty to guard against diversion to its own operations or its direct pharmacy customers. "With the privilege of lawfully manufacturing and distributing Schedule II narcotics—and thus enjoying the profits therefrom—comes the obligation to monitor, report, and prevent *downstream diversion* of those drugs." *In re National Prescription Opiate Litig.*, 2018 WL 6628898, at *9 (N.D. Ohio Dec. 19, 2018) (emphasis added). *Masters* found CSA violations because the registrant did not investigate the doctors and prescribing practices that its pharmacy customers had cited to justify their high opioid dispensing. *See* 861 F.3d at 218 (citing *Masters*, 80 Fed. Reg. at 55,458, 55,495). *Southwood* found a CSA violation because that registrant did not investigate its pharmacy customers' answers about the doctors they served. *See* 72 Fed. Reg. at 36,499-500.

The district court misread key precedent. JA6503-6504 (citing *Direct Sales Co. v. United States*, 319 U.S. 703 (1943); *Masters*, 861 F.3d 206; *Masters*, 80 Fed. Reg. 55,418; *Southwood*, 72 Fed. Reg. 36,487). None of these decisions

limits distributors' duties to wholly illegitimate customers or permits inattention to the doctors and patients whose prescriptions a pharmacy is filling. These decisions make clear that distributors must scrutinize the doctors and patients its pharmacies serve, not just the pharmacies themselves. *See Masters*, 861 F.3d at 218-19; *Southwood*, 72 Fed. Reg. at 36,499-500.

The district court worried that a broader interpretation would require distributors to "cut[] off dispensers completely" based on "a hunch that some of the pharmacy's customers may be engaged in misconduct." JA6508. But distributors must "design and operate a *system*" to identify suspicious orders, 21 C.F.R. § 1301.74(b) (emphasis added), not follow hunches. The duty to investigate or else block suspicious orders is specific to the order; the distributor need not necessarily cut off the customer altogether. *See Masters*, 861 F.3d at 222. And the distributor can investigate, scrutinizing the customer's explanations for its heightened ordering. *Id.* at 218, 222. The district court's misplaced worry is not a valid basis to narrow the CSA regulations' requirements.

2. The district court's misinterpretation of the CSA yielded erroneous fact-findings

Because the district court mistakenly concluded that distributors' duties are limited to not supplying wholly illegitimate pharmacies, JA6503, and it placed none of Appellees' Cabell/Huntington customers in that category, its analysis of the record was erroneous. The court did not examine Appellees' identification or

investigation of their customers' *orders*. Its fact-findings that Appellees complied with the CSA "were derived under an incorrect legal standard" and "made while ignoring 'substantial evidence' supporting the opposite conclusion," *Heyer*, 984 F.3d at 355, warranting reversal for clear error.

Identifying suspicious orders. The district court's opinion mentioned just one of ABDC's threshold increases for SafeScript. JA6420-6422. It ignored the rest of Appellees' many others, never considering that increasing thresholds meant fewer orders would be flagged or investigated. This oversight mars the court's analysis, notwithstanding its findings regarding the suspicious-order methodologies of Appellants' expert James Rafalski. The court's rejection of Rafalski's methodologies focused on whether they approximated Appellees' default flagging methods. JA6410-6415. But it disregarded how Appellees' repeated and unjustified *changes* to their default methods reduced their scrutiny of their highest-volume Cabell/Huntington pharmacy customers. And it ignored that DEA—where Rafalski formerly worked—criticized Appellees for failing to identify suspicious orders and violating the CSA. *See supra* pp. 17-20.

Investigating suspicious orders. By narrowing the diversion that distributors must prevent, the district court departed from settled law on the due diligence required before distributors may ship suspicious orders. The court did not acknowledge *Masters*' upholding of DEA's longstanding interpretation. *See*

861 F.3d at 217-19. Therefore, the court did not consider whether Appellees sought, much less verified, explanations for suspicious orders. *Id.*

Instead, the district court's review of the evidence asked only whether Appellees did enough due diligence to ensure their customers were not wholly illegitimate. It credited company witnesses' generalizations that they conducted adequate due diligence. *See*, *e.g.*, JA6418-6420 (ABDC), JA6423-6425 (Cardinal), JA6426-6427 (McKesson). The court also credited the due diligence that ABDC conducted for SafeScript, Drug Emporium #1, and McCloud; that Cardinal conducted for Medicine Shoppe; and that McKesson conducted for Rite Aid. JA6420-6423, JA6424-6425, JA6427-6428.

This analysis, however, answered the wrong question. Because the district court misinterpreted the CSA not to require Appellees to investigate suspicious orders, it overlooked the extensive evidence that Appellees failed to investigate these pharmacies' suspicious orders. As to SafeScript, the district court cited only a review that ABDC conducted in 2007, dashboards that tracked basic pharmacy data, and the post-hoc testimony of its local sales manager, Michael Perry, that he did not recall observing "red flags." JA6421. The court ignored that ABDC failed

to investigate hundreds of SafeScript orders its own system flagged as suspicious between that 2007 review and SafeScript's shutdown after the DEA raid in 2012.

As to Drug Emporium #1 and McCloud, the district court again relied only on a review that ABDC conducted in 2007 and on Perry's post-hoc testimony. JA6422. Despite shipping oxycodone to these pharmacies at roughly triple its nationwide per-pharmacy average, ABDC had no due-diligence files—and thus no evidence it had investigated any suspicious *orders*—for either pharmacy in 2015 when DEA requested them. *See supra* pp. 49-50. The court's opinion is silent on this fact.

The district court's analysis of Cardinal is no better. It credited Cardinal for having "hundreds of pages" in its due-diligence file for Medicine Shoppe. JA6424-6425. Yet it disregarded the near-absence of documentation in that file from November 2012 to 2018, even though Cardinal reported more than 100 orders to DEA as suspicious and shipped at least another 50 flagged orders to Medicine Shoppe that it did not report during that period. JA6106, JA6108 (¶¶ 232, 236); JA4994-5379; JA4939-4966; Trial Ex. P-14294, *Huntington* ECF No. 1519 (see JA Digital Media Volume).

The district court credited Cardinal for visiting Medicine Shoppe in August 2012, JA6425, but that visit raised more red flags than it resolved. Cardinal visited because Medicine Shoppe was a "black hole" with "significant growth" in opioid

sales from inheriting SafeScript's customers after the DEA raid. JA4883. Cardinal's post-visit report records that growth but no inquiry into the nature of SafeScript's business or the reasons for its closure. Trial Ex. CAH-WV-00770, *Huntington* ECF No. 1519 (see JA Digital Media Volume). The report also records Medicine Shoppe's explanation that 15-mg and 30-mg oxycodone were area prescribers' preference. JA6425. The court thought this innocuous. *Id.* But former DEA official Rannazzisi testified that these were among the most-diverted opioids nationwide, JA2383, and Cardinal's own training materials identified them as such, JA2202-2203 (Kave). Cardinal did nothing to verify the pharmacy's explanations—exactly what the D.C. Circuit faulted in *Masters*. *See* 861 F.3d at 219 ("[Masters] accepted, without seeking to verify, the half-baked or implausible explanations its customers supplied.").

The district court's analysis of McKesson's due diligence of Rite Aid is worse. JA6427-6428. It cited a McKesson employee's testimony that "Rite Aid was conducting [its] due diligence," JA6428; JA2259 (Oriente), ignoring McKesson's concession that *it* performed no due diligence. The CSA does not allow registrants to delegate their duties to other registrants. Each entity in the supply chain must prevent diversion by "seeking to verify" customers' explanations for large orders. *Masters*, 861 F.3d at 219. McKesson's efforts fall

below even the "tentative, pro forma, and incomplete" due diligence that the D.C. Circuit criticized in *Masters*. *Id.* at 218.

The district court's CSA misinterpretation also led it to reject Rafalski's opinion that Appellees conducted inadequate due diligence. The court found his opinion "unpersuasive" because "he employed an overbroad understanding of distributors' duty to maintain effective controls against diversion." JA6429. On the contrary, because the court's understanding was overly narrow, it incorrectly concluded that Appellees' cursory, sporadic reviews satisfied the CSA.

The district court gave Appellees the benefit of the doubt when their due-diligence files turned up empty. JA6417 ("[T]he fact such diligence files are not still available is not necessarily indicative of whether the diligence was previously done and recorded."). But "the lack of documentation was evidence that [due diligence] never took place." *Masters*, 861 F.3d at 218. The law requires Appellees, sophisticated nationwide businesses, to conduct due diligence, so they *should* have retained records. Indeed, Appellees retained certain records for many years, such as Cardinal possessing files for Medicine Shoppe back to 2008. JA4994-5379. The court's assumption that sufficient diligence must have been done and recorded, just not retained, is clearly erroneous.

3. The district court erroneously ignored DEA's allegations and Appellees' admissions of wrongdoing

The district court erred in ignoring nearly all DEA enforcement actions against Appellees. *See Heyer*, 984 F.3d at 355 (clear error to ignore substantial evidence supporting contrary conclusion). Ignoring these enforcement efforts that put Appellees on notice of deficiencies, the court credited self-serving testimony of Appellees' employees that they believed their systems complied with DEA requirements. *See*, *e.g.*, JA6383 ("Reardon understood from those conversations that the DEA thought Cardinal Health was headed in the right direction"); JA6400-6401. And it described the (superficial) changes in Appellees' systems without acknowledging that DEA enforcement prompted those changes. JA6384-6394. Contrary to Appellees' self-serving testimony, DEA made extensive allegations in its show-cause and immediate-suspension orders that Appellees were violating the CSA. *See supra* pp. 17-18, 20. The court gave no reason for disregarding these actions. It is clearly erroneous to find compliance with legal duties while ignoring many contrary statements of the enforcing agency.

Only one action appears in the district court's opinion: ABDC's 2007 settlement. JA6374. The court downplayed it, stressing that ABDC "did not [pay] any fine or financial penalty." *Id.* But the court ignored substantial penalties in other settlements, especially the $150 million penalty McKesson paid in 2017.

JA5441. It even ignored Appellees' admissions of unlawful conduct. In 2012, Cardinal admitted "that its due diligence efforts for some pharmacy customers" were "inadequate." JA3474. In 2017, McKesson admitted that "it did not identify or report to DEA certain orders" it should have detected as suspicious. JA5436.

The settlements cannot be written off as inapplicable to West Virginia. Appellees employ centralized policies nationwide. JA2107 (Zimmerman) (ABDC); JA2178 (Mone) (Cardinal); JA2216-2217 (Oriente) (McKesson). DEA alleged failures of Appellees' systems across the country. Cardinal's 2008 settlement resolved suspension orders for distribution centers in four States and alleged violations in three others. JA3491-3492. McKesson's 2017 settlement resolved allegations concerning distribution centers in 11 States, including at the facility serving Cabell/Huntington. JA5436-5437. Disregarding these actions was clear error.

C. The District Court Erred In Assessing The Reasonableness Of Appellees' Conduct

1. The district court applied erroneous legal standards

The district court's reasonableness analysis further fails because the court mistakenly applied West Virginia's *private* nuisance test, weighing only "the gravity and avoidability of the harm" against "the utility of defendants' conduct."

JA6496-6497 (citing *Duff*, 421 S.E.2d at 257 & n.5).[12] The court also held incorrectly that "conduct which the public convenience imperatively demands cannot be a public nuisance," JA6498 (citing *Pope v. Edward M. Rude Carrier Corp.*, 75 S.E.2d 584, 589 (W.Va. 1953)). But the WVSCA never has elicited that rule from *Pope*. It is settled law that even lawful, beneficial activities can be nuisances where they are unreasonable in relation to the particular locality. *See Duff*, 421 S.E.2d at 257; *supra* pp. 31-32. The district court failed to consider the "reasonableness . . . in relation to the particular locality" of shipping more than 80 million dosage units of opioids into a community of only 100,000 people—the proper inquiry for a *public* nuisance claim. *Duff*, 421 S.E.2d at 257.[13]

2. The district court ignored and mischaracterized evidence of opioids' harms

By applying the test for *private* nuisance claims, the district court incorrectly focused on evidence that might outweigh the harms Appellees caused, mischaracterizing that evidence in the process. The court concluded that opioids' utility in "the effective treatment of chronic pain" outweighed "the social costs

[12] The district court cited the correct standard in its summary-judgment ruling. JA2016.

[13] Appellees' conduct violates the private nuisance test, in any event. Appellees supplied opioids in quantities far beyond any medical utility, as Cabell/Huntington's catastrophic levels of addiction, overdose, and death demonstrate.

incurred by communities such as [Cabell/Huntington]." JA6497. In support, the court cited the testimony of DEA officials Rannazzisi and Prevoznik that 99% of doctors were prescribing opioids responsibly. JA6473-6474.[14] The court concluded that the volume of opioids Appellees supplied to Cabell/Huntington was "determined by the good faith prescribing decisions of doctors in accordance with established medical standards" and that Appellees "shipped prescription opioid pills to licensed pharmacies so patients could access the medication they were prescribed." JA6498.

That opinion ignores Rannazzisi's further testimony that "only a few untrained or unscrupulous physicians" can create "large pockets of addicts." JA2418-2419; JA1325 (Prevoznik) (1.5% of DEA-registered physicians could account for "millions of dosage units into [the] illicit market"). In a given year, the top 1% of opioid prescribers in Cabell/Huntington accounted for more than 40% of opioid dosage units and 60% of MMEs. JA2483 (Keller). The top 1% included Drs. Webb and Fisher, who, before losing their medical licenses, sent their customers to pharmacies supplied carelessly by Appellees. *See supra* pp. 55-56.

[14] This was the district court's only citation of the parties' extensive designations from the three-day deposition of Prevoznik, DEA's Rule 30(b)(6) witness. JA1244-1342, JA1344-1400.

The district court never acknowledged Drs. Webb or Fisher or addressed how Appellees' diversion-control failures enabled their overprescribing. Its reasonableness assessment therefore depended on "ignoring substantial evidence," *Heyer*, 984 F.3d at 355, and should be reversed.

III. THE DISTRICT COURT ERRED IN HOLDING THAT APPELLANTS DID NOT ESTABLISH CAUSATION

Appellees distributed massive quantities of opioids into Cabell/Huntington while failing to maintain effective controls against diversion. It was reasonably foreseeable that this would create a crisis, as DEA repeatedly warned Appellees. That evidence amply establishes nuisance causation. The district court erred by concluding that other causes of the opioid epidemic in Cabell/Huntington absolved Appellees of liability for their role in it and by ignoring West Virginia law's principles of concurrent causation.

A. Appellees Proximately Caused The Opioid Epidemic In Cabell/Huntington

1. An offender that joins or participates in creating or maintaining a nuisance is a cause of the nuisance

Under West Virginia law, "all persons who join or participate in the creation or maintenance of a nuisance are liable jointly and severally for the wrong and injury done thereby." *West*, 285 S.E.2d at 678 (citing 58 Am. Jur. 2d *Nuisances* § 56 (1971)). A defendant may be liable even if it did not *solely* create or maintain the nuisance. *See id.* And a defendant may be liable even if it did not *directly*

create or maintain the nuisance. *See* Restatement (Second) § 824(b) cmt. b (nuisance "liability . . . arises because one person's acts set in motion a force or chain of events resulting in the invasion," including acts that are "an indirect cause of the invasion"). "[T]he fact that other persons contribute to a nuisance is not a bar to the defendant's liability for his own contribution." *Id.* § 840E.

West Virginia's nuisance-causation requirement is consistent with its proximate-cause requirement for negligence. Proximate cause is "that cause which in actual sequence, unbroken by any independent cause, produced the wrong complained of, without which the wrong would not have occurred." *Wal-Mart Stores E., L.P. v. Ankrom*, 854 S.E.2d 257, 270 (W.Va. 2020). It "necessarily includes the element of reasonable anticipation that some injury might result from the act of which complaint is made." *Matthews v. Cumberland & Allegheny Gas Co.*, 77 S.E.2d 180, 188 (W.Va. 1953).

But an injury's proximate cause need not be the last negligent act in time. The "first act of negligence" can be a proximate cause if it "sets off a chain of events or creates a situation ultimately resulting in injury." *Evans v. Farmer*, 133 S.E.2d 710, 717 (W.Va. 1963). "Where two or more persons are guilty of separate acts" that "together proximately cause injury to another, they are guilty of concurrent negligence for which they may be held jointly and severally liable." *Marcus v. Staubs*, 736 S.E.2d 360, 372 (W.Va. 2012). An intervening cause

breaks the causal chain and relieves the alleged tortfeasor of liability only where it "constitutes a new effective cause and operates independently of any other act, making it and it only, the proximate cause of the injury." *Wal-Mart*, 854 S.E.2d at 270; *see also Evans*, 133 S.E.2d at 718 (same).

2. Appellees were a proximate cause of the nuisance

Appellants proved that Appellees each proximately caused the opioid epidemic in Cabell/Huntington; indeed, on this trial record, that is the only plausible conclusion. Appellants established without meaningful contradiction that Appellees shipped extreme volumes to Cabell/Huntington—orders of magnitude more than what they were shipping into other parts of West Virginia and the rest of the nation—and that they provided the vast majority of oxycodone, the leading cause of overdose deaths in West Virginia from 2001 to 2015. *See supra* pp. 14-15; JA5481, JA5485, JA5488, JA5491, JA5494. The myriad harms from the massive oversupply of prescription opioids in Cabell/Huntington were undisputed. *See* JA6356-6360; *supra* pp. 11-14. Appellants also proved Appellees' profound diversion-control failures, which included adjusting their systems to avoid identifying suspicious orders and failing to investigate the orders their systems flagged. *See supra* Part II.A.

Taken together, Appellees' massive volumes and diversion-control failures support the reasonable inference that Appellees caused the nuisance in

Cabell/Huntington. *See In re National Prescription Opiate Litig.*, 2019 WL 4178617, at *4 (N.D. Ohio Sept. 3, 2019) (holding causation could be established by showing that opioid distributors were responsible for "massive increases in the supply of prescription opioids" into plaintiffs' jurisdictions while failing "to maintain effective controls against diversion"); *see also National Prescription Opiate Litig.*, 589 F. Supp. 3d at 808-11 (holding that Ohio counties established that causal inference at trial against pharmacy defendants).

Appellants also proved these harms were not only foreseeable but known to Appellees: Appellees knew about the addictive, lethal nature of the opioids they sold and the burgeoning problems of opioid diversion and abuse, not least because DEA warned them repeatedly. *See supra* pp. 16-20. It was reasonably foreseeable that selling more opioids with few diversion controls would create a public-health crisis. *See Wehner*, 444 S.E.2d at 32; *Matthews*, 77 S.E.2d at 188.

B. The District Court Misapplied The Causation Standard

1. The district court misapplied the intervening-cause standard

The district court misapplied the intervening-cause standard. JA6511-6515. It held that "oversupply and diversion" in Cabell/Huntington "were made possible, beyond the supply of opioids by defendants, by overprescribing by doctors, dispensing by pharmacists of the excessive prescriptions, and diversion of the drugs to illegal usage." JA6515. These other acts, the court found, were "effective

intervening causes beyond the control" of Appellees that absolved them of liability. *Id.*

Concluding that overprescribing, overdispensing, and diversion were *intervening* causes, the court never considered whether they, along with the oversupply Appellees caused, might be *concurrent* causes. Under West Virginia law, a defendant's conduct "need not be the sole cause of the injury" as long as it is "one of the efficient causes thereof, without which the injury would not have resulted." *Wehner*, 444 S.E.2d at 33. Where two or more persons' conduct "together proximately cause[s] or contribute[s] to the injuries of another, . . . recovery may be had against any or all of them." *Evans*, 133 S.E.2d at 717. The court did not conduct this concurrent-cause analysis.

Nor did the district court find that these other causes "operate[d] independently of anything else," as they must to "insulate the original tort-feasor against liability." *Id.* at 718; *see Wal-Mart*, 854 S.E.2d at 270 ("to relieve a person" of liability, the other cause must "constitute[] a new effective cause and operate[] independently of any other act"). Quite the contrary. Throughout its opinion, the court emphasized the interrelatedness of Appellees' supply of opioids to Cabell/Huntington and the prescribing and dispensing of doctors and pharmacies. *See*, *e.g.*, JA6468 ("Doctors in Cabell/Huntington determined the volume of prescription opioids that pharmacies in the community ordered from

defendants and then dispensed pursuant to those prescriptions."); JA6469 ("the high volume of opioid prescriptions that doctors were writing 'became the foundation for the overall expansion in the opioid supply and opioid-related harm'") (quoting JA2476 (Keyes). As the court found, overprescribing and overdispensing created demand, and Appellees met that demand with "almost perfect[]" precision. JA6468.

2. The district court failed to analyze foreseeability

The district court failed to consider whether intervening acts were reasonably foreseeable by Appellees, such that they could not break the causal chain. Quoting *Sergent v. City of Charleston*, 549 S.E.2d 311, 320 (W.Va. 2001), the court held that proximate cause "'is the last negligent act contributing to the injury and without which the injury would not have occurred.'" JA6498-6499. But it omitted the next sentence in *Sergent*, which completes the causation standard: "[a] tortfeasor whose negligence is a substantial factor in bringing about injuries *is not relieved from liability by the intervening acts of third persons if those acts were reasonably foreseeable by the original tortfeasor at the time of his negligent conduct*." 549 S.E.2d at 320 (emphasis added). *Brooke County* applied this standard to opioid public nuisance claims, holding that "intervening actions, even multiple or criminal actions taken by third parties, do not break the chain of

causation" for a public nuisance claim "if a defendant could reasonably have expected their nature and effect." 2018 WL 11242293, at *7.

By failing to analyze foreseeability, the district court reached the incorrect conclusion that *any* intervening act, even a foreseeable one, breaks the causal chain and absolves Appellees of liability. That conclusion has no basis in West Virginia law. Uncontroverted evidence established that the intervening acts the court described—diversion, overprescribing, and overdispensing—were foreseeable consequences of Appellees' unreasonable conduct.

Diversion was a foreseeable consequence of Appellees' misconduct. The very existence of regulations requiring diversion controls evinces the foreseeability of diversion if Appellees failed to maintain those controls. *See* 21 C.F.R. § 1301.71(a). DEA's 30(b)(6) representative testified it was foreseeable that Appellees' "failure to comply [with federal law]" would "enable[] more diversion." JA1263 (Prevoznik). And DEA informed Appellees as early as 2005 that diversion controls were necessary to prevent diversion and abuse of opioids. *See supra* p. 16. Appellees' own witnesses acknowledged the foreseeability of diversion. *See*, *e.g.*, JA1198-1200 (Hartle) (McKesson corporate testimony that, "[u]sing common sense and basic logic, you could assume the more pills that are out there, the more potential for diversion there could be," and "one of the foreseeable harms of engaging in unlawful conduct in the distribution of

prescription opioids is diversion"). It also was foreseeable that Appellees' failure to investigate or block suspicious orders would enable the highest-volume prescribers and pharmacies in Cabell/Huntington to write and fill more and more opioid prescriptions. Appellees' failures ensured that opioids would be available to fill those orders.

West Virginia courts, applying the correct causation standard, have held that the opioid epidemic was a reasonably foreseeable consequence of distributors' conduct, notwithstanding other causes. *Brooke County* held that distributors' conduct "was not too remote from the opioid epidemic" and that "the acts of third parties (even criminals) were foreseeable and did not create a new effective cause or operative independently." 2018 WL 11242293, at *6. Most state and federal courts addressing opioid litigation agree. *See*, *e.g.*, *National Prescription Opiate Litig.*, 2018 WL 6628898, at *5 ("[T]he relationship between Plaintiffs' injury and Defendants' alleged conduct . . . is not too remote to support a finding of proximate cause here.").[15]

[15] *See also*, *e.g.*, *San Francisco*, 491 F. Supp. 3d at 676-84; *Massachusetts v. Purdue Pharma*, 2019 WL 6497887, at *3 (Mass. Super. Ct.); *Tennessee v. Purdue Pharma*, 2019 WL 2331282, at *5 (Tenn. Cir. Ct.); *Grewal v. Purdue Pharma*, 2018 WL 4829660, at *22-23 (N.J. Super. Ct. Ch. Div.); *New Hampshire*, 2018 WL 4566129, at *8-10; *Ohio v. Purdue Pharma*, 2018 WL 4080052, at *3 (Ohio Ct. Com. Pl.); *Alaska v. Purdue Pharma*, 2018 WL 4468439, at *7-8 (Alaska Super. Ct.); *Kentucky v. Endo Health Sols.*, 2018 WL 3635765, at *3-4

IV. THE DISTRICT COURT ERRED IN HOLDING THAT THE REQUESTED ABATEMENT REMEDY IS UNAVAILABLE

Despite recognizing that Appellants' requested remedy "addresses harms caused by opioid abuse and addiction," the district court denied abatement. JA6485, JA6518-6520. Abatement is an equitable remedy within the district court's discretion to craft, but the court did not exercise its discretion. Instead, it held the requested abatement remedy unavailable, based on two legal errors. First, the court erroneously ruled that abatement can be used only to eliminate "wrongful conduct," not harmful conditions that conduct causes. JA6515. Second, it miscast Appellants' requested abatement remedy as damages. JA6518.

Those conclusions misstate West Virginia law. Abatement remedies can include orders to pay funds to redress harmful *conditions* constituting a nuisance. They are not limited to injunctions ordering defendants to cease nuisance-creating conduct. Appellants properly sought such an abatement order, not damages.[16]

A. Abatement Can Require Defendants To Pay To Address Harmful Conditions

Injunctive relief is the means for abating a nuisance. *See Duff*, 421 S.E.2d at 257. This can include requiring defendants "to remedy the *conditions* giving rise

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(Ky. Cir. Ct.); *City of Chicago v. Purdue Pharma*, 211 F. Supp. 3d 1058, 1080-81 (N.D. Ill. 2016).

[16] Reversal of the district court's judgment on liability necessarily will require remand for consideration of the scope of the abatement remedy under the correct standard.

to the nuisance." *West*, 285 S.E.2d at 678-79 (citing *McGregor v. Camden*, 34 S.E. 936 (W.Va. 1899)) (emphasis added). Defendants remain liable for "the creation of a physical condition that is of itself harmful [even] after the activity that created it has ceased." Restatement (Second) § 834 cmt. e.

To remedy harmful conditions they created, defendants may be required to pay money for use in reducing the opioid crisis. In *Moats*—the only WVSCA opioid ruling—the court declined to set aside the MLP's determinations that its "powers to fashion equitable relief are broad" and that "nothing precludes it from ordering Defendants to pay the costs associated with abating the alleged public nuisance." 859 S.E.2d at 382. It cited precedent for injunctions "entail[ing] the payment of money by a defendant." *Id.* at 384 & n.43 (citing *United States v. Price*, 688 F.2d 204, 213 (3d Cir. 1982) (recognizing that injunctions that "compel expenditures of money" could be "permissible forms of equitable relief")). Concurring in *Moats*, Justice Hutchinson explained that equity permits courts "to formulate creative remedies to abate a nuisance, such as clean-up costs, or a common law fund to restore property values diminished by a nuisance." *Id.* at 394.

Following *Moats*, the MLP held that the State's public nuisance claims against opioid-dispensing pharmacies sought "prospective, equitable abatement," not "damages." *MLP Pharm MTD Order* ¶ 17. It cited the MDL court's ruling that, "'exercising its equitable powers, [it] has the discretion to craft a remedy that

will require Defendants, if they are found liable, to pay the prospective costs that will allow Plaintiffs to abate the opioid crisis.'" *Id.* ¶ 20 (quoting *In re National Prescription Opiate Litig.*, 2019 WL 4043938, at *2 (N.D. Ohio Aug. 26, 2019)).

Brooke County likewise held that "West Virginia caselaw recognizes broad remedies—including the recovery of costs—in abatement." 2018 WL 11242293, at *7 (citing *Witteried v. City of Charles Town*, 2018 WL 2175820, at *3 (W.Va. May 11, 2018) (memorandum decision) (holding that West Virginia law permits a city to abate a nuisance structure by demolishing it and recovering demolition costs from defendant)). *See also Kermit Lumber*, 488 S.E.2d at 923 n.26 ("temporary" nuisances include those "'abatable . . . by the expenditure of labor or money, by the defendant'") (quoting 58 Am. Jur. 2d *Nuisances* § 29 (1989)).

B. The District Court Erred In Holding That A Court Cannot Order Abatement Of A Condition That Endangers Public Health

1. The district court's holding that a nuisance is conduct, not a condition, contravenes West Virginia law

In rejecting Appellants' requested remedy, the district court cited *Kermit Lumber* for the proposition that, "[u]nder West Virginia law, a public nuisance consists of wrongful conduct." JA6515 (citing 488 S.E.2d at 925 n.28). But *Kermit Lumber* used the WVCSA's longstanding definition of public nuisance as "'an act *or condition*,'" *Kermit Lumber*, 488 S.E.2d at 921 (quoting *Sharon Steel*, 334 S.E.2d at 620) (emphasis added); it did not limit nuisances to conduct. There,

West Virginia's environmental agency sought abatement, penalties, and damages against defendants that contaminated a site and river with arsenic, "'*causing conditions to exist which endanger[] public health, safety and the environment*.'" *Id.* at 906 (quoting complaint). Defendants had vacated the site years earlier, yet the court permitted the action given the ongoing endangerment to public health. *Id.* at 925-26. It held that "'the "continuing" nature of the nuisance refers to the continuing damage caused by the offensive condition, not to the acts causing the offensive condition to occur.'" *Id.* at 925 (quoting *Arcade Water Dist. v. United States*, 940 F.2d 1265, 1268 (9th Cir. 1991)).

The district court's exclusion of conditions from the definition of public nuisance conflicts with the MDL court's and the MLP's rulings. Regarding MDL defendants that claimed "they discontinued the conduct that led to the existence of the nuisance," the court held "they are still subject to liability for abatement of any *ongoing consequential effects* of the nuisance." *National Prescription Opiate Litig.*, 589 F. Supp. 3d at 826 (emphasis added). The MLP found this ruling "persuasive and applicable to" opioid litigation under West Virginia law. *MLP Pharm MTD Order* ¶ 20.

None of the West Virginia decisions the district court cited (at JA6516-6518) to support its narrow understanding of abatement's proper scope purported to eliminate "condition" from nuisance's definition. The operation of a used car

lot in a residential neighborhood in *Martin v. Williams* is as much a "condition" as "conduct," and abatement included removing bothersome *conditions* (lights, displays, and equipment that remained after the business closed), illustrating that abatement can require more than forcing a defendant to stop harmful conduct. *See* 93 S.E.2d at 836.

The other cited cases merely recited the definition of a *private* nuisance: unreasonable "use of one's property" that "impairs the right of another to peacefully enjoy his or her property." *Burch v. Nedpower Mount Storm, LLC*, 647 S.E.2d 879, 886 (W.Va. 2007) (construction of wind turbines); *see also Duff*, 421 S.E.2d at 262 (proposed trucking); *Hendricks*, 380 S.E.2d at 203 (well interfering with neighbor's septic system). Those decisions do not purport to limit nuisances to conduct; they too define nuisance to include "acts *or conditions* that affect either the general public or a limited number of persons." *Hendricks*, 380 S.E.2d at 200 (emphasis added). The fact that some cases involve "conduct" or "use of land" does not preclude nuisance actions to abate harmful "conditions."

2. The district court erroneously limited abatement to injunctions to stop harmful conduct

Proceeding from its mistaken holding that a nuisance is limited to conduct, the district court held that abatement "has historically been limited to an injunction designed to eliminate allegedly tortious conduct or, in certain environmental

nuisance cases, an injunction to remove the contaminant." JA6517-6518. It erroneously limited abatement to "'seek[ing] court intervention to require one party to stop doing something that affects another.'" JA6517 (quoting *Moats*, 859 S.E.2d at 389-90 (Armstead, J., concurring in part and dissenting in part)).[17]

WVSCA cases say the opposite: a nuisance can be "'abatable at a reasonable cost, or by the expenditure of labor or money, by the defendant.'" *Kermit Lumber*, 488 S.E.2d at 923 n.26 (quoting 58 Am. Jur. 2d *Nuisances* § 29 (1989)). No West Virginia court has limited abatement to removing environmental contamination or enjoining harmful conduct. The WVSCA defines public nuisance actions broadly as "seek[ing] to have some *harm which affects the public health and safety abated*," without limiting that harm to an environmental one. *Id.* at 925 (emphasis added).

West Virginia cases requiring affirmative steps to address a nuisance—beyond stopping nuisance-causing conduct—are not limited to removing environmental contamination. *See*, *e.g.*, *Martin*, 93 S.E.2d at 836 (requiring removal of lights, installations, and structures of used car lot without discussion of environmental contamination or pollution); *Witteried*, 2018 WL 2175820, at *3

[17] Notably, the district court cited only Justice Armstead's partial dissent on this point, not the majority opinion. It also cited statutes authorizing governments to "abate" "hazards to public health and safety," but these statutes nowhere incorporate the limitation the district court imposed. JA6517 (citing W.Va. Code §§ 7-1-3kk, 8-12-5(23)).

(defendant must pay costs of demolishing nuisance structure, where environmental contamination was not at issue); *West*, 285 S.E.2d at 678-79 (holding parties were entitled to injunction requiring defendants to abate dusty road nuisance and permitting trial court to consider "variety of possible solutions").

In holding otherwise, the district court incorrectly limited the harms an abatement order can reach. It attempted to distinguish *Kermit Lumber*, where the plaintiff agency sought to have defendants clean up hazardous arsenic, on the ground that the WVSCA "did not hold that the plaintiff could recover, as abatement, for downstream harms to the community resulting from the contamination." JA6520 (citing 488 S.E.2d at 925). But the agency in *Kermit Lumber* did not request that relief, so it was not at issue. Here, Appellants seek funding for services to abate the "hurt or inconvenience" to "the general public," *Hark v. Mountain Fork Lumber Co.*, 34 S.E.2d 348, 354 (W.Va. 1945); namely, the epidemic of opioid addiction and overdoses arising from widespread opioid abuse and diversion. For example, Appellants seek funding to distribute naloxone, a drug that reverses overdoses. JA2552, JA2568 (Alexander). As in *Kermit Lumber*, this action "seeks to have some harm which affects the public health and safety abated." 488 S.E.2d at 925.

3. The district court miscast the abatement remedy as damages

The district court mischaracterized the abatement remedy Appellants seek as "remuneration for the costs of treating the horrendous downstream harms of opioid use and abuse"—damages, rather than abatement. JA6518. This miscasts the distinction between damages and abatement. Appellants did not present an accounting of how much the opioid epidemic has cost or seek compensation for those expenditures. Rather, Appellants sought measures to eliminate current dangerous conditions—widespread addiction and risk of overdose—that Appellees created. *See supra* pp. 21-22.

The fact that Appellants seek *funding* to carry out these measures does not convert the remedy into damages. Governments can charge the cost of abatement to the defendant. *See City of Flagstaff v. Atchison, T. & S.F. Ry. Co.*, 719 F.2d 322, 324 (9th Cir. 1983) ("[r]ecovery [is] allowed where the acts of a private party create a public nuisance which the government seeks to abate"); *Brancato v. City of New York*, 244 F. Supp. 2d 239, 245 (S.D.N.Y. 2003) ("It is well recognized that when a local government . . . summarily abates a public nuisance, it may compel the owner of the property involved to bear the cost of abatement.") (applying New York law); *see also Witteried*, 2018 WL 2175820, at *3 (same).

The nature of the opioid epidemic means public entities will provide and coordinate services to abate the public-health crisis, such as addiction treatment

and equipping first responders. Appellants logically sought to coordinate these remedial services through existing public institutions, rather than asking the court to order Appellees to administer public-health measures they have no experience administering.

To label Appellants' requested remedy damages, the district court cited authorities that do not require the result it reached. It misread Dobbs' *Law of Remedies*. JA6518 (citing 1 Dan B. Dobbs, *Law of Remedies* § 5.7(3) (2d ed. 1993)). The quoted passage—saying damages "might be based on . . . the cost of eliminating the nuisance effects"—merely explains how damages for private nuisance might be measured; it says nothing about public nuisance remedies. The court also cited *McMechen v. Hitchman-Glendale Consolidated Coal Co.*, 107 S.E. 480 (W.Va. 1921), on the "vast" difference between damages and abatement. JA6518. But *McMechen*—which predated the merger of law and equity, *see* W.Va. R.C.P. 1 (1960)—just addressed pleading issues under pre-merger rules, not any remedial issue in this case.

West Virginia courts disapproved the district court's conclusion that the requested abatement remedies are damages. The MLP held that the district court's opinion "d[id] not warrant reconsideration" of its own holding that the State's claims—seeking an equivalent abatement remedy against pharmacy defendants—"do not seek damages." *MLP Pharm MTD Order* ¶ 19. *Beckley*, where a West

Virginia city sought equivalent abatement from pharmacy defendants, characterized the district court's remedies ruling as "neither predictive nor consistent with West Virginia law." *City of Beckley* ¶ 12.

CONCLUSION

The district court's judgment should be reversed.

REQUEST FOR ORAL ARGUMENT

Because this appeal involves complex issues of law and fact, Appellants respectfully request oral argument.

Respectfully submitted,

/s/ *David C. Frederick*

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

No. 22-1819(L) **Caption:** City of Huntington v. AmerisourceBergen Drug. Corp.

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Party Name City of Huntington & Cabell Cnty. C

Dated: April 17, 2023

ATTACHMENT TO
CERTIFICATE OF COMPLIANCE

1. The foregoing Final Brief for Appellants complies with the type-volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B)(i) and with the Order of this Court dated December 14, 2022, which granted Appellants leave to file an opening brief not in excess of 18,000 words, because this Brief contains 17,678 words, excluding the parts of the Brief exempted by Federal Rule of Appellate Procedure 32(f).

2. The foregoing Final Brief for Appellants complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this Brief has been prepared in proportionally spaced typeface using Microsoft Office Word 2016 in 14 point Times New Roman.

Dated: April 17, 2023

By: /s/ *David C. Frederick*
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CERTIFICATE OF SERVICE

I hereby certify that, on April 17, 2023, I electronically filed the foregoing Final Brief for Appellants with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit using the appellate CM/ECF system.

Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

/s/ *David C. Frederick*
David C. Frederick

Nos. 22-1819(L) & 22-1822

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

CITY OF HUNTINGTON, WEST VIRGINIA and
CABELL COUNTY COMMISSION,
Plaintiffs-Appellants,

v.

AMERISOURCEBERGEN DRUG CORPORATION, *et al.*,
Defendants-Appellees.

On Appeals from the United States District Court
for the Southern District of West Virginia
Case Nos. 3:17-cv-01362 and 3:17-cv-01665, Hon. David A. Faber

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ADDENDUM TO FINAL BRIEF FOR APPELLANTS

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CIRCUIT COURT OF
MONTGOMERY COUNTY, ALABAMA
GINA J. ISHMAN, CLERK

IN THE CIRCUIT COURT FOR MONTGOMERY COUNTY, ALABAMA

THE STATE OF ALABAMA,	§	
	§	
Plaintiff,	§	
	§	**CIVIL ACTION NO.**
v.	§	**03-CV-2019-901174.00**
	§	
PURDUE PHARMA L.P., et al.,	§	
	§	
Defendants.	§	

ORDER

This matter is before the Court on three separate motions: Endo, Purdue, and Rhodes' Joint Motion to Dismiss the State of Alabama's Complaint ("Endo's Motion"), McKesson's Motion to Dismiss ("McKesson's Motion"), and Rhode's Supplemental Motion to Endo's Motion. This case is currently stayed as to the Purdue Defendants (Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; and Rhodes Pharmaceuticals, L.P.) due to the entry of a temporary stay in Purdue's Bankruptcy petition in the Southern District of New York. For the reasons that follow, and after review of the record, with the benefit of oral arguments of counsel, and considering the applicable law, the Court hereby **DENIES** all of the Motions as to the Endo Defendants (Endo Health Solutions, Inc. and Endo Pharmaceuticals, Inc.) and Defendant McKesson (McKesson Corporation).

I. FACTUAL ALLEGATIONS OF THE STATE'S COMPLAINT

The Complaint filed by the State of Alabama alleges that Endo, a pharmaceutical manufacturer, and McKesson, a pharmaceutical distributor, combined and concurred to create an opioid crisis in the State of Alabama. Endo, primarily through its aggressive and misleading marketing of opioids, and McKesson, through its reckless or intentional disregard for its State and Federal Controlled Substances Act responsibilities, wrought havoc on the public health and drained public coffers by unleashing a tidal wave of addictive and deadly painkillers.

Prescription opioids are a potent painkiller that is chemically similar to heroin, and equally as addictive. Compl. ¶¶ 3, 101. In fact, both heroin and prescription opioids, such as oxycodone and hydrocodone, are derived from the opium poppy. Opium has been known to be a dangerous and addictive substance for centuries, and until the mid-1990's, prescribers were reluctant to prescribe opium derived drugs for anything other than palliative care (where death was or appeared to be imminent) or post-surgery pain (and there, only for short durations). *See* Compl. ¶ 6

By binding to opioid receptors, opioids can block pain signals, but they also highjack the brain's pleasure systems (through the release of large amounts of dopamine), causing euphoria. Compl. ¶ 50. Repeated exposure to opioids alters the brain, causing opioid tolerance (the need to take higher and higher dosages of drugs to achieve the same opioid effect, such as analgesia) and drug dependence (susceptibility to withdrawal symptoms). Compl. ¶¶ 49, 51. This combination of dopamine release, opioid tolerance, and withdrawal works in concert to make opioids highly addictive. ¶¶ 45-46. Opioids are also very deadly. Opioids cause respiratory depression, which leads to overdoes death from respiratory failure. Compl. ¶ 52. The opioid crisis has in part been exacerbated because tolerance to opioid respiratory depressive effects develops at a slower rate than tolerance to opioid analgesic effects. *Id.* As a chronic pain patient's dosage is increased in

response to the diminishing return on pain-relief, there is not a concomitant increase in the body's resistance to respiratory depression, thus leading to death from overdose even where the opioid is taken as recommended. *Id.*

The State's complaint alleges that Endo sought to counteract the prevailing belief that opioids were too dangerous to prescribe long term for anything less than the most dire of circumstances in order to create a profitable market for opioids. Compl. ¶ 104.

These allegedly false and deceptive statements targeted regulators, doctors, and patients throughout the State of Alabama by using independent third parties including "front groups," "key opinion leaders" and other actors allegedly controlled to gain the appearance of impartiality. Compl. ¶ 10, 66. The Complaint alleges that Endo funded and controlled these advocacy groups and influential experts in order to overstate the benefits of opioids for chronic pain treatment while understating the risks of addiction.

The Complaint further alleges that Endo and co-defendant McKesson failed in their legal duties to serve as the critical choke point safeguarding the public and the State from the foreseeable harms if prescription opioids were diverted for illegitimate purposes. *See, e.g.*, Compl. ¶ 266, 322. The federal and state Controlled Substances Acts ("CSAs") require Endo and McKesson to register to manufacture or distribute opioids; to maintain effective controls against diversion of the controlled substances that they manufacture or distribute; and to design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the government authorities.

The State alleges the Endo and McKesson took no meaningful action to curtail the diversion of opioids in the state or to design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the government authorities.

The State further alleges that McKesson instead sent facially suspicious quantities of opioids into the State. *See, e.g.*, Compl. ¶ 157.

The State contends that but for the deceptive marketing by Endo and failure to monitor, report, and stop suspicious orders by McKesson and Endo, there would be no opioid crisis in Alabama.

The State alleges it has suffered a variety of significant injuries as a result of Defendants' conduct. In particular, the State alleges it has suffered damages in the form of "health care costs from opioid abuse," "costs related to overdose responses, naloxone spending for first responders, increased law enforcement spending, increased pretrial and post-trial incarceration costs, increased criminal defense costs, increased social services spending such as representing parents and children in neglect proceedings, loss of productivity, loss of tax revenues for the State of Alabama, and other costs and response measures needed to address the epidemic." Compl. ¶¶ 366-367.

II. PLEADING STANDARDS ON A MOTION TO DISMISS AND PARTICULARITY.

Alabama's pleading rules are liberal and emphasize simplicity. Alabama has not adopted the stringent federal pleading standard. *See McKelvin v. Smith*, 85 So. 3d 386, 389-391 (Ala. Civ. App. 2010). Under Rules 8 and 12(b)(6) of the Alabama Rules of Civil Procedure[1], "the dismissal

[1] The Defendants raise the question whether Rule 9(b) of the Alabama Rules of Civil Procedure applies to some or all of the State's claims. This Court finds that the only portion of the complaint that is subject to Rule 9(b)'s pleading standard is the State's allegation of fraudulent concealment of a cause of action. However, the Court notes that the State has pleaded sufficient facts to satisfy Rule 9(b) in the State's allegations of misrepresentations or false statements made by the defendants. The State has pleaded the "time, place and the content" of Defendants' alleged misleading or false messages, what was misrepresented, and what was gained — all that is required under Rule 9(b). "Malice, intent, knowledge, and other condition of mind of a person may be averred generally." Ala R. Civ. P 9(b). The pleading standard under Rule 9(b) does not require an allegation of every single statement the plaintiff intends to rely on at trial to make its case. In cases of "prolonged multi-act schemes," a plaintiff may "plead the overall nature of the fraud and then … allege with particularity one or more illustrative instances of the fraud." *Burgess v. Religious Technology Center, Inc.*, 600 Fed. Appx 657, 662 (11th Cir. 2015). The State has pled much more than a few illustrative instances of the Defendants false and misleading statements.

The Court also notes that there are legally sufficient claims made against McKesson and Endo that do not rely on allegations of false and misleading statements at all. Counts I, III, IV, V, and VI could proceed on allegations that the

of a complaint is not proper if the pleading contains 'even a generalized statement of facts which will support a claim for relief under [Rule] 8, [Ala. R. Civ. P.]'" *McKelvin v. Smith*, 85 So. 3d 386, 389 (Ala. Civ. App. 2010). "Under this rule the prime purpose of pleadings is to give notice. Such common law concepts as stating the facts each party believes to exist and narrowing the issues that must be litigated are completely abandoned. The distinctions between 'ultimate facts' and 'evidence' or conclusions of law are no longer important since the proposed new rules do not prohibit the pleading of facts or legal conclusions as long as fair notice is given to the parties." Ala. R. Civ. P. 8(a) (Committee Comments on 1973 Adoption). Thus, a complaint is sufficient if it contains nothing more than "a short and plain statement of the claim showing that the pleader is entitled to relief" and "a demand for judgment for the relief the pleader seeks." ALA. R. CIV. P. 8(a).

"In considering whether a complaint is sufficient to withstand a motion to dismiss under Rule 12(b)(6), ALA. R. CIV. P., a court 'must accept the allegations of the complaint as true.' *Creola Land Dev., Inc. v. Bentbrooke Housing, L.L.C.*, 828 So. 2d 285, 288 (Ala. 2002) (emphasis omitted). The court does "not consider whether the pleader will ultimately prevail but whether the pleader may possibly prevail." *Wilson v. University of Alabama Health Services Foundation, P.C.*, 266 So. 3d 674, 676 (2017) (internal quotes and citations omitted); A court must "construe all doubts regarding the sufficiency of the complaint in favor of the plaintiff." *Id.* "[A] dismissal for failure to state a claim is properly granted only when it appears beyond a doubt that the plaintiff can prove no set of facts entitling him to relief." *Winn-Dixie Montgomery, Inc. v. Henderson*, 371 So. 2d 899 (Ala. 1979). Stated another way, if under a provable set of facts, upon any cognizable theory of law, a complaint states a claim upon which relief could be granted, the complaint should

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Defendants did not adequately police the distribution of their opioids. The Court will assume Rule 8 applies throughout, excepting the fraudulent concealment allegation.

not be dismissed. *Childs v. Mississippi Valley Title Insurance Co.*, 359 So. 2d 1146 (Ala. 1978)." *Ex parte City of Birmingham*, 624 So. 2d 1018, 1020 (Ala. 1993) (quoting *Seals v. City of Columbia*, 575 So. 2d 1061, 1063 (Ala. 1991)).

Finally, with regard to the pleading standard, the Court disagrees with the Defendants' contention that the Complaint's claims must be dismissed for failure to specifically identify prescribing physicians who relied on Defendants' alleged misrepresentations or particular suspicious prescriptions for opioids. This Court finds no practical benefit in requiring the State to name a particular physician or list of prescriptions that were "suspect" in order to illustrate the alleged schemes that are otherwise well-pled in the Complaint. The Court finds that the Complaint is adequate to place all Defendants upon fair notice of the allegations they must meet in order to prepare a defense.

III. THE COMPLAINT ADEQUATELY ALLEGES ACTUAL AND PROXIMATE CAUSE.

One of Defendants' primary arguments is that the State has failed to properly allege proximate cause. *See, e.g.*, Endo's Br. at 24, McKesson's Br. at 6. However, the Court must resolve all doubts regarding the pleadings in the plaintiff's favor. *Wilson* at 676. Causation is a very fact-intensive analysis, and proximate cause is thus generally "a question of fact to be determined by a jury." *Green v. Alabama Power Co.*, 597 So. 2d 1325 (Ala. 1992). Indeed, "[p]roximate cause becomes a question of law only when there is a total lack of **evidence** from which the factfinder can reasonably infer" a causal relationship exists between the defendant's conduct and the resulting injury to the plaintiff. *Id.* at 1328 (emphasis supplied). That is not the case here.

Under Alabama law, "foreseeability is the cornerstone of proximate cause," *Alabama Power Co. v. Taylor*, 306 So. 2d 236, 249 (Ala. 1975), and is generally a question of fact for the jury. *See Thetford v. City of Clanton*, 605 So. 2d 835, 839 (1992). At this stage of the litigation,

the State has adequately alleged that the harms caused by Endo's marketing of opioids and McKesson's distribution of opioids were foreseeable by the defendants. Moreover, this case is currently at the pleading stage and thus it would be inappropriate to dismiss due to a lack of evidence, particularly in light of the facts alleged in the State's Complaint.

Defendants argue that the causal chain between their conduct and the State's alleged injuries is "too attenuated." Endo's Br. at 24; McKesson's Br. at 9. In support of this argument, they claim there is a several-steps-long chain, involving addicts and prescribers, separating their conduct from the harms suffered by the State. Endo's Br. at 23; McKesson's Br. at 9.

First, the Court notes that what constitutes the "causal chain" is an issue of fact that will be determined by the evidence, and is therefore inappropriate for adjudication at the pleading stage.

Second, the mere presence of other parties in the arguable "causal chain" does not foreclose that a legally sufficient causal connection may ultimately be established. Alabama law explicitly recognizes that the intervention of prescribers into the causal chain does not "break" the chain of causation in an action against a drug manufacturer if the prescriber is intentionally misinformed by the manufacturer. *Wyeth v. Weeks*, 159 So. 3d 649 (Ala. 2014). Even a criminal act might not "intervene" so as to sever the causal chain, if the result is foreseeable. *See Thetford*, 605 So. 2d at 839 (1992). Here, the injuries claimed by the State were especially foreseeable because they were allegedly caused by *intentional* conduct on the part of Defendants. And drug-seeking behavior of patients is certainly foreseeable where the drug is addictive, and patients were led to believe that the risk of addiction was low. Compl. ¶ 10.

The Defendants also portray the State's injuries as "derivative" of injuries of other parties less removed from Defendants' actions, such as losses sustained by Alabamians who became addicted (e.g. personal injury or wrongful death). The cases cited by defendants are inapposite.

The State is not attempting to stand in the shoes of the people of Alabama; it is instead standing in its own shoes, trying to protect the people of Alabama from the Defendants' misconduct.

The State also seeks to recover its own costs for its own injuries. Defendants are also essentially asking the Court to undermine (if not vitiate) the well-accepted, inherent authority of States to protect their citizens under the *parens patriae* doctrine. The State has unique, or "quasi-sovereign," interests in protecting the health and welfare of its citizens and markets. *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 607 (1982). These interests have without a doubt been harmed by the Opioid Crisis. Under the *parens patriae* doctrine, the "indirect effects of the injury must be considered as well in determining whether the State has alleged injury to a sufficiently substantial segment of its population" to have standing to sue. *Id.* The plaintiffs in the cases cited by Defendants were not domestic states, and they therefore lacked an American state's right to protect or mitigate an "injury to an identifiable group of individual residents." *Id.* Thus, the Defendants' cases addressing indirect injuries to third-parties are not applicable.

McKesson makes an additional causation argument; that they were not the cause-in-fact of the State's harms. As McKesson puts it, (1) if doctors acted with full information when they prescribed opioids, then those doctors were the cause-in-fact of a given patient's injury; (2) if doctors acted pursuant to a standard of care that developed as the result of marketing fraud, then the Manufacturers' alleged marketing campaign (or some combination of the marketing and the doctor's decision making) is the cause-in-fact, and (3) if the user "obtained or used the drugs illicitly, then his own wrongful conduct is the but-for cause of any resulting addiction." McKesson's Br. at 6. But this argument fails. An injury may have more than one cause-in-fact. *See, e.g. Thetford*, 605 So. 2d 835 (Ala. 1992). The State has alleged that the McKesson's conduct was the cause-in-fact of the State's injuries, and it has sufficiently pleaded those allegations.

IV. THE STATE'S CLAIMS ARE NOT TIME-BARRED.

Endo has also moved to dismiss the State's claims, arguing the claims "are entirely or predominately barred by the applicable statutes of limitations. *See* Endo's Br. at 39. McKesson moves to dismiss only the State's Alabama Deceptive Trade Practices Act Claims. McKesson's Br. 35. The State's claims are not subject to a statute of limitations for a number of reasons.

In Alabama, consistent with the United States, the doctrine of *nullum tempus occurrit reipublicae* immunizes the State from the application of statutes of limitation, unless the State "is expressly or by necessary implication included within the operation of the statute." *Bd. of School Com'rs v. Architects Group*, 752 So. 2d 489, 491 (Ala. 1999). This State's highest Court has held that "it is a cardinal rule that the statute of limitations, unless so expressed, does not run against the state; but it is equally a cardinal rule that [statutes of limitations] do run against the state, if so expressed." *Cox v. Board of Trustees of the University of Alabama*, 49 So. 814, 820 (Ala. 1909). This immunization from statutory limitations, on the State and Federal level, is "based upon the important public policy of preserving public rights and revenues from the negligence of public officers." *United States v. Weintraub*, 613 F.2d 612, 618 (6th Cir. 1979) (citing *Guaranty Trust Co. v. United States*, 304 U.S. 126, 132-33 (1938)). The case at hand falls within the parameters of applicability.

The Legislature did not include a time bar against the state within the State's nuisance statutes, Section 6-5-120, et seq. of the Code of Alabama. Furthermore, it is a firmly rooted common law principle that an action to abate an existing nuisance has no expiration date. The Legislature did not include a statute of limitations governing the State's filing of ACSA claims; thus the *nullum tempus* doctrine mandates that no time limitation applies to this action. The State is not mentioned in the two-year catch-all provision of Section 6-2-38(1) of the Code of Alabama.

The State of Alabama clearly has not voluntarily subjected itself to a statute of limitation for any of its pleaded counts

Defendants argue that "broad and general" language is enough "to bar the State of Alabama from presenting a claim after the time allowed by statute," without expressly implicating the State. *State v. Estate of Crocker*, 83 So. 2d 261, 262 (Ala. Ct. App. 1955). This argument fails because the Court of Appeals was interpreting a statute of non-claims. 83 So. 2d at 264. The argument also ignores subsequent decisions of the Supreme Court of Alabama expressly recognizing the continued validity of the doctrine that "no time runs against the state[.]" *Board of School Com'rs of Mobile County v. Architects Group, Inc.*, 752 So. 2d 489 (1999) .

The Defendants also argue that the State is subject to the Deceptive Trade Practices Act's statute of limitations, which applies a one-year statute of limitations to "persons." Ala. Code § 8-9-14. Defendants argue that the plain language of the statute defines "person" to include the Office of Attorney General. However, here, the Attorney General is not a "person" bringing the actions, but merely an extension of the State of Alabama. Separate definitions within the Act for "Attorney General" and "Persons" supports this dichotomy. Ala. Code § 8-19-3(1), (5). Also, the Legislature has treated the Attorney General differently than private "persons" throughout the DTPA, placing restrictions on private plaintiffs that it does not impose on the Attorney General. Lastly, if there is any question whether the Attorney General is a "person" to whom the limitation applies, the *nullumn tempus* doctrine dictates that the limitation does not apply, because the State is not expressly, or by necessary implication,[2] included within the operation of the DTPA's statute of limitations. *Bd. of School Com'rs*, 752 So. 2d at 491.

[2] The Endo Defendants wrongly argued during the hearing on their motion to dismiss that the statute of limitation under the DTPA that the limitations period can be applied to the State either expressly *or implicitly*. The *nullum tempus* doctrine does not hold this. Rather, it holds that a limitations period can be applied to the State either expressly or by *necessary implication*. *Bd. of School Com'rs*, 752 So. 2d at 491. The term "necessary implication" means "[a]n

Finally, Defendants argue that because claims are derivative of injuries to others, *nullum tempus* does not apply, citing *Miller v. State*, 38 Ala. 600, 604 (1863). In *Miller*, the litigation was "substantially between the township and the defendant," with the State playing a nominal role, resulting in the court finding the State was not entitled to *nullum tempus*. *Miller*, 38 Ala. at 604. Defendants also cite to *Miller* for the proposition that *nullum tempus* does not extend to claims that are derivative of harms to its residents. As discussed above, the State of Alabama has a substantial interest in this action and is the true plaintiff and seeks compensation for its own injuries distinct from those of individual citizens.

Because of the aforementioned reasons, the issue of whether the State's claims are time-barred is not appropriate for consideration in a motion to dismiss.

V. The Complaint Adequately States a Claim for Public Nuisance.

The Complaint alleges a valid claim under the theory of public nuisance. "The determination of the existence of a nuisance necessarily depends upon the circumstances of each case and is a question of fact for the jury or the judge sitting without a jury." *Morgan County Concrete Co. v. Tanner*, 374 So. 2d 1344, 1347. (Ala. 1979). Alabama law defines nuisance as "[a]nything that works hurt, inconvenience, or damage to another. The fact that the act done may otherwise be lawful does not keep it from being a nuisance." Ala. Code § 6-5-120. "A public nuisance does not necessarily involve interference with use and enjoyment of land." Restatement (Second) of Torts § 821B cmt h; *see also State v. Ellis*, 78 So. 71 (Ala. 1918) (injunction to protect

implication so strong in its probability that anything to the contrary would be unreasonable. *Implication*, Black's Law Dictionary (11th ed. 2019). Thus, for the State to be included under a statute of limitations by "necessary implication," the failure to apply the statute of limitations to the State must be so unreasonable that it frustrates the purpose of the statute. But the DTPA is a straightforward enforcement act that presents no reason on its face why its limitations period should apply to the State, particularly where the DTPA treats State actions differently from private actions in multiple ways. Moreover, this case presents a perfect illustration of why the Legislature would decline to extend the DTPA's statute of limitations to the State. At best, the Defendants can only argue – as they have done – that the State is implicitly included in the DTPA's statute of limitations. But that is simply not the standard.

the moral health of the community). "The conducting of a business, trade, industry or occupation or the doing of a thing, not inherently insanitary or a menace to public health, in such a manner as to make it a menace, or likely to become a menace, to public health," is a nuisance per se. Ala. Code § 22-10-1.

The Complaint charges the Defendants with causing injury to the public health and public safety through the sale and distribution of dangerous and addictive Opioid products. Alabama has the highest number of prescriptions per person in the nation, and the number of Alabamians on long-term opioid therapy well exceeds the national average. Comp. ¶16. This has caused public injuries such as statewide "addiction and abuse," "an elevated level of crime," and "loss of tax revenues for the State[.]" Compl. ¶ 380. The court finds that, at the pleading stage, this is sufficient to establish the existence of a nuisance.

The State also pleads sufficient facts to establish that the Opioid Crisis "damages all persons who come within the sphere of its operation." Ala. Code § 6-5-121. The sheer number of persons affected by the opioid crisis in Alabama is itself sufficient to constitute a public nuisance. *See West Morgan-East Lawrence Water and Sewer Authority v. 3M Company*, 208 F.Supp.3d 1227, 1234 (N.D.Ala.2016).

Defendants' argue that they cannot be liable for abating the public nuisance because other parties controlled the opioid distribution at some point. Endo's Br. at 33; McKesson Br. at 25. Both cite the same Alabama case, *Tipler v. McKenzie Tank Lines*, 547 So. 2d 438 (Ala. 1989), to support their argument. The Court finds *Tipler* inapposite.

James Tipler was injured by a truck that was driving to pick up liquid sulfur from an Exxon facility. Tipler added Exxon as a Defendant under the theory that the trucks driving to and from its facility created a public nuisance. Importantly, the Alabama Supreme Court applied Alabama's

proximate cause standard to determine whether Exxon had "control" over a public nuisance:

> we must look to the particular facts of each case to determine whether the party charged with creating and maintaining a nuisance has engaged in a course of conduct, or has permitted to exist a set of circumstances, that, in its natural and foreseeable consequences, proximately caused the hurt, inconvenience, or damage complained about.

547 So. 2d at 440-41. The Court said Exxon did not exert sufficient control because:

> [i]t is undisputed that Exxon had no agency relationship with either of the other defendants; that Exxon had no right of control, and exercised no control, over the hauling activities from its facility; and that Exxon did not engage in any activity relating to the construction or maintenance of the public roads here involved or relating to traffic control upon those roads.

Id. at 440. In other words, Exxon had nothing to do with the accident.

Unlike Exxon, the State pleaded that Endo exercised control over their production and marketing of opioids, and that the opioid epidemic was a foreseeable result of their deceptive marketing campaign. Unlike Exxon, McKesson was in control of the distribution of nearly 800 million opioids throughout Alabama; 16 million of which it delivered to one street. The opioid epidemic was certainly a foreseeable result of these controlled acts.

In short, "control" equals "proximate cause" under Alabama law. *See id.* at 440-41. Because the State adequately pleaded that each Defendant was a proximate cause of the opioid epidemic, the State adequately pleaded that each Defendant had control of the public nuisance.

McKesson also argue that the State's public nuisance claim (and other common law claims) are barred by the Municipal Cost Recovery Rule set out in *Flagstaff v. Atchison, Topeka, and Santa Fe Ry. Co.*, 719 F.2d 322 (9th Cir. 1983). McKesson's Br. at 12. But this claims fails for multiple reasons. First, as the name implies, the Municipal Cost Recovery Rule generally applies to local, not state, governments. McKesson acknowledges this but points out that one state appellate court (Wyoming) and one state trial court (Delaware) have applied the rule to their states. Second,

Alabama has not adopted the Municipal Cost Recovery Rule, and this Court does not see any reason to adopt it now. Plus, even if Alabama did follow the Municipal Cost Recovery Rule, the State's case falls within the many exceptions to the Rule, to wit: (1) the action is authorized by statute, *Flagstaff v. Atchison, Topeka, and Santa Fe Ry. Co.*, 719 F.2d 322, 324 (9th Cir. 1983); (2) the acts of private parties create a public nuisance which the government seeks to abate, *id.*; (3) the conduct is ongoing and persistent, *see, e.g., State ex rel. Jennings v. Purdue Pharma L.P.*, No. CVN18C01223MMJCCLD, 2019 WL 446382, at *6 (Del. Super. Ct. Feb. 4, 2019); and (4) the conduct of the defendants is "intentional" or "deceptive." *In re Opioid Litigation*, No. 4000002017, 2018 WL 4827862, at *5 (N.Y. Sup. Ct. July 17, 2018).

VI. The Complaint Adequately Pleads Claims Under the Law of Wantonness.

The State pleaded a common-law claim of wantonness, which in Alabama, is distinct from negligence. "To establish wantonness, the plaintiff must prove that the defendant, with reckless indifference to the consequences, consciously and intentionally did some wrongful act or omitted some known duty. To be actionable, that act or omission must proximately cause the injury of which the plaintiff complains." *Lemley v. Wilson*, 178 So. 3d 834, 841-42 (Ala. 2015). The State has sufficiently pleaded wantonness claims against all Defendants.

The State pleaded sufficient facts to establish that the Manufacturers "consciously and intentionally" committed acts with "reckless indifference to the consequences." *Id.* For example, the State has alleged that Endo knew about the addictive character of their opioids. They knew opioids were a dangerous health risk for people taking high doses. They knew that their products would not be suitable for long term, chronic non-cancer pain. And they knew extended-release opioids were susceptible to abuse and addiction. Despite knowing those opioid traits, Endo made public statements to the contrary, including hiring KOLs and front groups to misrepresent the facts

about opioids. Scientific studies, detailed prescription data, and reports of adverse effects and warnings from the FDA establish that the Manufacturers knew what they were saying was wrong—and they knew what the consequences of their actions could be. They simply did not care. That is the very definition of wantonness. *See Lemley*, 178 So. 3d at 841-42 ("To establish wantonness, the plaintiff must prove that the defendant, with reckless indifference to the consequences, consciously and intentionally did some wrongful act or omitted some known duty").

As to McKesson, the State pleaded that the DEA sent two letters in 2006 and 2007 warning Purdue, Endo, *and* McKesson to exercise diligence and avoid filling suspicious orders that might be diverted into illegitimate medical, scientific, and industrial channels. Yet, McKesson sold prescription opioids to retailers in the State of Alabama knowing they would likely be diverted. McKesson knew that its orders were excessive for the medical needs of the communities in Alabama and were facially suspicious, but it failed to take meaningful action to stop the diversion that was obviously, to McKesson, occurring in Alabama. McKesson knew that it was failing in its duty to report suspicious orders, and it knew what the consequences of those actions would be and made the decision to continue distributing in such a manner anyway. If the State's allegations are true, that makes McKesson's actions wanton. *See Lemley*, 178 So. 3d at 841-42

VII. The Complaint Adequately Pleads Claims Under the Law of Negligence.

Under Alabama law, an actionable negligence claim requires a plaintiff to show that the Defendants owed a duty, a breach of that duty, causation, and damages. *Glass v. Birmingham Southern Ry. Co.*, 905 So. 2d 789, 794 (Ala. 2004). The Defendants argue that the State failed to plead sufficient facts to establish the first three elements. The Court has addressed causation above. The court now turns to the duty elements.

Endo and McKesson assert they owe no duty to avoid damaging the State of Alabama and its citizens. The reasoning of Judge Polster in the Multi-District Litigation in Ohio is instructive as to why they owe a duty: "Defendants' assert that 'the [Report and Recommendation of the Magistrate Judge] identified no Ohio case recognizing a common-law *duty to report or halt suspicious orders of controlled substances*,' and 'even if there were a common-law duty to *report or halt suspicious orders*, no authority suggests that such a duty runs to the cities or counties' .... The duty that Plaintiffs allege is not so narrow. Plaintiffs allege that Defendants, like all reasonably prudent persons, have a duty "to not expose Plaintiffs to an unreasonable risk of harm." *County of Summit Ohio, et al. v. Purdue Pharma L.P.*, Opinion and Order, Case No. 18-op-4509 (N.D. Ohio, Dec. 19, 2018).

In their respective briefs, the Defendants attempt to narrow the duties the State's Complaint alleges they owe to the State. McKesson states the "sole source of this purported duty is a federal regulation." McKesson's Br. at 19. The Manufacturer Defendants limits the State's allegations of duty to only "three breaches of a duty." Endo's Br. at 36. What the Defendants fail to acknowledge, however, is that under Alabama law, duty is a much broader concept. In Alabama, "every person owes every other person a duty imposed by law to be careful" not to harm one another. *Southeastern Greyhound Lines v. Callahan*, 13 So. 2d 660, 663 (Ala. 1943). *Compare County of Summit Ohio*, Opinion and Order, Case No. 18-op-4509.

The "key factor" for determining whether this common-law duty of care exists is the "foreseeability" of the harm that might result if care is not exercised. *Taylor v. Smith*, 892 So. 2d 887, 892 (Ala. 2004) (emphasis original) (quoting *Key v. Compass Bank, Inc.*, 826 So. 2d 159, 170 (Ala. Civ. App. 2001)). "In determining foreseeability, it is not necessary to anticipate the ***specific*** event that occurred, but only that some general harm or consequence would follow." *Smith v.*

AmSouth Bank, Inc., 892 So. 2d 905, 910 (Ala. 2004) (emphasis in original). At the pleading stage, the State need only allege facts that, if taken as true, establish that Defendants could foresee that their lack of care would harm the State and/or its citizens. The Court finds that Alabama's opioid epidemic was a reasonably foreseeable result of Defendants' conduct as pled.

Finally, the Court rejects Defendants' argument that the State is improperly seeking to assert a private right of action under the federal Controlled Substance Act. In Alabama, statutes can and do create a duty of care, see *King v. National Spa and Pool Institute, Inc.*, 570 So. 2d 612, 614 (Ala. 1990) ("a legal duty to exercise care, therefore, arises… where the obligations are expressly or impliedly imposed by statute, municipal ordinance, or by administrative rules or regulations, or by judicial decisions"), and proof that a person violated that statute is proof of a breach of duty/negligence. *See Parker Bldg. Service Co., Inc. v. Lightsey ex rel. Lightsey*, 925 So. 2d 927, 930 (Ala. 2005).

The State is plainly not seeking to enforce the CSA. It simply asserts that the federal CSA (and the state CSA, which Alabama can enforce) provide the standard of care of care for common law negligence, a very different proposition.

VIII. The Complaint States a Claim for Unjust Enrichment.

In order to plead an unjust enrichment claim, the plaintiff must show that "the defendant holds money which, in *equity and good conscience*, belongs to the plaintiff or holds money which was improperly paid to defendant because of *mistake or fraud*." *Mantiply v. Mantiply*, 951 So. 2d 638, 654 (Ala. 2006)(emphasis in original). It is an equitable remedy permitting the court in equity and good conscience to disallow one to be unjustly enriched at the expense of another." *Id.* "One is unjustly enriched if his retention of a benefit would be unjust." *Id.* The retention of a benefit is unjust if "(1) the donor of the benefit . . . acted under a mistake of fact or in misreliance on a

right or duty, or (2) the recipient of the benefit . . . engaged in some unconscionable conduct, such as fraud, coercion, or abuse of a confidential relationship." *Id.* at 654-55. The State alleges that the cost of Defendants' wrongful acts includes increased health care services and treatments, which the State has paid for with public funds. Compl. ¶ 434. The State further alleges that Defendants' businesses created these costs, but Defendants are not paying for them. "[S]ociety's reasonable expectations of person and property would be defeated by nonpayment" of these monies back to the Government. *United States v. Halifax Hosp. Med. Ctr.*, 2013 WL 6017329, at *7 (M.D. Fla. Nov. 13, 2013) (citations omitted).

The success or failure of an unjust-enrichment claim depends on the particular facts and circumstances of each case. *Mantiply*, 951 So. 2d at 654. The Court finds that the State's Unjust Enrichment claim is adequately pleaded at this stage of the litigation.[3]

IX. The Complaint Adequately Pleads a Claim for Deceptive Trade Practices.

The State alleged that Defendants violated (at least) the following provisions:

- Causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods and services. Ala. Code § 8-19-5(2);
- Representing that goods have characteristics, uses, benefits, or qualities that they do not have. Ala. Code § 8-19-5(5);
- Representing that goods or services are of a particular standard, quality, or grade, if they are of another. Ala. Code § 8-19-5(7);
- Advertising goods or services with the intent not to sell them as advertised. Ala. Code § 8-19-5(9); and
- Engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce. Ala. Code § 8-19-5(27).

[3] McKesson also argues that unjust enrichment is unavailable because the State has pleaded other claims that provide a legal remedy. McKesson's Br. at 30-31. At this stage of the litigation, that argument is unavailing. "A party may state as many separate claims or defenses it has, regardless of consistency." Ala. R. Civ. P. 8(e)(2).

Compl. ¶ 389.

The State alleges that Endo, *inter alia*:

- Trained its sales representatives to tell Alabama prescribers that "Endo's opioids had a lower potential for abuse because they were 'designed to be crush resistant,' even though the 'clinical significance of INTAC Technology or its impact on abuse/misuse has not been established for Opana ER;' and that drug seeking behavior was a sign of undertreated pain rather than addiction[.]" Compl. ¶ 163;

- Operated a website, www.opana.com, that deceptively stated that "most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." Compl. ¶ 169;

- Endo operated another website, www.painaction.com, that similarly stated that "most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Compl. ¶ 172; and

- Wrongly promoted Opana ER as "crush-resistant," (and thus abuse resistant), even though "the FDA advised Endo that it could not market the new Opana ER as abuse-deterrent." Compl. ¶ 177.

A jury could find that these facts, if proven, establish that Endo violated subsections (2), (5), (7), and (9) of Section 8-19-5, which deal with various forms of false advertising.

As for McKesson, the State alleges that it has, *inter alia*, claimed that it had "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country," Compl. ¶ 298, even though it failed to report 'suspicious orders' originating from the State. A jury could find that these facts establish that McKesson violated Section 8-19-5(7)'s prohibition against "representing that goods or services are of a particular standard, quality, or grade, if they are of another," or Section 8-19-5(27)'s prohibition against "engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce."

In the end, the State pleaded "factual content that allows the court to draw the reasonable

inference that the defendant is liable for the misconduct alleged" for each. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

Defendants further argue that argue that the pleaded deceptive statements are nothing more than "broad promotional statements" that are not actionable because the State did not allege "that such statements were likely to be relied upon by or posed any harm to members of the public." The Court does not find this argument persuasive.

First "broad promotional statements" can be deceptive, and thus actionable, under the DTPA. Whether the State can prove this divide is a question for a factfinder, and dismissal is not appropriate here.

Second, unlike federal law, there is no requirement under the DTPA that the State prove that Defendants "mislead customers." To add such a requirement to the DTPA, when the Legislature did not, would violate the omitted case canon of construction. *See Pace v. Armstrong World Indus. Inc.*, 578 So. 2d 281, 284-85 (Ala. 1991); Antonin Scalia & Bryan Garner, *Reading Law: The Interpretation of Legal Texts* 93 (2012).

The Defendants also contend that the State's claims fail because their claims do not meet Rule 9(b)'s heightened pleading requirement for fraud claims. *See, e.g.*, Endo's Br. at 31. This argument fails for two reasons. First, Rule 9(b) does not apply because a DTPA claim is not a fraud claim. Although there is no case on point in Alabama, Rule 9(b) should not apply because, unlike fraud, a party asserting a deceptive trade practice claim need not show actual reliance on the representation or omission at issue." *See State, Office of Atty. Gen., Dep't of Legal Affairs v. Wyndham Int'l, Inc.*, 869 So. 2d 592, 598 (Fla. Dist. Ct. App. 2004). Because the DTPA does not require proof of the same essential elements as fraud, such as reliance, it makes sense not to impose Rule 9(b)'s heightened pleading standard for fraud claims on claims brought under the DTPA. *See*

Pelman ex rel. Pelman v. McDonald's Corp., 396 F.3d 508, 511 (2d Cir. 2005). Second, as noted above, the Court believes the State has met 9(b)'s heightened pleading requirement.

Finally, the defendants contend the State's DTPA claim should be dismissed because the State has not pled compliance with the DTPA's pre-suit notice requirement. This argument fails. There is nothing in the DTPA or the Rules of Civil Procedure that requires the State to plead compliance with the statute to satisfy Rule 8(a)(2). Moreover, the DTPA expressly provides that the Attorney General is not required to meet with a Defendant prior to filing an action under the DTPA if the Attorney General determines that the Defendant "designs . . . to continue practices unlawful under this chapter." *Id.* The State has invoked this exception by requesting an injunction preventing the Defendants from continuing their "unfair and deceptive acts and practices[.]" Compl. ¶ 444. Thus, this part of the Defendants' argument fails.

X. The State has Adequately Pleaded a State Controlled Substance Act Claim

Alabama alleges that each of the Defendants violated Alabama's Controlled Substances Act ("ACSA") by failing to report suspicious orders as they are statutorily required to do. Compl. ¶¶ 401-16. None of Defendants' arguments to the contrary warrants Rule 12(b) dismissal.

The ACSA requires McKesson and Endo to keep records in conformance with "federal law and with any additional rules issued by the State Board of Medical Examiners, the State Board of Health, or the State Board of Pharmacy." Ala. Code § 20-2-56. Rule 680-X-3-.05(2) of the State Pharmacy Board rules requires as follows:

> Such manufacturers, wholesalers, or distributors doing business in the State of Alabama who sell, furnish, give away, or otherwise dispose of controlled substances drugs enumerated in Schedule I, II, III, IV, or V or precursor agents used to manufacturer such controlled substances to a registrant other than another manufacturer or wholesaler, shall submit to the Alabama State Board of Pharmacy legible copies of records and reports required by the Drug Enforcement Administration concerning increases in purchases or high or unusual volumes purchased by pharmacies within 30 days.

By its plain text, this rule imposes a duty on McKesson and Endo to submit to the Pharmacy Board a copy of every suspicious order "report required by the [DEA]." The State alleges McKesson and Endo violated this rule when it should have, but did not, submit suspicious order reports to the DEA and state Pharmacy Board.

McKesson's argument that the rule "merely requires McKesson to forward to BOP ***legible copies*** of the records and reports that it submits to the DEA and that it does not create an independent obligation under Alabama law to generate reports concerning 'suspicious orders' of opioids." McKesson's Br. at 13. But McKesson's emphasis on "legible copies" is misplaced. The Rule's truly operative term is "required by." As the plain text shows, any time DEA/ federal rules require McKesson or Endo to submit a suspicious order report, they must also submit a report to the state Pharmacy Board. It does not matter whether McKesson ***actually*** submitted a report to the DEA; all that matters is that McKesson was "***required by***" federal rules to submit a report.

The State alleged that Endo and McKesson had specific knowledge about suspicious orders, and they had detailed information to monitor those orders, Compl. ¶¶ 310, 320, 321, and did not report any suspicious orders to the state Pharmacy Board. Compl. ¶¶ 77, 274, 277. Taken as true, these facts (individually or collectively) would establish a violation of the ACSA.

Finally, Endo argues that its only duty is "to monitor pharmacy orders ***only*** on the distributors who sell to pharmacies." Endo's Br. at 28 (emphasis in original). Such a limitation is not contained in the rule's plain text, and Endo's argument fails. The State has sufficiently pleaded a claim.

XI. FDA Preemption Doctrines Are Not Available to the Manufacturer Defendants, Including the Makers of Generic Opioids.

Endo argues the State's claims against them are entirely preempted by federal law because the FDA regulates of the contents of drug labels, i.e., the information that "accompanies" an FDA regulated pharmaceutical. Endo's Br. at 3-9. This argument has been routinely rejected by other courts that have heard this argument in opioid litigation. *See, e.g. In re Opioid Litig.*, Index No. 40000/2017, slip op. at 5-11 (Sup. Ct .Suffolk County, NY, June 18, 2018); *State of Washington v. Purdue Pharma. L.P*, No. 17-2-25505-8, slip op. at 2 (Sup. Ct. King County, WA, May 14, 2018).

As the United States Supreme Court has made clear, FDA approval of a drug or a drug's label is not a complete defense to traditional state tort law claims. *Wyeth v. Levine*, 555 U.S. 555 (2009). In fact, state tort law is intended to supplement the FDA's regulation of the industry. *Id.* Congress "determined that widely available state rights of action provided appropriate relief for injured consumers," *id.* at 574, because "the FDA traditionally regarded state law as a complimentary form of drug regulation." *Id.* at 578. Indeed, the "FDA long maintained that the state law offers an additional, and important, layer of consumer protection" because "[s]tate tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly." Id. at 579.

Furthermore, States "have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." *Medtronic, Inc. v. Lohr*, 518 U.S. 47, 475 (1996) (citation omitted). This is particularly true where a State protects its consumers from deceptive business practices, *see California v. ARC Am. Corp.*, 490 U.S. 93 (1989), including drug promotion. *See Wyeth*, 555 U.S. 555.

Endo next claims that the State's claims are preempted because "it is impossible to comply

with both state and federal law." Endo's Br. at 5, 13. Endo claims the FDA has approved the statements it has made in promoting its drugs. Endo oversimplifies what the State alleges in arguing that it was simply repeating what the FDA required them to say and omitting what the FDA did not require them to say. Endo is not accused of simply repeating the contents of its drug label to prescribers. Rather, the State alleges that, *inter alia*, Endo contradicted or downplayed the contents of its drug labels through aggressive detailing by sales representatives to deliver untruthful messaging portraying opioids as low risk and beneficent. Compl. ¶ 170. Passing along information (or misinformation) that contradicts FDA labeling is certainly not entitled to a preemption defense.

Endo is also accused of using independent third parties to deliver similar messaging, often delivered at continuing medical education programs. Compl.¶ 213. Essentially, Endo is accused of training doctors with non-FDA approved information. The FDA generally does not review "unbranded" promotional materials. *See, City of Chicago v. Purdue Pharma, L.P.*, 2015 WL 2208423,*2 (N.D. Ill 2015 This marketing was also used to promote opioids generally, including Endo's generics. Compl. 224-227. As such, the State's claims against Endo regarding Endo's generic pharmaceuticals are not preempted. *See, e.g., In re: Prescription Opiate Litigation*, Case No. 1:17-md-02804, Report and Recommendation on Motions to Dismiss Complaint of Muscogee (Creek) Nation, Doc. 1499 at 42 (April 1, 2019); *see also, e.g., Arters v. Sandoz, Inc.*, 921 F.Supp.2d 813, 819-20 (S.D. Ohio 2013) (state law fraud claims based on defendants' allegedly fraudulent or unreasonably dangerous promotion of generic drug were not preempted). Thus, Endo cannot use the FDA as a shield against non-branded false promotions.

Endo also argues that its messaging was consistent with its labelling. That is contradicted by the allegations in the State's complaint.

Finally, the determination of whether the FDA would approve a change to an opioid warning label (assuming that determination is even necessary, as this is not a failure to warn case) is not a determination that can be made at this stage of the litigation. Determinations such as whether a statement is conceivably FDA approved requires the gathering and presentation of evidence and the hearing of testimony from experts in order to guide that determination. *Merck Sharp & Dohme Corp., v. Albrecht*, 587 US ___, 139 S. Ct. 1668 (2019). For this reason, too, the Defendants' arguments fail.

For the foregoing reasons, Defendants' Motions to Dismiss are **DENIED**.

SO ORDERED, this 13 day of NOV. 2019.

Hon. J.R. Gaines
Circuit Judge

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA, Plaintiff, vs. PURDUE PHARMA L.P., et al., Defendants.	Case No. 3AN-17-09966CI CONSOLIDATED
STATE OF ALASKA, Plaintiff, vs. MCKESSON CORPORATION, et al., Defendants.	Case No. 3AN-18-10023CI
STATE OF ALASKA, Plaintiff, vs. MALLINKRODT, et al., Defendants.	Case No. 3AN-19-04861CI

ORDER DENYING DEFENDANTS' MOTION TO DISMISS THE COMPLAINT

I. INTRODUCTION

Defendants McKesson Corporation, et al., move to dismiss State of Alaska's complaint under Alaska Rule of Civil Procedure 12(b)(6) for failure to state a claim

upon which relief may be granted. After considering the briefing of the parties and oral argument, the court DENIES the motion.[1]

II. BACKGROUND

The State of Alaska ("the State") filed this action against pharmaceutical distributors McKesson Corporation, Cardinal Health Inc., and AmerisourceBergen Drug Company ("Distributors" or "Defendants") alleging the Distributors have contributed to the creation and perpetuation of the opioid epidemic and a public health crisis in Alaska by oversupplying opioids and disregarding their obligations to monitor and report suspicious orders. The State alleges it has paid and will pay expenses for the medical care of Alaska's population due to overuse, abuse, addiction, overdose, and death. The State seeks damages, injunctive relief, and civil penalties.[2]

The State asserts four claims: (1) public nuisance; (2) negligence/negligence *per se*; (3) violations of Alaska's Unfair Trade Practices and Consumer Protection Act (AS § 45.50.471 *et seq.*), and; (4) unjust enrichment.

III. LEGAL STANDARD

A motion to dismiss for failure to state a claim upon which relief may be granted, filed pursuant to Alaska Rule of Civil Procedure 12(b)(6), tests the legal sufficiency of

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1 No materials outside the pleadings were submitted or considered, except for copies of decisions from other jurisdictions submitted as "supplemental authority" by both parties.

2 The original complaint was filed under seal. Portions of confidential information were redacted. The complaint is 80 pages long with 262 points.

the complaint's allegations.[3] Motions to dismiss under CR 12(b)(6) are viewed with disfavor.[4] In determining the sufficiency of the stated claim in a CR 12(b)(6) motion, it is enough that the complaint set forth allegations of fact consistent with some enforceable cause of action on any possible theory.[5]

In resolving the merits of such motions, the court considers only well pled allegations of the complaint, while ignoring unwarranted factual inferences and conclusions of law.[6] Generally, such a motion is determined solely on the pleadings; however, the court may consider public record, including court files from other proceedings.[7]

The court must construe the complaint in the light most favorable to the non-moving party and presume the pleading's allegations to be true.[8] The court can affirm

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3 *Dworkin v. First Nat. Bank of Fairbanks*, 444 P.2d 777, 779 (Alaska 1968).

4 *State, Dep't of Health & Soc. Services, Div. of Family and Youth Serv. v. Native Village of Curyung*, 151 P.3d 388, 397 (Alaska 2006) (internal citations omitted).

5 *Id.*

6 *Dworkin* at 779.

7 *Nizinski v. Currington*, 517 P.2d 754, 756 (Alaska 1974) (internal citation omitted).

8 *Valdez Fisheries Development Ass'n, Inc. v. Alyeska Pipeline Service Co.*, 45 P.3d 657, 664 (Alaska 2002) (citing *Kollodge v. State*, 757 P.2d 1024, 1026 (Alaska 1998)).

dismissal for failure to state a claim only if "it appears beyond doubt" that the plaintiff can prove no set of facts which would entitle relief.[9]

IV. DISCUSSION

1. Public Nuisance

The State alleges the Distributors are responsible in part for creating and perpetuating a public nuisance, i.e., the opioid epidemic, by knowingly oversupplying opioids into Alaska and failing to monitor, report, and reject suspicious orders. The Distributors object to the public nuisance claim as an "unprecedented expansion of public nuisance law." In addition, the Distributors argue the State has not alleged a "public right" that has been affected; a public right, according to the Distributors, must refer to a shared public resource, not the private rights of many people in the public. The Distributors assert "public health" is not a "public right."

The Distributors' argument is not in accord with Alaska law. The Alaska Supreme Court has indicated its agreement with federal common law defining a public nuisance as an unreasonable interference with a right common to the general public, such as a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience.[10]

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9 *Id.*

10 *Friends of Willow Lake, Inc. v. State, Dept. of Transp. & Public Fac., et al.*, 280 P.3d 542, 548 (Alaska 2012) (quoting Restatement (Second) of Torts §821B(1) (1979) (defining public nuisance)). *See also, Taha v. State*, 366 P.3d 544, 547 (Alaska Ct. App. 2016) (defining public nuisance according to Black's Law Dictionary (10th ed. 2014) as "[a]n unreasonable interference with a right common to the general public, such as a condition dangerous to health, offensive

The State alleges the public right at issue is "the public health, safety, the public peace, the public comfort or the public convenience."[11] Reading the Complaint as a whole, the State is not pursuing a claim based on the rights of individuals to be healthy or free of addiction due to an alleged oversupply of opioids; the State is asserting a public right to expectations of public health, safety, peace, policing, and emergency services that are not significantly "interfered with." The State alleges facts to support its conclusion that Alaska is facing a health and safety crisis in response to an epidemic of opioid use, overuse, and abuse.[12]

The State alleges Distributors have contributed to the creation of the nuisance by knowingly oversupplying opioids into Alaska in disregard of their obligations to report and halt suspicious orders. The State alleges facts, such as: (1) Defendants have available extensive data regarding the volume of opioid sales in Alaska and nationally;[13] (2) this information allowed Defendants to track and identify instances of overprescribing;[14] (3) considering Defendants' important role in the closed system of opioid distribution, Defendants should have known their failure to comply with the

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to community moral standards, or unlawfully obstructing the public in the free use of public property").

11 Complaint, ¶ 188.

12 *Id.* at ¶¶ 1-3, 6, 11, 164-179.

13 *Id.* at ¶ 42.

14 *Id.* at ¶ 43.

obligations to report and halt suspicious orders would have serious consequences;[15] and, (4) Defendants' current compliance programs are inadequate. The State argues these facts show the Defendants sought to increase sales and profits from opioids by disregarding their obligations to prevent diversion and compounded the harms of the crisis by supplying opioids beyond what the market could bear, funneling so many opioids into Alaska that they could only have been delivering a significant portion of those opioids for diversion and illicit use.[16] The State alleges had the Defendants established and implemented programs to prevent diversion and identified, reported, and rejected suspicious orders, the supply of opioids would not have been as great, and fewer opioids would have been available for diversion and improper use.[17]

The Distributors also argue the nuisance claim is unsupportable because they did not "control the instrumentality … at the time of the damage." In other words, Distributors assert the nuisance arises when the opioid pill is diverted or consumed, which occurs after it leaves control of the Distributors. The court agrees with the State that this argument misconstrues the State's public nuisance theory. The State is arguing the Distributors have control over the supply and distribution of opioids and it is the "excessive and unreasonable" distribution of the opioids caused by Defendants' failure to create and operate a reporting system for suspicious orders that led to oversupply,

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15 *Id.* at ¶¶ 49, 68.

16 *Id.* at ¶ 164.

17 *Id.* at ¶ 166.

diversion, and therefore a public nuisance of addiction, abuse, illegal activity, health care burdens, social services, overdoses, and deaths.

The court finds the facts as alleged could reasonably be construed as demonstrating a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience and therefore an interference with a right common to the general public and as demonstrating Defendants' control over the instrumentality of the nuisance.

Therefore, the State has alleged facts sufficient to state a claim for public nuisance against Distributors.

2. Negligence/Negligence *per se*

The State has pled claims for negligence/negligence *per se*, alleging Distributors have breached a duty owed to the State to exercise reasonable care in the distribution of opioids. The State alleges Distributors' negligence was a substantial factor in causing damages, such as increased expense for police, emergency, and health care services. The Distributors argue the negligence claim must be dismissed because: (1) there is no private right of action to enforce the Federal or State Controlled Substance Act ("CSA"); (2) they do not owe the State a common law duty to report suspicious orders; and, (3) the complaint fails to allege a breach of any duty.

As to the first argument, the court agrees with the State that the Complaint is not alleging any violations of the CSA, nor is it seeking to enforce the Federal or State CSA. Under the common law, Alaska permits a claim of negligence if a plaintiff shows that a defendant breached a duty owed to the plaintiff, and that the breach caused the plaintiff

harm.[18] The State seeks to establish a standard of care required of a reasonably prudent pharmaceutical distributor by referencing the requirements of the State or Federal CSA. Such a method is permitted under Alaska common law. The State may also allege negligence *per se* by establishing a violation of the CSA has occurred, without seeking to enforce the CSA. Furthermore, Defendants' argument that allowing a common law duty would supplant federal authority is not persuasive. Indeed, it is difficult to ascertain how establishing a common law duty to report would "thwart the objectives" of the federal and state agencies regulating distributors.

The Distributors also argue the complaint does not establish a breach of any duty, but that is not supported. The Complaint does allege a breach, i.e., a failure to report suspicious orders.[19] The State may prove these allegations at trial by any method of proof it wishes. It is not necessary at the pleading stage for the State to identify, for

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18 *Cusack v. Abbott Lab. Inc., et al.*, 2017 WL 3688149 (D. Alaska 2017) (citing *Silvers v. Silvers*, 999 P.2d 786, 793 (Alaska 2000)).

19 Complaint, ¶¶ 192, 215, 218, 228.

example, individual orders, pharmacies, or prescriptions.[20] Lastly, the State adequately alleges the foreseeability of the harm.[21]

Therefore, the State has alleged facts sufficient to support a claim of negligence/negligence *per se*.

C. The Unfair Trade Practices and Consumer Protection Act

1. The Section 471(a) Claim

The State alleges violations under Alaska's Unfair Trade Practices and Consumer Protection Act ("UTPA") catch all provision, AS §45.50.471(a), which prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce."[22] To establish a prima facie case of unfair or deceptive acts, the State must allege facts which if proven would establish: (1) that the defendant is engaged in trade or commerce; and (2) that in the conduct of trade or commerce, an unfair act or practice has occurred.[23]

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20 The Complaint does refer to individual pharmacies by general location in Alaska in ¶¶ 69-71, alleging that McKesson failed to report any suspicious orders from any of the three pharmacies identified over a multiple year period; that Cardinal failed to report any suspicious orders from any of the specifically named pharmacies over a multiple year period ; that AmerisourceBergen failed to report any suspicious orders from pharmacies identified over a multiple year period. These allegations are satisfactory under pleading standards to put the Defendants on notice of the facts which the State intends to prove.

21 *Id.* at ¶¶ 84, 87, 93, 95, 96, 101.

22 AS § 45.50.471(a).

23 *Kenai Chrysler Center, Inc. v. Denison,* 167 P.3d 1240, 1255 (Alaska 2007) (quoting *State of Alaska v. O'Neill Inv., Inc.*, 609 P.2d 520 at 534-35 (Alaska 1980)).

Whether an act or practice is deceptive is determined simply by asking "whether it has the capacity to deceive."[24] The plaintiff need not prove that the defendant intended to deceive; it is enough to show that the acts and practices were "capable of being interpreted in a misleading way."[25] As a remedial statute intended to provide consumers more protection than its federal counterpart, Alaska's UTPA is applied broadly.[26]

Furthermore, an act or practice can be unfair without being deceptive.[27] Unfairness is determined by a variety of factors, including: (1) whether the practice, without necessarily having been previously considered unlawful, offends public policy as it has been established by statutes, the common law, or otherwise, whether, in other words, it is within at least the penumbra of some common law, statutory, or other established concept of fairness; (2) whether it is immoral, unethical, oppressive, or unscrupulous; and (3) whether it causes substantial injury to consumers (or competitors or other businessmen).[28]

The State alleges Distributors' unfair and deceptive practices include failing to maintain effective controls against opioid diversion by failing to use a compliance

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24 *Id.*

25 *Id.*

26 *Id.*

27 *State v. O'Neill* at 535.

28 *Id.* (internal citation omitted).

program that detects and prevents suspicious orders; failing to report suspicious orders; filling suspicious orders; and publicly representing that they are maintaining effective controls against diversion.[29] The State alleges the Distributors' conduct resulted in the oversupply of opioids into Alaska, and such conduct is contrary to public policy in Alaska, was immoral and unethical, and caused substantial injury to consumers.[30] The State's allegations are sufficient to establish a claim for unfair practices.

The Distributors contend the State's claim under AS 45.50.471(a) is barred by the regulated conduct exception, AS 45.50.481(a), because the State also alleges the Distributors have violated the Alaska CSA.[31] The State counters that the conduct at issue under its UTPA claim is not the failure to report, but the deceptive advertising that Distributors are complying with reporting requirements. The court agrees with the State that the regulated conduct exception does not apply. The CSA and the UTPA regulate different conduct. The UTPA is intended to prevent unfair or deceptive practices. The Distributors may or may not have failed to report, which would lead to violations of the CSA, but not necessarily UTPA violations. It is the alleged false statements, not any actual violation that the State is pursuing.

2. The Section 471 (b)(11) and (b)(12) Claims

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29 Complaint, ¶ 243.

30 *Id.* at ¶ 164.

31 AS 45.50.481 states in pertinent part: "(a) Nothing in AS 45.50.471- 45.50.561 applies to (1) an act or transaction regulated by a statute or regulation administered by the state…unless the statute or regulation does not prohibit the practice declared unlawful in AS 45.50.71."

The State also alleges specific violations of AS 45.50.471(b)(11) and (12) which make it unlawful: (1) to engage in any other conduct creating a likelihood of confusion or of misunderstanding and that misleads, deceives or damages a buyer or a competitor in connection with the sale of or advertisement of goods or services; and (2) to use or employ deception, fraud, false pretense, false promise, misrepresentation, or knowingly conceal, suppress, or omit a material fact with the intent that others rely upon the concealment, suppression, or omission in connection with the sale or advertisement of goods regardless of whether that person has been misled.

The State alleges the Distributors claimed in advertising that they had established programs and controls to prevent diversion, and that these statements were deceptive, fraudulent, and were misrepresentations.[32] The Distributors counter that these are mere "puffery," but the court cannot find that the statements alleged are, without question, puffery. The statements are specific and technical in nature and are not so exaggerated as to be unbelievable.

The State's UTPA claims under AS 45.50.471(a) and (b) are adequately pled.[33]

4. Unjust Enrichment

The Distributors argue the unjust enrichment claim must be dismissed because adequate remedies at law exist and because the State cannot establish the elements of

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32 Complaint, ¶ 156.

33 Defendants' remaining objections to the UTPA claims (the statute of limitation and whether the allegations were made in Alaska) are factual questions. In addition, materiality of the alleged misrepresentation is not required to establish a prima facie case under the UTPA.

unjust enrichment. As to the first argument, Alaska Rules of Civil Procedure allow a party to plead alternative theories of liability.[34] The State may plead unjust enrichment in addition to its claims at law.

Regarding the elements of unjust enrichment, in *Alaska Sales and Service v. Millet*, the Alaska Supreme Court explained unjust enrichment as follows:

> [a] person who has been unjustly enriched at the expense of another is required to make restitution to that person. A person is enriched if he receives a benefit; a person is unjustly enriched if the retention of the benefit without paying for it would be unjust.[35]

The Court then set forth three elements of unjust enrichment: (1) a benefit conferred upon the defendant by the plaintiff; (2) appreciation of such benefit; and (3) acceptance and retention by the defendant of such benefit under circumstances that it would be inequitable for the defendant to retain it without paying the value thereof.[36] Additionally, "[t]he courts are in accord in stressing that the most significant requirement for recovery in quasi-contract is that the enrichment to the defendant must be unjust; that is, the defendant must receive a true windfall or something for nothing."[37] Unjust enrichment is an equitable doctrine, which ordinarily falls within the court's

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34 Alaska Rule of Civil Procedure 8.

35 735 P.2d 745, 746 (Alaska 1987).

36 *Id.*

37 *Id.* (the Court uses the term quasi-contract, explaining: "[c]ourts generally treat actions brought upon theories of unjust enrichment, quasi-contract, contracts implied in law, and quantum meruit as essentially the same.").

broad discretion.[38] Whether there has been unjust enrichment is generally a question of fact.[39]

The State alleges Distributors benefit by not bearing the burden of the byproducts of their conduct while the State absorbs the costs, which allows Distributors to continue profiting from the oversupply of opioid.[40] The State also alleges Distributors were aware of the benefit and were enriched at the State's expense.[41]

The State has sufficiently pled the elements of unjust enrichment allowing the claim to proceed.

B. Distributors' Other Objections

1. Lack of Causation

Distributors argue the State's claims fail as a matter of law because the State has not and cannot adequately plead a causal nexus between Defendants' alleged misconduct and the State's alleged injuries. Distributors argue the conduct of the opioid manufacturers is the sole proximate cause of the opioid epidemic; Distributors were required to fill legal prescriptions and therefore could not be the proximate cause of the epidemic. In addition, Distributors argue the illegal activity of third parties (i.e., diversion of pills) breaks the chain of causation.

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38 *Id.* at 747.

39 *State, Dep't of Rev. Child Sup. Enfc't Div. v. Wetherelt,* 931 P.2d 383, 390 fn. 11 (Alaska 1997).

40 Complaint , ¶¶165, 171-79, 252, 259.

41 *Id.* at ¶¶149-150.

It is sufficient that the complaint alleges there is a connection between Distributors' conduct and the injuries to the State. The State's theory of causation is supported by factual allegations as described, *supra*, under the discussion of Public Nuisance. In essence, the State alleges Distributors' role in the opioid system is more involved than simply delivering pills. The State alleges Distributors have extensive prescribing information and control over developing reporting and monitoring systems. The State has alleged facts to support its theory that the Distributors had a role in creating and perpetuating the opioid crisis by knowingly disregarding red flags of diversion and failing to report and suspend suspicious orders. In Alaska, the issue of proximate cause is usually reserved for the trier of fact.[42]

2. The Derivative Injury Rule and the Free Public Services Doctrine

Distributors argue the State's claims are barred by the derivative injury rule and the free public services doctrine. Determining either of these theories, assuming they are applicable in Alaska, would require factual findings on issues of causation, liability, and damages that are not before the court at this stage of pleadings. The court finds it is premature to dismiss claims on these grounds.

V. CONCLUSION

In order to prevail against the motion to dismiss, the State must set forth allegations of fact consistent with some enforceable cause of action on any possible theory. Under notice pleading standards, the State has met its burden. It does not appear

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42 *See Winschel v. Brown*, 171 P.3d 142, 148 (Alaska 2017) (holding fact questions as to proximate cause and superseding causation precluded summary judgment).

beyond doubt that the State can prove no set of facts that would entitle relief. The State has sufficiently pled claims for public nuisance, negligence/negligence per se, unfair trade practices, and unjust enrichment.

Therefore, the *Motion to Dismiss* is DENIED.

Defendants' Answer to the Complaint is due TWENTY DAYS from the date of this order.

IT IS SO ORDERED.

DATED at Anchorage, Alaska this 28 August 2019.

Dani Crosby
Superior Court Judge

I certify that on 8/28/19 a copy of the above was mailed to each of the following at their address of record:

M. Pendell
D. Gross
M. Michaletz
S. Burke
M. Paton-Walsh
K. Parker
S. Johansen
H. Huggler
M. Baylous
S. Boranian
B. Jamieson
C. Rankin
C. Eppich
K. Kelly
J. Thorsness
R. Burns-Riley
B. O'Connor
H. Lazar
A. O'Connor
R. Gallagher
M. Knack
C. Franklin

CCT
Judicial Assistant

Clerk of the Superior Court
*** Electronically Filed ***
10/29/2020 8:00 AM

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

CV 2019-003439
CV 2019-010792
CV 2019-013252
CV 2019-014760
CV 2019-015233
CV 2020-000576
CV 2020-001434

10/28/2020

HONORABLE ROGER E. BRODMAN

CLERK OF THE COURT
M. Corriveau
Deputy

CITY OF SURPRISE

v.

ALLERGAN P L C, et al.

J CHRISTOPHER GOOCH

JENNIFER JOAN AXEL
BRADLEY J JOHNSTON
JOHN J KASTNER JR.
WILLIAM G KLAIN
ANDRE H MERRETT
COLE SCHLABACH
J STEVEN SPARKS
JON D WEISS
MEGAN ELIZABETH GAILEY
NATHAN D MEYER
JAKE D CURTIS
FREDERICK M CUMMINGS
DARRELL E DAVIS
GREGORY ALAN DAVIS
JOHN C KELLY
JEFFREY A GOLDBERG
RYAN J LINDER
AARON T LLOYD
RYAN J LORENZ
ROGER N MORRIS

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

CV 2019-003439 *et al.* 10/28/2020

BRIAN SCHULMAN
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18526 E CARRIAGE WAY
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JUDGE BRODMAN

UNDER ADVISEMENT RULING

The following Motions to Dismiss are pending before the Court:

1. Manufacturer Defendants' Motion to Dismiss filed in CV2019-010792 (City of Glendale – lead case) on March 4, 2020;
2. Manufacturer Defendants' Motion to Dismiss filed in CV2019-015233 (City of Prescott) on March 6, 2020;
3. Manufacturer Defendants' Motion to Dismiss filed in CV2020-000576 (Pinal County) on March 6, 2020;
4. Manufacturer Defendants' Motion to Dismiss filed in CV2020-001434 (County of Apache) on March 6, 2020;
5. Manufacturer Defendants' Motion to Dismiss filed in CV2019-003439 (City of Surprise) on March 6, 2020;
6. Manufacturer Defendants' Motion to Dismiss filed in CV2019-013252 (County of La Paz) on March 6, 2020;
7. Manufacturer Defendants' Motion to Dismiss filed in CV2019-014760 (Bullhead City) on March 6, 2020;
8. Defendants Watson and Actavis's Motion to Dismiss filed in CV2019-010792 (City of Glendale – lead case – applicable in all cases) on March 4, 2020;
9. Defendants Johnson & Johnson and Janssen's Motion to Dismiss filed in CV2019-010792 (City of Glendale – lead case – applicable in all cases) on March 4, 2020;

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

CV 2019-003439 *et al.* 10/28/2020

10. Defendants Teva and Cephalon's Motion to Dismiss filed in CV2019-010792 (City of Glendale – lead case – applicable in all cases) on March 4, 2020;
11. Defendant Kapoor's Motion to Dismiss filed in CV2019-010792 (City of Glendale – lead case – applicable in all cases) on March 4, 2020;
12. Defendants AmerisourceBergen and Cardinal Health's Motion to Dismiss filed in CV2019-010792 (City of Glendale – lead case – applicable in all cases) on March 4, 2020;
13. Pharmacy Defendants' Amended Motion to Dismiss filed in CV2019-015233 (City of Prescott) on January 8, 2020;
14. Pharmacy Defendants' Motion to Dismiss filed in CV2020-000576 (Pinal County) on March 4, 2020;
15. Defendants Harper and Western Drug's Motion to Dismiss or Motion for More Definite Statement filed in CV2020-001434 (County of Apache) on March 13, 2020.

The Court held oral argument on August 28, September 4, 11 and 18, 2020.

I. BACKGROUND

The plaintiffs are City of Glendale, City of Prescott, City of Surprise, Bullhead City, Pinal County, Apache County and La Paz County. Each plaintiff filed a separate complaint. The cases were either filed in or transferred to Maricopa County Superior Court where they were consolidated before this Court.

The complaints contain substantially similar allegations against many of the same defendants. There are five categories of defendants: Manufacturers, Distributors, Pharmacy Distributors, Pharmacy Dispensers and Prescribers.[1]

1. On August 31, 2020, plaintiff Pinal County filed a notice voluntarily dismissing its claims against defendants Mylan Institutional Inc. and Mylan Pharmaceuticals, Inc. from the Pinal County case. On September 16, 2020, plaintiffs filed a notice of intent to dismiss the claims against defendants Dr. Douglas Campbell, Dr. Robert Brownsberger, Dr. Dax Trujillo and Quezia Hall. On October 12, 2020, defendants Mallinckrodt, LLC, Mallinckrodt PLC, and SpecGx LLC filed a petition for relief under Chapter 11 of the Bankruptcy Code.

The Manufacturers[2] are: Allergan PLC, Actavis PLC, Actavis, Inc., Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. (collectively "Actavis")[3]; Teva Pharmaceuticals USA, Inc. and Cephalon, Inc. (collectively "Cephalon"); Endo Health Solutions, Inc. and Endo Pharmaceuticals, Inc. (collectively "Endo"); Janssen Pharmaceuticals, Inc. (and its predecessors Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc.) and Johnson & Johnson (collectively "Janssen"); Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (both in the Prescott and Pinal County cases only) (collectively "Par"); Indivior, Inc. (Pinal County case only); and John Kapoor and Michael Babich (collectively "Insys Individuals").

The Distributors are Cardinal Health, Inc. and AmerisourceBergen Drug Corporation.

The Pharmacy Distributors in the Prescott case are: Walgreen Co., Walmart, Inc. and Smith's Food and Drug Centers, Inc. ("Smith's"). The Pharmacy Distributors in the Pinal County case are: Walgreen Co., Walgreen Arizona Drug Co., Walmart Inc. and Smith's Food & Drug Centers Inc. d/b/a Fry's Pharmacies and Fry's Food and Drug Stores ("Smith's").

The Pharmacy Dispensers, named only in the Pinal County case, are: Smith's; American Drug Stores LLC (formerly known as American Drug Stores Inc.) d/b/a Osco Drug, Inc., Safeway Inc.; Walgreen Arizona Drug Co. and Walmart, Inc.

The Prescribers, named only in the Apache County case, are Western Drug, Inc. and Fred S. Harper (collectively "Harper").

II. SUMMARY OF COMPLAINT ALLEGATIONS

The following is a summary of allegations made in plaintiffs' complaints. For the purposes of a motion to dismiss, the Court must assume the truth of well-pled factual allegations.

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2. Unless otherwise indicated, a defendant is named in each of the seven consolidated cases. This ruling only refers to those defendants who filed or joined in at least one of the 15 motions to dismiss listed above.

3. Watson Laboratories, Inc., Actavis, LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. filed a separate motion to dismiss. Those entities only manufacture generic opioid medications. In the context of their separate motion, they are collectively referred to as the "Actavis Generic Entities."

A. Manufacturers' Scheme to Increase Sales of Opioid Medications[4]

Each Manufacturer makes and sells prescription opioid medicines, some branded, some generic. Opioids are prescribed for the treatment of pain. Opioids are related to illegal substances, such as opium and heroin. As such, they pose a high risk of addiction and abuse. Patients who take opioids at higher doses and for longer periods face higher risks of addiction and death. Due to the serious risks, before the mid-1990s, the generally accepted medical practice was to limit opioids to the treatment of acute pain, cancer-related pain and palliative care. Opioids were thought to be too addictive and debilitating to be used in the treatment of long-term chronic pain for conditions such as arthritis.

Beginning in the late 1990s Manufacturers developed a two-part scheme to dramatically increase the use of opioids. The first part of the scheme involved targeting economically and medically vulnerable populations within plaintiffs' communities who were predisposed to opioid addiction.

The second part of the scheme involved minimizing the risk of opioid addiction and death while overstating opioids' therapeutic benefits. Manufacturers advocated for expanding the use of opioids to patients suffering from chronic pain, despite knowing that there was no scientific evidence to support the long-term use of opioids for chronic pain.

Manufacturers misled patients into taking higher doses of opioids for longer periods by convincing them that opioids could improve the quality of life with low risk of addiction and abuse. Manufacturers promoted the false concept of "pseudoaddiction", which meant that the usual signs of addiction were an indication that the patient required more opioids to relieve pain. In 2016, however, CDC Guidelines rejected the concept of pseudoaddiction. Manufacturers also downplayed the difficulty of opioid withdrawal. They also falsely promoted the concept of "tapering"—a process by which withdrawal symptoms could be avoided by gradually reducing a patient's dosage.

Manufacturers used a variety of tactics to promote misleading claims about opioid medications. They employed aggressive sales representatives to convince and even bribe local prescribers into prescribing medically unnecessary opioids. Manufacturers employed key opinion leaders (KOLs), who appeared to be independent doctors, to promote the use of opioids at continuing medical education (CME) programs and other seminars. Manufacturers funded front

4. With the exception of factual allegations related to several additional manufacturer defendants in the Prescott and Pinal County complaints, the allegations against the Manufacturers are nearly identical in all seven complaints.

groups, such as the American Pain Society and the American Pain Foundation ("APF"), to distribute misleading educational materials to doctors and patients. Manufacturers also used unbranded advertising that was not subject to FDA review, but which often contradicted the branded materials reviewed by the FDA. The front groups, KOLs, and advertisements downplayed the risks of addiction to convince patients and doctors that prescription opioids could be safely used for chronic pain more regularly and at higher doses.

Manufacturers' success in expanding the market for opioids created an abundance of the drugs available for non-medical and criminal use and created an addiction epidemic in plaintiffs' communities. An estimated 60% of the opioids abused come directly or indirectly from prescriptions. The explosion in opioid use in plaintiffs' communities led to a public health crisis. Arizona has experienced skyrocketing opioid addictions and opioid-related overdoses and deaths. According to plaintiffs, more than two Arizonans die each day from an opioid overdose, a 74% increase in deaths since 2012. The increase in addiction created an illegal market for prescription opioids and an increased demand for heroin. Plaintiffs claim they have had to expend substantial tax dollars to address increased healthcare costs, crime and homelessness in their communities.

B. Manufacturer-Specific Allegations

The complaints set out allegations specific to each Manufacturer as summarized here.

1. Actavis. Actavis manufactures the branded drugs Kadian, Norco, a generic version of Kadian, and generic versions of Duragesic and Opana.

Since 2007, Actavis and its predecessor distributed a patient brochure for Kadian, which advised patients that over time they may become tolerant on their current dose and may require a dose adjustment to get the right amount of pain relief. Actavis also distributed an advertisement that claimed using Kadian to treat chronic pain could allow patients to return to work, relieve mental and physical stress and improve enjoyment of life.

In 2010, the FDA reprimanded Actavis for its deceptive marketing of Kadian that omitted and minimized its serious risks. The FDA warned Actavis that there was not substantial evidence demonstrating that Kadian resulted in an overall positive impact on a patient's work, physical and mental functions, daily activities or enjoyment of life after possible side effects were considered.

2. Cephalon. Cephalon manufactures Actiq and Fentora, both of which are approved for the treatment of persistent cancer pain for opioid tolerant individuals. Despite the limits on their

approved use, Cephalon used KOLs, speaker programs and front groups to market these drugs for the treatment of chronic pain.

Cephalon sponsored a 2007 publication of the APF entitled *Treatment Options: A Guide for People Living with Pain*, which falsely stated that addiction is rare and limited to extreme cases involving unauthorized dose escalation, duplicative prescriptions and theft. This guide endorsed the concept that pseudoaddiction described patients whose pain was undertreated. The guide further stated that, unlike over-the-counter nonsteroidal anti-inflammatories (NSAIDs), there was no ceiling dose for opioids. The guide promised that opioids would give patients the life they deserved.

In 2007, Cephalon and Endo sponsored *Responsible Opioid Prescribing*, which taught that demanding and manipulative behaviors, seeing more than one doctor to obtain opioids and hoarding were signs of pseudoaddiction, not actual addiction. The advertisement falsely stated that opioid use alone could improve patients' functioning. Cephalon and Endo distributed a pamphlet entitled *Living with Someone with Chronic Pain*, which also understated the risk of addiction.

In 2008, Cephalon pleaded guilty for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

3. Endo. Endo manufacturers branded opioid medications, such as Opana/Opana ER, Percodan, Percocet and Zydone, and various generic opioid medicines. The marketing statement on Endo's website gives the false impression that opioids can provide long-term relief and functional improvement. Endo falsely advertised that patients using Opana ER for chronic pain could perform demanding tasks like construction work, and portrayed users of the medication as healthy and unimpaired.

Endo's unbranded marketing materials contradicted its branded materials concerning the risks of addiction. In one example, an unbranded advertisement deceptively stated that "People who take opioids as prescribed usually do not become addicted," in contradiction to Endo's branded advertising for Opana ER, which stated that all patients treated with opioids have a risk of addiction even with appropriate medical use.

In 2009, Endo sponsored a National Initiative on Pain Control (NIPC) CME program titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo was also a sponsor of a series of educational programs titled persistent *Pain in the Older Patient*, which claimed that chronic opioid therapy had been shown to reduce pain

and improve depressive symptoms and cognitive functioning. Endo distributed a pamphlet entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which advised that doses could be increased to relieve pain.

In 2009, Endo sponsored a website, Painknowledge.com, which falsely claimed that "[p]eople who take opioids as prescribed usually do not become addicted." The website also advised patients that opioid dosages could be increased until they reached the correct dose to relieve pain. The website further touted that opioid patients could experience improved quality of life and functioning that would allow them to participate in activities of daily living, such as work and hobbies that could not be enjoyed because of pain. The website was maintained by NIPC, but did not disclose Endo's involvement.

Another Endo sponsored website, PainAction.com, falsely stated "[m]ost chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo and Cephalon distributed a pamphlet entitled *Living with Someone with Chronic Pain*, which also understated the risk of addiction.

In 2016, Endo settled a claim with the New York Attorney General ("NYAG") related to its unfounded advertising claims about addiction. As part of the settlement, Endo agreed to refrain from making statements in New York that opioids are non-addictive or that most patients who take opioids do not become addicted. The NYAG found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing. The NYAG also found that Endo paid bonuses to sales representatives for detailing prescribers who had been arrested or convicted for illegally prescribing opioids and failed to prevent sales representatives from visiting suspicious prescribers who had been placed on the no-call list. Endo's Vice President for Pharmacovigilance and Risk Management testified that he was not aware of any research validating the concept of pseudoaddiction and agreed not to use the term in its training and marketing materials in New York.

Endo marketed Opana ER as tamper or crush-resistant and less prone to misuse and abuse, even though its own studies showed that Opana ER could be ground and chewed. In 2012, the FDA rejected Endo's petition to approve Opana ER as abuse-deterrent and in 2013 warned Endo that there was no evidence that Opana ER would provide a reduction in intranasal or intravenous abuse. The NYAG found Endo's statements about Opana ER's crush resistance to be false and misleading. In 2017, the FDA requested that Endo withdraw Opana ER from the market.

4. Par. Par is the fifth largest manufacturer of generic pharmaceuticals in the world, including oxycodone, oxymorphone, and hydrocodone. In 2013, Par pleaded guilty to misbranding its drugs.

5. Janssen. Janssen manufacturers the opioid medication Duragesic and, until 2015, developed and sold the opioids Nucynta and Nucynta ER.

Although Janssen has disclaimed any responsibility for causing the opioid crisis, internal communications between high-level executives show that the company funded bogus research to lend credibility to the fiction that opioids are rarely addictive when used for chronic pain. Janssen used these studies to promote the idea that its medications were safer and less addictive than competitor brands.

In 2009, Janssen approved and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults*, which described addiction as a myth and falsely asserted that studies had shown that opioids are rarely addictive when used properly for chronic pain. The guide also listed dosage limitations as "disadvantages" of other pain medicines, but omitted any discussion of the risks of increased opioid dosages. The guide stated that use of opioids could make it easier to live a normal life and users could expect functional improvements in sleep, returning to work, recreation, sex, walking and climbing stairs, thus allowing people with chronic pain to return to a normal life.

In 2009, Janssen funded and edited the *Let's Talk Pain* website, which promoted falsehoods about pseudoaddiction. The website also featured an interview claiming that opioids allowed a patient to "continue to function." Janssen also ran the website, PrescribeResponsibly.com, which falsely claimed that concerns about addiction were "overestimated."

6. Insys Individuals: John Kapoor and Michael Babich. Insys Therapeutics, Inc. ("Insys") manufactures several types of opioids, including Subsys, a fentanyl sublingual spray and semi-synthetic opioid antagonist, and Syndros, a cannabinoid medicine used to treat side-effects of opioid use. Subsys is approved for breakthrough pain in opioid-tolerant cancer patients. In June 2019, Insys pleaded guilty to federal charges that the company bribed doctors to prescribe opioid medications to patients who did not need them, which was part of a $225 million deal with the federal government.

John Kapoor is the founder and majority owner of Insys. In May 2019, he was found guilty of racketeering conspiracy and running a scheme in several states, including Arizona, to bribe healthcare providers to prescribe Subsys. Kapoor personally made false and misleading

representations regarding the proper use of Subsys and engaged in a nationwide conspiracy using bribes and fraud to promote the illegal distribution of Subsys.

Michael Babich is the former CEO and President of Insys. In January 2019, Babich pleaded guilty to charges of racketeering conspiracy, conspiracy to commit wire fraud, and conspiracy to violate the anti-kickback law.

Kapoor and Babich conspired to bribe practitioners in Arizona and other states to encourage the prescription of Subsys. In exchange for bribes and kickbacks, the practitioners wrote large numbers of prescriptions for patients, many of whom had no medical need for Subsys. Kapoor and Babich also conspired to mislead health insurance providers who were reluctant to approve coverage for opioid medications for non-cancer patients. To do this, they set up a reimbursement unit dedicated to obtaining prior authorizations from insurers and pharmacy benefit managers.

C. Distributors'/Pharmacy Distributors' Involvement in Opioid Diversion

The Distributors supply opioids to hospitals, pharmacies and doctors in plaintiffs' communities. Since 2007, the Drug Enforcement Administration (DEA) has advised Distributors about diversion trends, "red flags" to identify potential diversion and their responsibility to maintain effective controls against diversion and report suspicious opioid orders. A Cardinal Health executive claimed that the company used "advanced analytics" to monitor supply chain and that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

Distributors knowingly or negligently allowed diversion, resulting in the assessment of numerous fines and penalties. In 2008, Cardinal Health paid a $34 million penalty to settle allegations about opioid diversion taking place at seven warehouses around the United States. In 2012, Cardinal Health reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. In 2016, Cardinal Health reached a $34 million settlement with the United States.

In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center due to allegations that it was not controlling shipments of prescription opioids to internet pharmacies. In 2012, AmerisourceBergen was implicated in failing to protect against the diversion of controlled substances into non-medically necessary channels.

Despite the various fines and penalties, Distributors have continued to allow the diversion of opioids. Distributors profited from the diversion of opioids by ignoring and not reporting the impossibly large orders they shipped into plaintiffs' communities.

Pharmacy Distributors Walmart, Walgreens and Smith's distributed opioids to their respective retail pharmacies in Prescott and Pinal County. Plaintiffs allege the Pharmacy Distributors failed to monitor and report suspicious orders of opioids. They ignored inconceivably large orders that far exceeded any legitimate medical need in the communities. They reaped enormous profits by flooding the market with prescription opioids.

D. Pharmacy Dispensers' Involvement

Pharmacy Dispensers dispensed prescription opioids to residents in Pinal County. Plaintiff Pinal County asserts that the Pharmacy Dispensers had a duty to prevent opioid diversion and to report any suspicious orders. The Pharmacy Dispensers failed to report suspicious orders made obvious by certain "red flags." They had unique knowledge about the excessive supply of opioids into Pinal County. The Pharmacy Dispensers earned enormous profits by flooding Pinal County with prescription opioids.

E. Prescribers

Fred Harper and Western Drug, Inc. (collectively "Harper") are pharmacists. The Apache County complaint improperly identified Harper as Prescribers. As discussed below, the complaint's allegations against these defendants are insufficient. Thus, the motion for more definite statement is granted and Apache County may amend its complaint against Harper.

F. Harms Alleged

The Complaints allege that defendants made untold billions of dollars from their involvement in the prescription opioid epidemic. At the same time, plaintiffs have been severely harmed by defendants' actions. The cities and counties allege that defendants' actions have caused a devastating public health crisis in their communities.

The specific harms alleged include increased costs for providing opioid-related health services, such as emergency medical services, skilled nursing care, substance abuse treatment, and pain management clinics. Plaintiffs have also had to increase spending on foster care placement, family services and other social programs due to the rise of abuse and neglect of children. Increased funds have also been used to pay crime-related costs, including for arrests and investigations, probation and supervision services, jail services, court costs and community

victim assistance services. Plaintiffs also claim they have lost tax revenue as a result of the incapacitation of their residents who were no longer productive citizens because of opioid addiction. The county plaintiffs assert that they have had to make larger contributions to AHCCCS and county health departments to cover increased demands for opioid-related services.

The complaints assert the following causes of action against each of the defendants: Count 1: Public Nuisance; Count 2: Negligence; Count 3: Negligence per se; and Count 4: Unjust Enrichment.[5]

III. PENDING MOTIONS TO DISMISS

There are 15 motions to dismiss pending. Manufacturers filed separate, but nearly identical, motions to dismiss in each of the seven consolidated cases. The only difference in these seven motions, responses and replies appears to be the arguments concerning the authority of the cities and counties to bring these actions. Defendants Kapoor and Babich joined in all the issues raised in Manufacturers' Motions to Dismiss. Pharmacy Distributors in the Prescott case joined in Manufacturers' Motion to Dismiss on two issues: 1) whether the plaintiffs have authority to bring these lawsuits; and 2) whether the claims are barred by the municipal cost recovery rule. Pharmacy Distributors/Dispensers in the Pinal County case joined in the Manufacturers' Motion to Dismiss on the same two issues.

The Actavis Generic Entities filed a separate Motion to Dismiss in all seven cases. Cephalon and Kapoor also filed separate Motions to Dismiss in all seven cases.

Janssen filed a separate Motion to Dismiss in all cases. Babich joined in the motion on two issues: 1) whether the fraud claims were pled with particularity; and 2) whether the claims should be dismissed because the product labels and other materials disclosed the known risks of opioid medications.

Distributors filed a separate Motion to Dismiss in all seven cases. Pharmacy Distributors in the Prescott case joined in Distributors' motion on seven issues: 1) whether the complaints pled causation-in-fact; 2) whether the claims are barred by the derivative injury rule; 3) whether the complaints state a claim for public nuisance; 4) whether the complaints state a claim for negligence; 5) whether the complaints state a claim for unjust enrichment; 6) whether the complaints state a claim for negligence *per se*; and 7) whether plaintiffs are authorized to bring

5. On August 21, 2020, plaintiffs filed a notice of intent to dismiss Count 5 for negligent failure to warn asserted against the Manufacturers. On September 2, 2020, plaintiffs filed a notice of intent to dismiss Count 8 for violations of the Arizona Consumer Fraud Act.

these lawsuits. Pharmacy Distributors/Dispensers in the Pinal County case joined in the same seven issues.

Pharmacy Distributors in the Prescott case filed a separate Motion to Dismiss. Babich joined in the motion to dismiss on the issue of proximate causation.

Pharmacy Dispensers/Dispensers in the Pinal County case filed a separate Motion to Dismiss. They incorporated most of the arguments raised in the motion filed by Pharmacy Distributors in the Prescott case, as well as raising some additional arguments. Babich joined in many of the issues raised in the motion to dismiss.

Harper filed a separate Motion to Dismiss or Motion for More Definite Statement in the Apache County case.

IV. STANDARD OF REVIEW

Motions to dismiss are not favored. The purpose of a Rule 12(b)(6) motion is to test the sufficiency of the complaint, and the motion will only be granted if it demonstrates that plaintiffs would not be entitled to relief "under any facts susceptible of proof in the statement of the claim." *ELM Retirement Center, LP v. Callaway*, 226 Ariz. 287, 289, ¶ 5 (App. 2010) (*quoting Mohave Disposal, Inc. v. City of Kingman*, 186 Ariz. 343, 346 (1996)). In ruling on a motion to dismiss, the Court will assume the truth of the well-pled factual allegations and indulge all reasonable inferences therefrom in favor of the opposing party. *Cullen v. Auto-Owners, Ins. Co.*, 218 Ariz. 417, 419, ¶ 7 (2008). The Arizona Supreme Court has warned trial courts against resolving factual disputes on an undeveloped record. *See Coleman v. City of Mesa*, 230 Ariz. 352, 363, ¶ 46 (2012).

"Arizona follows a notice pleading standard." *Id.* at 356, ¶ 9 (*quoting Cullen*, 218 Ariz. at 419, ¶ 6). The purpose of the complaint is to "give the opponent fair notice of the nature and basis of the claim and indicate generally the type of litigation involved." *Cullen*, 218 Ariz. at 419, ¶ 6. Thus, under Rule 8(a), a valid complaint need only have "a statement of the ground upon which the court's jurisdiction depends, a statement of the claim showing that the pleader is entitled to relief and a demand for judgment." *Rowland v. Kellogg Brown & Root, Inc.*, 210 Ariz. 530, 533, ¶ 10 (App. 2005) (finding complaint sufficient despite "numerous technical deficiencies").[6] Notice pleading does not require a plaintiff to allege the evidentiary details of its claims for relief. *Verduzco v. American Valet*, 240 Ariz. 221, 225, ¶ 9 (App. 2016).

6. Defendants cite *Steinberger v McVey*, 234 Ariz. 125 (App. 2014), and argue that the complaints improperly group defendants together without identifying the particular fraudulent

V. THE ARIZONA SUPREME COURT'S GRANT OF REVIEW IN *TUCSON MEDICAL*

Plaintiffs repeatedly referred to a decision in *Tucson Medical Center v. Purdue Pharma L.P., et al.*, No. C20184991 (Pima County Superior Court), as persuasive authority on several issues in this case. *Tucson Medical* also concerns the prescription opioid crisis.

In a January 23, 2020 decision, the trial court in *Tucson Medical* denied CVS Pharmacy's ("CVS") motion to dismiss. Among other things, the trial court found within the Arizona Controlled Substances Act (AZCSA) a "separate public policy in favor of regulating and preventing harm from opioids." CVS Petition for Review at 4. CVS filed a petition for special action, which the court of appeals denied. CVS filed a petition for review of the denial in the Arizona Supreme Court. One of the arguments made by CVS in its petition was that the trial court erred by finding a tort duty based on AZCSA. CVS Petition for Review at 10-11.

On September 16, 2020, the Arizona Supreme Court granted CVS's petition for review on two questions:

> (2) Whether a hospital may assert a direct claim against a third party it contends caused personal injuries to its patient, even if the patient is covered by Medicaid.
> (3) Whether a pharmacy that self-distributes prescription opioids to its affiliated pharmacies owes a duty to the hospital.

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statements made by each defendant. *Steinberger* holds that fraud-based claims, such as common law fraud, concealment, and consumer fraud, must be pled with particularity under Rule 9(b) as to each defendant. *Id.* at 141, ¶¶ 73-74. *Steinberger* does not hold that negligence and other non-fraud claims must be pled with particularity. In fact, while the court dismissed the fraud-based claims for lack of particularity, it sustained the negligence-based claims. *Id*. at 136-40, ¶¶ 44-62.

Here, plaintiffs have dismissed the consumer fraud claims. Thus, the pleading standard set out in *Steinberger* no longer applies. Defendants have not cited a case requiring particularized pleading of negligence and other non-fraud-based claims. There is nothing wrong with "group pleading" non-fraud claims where the defendants allegedly engaged in the same conduct. *See United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1184 (9th Cir. 2016) ("There is no flaw in a pleading, however, where collective allegations are used to describe the actions of multiple defendants who are alleged to have engaged in precisely the same conduct.").

Arizona Supreme Court minutes, 9/16/2020, *CVS Pharmacy v. Bostwick/Tucson Medical*, CV-20-0120-PR. CVS also asked the supreme court to address the public nuisance and unjust enrichment claims. CVS Petition for Review at 15.

These cases are related to *Tucson Medical*. The decision by the supreme court may have a bearing on one or more issues in this case, including the question of the duty of care, remoteness and derivative injuries. Thus, some of the issues addressed in this ruling may need to be reevaluated after the supreme court rules on the special action. The parties may wish to file a special action of this ruling and seek consolidation with the *Tucson Medical* case.

Based on the special action, defendants filed a Motion to Stay on October 8, 2020. Plaintiffs filed an objection on October 26, 2020. In light of the instant ruling on the motions to dismiss, the parties may file a supplemental pleading (not to exceed five pages) concerning the merits of a stay as affected by this ruling.

VI. ANALYSIS

Defendants first argue that the complaints are barred by the following six defenses common to all counts: (1) plaintiffs lack authority to bring the claims; (2) plaintiffs' injuries are derivative and too remote; (3) plaintiffs have not sufficiently pled causation; (4) local governments cannot recover for expenditures of funds to provide public services; (5) federal regulation of prescription opioid medications preempts plaintiffs' state tort claims; and (6) product labels disclosed the known risks of opioid medications.

Defendants then argue that each remaining count fails to state a claim upon which relief can be granted. Each issue will be addressed in turn.

A. Analysis of Defenses Common to Multiple Claims.

1. Plaintiffs' Authority to Bring These Actions.

Defendants challenge plaintiffs' authority to bring these actions. Defendants make two arguments: (1) the opioid crisis is a public health issue of statewide concern that the Arizona Attorney General has exclusive authority to address; and (2) the cities and counties have no authority to bring these actions.

a. Statewide concern

Defendants argue that the opioid crisis is a statewide public health concern and only the Attorney General can bring lawsuits to address statewide issues. Although the opioid crisis is an issue throughout the State, defendants have not demonstrated that plaintiffs are precluded from bringing these lawsuits.

Defendants cite to *City of Flagstaff v. Associated Dairy Prod. Co*., 75 Ariz. 254 (1953), and *Associated Dairy Prod. Co. v. Page*, 68 Ariz. 393 (1949). In both cases, the cities sought to regulate the milk industry through local ordinance. The Arizona Supreme Court struck down the ordinances because the legislature had enacted statutes to regulate the milk industry throughout the state to the exclusion of local government regulation.

Defendants claim that the Arizona Attorney General recognized that the opioid claims are a matter of statewide concern when he argued in an amicus brief before the Sixth Circuit in the Ohio multidistrict opioid litigation that, "the opioid crisis is a matter of statewide impact that requires a statewide response." Attorneys General Amicus Brief in Support of Writ of Mandamus, *In re Nat'l Prescription Opiate Litig*., No. 19-3827, at 14 (6th Cir. Sept. 6, 2019). There, the Attorney General urged the court to stay the multidistrict litigation, arguing that the states should bring the claims, not individual local agencies. *Id*. at 13-14. Defendants also note that the Attorney General has filed several opioid related actions, including *Brnovich v. Purdue Pharma L.P*., No. C20072471 (Pima Cty. Super. Ct. Sept. 10, 2018); *Brnovich v. Insys Therapeutics, Inc.*, No. CV2017-012008 (Maricopa Cty. Super. Ct. Aug. 30, 2017); and *Arizona v. Sackler*, No. 220151 (U.S. July 31, 2019).

Plaintiffs claim that their complaints are not public health lawsuits, and they are not seeking to address statewide problems. Rather, plaintiffs assert they are only bringing claims held by the cities and counties themselves for losses they sustained, not the public. Plaintiffs claim they are suing to recover on their own behalf the damages they incurred as a result of defendants' misconduct and that these are not matters of statewide harm, but only for harm distinct to them, based on health and crime expenses and losses specific to them.

The opioid crisis is certainly a statewide, and even a nationwide, concern. Defendants, however, have not cited any authority holding that local governments cannot sue for harms they have sustained. The *Associated Dairy Products* cases only held that a local government cannot regulate a field already regulated by the state. Those cases do not suggest that a local government cannot sue to recover for harms it has suffered.

Further, the Sixth Circuit denied the State of Ohio's attempt to stop the local governments from moving forward with their claims in the Multidistrict Opioid Litigation. *See* Order, *In re Nat'l Prescription Opiate Litig.,* No. 19-3827 (6th Cir. October 10, 2019).[7]

At oral argument, this Court expressed concerns about the inelegant and inefficient process of allowing every city, town or county affected by the opioid crisis (*i.e.*, every city, town or county) to bring a separate state court action against conduct occurring on a national scale particularly when, as here, the claim is based on nuisance and the requested relief includes an injunction.[8] Although defendants allege that the Attorney General "has made clear that local government suits like this one 'undermine' and 'impede' any statewide resolution," Pima County Motion at 1:19-20, the Attorney General has not expressed any opposition to plaintiffs' claims in the cases before this Court.

Federal courts on occasion will ask for amicus briefing from governmental agencies with an interest in the outcome of litigation. Here, the Court invites the Arizona Attorney General to weigh in by submitting an amicus brief addressing the issue of whether the Attorney General supports, objects to or has no position on these opioid-related actions filed by cities and counties in Arizona state court.

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7. Arizona Supreme Court Rule 111(c)(3) provides that "[a] party citing a memorandum decision must provide either a copy of the decision or a hyperlink to the decision where it may be obtained without charge." A memorandum decision is "a written disposition of a matter not intended for publication." Arizona Supreme Court Rule 111(a)(2). The parties have cited numerous unpublished trial court and appellate decisions from courts throughout the country. In most instances, the parties have failed to comply with this supreme court rule. The Court has tried to locate those cases. In the future, however, the Court will not consider the citation to an unpublished memorandum decision that does not comply with the supreme court rule.

8. This concern was expressed by the supreme court in *Hopi Tribe v. Arizona Snowbowl Resort Ltd*., 245 Ariz. 397, 400, ¶ 10 (2018). In discussing the "special injury" requirement for a private plaintiff's prima facie public nuisance claim, the court noted that the "so-called 'special injury' requirement serves two important functions. First, it 'relieves[s] defendants and the courts of the multiple actions that might follow if every member of the public were allowed to sue for a common wrong. Second, in keeping with the principles of separation of powers and judicial restraint, it ensures that 'harm[s]. . . affecting all members of the public [are] handled by public officials' rather than by courts in private litigation." (Citations omitted.) Multiple lawsuits from multiple jurisdictions concerning the same, statewide common conduct implicate the same concerns.

For the purpose of these motions, plaintiffs' complaints survive a Rule 12(b)(6) motion to dismiss on the basis that the Attorney General has exclusive authority to sue the opioid defendants.

b. Cities and counties as plaintiffs

Defendants next argue that the cities and counties have no authority to bring these lawsuits. They argue that cities and counties have only those powers granted by the State and plaintiffs have not been granted authority to bring these suits. Defendants rely on *City of Scottsdale v. Superior Court*, 103 Ariz. 204, 205 (1968), in which the Arizona Supreme Court stated, "cities and towns of this state are municipal corporations created by the state and possessory of no greater powers than those delegated to them by the constitution and the general laws of the state." Defendants further argue that plaintiffs cannot bring these suits to recover injuries to their residents. *See, e.g., Town of Wickenburg v. State*, 115 Ariz. 465, 469 (App. 1977) (Arizona law "does not allow the municipality to bring a lawsuit in court to protect personal rights guaranteed to its citizens as individuals.").

Plaintiffs concede that they are not authorized to sue on behalf of others, including their own residents. Plaintiffs argue they are not bringing claims for harm done to their residents. Rather, they claim they are seeking to recover for harm to plaintiffs themselves caused by defendants' conduct. The complaints allege plaintiffs have suffered harm that is direct and unique to them. Plaintiffs can bring these actions to seek redress for those harms. *See City of Tucson v. Woods*, 191 Ariz. 523, 525-26 (App. 1997).

The cities argue that, as municipal corporations, they are authorized to do business, just like any other corporation in Arizona. *See* Ariz. Const. Art. § 13, sec. 5 ("Every municipal corporation within this state shall have the right to engage in any business or enterprise which may be engaged in by a person, firm, or corporation, by virtue of a franchise from said municipal corporation."). The charters for Glendale, Bullhead City and Prescott provide that they have "all the powers granted to municipal corporations and to cities by the constitution and laws of this state and by this charter, together with all the implied powers necessary to carry into execution all the powers granted." *E.g.*, Glendale Charter, Article I, section 3. A.R.S. § 11-201(A)(1) gives counties the power to sue and be sued. Further, A.R.S. § 13-2917(C), expressly authorizes local governments (cities and counties) to bring public nuisance actions.

Defendants' argument is not persuasive. Constitutional and statutory authority support plaintiffs' ability to bring these actions to recover for their own harms.

2. Remoteness/Derivative Injury Rule

The doctrine of remoteness or derivative injury rule provides that "a plaintiff who complain[s] of harm flowing merely from the misfortunes visited upon a third person by the defendant's acts [is] generally said to stand at too remote a distance to recover." *Laborers' & Operating Engineers' Util. Agreement Health & Welfare Trust Fund for Ariz. v. Philip Morris, Inc.*, 42 F. Supp. 2d 943, 948 (D. Ariz. 1999) (*quoting Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258, 268–69 (1992)). In *Laborers' & Operating Engineers*, a pension fund sued tobacco companies for increased healthcare costs flowing from its participants' tobacco-related illnesses. *Id.* at 945. The plaintiff alleged that various companies "fraudulently misrepresented the risks associated with tobacco use and engaged in deceitful marketing" which "increased tobacco-related illnesses and associated health care costs," which plaintiff was responsible for paying. *Id.* The pension fund sought to recoup the increased healthcare costs from the tobacco companies. The court dismissed the RICO and state law claims because plaintiff's alleged injuries were "entirely dependent upon injuries sustained by [its] participants and beneficiaries, making [it] at least one step removed from the challenged harmful conduct." *Id.* at 947.

Manufacturers and Distributors argue that plaintiffs' alleged injuries are barred because they are too remote and derivative of injuries suffered by third-party opioid users. Defendants claim that plaintiffs' damages for lost tax revenue and expenditures for healthcare and criminal justice services flow from the injuries suffered by its residents who became addicted to opioids.

Plaintiffs respond that they are seeking recovery for their own damages, not for the harms inflicted on their residents. The complaints devote 10 to 15 pages each detailing the categories of damages plaintiffs allege they have suffered. Some of the injuries include: (1) healthcare costs for specialty services such as detoxification, residential and inpatient treatment; (2) cost of foster care for children abused and neglected because of opioid addiction; (3) costs for emergency medical services, including providing specialized treatment for drug overdoses; (4) increased crime-related costs, including specialized training, community and victim services; and (5) loss of tax revenue due to the decrease in the productive, working population.

Some of these categories of damages might be derivative, such as the healthcare-related costs, because they arise out of injuries to the residents. *See Id.* at 948; *Perry v. Am. Tobacco Co.*, 324 F.3d 845 (6th Cir. 2003) (plaintiffs were insureds who alleged their cost of premiums was increased by the tobacco companies' conduct; Sixth Circuit joined eight other federal circuit courts of appeal to rule that such claims fail because the alleged injuries are too remote). Other categories of damages, such as crime-related costs, do not appear to arise directly out of injuries to residents.

In *In re National Opiate Litigation*, 440 F.Supp.3d 773, 802 (N.D. Ohio 2020), the district court denied a motion to dismiss and distinguished the tobacco cases as follows:

> Plaintiffs have alleged a plausible claim that their injuries are the direct result of the RICO Marketing Defendants' misrepresentations to them and their agents, and have also alleged a plausible claim that the RICO Defendants' participation in the creation of an illicit opioid market resulted in Plaintiffs' damages. Although Defendants identify third parties within the causal chain, Plaintiffs' economic injuries were incurred by Plaintiffs and not passed on by any intermediate party that was "closer" to Defendants' actions. . . Plaintiffs seek damages for payments they made and these claims are theirs and theirs alone.

Id. at 801-02 (citations omitted). The district court expressed some reservations about whether a plaintiff can recoup actual monetary costs "paid as a result of treatment provided to or medical expenses incurred by third-party individuals" for whom the plaintiff had some obligation to provide or pay for care. The court nevertheless denied the motion to dismiss because plaintiffs asserted some direct damages:

> However, even if *Jackson [v. Sedgwick Claims Mgmt. Serv., Inc.*, 731 F.3d 556, 565-66 (6th Cir. 2013] precludes a RICO claim where the asserted economic harm is created by personal injury to a third-party, the Funds also allege other categories of injury: claims paid for reimbursement for opioids premised on misrepresentations made to them or their agents, and payments unknowingly made for opioids destined for diversion into the secondary black market created by the RICO Supply Chain Defendants. These claims do not arise from third-party personal injuries. Because some of Plaintiffs' claims are not dependent on medical costs and expenses, the Court will not, at the motion to dismiss stage, deny Plaintiffs the opportunity to proceed with their claims.

Id. at 802.

This Court cannot find on this motion that all of plaintiffs' injuries are derivative. These are issues more appropriate for summary judgment when the parties develop a record concerning plaintiffs' damages.

3. Causation

Defendants argue that all of plaintiffs' claims require proximate cause as an element and that the complaints fail to plead that defendants' conduct was the proximate cause of the alleged injuries.[9]

To establish causation, a plaintiff must show that the injury would not have occurred "but for" the defendant's negligent conduct. *Ontiveros v. Borak*, 136 Ariz. 500, 505 (1983). Proximate cause is defined as "that which, in a natural and continuous sequence, unbroken by any efficient intervening cause, produces an injury, and without which the injury would not have occurred." *Smith v. Chapman*, 115 Ariz. 211, 214 (1977) (*quoting McDowell v. Davis*, 104 Ariz. 69, 71 (1969)). The mere possibility of causation is not enough. *Grafitti-Valenzuela ex rel. Grafitti v. City of Phoenix*, 216 Ariz. 454, 460, ¶ 21 (App. 2007) (affirming grant of summary judgment on lack of proximate causation).

A defendant's acts are the proximate cause of a plaintiff's injury only if they are a substantial factor in bringing about the harm. *Barrett v. Harris*, 207 Ariz. 374, 381, ¶ 26 (App. 2004). However, the defendant's conduct does not need to be the sole cause of plaintiff's harm. Proximate cause can exist even if defendant's acts contributed only a little to plaintiff's injury. *Ontiveros*, 136 Ariz. at 505. Thus, more than one person may be liable for causing an injury and a defendant cannot escape liability by claiming that the conduct of some other person was also a contributing cause. *Id.*

In some circumstances, a supervening cause may be sufficient to relieve a defendant of liability but only when the intervening event was unforeseeable by a reasonable person in defendant's position and, when looking back, the event appears extraordinary. *Grafitti-Valenzuela*, 216 Ariz. at 462, ¶ 29. Whether an intervening act was foreseeable and extraordinary to break the chain of causation requires consideration of all the facts. *McMurtry v. Weatherford Hotel, Inc.*, 231 Ariz. 244, 256, ¶ 38 (App. 2013). A plaintiff must also show some reasonable connection between defendant's act or omission and plaintiff's damages. *Robertson v. Sixpence Inns of Am., Inc.*, 163 Ariz. 539, 546 (1990). The issue of causation is ordinarily a question for the trier of fact that can rarely be decided on a motion to dismiss.

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9. Because the failure to warn claims have been dismissed, the Court will not address the issues briefly alluded to in the motions concerning the learned intermediary doctrine and whether the complaints alleged doctors would have made different prescribing decisions had they been given different warnings. *See D'Agnese v. Novartis Pharmaceuticals, Corp.,* 952 F. Supp. 2d 880, 889 (D. Ariz. 2013).

a. Manufacturers' motions

Manufacturers argue that there are too many links in the chain of causation. Manufacturers list six links in the chain between their actions and the alleged harm: (1) Manufacturers misleadingly marketed opioid medications; (2) doctors wrote inappropriate prescriptions for opioid medications based on the misleading marketing claims; (3) patients in plaintiffs' communities took the medications based on the misleading claims; (4) the medications led to addiction, overdose or other injury; (5) the injuries led to hospitalization, job loss, foster care, crime or other harm; and (6) plaintiffs incurred costs to mitigate the problems in their communities. Manufacturers claim there are seven links in the chain of causation on the allegations that Manufacturers failed to report suspicious orders, the failure-to-prevent diversion claim. Defendants argue the causal chain from their conduct to plaintiffs' injury is far too attenuated.

Plaintiffs argue that they have adequately pled causation and the issue should not be decided on a motion to dismiss. Plaintiffs claim it was foreseeable to Manufacturers that their scheme to mislead doctors and the public about the risks and benefits of opioid medications would lead to an abuse and addiction crisis, which the cities and counties would have to address, leading to increased health and safety costs and lost revenue. They allege Manufacturers' targeted their communities and the vulnerable citizens within them in order to sell more of the opioids they produced, and used KOLs, front groups and other marketing ploys to convince doctors to prescribe the medications for purposes other than their intended use. Plaintiffs allege the scheme was designed to influence physicians in order to increase sales of opioids in plaintiffs' communities and, without Manufacturers' deception, the addiction and abuse of opioids would not have become such a widespread, severe problem.

Because the addictive qualities of opioids were known, it was foreseeable to Manufacturers that their misleading claims would lead to addiction and societal problems the local governments would have to address. If Manufacturers deceived doctors and targeted vulnerable residents, as alleged, they cannot claim that those doctors and patients who fell for the scheme are superseding causes that break the chain of causation. Thus, the Court cannot rule as a matter of law that causation is too attenuated. Taking the allegations as true and drawing all inferences therefrom in plaintiffs' favor, the Court finds that the causation allegations survive a motion to dismiss.

Courts in other opioid-related cases have come to the same conclusion on causation at the pleading stage. *See, e.g., In re National Prescription Opiate Litig.*, No. 1:17-md-2804, 2018 WL 6628898, *5 (N.D. Ohio Dec. 19, 2018) ("Under this potential chain of causation, the relationship between Plaintiffs' injury and Defendants' alleged conduct . . . is not too remote to

support a finding of proximate cause here."); *City of Everett v. Purdue Pharma L.P.*, No. C17-209RSM, 2017 WL 4236062, *6 (W.D. Wash. Sept. 25, 2017) (although there were multiple links in the chain of causation, issue was a fact question that could not be decided on a motion to dismiss).

Defendants also argue that the factual allegations of causation are insufficient. They complain that the complaints do not identify the specific prescribers who relied on a misleading statement in deciding to write an opioid prescription for a patient living in plaintiffs' communities.[10]

Rule 8 applies to causation. Under notice pleading, a plaintiff does not need to include all the factual support for its allegations in the complaint. Plaintiffs are not required to identify the doctors who prescribed specific medications and to whom. That level of specificity is unnecessary in a complaint. Nothing would be served by requiring plaintiffs to plead their claims with that level of detail, other than to double or triple the length of the already lengthy complaints.

In a related argument, defendants argue that plaintiffs' damages are too speculative and difficult, if not impossible, to calculate. *See Rancho Pescado, Inc. v. Northwestern Mut. Life Ins. Co.*, 140 Ariz. 174, 186 (App. 1984) (summary judgment granted where evidence of lost profits was nothing more than speculation and conjecture; "It is well settled that conjecture or speculation cannot provide the basis for an award of damages. The evidence must make an approximately accurate estimate possible."). Defendants argue that to prove damages plaintiffs must plead and prove: (1) which doctors prescribed opioid medications based on Manufacturers' misleading claims; (2) that the prescriptions were harmful to a resident within plaintiffs' communities; and (3) which instances of crime or other societal harm resulted from Manufacturers' wrongdoing.

Like causation, the potential difficulty in ascertaining and apportioning damages is not a basis for granting a motion to dismiss. *Lexmark Int'l, Inc. v. Static Control Components, Inc.*,

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10. Cephalon argues that plaintiffs cannot establish proximate causation because the labels for Actiq and Fentora have black box warnings and are subject to the TIRF REMS program, which imposes strict requirements on medical providers before prescribing those medications. Thus, Cephalon claims prescribers and patients could not have been misled about the appropriate uses and risks of those medications. As discussed below, the Court will only consider the complaints' allegations and will not consider the product labels and the documents concerning the TIRF REMS programs in ruling on these motions to dismiss. For purposes of these motions, the Court will accept as true the allegations that doctors and patients were misled.

572 U.S. 118, 135 (2014) (the "potential difficulty in ascertaining and apportioning damages is not . . . an independent basis for denying standing where it is adequately alleged that a defendant's conduct has proximately injured an interest of the plaintiff's that the statute protects"); *see* CJS Pleading § 653 (2020) ("[A] motion to dismiss will not lie on the ground that the damages claimed are remote, uncertain, or speculative in character and cannot be the subject of recovery.").

Manufacturers rely primarily on two opioid-related cases, *State ex. rel. Stenehjem v. Purdue Pharma L.P.*, No. 08-2018-CV-01300, at 10 (N.D. Dist. Ct. May 10, 2019), *and City of New Haven v. Purdue Pharma, L.P.*, No. X07-HHD-CV-17-6086134-S, 2019 WL 423990 (Conn. Super. Ct. Jan. 8, 2019). Both are unpublished trial court rulings. In both cases, the trial courts held that the multiple links between the opioid manufacturers' alleged misconduct and the plaintiffs' harm was too attenuated and dismissed the claims. These cases do not support dismissal of this case at this stage.

Stenehjem was decided on a motion to dismiss that had been converted to a motion for summary judgment. S*tenehjem*, No. 08-2018-CV-01300, at 4. The court stated that there were multiple intervening events and actors, such as a doctor's decisions to prescribe medications and the patient's response to the medication. The court believed that it is "nearly impossible to trace any of the harms the State alleges back to solely [defendant's] own medications" and it would be incomprehensible to hold defendant "solely responsible for the entire opioid epidemic in North Dakota" given defendant's small share of the market. *Id*. at 22. In *New Haven*, the court dismissed similar claims against opioid manufacturers finding the causal chain too remote. The court believed that deciding damages would be too complex and involve "rank speculation." *New Haven*, 2019 WL 423990, * 4.

Defendants also rely on tobacco-related cases, such as *Steamfitters Loc. Union No. 420 Welfare Fund v. Phillip Morris, Inc.*, 171 F.3d 912 (3d Cir. 1999). In *Steamfitters*, union health funds brought a class action against tobacco companies. The plaintiffs claimed that defendants' fraudulent misconduct caused plaintiffs' members and beneficiaries to suffer personal injuries in the form of increased smoking-related illnesses. *Id.* at 917–18. As a result, plaintiffs claimed that they were damaged by having to pay increased medical insurance costs to treat their members. *Id*. The court dismissed the case finding it would be too speculative to determine the extent to which plaintiffs' increased costs for smoking-related illnesses were caused by the tobacco companies' conspiracy to suppress information, as opposed to other factors, such as the smokers' other health problems or the smokers' independent decisions to ignore health and safety warnings and continue smoking. *Id.* at 933.

Stenehjem, *New Haven* and *Steamfitters* do not reflect Arizona law and are not persuasive authority to grant the motions to dismiss. Although proving causation and damages may be difficult, difficultly of proof is not a basis for dismissing the claims at the pleading stage. As the Arizona Supreme Court stated:

> The complexity of proving damages through multiple levels of sales is a daunting task, but one to which our courts are equal. The plaintiffs bear the burden of proving the damages caused by a defendant's wrongful conduct. If the plaintiffs cannot present admissible and convincing proof, they cannot recover. For the purposes of these cases, in which we are compelled to accept the allegations of the complaints as true, . . . we assume that these Plaintiffs can present sufficient evidence of injury caused by illegal conduct. Unlike the Supreme Court, we are unwilling to foreclose their opportunity to attempt to prove their injury.

Bunker's Glass Co. v. Pilkington PLC, 206 Ariz. 9, 18, ¶ 31 (2003) (citations omitted). Difficulty in proving damages is not a basis for dismissal and plaintiffs should be given an opportunity to present admissible and convincing proof of causation and damages.

Construing the allegations in the complaints as true, the Court finds that the complaints contain sufficiently detailed allegations of causation and the harms suffered by plaintiffs. The causal links are not too remote or the damages too speculative to require dismissal at this stage.

b. Distributors' motion

In their separate motion, Distributors argue that cause-in-fact and proximate cause have not been alleged against them. They assert that the upsurge in addiction in plaintiffs' communities resulting in plaintiffs' damages had nothing to do with the actions of the wholesale opioid distributors. They claim that plaintiffs' harms were actually caused by the opioid users' decisions to abuse drugs, the doctors who prescribed them and the manufacturers who made and sold them. Distributors claim their role is limited to shipping opioids to pharmacies and that the mere act of shipping these medications could not have caused the harms alleged. In short, they claim there are too many links in the causal chain. Distributors also rely on *Stenehjem* and *New Haven*.

Plaintiffs allege that Distributors ignored the impossibly large and suspicious opioid orders shipped into plaintiffs' communities, failed to take steps to stop these large orders and continued to supply these communities with large amounts of opioids in order to maximize their profits. By failing to stop the supply of opioids, Plaintiffs claim that Distributors contributed to the opioid crisis and the resulting harm to plaintiffs.

These allegations sufficiently allege causation. Whether there has been an intervening, superseding event cannot be determined at this stage. *See Robertson*, 163 Ariz. at 546.

c. Pharmacy Distributors'/Dispensers' motions (Prescott and Pinal County cases)

Pharmacy Distributors/Dispensers also argue causation is too attenuated. They assert that too many intervening events and actors, including the criminal acts and abuse by third parties, interrupt the causal chain. They claim there is no connection between shipping opioids to retail pharmacies and dispensing them to patients and plaintiffs' alleged injuries. For instance, the Pharmacy Distributors argue there are no allegations that a shipment was diverted to plaintiffs' communities that caused the need for more public services. The Pharmacy Dispensers assert that there are no allegations linking the dispensing of an opioid by a licensed pharmacist to plaintiffs' injuries. They contend that multiple third-party actors break the causal chain.

The cases defendants cite do not support dismissal. For example, *Hannosh v. Segal*, 235 Ariz. 108 (App. 2014), concerned whether gambling losses were injuries to the person under Arizona's racketeering statute. In *Bloxham v. Glock Inc.*, 203 Ariz. 271, 277, ¶ 20 (App. 2002), the court of appeals did not address the proximate cause issue, but held that the that the gun manufacturer and gun show operator owed no duty to parents of child killed by a gun purchased at a gun show.

The Court finds the complaints sufficiently plead causation. Plaintiffs are not required to plead every fact in the causal chain. Further, proximate causation is rarely decided on a motion to dismiss. *See, e.g., Patterson v. Thunder Pass, Inc.*, 214 Ariz. 435, 440, ¶ 19 (App. 2007) (on summary judgment motion, court found a superseding, intervening event of independent origin that negated any negligence on the part of defendant).

4. The Municipal Cost Recovery Rule

Defendants argue that the municipal cost recovery rule bars plaintiffs' claims. The municipal cost recovery rule holds that local governments cannot recover for the costs of providing public services from a tortfeasor whose conduct caused the need for the services. The principal case adopting this rule is *City of Flagstaff v. Atchison, Topeka & Santa Fe Ry. Co.*, 719 F.2d 322 (9th Cir. 1983).

In *Flagstaff*, the city sued to recover the costs of providing emergency services from a train derailment near the city. *Id.* at 323. The city alleged that its fire department had incurred expenses related to the evacuation of the city, including "overtime pay, emergency equipment,

emergency medical personnel, and the cost of food provided to evacuated residents.*" Id.* The city claimed that these costs were compensable damages arising from the railroad's negligence and ultrahazardous activity. *Id*. The Ninth Circuit, interpreting Arizona law, held that the city could not recover its costs.[11] The Ninth Circuit reasoned, "the cost of public services for protection from fire or safety hazards is to be borne by the public as a whole, not assessed against the tortfeasor whose negligence creates the need for the service. Where such services are provided by the government and the costs are spread by taxes, the tortfeasor does not expect a demand for reimbursement." *Id.* The court noted that while sometimes "new tort doctrines are required to cure an unjust allocation of risks and costs," such was not the case "where a fair and sensible system for spreading the costs of an accident is already in place." *Id*. The policy underpinning the rule is that the government has chosen to bear the cost of such expenditures, and any change in that "fiscal policy" should be addressed by the Legislature, rather than the courts. *Id*. The Ninth Circuit recognized that the rule was not a blanket prohibition and that a governmental entity could recover public service costs when authorized by statute or when the tortfeasor has created a public nuisance which the government seeks to abate. *Id.* at 324.

Manufacturers argue that the harms alleged here are the type of public expenditures that are barred by the municipal cost recovery rule. Manufacturers point out that in Glendale's complaint, for example, plaintiff alleges that defendants' involvement in the opioid crisis "imposed enormous tax-based economic damages on Glendale, including tax revenue expended incident to providing various public services that Glendale is required to provide to its citizens under Arizona law, including healthcare- and crime-related costs." (Glendale Complaint at ¶ 286). Glendale seeks, for instance, damages for "tax dollars [spent] to maintain the public safety of places, such as city parks, schools and public lands, where patients-turned-addicts attempt to congregate," and for services provided to crime victims. (*Id.* at ¶¶ 302, 305). Glendale also seeks damages for "foster care placement" and "arrests and investigations" costs. *(Id.* at ¶¶ 295-99, 302-04).

Plaintiffs argue that *Flagstaff* is not binding and no Arizona state court has adopted the rule. Plaintiffs further argue that *Flagstaff* does not apply here for two reasons: (1) their claims fall within the nuisance abatement exception recognized in *Flagstaff,* and (2) the rule has only been applied to discrete incidents, not persistent, ongoing misconduct as alleged here.

The municipal cost recovery rule does not bar plaintiffs' claims. *Flagstaff* expressly recognized that the rule does not apply to claims for abatement of a nuisance. As discussed

11. Although *Flagstaff* involved the interpretation of Arizona law, no Arizona appellate court has applied the municipal cost recovery rule. The Ninth Circuit acknowledged that its interpretation was not definitive. *Id.* at 323.

below, the complaints state a claim for public nuisance. Thus, the costs plaintiffs seek to recover here arguably fall within the exception recognized in *Flagstaff*.

Further, the train derailment in *Flagstaff* was a single, discrete incident requiring a single emergency response. By contrast, the alleged misconduct here is substantial, ongoing and persistent. The complaints allege this conduct has been occurring for decades. In similar cases, courts have declined to bar tort claims where a defendant engages in a course of repetitive conduct that causes substantial harm that imposes a repeated burden on government services. *See, e.g., Cincinnati v. Beretta U.S.A. Corp.*, 95 Ohio St. 3d 416, 428, ¶ 45 (2002) (public nuisance and negligence action by city against handgun manufacturers, trade associations, and handgun distributor); *James v. Arms Technology, Inc*., 820 A.2d 27, 49-50 (N.J. Super. 2003) (declining to apply the municipal cost recovery rule to a public nuisance claim against gun manufacturers, distributors, and dealers).

This decision is consistent with decisions by other courts in opioid-related cases. As Judge Polster noted in a recent decision in the MDL, "[t]he current trend among state court judges ruling in opioid-related cases around the country is that the municipal cost recovery rule does not apply when, as alleged here, an ongoing and persistent course of intentional misconduct creates an unprecedented, man-made crisis that a governmental entity plaintiff could not have reasonably anticipated as part of its normal operating budget for municipal [or] county . . . services*." In re National Prescription Opiate Litig*., 1:17-MD-2804, 2019 WL 3737023, *8 (N.D. Ohio June 13, 2019).

5. Federal Preemption

a. Manufacturers' Motion

"The preemption doctrine derives from the Supremacy Clause of the Constitution, which states: 'This Constitution, and the Laws of the United States ... shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.'" *Fiore v. Collagen Corp*., 187 Ariz. 400, 402-03 (App. 1996) (*quoting* U.S. Const. Art. VI, Cl. 2). Thus, federal law preempts state statutes, regulations and state-law causes of action that conflict with federal law. *Id*. (*citing Hillsborough County v. Automated Medical Lab., Inc.*, 471 U.S. 707, 713 (1985)). A conflict exists when it is impossible for defendant to comply with state and federal laws at the same time. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011); *Reed-Kaliher v. Hoggatt*, 237 Ariz. 119, 124, ¶ 19 (2015).

In the context of prescription drugs, federal preemption arises when a state enacts a statute or regulation which imposes labeling requirements on medications regulated by the FDA. *See Wyeth v. Levine*, 555 U.S. 555, 571 (2009). Preemption also can arise through a tort action alleging insufficient labeling that seeks to impose upon a manufacturer a duty to warn beyond what the FDA would approve. *Id*. Such claims are preempted because it would be impossible for the manufacturer to comply with both federal and state law. Defendants have the burden of showing by clear evidence that the claims are preempted. *Id.* at 571; *Conklin v. Medtronic, Inc*., 245 Ariz. 501, 504, ¶ 8 (2018).

Manufacturers argue that all of plaintiffs' claims are preempted because they conflict with federal law and FDA regulations regarding the approval and labeling of opioid medications. Manufacturers claim that plaintiffs seek to hold them liable for promoting opioid medications for FDA-approved uses. They assert their marketing and promotion was consistent with the FDA-approved labeling and any claims the warnings were inadequate or misleading are preempted.

Manufacturers characterize the complaints as alleging that they falsely represented prescription opioid medications as safe and effective for the long-term treatment of chronic, non-cancer pain. They claim that the FDA has approved the long-acting opioid medications for this use "for an extended period of time, which indicates the FDA found that the opioids to be safe and effective for this use, the benefits outweigh the potential risks and the approved labeling is not false or misleading." Manufacturers mostly rely on *Stenehjem*, No. 08-2018-CV-01300, at 10, an unpublished trial court decision, which held that claims alleging opioid labeling should have included additional warnings were preempted.

Plaintiffs dispute that their claims are based on the marketing of opioid medication for their FDA-approved uses. Rather, they assert that their claims are premised on Manufacturers' deceptive promotion of these medications. They insist that they are not claiming Manufacturers should have changed their FDA-approved labels or that they should have affirmatively disseminated information already contained in the labels. Rather, they contend Manufacturers deceptively marketed the drugs through aggressive and misleading claims about the risks and benefits of opioids. Plaintiffs cite a number of recent opioid-related cases which have held that state law claims based on the promotion of opioids in a manner inconsistent with the FDA-approved labeling were not preempted. *E.g., In re National Prescription Opiate Litigation*, No. 1:17 MD 2804, 2019 WL 4178591, at *5, n.12 (N.D. Ohio Sept. 3, 2019) (collecting cases holding that state law claims based on manufacturers' deceptive, off-label marketing of opioids were not preempted); *In re National Prescription Opiate Litig*., MDL No. 1:17-CV-02804, 2018 WL 4895856, *25 (N.D. Ohio Oct. 5, 2018) (Magistrate Judge Report and Recommendation) (holding that claims alleging misleading promotion of opioids are not preempted); *Commonwealth v. Purdue Pharma, L.P.*, No. 1884CV01808BLS2, 2019 WL 5495866, *3 (Mass.

Super. Sept. 17, 2019) (holding claims alleging marketing of opioids that were inconsistent with approved labels were not preempted); *see also, Arters v. Sandoz Inc.*, 921 F. Supp. 2d 813, 819-820 (S.D. Ohio 2013) (state law fraud claims based on defendants' allegedly fraudulent or unreasonably dangerous off-label promotion of generic drug were not preempted).

A fair reading of the complaints suggests that plaintiffs do not seek to require additional warnings or change opioid labeling. Rather, the allegations detail numerous instances of marketing that were inconsistent with the product labels, most notably the minimization of addiction risk. The complaints also allege that Manufacturers made marketing claims unsupported by scientific evidence, for example that opioids were indicated for the treatment of chronic pain, that opioids could improve patient's functioning and quality of life and that opioids were more efficacious and less dangerous than over-the-counter alternatives.

Stenehjem is distinguishable.[12] In that case, the court treated the motion to dismiss as a motion for summary judgment and considered several exhibits, including drug labels and FDA letters.[13] *Stenehjem*, No. 08-2018-CV-01300, at 3-4. The court found that although the plaintiff claimed it was not alleging inadequate labeling, it was in fact arguing that the manufacturer "could have, and should have, strengthened its labeling and warnings to include additional risk information without prior FDA approval." *Id.* at 10. The court further found that there was clear evidence the FDA would not have approved the labeling changes plaintiff claimed were required to make them not misleading. *Id.* at 14.

Here, the complaints allege Manufacturers deceptively marketed their products through branded and unbranded marketing, front groups, CME seminars, and KOLs. Plaintiffs claim that the off-label advertising often contradicted the FDA-approved material. Unlike *Stenehjem*, the complaints here do not propose that any changes should be made to the FDA-approved labels.

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12. The court in *Commonwealth*, 2019 WL 5495866, *3, criticized *Stenehjem*, stating it was "an outlier" and of "questionable value." In *In re National Opiate Litig.*, 2019 WL 4178591, at *5, the court stated that *Stenehjem* was "by leaps and bounds, an outlier on the question of preemption."

13. In support of their preemption argument, Manufacturers provide links to products labels for Opana ER, Duragesic, Nucynta ER, Kadian and other opioid medicines. They claim that the Court can consider these materials in its ruling on a motion to dismiss because the complaints referred to "opioid medication labeling" and the documents are publicly available. Plaintiffs respond that the Court cannot consider the labels in ruling on the motions without converting them to motions for summary judgment. As discussed more fully below, the labels are matters outside of the complaints and the Court will not consider them in deciding these motions.

Nor are plaintiffs claiming the labeling was inappropriate or misleading. Rather, they allege Manufacturers engaged in a deceptive marketing scheme to downplay the risks of opioid products. At this stage, Manufacturers have not shown by clear evidence that plaintiffs' claims would impose state law duties that would render it impossible for them to comply with federal law. As such, plaintiffs' claims are not preempted.

b. Actavis Generic Entities' Motion

The Actavis Genetic Entities make a slightly different preemption argument. They argue that as manufacturers of generic medications, they compete solely on price and avoid marketing their products to physicians. *See New York v. Actavis, PLC*, No. 14 CIV. 7473, 2014 WL 7015198, at *27 (S.D.N.Y. Dec. 11, 2014), aff'd sub nom. *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015).

The FDA requires all generic medications to be the same as their brand name counterparts. Generic medications must have the same active ingredients and therapeutic effects, the same route of administration and the same FDA-approved labeling as the brand-name drugs. *See* 21 U.S.C. § 355(j)(2)(A). This duty of "sameness" applies to any promotional and advertising materials as well. 21 U.S.C. § 321(m). In short, federal law requires that "generic drug labels be the same at all times as the corresponding brand-name drug labels." *Mensing*, 564 U.S. at 618 (state law claims seeking to require generic drug manufacturers to change FDA-approved labeling are preempted).

The Actavis Generic Entities argue that this duty of "sameness" preempts any state law claim alleging that they had a duty to provide additional or different warnings beyond the FDA-approved brand labeling. They argue that it would be impossible for them to comply with the supposed duty without violating the federal duty of sameness. They also deny marketing and promoting opioids, contrary to the allegation in the complaints.

Plaintiffs argue that defendants mischaracterize the complaints and insist that they are not alleging the Actavis Generic Entities failed to warn about opioid risks or that the labels should have included warnings other than those required by the FDA. Rather, plaintiffs' allegations against the generic entities are similar to the brand-name manufacturers. Like the brand-name manufacturers, the complaints allege that the Actavis Generic Entities marketed and promoted their opioid medications in a deceptive and misleading way that was inconsistent with the approved uses and contradicted the approved labels. The Actavis Generic Entities allegedly downplayed the risks of addiction and abuse and exaggerated the benefits through various marketing practices, such as front groups and KOLs. Other courts have held that similar allegations of off-label promotional activities against generic drug manufacturers are not

preempted by the doctrine of sameness. *See, e.g., Arters,* 921 F. Supp. 2d at 819-820 (plaintiffs' claims against generic drug manufacturer were "based on the idea that defendants promoted the drug in a fraudulent or unreasonably dangerous way" and the claims based on off-label promotion were not preempted); *In re National Prescription Opiate Litig*., 2018 WL 4895856, at *24-25 (N.D. Ohio Oct. 5, 2018).

As discussed below, these allegations are sufficient under Rule 8. Although Actavis Generic Entities deny that they were engaged in any of the alleged marketing and promotional activities, the Court must accept these allegation as true.[14]

6. Opioid Product Labels

Janssen and Cephalon argue that all claims must be dismissed because they did not make any misleading statements about their opioid medications. They assert that the FDA-approved product labels and other materials adequately disclosed the known risks of prescription opioid medications.

In support of its motion, Janssen submitted a large stack of materials, including current and previous versions of drug labels for Duragesic, Nucynta ER, and Nucynta IR and summaries of the labels created by counsel. Janssen attached various pamphlets, book excerpts, website materials and guidelines cited in the complaints. It also attached a copy of a document entitled "Extended-Release (ER) and Long-Acting (LA) Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS)."

Cephalon argues that the complaints fail to state a claim against it. Cephalon argues that the opioids it manufactured and sold, Actiq and Fentora, are different than the medications sold by other manufacturers because they were FDA-approved for the management of breakthrough cancer pain for opioid-tolerant individuals. Cephalon claims its sales represented only a small fraction of the opioid market. Further, it asserts that the risks of addiction were adequately disclosed in the approved labels. It further claims that its medications were subject to a Special REMS program applicable to transmucosal immediate release fentanyl ("TIRF") prescription medications. The TIRF REMS Program imposes rigorous requirements on prescribers of Actiq and Fentora to ensure they are only prescribed when medically appropriate. The TIRF REMS includes detailed educational materials and prescribing information and requires a knowledge assessment before being prescribed. Further, both patients and physicians must sign an

14. Plaintiffs have dismissed the failure to warn claims. Thus, the Court will not consider whether the failure to warn allegations are preempted. *See Strayhorn v. Wyeth Pharms., Inc*., 737 F.3d 378 (6th Cir. 2013).

agreement stating they understand the risks and approved uses. To support its motion, Cephalon referred to various materials outside of the complaints and attached copies of its product labels and documents related to the TIRF-REMS program.

Defendants ask the Court to take judicial notice of these product labels and other materials and consider them in ruling on the motions to dismiss. The Court only will consider the allegations in the complaint and will not consider the labels and other documents submitted by defendants.

Generally, when adjudicating a Rule 12(b)(6) motion to dismiss, the court can only consider the allegations in the complaint itself. *Coleman*, 230 Ariz. at 363, ¶ 46. If matters outside the complaint are considered, the motion must be treated as one for summary judgment. Ariz. R. Civ. P. 12(d). A complaint's exhibits, or public records regarding matters referenced in a complaint, are not "outside the pleading," and courts may consider such documents without converting a Rule 12(b)(6) motion into a summary judgment motion. *See ELM Retirement Center*, 226 Ariz. at 289, ¶¶ 6-8 (trial court's consideration of purchase contract attached to motion to dismiss did not convert it to a motion for summary judgment); *Strategic Dev. & Constr., Inc. v. 7th & Roosevelt Partners, LLC*, 224 Ariz. 60, 64, ¶ 13 (App. 2010) (court did not err in considering a notice of lien which was a matter of public record in the Maricopa County Recorder's office). The trial court has discretion to disregard matters submitted outside of complaint and consider the sufficiency of complaint based on the complaint allegations alone. *See Cullen v. Koty–Leavitt Ins. Agency, Inc.*, 216 Ariz. 509, 514, ¶ 10 (App. 2007), reversed and vacated in part on other grounds by *Cullen v. Auto–Owners Ins. Co.*, 218 Ariz. 417 (2008).

In its discretion, the Court will not consider the vast amount of material filed with the motions. The materials submitted are far beyond matters central to the complaint and cannot be considered without converting the motions into motions for summary judgment. The rule that allows the Court to consider attachments to the complaint and public records is reserved for documents that are central to a dispute, such as a contract. Here, there are not one or two documents that could resolve this case. Instead, defendants attached over a thousand pages of materials claiming that these materials prove they did nothing wrong.

Defendants claim that at least some of the materials, such as the product labels, are public records that the Court should consider. As plaintiffs point out, the fact that the documents are publically available on the internet does not make them public records. "Public records" are defined under Arizona law. *See Griffis v. Pinal Cty.*, 215 Ariz. 1, 4, ¶ 9 (2007). The Court does not need to decide now if these materials are public records because the Court declines to consider large volumes of contested documents when ruling on fifteen motions to dismiss. Even if the Court reviewed the labels and other documents, the Court could not determine whether

there was some inconsistency in defendants' messaging. That may be an issue for a motion for summary judgment or it may be a question for the trier of fact, but it cannot be resolved on a motion to dismiss.

B. Analysis of Plaintiffs' Specific Claims

Having addressed defendants' arguments concerning plaintiffs' authority to sue, remoteness, causation, municipal cost recovery, preemption and labeling, the Court now turns to the defendants' claim-specific arguments.

1. Count 1: Public Nuisance

The complaints allege a public nuisance claim under A.R.S. § 13-2917 against every defendant for having "created or assisted in the creation of a condition that is injurious to health and interferes with the comfortable enjoyment of life and property in entire communities or neighborhoods or of any considerable number of persons" in plaintiffs' jurisdictions. Defendants allegedly violated the public nuisance statute through the false and misleading promotion and distribution of opioids. Plaintiffs allege that defendants' conduct has caused and continues to cause a public health epidemic in their communities. Plaintiffs seek "to abate, enjoin, and prevent" the public nuisance created by defendants.

A.R.S. § 13-2917(A)(1) defines a public nuisance as "anything . . . injurious to health, indecent, offensive to the senses or an obstruction to the free use of property that interferes with the comfortable enjoyment of life or property by an entire community or neighborhood or by a considerable number of persons."

"[P]ublic nuisances are characteristically broad in scope and 'encompass[ ] any unreasonable interference with a right common to the general public.'" *Hopi Tribe,* 245 Ariz. at 400, ¶ 9 (*quoting Armory Park Neighborhood Ass'n v. Episcopal Community Services in Arizona*, 148 Ariz. 1, 4 (1985); *see also* Restatement (Second) of Torts § 821B(1). Arizona has adopted the Restatement (Second) of Torts § 821B, which recognizes that an "unreasonable interference with a public right includes circumstances in which 'the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience.'" *Mutschler v. City of Phoenix*, 212 Ariz. 160, 166, ¶ 20 (App. 2006) (*quoting* Restatement § 821B(2)(a)). A public nuisance "must affect a considerable number of persons or an entire community or neighborhood." *City of Phoenix v. Johnson*, 51 Ariz. 115, 123 (1938).

Defendants assert that the complaints fail to state a claim because Arizona nuisance law concerns the misuse or interference with real property and does not extend public nuisance to the sale and distribution of legal products such a prescription medications. Defendants have not cited an Arizona case rejecting a public nuisance claim on the basis that it alleged something other than harm to real property or involved the misuse of a legal product.

The Arizona Supreme Court has stated that public nuisance in Arizona is "broad in scope." *Armory Park*, 148 Ariz. at 4. The public nuisance statute is also broad. A.R.S. § 2917(A) defines a public nuisance as "anything . . . injurious to health." "Anything" could include the misuse of legal products. Moreover, in *Armory Park*, the court expressly rejected the argument that conduct must be illegal to be a nuisance, holding that "conduct which unreasonably and significantly interferes with the public health, safety, peace, comfort or convenience is a public nuisance within the concept of tort law, even if that conduct is not specifically prohibited by the criminal law." *Armory Park*, 148 Ariz. at 10.

Nor is the statute limited to nuisances directly affecting land. By its express terms, the statute applies to problems "injurious to health." Moreover, as noted in the comments to Restatement § 821B, "a public nuisance does not necessarily involve interference with use and enjoyment of land." Restatement (Second) of Torts § 821B, cmt. h.

Defendants argue they lack control over the instrumentality. However, the complaints allege that defendants controlled the continuous distribution of the opioids. Taking the allegations in the complaints to be true, the defendants were in a position to anticipate or prevent the claimed injuries.

Defendants urge this Court to adopt the approach in the Restatement (Third) of Torts, which appears to reject the expansion of public nuisance to the misuse of products. *See* Restatement (Third) of Torts: Liability for Economic Harm § 8, cmt. g. The Court rejects defendants' argument for a couple of reasons. First, Restatement Third § 8 applies to common-law claims brought by private plaintiffs, not civil actions brought by public officials. *See* Restatement Third § 8, cmt. a (public officials' ability to bring claims "is widely a matter of statute, and tends to be considerably broader than the common-law definition recognized by this Section as a basis for a private suit"). Second, even if Restatement Third § 8 took a more restrictive view of public nuisance claims than Restatement Second § 821B, Restatement Second § 821B has been adopted by Arizona's appellate courts, *see Mutschler v. City of Phoenix*, 212 Ariz. at 166, ¶ 20, and this trial court is in no position to disregard it.

Defendants claim that the plaintiffs have failed to plead substantial interference with a public right. The Court disagrees. The complaints allege that defendants' conduct was injurious

to the public health, affected a "considerable number of persons," and that plaintiffs incurred costs of abating the public health problem.

The Court will not strike the damage claim at the motion to dismiss stage. A.R.S. § 13-2917(C) allows counties and cities to bring actions to "abate, enjoin and prevent" a public nuisance. The word "abate" means to "decrease in force or intensity." Merriam-Webster Dictionary. The statute allows a plaintiff to recover the costs of abatement. *See Hughes v. City of Phoenix*, 64 Ariz. 331, 336 (1946) (city allowed to recover the costs to remove motor vehicles under a nuisance statute). If the Legislature's intent was to limit a public entity's nuisance claim to an injunction, there is no reason to include the word "abate" in the statute. In addition, the Arizona Supreme Court has recognized the right of a person "to recover damages for or enjoin the maintenance of a public nuisance." *Armory Park*, 148 Ariz. at 5.

The reasoning of courts dismissing public nuisance claims in other states is not persuasive because other states appear to have narrower definitions of public nuisance. For example, *In State ex rel. Jennings v. Purdue Pharma L.P.*, No. N18C-01-223 MMJ CCLD, 2019 WL 446382, *11-12 (Super. Ct. Del. Feb. 4, 2019), involved Delaware law which defined public nuisance as an "activity which produces some tangible injury to neighboring property or persons." Arizona's statute is much broader and includes "anything" that is "injurious to health."

The complaints allege that defendants created a condition that is injurious to health and interferes with the comfortable enjoyment of life in plaintiffs' communities at large. These allegations are sufficient to state a claim. The motions to dismiss the public nuisance claim are denied.

2. Count 2: Negligence

Count 2 in each complaint is a claim for negligence. The complaints allege that each of the defendants owed a duty to plaintiffs to take reasonable steps to prevent the misuse, abuse and over-prescription of opioids. Manufacturers violated their duty by making misleading claims about the risks and benefits of opioids. Distributors failed in their duty to prevent the diversion of large opioid orders. Pharmacy Distributors and Dispensers failed in their duty to keep accurate records and stem the overflow of opioids in the communities.

To plead negligence in Arizona, a plaintiff must allege: (1) a duty of care; (2) a breach of that duty; (3) a causal connection; and (4) damages. *Ontiveros*, 136 Ariz. at 504. All of the defendants have moved for dismissal of the negligence claim arguing that they owed no duty to plaintiffs. Whether a duty exists is a legal question for the court. *Gipson v. Kasey*, 214 Ariz. 141,

143, ¶ 9 (2007). Whether a defendant owes a duty of care is a threshold issue. If there is no duty, the negligence claim must be dismissed. *Id.* at 143, ¶ 11.

In Arizona, a duty must be based on either recognized common law special relationships or relationships created by public policy. *Quiroz v. ALCOA Inc*., 243 Ariz. 560, 565, ¶ 14 (2018). The special relationships that could give rise to a duty include those based on "contract, family relations, or conduct undertaken by the defendant." *Gipson*, 214 Ariz. at 145, ¶ 18. The primary source for identifying a duty based on public policy is state statutes. *Quiroz*, 243 Ariz. at 566, ¶ 18. Arizona courts are hesitant to recognize a public policy duty in the absence of a statute. *Id*. at ¶ 19.

Plaintiffs have not alleged a duty based on a recognized common law special relationship. Rather, they allege two sources of duty: (1) a common law duty "to plaintiffs to take reasonable steps to prevent the misuse, abuse and over-prescription of opioids"; and (2) a public policy duty based on the AZCSA and the Pharmacy Board dispensing statutes.[15]

Plaintiffs rely on *Ontiveros* to support their argument for a common law duty to prevent misuse and abuse of opioids. *Ontiveros* does not support such a duty. In *Ontiveros*, the Arizona Supreme Court found that tavern owners owed a duty of care and could be liable for the harm caused by their intoxicated patrons. The supreme court found a duty based on the combination of common law and liquor licensing statutes. *Ontiveros*, 136 Ariz. at 511. *Ontiveros* is limited to the duties of tavern owners. It does not create a generalized duty to prevent harm to others.

Later in *Gipson*, the supreme court expressly eliminated foreseeability as a factor in determining duty. *Gipson*, 214 Ariz. 141, 144, ¶ 17. In *Quiroz*, the supreme court clarified that a duty must be based on a special relationship or public policy. *Quiroz*, 243 Ariz. at 565, ¶ 14. The supreme court rejected a "duty of care owed by all people at all times." *Id.* at 576, ¶ 75. As the supreme court stated in *Quiroz*: "*Ontiveros* did not recognize the existence of a presumed duty based on risk creation," but found a duty based on "special relationships and public policy." *Id.* at 574, ¶ 65. Thus, based on these precedents, plaintiffs have not established that Arizona law

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15. In their responses and at oral argument, plaintiffs argued for a public policy duty based on the Arizona Consumer Fraud Act (AZCFA), claiming they were direct buyers of opioid medications. However, the complaints do not allege plaintiffs were direct purchasers of opioids. The complaints also do not assert that the AZCFA is the basis for a duty for the negligence and negligence *per se* claims. In any event, unless plaintiffs purchased opioids from a defendant, it is unlikely plaintiffs will be able to establish they are within the "class of persons", *i.e*., consumers, that the AZCFA was designed to protect. *See Estate of Hernandez v. Ariz. Bd. of Regents*, 177 Ariz. 244, 253 (1994). And plaintiffs dismissed their claims under the AZCFA.

recognizes a common law duty to prevent the misuse and abuse of prescription opioid medications.

Plaintiffs argue that a public policy duty arises under the AZCSA or the Pharmacy Board statutes regulating the dispensing of prescription medicines. A statute may create a public policy duty but only when the plaintiff "is within the class of persons to be protected by the statute and the harm that occurred ... is the risk that the statute sought to protect against." *Quiroz*, 243 Ariz. at 565, ¶ 15 (*quoting Gipson*, 214 Ariz. at 146, ¶ 26); *Estate of Hernandez*, 177 Ariz. at 253.

In the complaints, plaintiffs alleged violations of various provisions of the Pharmacy Board dispensing and record-keeping statutes. For example, A.R.S. § 32-1964(A) requires pharmacists to maintain records of every prescription order of drugs dispensed. A.R.S. § 32-1983 regulates the wholesale distribution of prescription medications. Although plaintiffs referred to these statutes in the complaints, plaintiffs made no argument that they are within the class of persons the statutes are intended to protect. These statutes were enacted to regulate the dispensing of prescription drugs in Arizona. Nothing in these statutes suggests they were intended to protect local governments against the effects of opioid addiction and abuse.

Plaintiffs argue that the AZCSA enumerates the responsibilities of manufacturers, distributors and dispensers of controlled substances. For example, the AZCSA makes it a crime to make false records (A.R.S. § 362531(A)(3)), to sell a controlled substance for other than a legitimate medical purpose (A.R.S. § 36-2531(A)(6)) and to acquire a controlled substance by means of forgery, fraud or deception (A.R.S. § 36-2531(E)).

Plaintiffs argue that these provisions and others in the AZCSA establish a public policy duty. They claim that they are within the class of persons the statute is intended to protect and that the injuries they have suffered are the type of harm the statute was enacted to prevent.

Plaintiffs rely on *Gipson.* In *Gipson*, the defendant gave an acquaintance his prescription pain medications for recreational purposes. When the acquaintance died from a drug overdose, decedent's family filed a wrongful death action. *Gipson*, 214 Ariz. at 142-43, ¶¶ 3-7. The supreme court found that the AZCSA and other statutes prohibiting the distribution of prescription drugs to persons lacking a valid prescription were designed "to avoid injury or death to people who have not been prescribed prescription drugs, who may have no medical need for them and may in fact be endangered by them, and who have not been properly instructed on their usage, potency, and possible dangers." *Id.* at 146, ¶ 26. Thus, the supreme court held that these drug laws created a legal duty of care between a person to whom opioids had been prescribed and a third person who was injured as a result of taking the unauthorized medications. *Id*. at 147, ¶ 32.

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Gipson does not support plaintiffs' positon. The *Gipson* court found the AZCSA's restrictions on controlled substances were designed to protect people who had not been prescribed medications because those people may be endangered by the drugs and may not have been properly instructed on their usage, potency, and possible dangers. *Id*. *Gipson* does not support expanding the class of persons protected by the AZCSA to local governments providing public services to mitigate the drug epidemic.

The prefatory notes to the Uniform Controlled Substances Act do not help plaintiffs' position. The prefatory notes state the uniform act from which the AZCSA was derived was designed to provide tools for state and local governments "to control more effectively the drug abuse problem." However, the notes do not suggest the controlled substances statutes are intended to give local governments a claim for damages to recover the costs of providing health and crime-related services in their communities.

In short, plaintiffs have not established that defendants owed a public policy duty based on the AZCSA because plaintiffs are not within the class of persons the statutes were enacted to protect and their damages are not the type of harm the statutes were designed to protect against. Courts in other opioid-related cases have reached the same conclusion. For example, in *In re: National Prescription Opiate Litig.*, 2019 WL 3737023 (N.D. Ohio June 13, 2019), the court dismissed the negligence *per se* claim based on violations of the federal version of the CSA and Oklahoma's CSA. Like plaintiffs here, several Native American nations sued to recover the costs of public services. The court found that the CSA was "not intended to protect sovereigns like the Tribes from spending more on addiction-related public services when rates of addiction increase." *Id*. at *13; *see also In re National Opiate Litig.*, 452 F.Supp.3d 745, 788 (N.D. Ohio 2020) (negligence claim allowed to continue under the "foreseeability" standard under Florida law, but dismissed negligence *per se* claims on the ground that a hospital is not an intended beneficiary of the CSA).

Plaintiffs have not cited an opioid–related case that found a duty under a controlled substances statute. The opioid cases that have allowed negligence claims to proceed have found a duty under a foreseeability standard, a standard that Arizona law rejects. *See, e.g*., *In re National Prescription Opiate Litig*., 2018 WL 4895856, *36 (N.D. Ohio Oct. 5, 2018) ("The existence of a duty depends on the foreseeability of the injury."); *City of Everett*, 2017 WL 4236062, *4 (duty existed centered on the extent to which the corporate manufacturer defendant "engaged in an affirmative act which created or exposed [the plaintiff city] to a high degree of risk of harm.").

The motions to dismiss the negligence counts based on a lack of duty are granted.

3. Count 3: Negligence *Per Se*

Count 3 in each complaint is a claim for negligence *per se*. The negligence *per se* claims are based on violations of the AZCSA and the Arizona Pharmacy Board statute. According to the complaints, the AZCSA is designed to protect the public from harm. The AZCSA has record-keeping requirements for opioids and prohibits the sale or distribution of opioids except for legitimate medical purposes. The statute further makes it unlawful to give false or misleading information in any required report or document. It makes it unlawful to obtain opioids through forgery, fraud or deception. The Pharmacy Board statutes set out requirements for dispensing medications, including maintaining records of prescription drugs they dispensed. The complaints allege that defendants violated the AZCSA and the Pharmacy Board statutes.

"A person who violates a statute enacted for the protection and safety of the public is guilty of negligence *per se*." *Alaface v. National Inv. Co.*, 181 Ariz. 586, 596 (App. 1994); *Good v. City of Glendale*, 150 Ariz. 218, 221 (App. 1986). There is no dispute here that the AZCSA and the Pharmacy Board statutes were enacted for the protection and safety of the public. However, violation of a statute is not enough to state a negligence *per se* claim. Like a duty based on public policy, to bring a negligence *per se* claim, a plaintiff must establish that it is "within the class of persons the statute is intended to protect." *Steinberger,* 234 Ariz. at 139, ¶ 57.

As discussed above, plaintiffs have not established a public policy duty because they are not within the class of persons the AZCSA and Pharmacy Board statutes were designed to protect. Plaintiffs' negligence *per se* claims fail for the same reasons their negligence claims are deficient.

4. Count 4: Unjust Enrichment

Under Arizona law, "[u]njust enrichment occurs when one party has and retains money or benefits that in justice and equity belong to another." *Trustmark Ins. Co. v Bank One, Arizona, NA*, 202 Ariz. 535, 541, ¶ 31 (App. 2002). A claim for unjust enrichment has five elements: "(1) an enrichment, (2) an impoverishment, (3) a connection between the enrichment and the impoverishment, (4) the absence of justification for the enrichment, and (5) the absence of a remedy provided by law." *Wang Elec., Inc. v. Smoke Tree Resort, LLC*, 230 Ariz. 314, 318, ¶ 10 (App. 2012). The essence of unjust enrichment is the conferral of a benefit on the defendant. *Freeman v. Sorchych*, 226 Ariz. 242, 251, ¶ 27 (App. 2011) (*citing Murdock–Bryant Constr., Inc. v. Pearson,* 146 Ariz. 48, 53 (1985)). Further, the plaintiff must show "that it was not intended or expected that the services be rendered or the benefit conferred gratuitously, and that the benefit was not 'conferred officiously.'" *Id*. at 251-52, ¶ 27. The "benefit may be any type of

advantage, including that which saves the recipient from any loss or expense." *Pyeatte v. Pyeatte*, 135 Ariz. 346, 352 (App. 1982). But, under Arizona law, there must be a nexus between the alleged impoverishment and the enrichment conferred. *See Laborers' and Operating Engineers' Utility*, 42 F. Supp. 2d at 951.

The unjust enrichment claims fail because plaintiffs have not alleged they were impoverished because of a benefit they conferred on defendants. The complaints allege that "[e]ach Defendant therefore received a benefit from the sale, distribution, or prescription of prescription opioids to and in [plaintiffs' communities], and these Defendants have been unjustly enriched at the expense" of plaintiffs. But this alleged benefit, the profits from sale and distribution of prescription opioids, is not a benefit conferred by plaintiffs on defendants. The purchasers of opioid medications conferred the benefit, not plaintiffs.

Plaintiffs argue they conferred a benefit by paying healthcare-related costs, foster care placement costs, and crime-related costs, etc. Plaintiffs also lost tax revenue. Plaintiffs fail to explain how the loss of tax revenue conferred a benefit on defendants. Further, plaintiffs have not alleged any nexus between the impoverishment, the payment for public services, and any enrichment conferred on defendants. In other words, public services benefit the residents of plaintiffs' communities. The services did not confer a benefit on defendants.

An unjust enrichment claim under Arizona law requires a connection between the enrichment and the impoverishment. *Id.* (applying Arizona law, "Laborers' Trust paid health care benefits to its participants and their beneficiaries. Laborers' Trust does not allege it conferred any benefit on Philip Morris. No benefit was conferred on Philip Morris."). Here, plaintiffs had increased costs for health care, crime and other programs to deal with the myriad of problems associated with addiction and abuse. However, plaintiffs cannot show that these costs conferred a benefit on defendants. Defendants benefited from the deceptive sale of opioids through sales and profits, but that benefit was not conferred by plaintiffs and is not connected to plaintiffs' costs. Plaintiffs have not alleged that they provided these services with the expectation of being repaid by defendants. *See Freeman*, 226 Ariz. at 251, ¶ 27.

Plaintiffs rely on a decision in the Ohio opioid MDL in which the court held that the plaintiff city conferred a benefit by paying for "defendants' externalities", meaning the costs of the harm caused by defendants' misconduct. *See, e.g., In re National Prescription Opiate Litig.*, 2018 WL 4895856, *46 (N.D. Ohio Oct. 5, 2018) ("Based on the alleged facts in this case, Plaintiffs state a facially plausible unjust enrichment claim on the theory that they conferred a benefit upon all Defendants by alleging that they paid for the cost of harm caused by the defendant's conduct, *i.e.*, the defendant's externalities."). Judge Polster agreed with this theory under Ohio law, stating that defendants' "conduct allowed the diversion of opioids and thereby

created a black market for their drugs", which "allowed Defendants to continue to ship large volumes of opioids into Plaintiff's communities at great profit to Defendants and great expense to Plaintiffs." *In re National Prescription Opiate Litig*., 2018 WL 6628898, at *21 (N.D. Ohio Dec. 19, 2018).

Here, however, plaintiffs have not cited an Arizona appellate decision that has accepted plaintiffs' externalities theory. Indeed, the theory runs counter to the requirement in Arizona law that there must be a connection between the impoverishment and the enrichment. *See Wang Elec*., 230 Ariz. at 318, ¶ 10. The externalities theory would change the elements and the very concept of unjust enrichment. Instead of requiring a connection between the enrichment and impoverishment, a plaintiff could state an unjust enrichment claim by simply alleging it was harmed by defendant's wrongdoing. Such a theory if adopted would create duties where none otherwise existed and would result in claims without boundaries. The unjust enrichment claims are dismissed.

C. Sufficiency of Allegations in the Complaints

1. Harper's Motion for More Definite Statement (Apache County case)

Western Drug owns and operates two retail pharmacies in Apache County. Fred Harper owns Western Drug. The Apache County Complaint identified Harper as "Prescriber Defendants" and accused Harper of engaging in the same conduct alleged against the "Prescribers." There are no allegations in the complaint specific to pharmacy defendants.

Harper argues that a more definite statement is required because the allegations are confusing. As pharmacists, Harper could not have done the things the prescribers are accused of doing. For example, Harper could not have passed out "savings cards" to encourage patients to try opioids or increased patient dosages. Indeed, it appears that the only allegations specific to Harper concern Harper's failure to adequately supervise one of its former pharmacists who was arrested for DUI and drug possession and disciplined by the Arizona State Board of Pharmacy more than four years ago for forging prescriptions and possessing illegal narcotics.

At oral argument, Apache County acknowledged the complaint misidentified Harper and that the allegations were confusing and deficient. Plaintiff even admitted that some of the allegations against Harper did not make sense. Plaintiff requested leave to amend the complaint to clarify the allegations and include some additional allegations concerning Harper's role in dispensing and compounding opioid medications. Plaintiff stated it also intended to add factual allegations about unlawful conduct of other pharmacists employed by Harper. Harper did not object to plaintiff's request to file an amended complaint.

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The decision to grant or deny a motion to amend a complaint is within the Court's discretion. *Tumacacori Mission Land Development, Ltd. v. Union Pacific R.R. Co*., 231 Ariz. 517, 519, ¶ 4 (App. 2013). Generally, amendments are liberally allowed to cure any defects in the initial pleading, absent a finding of undue delay, bad faith, undue prejudice, or futility of the amendment. *See Wigglesworth v. Maudlin*, 195 Ariz. 432, 439, ¶ 26 (App. 1999); Ariz. R. Civ. P. 15(a)(2) ("Leave to amend must be freely given when justice requires.").

The allegations against Harper are confusing, deficient and do not comply with Rule 8(a). The motion for more definite statement is granted, and the complaint is dismissed without prejudice. Plaintiff's oral motion for leave to amend is granted. Plaintiff has ten days to file an amended complaint.

Further, for the reasons discussed above, the negligence claim (Count 2), the negligence *per se* claim (Count 3) and the unjust enrichment claim (Count 4) against Harper are dismissed with prejudice.

2. Allegations against Actavis Generic Entities

The Actavis Generic Entities manufacture certain generic opioid medications. They allege that generic manufacturers compete on price and do not engage in any marketing or advertising. Thus, they claim they could not have participated in any of the alleged deception in the marketing campaigns that the branded manufacturers are alleged to have participated in. They claim there are no allegations they promoted generic medicines and no allegations linking their medications to a false or misleading statement.

The complaints allege: Manufacturers, which include the three Actavis Generic Entities, engaged in a deceptive marketing and distribution scheme to convince doctors and patients that long-term opioid use is both safe and beneficial for the treatment of chronic pain. Manufacturers downplayed the known risks of addiction and abuse and exaggerated the benefits. Manufacturers used various marketing tactics and funded front groups and KOLs to legitimize their false claims about opioids. These deceptive practices were perpetrated against doctors and patients in plaintiffs' communities. The three Actavis Generic Entities are included within the label "Actavis," along with four other manufacturing entitles. The group of "Actavis" entities distributed misleading information about Kadian.

Because the fraud claim has been dismissed, there is no requirement that the claims be pled with particularity, *see Steinberger*, 234 Ariz. at 136-40, ¶¶ 44-62, and including the Actavis Generic Entities within groups of other defendants is not fatal to the public nuisance claim. *See*

United Healthcare, 848 F.3d at 1184. Furthermore, when deciding this motion, the complaints' allegations must be accepted as true. The allegations in the complaints are sufficient to survive a motion to dismiss.

3. Allegations against Janssen/J&J

a. Allegations of wrongdoing against Janssen

Janssen argues that the complaints do not allege any wrongdoing against it and fail to state a claim based on unbranded promotional and educational activities. Janssen claims that it is not responsible for any statements made in the unbranded promotional materials referred to in the complaints. It further argues that those unbranded advertising materials are not false or misleading.

The complaints contain fairly detailed allegations about Janssen's involvement in the alleged scheme to relax the standards for prescribing opioids. The complaints allege that Janssen did several things to foster the scheme, such as funding bogus studies to promote the use of opioids for chronic pain. Janssen also funded and approved guides and websites that downplayed the risks of addiction and overstated the benefits of opioid use for chronic pain. The complaints also allege that Janssen funded front groups and KOLs.

The complaints allege that Janssen is responsible for the unbranded promotional materials and that the materials contain deceptive statements. These allegations must be accepted as true, and the Court cannot consider Janssen's denial of its involvement. *See Cullen*, 218 Ariz. at 419, ¶ 7. The Court finds that the allegations against Janssen are sufficient under Rule 8.

b. Allegations against J&J

The complaints allege direct wrongdoing against J&J. "Janssen" is used in the complaint to include both Janssen and J&J. Thus, the factual allegations against "Janssen" are also allegations against J&J.

The complaints also include allegations specific to J&J. For example, paragraph 34 of the Glendale complaint states "J&J made payments to front groups . . . who perpetrated and disseminated Defendants' misleading marketing messages regarding the risks and benefits of opioids." (*See also* Glendale Complaint at ¶ 98.) The complaints include more specific allegations against J&J. For example, paragraph 101h of the Glendale complaint alleges that J&J and others minimized the risks of opioid addiction and abuse to doctors in Arizona and specifically in Glendale. The complaints allege J&J was responsible for funding the bogus

research to support the use of opioids for chronic pain patients. (*Id.* at ¶ 108.) Taken as true, these allegations are sufficient to state a claim for direct liability against J&J.

4. Dispensing-related Allegations against the Pharmacy Distributors (Prescott case)

a. Sufficiency of Dispensing-related allegations

The Prescott complaint categorizes defendants Walmart, Walgreens and Smith's as "Pharmacy Distributors." The complaint alleges that the Pharmacy Distributors were within the chain of distribution of opioids and that, like the Distributors, they earned substantial profits flooding the market with opioid medications. The complaint further alleges that the Pharmacy Distributors had "a duty to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescriptions opioids." It further alleges that the Pharmacy Distributors participated in the diversion of opioids by regularly filling suspicious prescriptions and failing to report suspicious orders.

The Pharmacy Distributors argue that these allegations conflate the distinction between distribution and dispensing related conduct. The Pharmacy Distributors claim that they only delivered opioids to the pharmacies within their own chain stores. They did not fill prescriptions or dispense opioids to patients. Thus, they assert the dispensing allegations are deficient and do not state a claim based on dispensing-related conduct.

The Court finds the complaint states a claim based on dispensing-related activities. Although defendants deny they engaged in any dispensing activities, the complaints allege otherwise, and those allegations must be taken as true for purposes of this motion. *See Cullen*, 218 Ariz. at 419, ¶ 7.

b. Are the dispensing-related allegations barred?

The Pharmacy Distributors further argue that the Arizona Board of Pharmacy alone is charged with ensuring compliance with the AZCSA. Thus, they argue, plaintiffs have no common law claim based on dispensing activities and cannot bring a claim for enforcement under the AZCSA.

As discussed above, Prescott does not have a negligence *per se* claim based on a violation of the AZCSA. That does not mean, however, that there is no public nuisance claim based on the alleged dispensing conduct. Thus, the motion to dismiss is denied on this ground.

Next, the Pharmacy Distributors argue that Prescott failed to comply with the preliminary certification requirements for medical malpractice claims in A.R.S. § 12-2603(A). Prescott claims that although it does not believe the certification requirements apply to its claims, it filed an A.R.S. § 12-2603 certification with its complaint on April 23, 2019, and an amended certification on February 18, 2020.

Defendants do not deny that the certifications were timely filed. Rather, they raise two new issues in the reply: (1) the complaints do not plead the elements of a medical malpractice claim as required under A.R.S. § 12-563; and (2) plaintiff failed to serve the certifications with the complaint. The Court will not consider arguments raised for the first time in the reply. *Westin Tucson Hotel Co. v. State Dep't of Revenue*, 188 Ariz. 360, 364 (App. 1997) ("a claim raised for the first time in a reply is waived"). Nevertheless, as a practical matter the negligence count has been dismissed.

5. Allegations against Pharmacy Distributors and Dispensers (Pinal County case)

a. Medical malpractice

The Pharmacy Distributors and Dispensers in the Pinal County case argue that the complaint fails to plead the elements of negligent medical malpractice under A.R.S. § 12-563. They assert there are no allegations in the complaint that defendants failed to exercise the requisite standard of care in filling facially valid prescriptions for opioid medications.

Plaintiff responds that A.R.S. § 12-563 does not apply because it is not asserting a claim for medical malpractice. The negligence claims are dismissed. Thus, it is not necessary for the Court to decide whether the claims must be pled under A.R.S. § 12-563.

b. Sufficiency of allegations

The Pharmacy Distributors and Dispensers argue that the allegations against them in the Pinal County complaint are too ambiguous and not sufficient to state a claim.

The complaint alleges the Pharmacy Distributors and Dispensers had extensive knowledge of the oversupply of opioids in plaintiff's community through the data they collected and maintained. Although they were aware of the risks, defendants took no steps to stop the flood of opioids and profited handsomely from the oversupply. Defendants understood the harm their conduct was causing and, although they made public statements indicating they were taking steps to curb abuse, the misconduct continued.

The complaint adequately alleges that Pharmacy Distributors and Dispensers failed to prevent opioid diversion and report obvious suspicious orders. These allegations are sufficient to give defendants notice of the claims against them under Rule 8. The motion to dismiss on this ground is denied.

6. Allegations against Kapoor

Kapoor was the founder and on the board of Insys, the manufacturer of the opioid medication Subsys. Although Kapoor did not personally make and sell opioids, he is categorized as a Manufacturer in the complaints. Kapoor argues that the facts against him are meager and do not support the claims asserted against him.

The complaints allege that Kapoor and Babich, another Insys executive, participated in the scheme to profit from the sale of opioids using bribes, kickbacks and deception to cause the illegal distribution of Subsys. Plaintiffs allege that bribes and kickbacks caused doctors and pain clinics to write large numbers of prescriptions for many non-cancer patients who did not need Subsys. Plaintiffs allege that Kapoor was part of scheme to mislead health insurance companies to provide coverage for Subsys when prescribed for non-cancer patients and that, by promoting the unauthorized use of Subsys, Kapoor put patients at risk and contributed to the opioid crisis.

Kapoor should be aware of the nature of the claims against him. Kapoor was found guilty of fraud, conspiracy and racketeering based on some of the same conduct alleged here. He and Insys also have been named as defendants in other opioid-related civil cases around the country. These allegations are sufficient to state a claim under Rule 8. Plaintiffs do not need to amend the complaints to add detail about Kapoor's involvement.

VII. DISPOSITION

IT IS ORDERED granting defendants Harper and Western Drug's Motion to Dismiss or Motion for More Definite Statement. The complaint against defendants Harper and Western Drug in the Apache County case, CV2020-001434, is dismissed without prejudice.

IT IS FURTHER ORDERED granting plaintiff Apache County's motion for leave to amend its complaint against Harper and Western Drug in CV2020-001434. Apache County has ten business days from the filed date of this order to file an amended complaint.

IT IS FURTHER ORDERED dismissing the negligence claims (Count 2), the negligence *per se* claims (Count 3) and the unjust enrichment claims (Count 4) against defendants in each of the seven consolidated cases.

IT IS FURTHER ORDERED denying the motions to dismiss in all other respects.

IT IS FURTHER ORDERED that the parties may file a supplemental brief concerning defendants' Motion to Stay (filed October 8, 2020) reflecting on that Motion in light of the instant ruling. The supplemental brief is due ten business days from the filed date of this ruling. The supplemental brief may not exceed five pages.

VIII. FINAL OBSERVATIONS

After this ruling, the only remaining claim is for public nuisance. Public nuisance law is not well developed in Arizona, and the motion to dismiss the nuisance count is a close call. The law of nuisance is aptly described as an "impenetrable jungle" that has been "applied indiscriminately . . . as a substitute for any analysis of a problem." *Hopi Tribe*, 245 Ariz. at 404, ¶ 24 (citation omitted). As a result, this Court would encourage the Arizona Appellate Courts to add the public nuisance claim to the list of issues to be resolved by special action.

In addition, the Court will issue a separate minute entry inviting the Arizona Attorney General to submit an amicus brief on defendants' claim that local jurisdictions do not have the authority to bring these claims.

IN THE CIRCUIT COURT OF THE SIXTH JUDICIAL CIRCUIT
IN AND FOR PASCO COUNTY, FLORIDA

STATE OF FLORIDA, OFFICE OF THE ATTORNEY GENERAL, DEPARTMENT OF LEGAL AFFAIRS,

Plaintiff,

v. Case No. 2018-CA-001438

PURDUE PHARMA L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS INC., JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, CEPHALON, INC., TEVA PHARMACEUTICALS USA, INC., ALLERGAN FINANCE, LLC, ACTAVIS PHARMA, INC., ACTAVIS LLC, INSYS THERAPEUTICS, INC., AMERISOURCEBERGEN DRUG CORPORATION, CARDINAL HEALTH, INC., MCKESSON CORPORATION, MALLINCKRODT LLC, WALGREEN CO., CVS HEALTH CORPORATION, and CVS PHARMACY, INC.,

Defendants.

ORDER DENYING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT [004]

THIS CAUSE is before the Court on Defendants Teva Pharmaceuticals USA, Inc; Cephalon, Inc.; Actavis LLC; Actavis Pharma, Inc.; Allergan Finance, LLC; Walgreen Co.; CVS Health Corporation; and CVS Pharmacy, Inc.'s (hereinafter "Defendants") Motion for Summary Judgment [004] filed January 21, 2022 (the "Motion").

In the Motion, Defendants sought summary judgment on all claims based on a failure to create a triable issue of fact on causation. Defendants moved for summary judgment on Plaintiff's negligence and gross negligence claims (Counts III, V) based on a failure to create a

triable issue of fact on duty, breach, and damages. Defendants moved for summary judgment on Plaintiff's negligence *per se* claim (Count IV), based on the lack of a predicate statute. Defendants moved for summary judgment on Plaintiff's public nuisance claims (Counts I-II, X), based on lack of evidence of invasion of a public right, and based on the argument that Plaintiff's requested abatement remedy is unavailable. Defendants moved for summary judgment on Plaintiff's claims under Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA") based on FDUTPA's safe harbor provision, the learned intermediary doctrine, lack of actual damages, unavailability of disgorgement and restitution, statute of limitations, and lack of a FDUTPA predicate in the Florida Drug and Cosmetic Act (Count VI). Defendants moved for summary judgment on Plaintiff's claims under Florida's Racketeer Influenced and Corrupt Organization Act ("RICO") (Counts XII-XIII), based on lack of evidence of predicate acts, the operation and existence of an enterprise, and a RICO conspiracy. Defendants moved for summary judgment on Plaintiff's Civil Conspiracy claims (Counts VII-XI), based on lack of evidence of agreement to do any unlawful act. Defendants moved for summary judgment based on federal preemption by the Food, Drug, and Cosmetic Act and by the Controlled Substances Act. Defendants moved for summary judgment based on the existence of a political question and based on separation of powers concerns. Finally, Defendants moved for summary judgment on all claims based on the affirmative defense of statute of limitations.

Upon consideration of the parties' briefing and arguments held on March 10, 2022, it is hereby **ORDERED AND ADJUDGED:**

Causation: The Motion is denied as to lack of causation for the reasons given by the Court on the record at the March 10, 2022 hearing, and by the Court at the March 11, 2022 hearing. The evidence is sufficient for a jury to conclude that Defendants' marketing statements

and diversion-related conduct substantially caused Plaintiff's harms. The evidence also is sufficient for a jury to find that Defendants' conduct was the proximate cause of the harms alleged, because the harms were foreseeable.

Negligence, gross negligence, and negligence *per se*: The Motion is denied as to the negligence, gross negligence, and negligence *per se* claims in Counts III-V for the reasons given by the Court on the record at the March 10, 2022 hearing, and by the Court at the March 11, 2022 hearing. There are applicable legal duties at common law. As to Plaintiff's negligence *per se* claim, the Florida Drug and Cosmetic Act and Florida Pharmacy Act establishes applicable duties. Triable issues of fact exist as to breach of applicable duties by each Defendant. Triable issues of fact exist as to damages resulting from those breaches.

Public nuisance: The Motion is denied as to the public nuisance claims in Counts I-II, and X for the reasons given by the Court on the record at the March 9 and 10, 2022 hearings, and by the Court at the March 11, 2022 hearing. The evidence is sufficient to create a triable issue of fact as to whether the opioid epidemic of addiction and related harms, including opioid-related crime, is a public nuisance that invades a public right by injuring the health of the community and damaging the public welfare. The evidence creates a triable issue as to whether the opioid epidemic is a public nuisance affecting the public at large. A public nuisance need not be related to land, and Florida law contains no bar on public nuisances related to products. The Motion is denied as to Plaintiff's abatement remedy for the reasons given by the Court on the record at the March 9 and 10, 2022 hearings, and by the Court at the March 11, 2022 hearing.

FDUTPA: The Motion is denied as to the FDUTPA claim in Count VI for the reasons given by the Court on the record at the March 8 and 10, 2022 hearings, and by the Court at the March 11, 2022 hearing. The FDUTPA claim is not barred by the statute's safe harbor,

§ 501.212(1), Fla. Stat., or the learned intermediary doctrine. The FDUTPA claim is not barred by the statute of limitations for reasons set forth below. The evidence creates triable issues of fact as to "actual damages" under Section 501.207(1)(c), Florida Statutes, as to each Defendant. Plaintiff may seek to recover as "actual damages" the amount spent on medically unnecessary opioids by "consumers or governmental entities," *id.*, but Plaintiff may not seek to recover compensatory damages such as foster care costs as "actual damages." Plaintiff may also seek to recover "legal, equitable, or other appropriate relief." § 501.207(3), Fla. Stat.

Civil conspiracy: The Motion is denied as to the civil conspiracy claims in Counts VII-XI for the reasons given by the Court on the record at the March 10, 2022 hearing, and by the Court at the March 11, 2022 hearing. There are triable issues of fact as to whether there was a civil conspiracy as to each Defendant.

RICO: The Motion is denied as to the RICO claims in Counts XII-XIII for the reasons given by the Court on the record at the March 10, 2022 hearing, and by the Court at the March 11, 2022 hearing. There are triable issues of fact as to whether Defendants operated or managed a RICO enterprise and agreed to commit a RICO conspiracy (Count XIII). For Count XII, there are triable issues of fact as to whether each Defendant committed sufficient predicate acts under Sections 499.0051(11)(d), 817.034(4)(a)-(b), and 893.04(2)(a), Florida Statutes.

Preemption: The Motion is denied as to federal preemption for the reasons given by the Court on the record at the March 10, 2022 hearing, and by the Court at the March 11, 2022 hearing. Plaintiff's claims for false and misleading statements are not preempted by the federal Food, Drug, and Cosmetic Act. Plaintiff's diversion-based claims are not preempted by the federal Controlled Substances Act because of the Act's savings clause, 21 U.S.C. § 903, among other reasons.

Political question and separation of powers: The Motion is denied as to separation of powers for the reasons given by the Court on the record at the March 10, 2022 hearing, and by the Court at the March 11, 2022 hearing. Plaintiff's claims are not barred by the political question doctrine. Moreover, adjudicating those claims will not require the Court to co-opt the rights and duties of the State legislature or of any federal or state regulatory agency.

Statute of limitations: The Motion is denied as to statute of limitations for the reasons given by the Court on the record at the March 8 and 10, 2022 hearings, and by the Court at the March 11, 2022 hearing. The Motion is denied for the same reasons as Walgreens's, CVS Health Corporation's, and CVS Pharmacy Inc.'s Motion for Summary Judgment Based on Statute of Limitations, File Share No. 013, was denied. There are triable issues of fact regarding (1) whether Plaintiff's claims are continuing violations, (2) the date of accrual of Plaintiff's claims, and (3) whether each Defendant is estopped from relying on a statute of limitations defense because of its fraudulent concealment of Plaintiff's claims.

Accordingly, Plaintiff's Motion is **GRANTED IN PART AND DENIED IN PART**.

DONE AND ORDERED in Chambers at New Port Richey, Pasco County, Florida, this ____ day of March 2022.

Electronically Conformed 3/30/2022
Kimberly Sharpe Byrd

_____
Honorable Kimberly Sharpe Byrd
Circuit Court Judge

COMMONWEALTH OF KENTUCKY
BOONE CIRCUIT COURT
DIVISION III
CASE NO. 18-CI-00846

ENTERED
BOONE CIRCUIT/DISTRICT COURT
JUL 22 2019
DAVID S. MARTIN, CLERK
BY: D.C.

COMMONWEALTH OF KENTUCKY,
Ex. rel. ANDY BESHEAR, ATTORNEY GENERAL **PLAINTIFF**

VS.

WALGREENS BOOTS ALLIANCE, INC., WALGREEN CO., WALGREENS MAIL SERVICE, LLC, WALGREENS SPECIALTY PHARMACY, LLC, WALGREENS.COM INC. d/b/a WALGREENS #05823 **DEFENDANT**

ORDER

This matter comes before the Court on Defendants Walgreens Boots Alliance, Inc.; Walgreen Co.; Walgreens Mail Service, LLC; Walgreens Specialty Pharmacy, LLC; and Walgreens.com, Inc. d/b/a Walgreens #05823 ("Walgreens") Motion to Dismiss Plaintiff's Complaint pursuant to Civil Rule 12.02(f). Additionally, Defendant Walgreen Boots Alliance has filed a Motion to Dismiss the claims against it for lack of personal jurisdiction. The Court having reviewed the memoranda filed by the parties, the court file, heard argument from counsel, and being in all ways sufficiently advised, finds as follows:

The underlying Complaint was filed by Kentucky Attorney General Andy Beshear against Walgreens alleging that they perpetuated Kentucky's opioid crisis by abusing the closed distribution system created by Congress in an effort to exaggerate the need for opioid medications in Kentucky, then recklessly shipping and dispensing outrageous quantities of opioids into Kentucky. Plaintiff argues that Walgreens' actions violated Kentucky law and resulted in an opioid epidemic, devasting the Commonwealth's families and communities and

forcing the Commonwealth to fund the expenses associated with the epidemic and rehabilitation of its citizen victims.

Walgreens has now brought this Motion to Dismiss Pursuant to Civil Rule 12.02(f), requesting that this Court dismiss the Complaint against them in that it fails to adequately allege facts that would support its claims. Walgreens argues that although Attorney General Beshear has brought nine other lawsuits in eight different counties related to the opioid crisis, Walgreens occupies a much different place in the chain of distribution of opioids than the defendants in the other matters, in that they solely dispense opioid medications to patients who present prescriptions written by physicians. They do not manufacture opioid medications, nor do they advertise them to the public or promote them to doctors.

When considering a motion to dismiss, Civil Rule 12.02 requires the Court to construe the pleadings liberally "in a light most favorable to the plaintiff" and to take all factual allegations in the complaint to be true. *Gall v. Scroggy*, 725 S.W. 2d 867 (Ky. Ct. App. 1987) (citing *Ewell v. Central City*, 340 S.W. 2d 479 (Ky. 1960)). "The Court shall not grant the motion unless it appears the pleading party would not be entitled to relief under any set of facts which could be proved in support of his claim." *Mims v. W.S. Agency, Inc.*, 226 S.W.3d 833, 835 (Ky. Ct. App. 2007) (quoting *James v. Wilson*, 95 S.W. 3d 875, 883-84 (Ky. Ct. App. 2002). In reviewing a Motion to Dismiss, the trial court is not required to make any factual findings, and it may properly consider matters outside of the pleadings in making its decision. *D.F. Bailey, Inc. v. GRW Engineers, Inc.*, 350 S.W. 3d 818, 820 (Ky. Ct. App. 2011).

I. Public Nuisance

Walgreens argues the Commonwealth's public nuisance claim fails on two fronts. The first is that the Complaint does not identify any public right allegedly infringed upon as there is

no public right to be free from the threat that a lawful product will be abused and thereby cause injury. They cite to *City of Chicago v. Beretta* U.S.A., Corp., 821 N.E.2d 1099, 1116 (Ill. 2004) in which the Illinois Court stated; "[w]e are reluctant to state that there is a public right to be free from the threat that some individuals may use an otherwise legal product (be it a gun, liquor, a car, a cell phone, or some other instrumentality) in a matter that may create a risk of harm to another." Defendants argue that adopting the Attorney General's view that abuse by an individual who presents a valid prescription written by a physician, or abuse of a valid opioid prescription by someone subsequent, constitutes a "public right" would instantaneously convert into public nuisance virtually any societal ill that affects a substantial number of people—a floodgate which should not be opened.

The Commonwealth refutes this, arguing that the public nuisance claim is sufficiently pled and satisfies not one, but all, of the circumstances identified in the Restatement (Second) of Torts § 821B that may "sustain a holding that an interference with a public right is unreasonable." The Restatement asserts that an unreasonable violation of a public right can occur in the following circumstances:

> (a) whether the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, or
>
> (b) whether the conduct is proscribed by statute, ordinance or administrative regulation, or
>
> (c) whether the conduct is of a continuing nature or has produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect upon the public right.

Restatement (Second) of Torts § 821B. The Commonwealth contends that Walgreens interfered with the public health and safety of the citizens of Kentucky by saturating Kentucky

with addictive medications while ignoring applicable laws and regulations pertaining to the safe distribution of addictive drugs.

"A common or public nuisance is a condition of things which is prejudicial to the health, comfort, safety, property, sense of decency or morals of the citizens at large, resulting either (a) from an act not warranted by law, or (b) from neglect of a duty imposed by law." *Nuchols v. Commonwealth*, 226 S.W. 2d 796, 798 (Ky. App.1950). The Court finds that the Commonwealth has properly alleged a public right that Walgreens has violated.

Secondly, Walgreens argues the public nuisance claim fails in that the Complaint does not allege that Walgreens had control of the opioid medications at the time of the alleged harm. Defendants argue that the alleged public nuisance "increases in illicit drug use, crime, and overdoses," did not arise until after the prescription opioids were in the hands of third parties.

Conversely, the Commonwealth argues that the public harm occurred when Walgreens ignored applicable laws, regulations, and its own internal protocols in furtherance of flooding Kentucky's communities with addictive medications. They contend that Defendants controlled the products at the time of dispensation and distribution and, by virtue of its role as a licensed distributor, promised to control the supply of opioids into the Commonwealth.

The Court agrees with the Commonwealth that it has sufficiently pled the control element of the public nuisance claim, alleging the cause of the nuisance was the dispensation and distribution of the opioids at a time in which Walgreens had control of them.

II. Negligence

Walgreens argues that the Commonwealth's negligence claim fails because Walgreens does not owe a common law duty to the Commonwealth to protect it from the economic injuries alleged in the Complaint. They claim that even if the allegations against them are true, and they

did dispense an excessive number opioids medications without adequately investigating or reporting potential diversion, those acts alone could not have caused the harms alleged in the Complaint as those harms could only have occurred once third parties illicitly diverted the prescription opioid medications for improper use. They argue they cannot therefore be held liable for failing to prevent the criminal misconduct of third parties with whom they have no relationship and over whom they have no control. Thus, they claim they owed the Commonwealth no duty to protect it from the economic consequences of such third-party actions. They cite to *Briscoe v. Amazing Products, Inc.*, 23 S.W.3d 228, 230 (Ky. App. 2000) as instructive. In *Briscoe*, a suit was brought against the distributor of "Liquid Fire," a drain-cleaning product, after it was used to assault a third party. The Court looked to the analysis found in *Sturm, Ruger & Co., v. Bloyd*, 586 S.W. 2d 19 (Ky. 1979) which held that the manufacturer of a firearm could not be held liable for the gun's accidental discharge because the manufacturer had no duty to anticipate the unreasonable use of the firearm by its owner. The *Briscoe* Court then opined that the "principles at work in *Sturm* would apply with even greater force where, as here, the intervening cause was an intentional criminal act." *Id.* at 230. Walgreens contends that *Sturm* and *Briscoe* are controlling, and the application of such requires the Commonwealth's claim of negligence to fail as a matter of law.

The Commonwealth argues that Walgreens' reliance on *Sturm* and *Briscoe* is misplaced as the diversion and abuse of opioids is not an extraordinary or unforeseeable result of Walgreens' unabated, excessive distribution and dispensation of opioids in Kentucky, but rather the obvious result of supplying quantities of drugs that exceed the population and are not necessitated by legitimate medicals needs. They contend that Walgreens is mischaracterizing the claims against them as the Commonwealth is not arguing Walgreens' duty arises from the

intentional acts of third parties pursuant to *Norris v. Corr. Corp. of Am.*, 521 F. Supp. 2d 586, 590 (W.D. Ky. 2007), but that its duty arises based on its own actions of negligently failing to protect against theft and diversion and for saturating Kentucky with opioids.

The Court agrees that the Commonwealth has adequately pled their claim for negligence. Kentucky recognizes a general "universal" duty to exercise ordinary care to prevent foreseeable injury. "The examination of which must be focused so as to determine whether a duty is owed, and consideration must be given to public policy, statutory and common law theories in order to determine whether a duty existed in a particular situation." *T& M Jewelry, Inc., v. Hicks*, 189 S.W.3d. 526, 530-531 (Ky. 2006) (citing *Grand Aerie Fraternal Order of Eagles v. Carneyhan,* 169 S.W.3d 840, 849)). Here the Commonwealth has alleged harm - higher addiction and overdose rates, increased heroin usage, associated injuries like increased crime, more children placed in foster care, skyrocketing healthcare expenses, and a declining quality of life for its citizens, as a not unforeseeable result of Walgreens' actions - excessive distribution and dispensation of opioids.

III. Unjust Enrichment

Walgreens next argues that the Commonwealth has not adequately pled or established the elements of their unjust enrichment claim. A claim for unjust enrichment has three elements: "(1) a benefit conferred upon defendant at the plaintiff's expense; (2) a resulting appreciation of benefit by defendant; and (3) inequitable retention of benefit without payment for its value." *Collins v. Ky. Lottery Corp.*, 399 S.W.3d 449, 455 (Ky. App. 2012) (quoting *Jones v. Sparks,* 297 S.W.3d 73, 78 (Ky.App.2009)). Walgreens argues that although the Complaint alleges the Commonwealth "paid direct reimbursement to pharmacies or insurance programs, which were pass through entities in order to allow financial benefits to be received by Walgreens," it then

jumps to the legal conclusion that Walgreens "received an inequitable financial benefit" as a result of the Commonwealth's payment for opioid medicines. The Complaint, they argue, does not allege that the Commonwealth did not receive the opioid medication it paid for and, therefore, they cannot claim unjust enrichment, as "(t)he doctrine of unjust enrichment is an equitable and restitutionary tool designed to prevent one person from keeping money or benefits belonging to another." *Noble Royalties Access Fund V LP v. Elk Horn Coal Co., LLC, 2015 WL 7352587, at 5 (Ky. App. Nov. 20, 2015) (*quoting *Haeberle v. St. Paul Fire and Marine Ins. Co.*, 769 S.W.2d 64, 67 (Ky.App.1989)).

The Commonwealth contends that it has adequately alleged all the elements of their unjust enrichment claim, asserting that: (1) Walgreens benefited from improperly distributed and dispensed opioids, which were purchased in the Commonwealth as an intended result of its conscious wrongdoing; (2) that due to, and as intended by, its deceptive acts, Walgreens has made millions of dollars at the expense of the Commonwealth, and; (3) it would be inequitable for Walgreens to retain profits and benefits reaped from its oversight failures and unlawful activity.

The Court finds that the Commonwealth has adequately pled facts to support its unjust enrichment claim.

IV. Medicaid Claims

Walgreens argues that the Commonwealth's Medicaid claims should be dismissed as they fail to allege any false statements or concealments in connection with Medicaid or medical assistance. They further argue that these claims must be pled "with particularity" and the Commonwealth has failed to do so.

The Kentucky Medicaid Fraud Statute, KRS 205.8463, prohibits any person from "intentionally, knowingly, or wantonly…cause to be made or presented to an employee or officer of the Cabinet for Health and Family Services any false fictitious, or fraudulent statement, representation, or entry in any application, claim, report, or document used in determining rights to any benefit or payment." KRS 205.8463(2). It further prohibits any person from intentionally engaging in conduct to advance a scheme to receive or aid others to receive payments. KRS 205.8463(4). The Commonwealth argues that Walgreens, acting as a distributor, caused false Medicaid claims to be filled by virtue of their failure to report and halt suspicious orders, as well as through their failure to inform the Commonwealth of continuing violations when it renewed its licenses, constituting violations of Kentucky law and Kentucky Administrative Regulations. The Court finds that by alleging Walgreens failed to identify, report and halt suspicious prescriptions and inform the Commonwealth of specific violations in its license renewals, the Commonwealth has adequately pled its claim under the Kentucky Medicaid Fraud Statute.

As to the Kentucky Assistance Program Fraud Statute, Ky. Rev. Stat.§ 194A.505(6) which precludes "…intent to defraud or deceive, devise a scheme or plan a scheme or artifice to obtain benefits from any assistance program by means of false or fraudulent representations or intentionally engage in conduct that advances the scheme or artifice," the Court finds the Commonwealth's allegations that Walgreens perpetuated the filing of allegedly false claims constitutes a valid claim under this statute as well.

V. Kentucky's Consumer Protection Act

Walgreens argues that the Commonwealth's claims under Kentucky's Consumer Protection Act should be dismissed because the purpose of the Act is to protect customers from misleading practices in the marketplace and the Complaint does not allege that Walgreens did

anything "unfair, false, misleading, or deceptive" in its interactions with individual Kentucky consumers. They contend that they do not, and did not, engage in consumer-based conduct and, as the Commonwealth failed to allege that they defrauded consumers, the claim is not appropriate.

The Commonwealth argues that Walgreens' argument is meritless as the Kentucky Consumer Protection Act prohibits all acts "in trade or commerce" that are "unfair, false, misleading, or deceptive." KRS 367.170. Further, the Attorney General has broad authority to bring suit "in the public interest" and has the authority to ensure the compliance of all participants in the marketplace. KRS 367.190.

The Court agrees with the Commonwealth, and finds they have appropriately pled their claim under the Kentucky Consumer Protection Act. The Court also finds that the Kentucky Consumer Protection Act is not limited to "only those selected types of illegal business acts or practices which are used in the merchandising of goods or services intended for personal, family, or household use." *North American Van Line*, 600 S.W.2d 459, 462 (Ky. App. 1979).

VI. Fraud by Omission

Walgreens further argues that there is no basis for a claim of fraud by omission. They contend that the Complaint never identifies any provision of Kentucky statutory or common law that creates a duty to disclose "suspicious orders" to the Commonwealth and, absent such a duty, the claim must fail. They further argue that the claim must fail on the basis of proximate cause in that even if such a duty existed, the Complaint does not allege how increased reporting of suspicious orders to Kentucky regulators would have changed the Commonwealth's behavior and avoided or reduced the damages allegedly incurred.

A fraud by omission claim requires the following elements: (1) a duty to disclose a material fact at issue; (2) the defendant failed to disclose such fact, (3) the failure to disclose induced the plaintiff to act; and (4) the plaintiff suffered actual damages therefrom. *Giddings v. Lewis, Inc. v. Indus. Risk Insurers*, 348 S.W.3d 729, 747 (Ky. 2011) (quoting *Rivermont Inn, Inc. v. Bass Hotels Resorts, Inc.*, 113 S.W.3d 636, 641 (Ky.App.2003)). In its Complaint, the Commonwealth alleges Walgreens had a duty to disclose suspicious orders of prescription opioids and to prevent theft and diversion, and that by failing to report on these matters, providing inaccurate reporting and/or providing partial reporting with critical information omitted, Walgreens breached its duties.

Kentucky law requires all pharmacies to apply for and receive a license from the Kentucky Board of Pharmacy. KRS 315.035. They must also apply for and receive a license from the Kentucky Cabinet for Health and Human Services. KRS 218A.150, repealed by 2018 Kentucky Laws Chapter 112. Continuing licensure is dependent upon compliance with laws and regulations relating to controlled substances. KRS 218A.160(1) (repealed), 902 KAR 55.010, KRS 218A.240 and 21 U.S.C. § 823. The Commonwealth also argues Walgreens' omissions constituted a failure to comply with state and federal regulations when applying for and using its Kentucky licensure to distribute drugs in the Commonwealth, and further that the Commonwealth relied on the untruthful and/or incomplete information that Walgreens provided in its license applications to the detriment of the citizens of Kentucky.

The Court finds that the Commonwealth has adequately pled their claim for fraud by omission in that they have alleged Walgreens' failed to disclose suspicious orders of prescription opioids and to prevent theft and diversion, and that by failing to report on these matters, providing inaccurate reporting and/or providing partial reporting with critical information

omitted, Walgreens breached statutory duties, and the Commonwealth has adequately alleged with particularity facts to support its theory regarding each element of the claim.

VII. Negligence Per Se

As Walgreens argues, to bring a negligence *per se* claim, a plaintiff must show that (1) the plaintiff "comes within the class of person intended to be protected by the statute;" (2) the statute "must have been specifically intended to prevent the type of occurrence that took place;" and (3) the violation of the statute "must have been a substantial factor in causing the result." *McCarty v. Covol Fuel No. 2, LLC*, 476 S.W. 3d 224, 227-28 (Ky. 2015). Additionally, to bring a claim of negligence *per se* based on a violation of a regulation, the plaintiff must meet the same three requirements and, additionally, must aim at the safety of the citizenry and be specifically authorized by an enabling statute. *Id.* at 233. Walgreens argues that as the Commonwealth has not adequately alleged a violation of any statute or regulation, because there are no enumerated duties that they have violated, the Commonwealth's claim must fail as a matter of law. The Defendants further argue that 201 KAR 2:105§ 2(4)(d); 201 KAR 2:105§ 5(4); 201 KAR 2:105§ 7; 902 KAR 55:010 (repealed); KRS 205.5634; KRS 218A.160(10)(a) (repealed); KRS 218A.170, KRS 218A.200 and KRS 218A.180(3) do not create any obligation on Walgreens to "monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids" as alleged in the Complaint. Further, they argue, none of these provisions meet the basic requirements for a negligence *per se* claim because as the Commonwealth is not "within the class of person intended to be protected" and the statute was not "specifically intended to prevent the type of occurrence that took place." They contend that these statutes and regulations were intended to protect patients and consumers from physical harm, not against the economic injuries alleged by the Commonwealth.

Conversely, the Commonwealth argues that as a wholesale distributor, Walgreens has a duty to comply with all state laws and regulations relating to controlled substances. KRS 218.160(1)(a). Pursuant to this same statute, Walgreens is required to develop internal security policies to reasonably protect against theft and diversion, 201 KAR 2:105 § 5(2)(c). They must also:

> establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and to assure that the wholesale distributor prepares for, protects against, and handles crisis situation that affect the security or operation of the facility. These crises shall include fires, floods, or other natural disasters, and situations of local, state, or national emergency.

201 KAR 2:105 § 5(4)(a). They further argue that Kentucky statutes clearly require compliance with federal law and to the extent that Walgreens' conduct violated the Federal Controlled Substance Act, it, therefore, also violated state law. KRS 218A.170(8) (2018), 201 KAR 1:105 § 2(4)(d), KRS 218A.160(1)(a). They contend that Walgreens' breach of its duty to report and refuse to ship "suspicious orders" to the DEA caused devastating harm to the Commonwealth.

The Court finds that the Commonwealth has adequately pled its claims for relief for negligence *per se* as statutory duties of care exist for wholesale distributors of opioids in the Commonwealth. The Court also finds the Commonwealth to be a member of the protected class of the enumerated statutes as they create a way to safeguard wholesale distributors from acting in a way that violates public health and safety concerns.

VIII. Proximate Cause

Walgreens argues that the Commonwealth's Complaint does not adequately establish that Walgreens' actions are the proximate cause of the alleged injury. They claim that the asserted causal chain between the alleged conduct and the alleged injuries is too attenuated to sustain a

finding of proximate case in that, in order for the alleged damages to have occurred, there had to have been an intervening cause: a third party must have either abused the drug or illegally provided it to others who then abused it. They cite to *Liberty Mut. Fire Ins. V. JM Smith Corp.*, 602 F. Appx 115 (4th Cir. 2015), which found in favor of a wholesale pharmaceutical distributor, opining the chain of causation was hardly direct between the wholesaler and drugs ending up in an abuser's hands. The Commonwealth argues an intervening cause only supersedes proximity where the injury was not reasonably foreseeable. *NKC Hospitals, Inc. v. Anthony*, 849 S.W.2d 564, 568 (Ky. Ct. App. 1993). The criteria for determining whether an intervening act is superseding includes the requirement that the act be: (1) of independent origin, unassociated with the original act; (2) capable of bringing about the injury; (3) not reasonably foreseeable by the original actor, and (4) involved the unforeseen negligence of a third party or a natural force. *Id. See also*, *Briscoe v. Amazing Products, Inc.*, 23 S.W.3d 228, 229.

Walgreens also argues the Commonwealth cannot recover as their claimed injuries were suffered indirectly as a result of an injury to another. Walgreens relies on *Kentucky Laborers District Council v. Hill & Knowlton, Inc.*, 24 F. Supp. 2d 755, 761-64 (W.D. Ky..1998), a case in which third-party payors attempted to sue tobacco companies to recover medical costs they expended to treat people with smoking related ailments. The Western District Court dismissed the action, finding that the payor's claims were too "remote" and "entirely "derivative" of members injuries. *Id* at 762-763. The Commonwealth argues that the instant matter is distinguishable as this is not a case of a company misrepresenting the health risks, smoking, but that it involves Walgreens causing countless unnecessary prescriptions to be written and fraudulently inducing the Commonwealth to pay for them.

Additionally, the Commonwealth contends that proximate cause falls within the purview of the jury, becoming a matter of law only where "there is no dispute about the essential facts" and "reasonable minds cannot differ as to the existence of causation." *McCoy v. Carter*, 323 S.W. 2d 210, 215 (Ky. Ct. App. 1959). They argue that they must only show that Walgreens' conduct was a "substantial factor" in bringing about the harm alleged to establish legal causation. *Pathways, Inc. v. Hammons*, 113 S.W.3d 85, 91-92 (Ky. 2003) (adopting the substantial factor test from Restatement (Second) of Torts, § 431).

The Court finds that the Commonwealth has sufficiently pled proximate cause in its Complaint.

IX. Public Service Doctrine

Walgreens asserts that the Commonwealth's claims to recover response costs are barred under the Free Public Services Doctrine. Arguing that "absent authorizing legislation," the cost of public services, "is to be borne by the public as a whole, not assessed against the tortfeasor whose negligence creates the need for the service." *District of Columbia v. Air Fla., Inc.*, 750 F.2d. 1077, 1080 (D.C. Cir. 1984). They claim that numerous jurisdictions apply the doctrine to preclude the government from seeking reimbursement of police, medical, and other costs incurred in the performance of public duties and, therefore, there is no reason to think that Kentucky would differ from other states in this regard.

Conversely, the Commonwealth argues that the Free Public Services Doctrine does not apply as it has not been adopted by Kentucky. In the alternative, they argue that even if the Free Public Services Doctrine does apply, it does not preclude recovery as the doctrine permits recovery in a tort suit "where the acts of a private party create a public nuisance which the government seeks to abate." *Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099, 1145 (Ill. 2004).

The Court finds that it would not be appropriate to apply (and Adopt) the Free Public Services Doctrine under current Kentucky law.

X. Personal Jurisdiction over Walgreens Boots Alliance, Inc.

Defendant, Walgreens Boots Alliance, Inc. ("WBA") has filed an additional Motion to Dismiss which applies to them specifically. They argue that the Court has no personal jurisdiction over them under KRS 454.210 as WBA is a Delaware Company that conducts no activities in Kentucky. WBA was incorporated in September 2014 and, on December 31, 2014, became the parent company of Walgreen Co. pursuant to a merger and corporate reorganization into a holding company structure. WBA is incorporated under Delaware law and has its principal place of business in Deerfield, Illinois. They argue they are a legally distinct entity that does not conduct business in the name of Walgreen Co. or any of the other Walgreens Defendants. They are simply a parent holding company with no employees or operations outside of Illinois and have never distributed opioid medications and do not own or operate pharmacies. They further argue that even if personal jurisdiction were permissible through the Kentucky Long-Arm Statute, it would be barred by federal due process standards. The Commonwealth cites to WBA's public website to argue that WBA conducts activities including operating pharmacies and distributing and dispensing medications.

"The proper analysis of long-arm jurisdiction over a nonresident defendant consists of a two-step process. First, review must proceed under KRS 454.210 to determine if the cause of action arises from conduct or activity of the defendant that fits into one of the statute's enumerated categories. If not, then *in personam* jurisdiction may not be exercised. When that initial step results in a determination that the statute is applicable, a second step of analysis must be taken to determine if exercising personal jurisdiction over the non-resident defendant offends

his federal due process rights." *Caesars Riverboat Casino, LLC v. Beach*, Ky., 336 S.W.3d 51, 57 (2011).

KRS 454.210(2)(a) states in pertinent part:

> (2) (a) A court may exercise personal jurisdiction over a person who acts directly or by an agent, as to a claim arising from the person's:
> 1. Transacting any business in this Commonwealth;
> 2. Contracting to supply services or goods in this Commonwealth;
> 3. Causing tortious injury by an act or omission in this Commonwealth;
> 4. Causing tortious injury in this Commonwealth by an act or omission outside this Commonwealth if he regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered in this Commonwealth, provided that the tortious injury occurring in this Commonwealth arises out of the doing or soliciting of business or a persistent course of conduct or derivation of substantial revenue within the Commonwealth; …

The Commonwealth argues that KRS 454.210(2)(a) provides for agency as a basis for personal jurisdiction, and that the above 4 prongs of KRS 454.210(2)(a) apply to WBA's conduct as the parent company of all Walgreens entities, which are being operated and controlled by WBA. Therefore, they argue, this Court has personal jurisdiction over WBA pursuant to Kentucky's Long-Arm Statute.

The Commonwealth also argues Walgreens is the alter-ego of WBA, and Kentucky has jurisdiction over WBA as they dominate the Walgreens enterprise. See. *Audiovox Corp. v. Moody,* 737 S.W.2d 468, 470 (Ky. App. 1987).

Additionally, the Court's exercise of jurisdiction must also be consistent with constitutional due process, which can be satisfied by a showing of general jurisdiction, requiring general systematic contacts with the forum or, specific jurisdiction, requiring contacts relating to the specific transactions at issue. To be subject to general personal jurisdiction a nonresident defendant's affiliations with Kentucky must be so "continuous and systematic as to render them essentially at home there." *Daimler AG v. Bauman*, 57 U.S. 117, 127 (2014) (quoting *Goodyear*

Dunlap Tires Operations, S.A. v. Brown, 564 U.S. 915, 919 (2011)). Specific jurisdiction requires a showing of "minimum contacts" between the defendant and the forum and that the exercise of the Court's jurisdiction would be "consistent with traditional notions of fair play and substantial justice." *International Shoe Co. v. Washington,* 326 U.S. 310, 316 (1945). This does not require the defendant to be, or have been, physically present in the Commonwealth. Kentucky courts have long recognized the exercise of jurisdiction over a parent company if their subsidiary is doing business within the Commonwealth. *See Pro Tanks Leasing v. Midwest Propane & Refined Fuels*, LLC, 988 F.Supp. 2d (W.D.Ky. 2013); *Dare to be Great, Inc. v. Commonwealth ex rel. Hancock*, 511 S.W.2d 224, 227 (Ky. App. 1974).

WBA next argues that specific personal jurisdiction does not exist because federal due process requires a close nexus between the defendant's activities, the forum state, and the plaintiff's claims. *Intera Corp. v. Henderson*, 428 F.3d 605, 615 (6th Cir. 2005). The Court must find that: (1) the defendant "purposefully availed himself of the privilege of acting in the forum state;" (2) that the plaintiff's cause of action "arises from the defendant's activities" in the forum state; and (3) that the defendant's conduct has a "substantial enough connection" with the forum state to make the exercise of jurisdiction reasonable. *Id.* (*quoting S. Mach.Co. v. Mohasco Indus., Inc.*, 401 F.2d 374, 381 (6th Cir. 1968)). WBA argues that, based on this three-prong test, there is no conceivable basis for the Court to exercise specific personal jurisdiction over them.

Finally, WBA argues that potential jurisdiction over WBA subsidiaries does not create personal jurisdiction over WBA. They contend that specific jurisdiction over a parent company based on a subsidiary's contacts with the forum state requires a showing that "the parent company exerts so much control over the subsidiary that the two do not exist as separate entities, but are one and the same for the purposes of jurisdiction." *Estate of Thomson ex rel. Estate of*

Rakestraw v. Toyota Motor Corp. Worldwide, 545 F.3d 357, 362 (6th Cir. 2008). They claim that the Commonwealth has not alleged—and could not allege—any facts that would allow for specific jurisdiction over WBA.

The Commonwealth argues that WBA, as the parent company of all Walgreen entities, is subject to personal jurisdiction in Kentucky. They contend that, despite WBA's protestations to the contrary, they are intertwined with Walgreens so much as to be the same entity for purposes of jurisdiction. WBA manages and directs Walgreens' operations and, therefore, is involved in the distribution and dispensation of drugs in Kentucky.

The Court finds that WBA is the parent company of Walgreens and is directly involved in the management and directing of Walgreen's activities. They are therefore subject to the jurisdiction of this Court. Through Walgreens, WBA transacted business in Kentucky, contracted to supply services or goods in Kentucky, caused alleged tortious injury in Kentucky, and engaged in out-of-state conduct which allegedly caused tortious injury in Kentucky, while regularly soliciting and doing business in Kentucky and obtaining substantial revenue from these activities in Kentucky. These contacts satisfy both the requirements of Kentucky's Long Arm Statute, KRS 454.210, and the requirements of Constitutional due process.

IT IS HEREBY ORDERED AND ADJUDGED as follows:

1. Defendants Walgreens Boots Alliance, Inc.; Walgreen Co.; Walgreens Mail Service, LLC; Walgreens Specialty Pharmacy, LLC; and Walgreens.com, Inc. d/b/a Walgreens #05823 ("Walgreens") Motion to Dismiss Plaintiff's Complaint pursuant to Civil Rule 12.02(f) is **DENIED**;
2. Defendant Walgreen Boots Alliance's Motion to Dismiss the claims against it for lack of personal jurisdiction is **DENIED**.

DATED this 18th day of July 2019.

JAMES R. SCHRAND, JUDGE
BOONE CIRCUIT COURT

COPIES TO: ALL ATTORNEYS AND PARTIES OF RECORD

CERTIFICATE
I, DAVID S. MARTIN, CLERK OF THE BOONE DISTRICT/CIRCUIT COURT, THEREBY CERTIFY THAT I HAVE MAILED A COPY OF THE FOREGOING ORDER AND NOTICE TO ALL PARTIES HERETO AT THEIR LAST KNOWN ADDRESSES OR THEIR COUNSEL OF RECORD, THIS 19 DAY OF July
DAVID S. MARTIN
BOONE DISTRICT/CIRCUIT COURT
D.C.

19-016896-NZ FILED IN MY OFFICE Cathy M. Garrett WAYNE COUNTY CLERK 3/24/2021 11:06 AM Stacy Stallworth

STATE OF MICHIGAN

IN THE CIRCUIT COURT FOR THE COUNTY OF WAYNE

STATE OF MICHIGAN, EX REL
DANA NESSEL, ATTORNEY GENERAL,

Plaintiff,

-v-

Case No. 19-016896-NZ
Hon. Patricia Perez Fresard

CARDINAL HEALTH, INC., McKESSON CORPORATION, AMERISOURCEBERGEN DRUG CORPORATION, and WALGREEN CO.,

Defendants.
_____/

ORDER GRANTING PLAINTIFF'S MOTION FOR PARTIAL RECONSIDERATION

At a session of said Court,
held in the City of Detroit,
County of Wayne, State of Michigan
on 3/24/2021
PRESENT: Hon. Patricia Perez Fresard
Circuit Court Judge

On November 17, 2020, the Court entered an opinion and order granting in part and denying in part Defendants' respective motions for summary disposition. Now pending before the Court is Plaintiff's motion for partial reconsideration of the Court's November 17, 2020, opinion and order. The Court, having reviewed the motion, and otherwise being fully advised in the premises, issues the following order.

Whether or not to grant a motion for reconsideration is a matter within the trial court's discretion. *Cason v Auto Owners Ins Co*, 181 Mich App 600, 605; 450 NW2d 6 (1989). The *Cason* court stated:

> Generally, a motion for reconsideration must demonstrate a "palpable error" by which the court and the parties have been misled. A motion which merely

> presents the same issue as ruled on by the court, either expressly or by reasonable implication, will not be granted.

Id.

However, the "palpable error" standard merely provides guidance to the court and does not restrict its discretion. *Bakian v National City Bank (In re Estate of Moukalled)*, 269 Mich App 708, 714; 714 NW2d 400 (2006).

Michigan's public nuisance statute, MCL 600.3801, generally establishes that certain places, conduct, and things constitute nuisances as a matter of law. The nuisance statute contains a separate subsection that defines "[a]ll controlled substances" as nuisances, independent of whether they are used in connection with any real or personal property, and provides that they "shall be enjoined and abated." MCL 600.3801(3); *see also* Public Nuisance - Declared Nuisances, Controlled Substances, Public Act No. 2, HB 4317, 1988 Mich Legis Serv 2 (1988 amendments expanded the statutory definition of nuisance to include a separate clause designating controlled substances themselves, apart from any connection to a property, as nuisances); *Michigan ex rel Wayne County Prosecutor v Bennis*, 447 Mich 719, 734-35; 527 NW2d 483 (1994) (recognizing that the 1988 amendments broadened the definition of public nuisance to include controlled substances).

Section 600.3805 authorizes the Attorney General to bring "an action for equitable relief in the name of the state" to abate any public nuisance under section 660.3801. "In general, private persons,...are not proper plaintiffs in a suit to abate a public nuisance." *Plassey v S Loewenstein & Son*, 330 Mich 525, 528; 48 NW2d 126, 127 (1951).

Whether the State's allegations state a claim under the public nuisance statute is a question of statutory interpretation. *See Bennis, supra*. The Court's purpose in reviewing questions of statutory construction is to discern and give effect to the Legislature's intent. *People v Morey*, 461 Mich 325, 329–330; 603 NW2d 250 (1999). "We begin by examining the plain language of the statute; where that language is unambiguous, we presume that the Legislature intended the meaning clearly expressed—no further judicial construction is required or permitted, and the statute must be enforced as written." *Id* at 330.

In the present case, upon review of the State's complaint, the Court finds that it adequately pled the existence of a statutory public nuisance. The complaint alleges that the Attorney General, on behalf of the State, brought this action to protect the public and abate the nuisance caused by Defendants' unlawful distribution of opioids (i.e., controlled substances) in the State, which was done without diversion controls and in excess of any supply necessary for legitimate medical needs. Accepting those allegations as true, the State is entitled to proceed with

its statutory nuisance claim. Accordingly, IT IS HEREBY ORDERED that Plaintiff's motion for reconsideration is GRANTED.

/s/ Patricia Fresard 3/24/2021

Patricia Perez Fresard
Circuit Court Judge

IN THE CIRCUIT COURT OF HINDS COUNTY, MISSISSIPPI
FIRST JUDICIAL DISTRICT

STATE OF MISSISSIPPI **PLAINTIFF**

V. **CIVIL ACTION NO.: 25CI1:18-cv-00692**

CARDINAL HEALTH, INC., McKESSON CORPORATION, AMERISCOURCEBERGEN CORPORATION, WALGREEN CO., WALMART INC. f/k/a WAL-MART STORES, INC., AND DOES 1 THROUGH 100, INCLUSIVE, **DEFENDANTS**

ORDER DENYING MOTION TO DISMISS

THIS ACTION comes before the Court upon a Joint to Transfer Venue and to Dismiss Amended Complaint for Failure to State a Claim [Docket Nos. 44 & 46] filed by Defendants Walgreen Co. and Walmart Inc. (collectively, "Pharmacy Defendants"). Previously, the Court, issued an Order denying the Pharmacy Defendants' Motion to Transfer Venue [Docket No. 62]. The Court now turns its attention to their motion to dismiss and, having considered oral arguments of counsel on September 18, 2020, reviewed supplemental authority supplied through December 2020, and being otherwise fully advised in the premises, finds as follows:

On December 6, 2018, Plaintiff, the State of Mississippi (hereinafter, the "State"), through the Office of the Attorney General, filed suit naming multiple defendants and alleging their various roles and/or contribution to the Opioid Epidemic within the State of Mississippi. On September 12, 2019, the State amended its complaint [Dkt. #36] to include the self-titled Pharmacy Defendants – Walgreens Co. and Walmart Inc. The State asserts the Pharmacy Defendants, as wholesalers who distribute prescription drugs through their own pharmacies, failed to safely monitor and distribute prescription drugs. The State's Amended Complaint [Dkt. #36], filed on

September 12, 2019, alleges four claims against the Pharmacy Defendants: public nuisance, negligence, violation of the Mississippi Consumer Protection Act, and unjust enrichment.

On November 20, 2019, the Pharmacy Defendants filed the instant motion to dismiss. Therein, they argue that the Amended Complaint fails to sufficiently plead each of the four claims and that the claims are otherwise barred.

ANALYSIS

A Rule 12(b)(6) motion to dismiss for failure to state a claim raises an issue of law and challenges the legal sufficiency of the complaint. *Rose v. Tullos*, 994 So.2d 734 (Miss. 2008). In review of the motion, the allegations in the complaint must be taken as true. *Rose*, 994 So.2d 734. To succeed on the motion, there must be no set of facts that would allow the plaintiff to prevail. *Id.* at 734 (¶ 11).

I. Count I – Public Nuisance

A public nuisance is an unreasonable interference with a right common to the general public. *Comet Delta, Inc. v. Pate Stevedore Co. of Pascagoula, Inc.*, 521 So. 2d 857, 860 (Miss. 1988) (adopting Restatement (Second) of Torts § 821B)). A complainant seeking to recover for a public nuisance "must have sustained harm different in kind, rather than in degree, than that suffered by the public at large." *Prescott v. Leaf River Forest Prod., Inc.*, 740 So. 2d 301, 312 (Miss. 1999) (citing *Comet Delta, Inc. v. Pate Stevedore Co. of Pascagoula, Inc.*, 521 So.2d 857, 861 (Miss.1988)).

The Amended Complaint reads: "Defendants […] violated Mississippi law through their contribution to and/or assistance in creating and maintaining a condition that is harmful to the health of Mississippians and interferes with the comfortable enjoyment of life by its citizens." Am. Compl. ¶¶ 5, 47, 82-83, 85-87. The complaint details a public health hazard and interference with

aspects of public life in Mississippi. In addition, it discusses ongoing conduct continuing that produced a permanent or long-lasting effect; as well as, defendants' knowledge of the significant effect upon the public right. *See* Restatement (Second) of Torts § 821B(2)(c); Am. Compl. ¶¶ 36-42, 47, 76-77, & 82-89.

The Pharmacy Defendants' insufficiency argument and assertion that no public rights were identified are without merit. The same holds true with regard to their "control over the instrumentality" argument. Taken as true, the Court finds Count I sufficiently pled.

II. Count II – Negligence

To prevail on a claim of negligence, the "plaintiff must establish by a preponderance of the evidence each of the elements of negligence: duty, breach, causation and injury." *Sanderson Farms, Inc. v. McCullough*, 212 So. 3d 69, 76 (Miss. 2017) (citations omitted).

To this point, the Pharmacy Defendants argue (1) that they owe no duty to the State of Mississippi to protect it from the alleged harm associated with distributing opioids in their control, and (2) that there is no private right of action available to the State of Mississippi. The Court disagrees.

The Court finds no merit to these arguments because as discussed by the State: (1) there exists a legal duty and foreseeability of harm in the purchase, storage, sell and distribution of Schedule II drugs, (2) a common law negligence action can be based on the violation of a federal or state statute that does not create a corresponding right of action, and (3) the Attorney General is vested – by the Mississippi Constitution, by statute and common law – with the power and authority to bring this action. Am. Compl. ¶¶ 21-28, 35-49 & 92-97; *Wade v. Mississippi*, 392 F. Supp. 229, 233 (N.D. Miss 1975); *Gandy v. Reserve Life Ins. Co.*, 279 So. 2d 648 (Miss. 1973). Accordingly, the Court finds the claim of negligence sufficiently pled.

III. Count III – Violation of the Mississippi Consumer Protection Act (MISS. CODE ANN. § 75-24-1, *et seq.*)

"The purpose of the CPA is to protect the citizens of Mississippi from deceptive and unfair trade practices." *In re Miss. Medicaid Pharm. Average Wholesale Price Litig.*, 190 So. 3d 829, 841 (Miss. 2015). "A trade practice is unfair if (1) it causes or is likely to cause a substantial injury; (2) the injury is not 'outweighed by any countervailing benefits to consumers or competition that practice produces;' and (3) the injury could not have been 'reasonably avoided.'" *Id.* (quoting 5 U.S.C. § 45(n)). In considering if a practice is deceptive and unfair, the courts look to whether the use of "statements, representations, acts and practices, directly or by implication, has had and now has the capacity and tendency to mislead members of the public into the erroneous and mistaken belief that said statements and representations were and are true and complete." *Matter of Cliffdale Assocs., Inc.*, 103 F.T.C. 110 (1984) (cited with approval in *Watson Labs., Inc. v. State*, 241 So. 3d 573 (Miss. 2018)); *see*, generally, MISS. CODE. ANN. § 75-24-3(c).

Through its complaint, the State seeks a permanent injunction under Mississippi Code Annotated § 75-24-9 and civil penalties and fees under § 75-24-19(1)(b). Distributors' arguments herein focus on the marketing; however, the State contends Distributors' unfair practices implied orders were appropriate and did not reflect any abnormalities in amount, which would have indicated injury and harm that could reasonably be avoided. The complaint alleges defendants:

> knowingly, or with reason to know, and willing used unfair trade practices, in general, consisting of: engaging, and continuing to engage, in unfair trade practices that are illegal, immoral, unethical, oppressive, unscrupulous, or substantially injurious to aggrieved consumers including misrepresenting, failing to state, concealing, suppressing and/or omitting facts regarding the charging and collection of fees.

Am. Compl. ¶99. Paragraph 99, also, claims Distributors knowingly, or with reason to know, and willfully misrepresented the source, sponsorship, approval, or certification of goods or services

by: engaging, and continuing to engage, in misrepresentations that are immoral, unethical, oppressive, unscrupulous, or substantially injurious to aggrieved consumers including misrepresenting, failing to state, concealing, suppressing and/or omitting facts regarding the efficacy and usefulness of the opioids and collection of funds related to the sale of those opioids offered by the Defendants to consumers. *Id.*

Taken as true, Count III is sufficiently pled.

IV. Count IV – Unjust Enrichment

As quoted in *Owens Corning,* at ¶25:

> Mississippi law provides that, in an action for unjust enrichment, the plaintiff need only allege and show that the defendant holds money which in equity and good conscience belongs to the plaintiff. The requirements of proof of unjust enrichment are neither technical nor complicated and, [plaintiff] can state a claim against Defendants on the basis that [defendants] were unjustly enriched because they received the profits [which] they should not have been permitted to [receive].

Owens Corning, 868 So.2d 331 (citing *Fordice Construction Company v. Central States Dredging Company*, 631 F. Supp. 1536. (S.D. Miss. 1986)).

The State's Amended Complaint alleges:

> Defendants have benefited from their unlawful acts by causing millions of illegal and suspicious orders to be distributed in violation of their legal duties. It would be inequitable and not in good conscience for Defendants to retain any ill-gotten gains earned as a result of the conduct alleged herein, which gains would not exist but for the payments made by the State and other payors.

Am. Compl. ¶108.

Taken as true, the Court finds that Count IV is sufficiently pled.

V. Additional Defenses

a. Preemption by the Controlled Substances Act

Mississippi law demands nothing contrary or in addition to the provisions of the Control Substances Act ("CSA") found in Title 21 of the United States Code. As the United States Supreme

Court has recognized, "[t]he main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." *Gonzales v. Raich*, 545 U.S. 1, 12 (2005). Accordingly, Defendants' preemption argument fails.

b. Derivative Injury Rule

The indirect/derivative injury rule, also referred to as the remoteness doctrine, is a rule about proximate cause. *See, e.g., Owens Corning v. R.J. Reynolds Tobacco Co.*, 868 So. 2d 331, 337 (Miss. 2004). Defendants' reliance on *Owens Corning* for the proposition that indirect damages are not recoverable in Mississippi is misplaced.

c. Free Public Services Doctrine

The Free Public Services Doctrine is not recognized in the State of Mississippi, nor has the Supreme Court of Mississippi adopted the doctrine. Hence, the argument is unpersuasive to this Court.

d. Economic Loss Doctrine

Presently, Mississippi courts apply the economic loss doctrine to products liability cases, and the Mississippi Supreme Court has given no clear indication of adopting it in other cases. For that reason, this Court must decline to apply the rule. *State Farm Mut. Auto. Ins. Co. v. Ford Motor Co.*, 736 So.2d 384, 387 (Miss. Ct. App. 1999); *Walker v. Williamson*, 131 F. Supp. 3d 580, 594–95 (S.D. Miss. 2015).

CONCLUSION

Mississippi employs a liberal pleading standard through Rule 8 of the Mississippi Rules of Civil Procedure, which requires a "short and plain statement of the claim showing that the pleader is entitled to relief" and a demand for said relief. MRCP 8(a). In applying Mississippi law, the

Court finds the Amended Complaint sufficiently pled and in compliance with the Rules of Civil Procedure.

For the foregoing reasons, Distributors' Motion to Dismiss [Dkt. #44] is DENIED.

SO ORDERED AND ADJUDGED this the 5th day of April, 2021.

HONORABLE E. FAYE PETERSON
CIRCUIT COURT JUDGE

FILED
APR 06 2020
22ND JUDICIAL CIRCUIT COURT
CIRCUIT CLERK
BY MS DEPUTY

STATE OF MISSOURI)
) SS
CITY OF ST. LOUIS)

MISSOURI CIRCUIT COURT
TWENTY-SECOND JUDICIAL CIRCUIT
(City of St. Louis)

STATE OF MISSOURI, ex rel. ERIC S. SCHMITT, in his Official Capacity as Missouri Attorney General,	)	No. 1722-CC10626
Plaintiff,	)	Division No. 6
vs.	)	
PURDUE PHARMA, L.P., et al.,	)	
Defendants.	)	

ENTERED
APR 06 2020
MS

ORDER

The Court has before it Defendants Endo Health Solutions, Inc., Endo Pharmaceuticals, Inc., Janssen Pharmaceuticals, Inc., and Johnson & Johnson's (collectively "Defendants") Joint Motion to Dismiss Plaintiff's First Amended Petition for Failure to State a Claim Upon Which Relief Can Be Granted. The Court now rules as follows.

Plaintiff the State of Missouri ("the State") alleges that Defendants engaged in a fraudulent scheme to promote opioids for long-term treatment of chronic non-cancer pain, which the State argues is unsafe and ineffective. Eight of Plaintiff's claims allege violations of the Missouri Merchandising Practices Act ("MMPA")(Counts I-VIII). The State also alleges a claim brought under the Missouri Health Care Payment Fraud and Abuse Act ("HCPFAA")(Count IX), public nuisance (Count X), and two unjust enrichment claims (Counts XI & XII). The State alleges Defendants

individually and jointly disseminated false and misleading information about opioid treatment, minimizing its risks. The State specifically alleges the misrepresentations made by Defendants include:

- Defendants falsely represented that opioids pose a low risk of addiction and that patients who had not previously experienced addiction would become addicted to opioids;
- Defendants falsely represented that many individuals who exhibit signs of addiction are actually experiencing "pseudoaddiction" and doctors should treat this "pseudoaddiction" by increasing the patient's opioid use;
- Defendants misrepresented the signs of addiction and ease of preventing it;
- Defendants represented that opioids effectively produce positive long-term outcomes in cases of chronic pain;
- Defendants falsely represented the relative risks associated with non-opioid pain-relief and pain-treatment strategies; and
- Defendants targeted vulnerable populations, including senior citizens and veterans.

On August 26, 2019, Defendants along with Purdue Pharma, L.P., Purdue Pharma, Inc., and Purdue Frederick Company, Inc. ("Purdue Defendants") filed their Joint Motion to Dismiss the State's First Amended Petition. On September 16, 2019, Purdue Pharma L.P. filed a Notice of Suggestion of Bankruptcy and Automatic Stay of Proceedings with this Court, stating Purdue Pharma L.P. and affiliated debtors filed a voluntary petition for relief under Chapter 11 of the Bankruptcy Code. On December 10, 2019, Purdue Defendants filed in this case a Notice of Third Amended Preliminary Injunction Order stating that on November 6, 2019, Judge Robert D. Drain of the U.S. Bankruptcy Court for the Southern District of New York entered an order enjoining all opioid-related litigation

against the Purdue Debtors and Purdue Debtors-Related Parties (including Purdue Frederick Company) through April 8, 2020. Therefore, Defendants here agree Purdue Pharma, L.P., Purdue Pharma, Inc., and the Purdue Frederick Company, Inc., are no longer parties to this Motion to Dismiss.

A motion to dismiss for failure to state a claim is solely a test of the adequacy of the plaintiff's petition. The Court assumes that all of Plaintiff's averments are true, and liberally grants to Plaintiff all reasonable inferences therefrom. Bosch v. St. Louis Healthcare Network, 41 S.W.3d 462, 464 (Mo. banc 2001). No attempt is made to weigh any facts as to whether they are credible or persuasive. Instead, the petition is reviewed to see whether the facts alleged meet the elements of a recognized cause of action, or of a cause that might be adopted in that case. State ex rel. Henley v. Bickel, 285 S.W.3d 327, 329 (Mo. banc 2009).

I. Federal Preemption.

First, Defendants move to dismiss all counts of the State's First Amended Petition based on impossibility preemption. Defendants argue that all of the State's claims are preempted because they conflict with the FDA's regulatory determinations about the proper uses and labeling for Defendants' opioid medications. Defendants argue the State's claims would improperly hold Defendants liable for selling their medications pursuant to an FDA approved indication.

The State argues preemption is not a valid basis for a motion to dismiss, and it cannot be determined from the face of the First Amended Petition that preemption is applicable. The State argues Defendants rely on materials outside the pleadings to make their preemption arguments.

Defendants have brought this motion pursuant to Rule 55.27(a)(6). Federal preemption is an affirmative defense. See Jones v. Union Pac. R.R. Co., 508 S.W.3d 159, 160 (Mo. App. S.D. 2016). "Where an affirmative defense is asserted in a motion to dismiss, a trial court may dismiss the petition only if the petition clearly establishes on its face and without exception that the defense applies and the claim is barred." Nguyen v. Grain Valley R-5 Sch. Dist., 353 S.W.3d 725, 729 (Mo. App. W.D. 2011)(internal citations omitted); see also Allen v. Titan Propane, LLC, 484 S.W.3d 902, 905 (Mo. App. S.D. 2016). "If the court considers matters outside the pleadings, Rule 55.27(a) allows a motion to dismiss to be converted into a motion for summary judgment if certain procedures are followed." State ex rel. Cmty. Treatment, Inc. v. Missouri Comm'n on Human Rights, 561 S.W.3d 107, 112 (Mo. App. W.D. 2018).

Here, Defendants' arguments based on federal preemption rely on documents outside of the First Amended Petition, specifically the labels for Druagesic, Opana ER, Nucynta ER, Butrans, Hysingla ER, and documents relating to a citizen petition and a FDA Risk Evaluation and Mitigation Strategies (REMS). Defendants cite to case law, arguing that because the documents outside of the pleadings are on the FDA's website they are common knowledge and of public record. Therefore, Defendants argue the Court can take judicial notice of the exhibits. However, the cases cited by Defendants do not support that proposition. In any event, it is not clear under Missouri law the Court can consider those documents on a motion to dismiss even if the Court could take judicial notice of them as they are outside of the First Amended Petition.

Accordingly, it is clear that the Court must convert Defendant's Motion to Dismiss based on federal preemption into a

Motion for Summary Judgment. The Parties will be given opportunity to comply with Rule 74.04.

II. Municipal Cost Recovery Rule.

Next, Defendants contend the municipal cost recovery rule bars all of the State's claims. Defendants argue the State's claims seek recoupment of costs for the basic services the State ordinarily provides and is obligated to provide to its citizens. However, without specific authority from the legislature to recover such costs, the State is precluded from doing so under the municipal cost recovery rule.

The State argues that Missouri has never adopted what Defendants refer to as the municipal cost recovery rule. The State contends Defendants caused significant unplanned costs, and there is no State operating budget to account for these expenses, as there would be for typical government services like putting out fires.

The Court finds the case relied on by Defendants does not support a finding the municipal cost recovery rule applies in this case. In Montgomery County v. Gupton, 39 S.W. 447, 448 (Mo. 1897), the issue was whether the county could recover, from the estate of a deceased person, money spent by the county in maintaining that person during her lifetime in a state facility as a patient. The Court found it was well settled at common law that the provision made by law for the support of the poor is a charitable provision, from which no implication of a promise to repay arises, and moneys so expended cannot be recovered from the person, in the absence of fraud, without a special contract for repayment. Id. It is clear the court's finding has no bearing on this case based on the facts alleged by the State. In addition, Montgomery County was a probate case.

Further, while not binding in this case, it is worth noting that other state court judges around the country have ruled the municipal cost recovery rule does not apply "when, as alleged here, an ongoing and persistent course of intentional misconduct creates an unprecedented, man-made crisis that a governmental entity plaintiff could not have reasonably anticipated as part of its normal operating budget." In re Nat'l Prescription Opiate Litig., 1:17-MD-2804, 2019 WL 3737023, at *8 (N.D. Ohio June 13, 2019). This Court finds the same has been alleged here, an ongoing and persistent course of intentional misconduct creating a crisis that the State could not have reasonably anticipated as part of its normal operating budget. Accordingly, Defendants' Motion to Dismiss based on the municipal cost recovery rule is denied.

III. Failure to State Public Nuisance.

Next, Defendants argue that State's public nuisance claim (Count X) should be dismissed for failure to state a claim for several reasons.

a. Interference with a Public Right.

Defendants first argue the State fails to allege interference with a public right as part of its nuisance claim. Comparing this case to City of St. Louis v. Benjamin Moore & Co., 226 S.W.3d 110 (Mo. banc 2007), Defendants argue the State seeks to recoup costs it has allegedly incurred to address the use or misuse of opioids by certain individuals rather than to enforce any right belonging to the community as a whole.

The State argues the Missouri public has a common right to be free from unwarranted injuries, addictions, diseases and sicknesses caused by Defendants' misleading marketing of opioids. The State contends the alleged misconduct and harm in this case are the misrepresentations made by Defendants. The State contends

that in Benjamin Moore & Co., the harm was the actual product. Here, the harm is the Defendants' widespread deceptive marketing campaign.

"A public nuisance is any unreasonable interference with the rights common to all members of the community in general and encompasses the public health, safety, peace, morals or convenience." Benjamin Moore & Co., 226 S.W.3d at 116. "A public nuisance annoys, injures, endangers, renders insecure, interferes with, or obstructs the rights or property of the whole community." City of Lee's Summit v. Browning, 722 S.W.2d 114, 115 (Mo. App. W.D. 1986). "[A] public nuisance does not necessarily involve interference with the use and enjoyment of land." City of St. Louis v. Varahi, Inc., 39 S.W.3d 531, 536 (Mo. App. E.D. 2001). "A public nuisance that impinges upon a public right is not necessarily converted into a private nuisance because the nuisance disproportionately affects certain members of the community." City of Greenwood v. Martin Marietta Materials, Inc., 299 S.W.3d 606, 619 (Mo. App. W.D. 2009).

Here, the State has sufficiently alleged interference with the rights common to all members of the community. The State alleges that the public rights impacted in this case include the Missouri residents' right to an honest marketplace for healthcare treatment, right to public safety and order unburdened by the introduction of foreseeable dangers, such as the over-prescription and over-supply of opioids. The State alleges the repeated unlawful and unreasonable acts and omissions of the Defendants significantly interfered with the lives, health and safety of substantial numbers of Missouri residents, ruining the lives and damaging the public order and economy of Missouri. The State further alleges Defendants' campaign of deceptive marketing led to

long-lasting injury to the State and public. The State further alleges that the injury to the State and public include: opioid dependence, addiction, overdose, and death; increased or unwarranted health costs; increased public service costs to manage the harm, such as foster care and first responder costs; and lost productivity and economic harm due to increased addiction and incarceration.

In Benjamin Moore & Co., the Missouri Supreme Court found that although the City of St. Louis characterized the lawsuit as one of injury to public health, the City's damages sought were in the nature of a private tort action for costs the City allegedly incurred abating and remediating lead paint in certain properties. Benjamin Moore & Co., 226 S.W.3d at 116. The Missouri Supreme Court therefore found the City's claims to be like those of any plaintiff seeking particularized damages allegedly resulting from public nuisance. Id. Here, the damages sought by the State are for widespread public injury. The State does not seek payment for damages distinctive in kind from those suffered by the general community. In addition, the State does not simply allege the conduct impacts rights and interests of opioid users only, but rather rights and interests of the entire community.

b. Causation.

i. Actual and Proximate Cause.

Defendants also argue the State fails to allege facts showing that the nuisance was the natural and proximate cause of its alleged injury. Defendants contend the State's First Amended Petition is devoid of facts showing that Defendants' alleged marketing caused any physician to write medically unnecessary opioid prescriptions, and does not identify a single prescriber.

Defendants contend the State must identify the specific product that caused the State's injury, citing to Benjamin Moore & Co.

The State contends the nuisance in this case is the Defendants' misconduct. The State argues Defendants interfered with Missourians' public health and safety when they created and perpetuated a campaign of deceptive marketing. Therefore, the claim differs from those in Benjamin Moore & Co.

A plaintiff must show a causal link between the defendant and the alleged nuisance. Benjamin Moore & Co., 226 S.W.3d at 115. "{T]he evidence must show that defendant's acts were the proximate and efficient cause of the creation of a public nuisance." Varahi, 39 S.W.3d at 537. "It is essential to liability in either a public or private nuisance case that the defendant's acts have set in motion a force or chain of events resulting in the invasion." Id.

Here, the State alleges, in addition to those allegations already discussed above as to nuisance, Defendants, acting both individually and in concert, created and perpetuated a campaign of deceptive marketing, misleading doctors and consumers about opioids. The State alleges Defendants' actions have interfered with the health and safety of Missouri residents, ruining lives and damaging the public order and economy. The State alleges these actions led directly to an epidemic of opioid addiction and dependence, and substantial long-lasting injury to the State and the public. The State alleges at all times Defendants knew or had reason to know of the public nuisance created by their ongoing conduct. Accordingly, the Court finds that the State has sufficiently alleged causation.

This case is distinguishable from Benjamin Moore & Co. on the issue of causation as well. In Benjamin Moore & Co., the Court held that in that case, as in Zafft v. Eli Lilly & Co., 676 S.W.2d

241 (Mo. banc 1984), "where a plaintiff claims injury from a product, actual causation can be established only by identifying the defendant who made or sold that product." Benjamin Moore & Co., 226 S.W.3d at 115. Here, the alleged injury is not from the product alone. The alleged injury stems from Defendants' deceptive marketing campaign. Assuming all of Plaintiff's averments are true, and liberally granting the State all reasonable inferences therefrom, the State has alleged causation for its public nuisance claim. In addition, the damages sought by the State are not in the nature of a private tort action like those sought in Benjamin Moore & Co., as discussed above.

ii. Intervening Cause.

Next, Defendants, relying largely on the learned intermediary doctrine, contend intervening events and actors break the causal chain in this case. Defendants argue as a matter of law physicians prescribing opioid medications are presumed to have knowledge of, and to heed, warnings on these medications' product labeling. Defendants argue the State has failed to allege facts sufficient to establish that any prescriber was in fact unaware of the risks plainly described in Defendants' FDA-approved labeling, such that any alleged marketing could have deceived any doctor about the risks of prescription opioid medications. Defendants also argue any connection between Defendants' alleged marketing of FDA approved medications and the State's injuries is broken by each patient's decisions and treatment preference, the prescriber's independent judgment, and the dispenser's decision.

The State argues, in part, that the learned-intermediary doctrine does not apply because it is a defense to "failure to warn" claims, not public nuisance claims. In addition, the State argues that to the extent Defendants suggest that there were other

intermediaries that break the causal chain, Defendants raise fact-driven evidentiary issues that are not appropriate at this stage.

"The learned intermediary doctrine is a corollary to the rule that a manufacturer of prescription drugs or products discharges its duty to warn by providing the physician with information about risks associated with those products." Doe v. Alpha Therapeutic Corp., 3 S.W.3d 404, 419 (Mo. App. E.D. 1999). "The learned intermediary doctrine provides that the failure of a drug manufacturer to provide the physician with an adequate warning of the risks associated with a prescription product is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warnings should have communicated." Id. at 420, (internal quotations omitted). "Thus, the causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had substantially the same knowledge as an adequate warning from the manufacturer that should have been communicated to him." Id.

The Court finds the learned intermediary doctrine does not apply to this case based on the allegations in the First Amended Petition. The cases cited by Defendants apply the doctrine in the "failure to warn" context. Here, the State has not alleged Defendants failed to warn consumers of risks inherent in their products. Rather, at issue are Defendants' alleged misrepresentations and deceptive marketing campaigns.

Defendants also rely on Ashley Cty., Ark. v. Pfizer, Inc., 552 F.3d 659 (8th Cir. 2009) in support of their intervening cause argument. In Ashley County, the relevant issue was whether the intervening causes were the "natural and probable consequences of the Defendants' sales of cold medicine to retail stores and whether

the Counties' expenditures for government services to deal with the methamphetamine epidemic 'might reasonably have been foreseen [to the cold medication manufacturers] as probable.'" Ashley Cty., 552 F.3d at 668. In this case, the conduct at issue is not simply the selling of the product. Again, the State alleges numerous facts relating to the unlawful practices of Defendants, including misrepresentations which caused physicians to prescribe the opioids when they otherwise would not have, and patients to request and obtain opioids when they otherwise would not have. On the face of the First Amended Petition, there is not an intervening cause that breaks the causal chain.

c. Unreasonable Interference.

Next, Defendants argue the State does not plead an unreasonable interference.

Whether a particular use is reasonable or unreasonable is an issue for the jury and does not depend on exact rules but on the circumstances of each case. City of Greenwood, 299 S.W.3d at 616-17. Here, the issue of whether the interference was reasonable is not an issue the Court will consider on a motion to dismiss. The State has sufficiently alleged an unreasonable interference with a public right in this case.

d. Control over the Alleged Nuisance.

Next, Defendants argue the State fails to allege Defendants have control over the alleged nuisance. Once products enter the marketplace, a seller has no control over how purchasers or non-purchasers use it. Defendants argue the only means it could conceivably have to prevent or abate the nuisance is by ceasing sale of its lawful product. Defendants contend no Missouri court has extended public nuisance law to cover the use or misuse of

lawfully sold and highly regulated products like prescription medications.

Defendants again misconstrue the State's allegations. The State alleges Defendants' own misconduct interfered with public rights, and that conduct came prior to the sale of the product. Therefore, this case is unlike the cases cited by Defendants.

In sum, the State has stated a claim for public nuisance, and Defendants' Motion is denied as to the State's Count X of its First Amended Petition.

IV. Failure to State Unjust Enrichment.

Defendants argue the State's two unjust enrichment claims fail to state a claim.

Unjust enrichment is a quasi-contractual action. Dailing v. Hall, 1 S.W.3d 490, 492 (Mo. App. S.D. 1999). The elements of a claim of unjust enrichment are: (1) a benefit conferred upon the defendant by the plaintiff; (2) appreciation by the defendant of the fact of such benefit; and (3) acceptance and retention by the defendant of that benefit under circumstances in which retention without payment would be inequitable. Mays-Maune & Assoc., Inc. v. Werner Bros., Inc., 139 S.W.3d 201, 205 (Mo. App. E.D. 2004); Binkley v. Am. Equity Mortgage, Inc., 447 S.W.3d 194, 199 (Mo. banc 2014). Stated differently in other Missouri cases, the essential elements of unjust enrichment are: "(1) the defendant was enriched by the receipt of a benefit; (2) that the enrichment was at the expense of the plaintiff; and (3) that it would be unjust to allow the defendant to retain the benefit." Cent. Parking Sys. of Missouri, LLC v. Tucker Parking Holdings, LLC, 519 S.W.3d 485, 498 (Mo. App. E.D. 2017). The essence of a claim for unjust enrichment lies in the fact that the defendant has received a benefit which it would be inequitable for him to retain. Patrick

V. Koepke Const. v. Woodsage Const., 844 S.W.2d 508, 515 (Mo. App. E.D. 1992). "It has long been accepted that a payor's lack of care will not diminish his right to recover, or somehow justify retention of the windfall by an unintended beneficiary." Title Partners Agency, LLC v. Devisees of Last Will & Testament of M. Sharon Dorsey, 334 S.W.3d 584, 588 n. 3 (Mo. App. E.D. 2011)(internal quotations omitted). "Unjust retention of benefits only occurs when the benefits were conferred (a) in misreliance on a right or duty; or (b) through dutiful intervention in another's affairs; or (c) under constraint." Howard v. Turnbull, 316 S.W.3d 431, 436 (Mo. App. W.D. 2010).

a. The State's Count XI Unjust Enrichment Claim.

Defendants argue the benefit purportedly conferred by the State, payments for opioids and medical costs, was not conferred upon Defendants, but was conferred on third-party hospitals, physicians, and pharmacies. Defendants contend this claim is a repackaged Count IX, which the Court has already rejected. Defendants argue the State does not differentiate between the payments for opioids for acceptable uses and those with which the State disagrees with the FDA. In addition, Defendants argue the State cannot claim unjust enrichment because the State voluntarily made those payments for prescriptions that were allegedly improper, with no expectation of repayment by Defendants. Defendants also contend the State has not sufficiently alleged Defendants were enriched or received a benefit from the opioid crises.

The State argues the enrichment and expense need not be one direct transaction under Missouri law. The State contends countless other jurisdictions have recognized the viability of similar unjust enrichment claims in opioid-related cases.

The Court finds the State has alleged an unjust enrichment claim in Count XI. The State has alleged Defendants were enriched by the receipt of a benefit, namely the income and profits Defendants received, which they would not have received had Defendants not engaged in the alleged improper conduct. The State alleges facts regarding Defendants' deceptive marketing campaign.

In addition, the State has alleged that the enrichment was at the expense of the State. The State alleges Defendants participated in rebate programs with the MO HealthNet and/or Medicaid programs, and as a result of Defendants' misconduct, the State disbursed significant funds directly and/or indirectly to Defendants, including significant funds relating to opioid prescriptions written for purposes other than the treatment of acute post surgical pain, cancer treatment or end of life palliative care. The State further alleges Defendants' wrongful conduct caused opioids to be over-prescribed and improperly prescribed. The State further alleges it made payments for these improper prescriptions, and Defendants directly benefited from and appreciated those payments. Lastly, the State has alleged it would be unjust to allow Defendants to retain the benefit given the injury caused by Defendants' conduct.

b. The State's Count XII Unjust Enrichment Claim.

Next, Defendants argue Count XII also fails to state a claim because the State did not provide public services related to the opioid crisis in reliance upon any reasonable expectation that Defendants would pay for those services. Defendants did not enrich themselves or receive a benefit from the opioid crisis. Defendants argue the claim still fails if the benefit alleged is Defendants' profit from the sale of opioids and the State's expense is its costs in addressing the opioid epidemic. Defendants have never

accepted and retained the State's costs in addressing the opioid epidemic. In addition, Defendants argue the alleged benefit has no nexus to the alleged expense.

The State argues it has incurred substantial costs in mitigating the societal harms and negative externalities of Defendants' misconduct. The State argues its efforts to mitigate the negative externalities resulting from the Defendants' windfall profits also show that the Defendants' enrichment came at the State's expense. The State claims this negative externalities theory is well established nationwide.

Granting the State all reasonable inferences, the Court finds that the State has stated a claim for unjust enrichment in Count XII. The State alleges Defendants were enriched by the receipt of a benefit, the income and profits Defendants received, which they would not have received had Defendants not engaged in the alleged improper conduct. In addition, the State alleges Defendants' wrongful conduct resulted in substantial health care and public health needs directly attributable to opioid use and addiction. The State alleges it provided extensive services and bore substantial costs in response to the crises created by Defendants. The State alleges Defendants have a duty to bear and should bear the costs borne by the State. As alleged, the Defendants' enrichment was at the State's expense, as the State has incurred substantial costs by mitigating the effects of Defendants' misrepresentations and deceptive marketing campaign regarding opioids. Lastly, the State alleges it would be unjust for Defendants to retain those substantial profits while Plaintiff incurs substantial costs to mitigate the harm caused by the State.

In sum, Defendants' Motion to Dismiss is denied as to Counts XI and XII.

V. Failure to State a Claim under HCPFAA in Count IX.

In Count IX, the State alleges violations of §§ 191.900 to 191.914 RSMo against all Defendants. This claim was dismissed by the Court upon Defendants' Motion to Dismiss in its Order entered on April 25, 2018. Count IX of the First Amended Petition is identical to Count IX of the original Petition which was dismissed. Therefore, for the reasons stated in the Court's April 25, 2018 Order, the State fails to state a claim against Defendants under the HCPFAA.

THEREFORE, it is Ordered and Decreed that Endo Health Solutions, Inc., Endo Pharmaceuticals, Inc., Janssen Pharmaceuticals, Inc., and Johnson & Johnson's Joint Motion to Dismiss Plaintiff's First Amended Petition for Failure to State a Claim Upon Which Relief Can Be Granted is hereby DENIED as to Counts I-VIII, and Counts X-XII, and is hereby GRANTED as to Count IX. As to Defendants' Motion to Dismiss based on preemption, the Court hereby grants Defendants thirty (30) days from the issuance of this Order to present all materials pertinent to a summary judgment motion to the Court. Thereafter, the State shall have thirty (30) days to respond in accordance with Rule 74.04(c)(2).

SO ORDERED:

MICHAEL F. STELZER, Judge

Dated: 4/6/2020

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CLERK OF THE COURT

NEO

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DISTRICT COURT
CLARK COUNTY, NEVADA

STATE OF NEVADA, Plaintiff, v. MCKESSON CORPORATION; CARDINAL HEALTH INC.; CARDINAL HEALTH 105, INC.; CARDINAL HEALTH 108, LLC; CARDINAL HEALTH 110, LLC; CARDINAL HEALTH 200, LLC; CARDINAL HEALTH 414,LLC; CARDINAL HEALTH PHARMACY SERVICES, LLC; AMERISOURCEBERGEN DRUG CORPORATION; WALGREENS BOOTS ALLIANCE, INC.; WALGREEN CO; WALGREEN EASTERN CO, INC.; WALMART INC.; CVS PHARMACEY, INC.; TEVA PHARMACEUTICALS USA; TEVA PHARMACEUTICAL INDUSTRIES, LTD.;	Case No: A-19-796755-B Dept. No: XI NOTICE OF ENTRY OF ORDER GRANTING IN PART AND DENYING IN PART DISTRIBUTORS' JOINT MOTION TO DISMISS

Case Number: A-19-796755-B

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Defendants.

PLEASE TAKE NOTICE that the Order Granting In Part and Denying In Part Distributors' Joint Motion to Dismiss was entered on the 8th day of January 2020, a true and correct copy of the same is attached hereto.

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CERTIFICATE OF SERVICE

Pursuant to Nev. R. Civ. P. 5(b)(2)(D) and E.D.C.R. 8.05, I certify that I am an employee of MORRIS LAW GROUP and that on the date below, I caused the following document: **NOTICE OF ENTRY OF ORDER GRANTING IN PART AND DENYING IN PART DISTRIBUTORS' JOINT MOTION TO DISMISS** to be served via the Court's Odyssey E-Filing System. The date and time of the electronic proof of service is in place of the date and place of deposit in the mail.

AARON D. FORD Attorney General ERNEST FIGUEROA Consumer Advocate MARK J. KRUEGER Chief Deputy Attorney General **State of Nevada, Office of the Attorney General, Bureau of Consumer Protection** 100 North Carson Street Carson City, Nevada 89701-4717 mkrueger@ag.nv.gov MIKE PAPANTONIO TROY RAFFERTY PETER MOUGEY LAURA DUNNING NED MCWILLIAMS BRANDON BOGLE JEFF GADDY *(Pro Hac Vice Pending)* **LEVIN PAPANTONIO LAW FIRM** 316 S. Bavlen Street, Suite 400 Pensacola, Florida 32502 mpapantonio@levinlaw.com ROLAND TELLIS *(Pro Hac Vice Pending)* **BARON & BUDD** 3102 Oak Lawn Avenue, #1100 Dallas, Texas 75219	PAT LUNDVALL AMANDA C. YEN MCDONALD CARNAO LLP 2300 W. SAHARA AVE, SUITE 1200 LAS VEGAS, NEVADA 89102 lundvall@mcdonaldcarano.com ayen@mcdonaldcarano.com JOHN D. LOMBARDO (*pro hac vice* forthcoming) JAKE R. MILLER (*pro hac vice* forthcoming) ARNOLD & PORTER KAYE SCHOLER LLP 777 South Figueroa St, 44th Floor Los Angeles, CA 90017-5844 John.lombardo@arnoldporter.com Jake.miller@arnoldporter.com *Attorneys for Defendants Endo Health Solutions Inc., Endo Pharmaceuticals Inc., and Par Pharmaceutical, Inc.*

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DATED this 8th day of January 2020.

By: /a/ Patricia A. Quinn
An Employee of Morris Law Group

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DISTRICT COURT
CLARK COUNTY, NEVADA

STATE OF NEVADA,

Plaintiff,

v.

MCKESSON CORPORATION; CARDINAL HEALTH INC.; CARDINAL HEALTH 105, INC.; CARDINAL HEALTH 108, LLC; CARDINAL HEALTH 110, LLC; CARDINAL HEALTH 200, LLC; CARDINAL HEALTH 414, LLC; CARDINAL HEALTH PHARMACY SERVICES, LLC; AMERISOURCEBERGEN DRUG CORPORATION; WALGREENS BOOTS ALLIANCE, INC.; WALGREEN CO.; WALGREEN EASTERN CO., INC.; WALMART INC.; CVS HEALTH CORPORATION; CVS PHARAMCEY, INC.; TEVA PHARMACEUTICALS USA,; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; ACTAVIS PHARMA, INC; PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; PURDUE HOLDINGS, L.P.; THE PURDUE FREDERICK COMPANY, INC.; INC.; P.F. LABORATORIES, INC.; RICHARD S. SACKLER; JONATHAN D. SACKLER MORTIMER D.A. SACKLER; KATHE A. SACKLER; ILENE SACKLER LEFCOURT; DAVID A. SACKLER; BEVERLY SACKLER;

Case No.: A-1 9-796755-B

Dept. No.: XI

ORDER GRANTING IN PART AND DENYING IN PART DISTRIBUTORS' JOINT MOTION TO DISMISS

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Defendants.

This matter came on for hearing on Distributors' Joint Motion to Dismiss on December 2, 2019. Robert T. Eglet, Esq., Robert Adams, Esq., Mike Papantonio, Esq., and Mark Krueger, Esq. appeared on behalf of Plaintiff. Appearing on behalf of the Distributor Defendants were Steven Boranian, Esq. and Jarrod Rickard, Esq. for AmerisourceBergen Drug Corporation, Dan Polsenberg, Esq. on behalf of the Cardinal Health Defendants, and Rosa Solis-Rainey, Esq. on behalf of McKesson Corporation.

The Court having read and reviewed the pleadings and papers on file therein and considered the representation of counsel present at the hearing, the subsequent agreement of counsel, and good cause appearing,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the above-referenced Distributor Defendants' Joint Motion to Dismiss is granted in part and denied in part, as detailed below for each cause of action:

1. Public Nuisance – DENIED

2. Violation of Nevada Deceptive Trade Practices – DENIED
3. Violation of the Nevada Racketeering Act (NRS §§ 207.350 to 207.520) – DENIED
4. Violation of the Nevada False Claims act – THE COURT FINDS THAT THE ALLEGATIONS ARE INSUFFICIENT AT THIS TIME AND ORDERS PLAINTIFF TO CONDUCT DISCOVERY PURSUANT TO *ROCKER V. KPMG, LLP*, 148 P.3D 703 (NEV. 2006) AND TO AMEND THE CAUSE OF ACTION UPON CONCLUSION OF THE ROCKER DISCOVERY.
5. Negligence – DENIED
6. Negligence Per Se – DENIED
7. Punitive Damages - GRANTED as a separate cause of action. RPP

The Distributor Defendants shall each file their respective answers on or before January 13, 2020.[1]

DATED this 3 day of January, 2020.

DISTRICT COURT JUDGE
CEH

Submitted By:

MORRIS LAW GROUP

By: _____
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Attorneys for Defendant
McKesson Corporation

[1] Due to the holidays and with the understanding that *Rocker* discovery can take place before the answers are filed.

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IN THE COURT OF COMMON PLEAS OF DELAWARE COUNTY, PENNSYLVANIA

COUNTY OF DELAWARE, PA	:	
	:	
PLAINTIFF,	:	**CIVIL ACTION-LAW**
	:	
v.	:	**NO. CV-2017-008095**
	:	
PURDUE PHARMA L.P., et al.,	:	
	:	
DEFENDANTS.	:	
	:	

Carpenters Health and Welfare Fund of Philadelphia and Vicinity	:	
	:	**CIVIL ACTION-LAW**
PLAINTIFF,	:	
	:	**NO. CV-2017-008095 (Consolidated)**
v.	:	**NO. CV-2018-008920**
	:	
PURDUE PHARMA L.P., et al.,	:	**Philadelphia CCP NO. 108302264**
	:	
DEFENDANTS.	:	

ORDER DENYING PRELIMINARY OBJECTIONS OF MANUFACTURER DEFENDANTS JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNIEL-JANSSEN PHARMACEUTICALS, INC. (n/k/a JANSSEN PHARMACEUTICALS, INC.); JANSSEN PHARMACEUTICA, INC. (n/k/a JANSSEN PHARMACEUTICALS, INC.); ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS INC.; PAR PHARMACEUTICALS, INC.; PAR PHARMACEUTICAL COMPANIES INC.; PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; WATSON LABORATORIES, INC.; INSYS THERAPEUTICS, INC.; ALLERGAN plc f/k/a ACTAVIS plc; ALLERGAN FINANCE, LLC f/k/a ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC.; MALLINCKRODT LLC' SPECGX LLC; NORAMCO, INC.; RHODES PHARMACUEICALS L.P.; RHODES TECHNOLOGIES; RHODES TECHNOLOGIES INC.; AND RHODES PHARMACEUTICALS INC.

AND NOW, this 25 day of October 2019, in consideration of the Preliminary Objections of Manufacturer Defendants[1] Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. (n/k/a Janssen Pharmaceuticals, Inc.); Janssen

[1] Due to the filing of Suggestion of Bankruptcy, the following Defendants were severed from these matters and proceedings against them are stayed pursuant to 11 U.S.C. 362 (b): Insys Therapeutics, Inc., Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company Inc., Rhodes Technologies, Rhodes Technologies Inc., Rhodes Pharmaceuticals L.P., Rhodes Pharmaceuticals Inc., and P.F. Laboratories, Inc.

Pharmaceutica, Inc. (n/k/a Janssen Pharmaceuticals, Inc.); Endo Health Solutions Inc.; Endo Pharmaceuticals Inc.; Par Pharmaceuticals, Inc.; Par Pharmaceutical Companies Inc.; Teva Pharmaceuticals USA Inc.; Cephalon Inc.; Actavis LLC; Actavis Pharma Inc. f/k/a Watson Pharma Inc.; Watson Laboratories, Inc.; Allergan plc f/k/a Actavis plc; Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Mallinckrodt LLC' SpecGx LLC; Noramco, Inc. to Plaintiff's First Amended Complaint and Plaintiff's Response in Opposition, and Defendants' reply thereto, and a hearing on September 5, 2019, **NOW, THEREFORE**, it is hereby **ORDERED** and **DECREED** as follows;

The First Amended Complaint generally divided the Defendants' into two major categories; Manufacturer Defendants and Distributor Defendants (of which includes retailers and physicians). This order addresses the Manufacturer's Preliminary Objections.

LEGAL STANDARD

Pennsylvania is a fact-pleading jurisdiction and, therefore, a complaint must provide notice of the nature of the Plaintiff's claims and also summarize the facts upon which the claims are based. *Youndt v. First Nat'l Bank of Port Allegany*, 868 A.2d 539, 544 (Pa. Super. Ct. 2005). The material facts on which the cause of action is based should be "stated in a concise and summary form." Pa. R.C.P. 1019(a). But, "there is no requirement to plead the evidence upon which the pleader will rely to establish those facts." *Commonwealth ex rel. Shapiro v. Golden Gate Nat'l Senior Care LLC*, 194 A.3d 1010, 1029 (Pa. 2018) (citing *United Refrigerator Co. v. Applebaum*, 189 A.2d 253, 255 (Pa. 1963))). "Averments of fraud or mistake shall be averred with particularity," while "[m]alice, intent, knowledge, and other conditions of mind may be averred generally." Pa. R.C.P. 1019(b). The purpose of a complaint is to disclose material facts sufficient to notify the adverse party of the claims it will have to defend against. *See Martin v. Lancaster Battery Co.*, 606 A.2d 444, 448 (Pa. 1992); *Landau v. W. Pa. Nat'l Bank*, 282 A.2d 335, 339 (Pa. 1971). To determine whether a claim has been pled with the required specificity, the allegations must be viewed in the context of the pleading as a whole. See *Yacoub v. Lehigh Valley Med. Assocs., P.C.*, 805 A.2d 579, 589 (Pa. Super. Ct. 2002) (en banc).

When considering preliminary objections, courts must accept as true all well pleaded allegations and any reasonable inferences drawn from those allegations. *See Bayada Nurses, Inc. v. Commonwealth, Dep't of Labor & Indus.*, 8 A.3d 866, 884 (Pa. 2010). The question presented by a demurrer "is whether, on the facts averred, the law says with certainty that no recovery is possible. Where a doubt exists as to whether a demurrer should be sustained, this doubt should be resolved in favor of overruling it." *Vattimo v. Lower Bucks Hosp., Inc.*, 465 A.2d 1231, 1232-33 (Pa. 1983) (citation omitted).

FINDINGS AND CONCLUSIONS

1. The September 14, 2018 Case Management Order No. 1 ordered that the Carpenter's Plaintiff will be one of four "test cases" for Preliminary Objections and included Delaware County, Carbon County, (two counties/municipal plaintiffs) and the Commonwealth of Pennsylvania, acting by and through the District Attorney of Philadelphia.
2. This Court entertained extensive argument on September 5, 2019 on all outstanding Preliminary Objections pertaining to the Carpenters Health and Welfare Fund of Philadelphia and Vicinity v. Purdue Pharma, L.P., et. al., as captioned above.

3. The Plaintiff's Complaint sufficiently alleges negligent conduct and conspiracy among Defendants to mislead the public and doctors by false and misrepresented claims, and information, false advertisements, fraudulent sales, failing to effectively monitor and identify and report suspicious order(s), and failing to adequately control the supply chain of opioid products and prevent diversion, causing damages related to health care, costs, increased costs of workers' compensation claims, damages related to lost productivity and damages related to opioid abuse and addition.
4. The Amended Complaint sufficiently puts all Defendants on notice of the nature of all claims against them and summarizes the facts upon which these claims are based, including causes of action as a result of co-conspirator liability.
5. **Defendants' Derivative Injury Claim:**
    a. As this Plaintiff is a Third-Party Payor, seeking healthcare and other costs and expenses, the Defendant(s) plea that the "derivative injury rule", as they also refer to the "remoteness doctrine" prohibits the Plaintiff's claims because defendant's acts stand too remote a distance to recover and injury characterized as indirect.
    b. The Plaintiff fund alleges that it suffered a direct injury caused by the Defendant's conduct and actions, and fact questions remain outstanding, requiring discovery, and left to the trier of facts.
    c. This Court finds that the Plaintiff may seek recovery of their direct costs and excess costs as they arise directly from the Plaintiff's role as the business entity that paid for the drugs, suffered the loss and financial injury, and from which the Defendants may have relied upon for payment(s) of the Defendant(s) products. This burden of proof remains with the Plaintiff. The proven costs that Plaintiff incurred, arising directly from Defendants alleged wrongful conduct, pleaded to constitute a direct injury for which the Plaintiff may seek recovery and the Preliminary Objections are denied.
6. **Defendants' Preemption Claims:**
    a. The Defendants file Preliminary Objections on the issue of Federal Preemption of state law claims, arguing that Plaintiff's outstanding claims are preempted because they conflict with regulations and decisions of the Food and Drug Administration (FDA) regarding approval and labeling of prescription opiates.
    b. Plaintiffs allege that the Manufacturers promoted their drugs through false and misleading statements that were not part of the FDA approved label and that the FDA did not require them to make. Plaintiff alleges that these misrepresentations and omissions are misleading and contrary to the Manufacturers Defendants products labeling. Such alleged claims of false and deception marketing are not preempted at this stage in this proceeding.
    c. The Plaintiff's causes of Action, if successful, do not thereafter or become an obstacle to the accomplishment and exception of the purposes and objections of Federal Legislation and regulations of the FDA.
    d. The Plaintiffs cause of action and allegations thereto, do not challenge FDA approved labeling and preemption does not bar Plaintiff's claims founded upon allegations of misleading fraudulent and deceptive marketing, sales, distribution, and advertising activities that allegedly distorted and withheld

information about their drugs in order to harm Plaintiff by convincing physicians, pharmacies and individuals that their opioids were safe and effective for the treatment of pain, and further alleges inadequate monitoring and anti-diversion activities.

7. **Public Nuisance Claim:**
   a. The Defendant(s) plead that the Plaintiff's public nuisance claim should be dismissed for failing to allege a "special harm" that is "different in kind" from the public at large, and only public authorities may sue to redress a public nuisance, and the Plaintiffs alleged injury is not "special" and a claim for public nuisance has no basis in the law and should be dismissed.
   b. The Court finds a litany of precedent cases confirming that a private entity has standing to bring a public nuisance claim and a private action for a public nuisance is maintainable by one who suffers a direct particular loss or damage beyond that suffered by him in common with all others affected by the nuisance.
   c. The Amended Complaint sufficiently pled that the Plaintiff has allegedly suffered particular injury beyond that suffered by the general public as the result of the actions and conduct of the Defendants.
   d. The Plaintiff's alleged suffered injury and loss are the unnecessary and excessive prescriptions, treatment, medical services, expenses and costs, incurred specifically and particularly by the Plaintiff, and not costs paid for by members of the general public. This alleged separate, specific and particular loss and injury to the Plaintiff is sufficient to provide standing to seek damages for injuries directly caused by the public nuisance if Defendant(s) are proven to have caused and created the injury and damages; and the Preliminary Objections are dismissed.
8. This Court has jurisdiction over all the claims presented in the Amended Complaint and the Complaint does not fail to conform to the rule of law and rules of procedure and sufficiently pleads with specificity.
9. The Plaintiff sufficiently pleads the capacity to bring this suit and the Amended Complaint sufficiently pleads liability on the part of each Manufacturer Defendant for each cause of action, including as a result of co-conspirator liability.
10. Limited to the Court's Standard of Review for Preliminary Objections, the Plaintiff sufficiently pleads claims for relief, not preempted by the FDA's Regulation of Opioids, sufficiently pleads causation and standing to bring negligence, consumer and common law fraud, and public nuisance claims.
11. The Plaintiff sufficiently pleads and provides notice of all causes of action, including negligence, negligence per se, public nuisance, unjust enrichment, fraud, express and implied warranty, civil conspiracy, and violations of the Uniform Trade Practices and Consumer Protection Law (UTPCPL), including sufficient allegations of causation and damages. This Court further finds that the Amended Complaint sufficiently alleges a claim under the Uniform Trade Practices and Consumer Protection Law (UTPCPL). Allegations that Defendants not only failed to warn of all potential damages of excess use of Opioids of which they were aware, but also knowingly and intentionally misled physicians with false information, alleged to be a foundation for UTPCPL claims.

12. The Plaintiff sufficiently pleads a claim for unjust enrichment and claims for civil conspiracy of all claims of action.
13. The Plaintiff has standing to assert various unfair or deceptive acts and practices declared to be unlawful under section 201-3 of the UTPCPL (73 Pa. Cons. Stat 201)
14. Defendants request to strike references to prior settlement agreements remain a Motion in Limine and shall be addressed prior to trial.
15. As to all the various causes of action, the Court notes, at trial, the trial Judge will have an opportunity to reevaluate the sufficiency of the evidence as to each Defendant and nothing in this Order prevents the Court from granting summary judgment or other relief as a matter of law, if warranted.

This Courts' findings as set forth above are limited to the standard required for the Courts review of the Preliminary Objections, and are not dispositive of Motions for Summary Judgment that may or may not be approved upon the completion of discovery.

Therefore, for all the foregoing reasons, the Court hereby **DENIES** the named Manufacturer Defendants' Preliminary Objections to the Amended Complaint.

BY THE COURT:

J. Barry C. Dozor

-IN THE COURT OF COMMON PLEAS OF DELAWARE COUNTY, PENNSYLVANIA

COUNTY OF DELAWARE, PA	:	
	:	
PLAINTIFF,	:	**CIVIL ACTION-LAW**
	:	
v.	:	**NO. CV-2017-008095**
	:	
PURDUE PHARMA L.P., et al.,	:	
	:	
DEFENDANTS.	:	
	:	
Carpenters Health and Welfare Fund of Philadelphia and Vicinity	:	
	:	**CIVIL ACTION-LAW**
PLAINTIFF,	:	
	:	**NO. CV-2017-008095 (Consolidated)**
v.	:	**NO. CV-2018-008920**
	:	
PURDUE PHARMA L.P., et al.,	:	**Philadelphia CCP NO. 180302264**
	:	
DEFENDANTS.	:	

ORDER DENYING PRELIMINARY OBJECTIONS OF MANUFACTURER DEFENDANTS ALLERGAN PLC f/k/a ACTAVIS PLC AND ALLERGAN FINANCE, LLC f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.

AND NOW, this 4th day of December 2019, in consideration of the Preliminary Objections of the Defendants, Allergan PLC f/k/a Actavis PLC and Allergan Finance, LLC f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc. to Plaintiff's First Amended Complaint, and Plaintiff's Response in Opposition, and Defendants' sur reply thereto, and argument on September 5, 2019, **NOW, THEREFORE**, it is hereby **ORDERED** and **DECREED** as follows;

The First Amended Complaint generally divided the Defendants' into two major categories; Manufacturer Defendants and Distributor Defendants (of which includes retailers). This order addresses the above-mentioned Manufacturers' Preliminary Objections.

LEGAL STANDARD

Pennsylvania is a fact-pleading jurisdiction and, therefore, a complaint must provide notice of the nature of the Plaintiff's claims and also summarize the facts upon which the claims are based. *Youndt v. First Nat'l Bank of Port Allegany*, 868 A.2d 539, 544 (Pa. Super. Ct. 2005). The material facts on which the cause of action is based should be "stated in a concise and summary form." Pa. R.C.P. 1019(a). But, "there is no requirement to plead the evidence upon which the pleader will rely to establish those facts." *Commonwealth ex rel. Shapiro v. Golden Gate Nat'l Senior Care LLC*, 194 A.3d 1010, 1029 (Pa. 2018) (citing *United Refrigerator Co. v. Applebaum*, 189 A.2d 253, 255 (Pa. 1963))). "Averments of fraud or mistake shall be averred

with particularity," while "[m]alice, intent, knowledge, and other conditions of mind may be averred generally." Pa. R.C.P. 1019(b). The purpose of a complaint is to disclose material facts sufficient to notify the adverse party of the claims it will have to defend against. *See Martin v. Lancaster Battery Co.*, 606 A.2d 444, 448 (Pa. 1992); *Landau v. W. Pa. Nat'l Bank*, 282 A.2d 335, 339 (Pa. 1971). To determine whether a claim has been pled with the required specificity, the allegations must be viewed in the context of the pleading as a whole. See *Yacoub v. Lehigh Valley Med. Assocs., P.C.*, 805 A.2d 579, 589 (Pa. Super. Ct. 2002) (en banc).

When considering preliminary objections, courts must accept as true all well pleaded allegations and any reasonable inferences drawn from those allegations. *See Bayada Nurses, Inc. v. Commonwealth, Dep't of Labor & Indus.*, 8 A.3d 866, 884 (Pa. 2010). The question presented by a demurrer "is whether, on the facts averred, the law says with certainty that no recovery is possible. Where a doubt exists as to whether a demurrer should be sustained, this doubt should be resolved in favor of overruling it." *Vattimo v. Lower Bucks Hosp., Inc.*, 465 A.2d 1231, 1232-33 (Pa. 1983) (citation omitted).

FINDINGS AND CONCLUSIONS

1. The September 14, 2018 Case Management Order No. 1 ordered that the Carpenter's Plaintiff will be one of four "test cases" for Preliminary Objections and included Delaware County, Carbon County, (two counties/municipal plaintiffs) and the Commonwealth of Pennsylvania, acting by and through the District Attorney of Philadelphia.
2. This Court entertained extensive argument on September 5, 2019 on all outstanding Preliminary Objections pertaining to the Carpenters Health and Welfare Fund of Philadelphia and Vicinity v. Purdue Pharma, L.P., et. al., as captioned above.
3. The Plaintiff has properly reinstated the Amended Complaint pursuant to Pa. R.C.P. 401(b)(1) and the parties have stipulated to service being completed, and forego any further objection to service.
4. The Amended Complaint alleges sufficient personal jurisdiction over Defendant Allergan PLC and minimum contacts with the Commonwealth of Pennsylvania.
5. The Plaintiff's Amended Complaint sufficiently alleges negligent conduct and details a conspiracy among Defendants to mislead the public and doctors by false and misrepresented claims, and information, false advertisements, fraudulent sales, failing to effectively monitor and identify and report suspicious order(s), and failing to adequately control the supply chain of opioid products and prevent diversion, causing damages related to health care, costs, increased costs of workers' compensation claims, damages related to lost productivity and damages related to opioid abuse and addition.
6. The Amended Complaint sufficiently puts all Defendants on notice of the nature of all claims against them and summarizes the facts upon which these claims are based, including causes of action as a result of co-conspirator liability.
7. This Court has jurisdiction over all the claims presented in the Amended Complaint and the Complaint does not fail to conform to the rule of law and rules of procedure and sufficiently pleads with specificity.
8. Allergan Defendants are referred to as a part of "Actavis" in the Amended Complaint, and with sufficient notice and description of tortious conduct, all allegations in the Amended Complaint that refer to Actavis also refers to the Allergan Defendants. The

burden of proof of such remains with the Plaintiff. The Amended Complaint also sufficiently established jurisdiction and liability over the Allergan and Actavis Defendants for each cause of action as a result of co-conspirator liability on the part of Manufacturer and Distributors' co-conspirator liability.

9. As to all the various causes of action, the Court notes, at trial, the trial Judge will have an opportunity to reevaluate the sufficiency of the evidence as to each Defendant and nothing in this Order prevents the Court from granting judgment as a matter of law, if warranted.

This Courts' findings as set forth above are limited to the standard required for the Courts review of the Preliminary Objections, and are not dispositive of Motions for Summary Judgment that may or may not be approved upon the completion of discovery.

Therefore, for all the foregoing reasons, the Court hereby **DENIES** the Manufacturer Defendants' Preliminary Objections to the Amended Complaint.

BY THE COURT:

J. Barry C. Dozor

FILED
12-04-2019 05:06 PM
OFFICE OF JUDICIAL SUPPORT
DELAWARE COUNTY, PA

IN THE COURT OF COMMON PLEAS OF DELAWARE COUNTY, PENNSYLVANIA

COUNTY OF DELAWARE, PA	:	
	:	
PLAINTIFF,	:	**CIVIL ACTION-LAW**
	:	
v.	:	**NO. CV-2017-008095**
	:	
PURDUE PHARMA L.P., et al.,	:	
	:	
DEFENDANTS.	:	
	:	

Carpenters Health and Welfare Fund of Philadelphia and Vicinity	:	
	:	
	:	**CIVIL ACTION-LAW**
PLAINTIFF,	:	
	:	**NO. CV-2017-008095 (Consolidated)**
v.	:	**NO. CV-2018-008920**
	:	
PURDUE PHARMA L.P., et al.,	:	**Philadelphia CCP NO. 180302264**
	:	
DEFENDANTS.	:	

ORDER DENYING PRELIMINARY OBJECTIONS OF DISTRIBUTOR DEFENDANTS' AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; AND MCKESSON CORPORATION

AND NOW, this 4th day of December 2019, in consideration of the Preliminary Objections of the Distributor Defendants' AmerisourceBergen Drug Corporation; Cardinal Health Inc.; and McKesson Corporation to Plaintiff's First Amended Complaint, and Plaintiff's Response in Opposition, and any reply thereto, and a hearing on September 5, 2019, **NOW, THEREFORE,** it is hereby **ORDERED** and **DECREED** as follows;

LEGAL STANDARD

Pennsylvania is a fact-pleading jurisdiction and, therefore, a complaint must provide notice of the nature of the Plaintiff's claims and also summarize the facts upon which the claims are based. *Youndt v. First Nat'l Bank of Port Allegany*, 868 A.2d 539, 544 (Pa. Super. Ct. 2005). The material facts on which the cause of action is based should be "stated in a concise and summary form." Pa. R.C.P. 1019(a). But, "there is no requirement to plead the evidence upon which the pleader will rely to establish those facts." *Commonwealth ex rel. Shapiro v. Golden Gate Nat'l Senior Care LLC*, 194 A.3d 1010, 1029 (Pa. 2018) (citing *United Refrigerator Co. v. Applebaum*, 189 A.2d 253, 255 (Pa. 1963))). "Averments of fraud or mistake shall be averred with particularity," while "[m]alice, intent, knowledge, and other conditions of mind may be averred generally." Pa. R.C.P. 1019(b). The purpose of a complaint is to disclose material facts

sufficient to notify the adverse party of the claims it will have to defend against. *See Martin v. Lancaster Battery Co.*, 606 A.2d 444, 448 (Pa. 1992); *Landau v. W. Pa. Nat'l Bank*, 282 A.2d 335, 339 (Pa. 1971). To determine whether a claim has been pled with the required specificity, the allegations must be viewed in the context of the pleading as a whole. See *Yacoub v. Lehigh Valley Med. Assocs., P.C.*, 805 A.2d 579, 589 (Pa. Super. Ct. 2002) (en banc).

When considering preliminary objections, Courts must accept as true all well pleaded allegations and any reasonable inferences drawn from those allegations. *See Bayada Nurses, Inc. v. Commonwealth, Dep't of Labor & Indus.*, 8 A.3d 866, 884 (Pa. 2010). The question presented by a demurrer "is whether, on the facts averred, the law says with certainty that no recovery is possible. Where a doubt exists as to whether a demurrer should be sustained, this doubt should be resolved in favor of overruling it." *Vattimo v. Lower Bucks Hosp., Inc.*, 465 A.2d 1231, 1232-33 (Pa. 1983) (citation omitted).

Findings and Conclusion

1. The September 14, 2018 Case Management Order No. 1 ordered that the Carpenter's Plaintiff be one of four "test cases" for Preliminary Objections and included Delaware County, Carbon County, (two counties/municipal plaintiffs) and the Commonwealth of Pennsylvania, acting by and through the District Attorney of Philadelphia.
2. This Court entertained extensive argument on September 5, 2019 on all outstanding Preliminary Objections pertaining to the Carpenters Health and Welfare Fund of Philadelphia and Vicinity v. Purdue Pharma, L.P., et. al., as captioned above.
3. The Plaintiff's Complaint alleges negligent conduct and further details a conspiracy among Defendants to mislead the public and doctors by false and mispresented claims, negligent marketing, failing to effectively monitor and identify and report suspicious orders, and failing to adequately control the supply chain of opioid products and prevent diversion, causing damages related to health care costs, increased cost of workers' compensation claims, damages related to lost productivity, and damages related to opioid abuse and addiction.
4. The Amended Complaint sufficiently states all claims against the Distributor Defendants.
5. Plaintiff's Amended Complaint alleges and details a conspiracy among Defendants and sufficiently states all claims against the Distributor Defendants.
6. The Plaintiff sufficiently pleads damages alleged in the Amended Complaint and directly suffered by Plaintiff.
7. The Court further finds that the question of proximate causation is left to the finder of fact.
8. The Court further finds that the Amended Complaint adequately alleges causation, causing effect, proximate cause, damages, and conspiratory conduct and liability.
9. **Public Nuisance Claim:**
    a. The Defendant(s) plead that the Plaintiff's public nuisance claim should be dismissed for failing to allege a "special harm" that is "different in kind" from the public at large, and only public authorities may sue to redress a public nuisance, and that the Plaintiffs alleged injury is not "special" and a claim for public nuisance has no basis in the law and should be dismissed.

b. The Court finds a litany of precedent confirming that a private entity has standing to bring a public nuisance claim and a private action for a public nuisance is maintainable by one who suffers a direct particular loss or damage beyond that suffered by him in common with all others affected by the nuisance.
c. The Amended Complaint sufficiently pled that the Plaintiff has suffered particular injury beyond that suffered by the general public as the result of the alleged actions and conduct of the Defendants.
d. The Plaintiff's alleged injury and loss are the unnecessary and excessive prescriptions, treatment, medical services, expenses and costs, incurred specifically and particularly by the Plaintiff, and not costs paid for by members of the general public. This alleged separate, specific and particular loss and injury to the Plaintiff is sufficient to provide standing to seek damages for injuries directly caused by the public nuisance if Defendant(s) are proven to have caused and created the injury and damages.

10. Defendants' Derivative Injury Claim:

a. As this Plaintiff is a Third-Party Payor, seeking healthcare and other costs and expenses, the Defendant(s) plead that the "derivative injury rule", as they also refer to the "remoteness doctrine" prohibit the Plaintiff's claims because Defendant's acts stand too remote a distance to recover and injury characterized as indirect.
b. The Plaintiff Fund alleges that it suffered a direct injury caused by the Defendants' conduct and actions, and fact questions remain outstanding, requiring discovery, and left to the trier of facts.
c. This Court finds that the Plaintiff may seek recovery of their alleged direct and excess costs as they arise directly from the Plaintiff's role as the business entity that paid for the drugs, sustained the loss and financial injury, and from which the Defendants may have relied upon for payment(s) of the Defendant(s) products. This burden of proof remains with the Plaintiff. The proven costs that Plaintiff incurred, arising directly from Defendants alleged wrongful conduct, constitute a direct injury for which the Plaintiff may seek recovery.

11. Again, with the Court limited to the standard for reviewing Preliminary Objections, the Amended Complaint provides notice and sufficiently states a claim(s) for all causes of action, including negligence, negligence per se, public nuisance, unjust enrichment, fraud, and civil conspiracy.

12. As to all the various causes of action, the Court notes, at trial, the trial Judge will have an opportunity to reevaluate the sufficiency of the evidence as to each Defendant and nothing in this Order prevents the Court from granting judgment as a matter of law, if warranted.

This Courts' findings as set forth above are limited to the standard required for the Courts review of the Preliminary Objections, and are not dispositive of Motions for Summary Judgment that may or may not be approved upon the completion of discovery.

For all foreby reasons the Distributor Defendants' Preliminary Objections to the Amended Complaint are **DENIED** in their entirety.

BY THE COURT:

J. Barry C. Dozor

FILED
12-04-2019 04:43 PM
OFFICE OF JUDICIAL SUPPORT
DELAWARE COUNTY, PA

IN THE COURT OF COMMON PLEAS OF DELAWARE COUNTY, PENNSYLVANIA

COUNTY OF DELAWARE, PA	:	
	:	
PLAINTIFF,	:	**CIVIL ACTION-LAW**
	:	
v.	:	**NO. CV-2017-008095**
	:	
PURDUE PHARMA L.P., et al.,	:	
	:	
DEFENDANTS.	:	
	:	
Carpenters Health and Welfare Fund of Philadelphia and Vicinity	:	
	:	**CIVIL ACTION-LAW**
PLAINTIFF,	:	
	:	**NO. CV-2017-008095 (Consolidated)**
v.	:	**NO. CV-2018-008920**
	:	
PURDUE PHARMA L.P., et al.,	:	**Philadelphia CCP NO. 180302264**
	:	
DEFENDANTS.	:	

ORDER DENYING PRELIMINARY OBJECTIONS OF DEFENDANTS' TEVA PHARMACEUTICALS USA, INC. AND CEPHALON, INC.

AND NOW, this 4th day of December 2019, in consideration of the Preliminary Objections of Defendants' Teva Pharmaceuticals USA, Inc. and Cephalon, Inc. to Plaintiff's First Amended Complaint and Plaintiff's Response in Opposition, and Defendants' response thereafter, and a hearing on September 5, 2019, **NOW THEREFORE**, it is hereby **ORDERED** and **DECREED** as follows;

LEGAL STANDARD

Pennsylvania is a fact-pleading jurisdiction and, therefore, a complaint must provide notice of the nature of the Plaintiff's claims and also summarize the facts upon which the claims are based. *Youndt v. First Nat'l Bank of Port Allegany*, 868 A.2d 539, 544 (Pa. Super. Ct. 2005). The material facts on which the cause of action is based should be "stated in a concise and summary form." Pa. R.C.P. 1019(a). But, "there is no requirement to plead the evidence upon which the pleader will rely to establish those facts." *Commonwealth ex rel. Shapiro v. Golden Gate Nat'l Senior Care LLC*, 194 A.3d 1010, 1029 (Pa. 2018) (citing *United Refrigerator Co. v. Applebaum*, 189 A.2d 253, 255 (Pa. 1963))). "Averments of fraud or mistake shall be averred with particularity," while "[m]alice, intent, knowledge, and other conditions of mind may be averred generally." Pa. R.C.P. 1019(b). The purpose of a complaint is to disclose material facts sufficient to notify the adverse party of the claims it will have to defend against. *See Martin v.*

Lancaster Battery Co., 606 A.2d 444, 448 (Pa. 1992); *Landau v. W. Pa. Nat'l Bank*, 282 A.2d 335, 339 (Pa. 1971). To determine whether a claim has been pled with the required specificity, the allegations must be viewed in the context of the pleading as a whole. See *Yacoub v. Lehigh Valley Med. Assocs., P.C.*, 805 A.2d 579, 589 (Pa. Super. Ct. 2002) (en banc).

When considering preliminary objections, Courts must accept as true all well pleaded allegations and any reasonable inferences drawn from those allegations. *See Bayada Nurses, Inc. v. Commonwealth, Dep't of Labor & Indus.*, 8 A.3d 866, 884 (Pa. 2010). The question presented by a demurrer "is whether, on the facts averred, the law says with certainty that no recovery is possible. Where a doubt exists as to whether a demurrer should be sustained, this doubt should be resolved in favor of overruling it." *Vattimo v. Lower Bucks Hosp., Inc.*, 465 A.2d 1231, 1232-33 (Pa. 1983) (citation omitted).

FINDINGS AND CONCLUSIONS

1. The September 14, 2018 Case Management Order No.1 ordered that the Carpenters' Plaintiff be one of four "test cases" for Preliminary Objections and included Delaware County, Carbon County, (two counties/municipal plaintiffs) and the Commonwealth of Pennsylvania, acting by and through the District Attorney of Philadelphia.
2. This Court entertained extensive argument on September 5, 2019 on all Preliminary Objections pertaining to Carpenters Health and Welfare Fund of Philadelphia and Vicinity v. Purdue Pharma, L.P., et al., as captioned above.
3. This Court finds that the Plaintiff has plead all its causes of action, including, its fraud-based claims against the Teva and Cephalon Defendants with sufficient specificity and particularity as the precedent and Rules of Procedure require.
4. The Plaintiff alleges that Defendant Teva and Defendant Cephalon worked together to manufacture, promote, distribute, and sell both brand name and generic versions of opioids nationally and in Philadelphia County, Pennsylvania. The Amended Complaint further alleges that Defendant Cephalon made thousands of payments to physicians for various activities in deceptively and illegally marketing opioids designed to expand the market, causing injury and damage to Plaintiff.
5. The pleadings adequately explained the nature of the claim to the opposing party so as to permit the Defendants to prepare a defense.
6. The Amended Complaint specifically alleges that the Defendants' false and misleading statements, actions, and misconduct directly caused harm to Plaintiff.
7. For the purpose of reviewing the standard for the Courts review of Preliminary Objections, Plaintiff has adequately pled causation with respect to the Teva and Cephalon Inc. Defendants and Plaintiff's claims against the Teva and Cephalon Inc. Defendants do not fail for lack of an injury, nor are Plaintiff's claims preempted by the FDA's Regulation of Opioids nor barred by the Statute of Limitations.
8. The Plaintiff has sufficiently alleged misconduct, negligence, (etc), fraud, civil co-conspirator liability, and the Amended Complaint is not required to identify specific Doctors.
9. Plaintiff has adequately alleged that Defendants' conduct gives rise to this lawsuit. The allegations, sufficiently pled Defendants' alleged fraudulent misleading marketing campaign, including the alleged untruthful promoting of the off-label use

of an FDA-approved drug(s), and the Amended Complaint is not defective as a matter of law, but shall be left to a finder of fact.

10. With regards to Defendants' claims that they are not liable for statements of third parties and whether an agency or relationship exist or existed between the Teva and Cephalon Inc., these issues are a question of fact and not appropriate for determination at this stage of the proceedings, and the fraud allegations are presently sufficient to assert liability of third party statements.
11. The Court further finds that the Plaintiff has adequately pled causation with respect to the Defendants' injury and causation is sufficiently pled for harm and injury, including economic loss is appropriately pled. Plaintiff's claims are not preempted by the FDA's Regulation of Opioids, nor barred by the Statute of Limitations.
12. **Defendants' Preemption Claims:**
    a. The Defendants filed Preliminary Objections on the issue of Federal Preemption of state law claims, arguing that Plaintiff's outstanding claims are preempted because they conflict with regulations and decisions of the Food and Drug Administration (FDA) regarding approval and labeling of prescription opiates.
    b. Plaintiffs allege that the Manufacturers promoted their drugs through false and misleading statements that were not part of the FDA approved label and that the FDA did not require them to make. Plaintiff alleges that these misrepresentations and omissions are misleading and contrary to the Manufacturers Defendants products labeling. Such alleged claims of false and deception marketing are not preempted.
    c. The Plaintiff's causes of Action, if successful, do not thereafter or become an obstacle to the accomplishment and exception of the purposes and objections of Federal Legislation and regulations of the FDA.
    d. The Plaintiff's cause of Action and allegations thereto, do not challenge FDA approved labeling and preemption does not bar Plaintiff's claims founded upon allegations of misleading fraudulent and deceptive marketing, sales, distribution, and advertising activities that allegedly distorted and withheld information about their drugs in order to harm Plaintiff by convincing physicians, pharmacies and individuals that their opioids were safe and effective for the treatment of pain, and further alleges inadequate monitoring and anti-diversion activities.
13. As the Plaintiff's claims are of ongoing tortious actions and conspiracy with other Defendants, the Preliminary Objections as to the Statute of Limitations is denied. The Defendants failed to establish, at this time, a Statute of Limitations for public nuisance. Furthermore, as a result of the allegations of Defendants conspiracy being ongoing, the "continuing violations doctrine", discovery required, and the allegations of fraudulent concealment, the Preliminary Objections are Denied.

This Court's findings as set forth above are limited to the standard required for the Courts review of Preliminary Objections, and are not dispositive of Motions for Summary Judgment that may or may not be appropriate upon the completion of discovery.

For the foregoing reasons all set forth herein, the Teva and Cephalon Inc. Defendants' Preliminary Objections to the Amended Complaint are **DENIED** in its entirety.

BY THE COURT:

J. Barry C. Dozor

FILED
12-04-2019 04:53 PM
OFFICE OF JUDICIAL SUPPORT
DELAWARE COUNTY, PA

IN THE COURT OF COMMON PLEAS OF DELAWARE COUNTY, PENNSYLVANIA

COUNTY OF DELAWARE, PA	:	
	:	
PLAINTIFF,	:	**CIVIL ACTION-LAW**
	:	
v.	:	**NO. CV-2017-008095**
	:	
PURDUE PHARMA L.P., et al.,	:	
	:	
DEFENDANTS.	:	
	:	
Carpenters Health and Welfare Fund of Philadelphia and Vicinity	:	
	:	**CIVIL ACTION-LAW**
PLAINTIFF,	:	
	:	**NO. CV-2017-008095 (Consolidated)**
v.	:	**NO. CV-2018-008920**
	:	
PURDUE PHARMA L.P., et al.,	:	**Philadelphia CCP NO. 180302264**
	:	
DEFENDANTS.	:	

ORDER DENYING PRELIMINARY OBJECTIONS OF DEFENDANTS WATSON LABORATORIES, INC.; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; AND ACTAVIS LLC.

AND NOW, this 4th day of Dec 2019, in consideration of the Preliminary Objections of Defendants Watson Laboratories, Inc.; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; and Actavis LLC to Plaintiff's First Amended Complaint and Plaintiff's Response in Opposition, and Defendants sur reply thereafter, and argument on September 5, 2019, **NOW, THEREFORE**, it is hereby **ORDERED** and **DECREED** as follows;

LEGAL STANDARD

Pennsylvania is a fact-pleading jurisdiction and, therefore, a complaint must provide notice of the nature of the Plaintiff's claims and also summarize the facts upon which the claims are based. *Youndt v. First Nat'l Bank of Port Allegany*, 868 A.2d 539, 544 (Pa. Super. Ct. 2005). The material facts on which the cause of action is based should be "stated in a concise and summary form." Pa. R.C.P. 1019(a). But, "there is no requirement to plead the evidence upon which the pleader will rely to establish those facts." *Commonwealth ex rel. Shapiro v. Golden Gate Nat'l Senior Care LLC*, 194 A.3d 1010, 1029 (Pa. 2018) (citing *United Refrigerator Co. v. Applebaum*, 189 A.2d 253, 255 (Pa. 1963))). "Averments of fraud or mistake shall be averred with particularity," while "[m]alice, intent, knowledge, and other conditions of mind may be averred generally." Pa. R.C.P. 1019(b). The purpose of a complaint is to disclose material facts

sufficient to notify the adverse party of the claims it will have to defend against. *See Martin v. Lancaster Battery Co.*, 606 A.2d 444, 448 (Pa. 1992); *Landau v. W. Pa. Nat'l Bank*, 282 A.2d 335, 339 (Pa. 1971). To determine whether a claim has been pled with the required specificity, the allegations must be viewed in the context of the pleading as a whole. See *Yacoub v. Lehigh Valley Med. Assocs., P.C.*, 805 A.2d 579, 589 (Pa. Super. Ct. 2002) (en banc).

When considering preliminary objections, courts must accept as true all well pleaded allegations and any reasonable inferences drawn from those allegations. *See Bayada Nurses, Inc. v. Commonwealth, Dep't of Labor & Indus.*, 8 A.3d 866, 884 (Pa. 2010). The question presented by a demurrer "is whether, on the facts averred, the law says with certainty that no recovery is possible. Where a doubt exists as to whether a demurrer should be sustained, this doubt should be resolved in favor of overruling it." *Vattimo v. Lower Bucks Hosp., Inc.*, 465 A.2d 1231, 1232-33 (Pa. 1983) (citation omitted).

FINDINGS AND CONCLUSIONS

1. The September 14, 2018 Case Management Order No.1 ordered that the Carpenter's Plaintiff will be one of four "test cases" for Preliminary Objections and included Delaware County, Carbon County, (two counties/municipal plaintiffs) and the Commonwealth of Pennsylvania, acting by and through the District Attorney of Philadelphia.
2. This Court entertained extensive argument on September 5, 2019 on all outstanding Preliminary Objections pertaining to the Carpenters Health and Welfare Fund of Philadelphia and Vicinity v. Purdue Pharma, L.P., et. al., as captioned above.
3. The Amended Complaint sufficiently pleads all causes of actions.
4. The Amended Complaint puts the Defendants on sufficient notice to prepare a defense, sufficient to establish all claims on the basis of civil co-conspirator liability.
5. The Amended Complaint sufficiently pleads allegations of causation and a cognizable injury.
6. Presently the Court finds that the claims in the Amended Complaint are not preempted nor in conflict with any federal law duty.
7. The Defendants did not raise or plead any expressed, statutory, or regulatory specific exemptions, only alleged an expression of potential conflict preemption. The Plaintiff's causes of action at this time, if successful, may not become an obstacle to the purpose, and objectives with federal legislation and regulation.
8. Preemption does not bar Plaintiff's claims if established upon allegations of misleading, fraudulent and deceptive marketing, sales promotion, and an alleged distribution scheme and advertising that allegedly distorted and withheld information about their drugs in order to harm Plaintiff by convincing physicians, pharmacies, and individuals that their opioids, were safe and effective for the treatment of pain.
9. The Court further finds the Amended Complaint sufficiently provides Defendants with notice of the nature of the claims against them, and sufficiently summarizes the facts upon which the claims are based and properly alleges all causes of action.
10. As to all the various causes of action, the Court notes, at trial, the trial Judge will have an opportunity to reevaluate the sufficiency of the evidence as to each Defendant and nothing in this Order prevents the Court from granting judgment as a matter of law, if warranted.

The Courts findings as set forth above are limited to the standard of review required of Defendants'

Preliminary Objections, and the Court may review and further consider Motions for Summary Judgment, if and when they are timely and appropriately raised.

Therefore, for all the foregoing reasons, the Court hereby **DENIES** Defendants' Preliminary Objections in their entirety.

BY THE COURT:

J. Barry C. Dozor

FILED
12-04-2019 05:20 PM
OFFICE OF JUDICIAL SUPPORT
DELAWARE COUNTY, PA

IN THE COURT OF COMMON PLEAS OF DELAWARE COUNTY, PENNSYLVANIA

COUNTY OF DELAWARE, PA	:	
	:	
PLAINTIFF,	:	**CIVIL ACTION-LAW**
	:	
v.	:	**NO. CV-2017-008095**
	:	
PURDUE PHARMA L.P., et al.,	:	
	:	
DEFENDANTS.	:	
	:	

COUNTY OF CARBON, PA	:	
	:	
PLAINTIFF,	:	**CIVIL ACTION-LAW**
	:	
v.	:	**NO. CV-2018-000990 (Carbon County)**
	:	
PURDUE PHARMA L.P., et al.,	:	
	:	
DEFENDANTS.	:	
	:	

ORDER DENYING PRELIMINARY OBJECTIONS OF MANUFACTURER AND DISTRIBUTOR DEFENDANTS

AND NOW, this 13 day of March 2020, in consideration of the Preliminary Objections of the Distributor and Manufacturer Defendants to Plaintiffs' First Amended Complaint, and Plaintiffs Responses in Opposition, and any reply thereto, and a hearing on November 15, 2019, with the following Defendants' Preliminary Objections are addressed herein:

- Johnson & Johnson;
- Jansen Pharmaceuticals, Inc;
- Ortho-McNeil – Jansen Pharmaceuticals, Inc;
- Par Pharmaceuticals, Teva, Cephalon;
- Actavis, Watson, Allergan, Mallinckrodt, Spec GX, Noroto;
- Amerisource Bergen Drug Corporation;
- Cardinal Health, Inc.;
- McKesson Corporation
- Anda Inc.
- Allergan PLC f/k/a Actavis PLC; Allergen Financial LLC f/k/a Actavis Inc. f/k/a Watson Pharmaceuticals;
- Watson Laboratories Inc.;
- Actavis LLC;

- Actavis Pharma, Inc.;
- H.D. Smith
- Walmart, Inc.;
- Rite Aid Corp. and Rite Aid of Maryland Inc.;
- Walgreen Co. and Walgreen Eastern Co.;
- CVS Pharmacy, Inc., CVS Indiana LLC, CVS Rx Services Inc., CVS TN Distribution, and Pennsylvania CVS Pharmacy LLC.

NOW, THEREFORE, it is hereby **ORDERED** and **DECREED** as follows;

LEGAL STANDARD

Pennsylvania is a fact-pleading jurisdiction and, therefore, a complaint must provide notice of the nature of the Plaintiff's claims and also summarize the facts upon which the claims are based. *Youndt v. First Nat'l Bank of Port Allegany*, 868 A.2d 539, 544 (Pa. Super. Ct. 2005). The material facts on which the cause of action is based should be "stated in a concise and summary form." Pa. R.C.P. 1019(a). But, "there is no requirement to plead the evidence upon which the pleader will rely to establish those facts." *Commonwealth ex rel. Shapiro v. Golden Gate Nat'l Senior Care LLC*, 194 A.3d 1010, 1029 (Pa. 2018) (citing *United Refrigerator Co. v. Applebaum*, 189 A.2d 253, 255 (Pa. 1963))). "Averments of fraud or mistake shall be averred with particularity," while "[m]alice, intent, knowledge, and other conditions of mind may be averred generally." Pa. R.C.P. 1019(b). The purpose of a complaint is to disclose material facts sufficient to notify the adverse party of the claims it will have to defend against. *See Martin v. Lancaster Battery Co.*, 606 A.2d 444, 448 (Pa. 1992); *Landau v. W. Pa. Nat'l Bank*, 282 A.2d 335, 339 (Pa. 1971). To determine whether a claim has been pled with the required specificity, the allegations must be viewed in the context of the pleading as a whole. See *Yacoub v. Lehigh Valley Med. Assocs., P.C.*, 805 A.2d 579, 589 (Pa. Super. Ct. 2002) (en banc).

When considering preliminary objections, Courts must accept as true all well pleaded allegations and any reasonable inferences drawn from those allegations. *See Bayada Nurses, Inc. v. Commonwealth, Dep't of Labor & Indus.*, 8 A.3d 866, 884 (Pa. 2010). The question presented by a demurrer "is whether, on the facts averred, the law says with certainty that no recovery is possible. Where a doubt exists as to whether a demurrer should be sustained, this doubt should be resolved in favor of overruling it." *Vattimo v. Lower Bucks Hosp., Inc.*, 465 A.2d 1231, 1232-33 (Pa. 1983) (citation omitted).

Findings and Conclusion

1. The September 14, 2018 Case Management Order No. 1 ordered that the Delaware County and Carbon County Plaintiffs be two of four "test cases" for Preliminary Objections. The Commonwealth of Pennsylvania, acting by and through the District Attorney of Philadelphia, and the Carpenters Health and Welfare Fund of Philadelphia and Vicinity are the remaining two "test" cases.

2. This Court entertained extensive argument on November 15, 2019 on all outstanding Preliminary Objections pertaining to Delaware County and Carbon County as captioned above. For sake of brevity, clarity, and economy, various Defendants consolidated Preliminary Objections, and/or incorporated other Defendants' Objections, and filed common memorandums, that require a comprehensive order referring to a myriad of Preliminary Objections.
3. The Plaintiffs' Complaint(s) allege negligent and negligent per-se conduct, unjust enrichment, fraud, public nuisance, UTPCPL claims and further detail an alleged civil conspiracy among Defendants to mislead the public and doctors by false and mispresented claims, negligent marketing, failing to effectively monitor and identify and report suspicious orders, and failing to adequately control the supply chain of opioid products and prevent diversion, causing damages related to incurred expenses, costs and services, health care costs and treatment, increased cost of all services, damages allegedly related to the Defendants' tortious and wrongful conduct, and damages related to opioid abuse and addiction.
4. Manufacturer and Distributor Defendants, all intended to be referred to herein, raise some if not most, of the same legal doctrines, this Court previously denied when ruling on the same Defendants' Preliminary Objections in the two other coordinated cases, the Commonwealth of Pennsylvania, acting by and through the District Attorney of Philadelphia and Carpenters Health and Welfare Fund of Philadelphia and Vicinity cases. This Court still entertained further argument and consideration as new or distinguishable Preliminary Objections might warrant further review.
5. The Amended Complaints sufficiently place all Defendants on notice of the nature of all claims against them and sufficiently summarize the facts upon which these claims are based, including causes of action as a result of co-conspirator liability.
6. The Court further finds that the Amended Complaints adequately allege causation, proximate cause, damages, and conspiratory conduct and theories of liability.
7. The Court further finds that the question of proximate cause and causation is left to the finder of fact.
8. **Public Nuisance Claim:**
    a. The Plaintiffs assert common law public nuisance and civil conspiracy claims based on an alleged failure to maintain effective controls against diversion, as well as various other causes of action referred herein or addressed in prior Court Orders disposing of Preliminary Objections.
    b. The Defendants' Preliminary Objections, including the Distributor/Pharmacy Defendants, move to Dismiss the Counties public nuisance claims.
    c. The Amended Complaints sufficiently plead that the Plaintiff has suffered particular injury, damage and harm as the result of the alleged actions and conduct of the Defendants, and are entitled to plead claims for compensatory relief, restitution, restoration, costs and expenses.
    d. The Plaintiffs' alleged injury and loss are the unnecessary and excessive costs of services, prescriptions, expenses, treatment, medical services, costs of abating a public nuisance, incurred specifically and particularly by the Plaintiffs. This alleged separate, specific and particular loss and injury to the Plaintiffs are sufficient to provide standing to seek restitution, restoration and

damages for injuries and costs directly caused by the public nuisance if Defendant(s) are proven to have caused and created the injury and damages.

e. As a party that allegedly created a nuisance, that party, if proven by a preponderance of the evidence, may be legally obligated to abate the nuisance and provide for the reimbursement and restoration as to the costs of remediation and abatement. The recovery of abatement cost do not represent routine and customary municipal services, and are not precluded even where the Municipal Cost Recovery Doctrine otherwise may apply.

9. **Defendants' Derivative Injury Claim:**
   a. The Defendants plead that the "derivative injury rule," as they also refer to the "remoteness doctrine" prohibit the Plaintiffs' claims for lack of causation and because Defendants' acts stand too remote and distant to recover for an injury characterized as indirect.
   b. The Plaintiffs allege that it suffered a direct injury caused by the Defendants' conduct and actions, and that fact questions remain outstanding, requiring discovery and causation is left to the trier of facts.
   c. The Counties plead with clear notice to all Defendants that certain costs, expenses, and damages are directly sustained by the Counties as a result of the Defendants' wrongful conduct, both tortious, and fraudulent, and the violation of the law, and the question of proximate cause is left to the finder of fact.
   d. Foreseeability and direct injury (or remoteness) remains to be established by the finder of fact.
   e. Subject to Pre-Trial Motions in Limine that may identify specific costs, this Court find that the Counties may seek recovery of their direct costs and excess costs arising from the Defendants alleged wrongful conduct, pleaded to constitute a direct injury of which the Plaintiffs may seek recovery and the Preliminary Objections are denied.
   f. This Court finds that the Plaintiffs may seek recovery of their alleged direct and excess costs as they arise directly from the Plaintiffs' role as the entity that assumed and paid expenses and costs arising from the Defendants conduct and sustained the loss and financial injury. This burden of proof remains with the Plaintiffs. The proven costs that Plaintiffs incurred, arising directly from the Defendants alleged neglect and wrongful conduct, constitute a direct injury for which the Plaintiffs may seek recovery.

10. **Lacking standing to bring UTPCPL claims:**
    a. The UTPCPL establishes a cause of action for "any person who purchases or leases goods or services primarily for personal, family, or household purposes and thereby suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment by any person of a method, act, or practice declared unlawful by Section 3 of this Act …" 73 P.S. §§201-9.2.
    b. Distributor Defendants have asserted that the Counties lack standing to bring its UTPCPL claims because it is not a "person" within the meaning of the statute.
    c. As the term "person" is defined in the UTPCPL to include "natural persons, corporations, trusts, partnerships, incorporated or unincorporated associations, and any other legal entities." 73 P.S. §§201-2(2). The Plaintiffs are found to

be a "legal entity" or person in interest for purposes of receiving restoration or restitution on behalf of the government and taxpayers.

d. Precedent confirms that a political subdivision (or county) is a "person in interest" for purposes of receiving restitution, even though it would not be a "person" for purposes of being sued. This proposition does not preclude a political subdivision, (or county), as a Plaintiff, to pursue restitution, recovery, or damages.

e. Here, as in *Commonwealth v. Golden Gate National Senior Care LLC,* 194 A.3d 1010 (Pa. 2018), there are "obvious and compelling reasons' to treat government entities differently in circumstances where they are attempting to obtain restitution or restoration on behalf of the government and taxpayers, as opposed to situations in which they are claiming an immunity from liability to provide such relief." *Id.* at 1031. This applies with equal force when a County seeks to recover its own expenditures. This is especially true in light of the "long-recognized directive that the UTPCPL be construed liberally to achieve its objective of preventing fraud or unfair or deceptive business practices and leveling the playing field between businesses and consumers." *Id.* at 1034. There is no logical reason that a County should not be able to make use of this statute when it acts as a consumer of the Defendants' products merely because any alleged policies that underlie the statute do not extend to permitting recovery against a political subdivision.

11. Pre-emption:

a. The Defendants raise various types of pre-emption to submit that the Plaintiffs claims for relief should be dismissed.

b. This Court does not find any conflict with Federal or State regulations that would cause the Plaintiffs' Amended complaints be extinguished or dismissed.

c. The Plaintiffs' allege far more than mere violation of Federal or State regulations, but assert various claims of traditional state tort law, negligence, false and misleading statements, false and fraudulent marketing, fraud and unjust enrichment and civil conspiracy; these actions stand entirely independent of the federal or state scheme for regulating prescription drugs and does not conflict with federal law.

12. Municipal Cost Recovery Rule, or referred to by Defendants as the "Free Public Service Doctrine":

a. The Defendants argue that the damages being claimed are "traditionally" barred by the Municipal Cost Recovery Rule, which they contend prohibits a county government from recovering in tort damages for the costs of providing public services.

b. The Defendants appear to concede that this Rule does not apply to the Counties' statutorily authorized claims (public nuisance and UTPCPL claims) but argue that the Counties' other claims are barred and should be dismissed.

c. We are asked, that when a governmental authority, a county, or township, or borough, pleads with a burden to prove, that a Defendant's wrongful and negligent conduct, fraudulent or negligence per-se conduct was a factual cause in bringing about the harm and damages, the Plaintiffs' claims are simply

precluded under Pennsylvania law. If not, the Plaintiffs continue to have the burden of proving the extent of damages caused by the Defendants negligence and wrongful conduct.

d. The Plaintiffs' allege a continuous and repeated wrongful conduct, conduct allegedly rising to the level of fraud and a pattern of conduct that created a great public nuisance and expense. The Plaintiffs argue that the application of the Defendants' argument would be to wrongfully shield an intentional tortfeasor from liability and unjustifiably favors tortfeasors who harm governmental municipal authorities.

e. This Court finds that this Rule, or proposition of authority does not bar recovery for county/municipality expenses incurred to remedy an alleged public harm caused by an alleged actor, and/or intentional tortfeasor, and claims relating to alleged continuous and repeated wrongful and tortious conduct.

f. Claims for compensatory relief, restitution, and restoration are not precluded, and Preliminary Objections are dismissed thereto.

g. And finally, this doctrine is entirely inapplicable to claims for the costs of abating a public nuisance and statutorily authorized claims.

13. Statute of Limitations:

Various Defendants assert the longest possible statute of limitations of four (4) years, would bar any claims based on opioid manufacture or distribution.

Upon the completion of discovery, and by way of Pretrial Motions and/or Motions in Limine, the term of the various causes of action will be determined.

No Statute of Limitations applies to public nuisance claims or to conspiracy claims thereof.

14. Certificate of Merit:

a. This Court has found that Plaintiffs' are not asserting any professional negligence claims against any pharmacist. Prior Court Orders dated December 26, 2019 and January 8, 2020, found that a Certificate of Merit is not required.

b. The Plaintiffs' allege that the tortious conduct and business practices utilized as retailers contributed to the violations of the Distributor/Retail Defendants' duties and the diversion of opioids. All of these allegations arise from alleged business policies, business management, business practices, actions and inactions of Defendants, and do not allege professional negligence on the part of individual pharmacists, nor professional malpractice, nor medical treatment to a patient.

c. The Defendants are granted leave of Court to file, if any, appropriate Motions in Limine, in advance of trial, to limit testimony regarding any proffered evidence regarding professional standards and practices

15. Again, with the Court limited to the standard for reviewing Preliminary Objections, the Amended Complaints provide notice and sufficiently states claim(s) for all causes of action, including negligence, negligence per-se, public nuisance, unjust enrichment, fraud, and civil conspiracy and UTPCPL violations.

16. As to all the various causes of action, the Court notes, every individual Defendant, and their alleged conduct, is distinct from each other, and upon the close of discovery, or at trial, the trial Judge will have an opportunity to re-evaluate the sufficiency of the

evidence as to each Defendant and nothing in this Order prevents the Court from granting judgment as a matter of law, if warranted.

This Courts' findings as set forth above are limited to the standard required for the Courts' review of the Preliminary Objections, and are not dispositive of Motions for Summary Judgment that may or may not be approved upon the completion of discovery.

For all the foreby reasons the Distributor and Manufacturer Defendants' Preliminary Objections to the Amended Complaints are DENIED in their entirety.

BY THE COURT:

J. Barry C. Dozor

FILED
03-14-2020 10:19 AM
OFFICE OF JUDICIAL SUPPORT
DELAWARE COUNTY, PA

IN THE COURT OF COMMON PLEAS OF DELAWARE COUNTY, PENNSYLVANIA

COUNTY OF DELAWARE, PA	:	
	:	
PLAINTIFF,	:	**CIVIL ACTION-LAW**
	:	
v.	:	**NO. CV-2017-008095**
	:	
PURDUE PHARMA L.P., et al.,	:	
	:	
DEFENDANTS.	:	
	:	

COUNTY OF CARBON, PA	:	
	:	
PLAINTIFF,	:	**CIVIL ACTION-LAW**
	:	
v.	:	**NO. CV-2018-000990 (Carbon County)**
	:	
PURDUE PHARMA L.P., et al.,	:	
	:	
DEFENDANTS.	:	
	:	

ORDER DENYING PRELIMINARY OBJECTIONS OF PHARMACY DEFENDANTS; WALMART, INC., RITE AID CORP., RITE AID OF MARYLAND INC., WALGREEN CO., WALGREEN EASTERN CO., AND CVS[1]

AND NOW, this 13 day of March 2020, in consideration of the Preliminary Objections of the Pharmacy Defendants' to Plaintiffs'[2] First Amended Complaint, and Plaintiff's Response in Opposition, and any reply thereto, and a hearing on November 15, 2019, **NOW, THEREFORE**, it is hereby **ORDERED** and **DECREED** as follows;

LEGAL STANDARD

Pennsylvania is a fact-pleading jurisdiction and, therefore, a complaint must provide notice of the nature of the Plaintiff's claims and also summarize the facts upon which the claims are based. *Youndt v. First Nat'l Bank of Port Allegany*, 868 A.2d 539, 544 (Pa. Super. Ct. 2005). The material facts on which the cause of action is based should be "stated in a concise and summary form." Pa. R.C.P. 1019(a). But, "there is no requirement to plead the evidence upon which the pleader will rely to establish those facts." *Commonwealth ex rel. Shapiro v. Golden Gate Nat'l Senior Care LLC*, 194 A.3d 1010, 1029 (Pa. 2018) (citing *United Refrigerator Co. v.*

[1] CVS Pharmacy, Inc., CVS Indiana LLC, CVS Rx Services Inc., CVS TN Distribution LLC, and Pennsylvania CVS Pharmacy, LLC.

[2] Delaware County v. Purdue Pharma L.P., et al. NO. 2017-008095 and County of Carbon, Pennsylvania v. Purdue Pharma L.P., et al. NO. 2018-000990

Applebaum, 189 A.2d 253, 255 (Pa. 1963))). "Averments of fraud or mistake shall be averred with particularity," while "[m]alice, intent, knowledge, and other conditions of mind may be averred generally." Pa. R.C.P. 1019(b). The purpose of a complaint is to disclose material facts sufficient to notify the adverse party of the claims it will have to defend against. *See Martin v. Lancaster Battery Co.*, 606 A.2d 444, 448 (Pa. 1992); *Landau v. W. Pa. Nat'l Bank*, 282 A.2d 335, 339 (Pa. 1971). To determine whether a claim has been pled with the required specificity, the allegations must be viewed in the context of the pleading as a whole. See *Yacoub v. Lehigh Valley Med. Assocs., P.C.*, 805 A.2d 579, 589 (Pa. Super. Ct. 2002) (en banc).

When considering preliminary objections, Courts must accept as true all well pleaded allegations and any reasonable inferences drawn from those allegations. *See Bayada Nurses, Inc. v. Commonwealth, Dep't of Labor & Indus.*, 8 A.3d 866, 884 (Pa. 2010). The question presented by a demurrer "is whether, on the facts averred, the law says with certainty that no recovery is possible. Where a doubt exists as to whether a demurrer should be sustained, this doubt should be resolved in favor of overruling it." *Vattimo v. Lower Bucks Hosp., Inc.*, 465 A.2d 1231, 1232-33 (Pa. 1983) (citation omitted).

Findings and Conclusion

1. Plaintiffs brings claims against Pharmacy Defendants; Walmart Inc., Rite Aid Corp., Rite Aid of Maryland, Inc., Walgreen Co., Walgreen Eastern Co., CVS Pharmacy, Inc.; CVS Indiana, LLC; CVS Rx Services, Inc.; CVS TN Distribution, LLC; and Pennsylvania CVS Pharmacy, LLC ("CVS Defendants"[3] or "CVS") as both distributors and retailers of dangerous drugs under the Pennsylvania Controlled Substances Drug Device Cosmetic Act ("PACSA", 35 PS. § 780-101 *et seq*), the Pennsylvania Wholesale Prescription Drug Distributors License Act, ("WPDDLA") 63 Ps. § 391.1 et seq, and the Federal Controlled Substances Act, ("CSA"), 21 U.S.C. §§ 821-23 *et seq*. The Amended Complaints specifically allege that the Pharmacy Defendants owed Plaintiffs' duties as both distributors and retailers based on statutory and common law.
2. The Plaintiffs allege that the Pharmacy Defendants violated these duties by 1) failing to monitor and report suspicious orders and control the supply of prescription opioids to Plaintiffs' members and beneficiaries; and 2) entering into an unlawful conspiracy with other Distributors and Manufacturers designed to harm the Plaintiffs and generate massive profits for Defendants.
3. Plaintiffs aver that injuries are directly related to the costs of unnecessary and excessive prescriptions, which it would not have paid for but for the Pharmacy Defendants' actions, and the costs of addiction treatment, emergency and social services that have resulted from the Pharmacy Defendants' actions. Plaintiffs' Amended Complaints are premised upon the Pharmacy Defendants' violations of

[3] By way of Stipulation, and Order of October 1, 2019, CVS Health Corporation ("CVS Health"), was dismissed with regards to Carbon County, PA (CV-2018-000990) case, and CVS Health Corporation Preliminary Objections are thereby moot. The following parties were substituted for CVS Health Corporation: CVS Pharmacy, Inc.; CVS Indiana, LLC.; CVS Rx Services, Inc.; and CVS TN Distribution LLC. Pennsylvania CVS Pharmacy, LLC is also a named party.

their statutory and common law duties as distributors and retailers of prescription opioids.

4. The September 14, 2018 Case Management Order No. 1 ordered that the Delaware County and Carbon County Plaintiffs be two of four "test cases" for Preliminary Objections.
5. This Court entertained extensive argument on November 15, 2019 on all outstanding Preliminary Objections pertaining to Delaware County and Carbon County, as captioned above.
6. **(A)** The Amended Complaints bring claims against Pharmacy Defendants as both distributors and retailers. As distributors of opioids, Plaintiffs plead that Pharmacy Defendants have allegedly violated their duties to monitor, report, and halt suspicious orders and to prevent diversion. As a retailer of opioids, Plaintiffs further avers that Pharmacy Defendants have allegedly violated its duties to act with a reasonable standard of care in the sale of these inherently dangerous prescription drugs. These alleged violations are the basis of the claims against them as retailers and are properly alleged in the Amended Complaints.

   (B) The Amended Complaints allege that the Pharmacy Defendants were "aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and dispensaries. Plaintiffs allege that the pharmacies had a duty, separate and apart from the Distributors, to provide effective controls and procedures to guard against diversion. Plaintiffs also allege that the Pharmacy Defendants distributed and dispensed substantial quantities of opioids that were diverted. Plaintiffs further allege that the Pharmacy Defendants ignored signs at the retail pharmacy level that they knew or should have known were indicative of diversion.

   (C) The Amended Complaints also specifically allege that the business practices, metrics, quotas, and bonus structures that the Pharmacy Defendants utilized for purposes of retailing opioids contributed to the violations of their duties and the diversion of opioids. All of these allegations arise from the negligence of the pharmacies themselves, they do not allege professional negligence on the part of individual pharmacists.
7. **DEFENDANT'S PREEMPTION CLAIMS:**

   (A) The Defendants' file Preliminary Objections on the issue of Federal Preemption of state law claims, arguing that Plaintiffs' outstanding claims are preempted because they conflict with regulations and decisions of Federal and State Agencies and regulators, including the Food and Drug Administration (FDA). The Federal and State Legislation promulgates a standard of care from which the Plaintiffs' allege the Defendants have deviated, giving rise to Plaintiffs' common law claims. The Defendants did not raise or plead any expressed or statutory or regulatory specific exemptions, only an expression of potential conflict preemption.

   (B) The Plaintiffs' causes of action, if successful, do not thereafter become an obstacle to the accomplishment and expression of the purposes and objects of any Federal or State Legislation and regulations.

(C) This Court further finds that State Pharmacy Licensing regulations do not preempt or supersede common law principles of negligence, and the burden of proof of Plaintiffs' various causes of action remains with Plaintiffs.

(D) The Plaintiffs' causes of action and allegations thereto, do not challenge state licensing and regulations, and FDA approved labeling and preemption does not bar Plaintiffs' claims founded upon allegations of misleading or fraudulent business practices and deceptive marketing, sales, distribution, and advertising activities that allegedly distorted and withheld information about their drugs in order to harm Plaintiffs, and further alleges inadequate monitoring and anti-diversion activities.

8. **CERTIFICATE OF MERIT:**
   (A) Defendants assert that the Plaintiffs' claims are sound in professional negligence and a Certificate of Merit is required. This Court by Orders found that a "Certificate of Merit" is not required (see 12/26/19 and 1/8/2020 dated Orders) and disposed of this assertion.
   (B) This Court finds that Plaintiffs' allegations arise from the alleged negligence of the business practices, systems, policies, and common law duties of the pharmacies themselves, and Plaintiffs' do not allege professional negligence on the part of individual pharmacies.
   (C) The Plaintiffs' allegations of ordinary negligence by Retail Pharmacies, not the dispensing practices of individual pharmacists, are the foundation of Plaintiffs' claims, including the business and management practices, record keeping, corporation policies, plus a list of actions pled.
9. The Plaintiffs' Amended Complaints allege negligent conduct and further details a conspiracy among Defendants to mislead the public and doctors by false and misrepresented claims, negligent marketing, failing to effectively monitor and identify and report suspicious orders, and failing to adequately control the supply chain of opioid products and prevent diversion, causing damages related to health care costs, increased cost of workers' compensation claims, damages related to lost productivity, and damages related to opioid abuse and addiction.
10. The Amended Complaints sufficiently state all claims against the Defendants.
11. Plaintiffs' Amended Complaints allege and detail a conspiracy among Defendants and sufficiently states all claims against the Defendants.
12. The Plaintiffs sufficiently pleads damages alleged in the Amended Complaints directly suffered by Plaintiffs.
13. The Court further finds that the question of proximate causation is left to the finder of fact.
14. The Court further finds that the Amended Complaints adequately allege causation, causing effect, proximate cause, damages, and conspiratory conduct and liability.
15. Again, with the Court limited to the standard for reviewing Preliminary Objections, the Amended Complaints provide notice and sufficiently state a claim(s) for all causes of action, including negligence, negligence per se, public nuisance, unjust enrichment, fraud, and civil conspiracy.
16. As to all the various causes of action, the Court notes, at trial, the trial Judge will have an opportunity to re-evaluate the sufficiency of the evidence as to each Defendant and

nothing in this Order prevents the Court from granting judgment as a matter of law, if warranted.

This Courts' findings as set forth above are limited to the standard required for the Courts' review of the Preliminary Objections, and are not dispositive of Motions for Summary Judgment that may or may not be approved upon the completion of discovery.

For all foreby reasons the Pharmacy Defendants' Preliminary Objections to the Delaware County and Carbon County Amended Complaints all captioned above, are **DENIED** in their entirety.

BY THE COURT:

J. Barry C. Dozor

FILED
03-14-2020 10:37 AM
OFFICE OF JUDICIAL SUPPORT
DELAWARE COUNTY, PA

IN THE COURT OF COMMON PLEAS OF DELAWARE COUNTY, PENNSYLVANIA

COUNTY OF DELAWARE, PA	:	
	:	
PLAINTIFF,	:	**CIVIL ACTION-LAW**
	:	
v.	:	**NO. CV-2017-008095**
	:	
PURDUE PHARMA L.P., et al.,	:	
	:	
DEFENDANTS.	:	
	:	
Carpenters Health and Welfare Fund of Philadelphia and Vicinity	:	
	:	**CIVIL ACTION-LAW**
PLAINTIFF,	:	
	:	**NO. CV-2017-008095 (Consolidated)**
v.	:	**NO. CV-2018-008920**
	:	
PURDUE PHARMA L.P., et al.,	:	**Philadelphia CCP NO. 180302264**
	:	
DEFENDANTS.	:	

ORDER DENYING PRELIMINARY OBJECTIONS OF CVS DEFENDANTS[1]

AND NOW, this 13 day of March 2020, in consideration of the Preliminary Objections of the CVS Defendants' to Plaintiff's First Amended Complaint, and Plaintiff's Response in Opposition, and any reply thereto, and a hearing on November 15, 2019, **NOW, THEREFORE**, it is hereby **ORDERED** and **DECREED** as follows;

LEGAL STANDARD

Pennsylvania is a fact-pleading jurisdiction and, therefore, a complaint must provide notice of the nature of the Plaintiff's claims and also summarize the facts upon which the claims are based. *Youndt v. First Nat'l Bank of Port Allegany*, 868 A.2d 539, 544 (Pa. Super. Ct. 2005). The material facts on which the cause of action is based should be "stated in a concise and summary form." Pa. R.C.P. 1019(a). But, "there is no requirement to plead the evidence upon which the pleader will rely to establish those facts." *Commonwealth ex rel. Shapiro v. Golden Gate Nat'l Senior Care LLC*, 194 A.3d 1010, 1029 (Pa. 2018) (citing *United Refrigerator Co. v. Applebaum*, 189 A.2d 253, 255 (Pa. 1963))). "Averments of fraud or mistake shall be averred with particularity," while "[m]alice, intent, knowledge, and other conditions of mind may be averred generally." Pa: R.C.P. 1019(b). The purpose of a complaint is to disclose material facts sufficient to notify the adverse party of the claims it will have to defend against. *See Martin v.*

[1] CVS Pharmacy, Inc., CVS Indiana LLC, CVS Rx Services Inc., CVS TN Distribution, and Pennsylvania CVS Pharmacy, LLC.

Lancaster Battery Co., 606 A.2d 444, 448 (Pa. 1992); *Landau v. W. Pa. Nat'l Bank*, 282 A.2d 335, 339 (Pa. 1971). To determine whether a claim has been pled with the required specificity, the allegations must be viewed in the context of the pleading as a whole. See *Yacoub v. Lehigh Valley Med. Assocs., P.C.*, 805 A.2d 579, 589 (Pa. Super. Ct. 2002) (en banc).

When considering preliminary objections, Courts must accept as true all well pleaded allegations and any reasonable inferences drawn from those allegations. *See Bayada Nurses, Inc. v. Commonwealth, Dep't of Labor & Indus.*, 8 A.3d 866, 884 (Pa. 2010). The question presented by a demurrer "is whether, on the facts averred, the law says with certainty that no recovery is possible. Where a doubt exists as to whether a demurrer should be sustained, this doubt should be resolved in favor of overruling it." *Vattimo v. Lower Bucks Hosp., Inc.*, 465 A.2d 1231, 1232-33 (Pa. 1983) (citation omitted).

Findings and Conclusion

1. The September 14, 2018 Case Management Order No. 1 ordered that the Carpenter's Plaintiff be one of four "test cases" for Preliminary Objections and included Delaware County, Carbon County, (two counties/municipal plaintiffs) and the Commonwealth of Pennsylvania, acting by and through the District Attorney of Philadelphia.
2. This Court entertained extensive argument on November 15, 2019 on the outstanding Preliminary Objections pertaining to the Carpenters Health and Welfare Fund of Philadelphia and Vicinity v. Purdue Pharma, L.P., et. al., as captioned above.
3. This Court had on September 5, 2019 conducted oral argument on numerous Co-Defendant Manufacturers, Distributors and Retailers' Preliminary Objections to the Carpenters' First Amended Complaint.
4. This Court on December 4, 2019 entered an Order disposing of the Co-Defendants Preliminary Objections.
5. The CVS Defendants had been served after original process had been completed on Co-Defendants and argument on these CVS Preliminary Objections was conducted for November 15, 2019.
6. Plaintiff brings claims against CVS Defendants as both distributors and retailers of dangerous drugs under the Pennsylvania Controlled Substances Drug Device Cosmetic Act ("PACSA"), 35 Ps. § 780-101 et seq., the Pennsylvania Wholesale Prescription Drug Distributors License Act, ("WPDDLA") 63 Pa. § 391.1 et seq, and the Federal Controlled Substances Act, ("CSA"), 21 U.S.C. §§ 821-23 et seq. The Amended Complaint specifically alleges that the CVS Defendants owed Plaintiff duties as both distributors and retailers based on statutory and common law.
7. The Plaintiff allege that the CVS Defendants violated these duties by 1) failing to monitor and report suspicious orders and control the supply of prescription opioids to Plaintiff's members and beneficiaries; and 2) entering into an unlawful conspiracy with other Distributors and Manufacturers designed to harm the Plaintiff and generate massive profits for Defendants.
8. Plaintiff's aver that injuries are directly related to the costs of unnecessary prescriptions, which it would not have paid for but for the CVS Defendants' actions, and the costs of addiction, treatment, emergency and social services that have resulted from the CVS Defendants' actions. Plaintiff's Amended Complaint is premised upon

the CVS Defendants' violations of their statutory and common law duties as distributors and retailers of prescription opioids.

9. The Plaintiff's Amended Complaint alleges negligent conduct and further details a conspiracy among Defendants to mislead the public and doctors by false and mispresented claims, negligent marketing, failing to effectively monitor and identify and report suspicious orders, and failing to adequately control the supply chain of opioid products and prevent diversion, causing damages related to health care costs, increased cost of workers' compensation claims, damages related to lost productivity, and damages related to opioid abuse and addiction.
10. The Amended Complaint sufficiently states all claims against the CVS Defendants.
11. Plaintiff's Amended Complaint alleges and sufficiently details a conspiracy among Defendants.
12. The Plaintiff sufficiently pleads damages alleged in the Amended Complaint and directly suffered by Plaintiff.
13. The Court further finds that the question of proximate causation is left to the finder of fact.
14. The Court further finds that the Amended Complaint adequately alleges causation, causing effect, proximate cause, damages, and conspiratory conduct and liability.
15. **DEFENDANT'S PREEMPTION CLAIMS:**
    - **(A)** The Defendants' file Preliminary Objections on the issue of Federal Preemption of state law claims, arguing that Plaintiffs' outstanding claims are preempted because they conflict with regulations and decisions of Federal and State Agencies and regulators, including the Food and Drug Administration (FDA). The Federal and State Legislation promulgates a standard of care from which the Plaintiffs' allege the Defendants have deviated, giving rise to Plaintiffs' common law claims. The Defendants did not raise or plead any statutory or regulatory specific exemptions, only an expression of potential conflict preemption.
    - **(B)** The Plaintiffs' causes of Action, if successful, do not thereafter become an obstacle to the accomplishment and expression of the purposes and objects of any Federal or State Legislation and regulations.
    - **(C)** This Court further finds that State Pharmacy Licensing regulations do not preempt or supersede common law principles of negligence, and the burden of proof of Plaintiffs' various causes of action remain with Plaintiffs.
    - **(D)** The Plaintiffs' causes of action and allegations thereto, do not challenge state licensing and regulations, and FDA approved labeling and preemption does not bar Plaintiffs' claims founded upon allegations of misleading or fraudulent business practices and deceptive marketing, sales, distribution, and advertising activities that allegedly distorted and withheld information about their drugs in order to harm Plaintiffs, and further alleges inadequate monitoring and anti-diversion activities.
16. **DEFENDANTS' DERIVATIVE INJURY CLAIM:**
    - (A) As this Plaintiff is a Third-Party Payor, seeking healthcare and other costs and expenses, the Defendant(s) plead that the "derivative injury rule", as they also refer to the "remoteness doctrine" prohibit the Plaintiff's claims because Defendants' acts stand too remote and distant to recover for an injury characterized as indirect.

(B) The Plaintiff Fund alleges that it suffered a direct injury caused by the Defendants' conduct and actions, and fact questions remain outstanding, requiring discovery, and reviewed by the trier of facts.

(C) This Court finds that the Plaintiff may seek recovery for their alleged direct costs of prescription medications as they arise directly from the Plaintiff's role as the business entity that paid for the drugs.

17. Again, with the Court limited to the standard for reviewing Preliminary Objections, the Amended Complaint provides notice and sufficiently states a claim(s) for all causes of action, including negligence, negligence per se, public nuisance, unjust enrichment, fraud, and civil conspiracy.

18. As to all the various causes of action, the Court notes, at trial, the trial Judge will have an opportunity to reevaluate the sufficiency of the evidence as to each Defendant and nothing in this Order prevents the Court from granting judgment as a matter of law, if warranted.

This Courts' findings as set forth above are limited to the standard required for the Courts' review of the Preliminary Objections, and are not dispositive of Motions for Summary Judgment that may or may not be approved upon the completion of discovery.

For all foreby reasons the CVS Defendants' Preliminary Objections to the Amended Complaint are **DENIED** in their entirety.

BY THE COURT:

J. Barry C. Dozor

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OFFICE OF JUDICIAL SUPPORT
DELAWARE COUNTY, PA

ELECTRONICALLY FILED - 2018 Apr 12 2:12 PM - RICHLAND - COMMON PLEAS - CASE#2017CP4004872

STATE OF SOUTH CAROLINA)	IN THE COURT OF COMMON PLEAS
)	
COUNTY OF RICHLAND)	FIFTH JUDICIAL CIRCUIT
THE STATE OF SOUTH CAROLINA, ex rel. Alan Wilson, in his official capacity as Attorney General of the State of South Carolina, Plaintiff, vs. Purdue Pharma L.P., Purdue Pharma, Inc., and the Purdue Frederick Company, Defendants.)	Civil Action No.: 2017-CP-40-04872 Judge Robert E. Hood

ORDER

This matter is before the Court on motions by Defendants Purdue Pharma L.P., Purdue Pharma, Inc. and the Purdue Frederick Company (collectively, "Defendants") seeking Judgment on the Pleadings and a stay of this case, and on motions by the Plaintiff, the State of South Carolina (the "State"), to unseal the allegations of the Amended Complaint and for entry of a proposed scheduling order. The Court heard oral argument on these Motions on March 27, 2018. Having considered the briefing and argument of the Parties, the Amended Complaint, and the requirements of law, the Court hereby ORDERS as follows:

1. Defendants' Motion for Judgment on the Pleadings is hereby **DENIED**.

2. Defendants' Motion to Stay this Case Under the Primary Jurisdiction Doctrine and the Court's Inherent Authority to Stay Proceedings is hereby **DENIED**.

3. Plaintiff's Motion to Initially File the Amended Complaint under Seal and then to Unseal the Amended Complaint is **GRANTED IN PART AND DENIED IN PART**, as follows: Paragraphs 125, 130, 133, 147, and 156 are unsealed. Paragraphs 38, 132, and 146 shall remain sealed. The Court also understands that the parties have agreed to unseal additional paragraphs of the Amended Complaint. The Clerk of Court is directed to replace the publicly available

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version of the Plaintiff's Amended Complaint with the version of the Amended Complaint attached to this order. As Defendants have already answered the Amended Complaint, they need not respond to the substituted version of the Amended Complaint.

4. The Court defers a ruling on the State's Motion for Entry of Proposed Scheduling Order and will confer with the Parties regarding scheduling within thirty (30) days of the date of this Order.

IT IS SO ORDERED.

_____
The Honorable Robert E. Hood

April __ 2018
Columbia, South Carolina

ELECTRONICALLY FILED - 2018 Apr 12 2:12 PM - RICHLAND - COMMON PLEAS - CASE#2017CP4004872

Richland Common Pleas

Case Caption: State Of South Carolina , plaintiff, et al vs Purdue Pharma L P , defendant, et al

Case Number: 2017CP4004872

Type: Order/Other

So Ordered

s/ R.E. Hood #2164

Electronically signed on 2018-04-12 11:52:48 page 3 of 3

IN THE CIRCUIT COURT FOR KNOX COUNTY, TENNESSEE

STATE OF TENNESSEE, *ex rel.* HERBERT H. SLATERY III, ATTORNEY GENERAL and REPORTER,	)	
Plaintiff,	)	
v.	)	Case No. 1-345-19
AMERISOURCEBERGEN DRUG CORPORATION, a foreign corporation,	)	
Defendant.	)	

FILED
CHARLES D. SUSANO III
CLERK
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KNOX COUNTY CIRCUIT
CIVIL SESSIONS
AND JUVENILE COURTS

ORDER

In this case, the State of Tennessee makes various allegations against Amerisourcebergen Drug Corporation ("Amerisource") related to Amerisource's distribution of opioid medications throughout Tennessee, but particularly in East Tennessee. The State alleges three causes of action: (1) violation of the Tennessee Consumer Protection Act; (2) common law or public nuisance; and (3) violation of the Tennessee Racketeer Influences and Corrupt Organization Act of 1989 ("RICO"). Amerisource has filed a motion to dismiss, contending generally that, as a distributor, it is simply a "middleman," and cannot be liable for its distribution to pharmacies for the fulfillment of customers' prescriptions. Amerisource makes specific arguments with respect to each of the causes of action. For the reasons set forth herein, Amerisource's motion is denied.

I. STANDARD OF REVIEW

When considering a motion to dismiss for failure to state a claim upon which relief can be granted, the Court is limited to an examination of the complaint alone. *See Walcotts Fin. Serv., Inc. v. McReynolds*, 807 S.W. 708, 710 (Tenn. Ct. App. 1990). Such a motion avers that the allegations in the complaint, when considered alone and taken as true, are insufficient to state a

claim as a matter of law. *See Cornpropst v. Sloan*, 528 S.W.2d 188 (Tenn. 1975). In other words, such a motion tests the legal sufficiency of the complaint, not the strength of the plaintiff's proof. *See Bell ex rel. Snyder v. Icard*, 986 S.W.2d 550, 554 (Tenn. 1999). The Court is required to construe the complaint liberally in favor of the plaintiff, taking all the allegations of fact therein as true. *See Cook ex rel. Uithoven v. Spinnaker's of Rivergate, Inc.*, 878 S.W.2d 934, 938 (Tenn. 1994).

II. AMERISOURCE'S STATUS AS A REGISTERED DISTRIBUTOR

The Court will first address Amerisource's claim that it is insulated from all liability because it merely distributed opioids in accordance with its authorization to do so. Amerisource contends that as a "middleman," it simply processes and ships the orders it receives from its customers and, therefore, has no responsibility for unlawful prescriptions or diversions. The Complaint alleges otherwise. Specifically, the Complaint alleges that distributors of controlled substances have a duty under both Tennessee and federal regulations to maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." Tenn. Code Ann. § 53-11-303; 21 U.S.C. § 823(b)(1). Distributors are required to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and to inform the Board of Pharmacy and the Drug Enforcement Agency of suspicious orders when discovered by the registrant. Tenn. Code Ann. § 53-10-312(c); 221 C.F.R. § 1301.74(b). The Complaint alleges that distributors are also required to stop shipment of any order that is flagged as suspicious. Far from being just a supplier, these statutes place the distributor squarely within the chain of entities responsible for ensuring safe, compliant, legal distribution of controlled substances. In other words, the distributor has a statutory responsibility to take action to prevent diversion of controlled substances.

The Complaint, spanning 232 pages, is replete with allegations that Amerisource ignored its statutory duties and continued to distribute opioids to its customers (grocery stores, chain pharmacies, and independent pharmacies) in mind-boggling amounts despite significant and repeated diversionary "red flags." The State alleges that Amerisource's failure to comply with its statutory requirements as a distributor rendered its subsequent distribution "unlawful." The Court agrees with the State that a company's registration as a distributor does not, *ipso facto*, insulate the company from liability if the company fails to fulfill its statutory duties. This is the State's allegation, and the Court declines Amerisource's invitation to grant wholesale immunity to it based on the simple fact that it is a registered distributor of controlled substances.

The Court will also address Amerisource's claim that it is too far removed from the ultimate injurious acts to be legally responsible for them. In other words, Amerisource challenges the State's ability to prove causation, both for its Tennessee Consumer Protection Act claims and its public nuisance claims. With respect to causation, the Court finds that the Complaint is adequately pleaded. The Complaint alleges with great specificity that Amerisource failed in its duties as a distributor by: (1) continuing to ship opioids to its customers even when the amounts were suspiciously high and repeatedly over set thresholds; (2) ignoring red flags, including out-of-state license plates in its customers' parking lots, cash-only policies, the presence of armed guards, direct solicitation in parking lots for controlled substances, and its own employee's notation that "we know this stuff is being diverted"; and (3) shipping more OxyContin 30's to one pharmacy than it did to thirty-eight other individual states. These are just a few of the examples of the allegations in the Complaint. Furthermore, the Complaint alleges resulting damages, including but not limited to a "greater demand for emergency services, law enforcement, addiction treatment,

children's services, foster care, and other social services [that] places an unreasonable burden on governmental resources including the State and its political subdivisions." (Complaint, ¶ 608).

To the extent Amerisource argues that other intervening and superseding acts prohibit a finding of causation, the Court notes that "[t]here is no requirement that a cause, to be regarded as the proximate cause of an injury, be the sole cause, the last act, or the one nearest to the injury, provided it is a substantial factor in producing the end result.... An intervening act will not exculpate the original wrongdoer unless it appears that the negligent intervening act could not have been reasonably anticipated." *McClenahan v. Cooley*, 806 S.W.2d 767, 775 (Tenn. 1991).

Amerisource also contends that the State's claims are barred by the derivative injury rule and the free public services doctrine. Amerisource contends that the Complaint should be dismissed because the State alleges derivative injuries that are contingent on harm to third-party users. The Court disagrees with Amerisource's interpretation of the Complaint. The Complaint does not seek damages for the injuries of specific, individual opioid users. Rather, it seeks damages allegedly sustained by the State and its political subdivisions as a foreseeable result of over-distribution of and subsequent abuse of opioids. In this way, the claims are different from those in *Steamfitters Local Union No. 614 Health & Welfare Fund v. Philip Morris, Inc.*, 2000 WL 1390171 (Tenn. Ct. App. Sept. 26, 2000), a case relied upon by Amerisource. In *Steamfitters,* the union's Health and Welfare Fund sued tobacco companies to recover money spent by the Fund to treat its members' smoking-related illnesses. The premise of the Fund's claim was that the tobacco companies' activities prevented the Fund from implementing programs to educate its participants on the addictive qualities of tobacco. Ultimately, the Court of appeals held that "it would be 'virtually impossible' for the Funds to prove with reasonable certainty the effect education or smoking cessation programs would have had on the physical injuries suffered by plan

participants since the damages stem from individual smokers' decisions whether to continue smoking and, if so, how frequently to smoke." *Id.* at *6. The Court noted that "'it would be the sheerest sort of speculation to determine how these damages might have been lessened had the Funds adopted the measures defendants allegedly induced them not to adopt.'" *Id.* (citing *Laborers Local 17 Health & Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229, 238-39 (2d Cir. 1999)).

The allegations in the present case are wholly different in that they are not based upon the State being fraudulently induced to inaction, nor does the State seek damages for the physical injuries of the individual opioid users. Rather, the State seeks damages sustained by it and its political subdivisions as a direct result of Amerisource's failure to comply with its statutory duties to prevent and report diversion. The claims are simply different.

With respect to the free public services doctrine, the State correctly asserts that Tennessee courts have not recognized the doctrine, that there is an exception for public nuisance actions in those states that do recognize the doctrine, and that the Tennessee legislature has expressly announced the State's public policy of shifting the costs sought by the State from taxpayers to those who are responsible for the public nuisance. *See* Tenn. Code Ann. § 29-3-110(c) (authorizing courts to "assess costs of public services required to abate or manage the nuisance, including but not limited to, law enforcement costs, if any, caused by the public nuisance.").

III. TENNESSEE CONSUMER PROTECTION ACT

Amerisource seeks dismissal of the Tennessee Consumer Protection Act ("TCPA") claim, contending that (1) it did not sell illegal or unlawful goods because it held a valid registration to distribute opioids; (2) the claim is not pled with particularity; (3) the complaint does not allege facts showing that Amerisource misled or injured consumers; (4) the complaint fails to allege that

the State suffered an ascertainable loss of money or property; and (5) the complaint is barred by the one-year statute of limitations.

The Court rejects Amerisource's first contention, that it had a valid registration for distribution, for the reasons set forth in Section II, *supra*. The Court also rejects Amerisource's clam that the State failed to plead TCPA violations with particularity. The TCPA defines "trade or commerce" to include "the distribution of any goods … or things of value wherever situated." Tenn. Code Ann. § 47-18-103(20). Further, the TCPA prohibits "directly or indirectly … selling or offering for sale any good or service that is illegal or unlawful to sell in this state." Tenn. Code Ann. § 47-18-104(b)(43)(C). Again, the State's complaint sets forth myriad, detailed factual allegations to support its claim that Amerisource unlawfully distributed opioids.

Amerisource next contends that the TCPA claim should be dismissed because the Complaint does not allege facts showing that Amerisource misled or injured consumers, does not allege that the State suffered an ascertainable loss of money or property, and is barred by the one-year statute of limitations. In response, the State contends that none of these arguments apply because its cause of action arises under the Act's state enforcement provisions, not its private right of action. The Court agrees.

The TCPA's enforcement provision, Tenn. Code Ann. § 47-18-108, requires the State to establish a violation of the TCPA to obtain civil penalties, injunctive relief, and attorney fees. The State has alleged that Amerisource violated the TCPA by "directly or indirectly advertising, promoting, selling, or offering for sale any good or service that is illegal or unlawful to sell in this state." With respect to an ascertainable loss of money or property, the State correctly argues that state enforcement does not require such a showing. Thus, to the extent the State's Complaint seeks injunctive relief, civil penalties, and other remedies contemplated by the enforcement provision of

the TCPA, pleading an ascertainable loss of money or property is not required. To the extent the State also seeks recovery of ascertainable losses under Tenn. Code Ann. § 47-18-108(b)(1), the Court finds Amerisource's reliance on *Birdsong v. Eli Lilly & Co.*, 2011 WL 1259650 (M.D. Tenn. Mar. 31, 2011), misplaced. The Court in *Birdsong* determined that the plaintiff failed to allege an ascertainable loss of money or property that exists independently of the personal injuries suffered. In contrast, the State in the present case does not seek damages for the personal injuries sustained by the individual opioid users. Rather, the State seeks damages sustained directly by the State and its political subdivisions, including monies allocated to "the greater demand for emergency services, law enforcement, addiction treatment, children's services, foster care, and other social services...." (Complaint, ¶503). Lastly, the State correctly asserts that the TCPA does not contain a statute of limitation or repose for state enforcement actions. *See* Tenn. Code Ann. § 28-1-113.

IV. PUBLIC NUISANCE

Amerisource challenges the State's claim of public nuisance. Amerisource contends that the State seeks to expand the doctrine and that the State has not alleged interference with a public right, has not alleged that Amerisource was in control of the opioids at the time the injury occurred, has not complied with the Tennessee Products Liability Act, and is barred from recovery by the economic loss doctrine.

A public nuisance is an act or omission that unreasonably interferes with or obstructs rights common to the public. *See Metropolitan Gov't of Nashville v. Counts*, 541 S.W.2d 133, 138 (Tenn. 1976); Restatement (Second) of Torts §821B (1977). In *Sherrod v. Dutton*, 635 S.W.2d 117, 119 (Tenn. Ct. App. 1982), the Tennessee Court of Appeals explained that a nuisance "extends to everything that endangers life or health, gives offense to the senses, violates the laws of decency, or obstructs the reasonable and comfortable use of property." (Citations omitted); *see also State*

ex rel. Swann v. Pack, 527 S.W.2d 99, 113 (Tenn. 1975) (defining a public nuisance as "a condition of things which is prejudicial to the health, comfort, safety, property, sense of decency, or morals of the citizens at large, resulting either from an act not warranted by law, or from neglect of a duty imposed by law.") (Citations omitted).

Given the foregoing, the Court rejects Amerisource's claim that application of the public nuisance doctrine is too broad in this case. The Complaint has alleged that because of Amerisource's unlawful opioid distribution, the State of Tennessee and its political subdivisions have suffered damages due to the resulting endangerment of the health and safety of the citizens of Tennessee. The Complaint states a claim for public nuisance.

The Court also finds unavailing Amerisource's argument that it did not have control over the opioids at the time they allegedly caused injury to the State or its residents. As the State points out, the Tennessee Supreme Court has held that liability for a public nuisance can be applied to those who aid and abet. *See Pack*, 527 S.W.2d at 113. In addition, the Complaint alleges that Amerisource had control over the opioids because it delivered the product to customers when it knew the product was being diverted.

With respect to the Products Liability Act, the State correctly notes that "[p]roducts liability law governs the private litigation of product accidents." 1 Owen & Davis on Prod. Liab. § 1.2 (4th ed.), at 3 (2019). Likewise, the TPLA speaks to consumer use, not state enforcement: "[A] primary purpose of [the TPLA] is to 'ensure that an injured consumer may maintain a strict liability action against whomever is most likely to compensate him for his injuries.'" *Fox v. Amazon.com, Inc.*, 930 F.3d 415, 424 (6th Cir. 2019) (quoting *Owens v. Truckstops of Am.*, 915 S.W.2d 420, 432 (Tenn. 1996)). The State's Complaint simply does not sound in products liability. It is not a claim for injuries due to a defective or unreasonably dangerous product.

Lastly, the Court disagrees with Amerisource's assertion that the economic loss doctrine bars the State's claims. The economic loss doctrine "is a judicially created principle that requires the parties to live by their contracts rather than to pursue tort actions for purely economic losses arising out of the contract[,]" which "comes into play when the purchaser of a product sustains economic loss without personal injury or damage to property under the product itself." *McLean v. Bourget's Bike Works, Inc.*, 2005 WL 2493479 (Tenn. Ct. App. Oct. 7, 2005). The State is not seeking tort damages for a breach of contract. There is no contract between the State and Amerisource. The economic loss doctrine is simply inapplicable to the facts of this case.

V. RICO

Amerisource seeks dismissal of the State's RICO claims. Amerisource contends that the State failed to plead a predicate act of racketeering activity and, further, that application of RICO is limited to organized crime. The Court respectfully disagrees.

A civil RICO claim in Tennessee requires a showing that: (1) the defendant received proceeds derived directly or indirectly from a pattern of racketeering activity; (2) the defendant used or invested such proceeds into the acquisition of real or personal property or in the establishment or operation of an enterprise; and (3) the defendant did so with criminal intent. *See* Tenn. Code Ann. § 39-12-204(a). Racketeering activity includes criminal offenses involving controlled substances. *See* Tenn. Code Ann. § 39-12-203(9). Amerisource contends that because it was a registered distributor of controlled substances, it could not have engaged in a criminal offense involving a controlled substance. The Court, however, agrees with the State that a claim for RICO can be established when it is alleged, as here, that Amerisource knowingly distributed controlled substances for *improper purposes.*[1] In its brief, Amerisource cites to Tenn. Code Ann.

[1] The Complaint alleges that: (1) Oxycodone is a Schedule II controlled substance that is unlawful to distribute absent limited exceptions; (2) registered distributors must lawfully possess a controlled substance, and no statute allows a

§ 53-11-302, which provides that one who is registered by the appropriate occupational or professional licensing board may "possess, manufacture, warehouse, distribute, or dispense those substances *to the extent authorized by their registration.*" (Emphasis added). The State's Complaint alleges that Amerisource's distribution was *not authorized* because it knowingly shipped to customers engaging in diversion. The allegations are sufficient to state a claim under RICO.

Lastly, Amerisource contends that RICO claims should be limited to cases involving organized crime. However, Tenn. Code Ann. § 39-12-202(b)(1) and (b)(2) speak directly to the liability of owners or businesses licensed to dispense controlled substances when the owners or corporations know or have reason to know of violations involving controlled substances, i.e., the repeated, knowing unauthorized distribution of controlled substances, as alleged by the State in this case.

VI. CONCLUSION

Having carefully considered the arguments set forth in Amerisource's motion to dismiss, the Court finds that the State's Complaint sets forth a cause of action violation of the Tennessee Consumer Protection Act, public nuisance, and RICO violations. Accordingly, Amerisource's motion to dismiss is respectfully **DENIED.**

Entered this 14 day of July, 2020.

JUDGE KRISTI M. DAVIS

registered distributor to knowingly ship a Schedule II narcotic to a pharmacy where diversion is occurring and from which the pharmacy is dispensing invalid prescriptions; (3) it is unlawful to distribute a controlled substance in a manner *not* authorized by the registrant's registration, which is based on, among other things, "maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels" (Tenn. Code Ann. § 53-11-303(a)(1); (4) Amerisource knowingly shipped significant amounts of oxycodone after it knew that diversion was occurring and that its customers were dispensing significant quantities of invalid prescriptions.

CERTIFICATE OF SERVICE

I, the undersigned, do hereby certify pursuant to Rule 58, Tenn. R. Civ. P., that a copy of this ORDER has been served on all parties or their counsel of record by mail.

This 14 day of July, 2020.

Charles D. Susano, III
Knox County Circuit Court Clerk

By: _____
Deputy Clerk

P-1
DISMY

MDL PRETRIAL CAUSE NO. 2018-77098

COUNTY OF DALLAS, *Plaintiff*,	§	IN THE DISTRICT COURT OF
v.	§	HARRIS COUNTY, TEXAS
PURDUE PHARMA, L.P. ET. AL., *Defendants*.	§	152nd JUDICIAL DISTRICT

MASTER FILE NO. 2018-63587

IN RE: TEXAS OPIOID LITIGATION	§	IN THE DISTRICT COURT OF
	§	HARRIS COUNTY, TEXAS
	§	152nd JUDICIAL DISTRICT

ORDER

Pending before the Court is the First Amended Rule 91A Motion to Dismiss ("Motion") of Defendants AmerisourceBergen Drug Corporation, Cardinal Health, Inc., Cardinal Health 110, LLC, and McKesson Corporation (collectively "Distributors). The Court, having considered the Motion, any responses and replies thereto, the arguments of counsel, the pleadings on file, the applicable law and all other matters properly before the Court, determines that the Motion should be denied.

It is, therefore, Ordered that Distributors' Motion is denied.

SIGNED June 6, 2019.

Robert K. Schaffer
Presiding Judge

FILED
Marilyn Burgess
District Clerk
JUN 06 2019
Time:
Harris County, Texas
By
Deputy Katina Williams

Unofficial Copy Office of Marilyn Burgess District Clerk

RECORDER'S MEMORANDUM
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at the time of imaging

STATE OF VERMONT

SUPERIOR COURT
Chittenden Unit

CIVIL DIVISION
Docket No. 279-3-19 Cncv

State of Vermont vs. Cardinal Health, Inc. et al

ENTRY REGARDING MOTION TO DISMISS

Count 1, Duty to Prevent Misuse, Abuse & Diversion (279-3-19 Cncv)

VERMONT SUPERIOR COURT
FILED
MAY 12 2020
CHITTENDEN UNIT

Title: Motion to Dismiss (Motion 4)
Filer: Defendants
Attorney: Jonathan A. Lax et al.
Filed Date: June 17, 2019

Opposition filed on 08/01/2019 by Attorney Jill S. Abrams et al. for Plaintiff State of Vermont;
Reply filed on 09/16/2019 by Attorney Jonathan A. Lax et al. for Defendants;
Defendants' Supplemental Brief filed 01/14/2020;
State's Supplemental Brief filed 01/29/2020;
Defendants' Supplemental Reply filed 02/05/2020;
State's Notice of Supplemental Authority filed 02/21/2020

The State brings this case seeking damages and injunctive relief for defendants' role in distributing opioids in Vermont. Defendants move to dismiss. Oral argument took place on the motion in December, and post-trial memoranda were complete in February.

Discussion

The complaint asserts four causes of action: two counts of Consumer Protection Act violations, negligence, and public nuisance. Defendants Cardinal Health, Inc. and McKesson Corporation (jointly "Distributors") are alleged to be two pharmaceutical wholesalers that distribute opioids in Vermont. Their motion seeks dismissal of all four counts of the complaint.

Grant of a motion to dismiss for failure to state a claim "is proper only when it is beyond doubt that there exist no facts or circumstances[] consistent with the complaint

that would entitle the plaintiff to relief. . . [T]he threshold a plaintiff must cross in order to meet our notice-pleading standard is exceedingly low." Bock v. Gold, 2008 VT 81, ¶ 4, 184 Vt. 575 (quotation and citations omitted). Such motions "are disfavored and should be rarely granted." Id. In analyzing the motion, the court must "assume as true all factual allegations pleaded by the nonmoving party." Amiot v. Ames, 166 Vt. 288, 291 (1997)(citation omitted). In other words, the question is whether Plaintiff could win at trial if the allegations were proved.

Negligence

The negligence claim is, in sum, that Distributors breached common law and statutory duties to "prevent the diversion of controlled substances into illegitimate channels." Complaint ¶ 386. They are alleged to have breached these duties by creating ineffective monitoring systems, failing to implement adequate anti-diversion programs, failing to report suspicious orders, and failing to prevent shipment of suspicious orders. Id. ¶ 389. This allegedly "fueled the widespread circulation of opioids into illegitimate channels in Vermont," causing or substantially contributing to "the abuse, misuse and diversion" of opioids, leading to widespread addiction and increased costs to the State to address that epidemic. Id. ¶ 390.

The economic loss doctrine bars the State's claim here. With some exceptions, that doctrine "prohibits recovery in tort for purely economic losses." Sutton v. Vermont Reg'l Ctr., 2019 VT 71, ¶ 30. The State argues that the doctrine applies only when there was a contract between the parties. At least one other court has accepted such an argument in a similar case. City of Boston v. Purdue Pharma, LP, No. 1884CV02860, 2020 WL 416406, at *9 (Mass. Super. Jan. 3, 2020)(rejecting economic loss theory because "the claims are not contract-related"). The doctrine, however, is not so limited in Vermont. That is clear

from the Court's recent decision in Sutton. First, the Court quoted an earlier decision for the proposition that "negligence law does not generally recognize a duty to exercise reasonable care to avoid intangible economic loss to another unless one's conduct has inflicted some accompanying physical harm, which does not include economic loss." Sutton, 2019 VT 71, ¶ 30 (quoting Gus' Catering, Inc. v. Menusoft Sys., 171 Vt. 556, 558 (2000) (mem.)). Next, the Court explained that one of the reasons for the doctrine is the very fact that economic injuries can be widespread, "causing economic loss to thousands of people" without a direct connection to the defendant. Sutton, 2019 VT 71, ¶ 32 (quoting Restatement (Third) of Torts § 1 cmt. (c)(1))(noting distinction between impact of badly driven car, causing physical harm only to others nearby, and potential impact of single negligent utterance, causing economic loss to many people who rely on it). As another court has explained, the doctrine "bars recovery for economic loss even if the loss does not arise from a commercial relationship between the parties—even if for example a negligent accident in the Holland Tunnel backs up traffic for hours, imposing cumulatively enormous and readily monetizable costs of delay." Rardin v. T & D Mach. Handling, Inc., 890 F.2d 24, 28 (7th Cir. 1989). Thus, the Court has rejected the argument that the doctrine only applies when the parties have a contract. Long Trail House Condo. Ass'n v. Engelberth Const., Inc., 2012 VT 80, ¶¶ 13-15, 192 Vt. 322 (doctrine does not turn on "whether the parties had the opportunity to allocate risks"); *accord* Aetna Inc. v. Insys Therapeutics, Inc., 324 F. Supp. 3d 541, 556 (E.D. Pa. 2018) under Pennsylvania law, "contractual privity is not a prerequisite for the application of the doctrine").

The State argues that its injuries are not economic losses, but "social losses." Opp. at 21-22. The court is not persuaded. The court has found no cases creating a special legal category of "social loss" distinct from physical or economic damages in tort law. The

quotation the State provides from Dobbs is misleading, as it leaves out a crucial part of the sentence: the quotation is merely a view attributed to Judge Posner,[1] not a statement of the current state of the law or even Dobbs' view of what the law should be. The absence of physical injury here is what matters. The fact that the State's claimed damages are for increased health care costs, law enforcement costs, and addiction treatment costs does not change the analysis. *Accord* Springfield Hydroelectric Co. v. Copp, 172 Vt. 311, 315 (2001)("compensation for the damages [Plaintiffs] were forced to pay to third parties," were barred as solely economic damages.)

There can be exceptions to the economic loss rule when there is a special relationship between the parties. Sutton, 2019 VT 71, ¶ 31. The State argues that it has a "special relationship" with Distributors justifying an exception here. However, the sorts of special professional relationships that are considered as exceptions to this rule are not analogous to the situation here. Such exceptions apply when the defendant is a "provider of a specialized professional service." EBWS, LLC v. Britly Corp., 2007 VT 37, ¶ 32, 181 Vt. 513. Examples are a lawyer-client, investor-recruiter, or doctor-patient relationship. *See* Sachs v. Downs Rachlin Martin PLLC, 2017 VT 100 n. 5, 206 Vt. 157; Sutton, 2019 VT 71, ¶ 33; Walsh v. Cluba, 2015 VT 2, ¶ 30, 198 Vt. 453. The fact that Distributors shipped their product into Vermont, or were subject to statutory requirements, does not create such a special relationship. Although the State argues that its interests are not "disappointed business expectations," but something more important, it is not the magnitude of the harm that determines whether the doctrine applies. Since the injuries alleged by the State are purely economic harms, a negligence claim cannot succeed.

[1] Despite the fact that the undersigned was once his student, his views are not always persuasive.

Public Nuisance

The public nuisance claim is that the defendants' actions contributed to the opioid crisis in Vermont, thereby interfering with the public's right "to be free from [a] substantial injury to public health, safety, peace, comfort, and convenience." Complaint ¶ 396. The State asserts that the public has been harmed in various ways, including increased diversion of opiates, escalating sales of street drugs, higher rates of opioid misuse and addiction, overdose deaths, neonatal abstinence syndrome, increased health care costs and greater demand for law enforcement and treatment of addicted prisoners. Distributors argue that the claim fails because there are insufficient allegations as to any public right, control of the instrumentality, or interference with land, and because the law of public nuisance does not encompass this sort of claim.

First, Distributors contend that the rights at issue here are only private, not public, rights. A public nuisance is "an unreasonable interference with a right common to the general public." Restatement (Second) of Torts § 821B (1979). "Circumstances that may sustain a holding that an interference with a public right is unreasonable include the following: (a) Whether the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience." Id. Thus, historically "public nuisances included interference with the public health, as in the case of keeping diseased animals or the maintenance of a pond breeding malarial mosquitoes." Id. cmt b.

The allegations here include that as a result of Distributors' actions "[p]ublic resources have been, and are being, consumed in efforts to address the opioid epidemic, reducing the available resources that could be used to benefit the public at large." Complaint ¶ 398. The complaint also alleges that Distributors' actions have created

increased diversion of opiates, high rates of opioid "misuse, abuse, injury, overdose , and death, and their impact on Vermont families and communities," as well as "[i]increased health care costs for individuals, families, employers, and the State." Id. ¶ 397. While the proof of such claims may be challenging, they adequately allege "a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience." Restatement, § 821B. While the impacts upon those who became addicted to the drugs distributed by Defendants are individual, the broader effects upon the public health system, law enforcement and the prison system are impacts shared by the public at large. The State does not allege interference with the individual opiate user's right to be "free from an allegedly harmful product"—Motion at 20—but with the community's right to adequate police protection, health care, and the safety of its citizens.

Distributors argue that this is just not what nuisance law is designed to address. They point to a recently adopted Restatement provision addressing claims for harm to public resources. Restatement (Third) of Torts: Liability for Econ. Harm § 8 (2019). That provides for liability for harm to a public resource "if the claimant's losses are distinct in kind from those suffered by members of the affected community in general," and notes as follows:

> Tort suits seeking to recover for public nuisance have occasionally been brought against the makers of products that have caused harm, such as tobacco, firearms, and lead paint. These cases vary in the theory of damages on which they seek recovery, but often involve claims for economic losses the plaintiffs have suffered on account of the defendant's activities; they may include the costs of removing lead paint, for example, or of providing health care to those injured by smoking cigarettes. Liability on such theories has been rejected by most courts, and is excluded by this Section, because the common law of public nuisance is an inapt vehicle for addressing the conduct at issue. Mass harms caused by dangerous products are better addressed through the law of products liability, which has been developed and refined with

> sensitivity to the various policies at stake. Claims for reimbursement of expenses made necessary by a defendant's products might also be addressed by the law of warranty or restitution. If those bodies of law do not supply adequate remedies or deterrence, the best response is to address the problems at issue through legislation that can account for all the affected interests.

Id. cmt g. The State responds that this provision of the Restatement (which was first proposed in 2014 and only recently finalized)[2] is not binding on the court, does not adequately address claims brought by states as opposed to private entities, and overlooks developing caselaw in this area in recent years.

The State is correct that the court is not required to follow the Restatement. Although our Supreme Court has often done so with select provisions, unless and until it adopts this provision, the trial courts are not bound to do so. Restatements are, however, often persuasive authority to which this court frequently looks for guidance as to the majority view on issues not directly resolved by Vermont case law.

The State is also correct that there are a number of recent trial court cases from around the country that reach conclusions contrary to this newly adopted Restatement provision. This is unsurprising, given that the opioid epidemic has swept the country in recent years and led to a spate of lawsuits seeking to address its dire impacts. Distributors note that those are trial court decisions, not controlling higher court rulings, but that is how the law develops: from the bottom up. The question here is not whether either those decisions or the Restatement provision are controlling here: they are not. The question is how persuasive they are.

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[2] The note on Westlaw indicating it was a tentative draft not yet adopted disappeared sometime between October and today. *See also*, The ALI Advisor, Restatement of the Law Third, Torts: Liability for Economic Harm Approved (May 21, 2018).

The point made by Section 8 of the Restatement is that there are other ways, such as product liability or breach of warranty suits, to address "[m]ass harms caused by dangerous products." Id. That analysis addresses claims by plaintiffs who purchased a product, such as tobacco smokers or opiate users, but does not account for the kinds of harms the State seeks to remedy here: losses incurred by the public as a whole, such as increased costs for public services and health care. The Restatement itself seems to recognize this, noting: "In addition to the common-law claims recognized here, public officials may bring civil or criminal actions against a defendant who creates a public nuisance. An action of that type is the most common response to a defendant's invasion of a public right." Id. cmt b; *see also*, Restatement (Second) of Torts § 821C (1979) (referring to courts' "belief that to avoid multiplicity of actions invasions of rights common to all of the public should be left to be remedied by action by public officials."). Moreover, as the State notes, it is not asserting that the product itself was unreasonably dangerous. Instead, it bases its claims on Distributors' marketing and distribution practices. A products liability or warranty claim would not address these issues.

The focus of the Restatement provision appears to be on the impact of allowing a multiplicity of suits by people or entities who incurred losses as a result of a manufacturer's product. Allowing the State to bring one action does not create such a problem.

Distributors also argue that the State cannot show that they had control over the instrumentalities at the time of the harm, because they relinquished control of the drugs prior to the time the drugs were used. The complaint alleges: "Defendants controlled the instrumentalities of the nuisance: distribution channels that moved prescription opioids from manufacturers to pharmacies in the State and the systems (or lack thereof) for

monitoring and identifying suspicious orders of prescription opioids and the protocols for halting, investigating, and reporting those orders." Complaint ¶ 399. It may be that the State will not ultimately be able to prove that the distribution channels created the harm here, but that is an issue for trial or summary judgment. Under Vermont's generous pleading rules, although somewhat conclusory, this is sufficient. In any case, although Distributors cite numerous out-of-state authorities, the only Vermont case they cite is not on point. Although it discussed the idea of control, it addressed an entirely different situation in which the defendant railroad was in the hands of a receiver and thus not liable for the receiver's actions. State v. Vermont Cent. R. Co., 30 Vt. 108, 110 (1858). Moreover, the State accurately points to language in the Second Restatement suggesting that a defendant may be held liable for harm that continues after that defendant's actions have ceased, and that "substantial participation" in a chain of actions can be sufficient. Restatement (Second) of Torts § 834 (1979). For purposes of a motion to dismiss, the pleading is sufficient.

Finally, Distributors argue that "licensed distribution of a lawful product" cannot be a nuisance, that nuisance is historically a remedy for harms to property, and that the national trend is to limit such claims to impacts on land. However, the Vermont case they cite does not so limit the doctrine. Napro Dev. Corp. v. Town of Berlin, 135 Vt. 353, 357 (1977). While the Court noted that originally nuisance began "as a tort against land," it described *public* nuisance as developing as a "second similar yet distinct principal." Id. The Court went on to discuss at length whether obscenity could be a nuisance, clearly demonstrating that the question was not simply whether the harm was to land. Other authorities make clear that "a public nuisance does not necessarily involve interference with use and enjoyment of land." Restatement (Second) of Torts, § 821B (1979); *see also*

58 Am.Jur.2d *Nuisances* § 31, at 592 (2002)("A public nuisance, unlike a private nuisance, does not necessarily involve an interference with the use and enjoyment of land, or an invasion of another's interest in the private use and enjoyment of land, but encompasses any unreasonable interference with a right common to the general public.").

The court is also not persuaded that "distribution of a lawful product" can never be a public nuisance. Airports are lawful and regulated enterprises, but can be the source of a nuisance claim. In re Request for Jurisdictional Opinion re Changes in Physical Structures & Use at Burlington Int'l Airport for F-35A, 2015 VT 41, ¶ 36, 198 Vt. 510 (Morse, J., concurring)("Here, the right is to be free from the assault of ear-splitting noise generated by jet aircraft."); *accord* Gardiner v. Conservation Comm'n of Town of Waterford, 608 A.2d 672, 676 (Conn. 1992) (it has been clear for over 100 years that unreasonable conduct of "an otherwise lawful activity" can be a nuisance)(citation omitted); Krueger v. Mitchell, 332 N.W.2d 733, 741 (Wis. 1983)("It is well established that a business or activity may constitute a private nuisance even though it is operating in conformity with the law.").

Vermont case law does not resolve the exact scope of public nuisance law, and the State's claim here has no direct precedent. Thankfully, the opiate epidemic is somewhat sui generis. As counterintuitive as it sounds, "courts should be especially reluctant to dismiss on the basis of pleadings when the asserted theory of liability is novel or extreme." Ass'n of Haystack Prop. Owners, Inc. v. Sprague, 145 Vt. 443, 447 (1985). "The legal theory of a case should be explored in the light of facts as developed by the evidence, and, generally, not dismissed before trial because of the mere novelty of the allegations." Id. Thus, at this stage of the case, the State meets its burden.

Derivative Injury

Distributors next argue that the State's common law claims—now reduced to the nuisance claim—are barred because the State's injuries are "derivative." While this might be an issue with the negligence claim, depending upon the damages sought, the court is dismissing that claim. As to the nuisance claim, the argument fails. The cases Distributors cite involve claims to recover the medical expenses or other costs incurred by parties other than the plaintiff. The only Vermont case they cite—a colorful one, though outdated in at least some respects—said only that "a third person suffers an indirect and consequential loss because of some *contract obligation* to the injured party, the loss suffered by such third person does not constitute a cause of action." Nieberg v. Cohen, 88 Vt. 281, 287 (1914)(emphasis added). In fact, the case goes on to note that there are other claims that can be brought when an injury to one person impacts another, such as the loss of a spouse's services when they are injured. Id. Distributors cite nothing to suggest that this doctrine is relevant to a nuisance claim.

In any case, the State does not assert some consequential injury: it seeks injunctive relief and damages "as compensation for funds the State has already used to abate the nuisance." Complaint p. 124, ¶ F. That is a direct claim by the State, not a derivative one.

Free Public Services Doctrine

The last argument Distributors raise with regard to the common law claims is that the costs of public services such as police or public health care services are "to be borne by the public as a whole, not assessed against the tortfeasor whose negligence creates the need for the service." District of Columbia v. Air Fla., Inc., 750 F. 2d 1077, 1080 (D.C. Cir. 1984). This is known as the "free public services doctrine" or the "municipal cost recovery rule." While there are numerous jurisdictions that have adopted such a doctrine, Vermont

has not. In any case, the doctrine does not appear to apply to public nuisance claims. *See, e.g.*, In re Opioid Litigation, No. 400000/2017, 2018 WL 3115102, at *10 (N.Y. Sup. Ct. June 18, 2018)("The municipal cost recovery rule, however, does not bar a cause of action for public nuisance."); City of Flagstaff v. Atchison, Topeka & Santa Fe Ry. Co., 719 F.2d 322, 324 (9th Cir. 1983)(rule does not apply "where the acts of a private party create a public nuisance which the government seeks to abate").

Other courts in cases similar to this one have held that the doctrine is inapplicable to a pattern of conduct rather than a one-time catastrophic event. *See, e.g.*, State ex rel. Jennings v. Purdue Pharma L.P., No. CVN18 C01223MMJCCLD, 2019 WL 446382, at *6 (Del. Super. Ct. Feb. 4, 2019). "The current trend among state court judges ruling in opioid-related cases around the country is that the municipal cost recovery rule does not apply when, as alleged here, an ongoing and persistent course of intentional misconduct creates an unprecedented, man-made crisis that a governmental entity plaintiff could not have reasonably anticipated as part of its normal operating budget. . ." In re Nat'l Prescription Opiate Litig., No. 1:17-MD-2804, 2019 WL 3737023, at *8 (N.D. Ohio June 13, 2019); *see also* In re Opioid Litigation, No. 400000/2017, 2018 WL 3115102, at *10 (N.Y. Sup. Ct. June 18, 2018)(quotation omitted)("[A] review of the current state of the law revealed no case law supporting the manufacturer defendants' contention that such rule bars recovery for municipal expenses incurred, not by reason of an accident or an emergency situation necessitating the normal provision of police, fire and emergency services but to remedy public harm caused by an intentional, persistent course of deceptive conduct.").

It is far from clear that our Supreme Court would apply the doctrine here. Absent a ruling from our Supreme Court requiring application of the municipal cost recovery

doctrine, this court cannot say that it is "beyond doubt that there exist no facts or circumstances[] consistent with the complaint that would entitle the plaintiff to relief." Bock v. Gold, 2008 VT 81, ¶ 4.

Consumer Protection

There are two consumer protection claims asserted under the Vermont Consumer Protection Act, 9 V.S.A. § 2451 et seq (the Act). The first claim alleges unfair acts in commerce by Defendants in transporting and selling opiates while failing to comply with statutory duties to detect, prevent, and report diversion; improperly advertising and promoting opioids to increase sales; and providing "Savings Cards" to encourage long-term use of opioids. Complaint ¶ 376. The second alleges deceptive trade practices by Defendants in making and disseminating misleading statements about the risks and benefits of opioids, and in omitting or concealing material facts, thereby misleading prescribers and pharmacists. Id. ¶¶ 381-83. Distributors argue that these claims cannot succeed because they fail to allege any act in commerce, any deceptive practice, or any unfair practice.

The first argument is that the wholesaling of opioids to pharmacies is not covered because it does not involve marketing to consumers, and is thus not "in commerce." The Act "is designed not merely to compensate consumers for actual monetary losses resulting from fraudulent or deceptive practices in the marketplace, but more broadly to protect citizens from unfair or deceptive acts in commerce . . . and to encourage a commercial environment highlighted by integrity and fairness." Anderson v. Johnson, 2011 VT 17, ¶ 7, 189 Vt. 603 (quotations and citations omitted). It is to be interpreted broadly in favor of protecting consumers. Carter v. Gugliuzzi, 168 Vt. 48, 52 (1998). The law permits claims not only against direct sellers, but also against "other violators." 9 V.S.A. § 2461(b).

Our Supreme Court has thus allowed claims to be brought against manufacturers who had no direct contact with the consumers. Elkins v. Microsoft Corp., 174 Vt. 328, 331 (2002). There is no privity requirement. Id. Distributors cannot defeat this claim merely by saying they did not sell opioids directly to consumers. The Foti Fuels case on which they rely is not on point: it addressed a one-time business transaction the court described as a "purely private transaction" that was not part of a "consumer marketplace." Foti Fuels, Inc. v. Kurrle Corp., 2013 VT 111, ¶ 24, 195 Vt. 524.

Distributors next argue that the "deceptive act" claim must fail because they were merely disseminating the drug companies' materials, made no false statements, and did nothing likely to mislead consumers. The complaint, however, alleges that they did more. It includes allegations that they proposed deceptive marketing tactics and strategies, and that they knew or should have known the marketing was deceptive. Complaint ¶¶ 196, 198, 231, 237-42, 272, 381-83. Nor is the State required to allege that specific consumers were misled. The statute allows the Attorney General to sue when a defendant "is using *or is about to use*" any deceptive or unfair practice. 9 V.S.A. § 2458(a) (emphasis added). The Act thus does not require proof of the ultimate impact on a particular consumer, just a likelihood that consumers will be misled. In any case, the complaint alleges that Distributors marketed to pharmacists for the express purpose of influencing consumers, as well as by distributing "Savings Cards" for use by consumers, and that their misrepresentations were interpreted reasonably. Complaint, ¶¶ 194-200, 241-42, 272-80, 283, 383.

Finally, Distributors argue that the allegations are insufficient because they do not satisfy the three requirements necessary to determine whether a practice is unfair: (1) whether it "offends public policy," (2) whether it is "immoral, unethical, oppressive, or

unscrupulous," and (3) whether it "causes substantial injury to consumers." Christie v. Dalmig, Inc., 136 Vt. 597, 601 (1979), quoting F.T.C. v. Sperry & Hutchinson Co., 405 U.S. 233, 244 n.5 (1972). This court recently concluded that the three criteria are independent, and one is therefore sufficient. *See* State v. Big Brother Security Programs, No. 326-4-20 Cncv (April 26, 2020)(Toor, J.). If the allegations here are proved—transporting and selling opiates while failing to comply with statutory duties to detect, prevent, and report diversion; improperly and deceptively advertising and promoting opioids to increase sales; and providing "Savings Cards" to encourage long-term use of opioids—they would certainly be sufficient for a jury to conclude that they were immoral and unethical.

Order

Defendants' motion to dismiss is granted as to the negligence claim, but otherwise denied. Answers shall be filed within 14 days pursuant to V.R.C.P. 12(a)(3); a discovery schedule shall be filed within 30 days thereafter pursuant to V.R.C.P. 16.3(b).

Electronically signed on May 12, 2020 at 03:36 PM pursuant to V.R.E.F. 7(d).

Helen M. Toor
Superior Court Judge

Notifications:
Jill S. Abrams (ERN 5583), Attorney for Plaintiff State of Vermont
Jonathan A. Lax (ERN 5316), Attorney for Defendant Cardinal Health, Inc.
Geoffrey J. Vitt (ERN 1787), Attorney for Defendant McKesson Corporation
Betsy A. Miller (ERN 10006), Attorney for party 1 Co-Counsel
Victoria S. Nugent (ERN 10008), Attorney for party 1 Co-Counsel
Johanna M Hickman (ERN 10007), Attorney for party 1 Co-Counsel
Maya Sequeira (ERN 10045), Attorney for party 1 Co-Counsel
Carolyn G. Anderson (ERN 9968), Attorney for party 1 Co-Counsel
June P. Hoidal (ERN 9969), Attorney for party 1 Co-Counsel

Behdad C. Sadeghi (ERN 10405), Attorney for party 1 Co-Counsel
Neil K. Roman (ERN 10483), Attorney for party 3 Co-Counsel
Marianne Kies (ERN 10560), Attorney for party 3 Co-Counsel
Claire C. Dean (ERN 10931), Attorney for party 3 Co-Counsel
Juli Ann Lund (ERN 10930), Attorney for party 2 Co-Counsel

STATE OF WEST VIRGINIA

At the Supreme Court of Appeals continued and held at Charleston, Kanawha County, on the 5th day of January, 2016, the following order was made and entered **in vacation**:

State of West Virginia ex rel.
Amerisourcebergen Drug Corporation;
Miami-Luken, Inc.;
JM. Smith Corporporation, doing
business as Smith Drug Co.;
The Harvard Drug Group, LLC;
Anda Inc.;
Associated Pharmacies, Inc.;
H.D. Smith Wholesale Drug Company;
Keysource Medical, Inc.;
Masters Pharmaceuticals, Inc.;
Quest Pharmaceuticals, Inc.;
Richie Pharmacal Company, Inc.;
and Top Rx, Inc.,
Petitioners

vs.) No. 15-1026

The Honorable William S. Thompson, Judge
of the Circuit Court of Boone County;
Patrick Morrisey, Attorney General;
Joseph Thorton, in his capacity as the Secretary of the
West Virginia Department of Military Affairs and Public Safety;
and Karen Bowling, in her capacity as the Secretary of
the West Virginia Department of Health and Human Resources,
Respondents

ORDER

On October 23, 2015, the petitioners, Amerisourcebergen Drug Corp., et al., by counsel, A.L. Emch, and Robert O. Passmore, Jackson Kelly PLLC, presented to the Court a petition praying for a writ of prohibition to be directed against the respondent, the

Honorable William S. Thompson, Judge of the Circuit Court of Boone County, as therein set forth. On the same day, Cardinal Health, Inc., by counsel W. Henry Jernigan, Jr., Dinsmore & Shohl LLP, filed an *amicus curiae* brief in support of the petitioners. Thereafter, on October 26, 2015, the Healthcare Distribution Management Association and the National Association of Wholesaler-Distributors, by counsel John H. Tinney, Jr. and John K. Cecil, The Tinney Law Firm, filed an *amici curiae* brief in support of the petitioners.

Finally, on November 30, 2015, the respondents, Patrick Morrisey, Attorney General, et al., by James Cagle and P. Rodney Jackson, Cagle & Jackson; and Sean P. McGinley, DiTrapano, Barrett DiPiero, McGinley & Simmons, PLLC, filed a response to the petition.

Upon consideration and review, the Court is of the opinion that a rule should not be awarded, and the writ prayed for by the petitioner is hereby refused. Chief Justice Ketchum and Justice Loughry would issue a rule to show cause.

A True Copy

Attest: //s// Rory L. Perry II
Clerk of Court

STATE OF WEST VIRGINIA

At a Regular Term of the Supreme Court of Appeals, continued and held at Charleston, Kanawha County, on June 4, 2019, the following order was made and entered:

State of West Virginia ex rel.
Amerisourcebergen Drug Corporation,
Cardinal Health, Inc., and
McKesson Corporation,
Petitioners

vs.) No. 19-0210

Honorable David W. Hummel, Jr., Judge of the
Circuit Court of Marshall County, et al.,
Respondents

ORDER

On March 8, 2019, the petitioners, Amerisourcebergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation, by counsel A.L. Emch and Gretchen M. Callas, Jackson Kelly PLLC; Russell D. Jessee and William D. Wilmoth, Steptoe & Johnson PLLC; Harry G. Shaffer III and Todd A. Mount, Shaffer & Shaffer, PLLC; Jeffrey M. Wakefield, Flaherty Sensabaugh Bonasso PLLC; Daniel C. Cooper and Jamison H. Cooper, Cooper Law Offices, PLLC; and Brian A. Glasser, Steven R. Ruby, and Raymond S. Franks II, Bailey Glasser LLP, presented to the Court a petition praying for a writ of prohibition to be directed against the respondent, the Honorable David W. Hummel, Jr., Judge of the Circuit Court of Marshall County, as therein set forth.

Thereafter, on May 13, 2019, the respondents, Brook County Commission, et al., by counsel Clayton J. Fitzsimmons, Robert P. Fitzsimmons, and Mark A. Colantonio, Fitzsimmons Law Firm, PLLC; Samuel D. Madia, Shaffer Madia Law, PLLC; Paul J. Napoli and Joseph L. Ciaccio, Napoli Shkolnik, LLP; Jonathan E. Turak, Gold, Khourey & Turak; and Daniel J. Guida, Guida Law Office, filed a response to the petition.

On the same day, May 13, 2019, Thirty West Virginia Counties and Forty-Four West Virginia Cities, by counsel Paul T. Farrell, Jr., Greene, Ketchum, Farrell, Bailey & Tweel, LLP;

JUN 12 2019

and Anthony J. Majestro, Powell & Majestro, PLLC, filed an amici curiae brief in support of the respondents. The West Virginia Municipal League and the County Commissioners' Association of West Virginia, by counsel Mark W. Matkovich, White Law Offices, PLLC; and Eldon A. Callen, filed a motion for leave to join in the brief of amici curiae also on May 13, 2019. The motion of the West Virginia Municipal League and the County Commissioners' Association of West Virginia is hereby granted.

Upon consideration and review of the petition and all pleadings filed herein, the Court is of the opinion that a rule should not be awarded, and the writ prayed for by the petitioner is hereby refused. Justice Workman disqualified.

A True Copy

Attest: /s/ Edythe Nash Gaiser
Clerk of Court

EFiled: Oct 31 2019 02:57PM EDT
Transaction ID 64374772

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

IN RE: OPIOID LITIGATION **Civil Action No. 19-C-9000**

THIS DOCUMENT APPLIES TO:

MONONGALIA COUNTY COMMISSION, et al., *Plaintiffs,* v. PURDUE PHARMA L.P., et al., *Defendants.*	Civil Action Nos. 18-C-222 MSH 18-C-233 MSH 18-C-234 MSH 18-C-235 MSH 18-C-236 MSH

ORDER DENYING PHARMACY DEFENDANTS'[1] MOTION TO DISMISS PLAINTIFFS' COMPLAINT

Pending before the Court is the *Pharmacy Defendants' Motion to Dismiss Plaintiffs' Complaint* (Transaction ID 63617464), filed in *Monongalia County Commission, et al. v. Purdue Pharma L.P., et al.,* Civil Action Nos. 18-C-222 MSH and 18-C-233 MSH through 18-C-236 MSH (the *Monongalia County* cases), which has been fully briefed by the parties. The Court has reviewed the parties' briefing of the instant motion, as well as the Circuit Court of Marshall County's *Order Denying Walmart Stores East, L.P., Rite Aid of Maryland, Inc., Kroger Limited Partnership II, and CVS Indiana, L.L.C.'s Motion to Dismiss* filed in *Brooke County Commission, et al. v. Purdue Pharma L.P., et al.,* Civil Action Nos. 17-C-248 MSH through 17-C-255 MSH (the *Brooke County* cases). A copy of the Order is attached as Exhibit A.

In addition, the Court has reviewed *Plaintiffs' Motion for Entry of Orders Denying Defendants' Pending Motions to Dismiss* and proposed Orders (Transaction ID 64344046), the

[1] The Pharmacy Defendants refer to Walmart Stores East, L.P., Rite Aid of Maryland, Inc., Kroger Limited Partnership II, and CVS Indiana, L.L.C.

Pharmacy Defendants' *Notice Pursuant to the Court's Order of October 9, 2019 Respecting Pharmacy Defendants' Monongalia Motion to Dismiss* (Transaction ID 64346542) and *Response to Plaintiffs' Motion for Entry of Orders Denying Defendants' Pending Motions to Dismiss* (Transaction ID 64367308), and Defendants' *Objection to Interlocutory Decision, Notice of Intent to Seek Extraordinary Writ, and Request for Findings of Fact and Conclusions of Law* (Transaction ID 64346834). Having conferred with one another to ensure uniformity of their decision, as contemplated by *Rule 26.07(a)* of the *West Virginia Trial Court Rules*, the Presiding Judges unanimously **DENY** the *Pharmacy Defendants' Motion to Dismiss Plaintiffs' Complaint* (Transaction ID 63617464) for the following reasons.

The claims asserted by Plaintiffs in the *Monongalia County* cases are identical to those asserted by the Plaintiffs in the *Brooke County* cases, which are companion Opioid Litigation cases now pending before the Mass Litigation Panel. Prior to referral of the Opioid Litigation to the Panel, both the *Brooke County* cases and the *Monongalia County* cases were pending before the Honorable David W. Hummel, Jr. in the Circuit Court of Marshall County, West Virginia. The Pharmacy Defendants filed a motion to dismiss the complaint in the *Brooke County* cases, asserting the same arguments and issues raised in the instant motion to dismiss. The motion was fully briefed and argued before Judge Hummel, who denied the motion to dismiss in its entirety. See Exhibit A.

Thereafter, Defendants Amerisourcebergen Drug Corporation, Cardinal Health and McKesson Corporation filed a Petition for a Writ of Prohibition with the Supreme Court of Appeals of West Virginia concerning the Marshall County Circuit Court's denial of their motions to dismiss the Complaint in the *Brooke County* cases, and the Pharmacy Defendants filed a Motion to Join the Distributor Defendants' Petition for Writ of Prohibition. The Petition was unanimously refused.

As previously held, Judge Hummel has entered numerous Orders denying motions to dismiss in the *Brooke County* cases which the Court finds are well-founded. Those Orders are the law of the case. The Court will not revisit Judge Hummel's rulings, to the extent the same parties who filed motions to dismiss in the *Brooke County* cases have filed identical motions to dismiss in the *Monongalia County* cases. See *Order Regarding Rulings Issued During the September 20, 2019 Status Conference* (Transaction ID 64297517). Accordingly, the Court hereby adopts and incorporates by reference, as if fully set forth herein, the findings of fact and conclusions of law set forth in the Marshall County Circuit Court's *Order Denying Walmart Stores East, L.P., Rite Aid of Maryland, Inc., Kroger Limited Partnership II, and CVS Indiana, L.L.C.'s Motion to Dismiss* entered in the *Brooke County* cases. See Exhibit A.

The Pharmacy Defendants contend their motion and reply filed in the *Monongalia County* cases rely upon decisions rendered after Judge Hummel's Order denying the motion to dismiss filed in the *Brooke County* cases and, therefore, the Court should consider the pending motion and new authority. Pharmacy Defendants' *Notice Pursuant to the Court's Order of October 9, 2019 Respecting Pharmacy Defendants' Monongalia Motion to Dismiss* (Transaction ID 64346542) and *Response to Plaintiffs' Motion for Entry of Orders Denying Defendants' Pending Motions to Dismiss* (Transaction ID 64367308). The Court is not persuaded by this argument. The new authority cited by the Pharmacy Defendants is from trial courts in other jurisdictions that have no precedential value.

Based upon the foregoing, it is accordingly **ORDERED** that *Pharmacy Defendants' Motion to Dismiss Plaintiffs' Complaint* (Transaction ID 63617464) is **DENIED.**

It is further **ORDERED** that all exceptions and objections are noted and preserved.

A copy of this Order has been electronically served on all counsel of record this day via File & Serve*Xpress*.

ENTERED: October 31, 2019.

/s/ Alan D. Moats
Lead Presiding Judge
Opioid Litigation

Total Pages:(338 of 465)

STATE OF WEST VIRGINIA

At a Regular Term of the Supreme Court of Appeals, continued and held at Charleston, Kanawha County, on January 30, 2020, the following order was made and entered:

State of West Virginia ex rel.
AmerisourceBergen Drug Corporation, et al.,
Petitioners

vs.) No. 19-1051

Honorable Alan D. Moats, Lead Presiding Judge,
Opioid Litigation Mass Litigation Panel, et al.,
Respondents

ORDER

On November 18, 2019, the petitioners, AmerisourceBergen Drug Corporation, et al., by counsel, Russell D. Jessee and John J. Meadows, Steptoe & Johnson, PLLC, presented to the Court a petition praying for a writ of prohibition to be directed against the respondents, as therein set forth. Thereafter, on December 19, 2019, the respondents, Monongalia County Commission, Marion County Commission, Doddridge County Commission, Randolph County Commission, and Upshur County Commission, by counsel, Robert P. Fitzsimmons, Clayton J. Fitzsimmons, and Mark A. Colantonio, Fitzsimmons Law Firm PLLC, filed a response to the petition.

Upon consideration and review, the Court is of the opinion that a rule should not be awarded, and the writ prayed for by the petitioners is hereby refused.

A True Copy

Attest: /s/ Edythe Nash Gaiser
Clerk of Court

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EFiled: May 23 2022 05:59PM EDT
Transaction ID 67650385

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

IN RE: OPIOID LITIGATION **CIVIL ACTION NO. 21-C-9000 MFR**

THIS DOCUMENT APPLIES TO ALL MANUFACTURER CASES

AMENDED ORDER REGARDING RULINGS ISSUED DURING MARCH 25, 2022, PRETRIAL CONFERENCE

On March, 25, 2022, Presiding Judge Derek C. Swope conducted a status conference and issued rulings on motions for summary judgment, motions to exclude expert testimony, and motions *in limine* filed by the following parties: State of West Virginia ex rel. Patrick Morrisey, Attorney General (the "State"); Teva Pharmaceuticals USA, Inc. ("Teva USA"), specially-appearing Teva Pharmaceuticals Industries Ltd. ("Teva Ltd."); Cephalon, Inc. ("Cephalon"); Defendants Watson Laboratories, Inc., Warner Chilcott Company LLC, Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.), Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.-Salt Lake City), and Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc.-Florida) (collectively the "Actavis Generic Entities"); Allergan Finance, LLC (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.), Allergan USA, Inc., and Allergan Sales, LLC (collectively "Allergan"); Defendants Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., and Johnson & Johnson (collectively "Janssen"). *Order Regarding Rulings Issued During March 25, 2022, Pretrial Conference* (Transaction ID 67434309, entered on March 29, 2022). The Court amends its March 29, 2022, Order to provide the following additional bases for its rulings.

MOTIONS FOR SUMMARY JUDGMENT

Summary judgment "shall be granted" if there is no "genuine" dispute of material fact and the movant is entitled to judgment as a matter of law. *Conrad v. ARA Szabo*, 198 W. Va. 362, 480 S.E.2d 801, 809 (1996). "A motion for summary judgment should be granted only when it is clear that there is no genuine issue of fact to be tried and inquiry concerning the facts is not desirable to clarify the application of the law." *Painter v. Peavy*, 192 W. Va. 189, 192, 451 S.E.2d 755, 768 (1994). Avoiding summary judgment requires a party to present sufficient evidence for a reasonable trier of fact to find in its favor. Syl. Pt. 5, *Jividen v. Law*, 194 W. Va. 705, 461 S.E.2d 451 (1995). If the nonmoving party fails "to make sufficient showing on an essential element" of its claim, the movant is entitled to judgment as a matter of law. Syl. Pt. 3, *Jochum v. Waste Mgmt. of W. Virginia, Inc.*, 224 W. Va. 44, 680 S.E.2d 59 (2009). With this standard in mind, the Court rules as follows on the Motions for Summary Judgment filed by the parties.

1. **Plaintiff's Motion for Partial Summary Judgment on Defendants' Statutory and Regulatory Duties and Memorandum of Law in Support (Transaction ID 67347633).**

West Virginia law prohibits courts from issuing advisory opinions, dictating that courts "not … adjudicate rights which are merely contingent or dependent upon contingent events, as distinguished from actual controversies." *Farley v. Graney*, 146 W. Va. 22, 119 S.E.2d 833, 838 (1960). Summary judgment is "not appropriate … as a vehicle for fragmented adjudication of non-determinative issues." *S.E.C. v. Thrasher*, 152 F. Supp. 2d 291, 295 (S.D.N.Y. 2001). Because the State's Motion seeks judgment divorced from the facts of this litigation, it seeks an advisory opinion. Evaluating the defendants' implementation of the Controlled Substances Act and its connection to State law is a highly-fact specific inquiry that goes to the heart of the matter before the Court; resolution of this issue based entirely on hypotheticals is not beneficial. Therefore, the Court **DENIES** this motion.

2. The State's Motion for Summary Judgment on Defendants' Affirmative Defenses and Memorandum of Law in Support (Transaction ID 67347633).

The State brings claims for public nuisance and for violations of the West Virginia Consumer Credit and Protection Act. The State is not seeking damages in connection with either claim.

Defendants' fault-shifting defenses are inapplicable to the State's Public Nuisance claim because comparative fault is not an element of the liability phase (Phase I) of this public nuisance case. *See City of Huntington v. AmerisourceBergen Drug Corp.*, 2021 WL 1711382, at *2 (S.D. W. Va. Apr. 29, 2021). Similarly, Defendants' fault-shifting defenses do not apply to the State's West Virginia Consumer Credit Protection Act ("WVCCPA") claims, because the State seeks only civil penalties and other appropriate relief. Under that claim, the fault of the State or anyone else is irrelevant. *See State ex rel. 3M Co. v. Hoke*, 244 W. Va. 299, 852 S.E.2d 799, 813 (2020).

Further, Defendants' affirmative defenses related to offset and collateral source payments are also inapplicable to the Phase I liability trial; those defenses are relevant to the issue of abatement but are not relevant to liability. *See, e.g.*, Restatement (Second) of Torts § 920A cmt. (b) ("Payments made to or benefits conferred on the injured party from other sources [i.e., those unconnected to the defendant] are not credited against the tortfeasor's liability, although they cover all or a part of the harm for which the tortfeasor is liable.").

However, the same reasoning does not apply with regard to the Defendants' time-based defenses centered on the statute of limitations and laches.

Therefore, this Motion is **GRANTED IN PART, DENIED IN PART.** The Court **GRANTS** the State's Motion for Partial Summary Judgment with regard to the Defendants' fault-shifting, offset, and other similar affirmative defenses, but **DENIES** the Motion with regard to statute of limitations and laches affirmative defenses.

3. Manufacturers' Joint Motion for Summary Judgment on the State's Public Nuisance Claim and Memorandum of Law in Support (Transaction ID 67359984).

West Virginia defines public nuisance as an "an act or condition that unlawfully operates to hurt or inconvenience an indefinite number of persons." *Hark v. Mountain Fork Lumber Co.,* 127 W.Va. 586, 595-96, 34 S.E.2d 348, 354 (1945). The Supreme Court of Appeals of West Virginia has determined this definition is consistent with the *Restatement (Second) of Torts §* 821B(1) (1979), which defines a public nuisance as "unreasonable interference with a right common to the general public." *Duff v. Morgantown Energy Ass'n*, 187 W. Va. 712, 716 n.6, 421 S.E.2d 253, 257 n.6 (1992). In West Virginia, "nuisance is a flexible area of the law that is adaptable to a wide variety of factual situations." *Sharon Steel Corp. v. City of Fairmont*, 175 W. Va. 479, 483, 334 S.E.2d 616, 621 (1985). This is a fact-specific determination. The Court further notes that at least 22 states have found public nuisance claims based on the marketing of prescription opioids to be viable.

The Court is not persuaded to follow the ruling from Oklahoma, *State ex rel. Hunter v. Johnson & Johnson*, 499 P.3d 719 (Okla. 2021). In Oklahoma's opioid litigation, the court dismissed Oklahoma's public nuisance claim because in Oklahoma, public nuisance is statutory and West Virginia has no statute equivalent to the Oklahoma Supreme Court's interpretation of the Oklahoma statute.

Based on West Virginia's public nuisance jurisprudence Manufacturers' Joint Motion on the State's Public Nuisance Claim is **DENIED**.

4. Manufacturers' Joint Motion for Partial Summary Judgment on the State's West Virginia Consumer Credit and Protection Act Claim (Transaction ID 67359676) and Memorandum of Law in Support (Transaction ID 67367412).

"[A] cause of action by the Attorney General accrues, and the statute of limitation in West Virginia Code § 46A-7-111(2) begins to run, from the time the Attorney General discovers or

reasonably should have discovered the deception, fraud, or other unlawful conduct supporting the action." Syl. Pt. 8, *State ex rel. 3M Co. v. Hoke*, 244 W. Va. 299, 852 S.E.2d 799 (2020). Such determinations generally involve questions of material fact to be resolved by the trier of fact. *Id.*

To the extent Manufacturers rely on *White v. Wyeth*, 227 W. Va. 131, 141 (2010), that case is distinguishable. *White v. Wyeth* involved a private consumer's claim, not an action brought by the Attorney General, as is the case here.

Nor is the Court persuaded that the WVCCPA does not apply to third-party statements. "[R]ecruiting and paying affiliates" who engaged in false and deceptive advertising practices, "managing those affiliates," "suggesting substantive edits" to the content disseminated by those affiliates, and "purchasing banner space" to run the content of its affiliates can sufficiently demonstrate the defendant's direct participation in the affiliates' conduct. *Fed. Trade Comm'n v. LeadClick Media, LLC*, 838 F.3d 158, 171–72 (2d Cir. 2016).

Finally, to the extent Defendants argue the State's WVCCPA claim implicates the First Amendment to the United States Constitution, the Court notes misleading commercial speech is not constitutionally protected. *See State ex rel. McGraw v. Imperial Mktg.*, 196 W. Va. 346, 361, 472 S.E.2d 792, 807 (1996) (citing *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980)).

Therefore, Manufacturers' Motion for Partial Summary Judgment on the State's West Virginia Consumer Credit and Protection Act Claim is **DENIED**.

5. **Renewed Motion of Specially-Appearing Defendant Teva Pharmaceuticals Industries Ltd. to Dismiss All Claims Against It for Lack of Personal Jurisdiction, or, in the Alternative, for Summary Judgment (Transaction ID 67346726) and Memorandum of Law in Support (Transaction ID 67367412).**

Teva Ltd. is a foreign Israeli company with its headquarters in Israel. Teva Ltd. argues that it does not manufacturer, market, promote, or sell opioids in West Virginia or in the United

States, and it has no office, property, employees, or registered agent in the United States. As a result, Teva Ltd. requests dismissal or summary judgment for lack of personal jurisdiction. The State argues that Teva Ltd. itself engaged in the alleged misconduct via its subsidiaries and is concerned about the financial wherewithal of its US-based subsidiaries, Teva USA and Cephalon, and has included Teva Ltd. in the action because it believes there is a valid jurisdiction claim and because of the potential necessity of piercing the corporate veil. Under West Virginia law, "[t]he propriety of piercing the corporate veil should rarely be determined upon a motion for summary judgment. Instead, the propriety of piercing the corporate veil usually involves numerous questions of fact for the trier of the facts to determine upon all of the evidence." Syl. Pt. 6, *Laya v. Erin Homes, Inc.*, 177 W.Va. 343, 352 S.E.2d 93 (1986)." *Dailey v. Ayers Land Dev., LLC*, 241 W. Va. 404, 825 S.E.2d 351, 353 (2019). The Court finds this reasoning and the reasoning of Judge Polster in the federal MDL persuasive, as well as that cases of corporate identity, such as this, should rarely be determined upon a motion for summary judgment, and therefore **DENIES** Teva Ltd.'s Motion.

6. **Teva Pharmaceuticals USA Inc.'s Motion for Summary Judgment (Transaction ID 67347144) and Memorandum of Law In Support (Transaction ID 67367542).**

Teva USA argues that summary judgment should be granted in its favor for several reasons. First, the State's claims against Teva USA fail because there is no evidence that its conduct constitutes a public nuisance. Teva USA claims there is no evidence of misleading statements from Teva USA in West Virginia, and that there is no evidence Teva USA failed to monitor for and report suspicious orders. Second, Teva USA argues there is no evidence of causation to support a public nuisance claim. Third and finally, Teva USA argues the State's WVCCPA claims are untimely.

In opposition, the State argues that Teva USA engaged in misleading marketing in West Virginia, including, but not limited to, the marketing of Actiq and Fentora, which were only approved for opioid tolerant cancer patients. State Resp. to Teva USA and Cephalon at 5–9. In support, the State identified several documents produced in discovery regarding these allegations. *Id.* Further, the State points to deposition testimony regarding alleged off-label promotion and misrepresentations about the efficacy of opioids as a class. *Id.* at 9–14.

Therefore, as in *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 4178617 (N.D. Ohio Sept. 3, 2019), the State here has provided adequate evidence to demonstrate that a genuine issue of material fact exists in relation to the arguments raised in Teva USA's Motion for Summary Judgment. Therefore, the Court **DENIES** Teva USA's Motion.

7. Cephalon, Inc.'s Motion for Summary Judgment (Transaction ID 67348500) and Memorandum of Law in Support (Transaction ID 67367216).

Cephalon argues that the State's claims against it fail because there is no evidence of false or misleading marketing by Cephalon in West Virginia after September 13, 2013. Further, there is no evidence that Cephalon violated the Controlled Substances Act by failing to identify or report suspicious orders. Finally, Cephalon argues that the State's public nuisance claim fails for a lack of causation.

The State's opposition to Cephalon's Motion was combined with its response to Teva USA's Motion due, in part, to the similarity of the arguments between the two Motions for Summary Judgment. State Resp. to Mot. at 2. The Court adopts the reasoning set forth in its ruling denying Teva USA's Motion for Summary Judgment and finds that there is adequate evidence to create a genuine issue of material fact concerning the arguments raised by Cephalon, and therefore the Court **DENIES** Cephalon's Motion.

8. Defendants Actavis Generic Entities' Motion for Summary Judgment (Transaction ID 67348201) and Memorandum of Law in Support (Transaction ID 67367109).

The Actavis Generic Entities identify several reasons why the State's claims against them fail. First, both claims fail to the extent they are based upon false marketing because there is no evidence of false or misleading marketing by any Actavis Generic Entity in West Virginia, and because any "failure to disclose" theory is preempted by federal law. Second, both claims fail to the extent they are based upon suspicious order monitoring because the State has no evidence that any Actavis Generic Entity failed to report suspicious orders. Third, the Actavis Generic Entities assert the State's public nuisance claim fails due to lack of causation. Fourth and finally, the Actavis Generic Entities argue that the WVCCPA claim fails due to the statute of limitation period.

In response, the State points to evidence that it claims demonstrates that the Actavis Generic Entities engaged in misleading marketing of their branded and generic opioids. State Resp. to Actavis Mot. at 15–16. The State similarly argues there is evidence supporting its claims based on SOM conduct. *Id.* at 17–18. Further, the State argues the marketing claims are not preempted because their claims are not predicated on FDA-approved language. *Id.* at 17. Also, the State argues it has established causation for the alleged public nuisance, and that West Virginia law does not require the State to prove medically inappropriate prescribing and does not require the State to prove its claims through individualized proof of harm. *Id.* at 18–19. Finally, the State argues that its WVCCPA claims are not barred by the statute of limitations because it was tolled by the discovery rule and fraudulent concealment doctrine. *Id.* The State also points out that there is evidence of WVCCPA violations after September 2013. *Id.* at 20.

The Court believes the State has provided adequate evidence to demonstrate that a genuine issue of material fact exists in relation to the arguments raised in the Actavis Generic Entities' Motion for Summary Judgment and that the State's allegations do not concern the nature of the

Actavis Generic Entities' warning labels, but misleading marketing. Therefore, the Court **DENIES** Actavis Generic Entities' Motion.

9. Allergan Defendants' Motion for Partial Summary Judgment (Transaction ID 67348216) and Memorandum of Law in Support (Transaction ID 67379957).

Allergan Defendants have moved for partial summary judgment. In support, they argue that the State has made no claims against the Allergan Defendants for drugs other than Kadian. They also argue that the State does not dispute that Alpharma retained sole liability for pre-2009 marketing of Kadian and cannot rely on that conduct in its claims against the Allergan Defendants. As such, the State's claims against Allergan Defendants should be limited to conduct related to Kadian after 2009.

The State contends that it's Complaint alleges that Allergan "helped cause the opioid epidemic by engaging in strategic campaigns of misrepresentations about the risks and benefits of *opioid* use." Am. Compl. ¶ 17. The State points to several other allegations in the Complaint that allege conduct of all Defendants, including the Allergan Defendants, that allege conduct related broadly to opioids. The State further points to discovery that was conducted that it claims put Allergan on notice that all opioids were being referenced, including both written discovery and expert discovery. Finally, the State argues that it can rely on Alpharma marketing materials because after Kadian was acquired by Actavis Elizabeth, LLC in December 2008, Alpharma marketing materials continued to be used to market Kadian for at least some period of time.

The Court finds the State has pleaded sufficient allegations to allow claims other than Kadian post-2009 claims to proceed to trial and be adjudicated on the merits of the evidence at trial. Therefore, the Court **DENIES** the Allergan Defendants' Motion.

10. Janssen's Motion for Partial Summary Judgment on the Marketing of Duragesic as a Basis for Liability (Transaction ID 67339302) and Memorandum of Law in Support (Transaction ID 67379957).

Janssen moves for partial summary judgment on the marketing of Duragesic, arguing that the State released it from such claims in 2010. A release "is the giving up or abandoning of a claim or right to the person against whom the claim exists or the right is to be exercised and enforce." *McDaniel v. Kleiss*, 202 W. Va. 272, 503 S.E.2d 840, 847 (1998). In West Virginia, "settlements are highly regarded and scrupulously enforced, so long as they are legally sound." *DeVane v. Kennedy*, 205 W. Va. 519, 519 S.E.2d 622, 637 (1999). The 2010 Release the State entered into with Janssen states that "Johnson & Johnson and Janssen … are hereby released forever and discharged from all manner of claims, demands, actions, suits, causes of action, damages whenever incurred, liabilities of any nature whatsoever, [by] the State of West Virginia … arising out of or relating in any way to any conduct of any Released Party regarding the prescription drug Duragesic prior to dismissal of this action." Therefore, the Court **GRANTS** Janssen's Motion on the basis of the prior release entered into with the State as it relates to claims against Janssen involving Duragesic-related conduct through the December 23, 2010, dismissal date. The State may prove claims involving Janssen's other opioids and claims regarding Janssen's conduct in promoting opioids in general through unbranded marketing or third-party promotion.

11. Janssen's Motion for Partial Summary Judgment on the State's Claims Targeting Unjoined Former Subsidiaries and Memorandum of Law in Support (Transaction ID 67336546).

This Motion for Partial Summary Judgment seeks summary judgment on claims related to Tasmanian Alkaloids and Normaco, two former subsidiaries of Janssen not parties to this litigation. In response, the State argues that it is not attempting to impose liability on either Tasmanian Alkaloids or Noramco. Instead, the State merely seeks to introduce evidence related to those two

former subsidiaries to show motive, knowledge, and notice. (Trans. ID 67397285), at 8. As the State is not seeking to impose liability on either Tasmanian Alkaoids or Noramco, the Court **DENIES** Janssen's Motion for Partial Summary Judgment on Unjoined Former Subsidiaries.

MOTIONS TO EXCLUDE EXPERT TESTIMONY

West Virginia relies on the *Daubert* analysis for admission of novel scientific expert testimony under West Virginia Rule of Evidence 702. *Wilt v. Buracker*, 191 W. Va. 39, 443 S.E.2d 196 (W. Va. 1993) (adopting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 113 S. Ct. 2786 (1993)). Under *Daubert*, expert testimony is admissible where the witness is qualified by "knowledge, skill, experience, training, or education." *Daubert*, 509 U.S. at 588.

Rule 702 of the West Virginia Rules of Evidence provides:

> (a) If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise.
>
> (b) In addition to the requirements in subsection (a), expert testimony based on a novel scientific theory, principle, methodology, or procedure is admissible only if:
>
> (1) the testimony is based on sufficient facts or data;
>
> (2) the testimony is the product of reliable principles and methods; and
>
> (3) the expert has reliably applied the principles and methods to the facts of the case.

Pursuant to Rule 702, expert testimony is admissible at trial where (1) the witness is qualified as an expert and (2) the expert's testimony is relevant and reliable. *Harris v. CSX Transp., Inc.*, 232 W. Va. 617, 621 (2013) (citing *San Francisco v. Wendy's Int'l, Inc.*, 221 W. Va. 734, 741, 656 S.E.2d 485, 494 (2007)). The party seeking admission of an expert bears the burden of

proof on satisfaction of these requirements. *See, e.g.*, *San Francisco v. Wendy's Int'l, Inc.*, 221 W. Va. at 743 (relying on *Gentry v. Mangum*, 195 W. Va. 512 522, 466 S.E.2d 171, 181 (1995)).

The Court must assess the "soundness of the expert's methodology," not the correctness of his or her opinion. *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995) ("*Daubert* II"). The expert's opinion must be based on "'knowledge' not merely 'subjective belief or unsupported speculation.'" *Daubert*, 509 U.S. at 590.

With these legal principles in mind, the Court turns to the Motions to Exclude various expert testimony filed by the parties.

1. **State's Motion to Exclude Certain Testimony of M. Laurentius Marais., Ph.D. on State Expert Maureen Gorman's Marketing Opinions and Memorandum of Law in Support (Transaction ID 67387135).**

As stated above, Rule 702 allows "a circuit court to qualify an expert by virtue of education or experience or by some combination of those attributes." *Gentry v. Mangum*, 195 W. Va. 512, 466 S.E.2d 171, 188 (1995). There is no "best expert" rule in West Virginia, and "the issue of whether the witness is the best expert witness on the specific subject is a matter that goes to weight of testimony," not to admissibility. *W. Va. Dep't of Transp. v. Parkersburg Inn, Inc.*, 222 W. Va. 688, 697, 671 S.E.2d 693, 702 (2008).

The State seeks to bar Dr. Marais's testimony with respect to Maureen Gorman by arguing that he is not a "media consultant" like Ms. Gorman. However, as Janssen argues, Dr. Marais is a statistician and is not attacking Ms. Gorman's marketing opinions. Instead, he attacks the statistical basis and methodology for Ms. Gorman's opinions. Per *Gentry v. Mangum*, whether Dr. Marais is the best expert witness to counter Ms. Gorman's testimony goes to the weight, rather than the admissibility, of his testimony. Therefore, the State's Motion to Exclude Testimony of Dr. Laurentius Marais with Regard to Maureen Gorman is **DENIED**.

2. **State's Motion to Exclude Specific Testimony of Edward Michna, M.D., on Numbers of Actiq and Fentora Prescriptions in West Virginia and Memorandum of Law in Support (Transaction ID 67373014).**

The arguments raised by the State in regard to Dr. Edward Michna's testimony are unpersuasive for the same reasons the Court noted in its denial of the State's Motion to Exclude certain testimony of Dr. Laurentius Marais; those arguments go to the weight of Dr. Michna's testimony, not its admissibility. *See W. Va. Dep't of Transp. v. Parkersburg Inn, Inc.*, 222 W. Va. at 697, 671 S.E.2d at 702. To the extent the State argues the evidence relied upon by Dr. Michna is inadmissible, West Virginia law allows experts to rely on inadmissible evidence. *See* W. Va. R. Evid. 703. Therefore, the State's Motion to Exclude Specific Testimony of Edward Michna, M.D., on Numbers of Actiq and Fentora Prescriptions in West Virginia is **DENIED**.

3. **State's Motion to Exclude Testimony of Jonathan Ketcham, Ph.D. as Not Relevant and Unqualified and Memorandum of Law in Support (Transaction ID 67373067).**

In its Motion to Exclude the Testimony of Johnathan Ketcham, Ph.D., the State argues that Dr. Ketcham's opinions are irrelevant as he is, in part, offering testimony related to the misconduct of entities other than the Defendants. In support of this argument, the State cites a prior order of this Court striking Defendants' Notices of Nonparty Fault, (Trans. ID 65820504), in which the Court stated that the West Virginia Modified Comparative Fault statute did not apply, as no damages are being sought in this matter. "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591. The Court agrees and finds Dr. Ketchum's testimony is a back door attempt to raise third-party defenses such as non-party fault. Such fault-shifting testimony is not relevant based on this Court's prior ruling, as well as the above ruling regarding the State's Motion for Summary Judgment on Defendants' Affirmative Defenses (Transaction ID 67347633). Therefore, the Court **GRANTS** the State's Motion to Exclude the Testimony of Johnathan Ketcham, Ph.D.

4. Manufacturers' Motion to Exclude the Marketing Causation Opinions of Andrew Kolodny, Danesh Mazloomdoost, David Courtwright, Katherine Keyes, Matthew Perri, and Aaron Kesselheim (Transaction ID 67359428) and Memorandum of Law in Support (Transaction ID 67359563).

Manufacturers jointly move to exclude the marketing causation opinions of Andrew Kolodny, Danesh Mazloomdoost, David Courtright, Katherine Keyes, Matthew Perri, and Andrew Kesselheim. Under West Virginia law, in order to qualify as an expert on the topic, the expert's "area of expertise" must "cover[] the particular opinion as to which the expert seeks to testify." *Gentry v. Mangum*, 195 W. Va. 512, 466 S.E.2d 171, 174 (1995). However, "[n]either a degree nor a title is essential, and a person with knowledge or skill borne of practical experience may qualify as an expert." *Tracy v. Cottrell ex rel. Cottrell*, 206 W. Va. 363, 524 S.E.2d 879 (1999) (citing *Gentry*). In light of these principles, and those stated above, the Court issues the following rulings on this matter:

- **Andrew Kolodny**

Dr. Kolodny currently serves as the Medical Director of the Opioid Policy Research Collaborative at the Heller School for Social Policy and Management at Brandeis University, but he has no particular expertise in marketing. The Court notes that, based on the lack of this specific qualification, other jurisdictions have been split regarding admission of Dr. Kolodny's marketing causation opinions. Oklahoma and Rhode Island permitted those opinions, while New Hampshire excluded them. Similarly, in *City of Huntington v. AmerisourceBergen Drug Corp*., Judge Faber excluded the marketing causation opinions of Dr. Kolodny.

Based on the concerns raised by the Manufacturers that Dr. Kolodny is unqualified to opine on marketing causation, Manufacturers' Motion to Exclude Marketing Causation Opinions, as it relates to Dr. Andrew Kolodny, is hereby **TAKEN UNDER ADVISEMENT**. Dr. Kolodny will be permitted to testify, and Defendants should object as appropriate.

- **Danesh Mazloomdoost**

Dr. Danesh Mazloomdoost is an anesthesiologist and pain specialist. He is currently board-certified in anesthesiology. The State offers Dr. Mazloomdoost to opine on his first-hand observation of the impact of Defendants' marketing practices. The Court notes that a similar motion to exclude Dr. Mazloomdoost's marketing causation testimony was denied in *Oklahoma ex rel. Hunter v. Purdue Pharma LP et al.*, No. CJ-2017-816, and the rationale for that decision was sound. Based on Dr. Mazloomdoost's experience and his expected testimony, as well as the ruling in the Oklahoma litigation, the Court **DENIES** the Manufacturers' Motion with regard to the marketing causation opinions of Dr. Mazloomdoost.

- **David Courtwright**

David Courtwright, Ph.D., is an Emeritus Professor of History and has written about the history of drug use and drug policy in the United States. His work as a medical historian has led him to review historical marketing materials, and the State argues that the marketing materials reviewed by Dr. Courtwright for this litigation are similar to those he has reviewed and analyzed as part of his historical research. The Court also notes that similar motions seeking to exclude Dr. Courtwright's testimony, filed in the Rhode Island and Oklahoma litigation, were both denied. Based on Dr. Courtwright's experience, his expected testimony, and the rulings of other jurisdictions on similar motions, the Court **DENIES** the Manufacturers' Motion with regard to the marketing causation opinions of Dr. Courtwright.

- **Katherine Keyes**

Dr. Katherine Keyes is an epidemiologist at Columbia University where she specializes in substance use and substance use disorder epidemiology. Part of her work has included researching factors that influence opioid prescribing, use, and misuse. The Court notes that although Judge

Polster initially excluded Dr. Keyes' marketing causation testimony, Judge Polster revisited the issue on September 13, 2021. In that September 2021 Order, Judge Polster noted that additional expertise developed by Dr. Keyes following her initial exclusion qualified her to provide marketing causation opinions. *See In re Nat'l Prescription Opiate Litig.*, MDL 2804, 2021 WL 4146245, at *3 (N.D. Ohio Sept. 13, 2021). The Court finds Judge Polster's reasoning persuasive. Manufacturers' Motion to Exclude Marketing Causation Opinions with regard to Dr. Katherine Keyes is **DENIED**.

- **Matthew Perri**

Dr. Matthew Perri is a Professor Emeritus at the University of Georgia, and holds a Ph.D. with a dual concentration in Pharmacy and Marketing. Dr. Perri has authored books and academic articles on pharmaceutical marketing. The State asserts that Dr. Perri will provide testimony regarding the aggressive marketing of the Defendants. The Court Notes that California, New Hampshire, and Rhode Island have all permitted Dr. Perri to testify. Those jurisdictions, like West Virginia, follow a similar form of the Federal Rules of Evidence. As such, the Manufacturers' Motion is **DENIED** with regard to the marketing causation opinions of Dr. Perri.

- **Aaron Kesselheim**

Dr. Aaron Kesslheim is a Professor of Medicine at the Harvard School of Medicine. He has conducted a number of studies on drug labeling, use, and marketing, including the range of strategies and practices used to promote prescribing. The State asserts he will provide testimony on how pharmaceutical promotion drives physician prescribing practices, and that there is limited active FDA oversight of promotion of approved prescription drugs. Based on his expected testimony, the Court **DENIES** Manufacturers' Motion with regard to the marketing causation opinions of Dr. Kesselheim.

5. Motion to Exclude Opinions and Testimony of Plaintiff's Expert Alec Fahey (Transaction ID 67347559) and Memorandum of Law in Support (Transaction ID 67367486).

Teva Ltd., Teva USA, Cephalon, and the Actavis Generic Entities moved this Court to exclude the expert opinions and testimony of Plaintiff's expert Alec Fahey. (Transaction ID 67347559). Mr. Fahey is a Certified Public Accountant and Certified Fraud Examiner with a Certification in Financial Forensics. The State has offered Mr. Fahey to opine on the extent of control exercised by Teva Ltd., an Israeli company, of its United States-based subsidiaries. As stated above in this Court's ruling on Teva Ltd.'s Motion to Dismiss or Motion for Summary Judgment, "[t]he propriety of piercing the corporate veil should rarely be determined upon a motion for summary judgment. Instead, the propriety of piercing the corporate veil usually involves numerous questions of fact for the trier of the facts to determine upon all of the evidence." Syl. Pt. 6, *Laya v. Erin Homes, Inc.*, 177 W.Va. 343, 352 S.E.2d 93 (1986). Teva Ltd., Teva USA, Cephalon, and Actavis Generic Entities' arguments against Mr. Fahey go to the weight, not the admissibility, of that testimony. As such, their Motion to Exclude Opinions and Testimony of Plaintiff's Expert Alec Fahey is **DENIED**.

6. Manufacturers' Motion to Exclude the Opinions of Maureen Gorman and Memorandum of Law in Support (Transaction ID 67347942).

The State offers Maureen Gorman as an expert in the field of marketing and advertising, specifically relating to audience measurement, media audience analysis, media buying, and media planning, as well as an expert in class action notification. Manufacturers have moved to exclude Ms. Gorman's testimony on the basis that her opinions will not assist the trier of fact in understanding the effects of allegedly misleading statements because Ms. Gorman's opinions do not distinguish between lawful and unlawful marketing. However, because of the "liberal thrust" of the rules pertaining to experts, West Virginia courts should err on the side of admissibility. *See*

In re Flood Litig. Coal River Watershed, 222 W. Va. 574, 582, 668 S.E.2d 203, 211 (2008) (citing *Gentry*, 195 W. Va. at 525–27, 466 S.E.2d at 184–86). The Court does so here. The Court further notes that Ms. Gorman was permitted to offer expert opinions in both New Hampshire and California. Manufacturers' Motion to Exclude the Opinions of Maureen Gorman is **DENIED**.

7. **Defendants' Motion to Exclude Dr. Andrew Kolodny, Dr. Matthew Perri, III, and Dr. David Courtwright Concerning Manufacturers' Corporate Knowledge, Intent, and Conduct and Extra-Legal Issues and Memorandum of Law in Support (Transaction ID 67347840).**

Defendants have moved the Court to exclude the opinions of Dr. Kolodny, Dr. Perri, and Dr. Courtwright concerning Manufacturers' corporate knowledge, intent, conduct, and extra-legal issues. Specifically, Manufacturers take issue with the possibility of speculative testimony regarding their knowledge or state of mind, or will otherwise be improperly reading Manufacturers' documents into the record. The Manufacturers' concerns are well-taken. Further, in *City of Huntington*, 2021 WL 1320716, at *3, Judge Faber excluded similar testimony on the basis that inferences from Defendants' documents should be drawn by the trier of fact, not opined upon by an expert witness. The Court finds this reasoning persuasive. Manufacturers' Motion is **GRANTED IN PART, DENIED IN PART**. The State's experts will not be permitted to speculate regarding knowledge, state of mind, or motive of the Defendants. Nor can experts simply read documents into the record. However, experts will be permitted to summarize voluminous technical documents. To the extent an expert will opine regarding any Defendants' knowledge, the State must first lay a proper foundation.

8. **Manufacturers' Partial Motion to Exclude Dr. Andrew Kolodny's "Simulation" and All Opinions Based on It and Memorandum of Law in Support (Transaction ID 67348117).**

Manufacturers move the Court to exclude Dr. Kolodny's "simulation" and opinions based on it, arguing that the simulation is irrelevant and unhelpful to the trier of fact because Dr.

Kolodny's overly narrow view of "appropriate" prescribing and because it lacks all indicia of reliability. The reliability of expert testimony is "based on the use of knowledge and procedures that have been arrived at using the methods of science—rather than being on irrational and intuitive feelings, guesses, or speculation." *Harris v. CSX Transp., Inc.*, 232 W. Va. 617, 753 S.E.2d 275, 279–80 (2013). If a theory is novel, it is admissible only if it is reliable. W. Va. R. Evid. 702. In conducting that inquiry, West Virginia courts rely on the *Daubert* factors: "(a) whether the scientific theory and its conclusion can be and have been tested; (b) whether the scientific theory has been subjected to peer review and publication; (c) whether the scientific theory's actual or potential rate of error is known; and (d) whether the scientific theory is generally accepted within the scientific community." *Wilt v. Buracker*, 191 W. Va. 39, 46, 443 S.E.2d 196, 203 (1993). Courts also look at whether the method was developed "independent of litigation." *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 886 (10th Cir. 2005). Manufacturers' Partial Motion to Exclude Andrew Kolodny's "Simulation" and All Opinions Based On It is hereby **TAKEN UNDER ADVISEMENT**. The State will be permitted to present Dr. Kolodny's simulation but must lay proper foundation for the numbers used.

9. **Defendants' Motion to Exclude Opinions of Plaintiff's Expert Witness, Ruth Carter and Memorandum of Law in Support (Transaction ID 67348556).**

Defendants move this Court to exclude opinions of Plaintiff's expert witness Ruth Carter. The State offered Ms. Carter to opine on the quality of the Defendants' suspicious order monitoring systems ("SOMS"). Defendants argue that certain of her opinions are improper because they concern questions of law, such as the principle laws applicable to the case, the interpretation of a statute, the meaning of terms in a statute, the interpretation of case law, or the legality of conduct. *See France v. S. Equip. Co.*, 225 W. Va. 1, 14–15, 689 S.E.2d 1, 14–15 (2010). Further, Defendants argue that Ms. Carter's "made-for-litigation list of 'elements'" was created solely for the purpose

of this litigation and is therefore unhelpful to the Court. Certain of the Defendants' concerns are well-taken. Defendants' Motion to Exclude Opinions of Plaintiff's Expert Ruth Carter is **GRANTED IN PART, DENIED IN PART**. The Motion is granted to the extent Ms. Carter is intending to give legal opinions. However, the Motion is denied to the extent that Ms. Carter is qualified to testify regarding what an adequate SOMS should have and what Defendants' SOMS were lacking.

10. Janssen's Motion to Exclude Expert Opinion of Matthew Perri and Memorandum of Law in Support (Transaction ID 67346179).

Janssen individually moves to exclude the expert opinion of Matthew Perri on the grounds that his opinions are based substantially on Janssen's marketing of Duragesic. Under West Virginia law, expert testimony is inadmissible if it lacks relevance. *Gentry v. Mangum*, 196 W. Va. 512, 466 S.E.2d 171, 174 (1995). "Relevance means determining whether the testimony logically advances a consequential aspect of the movant's case." *Id.* at 182 n.13; *accord* W. Va. R. Evid. 401. By virtue of the 2010 release between the State and Janssen related to Duragesic, Dr. Perri's opinions, to the extent he offers testimony against Janssen about Duragesic, are irrelevant. Therefore, the Court **GRANTS** Janssen's Motion to the extent Dr. Perri would offer testimony against Janssen about Duragesic that pre-dates the December 23, 2010, settlement. However, Dr. Perri will be permitted to otherwise testify.

MOTIONS *IN LIMINE*

Under West Virginia law, a motion *in limine* is an appropriate device for saving time at trial by excluding irrelevant evidence. *See, e.g.*, *Smith v. Clark*, 241 W. Va. 838, 856, 828 S.E.2d 900, 918 (2019) (affirming grant of motion *in limine* where "[e]vidence which is irrelevant and immaterial and has no probative value in determing any material issue is inadmissible and should be excluded.'") (quoting *Smith v. Edward M. Rude Carrier Corp.*, 151 W. Va. 322, 331, 151 S.E.2d

738, 743 (1966)); *State ex rel. Tinsman v. Hott*, 188 W. Va. 349, 353, 424 S.E.2d 584, 588 (1992) (affirming grant of motion *in limine* on relevancy grounds). Evidence is relevant if it tends to make a fact at issue in the litigation more or less probable and is "of consequence in determining the action." W. Va. R. Evid. 401; *State v. Guthrie*, 194 W. Va. 657, 681 (1995). On the other hand, "[i]rrelevant evidence is not admissible." W. Va. R. Evid. 402; *Wolfe v. Sutphin*, 201 W. Va. 35, 40 (1997). Further, relevant evidence may be excluded "if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." W. Va. R. Evid. 403. Motions *in limine* are within the sound discretion of the trial court. *McKenzie v. Carrol, Intern. Corp*., 216 W. Va. 686, 692 (2004). With these principles of West Virginia law in mind, the Court turns to the motions *in limine* filed by the parties.

1. **Plaintiff's Motion *in Limine* to Exclude Evidence or Argument Claiming or Suggesting a Defendant Has a Small Market Share by Focusing on Brand Name Opioids and Memorandum of Law in Support. (Transaction ID 67379488).**

Plaintiff argues, in its motion, that arguments related to market share are irrelevant to its public nuisance claim because they need only prove a Defendant's actions were a proximate cause, not the sole proximate cause. (Transaction ID 67379488), at 3. Plaintiff also argues that the WVCCPA does not have a numerical threshold for determining if a commercial practice was unfair or deceptive. *Id.* at 4. Defendants argue, in part, that Plaintiff is also offering its own market share testimony through its experts. (Transaction ID 67407728), at 4; (Transaction ID 67407605), at 4. Defendants also argue that market share is directly relevant to whether an individual Defendant's conduct unreasonably interfered with a right common to the general public by causing an oversupply of opioids and related harms in West Virginia. The Court finds persuasive the decisions by courts in other states denying the same motion against the same defendants. Therefore, the

Court **DENIES** Plaintiff's Motion *in Limine* to Exclude Evidence or Argument Claiming or Suggesting Defendant Has a Small Market Share by Focusing on Brand Name Opioids.

2. **The State's Motion *in Limine* Regarding the Propriety of the State's (a) Licensure and Registration Determinations for Healthcare Professionals and Entities; and (b) Decisions to Investigate, Prosecute, or Discipline Particular Healthcare Professionals or Entities (Transaction ID 67379900).**

The State argues that the propriety of its licensure and registration determinations, as well as its decision to investigate, prosecute, or discipline particular healthcare providers, is irrelevant for the reasons articulated in its Motion for Summary Judgment on Defendants' Affirmative Defenses (Transaction ID 67347633). Defendants argue that the evidence is relevant to causation. (Transaction ID 67405351). The Court was persuaded by the State's reasoning in its Motion for Summary Judgment on Defendants' Affirmative Defenses, and agrees that the same reasoning applies here. This is not a damages case, and summary judgment was granted above with respect to the Defendants' fault-shifting defenses. Therefore, the Court **GRANTS** this motion.

3. **The State's Motion *in Limine* Regarding the "Inaction" of the DEA and FDA and the State's, FDA's, and DEA's Performance of Duties (Transaction ID 67379900).**

In support of this Motion, the State argues that the evidence it seeks to exclude is irrelevant, or would otherwise run afoul of West Virginia Rule of Evidence 403. (Transaction ID 67379900). Manufacturers' counter that the evidence tends to show Manufacturers did not violate applicable law, and that West Virginia's Rules of Evidence do not exclude everything short of conclusive proof. (Transaction IDs 67407292 and 67407367). Both the State and Manufacturers have valid points. As such, this Motion is **GRANTED IN PART, DENIED IN PART**. It is granted to the extent Manufacturers would use this evidence to bring in improper third-party or nonparty fault arguments. However, it is denied to the extent Manufacturers argue that a lack of sanction implies compliance with applicable law.

4. **The State's Motion *in Limine* to Exclude Evidence or Argument Regarding Purported Loss of Access to Prescription Medications (Transaction ID 67380213).**

The State argues this evidence should be excluded because the action brought is to remedy the harms caused by Defendants' allegedly aggressive and misleading marketing. (Transaction ID 67380213). As such, arguments related to loss of access to prescription medications are irrelevant and will confuse the issues. *Id.* Manufacturers respond by arguing that the State's request is overbroad and as such would unduly hinder the Manufacturers' defense, and that the order is unnecessary. (Transaction IDs 67407149 and 67405536). The Court is persuaded by the State. This litigation does not seek to enjoin medically necessary prescriptions. Therefore, this Motion is **GRANTED**.

5. **State's Motion *in Limine* to Exclude Evidence and Argument Concerning any Purported Absence of Evidence Showing Reliance (Transaction ID 67380456).**

The State asserts that, because reliance is not an element to either public nuisance or WVCCPA claims, the information is irrelevant. (Transaction ID 67380456). Manufacturers argue such evidence and argument is relevant, as it goes to causation. (Transaction IDs 67406715 and 67406347). Similar motions to exclude were denied in opioid litigation in both California and New Hampshire. *Id.* The Court finds Manufacturers' arguments persuasive. This Motion is **DENIED**.

6. **The State's Motion *in Limine* to Preclude the Defendants from Discussing the FDA Approval of Their Opioid Medications Without Discussion of Their Specific Indications (Transaction ID 67381389).**

The State argues Defendants should be precluded from discussing FDA approval absent discussion of specific indications to avoid confusion. (Transaction ID 67381389). Further, the State argues that allowing such argument would put an undue burden on the State to correct the record. *Id.* Defendants respond by arguing the requested relief is unneeded as the State is welcome to present indications for Defendants' medicines in its case and in its examination of witnesses.

(Transaction IDs 67407292 and 67407562). Defendants also argue that this Motion improperly seeks to control the presentation of their defense. *Id.* The Court agrees with Defendants. To the extent it wishes to do so, the State can present said indications to the Court and cross-examine Defendants' witnesses on the same. This Motion is **DENIED**

7. **State's Motion *in Limine* to Preclude Defendants' Experts from Offering Legal Opinions or Opinions Applying Fact to Law (Transaction ID 67381516).**

The State moves this Court to preclude Defendants' experts from offering legal opinions or opinions applying fact to law on the basis that West Virginia law prohibits expert witnesses from offering legal opinions. (Transaction ID 67381516) (citing *Jackson v. State Farm Mutual Auto Insurance Co.*, 215 W. Va. 634, 644, 600 S.E.2d 346, 356 (2004)). Manufacturers agree that expert and fact witnesses should not offer such testimony, including the State's own expert and fact witnesses. Manufacturers also respond by arguing that the State is untimely seeking to challenge expert testimony and that it mischaracterizes said expert testimony. (Transaction ID 67407630). The Court **GRANTS** this Motion to the extent any witness seeks to offer legal opinions or opinions applying fact to law. Moreover, this ruling applies to all parties.

8. **Plaintiff's Motion *in Limine* to Exclude Evidence or Argument that Documents Produced by the Defendants are not Authentic or Business Records (Transaction ID 67380905).**

In this Motion, the State argues that Defendants should not be permitted to argue that the voluminous documents produced in discovery are not authentic or are not business records. (Transaction ID 67380905). Defendants should be precluded from doing so, the State argues, because it will waste time and resources and prevent the efficient presentation of witnesses. *Id.* The Defendants argue that merely producing a document does not render it authentic nor does it render it a business record. (Transaction IDs 6740740 and 67407383). The Court **GRANTS** this

Motion. The parties are also directed to meet and confer to come to an agreement upon stipulations to the authenticity of documents.

9. **Manufacturers' Joint Motion *in Limine* to Exclude Evidence that the State Disavowed in Discovery and Memorandum of Law in Support (Transaction ID 67379507).**

Manufacturers argue that the State should be prevented from introducing individualized evidence because the State successfully evaded discovery on those topics by pledging to rely exclusively on aggregate proof. (Transaction ID 67379507). Manufacturers also point to the Panel's February 10, 2022, Order directing the State to affirm its disclaimers in supplemental responses, which it did. (Transaction ID 67305440). The State responds by asserting that Manufacturers' Motion is premature, and that they are trying to block more evidence than what was covered in the order and that the evidence is relevant. (Transaction ID 67407834). The Court finds Manufacturers' arguments more persuasive. The State agreed it would not assert, either in expert opinions or factual presentation, that any individual prescriber was misled by any manufacturer by its marketing, or that any individual prescription for an opioid medication was medically unnecessary. The State will be bound by that agreement. This Motion is **GRANTED**.

10. **Manufacturers' Joint Motion *in Limine* to Preclude Evidence Concerning Manufacturers' Conduct Outside of, and Unrelated to, West Virginia (Transaction ID 67380387).**

Manufacturers argue that evidence concerning their out-of-state conduct is irrelevant, that it violates West Virginia Rule of Evidence 404(b), and that the evidence is unfairly prejudicial and a waste of judicial resources. (Transaction ID 67380387). The State counters by arguing that much of the alleged misconduct it will prove at trial occurred on a national level and that the opioids marketed and shipped by Manufacturers migrated beyond West Virginia's borders. (Transaction ID 67413379). This Motion is **DENIED**. The State will be permitted to introduce evidence that is

national in scope which could have an effect in West Virginia. Any evidence related to states and counties contiguous to West Virginia will also be permitted.

11. Manufacturers' Motion *in Limine* to Exclude Generic References to Defendants as a Group and Memorandum of Law in Support (Transaction ID 67380629).

Manufacturers argue that the State should be prevented from collectively referencing the Manufacturers at trial because the State bears the burden of proving its claims against each manufacturer individually. (Transaction ID 67380629). The State argues that there will be times where it appropriate to refer to Defendants collectively, that the Manufacturers failed to identify any prejudice, and that Manufacturers have changed names multiple times over the years. (Transaction ID 67407457). The Court believes both parties raise valid points. As such, this Motion is **GRANTED IN PART, DENIED IN PART**. If a witness uses the term "defendants" and is not referring to all Defendants, the witness must specify which Defendant their testimony covers.

12. Manufacturers' Joint Motion *in Limine* to Preclude the State from Presenting Evidence on Restitution or Disgorgement (Transaction ID 67380514).

Manufacturers assert that the State should be precluded from offering evidence on restitution or disgorgement because the State refused to participate in discovery on those issues until after the close of discovery when the State served responses identifying disgorgement documents. (Transaction ID 67380514). The Manufacturers also argue that the State provided no expert testimony to support its claims for restitution and disgorgement. (*Id.*) In response, the State argues disgorgement is an equitable remedy available under the WVCCPA, and that the State sought documents from Manufacturers related to disgorgement during discovery. (Transaction ID 67408183). This Motion is **DENIED**. The State is not seeking restitution, only disgorgement. The

State will be permitted to introduce disgorgement evidence but must prove it, which may include separating illegal or illicit prescriptions from those that were legitimate.

13. Manufacturers' Joint Motion *in Limine* to Exclude Testimony of Undisclosed Expert Dr. David Kessler and Memorandum of Law in Support (Transaction ID 67381271).

Manufacturers move for the exclusion of Dr. David Kessler's testimony because the State failed to disclose Dr. Kessler as an expert witness prior to the deadline for disclosure of expert witnesses. (Transaction ID 67381271). Manufacturers argue Dr. Kessler cannot simply be recast as a lay witness. *Id.* The State responds by asserting that Dr. Kessler is being offered for fact testimony based on Dr. Kessler's personal observations and experience as FDA Commissioner. (Transaction ID 67408287). The Court agrees with the State. This Motion is **DENIED**.

14. Manufacturers' Motion *in Limine* to Exclude Evidence of Individual Purported Suspicious Orders and Memorandum of Law in Support (Transaction ID 67391002).

Manufacturers argue that the State should not be permitted to introduce evidence of individual purported suspicious orders because it has not identified any such orders. (Transaction ID 67391002). Further, the chargeback data identified by the State relate only to distributors requesting reimbursement for selling medication for a lower price than the distributor paid to acquire that medical from the manufacturer. *Id.* In opposition, the State claims it does not intend to rely on evidence of individual suspicious orders and contends one of its experts, Ruth Carter, has opined that chargeback data would have enabled Manufacturers to identify large orders. (Transaction ID 67407942). This Motion is **DENIED**.

15. Defendants' Motion *in Limine* to Exclude Purported Sample of Autopsy Reports and Memorandum of Law in Support (Transaction ID 67390554).

Defendants argue sample autopsy reports produced in MDL Track Two should be excluded here because those reports conflict with the State's aggregate theory of proof and are not the result of any valid sampling methodology. (Transaction ID 67390554). As such, the reports are

misleading and unduly prejudicial. *Id.* The State opposes by arguing that the autopsy reports are relevant and were produced in response to a discovery request by Defendants. (Transaction ID 67410983). This Motion is **DENIED**. Defendants are permitted to cross-examine the State's witnesses on the reports.

16. **Manufacturers' Motion *in Limine* to Exclude FDA Warning and Untitled Letters and Memorandum of Law in Support (Transaction ID 67391297).**

Manufacturers argue FDA Warning and Untitled Letters should be excluded because those letters are irrelevant and are inadmissible hearsay as the letters are informal and therefore do not qualify for the public records exception to the rule against hearsay. (Transaction ID 67391297). Janssen is further concerned about introduction of letters related to Duragesic. *Id.* The State argues that the documents are not inadmissible hearsay as they qualify for the public records exception. (Transaction ID 67414205). Additionally, several of the letters would qualify as "ancient documents." *Id.* Finally, the State says that the letters can be introduced for purposes other than showing the truth of the matter asserted. *Id.* This Motion will be **GRANTED IN PART, DENIED IN PART**. The Motion is granted in relation to any letters to Janssen about Duragesic, as the State has entered a settlement regarding that medication. With respect to all other letters subject to the Motion, they are admissible only to show notice and not admissible for the truth of the matter asserted.

17. **Manufacturers' Motion *in Limine* to Exclude Evidence Regarding Prescription Opioids Being a "Gateway" to Illicit Drug Use and Memorandum of Law in Support (Transaction ID 67390415).**

The Manufacturers seek to have lay opinion evidence regarding the "gateway" between prescription opioid use and misuse and later abuse of illegal drugs excluded because the gateway theory is an area for expert witness testimony. (Transaction ID 67390415). Manufacturers specifically point to potential testimony of Kathy Paxton, Diana Shepard, Michael Smith, Carrie

Summers, and Linda Watts. *Id.* The State counters by saying that all witnesses identified by Manufacturers have made personal observations, though their work, that would support gateway theory. (Transaction ID 67411340). This Motion is **DENIED**. There needs to be a factual basis for any opinion asserted, but the State will be permitted to introduce the identified testimony.

18. Omnibus Motion *in Limine* by Cephalon, Inc., Teva Pharmaceuticals USA, Inc., and the Actavis Generic Entities and Memorandum of Law in Support (Transaction ID 67380829).

i. MIL #1: The Court should Exclude Reference to the Cephalon Misdemeanor Plea.

Teva USA, Cephalon, and the Actavis Generic Entities argue reference to Cephalon's misdemeanor plea should be excluded because it constitutes improper and irrelevant character evidence, does not address false or misleading marketing, has no connection to West Virginia, and is unduly prejudicial propensity evidence. (Transaction ID 67380829). They also note that this evidence has been excluded elsewhere. *Id.* The State responds by arguing the evidence is relevant, as it was a plea related to the off-label marketing of Actiq, an opioid at issue in this litigation. (Transaction ID 67408258). The Court finds both parties raise valid concerns. MIL #1 is **GRANTED IN PART, DENIED IN PART**. It is granted as to liability but denied as to notice or knowledge.

ii. MIL #2: The Court Should Exclude Reference to "Off-Label" Promotion by Cephalon or Teva USA of their Branded Medicines (Actiq or Fentora).

Teva USA, Cephalon, and the Actavis Generic Entities assert reference to off-label promotion should be excluded because "off-label marketing" is a specific violation of FDA regulations that does not imply false or misleading marketing as a matter of law. (Transaction ID 67380829). As such, "off-label marketing" is irrelevant, and the term is misleading and should be excluded under West Virginia Rule of Evidence 403. *Id.* The State argues that Teva USA,

Cephalon, and the Activas Generic Entities conflate off-label prescribing with off-label marketing, and that off-label marketing is relevant to demonstrate intentionality, scope, and the systemic nature of Teva Defendants' allegedly deceptive conduct over time. (Transaction ID 67408258). MIL #2 is **DENIED**.

iii. MIL #3: The Court Should Exclude Any Reference to the 2008 Civil Settlement Between Cephalon and the Federal Government and the Opioid-Related Civil Settlements from Other Jurisdictions Involving Defendants.

Teva USA, Cephalon, and the Actavis Generic Entities argue that reference to 2008 civil settlements between Cephalon and the federal government, and to civil settlements involving Teva Defendants in other jurisdictions would violate West Virginia Rule of Evidence 408. (Transaction ID 67380829). They also argue that the settlements are irrelevant and prejudicial. (*Id.*) The State responds by arguing that such evidence is admissible for purposes other than establishing liability, specifically notice and knowledge. (Transaction ID 67408258). Teva USA, Cephalon, and the Actavis Generic Entities and the State have valid arguments. MIL #3 is **GRANTED IN PART, DENIED IN PART**. The State cannot use these settlements to establish liability but can use them to establish notice and knowledge.

iv. MIL #4: The Court Should Exclude Evidence and Argument Regarding Conduct Protected by the First Amendment.

Teva USA, Cephalon, and the Actavis Generic Entities point to financial contributions to third parties and truthful marketing are speech protected by the First Amendment to the United States Constitution. (Transaction ID 67380829). They argue this Court should not allow any suggestions that this First Amendment activity can form the basis for civil liability. *Id.* The State counters by arguing it should not be precluded from offering evidence of financial support and marketing to demonstrate that Teva USA, Cephalon, and the Actavis Generic Entities are not entitled to First Amendment protection. (Transaction ID 67408258). The Court agrees with the

State. The First Amendment does not protect false marketing or false or misleading speech. MIL #4 is **DENIED**.

v. MIL #5: The Court Should Exclude Alec Burlakoff's Deposition Testimony.

Teva USA, Cephalon, and the Actavis Generic Entities argue Alec Burlakoff's deposition testimony should be excluded because Mr. Burlakoff only asserted his Fifth Amendment privilege and therefore offered no relevant testimony. (Transaction ID 67380829). They believe the State will attempt to use this testimony to attribute the conduct of Insys Therapeutics, Inc.—where Mr. Burlakoff went to work after he left Cephalon—to Cephalon, which would be improper and unduly prejudicial. *Id.* The State argues in opposition that Mr. Burlakoff had offered interviews to CBS's *60 Minutes*, and that the Supreme Court of the United States has made clear that the Fifth Amendment does not forbid adverse inferences against parties in civil actions. (Transaction ID 67408258) (quoting *Baxter v. Palmigiano*, 425 U.S. 308, 318 (1976)). The Court respects Mr. Burlakoff's Fifth Amendment rights, and as such MIL #5 is **GRANTED**. However, the State will be permitted to vouch the record.

vi. MIL #6: The State Should Be Precluded From Arguing That The Actavis Generic Defendants Should Have Made Additional Warnings Regarding Their Generic Medicines Or Should Have Stopped Selling Them.

The basis for this Motion is that federal law precludes the State from making such arguments. (Transaction ID 67380829). Specifically, the Food Drug & Cosmetic Act prohibits manufacturers of generic medicines from providing warnings or communications beyond the FDA approved labels for their generic medicines – label which must be the same as those of their branded equivalents under the FDCA. The State responds by arguing that this litigation is not about warning labels; it is about misleading marketing. (Transaction ID 67408258). MIL #6 is **GRANTED IN PART, DENIED IN PART**. It is granted as to arguments related to additional

warnings regarding generic medicines or that the Actavis Generic Entities should have stopped selling generics. However, this is not a case about the accuracy of the warning labels on Defendants' drugs and the motion is denied as to the State's ability to show false or misleading marketing.

vii. MIL #7: The Court Should Exclude Reference to the Purchase Price Paid by Teva Pharmaceutical Industries Ltd. for the Actavis Generic Defendants.

Teva USA, Cephalon, and the Actavis Generic Entities argue that the purchase price paid is irrelevant to this action. (Transaction ID 67380829). Further, such references may result in inferences regarding the financial health of Teva Ltd., the Actavis Generic Entities, Cephalon, and Teva USA which are unduly prejudicial and not the proper basis for a verdict. *Id.* The State argues that the purchase price is relevant because generic drugs are subject to intense competition. (Transaction ID 67408258). Further, the State claims that the evidence would not mislead the Court regarding the current financial health of these companies. *Id.* MIL #7 is **GRANTED**.

viii. MIL #8: The Court Should Exclude Reference to the Settlement Agreement Between Allergan plc and Teva Ltd.

Teva USA, Cephalon, and the Actavis Generic Entities' MIL #8 is hereby **GRANTED** because the Parties agree such evidence should be excluded.

ix. MIL #9: The State Should Be Precluded from Arguing That a Defendant is Liable Based Upon the Past Actions of Its Current Affiliate.

Teva USA, Cephalon, and the Actavis Generic Entities assert that the argument that one Defendant is liable based on the actions of an affiliate is legally improper and prejudicial; most of the facts relied upon by the State occurred when these companies were unaffiliated, and their separate actions cannot now be conflated. (Transaction ID 67380829). Further, there is no claim for piercing the corporate veil under the circumstances of this litigation. *Id.* The State responds by arguing that it seeks to hold each of these companies accountable for their own action and that the

evidence will be presented carefully at trial. (Transaction ID 67408258). The State also argues there are facts that support piercing the corporate veil; specifically, that if piercing the veil becomes necessary, it will be because of the way these companies operated their business. *Id.* MIL #9 is **HELD IN ABEYANCE**.

x. MIL #10: The Court Should Preclude the State from Introducing Any Evidence of Call Notes from Teva USA or Cephalon.

Teva USA, Cephalon, and the Actavis Generic Entities believe evidence of call notes from Teva USA and Cephalon should be excluded because they are unwieldy, impossible to decipher without a sponsoring witness to lay foundation for how to read them, contain large amounts of data exclusively related to matters outside of West Virginia, contradict the State's reliance on "aggregate proof," and contain large amounts of data from outside the statute of limitations and pertaining to non-opioid products. (Transaction ID 67380829). Further, the call notes are all hearsay, and some contain hearsay-within-hearsay. *Id.* The State argues the call logs are relevant, as they show marketing activity. (Transaction ID 67408258). As such they are crucial to the State's WVCCPA claims. *Id.* MIL #10 is **DENIED**. The State will be permitted to introduce call logs related to West Virginia, national scope evidence that could affect West Virginia, and evidence related to states and counties contiguous with West Virginia.

xi. MIL #11: The Court Should Preclude the State from Referring to a Non-Existent Duty to Police All Downstream Diversion in the Supply Chain.

Teva USA, Cephalon, and the Actavis Generic Entities argue reference to this duty should be excluded because no such duty exists under West Virginia law. (Transaction ID 67380829). Further, it is contrary to the requirements of W. Va. Code St. R. § 15-2-5 and to common sense. *Id.* The State argues that federal law imposes such a duty, and as such it should be allowed to make such arguments. (Transaction ID 67408258). MIL #11 is **DENIED**. Though the Court does not

rule on whether such duties exist, the State will be permitted to introduce evidence and argument on that issue at trial.

xii. MIL #12: The Court Should Preclude the State from Displaying Certain Videos from Cephalon's 2006 Sales Conference.

Teva USA, Cephalon, and the Actavis Generic Entities argue that these videos are irrelevant, entirely hearsay, and would waste time and resources. (Transaction ID 67380829). The State argues the videos are relevant because they were played at a national meeting of their sales force. (Transaction ID 67408258). Further, the videos are not hearsay under W. Va. R. Evid. 801(d)(2)(a) as they were produced by Teva USA, Cephalon, and the Actavis Generic Entities. *Id.* MIL #12 is **DENIED**.

xiii. MIL #13: The Court Should Exclude the State from Introducing Irrelevant Emails Sent by Someone Who Was Not an Employee of and Had No Connection to Defendants at the Time.

Teva USA, Cephalon, and the Actavis Generic Entities argue these emails from Joseph Tomkiewicz should be excluded because they were unconnected to his work for Teva USA, and as such are irrelevant, are hearsay, and would be unduly prejudicial. (Transaction ID 67380829). The State argues these emails show the grave indifference to the harms caused by opioids in West Virginia, and that the emails go to Mr. Tomkiewicz's character and should be permitted for impeachment purposes. (Transaction ID 67408258). The Court will allow such evidence to come in if Teva USA, Cephalon, and the Actavis Generic Entities call Mr. Tomkiewicz to testify live at trial because Cephalon hired Mr. Tomkiewicz to handle their diversion program and agrees that those emails can be properly used for impeachment. MIL #13 is **DENIED**.

xiv. MIL #14: The Court Should Exclude Reference to Pharmaceuticals Manufactured by Defendants that are not Expressly Named in the Operative Complaint.

Teva USA, Cephalon, and the Actavis Generic Entities believe evidence or reference to pharmaceutical medications manufactured by Defendants, but not named in the operative complaint, are irrelevant. (Transaction ID 67380829). Further, Teva Defendants argue this was confirmed by the State's 30(b)(7) representative, Christina Mullins, at deposition. *Id.* In opposition, the State argues that Ms. Mullins' testimony does not limit the State to the medications listed in the Complaint, which is pled to cover opioids not specifically identified. (Transaction ID 67408258). The Court agrees with the State. MIL #14 is **DENIED**.

19. Allergan Defendants' Omnibus Motion *in Limine* (Transaction ID 67381445).

i. MIL #1: The Court Should Preclude All Evidence and Argument Concerning MoxDuo.

The Allergan Defendants argue evidence and argument concerning MoxDuo is irrelevant, as MoxDuo is an opioid that was never commercially manufactured, marketed, distributed, or sold. (Transaction ID 67398646). Further, even if it is relevant, it would be unduly prejudicial. *Id.* The State responds by arguing evidence related to MoxDuo is admissible to demonstrate the Allergan Defendants' knowledge of opioid-related harms and their pervasive marketing techniques, and that there would be no undue prejudice. (Transaction ID 67408264). MIL #1 is **DENIED.** MoxDuo may not have been sold, but evidence related to it can be used to show the nature of Allergan Defendants' ground-up marketing plan.

ii. MIL #2: The Court Should Preclude All Evidence and Argument that Industry-Funded Medical Education Required or Encouraged by the FDA was Improper.

Allergan Defendants assert that, because the continuing medical education they funded was required by the FDA, that federal law preempts the State's state-law based claims. (Transaction

ID 67398646). The State asserts Allergan Defendants' Motion in Limine 2 is an improper motion for partial summary judgment masquerading as an evidentiary motion. (Transaction ID 67408264). Further, the State argues that FDA requiring continuing medical education does not excuse the Allergan Defendants' misinformation campaign. *Id.* MIL #2 is **DENIED**. The allegations in this lawsuit are that the Allergan Defendants did what the FDA permitted them to do in a false or misleading way.

iii. MIL #3: The Court Should Preclude Plaintiff from Raising or Pursuing Any Veil-Piercing or Analogous Theories at Trial.

The Allergan Defendants argue the State should be precluded from raising veil-piercing and similar theories at trial because the State has not alleged any basis for doing so in the Complaint. (Transaction ID 67398646). Further, no discovery has been conducted on this issue. *Id.* The State responds that it did plead bases for piercing the corporate veil, and that adequate discovery has taken place, as the Allergan Defendants' 30(b)(6) representative testified concerning the corporate structure of Allergan PLC. (Transaction ID 67408264). The Court will allow the State to attempt to prove its theory at trial, in part because, as stated in *Dailey v. Ayers Land Development*, the propriety of piercing the corporate veil is heavily fact dependent. Therefore, MIL #3 is **DENIED**.

20. Janssen's Motion *in Limine* No. 1 to Exclude Evidence of Unjoined Former Subsidiaries (Transaction ID 67378505).

Janssen argues evidence related to Noramco and Tasmanian Alkaloids should be excluded because it has no probative value. (Transaction ID 67378505). Further, the State failed to allege fact supporting piercing the corporate veil. *Id.* Moreover, federal preemption and state safe-harbor principles preclude the State from premising liability on Noramco's sale of active pharmaceutical ingredients to other opioid manufacturers or Tasmanian Alkaloids' sales of raw materials to

Noramco. *Id.* As such, introduction of such evidence would waste judicial resources and unnecessarily complicate trial. *Id.* The State responds by claiming that the evidence is relevant to helping explain Janssen's unbranded marketing campaigns, to demonstrating Janssen's knowledge of the supply and strength of prescription opioids, and that the evidence will rebut Janssen's anticipated defenses at trial. (Transaction ID 67405751). The Court agrees with the State. Janssen's MIL No. 1 is **DENIED**.

21. Janssen's Motion *in Limine* No. 2 to Exclude Evidence of Conduct Related to Duragesic (Transaction ID 67391516).

Janssen argues that evidence of conduct related to Duragesic should be excluded on the basis of the 2010 Settlement between Janssen and the State. (Transaction ID 67391516). According to Janssen, the 2010 Settlement renders this evidence irrelevant. *Id.* The State argues this evidence is relevant to the State's unreleased claims to the extent it is based on post-settlement sales of opioids in West Virginia. (Transaction ID 67405632). Janssen's Motion in Limine No. 2 is **GRANTED**. The State settled its claims related to the marketing of Duragesic in 2010. As such, the State cannot present evidence against Janssen related to the marketing of Duragesic covered by the Settlement.

22. Janssen's Motion *in Limine* No. 3 to Exclude Evidence of Call Notes (Transaction ID 67378580).

Janssen argues its call notes should be excluded because the State has made a commitment to refrain from using individualized evidence at trial. (Transaction ID 67378580). Further, Janssen points to the lack of discovery on the issue. *Id.* The State argues the call notes are relevant to showing Janssen's conduct, and notes that Janssen could have engaged in third-party discovery if it wished to do so. (Transaction ID 67405632). The Court is persuaded by the State. Consistent with similar motions from the other Defendants, Janssen's Motion in Limine No. 3 is **DENIED**.

23. Janssen's Motion *in Limine* No. 4 to Exclude Evidence of Lobbying (Transaction ID 67378290).

Janssen argues that the First Amendment shields it from liability in connection with Janssen's lobbying activities. (Transaction ID 67378290). Janssen claims both its legislative and administrative lobbying efforts are protected. *Id.* The State responds by arguing that it is not attempting to hold Janssen liable for its protected First Amendment activity. (Transaction ID 67408095). Rather, the State is attempting to hold Janssen liable for its misleading or deceptive marketing, which enjoys no First Amendment protection. *Id.* The Court agrees with the State. This case concerns misleading marketing, or false or misleading speech, which is not protected by the First Amendment. Therefore, Janssen's Motion in Limine No. 4 is **DENIED**.

A copy of this Order has been electronically served on all counsel of record via File & Serve*Xpress*.

It is so **ORDERED.**

ENTERED: May 23, 2022.

/s/ Derek C. Swope
Presiding Judge
Opioid Litigation

EFiled: Jul 01 2022 03:10PM EDT
Transaction ID 67786397

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

IN RE: OPIOID LITIGATION **CIVIL ACTION NO. 21-C-9000 DISTRIBUTOR**

THIS DOCUMENT APPLIES TO ALL DISTRIBUTOR CASES

FINDINGS OF FACT AND CONCLUSIONS OF LAW AND ORDER DENYING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT RE "FACTUAL ISSUE #2"

The Mass Litigation Panel ("MLP" or "Panel") has previously denied the Distributor Defendants' Motion for Summary Judgment Re "Factual Issue #2" as set forth in the Court's June 9, 2022, Order (Transaction ID 67707770). The Panel now makes the following findings of fact and conclusions of law in support of its decision:

In their motion, Defendants make two arguments in support of summary judgment. First, Defendants argue that the law of public nuisance does not encompass Plaintiffs' product-based claims. Distributors' Motion for Summary Judgment Re "Factual Issue #2" (Transaction ID at 67621963) ("Motion") at 3-8. Second, Defendants argue that there is no evidence that distributors interfered with a public right. Motion at 8-14. This Panel and a number of courts across the country have previously rejected both of these arguments. The Panel reaffirms its prior rulings and **DENIES** Defendants' motion.

I. West Virginia Public Nuisance Law Encompasses Plaintiffs' Opioid Claims.

In denying a similar motion in Phase 1a, this Panel previously held:

> West Virginia defines public nuisance as an "an act or condition that unlawfully operates to hurt or inconvenience an indefinite number of persons." *Hark v. Mountain Fork Lumber Co.,* 127 W.Va. 586, 595-96, 34 S.E.2d 348, 354 (1945). The Supreme Court of Appeals of West Virginia has determined this definition is consistent with the *Restatement (Second) of Torts §* 821B(1) (1979), which defines a public nuisance as "unreasonable interference with a right common to the general public." *Duff v. Morgantown Energy Ass'n*, 187 W. Va. 712, 716 n.6, 421 S.E.2d 253, 257 n.6 (1992). In West Virginia, "nuisance is a flexible area of the law that is adaptable to a wide variety of factual situations." *Sharon Steel Corp. v. City of Fairmont*, 175 W. Va. 479, 483, 334 S.E.2d 616, 621 (1985). This is a fact-specific

> determination. The Court further notes that at least 22 states have found public nuisance claims based on the marketing of prescription opioids to be viable.

In Re: Opioid Litigation Civil Action, No. 21-C-9000 (MFR), Amended Order Regarding Rulings Issued During March 25, 2022, Pretrial Conference, p. 4 (May 23, 2022) (ID 67650385).

This ruling in the Manufacturer Cases aligns with the four other West Virginia trial courts – including this Panel – which have found that governmental opioid claims are cognizable as public nuisance claims.[1] The previous decision of this Panel in *Monongalia County,* along with the decision by Judge Thompson in *Morrisey* and Judge Hummel in *Brooke County,* were all the subject of unsuccessful writ proceedings in the Supreme Court Appeals brought by these same Defendants.[2] Moreover, these decisions are also consistent with Judge Polster's decisions in the MDL,[3] along with the courts in 22 other states that have recognized public nuisance claims in the opioid litigation.[4]

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[1] *See State ex rel. Morrisey v. AmerisourceBergen Drug Corp.*, No. 12-C-141, 2014 WL 12814021, at *10 (W. Va. Boone Cty. Cir. Ct. Dec. 12, 2014) (Thompson, J.), *writ denied*, *State ex. rel. AmerisourceBergen Drug Corp. v. Thompson*, No. 15-1026 (W. Va. Jan. 5, 2016); *Brooke Cty. Comm'n v. Purdue Pharma, L.P.*, No. 17-C-248, p. 13 (W. Va. Marshall Cty. Cir. Ct. Dec. 28, 2018) (Hummel, J.), *writ denied*, *State ex rel. Cardinal Health, Inc. v. Hummel*, No. 19-0210 (W. Va. June 4, 2019); *Monongalia County, et al. v. Purdue Pharma L.P.*, et al., Nos. 18-C-222-236 (adopting and applying the reasoning and rulings from *Brooke County*) (W.Va. M.L.P. Oct. 31, 2019), *writ denied*, *State ex rel. AmerisourceBergen Drug Corp. v. Moats,* No. 19-1051 (W.Va. January 30, 2020); *The City of Huntington v. AmerisourceBergen Drug Corp.,* No. 3:17-01362, Doc. # 1291 (S.D. W.Va. Apr. 28, 2021) (Faber, J.).

[2] *See, infra* n. 1.

[3] *See*, e.g., *In Re Nat'l Prescription Opiate Litig.,* 406 F. Supp. 3d 672, 674 (N.D. Ohio 2019) (noting previous opinions and concluding "[a] factfinder could reasonably conclude that this evidence demonstrates an interference with public health and public safety rights.").

[4] *See*, *e.g.*, *Alabama v. Purdue Pharma L.P.*, 03-CV-2019-901174.00, slip op. at 11-12 (Ala. Cir. Ct. Nov. 13, 2019); *Alaska v. McKesson Corp.*, No. 3AN-18-10023CI, slip op. at 7 (Alaska Super. Ct. Aug. 28, 2019); *City of Surprise v. Allergan PLC,* No. CV2019-003439, slip op. at 35-36 (Ariz. Super. Ct. Oct. 28, 2020); *Arkansas v. Purdue Pharma L.P.*, 2019 WL 1590064 (Ark. Cir. Ct. Apr. 5, 2019); *City and Cnty. of San Francisco v. Purdue Pharma L.P.*, 491 F. Supp. 3d 610, 669 (N.D.

These courts have specifically rejected the arguments of these and other opioid defendants that governmental public nuisance claims are limited to claims arising out of the use of property.[5]

Cal. Sept. 30, 2020); *In re Nat'l Prescr. Opiate Litig.* (West Boca Med. Ctr.), 452 F. Supp. 3d 745 (N.D. Ohio 2020); *Kentucky ex rel. Beshear v. Walgreens Boots Alliance, Inc.,* No. 18-CI-00846, slip op. (Ky. Cir. Ct. July 18, 2019); *City of Boston v. Purdue Pharma, LP*, 2020 WL 416406 (Mass. Super. Ct. Jan. 3, 2020); *Michigan ex rel. Kessel v. Cardinal Health, Inc.*, No. 19016896-NZ, slip op., at 2 (Mich. Cir. Ct. Mar. 24, 2021), *reversing on reconsid.* slip. op. (Mich. Cir. Ct. Nov. 17, 2020); *Mississippi v. Cardinal Health, Inc.*, No. 25Cll:18-cv00692, slip op. (Miss. Cir. Ct. Apr. 5, 2021); *Missouri ex rel. Schmitt v. Purdue Pharma, L.P.*, No. 1722-CC10626, slip op., *7-8 (Mo. Cir. Ct. Apr. 6, 2020); *Nevada v. McKesson Corp.*, No. A-19-796755-B, slip order (Nev. Dist. Ct. Jan. 3, 2020); *New Hampshire v. Purdue Pharma Inc.*, 2018 WL 4566129 (N.H. Super. Ct. Sept. 18, 2018); *New Mexico ex rel. Balderas v. Purdue Pharma L.P.*, No. D-101-CV-2017-02541 slip op. (N.M. Dist. Ct. Dec. 17, 2020); slip op. (Dist. Ct. Sept. 10, 2019); *In re Opioid Litig.*, slip op. 2018 WL 3115102, *28 (N.Y. Sup. Ct. June 18, 2018); *County of Delaware v. Purdue Pharma, L.P.,* CV- 2017008095, slip ops. (Pa. Ct. C.P., March 13, 2020, Dec. 4, 2019, and Oct. 25, 2019); *Rhode Island ex rel. Neronha v. Purdue Pharma L.P.*, 2019 WL 3991963, *9 (R.I. Super. Ct. Aug. 19, 2019); *South Carolina v. Purdue Pharma L.P.*, No. 2017-CP40-04872, slip order (S.C. Ct. C.P. Apr. 12, 2018); *Tennessee ex rel. Slatery v. Purdue Pharma L.P.*, 2019 WL 2331282, *5 (Tenn. Cir. Ct. Feb. 22, 2019); *In re Texas Opioid Litig.* (*Cnty. of Dallas*), No. 2018-77098, slip op. (Tex. Dist. Ct. June 9, 2019); *Vermont v. Cardinal Health, Inc.*, No. 279-3-19 Cncv, slip op. (Vt. Super. Ct. May 12, 2020); *Washington v. Purdue Pharma L.P.*, 2018 WL 7892618 (Wash. Super. Ct. May 14, 2018).

[5] *Morrisey*, 2014 WL 12814021 at *9 (holding that State of West Virginia's claims against opioid distributors "fit squarely" within this definition of public nuisance); *Brooke Cty. Comm'n* at p. 13 ("a claim for public nuisance is not limited to property disputes and that West Virginia courts have applied the public nuisance doctrine in numerous contexts, including in opioids cases like this."); *see also Lemongello v. Will Co.*, No. CIV.A. 02-C-2952, 2003 WL 21488208, at *2 (W. Va. Cir. Ct. June 19, 2003) (holding, in case alleging that the defendants' sale of handguns supplied an illegal handgun market, that "West Virginia law does not limit claims of public nuisance to those dealing with real property"); *City of Bos. v. Purdue Pharma, L.P.,* No. 1884CV02860, 2020 WL 977056, at *5 (Mass. Super. Jan. 31, 2020) (rejecting "Distributor Defendants' arguments that public nuisance is limited to property or land-based claims"); *In re Nat'l Prescription Opiate Litig.*, 452 F. Supp. 3d 745, 774–75 (N.D. Ohio 2020) (rejecting argument by Distributor Defendants that nuisance law in Florida requires an interference with the use and enjoyment of property); *In re Nat'l Prescription Opiate Litig.*, No. 1:17-CV-02804, 2019 WL 2477416, at *14 (N.D. Ohio Apr. 1, 2019) ("Based on those legislative and judicial sources, the court concludes that the Montana Supreme Court would not hold that the definition of nuisance is limited to acts or conditions that interfere with property rights and that it would recognize as actionable a public nuisance claim that is based on a defendant's alleged affirmative misconduct in the manufacture, distribution and sale of the products at issue in this action."), *report and*

And, a number of these courts have also rejected these Defendants' arguments that product-based public nuisance claims are not cognizable.[6]

Defendants place great weight on language in the Restatement (Third) of Torts: Liability for Economic Harm § 8 (2020). Motion at 1-3, 7-8. Section 8 of the Third Restatement has not been adopted by any court in West Virginia. Without citation to any West Virginia authority, Defendants argue that the Third Restatement reflects West Virginia law. While West Virginia has explicitly equated West Virginia's public nuisance law with the Second Restatement, it has never adopted the Third Restatement.[7] Unlike its predecessor, the Third Restatement has not been

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recommendation adopted in relevant part, No. 1:17-MD-2804, 2019 WL 3737023 (N.D. Ohio June 13, 2019); *see also* Restatement (Second) of Torts § 821B, comment h ("unlike a private nuisance, a public nuisance does not necessarily involve interference with use and enjoyment of land").

[6] *See, e.g., In re Nat'l Prescription Opiate Litig.*, 458 F. Supp. 3d 665, 681 (N.D. Ohio 2020); *In re Opioid Litig.*, 2018 WL 3115102 (N.Y. Sup. Ct. June 18, 2018) (opioids). The decisions rejecting the exclusion of products from public nuisance claims are not limited to opioid cases. Multiple state supreme courts have upheld product-based nuisance claims in the context of handguns, *see, e.g.*, *City of Cincinnati*, 768 N.E.2d 1136; *City of Gary ex rel. King v. Smith & Wesson Corp.*, 801 N.E.2d 1222, 1229-33 (Ind. 2003); *People ex rel. Gallo v. Acuna*, 929 P.2d 596 (Cal. 1997); *Nat'l Ass'n for the Advancement of Colored People v. Acusport, Inc.*, 271 F.Supp.2d 435, 484 (E.D.N.Y.2003) *James v. Arms Tech., Inc.,* 359 N.J. Super. 291, 315, 820 A.2d 27, 41 (App. Div. 2003) (handguns), while numerous other courts have recognized public nuisance claims involving other products including lead paint, "flushable" wipes, asbestos, and gasoline additives. *See, e.g.*, *People v. ConAgra Grocery Prods. Co.*, 227 Cal. Rptr. 3d 499, 546 (Cal. Ct. App. 2017) (lead paint); *City of Milwaukee v. NL Indus., Inc.*, 278 Wis. 2d 313, 325, 691 N.W.2d 888, 894 (WI App 2005) (lead paint); *City of Wyoming v. Procter & Gamble Co.*, 210 F. Supp. 3d 1137, 1162 (D. Minn. 2016) ("flushable" wipes); *State of Maryland v. Exxon Mobil Corp.*, 406 F. Supp. 3d 420 (D. Md. 2019) (MTBE); *Venuto v. Owens–Corning Fiberglas Corp.*, 22 Cal.App.3d 116, 99 Cal.Rptr. 350, 355 (1971) (asbestos); *Gov't of U.S. Virgin Islands v. Takata Corp.*, No. ST-16-CV-286, 2017 WL 3390594, at *40-44 (V.I. Super. Ct. June 19, 2017) (airbags). More recently, Judge Bryer in *In re JUUL Labs, Inc., Mktg., Sales Pracs., & Prod. Liab. Litig.*, 497 F. Supp. 3d 552, 645 (N.D. Cal. 2020), rejected this defense and upheld a multistate class claim brought by government entities arising out of the distributing and marketing of JUUL electronic cigarettes for underage use in violation of each state's public nuisance law.

[7]Many other courts adjudicating governmental opioid lawsuits have applied the Second

widely adopted by the states; indeed, it has been rejected by many courts.[8] Here, the Supreme Court of Appeals' explanation that West Virginia's definition of public nuisance tracks Section 821B of the Second Restatement offers clear guidance on this State's law.

In any event, the Panel concludes that Section 8 of the Third Restatement does not apply to the Plaintiffs' abatement claim here. Section 8 of Third Restatement applies to claims for economic loss by a private party who has suffered an injury "distinct in kind from those suffered by members of the affected community in general."[9] The comments to Section 8 state that Section 8 is not intended to apply to public nuisance actions seeking abatement brought by public officials.[10] Plaintiffs have disclaimed all damage claims, and this action seeks only equitable relief. *Cf. State ex rel. Amerisourcebergen Drug Corp. v. Moats,* 245 W. Va. 431, 443, 859 S.E.2d 374, 386 (2021) (refusing writ of prohibition challenge to order "denying Defendants' requests for a jury trial of Plaintiffs' public nuisance claims (liability only) on the grounds that those claims are

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Restatement to public nuisance claims. *See,* e.g., cases cited *supra n. 4.*

[8] *See, e.g.*, *Delaney v. Deere and Co.*, 999 P.2d 930, 946 (Kan. 2000) (stating that the (Third) Restatement "goes beyond the law" and is "contrary to the law in Kansas"); *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 415 (Pa. 2014) (declining to adopt a product liability portion of the Third Restatement and discussing other courts across the country that have done the same); *Potter v. Chicago Pneumatic Tool Co.*, 694 A.2d 1319, 1331 (Conn. 1997) (observing that a provision of the Draft Restatement (Third) "has been a source of substantial controversy among commentators" and stating that rule promulgated in the Draft Restatement (Third) was inconsistent with the court's "independent review of the prevailing common law"). Only one state supreme court has adopted the Third Restatement. *Oklahoma ex rel. Hunter v. Johnson & Johnson*, 499 P.3d 719 (Okla. 2021).

[9] Restatement (Third) of Torts: Liab. for Econ. Harm, § 8.

[10] *Id.*, § 8 cmt. a ("In addition to the common-law claims recognized here, public officials may bring civil or criminal actions against a defendant who creates a public nuisance. . . . The definition of 'public nuisance' for those purposes is widely a matter of statute and tends to be considerably broader than the common-law definition recognized by this Section as a basis for a private suit.").

legal, and not equitable."). Thus, the Panel concludes Section 8 is inapplicable to governmental abatement claims.

Defendants' motion also ignores contrary authority (including the decisions of this Panel). Defendants rest much of their argument on the Oklahoma Supreme Court's decision in *Hunter*. *Hunter* is contrary to the numerous West Virginia opioid decisions in this litigation and most opioid decisions elsewhere. This Panel has already rejected *Hunter* as a bar to West Virginia opioid public nuisance claims, finding that Oklahoma's nuisance statutes are not equivalent to West Virginia law.[11] Judge Polster has also rejected the decision as a matter of both Ohio and Georgia law.[12] Finally, the Panel notes that the non-opioid cases cited by Defendants are far from overwhelming and, as previously noted, ample contrary authority exists.

In the end, the contrary opioid decisions of 22 other states and the other courts interpreting West Virginia law are far more persuasive. Therefore, the Panel finds and concludes that West Virginia public nuisance law encompasses Plaintiffs' opioid claims. The Panel, therefore, **DENIES** the Defendants' motion for summary judgment on this basis.

II. There Are Disputed Issues of Fact for Trial as to Whether Distributors' Conduct Substantially Interfered with Public Rights.

Defendants next attempt to convince the Panel that there is no evidence that Defendants' conduct interfered with public rights. Defendants claim that the harms Plaintiffs seek to abate

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[11] May 23, 2022 Order, *supra* p. 4.

[12] *In re Nat'l Prescription Opiate Litig.,* No. 1:17-MD-2804, 2022 WL 228150, at *4 (N.D. Ohio Jan. 26, 2022) ("As for *Hunter*, the Oklahoma Supreme court examined "legal interpretation of *Oklahoma's* nuisance statutes," which are clearly different from Georgia's statutes"); *In re Nat'l Prescription Opiate Litig.,* No. 18-OP-45032, 2022 WL 671219, at *17–18 (N.D. Ohio Mar. 7, 2022) ("Put simply, Oklahoma law is different and inapplicable. Plaintiffs bring their public nuisance claim under Ohio law and Defendants do not persuade the Court to adjudicate the claim under contrary law of other jurisdictions.").

"implicate only the inherently private right that each individual has to not be injured by a product."[13]

Plaintiffs respond that their claims are based on harms to public health and public safety. Response at 9. Plaintiffs point out that the opioid epidemic in Plaintiffs' communities has affected the general public and the public entities tasked with addressing public health and public safety. *Id.* They argue that the burden of the opioid epidemic is borne by the community as a whole—including law enforcement, first responders, healthcare workers, the courts, employers, teachers, and families—and by local governments like Plaintiffs that are responsible for serving their citizens. *Id.*

Like Defendants' other arguments, the argument that the opioid epidemic does not implicate public rights has been repeatedly rejected by this Panel and other courts applying West Virginia law.[14]

The Plaintiffs point to the evidence submitted in the Phase 1a trial and argue that this evidence dispels the argument that no public rights are involved in this case. Response at 2. The

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[13] Motion at 9.

[14] *See Brooke Cty. Comm'n v. Purdue Pharma, L.P.*, No. 17-C-248, p. 13 (W. Va. Marshall Cty. Cir. Ct. Dec. 28, 2018) ("The Court further finds and concludes that Plaintiffs have adequately alleged that Defendants interfered with a public right."), *writ denied*, *State ex rel. Cardinal Health, Inc. v. Hummel*, No. 19-0210 (W. Va. June 4, 2019); *State ex rel. Morrisey v. AmerisourceBergen Drug Corp.*, No. 12-C-141, 2014 WL 12814021, at *10 (W. Va. Boone Cty. Cir. Ct. Dec. 12, 2014), (concluding that "the State's public nuisance claim sufficiently alleges the safety and health and morals of the people of West Virginia has been compromised due to Defendants' alleged wrongful influx of addictive, controlled substances into West Virginia, thereby causing substantial injury to West Virginia citizens and taxpayers"), *writ denied*, *State ex. rel. AmerisourceBergen Drug Corp. v. Thompson*, No. 15-1026 (W. Va. Jan. 5, 2016); *see also Monongalia County, et al. v. Purdue Pharma L.P.*, et al., Nos. 18-C-222-236 (adopting and applying the reasoning and rulings from *Brooke County*), *writ denied*, *State ex rel. AmerisourceBergen Drug Corp. v. Moats,* No. 19-1051 (W.Va. January 30, 2020).

Panel finds that there is a triable issue of fact concerning Plaintiffs' claims of interference with public rights.

Defendants acknowledge that "it is the inherent nature of the right, not the number of persons affected, that defines a public right for purposes of public nuisance law."[15] The Panel concludes that Plaintiffs' claims are based on rights common to the general public: the rights to the health and safety of the community at large. Because the interest allegedly invaded "is an interest shared equally by members of the public, . . . the alleged nuisance is public in nature if it is proved at trial."[16] The Panel concludes that the fact any interference with a public right will invariably affect individual members of the public does not change the nature of the right.[17]

The Panel notes that courts in twenty-two states have rejected the Defendants' claim that no public rights are at issue in these opioid cases.[18] And recent decisions accepting similar public nuisance claims in non-opioid contexts confirm that these kinds of public health harms can constitute an interference with a public right.[19] Given this precedent to the contrary, Defendants' citations to *Hunter* and various non-opioid decisions are unpersuasive.

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[15] Motion at 9.

[16] *Rhodes v. E.I. du Pont de Nemours & Co.*, 636 F.3d 88, 96 (4th Cir. 2011).

[17] *Id.* (explaining that, where the defendant's conduct "interfered with the general public's access to clean drinking water," "[t]he fact that the water eventually was pumped into private homes did not transform the right interfered with from a public right to a private right").

[18] See Doc. 1290-1 (Plaintiffs' Appendix of Decisions).

[19] *See, e.g., In re JUUL Labs, Inc., Mktg., Sales Practices, & Prod. Liab. Litig.,* No. 19-MD-02913-WHO, 2020 WL 6271173, *63 (N.D. Cal. Oct. 23, 2020) (claims by school boards that manufacturer of electronic cigarettes interfered with public health stated a claim for interference with public rights sufficient to support a claim for public nuisance under laws of Arizona, New York, Pennsylvania, Florida, and California).

The Panel finds and concludes that Plaintiffs' claims implicate public rights and constitute viable public nuisance claims. The Panel, therefore, **DENIES** the Defendants' motion for summary judgment on this basis.

* * * *

This Panel simply cannot ignore the many decisions (of this Panel and other courts) rejecting similar motions for summary judgement. Nothing in Defendants' motion justifies reconsidering this Panel's prior decisions or ignoring the substantial precedent supporting Plaintiffs' claims.

For the foregoing reasons, Defendants' Motion for Summary Judgment Re "Factual Issue #2" is **DENIED**.

The Panel notes the Defendants' objection and exception to this Order.

A copy of this Order has this day been electronically served on all counsel of record via File & Serve*Xpress.*

It is so **ORDERED.**

ENTERED: July 1, 2022.

/s/ Alan D. Moats
Lead Presiding Judge
Opioid Litigation

/s/ Derek C. Swope
Presiding Judge
Opioid Litigation

EFiled: Aug 03 2022 10:53AM
EDT Transaction ID 67895252

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

IN RE: OPIOID LITIGATION **CIVIL ACTION NO. 21-C-9000-PHARM**

THIS DOCUMENT APPLIES TO ALL STATE CASES AGAINST PHARMACIES

FINDINGS OF FACT AND CONCLUSIONS OF LAW ON ORDER DENYING PHARMACY DEFENDANTS' MOTIONS TO DISMISS COMPLAINTS AND AMENDED COMPLAINTS

Pending before the Mass Litigation Panel ("Panel") are the Pharmacy Defendants'[1] Motions to Dismiss complaints filed against them by the State of West Virginia, acting through its Attorney General ("the State"):[2]

1. **CVS** – Motion to Dismiss Complaint (Transaction ID 66812516) and Motion to Dismiss First Amended Complaint (Transaction ID 67074618);

2. **Rite Aid** – Motion to Dismiss Complaint (Transaction ID 66805397),[3] Rite Aid of Maryland's Motion to Dismiss First Amended Complaint (Transaction ID 6689210), and Rite Aid of West Virginia's Motion to Dismiss Second Amended Complaint (Transaction ID 67072600)[4];
3. **Walgreens** – Motion to Dismiss Complaint (Transaction ID 66816944),[5] and Motion to Dismiss First Amended Complaint (Transaction ID 67074136); and

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[1] CVS Pharmacy, Inc.; CVS Indiana, L.L.C.; CVS Rx Services, Inc.; and CVS TN Distribution, L.L.C.; West Virginia CVS Pharmacy, L.L.C. (collectively, "CVS") Civil Action No. 20-C-131 PNM; Rite Aid of Maryland, Inc. ("Rite Aid of Maryland"); Rite Aid of West Virginia, Inc. ("Rite Aid of West Virginia") (collectively, "Rite Aid") Civil Action No. 20-C-83 PNM; Walgreens Boots Alliance, Inc.; Walgreen Co.; Walgreen Eastern Co., Inc. (collectively, "Walgreens") Civil Action No. 20-C-82 PNM; and Walmart, Inc. ("Walmart") Civil Action No. 20-C-132 PNM.

[2] Because the Pharmacy Defendants provide a detailed recitation of the procedural history of their motions to dismiss in their Motion for Hearing or a Ruling on the Briefs (Transaction ID 67447693), the Panel will not repeat it here.

[3] Defendant Rite Aid Corporation ("RAC") filed a separate motion to dismiss the Complaint for lack of personal jurisdiction (Transaction ID 66805303). RAC was subsequently dismissed without prejudice (Transaction ID 66815276).

[4] On July 27, 2022, the Panel was informed by the State and Rite Aid that they have reached an agreement in principle to resolve this litigation. *Notice of Settlement in Principle and Joint Motion for Stay of Proceedings* (Transaction ID 67866902). The Panel granted the State and Rite Aid's joint motion for a stay of proceedings with respect to Rite Aid to permit the parties to finalize settlement, including completion and execution of a formal settlement agreement. *Order Staying Proceedings Against Rite Aid* entered on July 27, 2022 (Transaction ID 67867052).

4. **Walmart** – Motion to Dismiss First Amended Complaint (Transaction ID 66979844).

Having reviewed and considered the arguments raised in Defendants' Motions and Memoranda of Law in Support, the State's Oppositions and Memoranda of Law in Opposition, the *Pharmacy Defendants' Notice of Supplemental Authority* filed on June 21, 2022 (Transaction ID 67746756), the State's *Response* filed on June 23, 2022 (Transaction ID 67755204), the *Pharmacy Defendants' Notice of Supplemental Authority* filed on July 8, 2022 (Transaction ID 67804904), and the State's *Response* filed on July 11, 2022 (Transaction ID 67806525), the Panel previously denied the motions to dismiss, as set forth in the July 11, 2022, Order (Transaction ID 67809204). The Panel has also reviewed and considered the Pharmacy Defendants' *Objections to the State's Proposed Findings of Fact and Conclusions of Law on Order Denying Pharmacy Defendants' Motions to Dismiss Complaints and Amended Complaints* (Transaction ID 67884238) filed on July 29, 2022, and Plaintiff's *Response* (Transaction ID 67886261) filed on August 1, 2022. The Panel finds the Pharmacy Defendants' objections are unpersuasive, and makes the following findings of fact and conclusions of law in support of its decision:

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. The State has sued the Pharmacy Defendants in connection with their wholesale distribution and retail dispensing of prescription opioids in West Virginia, alleging that their unlawful and/or unreasonable conduct in both activities constituted unfair practices in violation of the West Virginia Consumer Credit and Protection Act ("WVCCPA"), W. Va. Code §§ 46A-

[5] Defendant Walgreens Boots Alliance, Inc. separately moved to dismiss the Complaint for lack of personal jurisdiction (Transaction ID 66817018), but subsequently withdrew the motion (Transaction ID 67304457).

6-101 *et seq.*, and that they contributed to a public nuisance by helping to trigger and sustain the public health and safety crises of the opioid epidemic in West Virginia.

The Legal Standard

2. As explained by the Court in *John W. Lodge Distributing Co., Inc. v. Texaco, Inc.*, 161 W. Va. 603, 245 S.E.2d 157 (1978):

> The purpose of a motion under Rule 12(b)(6) of the West Virginia Rules of Civil Procedure is to test the formal sufficiency of the Complaint. For purposes of the motion to dismiss, the complaint is construed in the light most favorable to plaintiff, and its allegations are to be taken as true. Since common law demurrers have been abolished, pleadings are now liberally construed so as to do substantial justice. W. Va. R. Civ. P. 8(f). The policy of the rule is thus to decide cases upon their merits, and if the complaint states a claim upon which relief can be granted under any legal theory, a motion under Rule 12(b)(6) must be denied.
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> In view of the liberal policy of the rules of pleading with regard to the construction of plaintiff's complaint, and in view of the policy of the rules favoring the determination of actions on the merits, the motion to dismiss for failure to state a claim should be viewed with disfavor and rarely granted. The standard which plaintiff must meet to overcome a Rule 12(b)(6) motion is a liberal standard, and few complaints fail to meet it. The plaintiff's burden in resisting a motion to dismiss is a relatively light one.

Id. at 604-06, 158-59.

3. A trial court considering a motion to dismiss under Rule 12(b)(6) must "liberally construe the complaint so as to do substantial justice." *Cantley v. Lincoln Cnty. Comm'n*, 221 W. Va. 468, 470, 655 S.E.2d 490, 492 (2007) (citing W. Va. R. Civ. P. 8(f)). "The trial court, in appraising the sufficiency of a complaint on a Rule 12(b)(6) motion, should not dismiss the complaint unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Id.* at Syl. pt. 2 (*quoting* Syl. pt. 3, *Chapman v. Kane Transfer Co.*, 160 W. Va. 530, 236 S.E.2d 207 (1977)).

Application of Standard

A. Medical Professional Liability Act and Opioid Dispensing-Based Claims

4. The State alleges that Defendants violated the WVCCPA and contributed to a public nuisance—the public health and safety crisis of the opioid epidemic in West Virginia—through their wholesale distribution and retail dispensing of opioids in West Virginia. *See*, *e.g.*, *State v. CVS* First Amended Complaint ("CVS FAC") (Transaction ID 66994002), ¶¶ 178-99. They did so, the State alleges, by failing to maintain systems to prevent diversion and ensure that prescriptions were issued for legitimate purposes, including by not using their own statewide and national dispensing and claims data to enable pharmacists to assess opioid prescribing practices and trends. *Id.*, ¶¶ 44-46, 50-57, 102-54, 167-72.

5. Defendants argue that the Panel lacks subject matter jurisdiction over the State's claims based on opioid *dispensing* because these are "medical professional liability" claims governed by the Medical Professional Liability Act ("MPLA"), W. Va. Code §§ 55-7B-1 *et seq.*, and the State has not complied with the Act's prerequisites for filing suit. *See, e.g.,* CVS Memo. of Law in Support of Motion to Dismiss Dispensing Claims ("CVS Dispensing MOL") (Transaction ID 67074618) at 7-11 (citing W. Va. Code § 55-7B-6). Defendants do not raise this argument as to the State's claims based on opioid *distribution*.

6. The Panel concludes that the MPLA does not apply to the State's WVCCPA and public nuisance claims based on opioid dispensing by Defendants through their pharmacy stores in West Virginia.

7. The MPLA's prerequisites to suit apply only to a "medical professional liability action." W. Va. Code § 55-7B-6(a). "Medical professional liability" is a defined term:

> "Medical professional liability" means any liability for damages resulting from the death or injury of a person for any tort or breach of contract based on health

> care services rendered, or which should have been rendered, by a health care provider or health care facility to a patient. It also means other claims that may be contemporaneous to or related to the alleged tort or breach of contract or otherwise provided, all in the context of rendering health care services.

W. Va. Code § 55-7B-2(i).

8. The MPLA defines "Plaintiff" as "a patient or representative of a patient who brings an action for medical professional liability under this article," W. Va. Code § 55-7B-2(n), and "Patient" as "a natural person who receives or should have received health care from a licensed health care provider under a contract, express or implied." W. Va. Code § 55-7B-2(m).

9. The MPLA also defines "health care" services to include, in relevant part, "[a]ny act, service or treatment provided under, pursuant to or in the furtherance of a physician's care, a health care facility's plan of care, medical diagnosis or treatment[.]" W. Va. Code § 55-7B-2(e)(1).

10. Thus, for the MPLA to apply, the plaintiff must be a "patient or representative of a patient" who is or was a "natural person" who suffered "death or injury" from the provision of or failure to provide "health care services" that are in furtherance of medical treatment, for which the plaintiff seeks tort or breach of contract damages and related relief. The State is not such a plaintiff covered by the MPLA for at least three independent reasons.

11. First, the State is not a patient or representative of a patient, as the Act requires for its provisions to apply. Rather, the State filed these lawsuits in its capacity as sovereign charged to enforce State laws and protect the public health and safety.

12. The State has express statutory authority to enforce the WVCCPA. *See* W. Va. Code § 46A-7-108 ("The attorney general may bring an action to restrain a person from violating this chapter and for other appropriate relief."); § 46A-7-111(2) ("The attorney general may bring a civil action against a creditor or other person to recover a civil penalty for willfully violating

this chapter[.]"). It does so not as an injured consumer or the representative of injured consumers, but as sovereign charged with enforcing the Act to help ensure a fair and honest marketplace:

> [The Attorney General] is authorized to file suit independently of any consumer complaints, as a *parens patriae*, that is, as the legal representative of the State to vindicate the State's sovereign and quasi-sovereign interests, as well as the interests of the State's citizens. Indeed, the fact that the Attorney General is acting to obtain disgorgement of ill-gotten gains, separate and apart from the interest of particular consumers in obtaining recompense, validates this action as a *parens patriae* action.

State of West Virginia ex rel. McGraw v. CVS Pharmacy, Inc., 646 F.3d 169, 176 (4th Cir. 2011) (internal quotation marks and citation omitted).

13. So, too, is the State, through its officers and agencies, empowered at common law to bring suit to remedy a public nuisance that is interfering with the public health and safety. *See, e.g., State ex rel. Smith v. Kermit Lumber & Pressure Treating Co.*, 200 W. Va. 221, 242, 488 S.E.2d 901, 922 (1997) ("The [Department of Environmental Protection's] allegation of public nuisance does not encompass damages to property owned by the DEP nor does it encompass damages for personal injuries to the DEP. Instead, the DEP is seeking damages for the harm caused to the public health, safety, and the environment.") (internal quotation marks omitted).

14. Since the State brings its WVCCPA and public nuisance claims as sovereign vindicating the interests of the public, not as an injured patient or representative of an injured patient, the MPLA does not apply to these claims.

15. Second, the conclusion that the MPLA does not apply is underscored by the fact that the State also does not seek damages.

16. The Panel already has ruled that the State's WVCCPA statutory remedies of an injunction, equitable relief, and civil penalties are not damages, which the State has waived. *See Order Regarding the State's Motion to Strike Defendants' Notices of Non-Party Fault* ("State NNPF Order") (Transaction ID 65820504) at 4 ("[T]he State seeks . . . civil penalties and equitable relief under the WVCCPA, not damages . . . .").

17. The Panel also has ruled that the State's public nuisance remedy of prospective, equitable abatement likewise is not damages, which the State has waived. *See id.* at 3, 4; *see also Order Granting Plaintiffs' Motion to Strike Defendants' Notices of Non-Party Fault* ("Cities-Counties NNPF Order") (Transaction ID 65807300) at 4-5 ("[T]he 'distinction between abatement of nuisances and recovery of damages for injuries occasioned by wrongful acts constituting nuisances' is both 'apparent' and 'vast.'") (quoting *McMechen v. Hitchman-Glendale Consol Coal Co.*, 88 W. Va. 633, 107 S.E. 480, 482 (1921)).

18. The Supreme Court of Appeals of West Virginia considered the Panel's rulings on these points and left them undisturbed. *See State ex rel. AmerisourceBergen Drug Corp. v. Moats*, 245 W. Va. 431, 443 and n.55, 859 S.E.2d 374, 386 and n.55 (2021) (defendants' argument concerning "joinder of legal and equitable claims" and right to jury trial "does not apply to the State, which has brought claims for public nuisance and violation of the WVCCPA.").

19. The recent decision in *City of Huntington v. AmerisourceBergen Drug. Corp.*, No. 3:17-01362, ___ F. Supp. 3d ___, 2022 WL 2399876 (S.D. W. Va. July 4, 2022), does not warrant reconsideration of the Panel's rulings that the State's WVCCPA and public nuisance claims do not seek damages, as required under the MPLA.

20. The Panel finds the discussions by the court in the federal multidistrict litigation (MDL) and in the *Restatement (Second) of Torts*' regarding the nature and scope of public nuisance abatement persuasive and applicable to this case. *See In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804, 2019 WL 4043938, at *2 (N.D. Ohio Aug. 26, 2019) ("Thus, the Court, exercising its equitable powers, has the discretion to craft a remedy that will require Defendants, if they are found liable, to pay the prospective costs that will allow Plaintiffs to abate the opioid crisis."); *id.*, ___ F. Supp. 3d ___, 2022 WL 671219, at *27 (N.D. Ohio March 7, 2022) ("Even if as Defendants assert, they discontinued the conduct that led to the existence of the nuisance, they are still subject to liability for abatement of any ongoing consequential effects of the nuisance."); *Restatement (Second) of Torts* (1979), § 834 cmt. e ("[I]f the activity has resulted in the creation of a physical condition that is of itself harmful after the activity that created it has ceased, a person who carried on the activity that created the condition or who participated to a substantial extent in the activity is subject to the liability for a nuisance, for the continuing harm."). The remedy the State seeks here is not damages, but equitable abatement to which the MPLA does not apply.

21. Third, the State's WVCCPA and public nuisance claims are not based on "health care services rendered," W. Va. Code §55-7B-2(i), in furtherance of a physician or health care facility's plan of care, medical diagnosis or treatment. § 55-7B(2)(e)(1). Rather, the State alleges that Defendants failed to discharge their duties as registrants under the federal and West Virginia Controlled Substances Acts to maintain "effective controls against diversion of controlled substances into *other than* legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1) (emphasis added); *see also* W. Va. Code § 60A-3-303(a)(1) (same), 21 C.F.R. § 1301.71(a), W. Va. C.S.R. § 15-2-5.1.1. This includes the requirement that dispensing

pharmacies operate systems to detect and block medically *illegitimate* prescribing. *See* 21 C.F.R. § 1306.04(a), W. Va. C.S.R. § 15-2-8.4.1. The State alleges that Defendants violated these duties by, *inter alia*, failing to use their own national and statewide dispensing and claims data to identify doctors with prescribing patterns that present red flags for diversion and *non-medical* use. *See, e.g.*, CVS FAC, ¶¶ 44-46, 50-57, 102-54, 167-72.

22. The federal and state regulations that the State alleges Defendants failed to comply with provide specifically that:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription . . . .

21 C.F.R. § 1306.04(a); *see also* W. Va. C.S.R. § 15-2-8.4.1 (same). The alleged failure of Defendants to prevent diversion by failing to investigate red flags of diversion and illegitimate prescribing does not fall under the MPLA's protections. *Cf. East Main St. Pharmacy; Affirmance of Suspension Order*, 75 FR 66149-01, 66157, 2010 WL 4218766 (D.E.A. Oct. 27, 2010) ("'[A] pharmacist can know that prescriptions are issued for no legitimate medical purpose without his needing to know anything about medical science.'") (quoting *U.S. v. Hayes*, 595 F.2d 258, 261 n.6 (5th Cir. 1979)). Since the duties underpinning the State's WVCCPA and public nuisance claims are not performed in furtherance of patient treatment, but pursuant to registrants' duties to prevent diversion outside of legitimate patient care, the MPLA does not apply to these claims.

23. Defendants' arguments for broader application of the MPLA do not have merit. CVS relies upon the Act's provision for claims involving controlled substances dispensing. *See*

CVS Dispensing MOL at 9 (citing W. Va. Code § 55-7B-5(d)). This provision, however, refers to claims "by or on behalf of a *person* whose *damages* arise as a proximate result of a violation of the Uniform Controlled Substances Act[.]" W. Va. Code § 55-7B-5(d) (emphasis added). These limitations echo and thus underscore those in the Act's provisions limiting its application to claims by or on behalf of patients for damages sustained from receiving medical treatment.

24. Rite Aid's argument relying on the MPLA's "other claims" clause, Rite Aid Memo. in Support of its Motion to Dismiss Second Amended Complaint ("Rite Aid 2AC MOL") (Transaction ID 67072600) at 6 (citing W. Va. Code § 55-7B-2(i)), and authority applying it to an equitable claim, also is unavailing. This provision covers "other claims that may be contemporaneous to or related to the alleged tort or breach of contract or otherwise provided[.]" W. Va. Code § 55-7B-2(i). It thus does not *eliminate* the requirement of a plaintiff's tort or contract claim for damages resulting from the death or injury of a patient-natural person, but rather also captures other claims that are supplemental to that claim. The authority Rite Aid cites demonstrates this. *See State ex rel. W. Va. Univ. Hosps., Inc. v. Scott*, 246 W. Va. 184, 866 S.E.2d 350, 360 (2021) ("The 'health care' claim is the 'anchor,' it gets you in the door of MPLA application to allow for inclusion of claims that are 'contemporaneous to or related to' that claim, but still must be in the overall context of rendering health care services."); *Brown v. Ohio Valley Health Servs. & Educ. Corp.*, No. 20-0156, 2021 WL 2023532, at *3 (W. Va. May 20, 2021) (where injury victim filed negligence claim against hospital covered by MPLA, Act also covered co-plaintiff employer's equitable subrogation claim against hospital based on same injury).

25. Defendants' reliance on two recent orders by the federal MDL court referencing the MPLA, *see Pharmacy Defendants' Notice of Supplemental Authority*, 6/21/21 (Transaction

ID 67746756), is misplaced. In its first order, the MDL court ruled in denying remand that the MPLA applied to certain West Virginia city and county plaintiffs' claims against physicians, a pharmacist, and a pharmacy because those defendants fell under the Act's definition of "health care provider" in W. Va. Code § 55-7B-2(g). *See In re Nat'l Prescription Opiate Litig., supra* (N.D. Ohio June 8, 2022) (Dkt. 4502) at 7 n.9. The State specially appeared in that action and requested clarification concerning the decision's scope. In response, the MDL court clarified that the "***sole*** argument raised by the seven West Virginia Plaintiffs in their remand motion, to support their assertion that the MPLA's 30-day notice requirement did not apply, was that they were not 'persons.'" *In re Nat'l Prescription Opiate Litig., supra* (N.D. Ohio June 14, 2022) (Dkt. 4516) at 2 (emphasis in original). The MDL court thus was not presented with and did not rule on the issues decided herein.

26. Similarly, the decision in *State v. Judy's Drug Store, Inc.*, No. 16-C-54 (W. Va. Cir. Ct., Hardy Cnty. Nov. 8, 2019), relied upon by Defendants, addressed different types of claims. *See id.* at 8, ¶ 25 ("Plaintiff seeks relief and damages allegedly resulting from the death or injury of persons . . . ."). The decision in *State v. Crab Orchard Pharmacy, Inc.*, No. 17-C-12-D (W. Va. Cir. Ct., Raleigh Cnty., March 8, 2019), held that the MPLA applies to a public nuisance claim "because the allegations in paragraph VI of the Complaint relate to the provision of health care," *id.* at 12, without addressing whether this claim was brought on behalf of individual patients or sought damages as opposed to equitable abatement relief.

27. The Panel holds that the MPLA does not apply to the State's WVCCPA claims for an injunction, other equitable relief, and civil penalties or its public nuisance claims for equitable abatement because these claims are not brought by or on behalf of a patient and do not seek damages for a patient's death or injury in receiving medical services.

B. Comprehensive Regulation and Federal or State Statutory Preemption

28. The Panel further rejects Defendants' arguments that purportedly comprehensive regulation of controlled substances distribution and dispensing under federal and state law preempt or otherwise preclude the State's WVCCPA and public nuisance claims. *See* CVS Dispensing MOL at 23-26, 28-30; Rite Aid Dispensing MOL at 10-14; Walgreens Dispensing MOL at 18-24; Walmart MOL at 25-27, 30-32.

29. First, the federal Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801 *et seq.*, and U.S. Drug Enforcement Administration ("DEA") regulations do not preempt the State's West Virginia state-law claims. The State seeks to hold Defendants liable for conduct that it alleges violates state law as well as the CSA. *See, e.g.*, CVS FAC, ¶¶ 61-63, 66-67, 78, 94, 119, 182-83, 191. The CSA specifically contemplates and preserves this type of state-law liability. The Act contains an express savings clause, titled "Application of State law," which provides that:

> No provision of this subchapter shall be construed as indicating an intent on the part of Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and the State law so that the two cannot consistently stand together.

21 U.S.C. § 903. This savings clause alone demonstrates that the CSA does not occupy the field of controlled substances regulation and does not preempt liability under state law absent a positive conflict between the CSA and state law, which Defendants do not demonstrate.

30. The DEA's regulatory guidance underscores this conclusion that the CSA and federal regulation do not *per se* preempt state-law liability for improper conduct in dispensing opioids. In a 2006 policy statement titled "*Dispensing Controlled Substances for the Treatment of Pain*," the DEA explained that:

> [I]t has been the case for more than 70 years that a practitioner who dispenses controlled substances for other than a legitimate medical purpose, or outside the usual course of professional practice, is subject to legal liability under both State and Federal law.

71 FR 52716-01, 52717, 2006 WL 2540907 (D.E.A. Sept. 6, 2006).

31. In light of the statutory command and DEA statement, courts uniformly have rejected the argument that the CSA and comprehensive DEA regulation preempt state-law public nuisance and consumer protection statute claims based on diversion-control failures in the distribution or dispensing of prescription opioids. *See City and Cnty of San Francisco v. Purdue Pharma L.P.*, 491 F. Supp. 3d 610, 662 (N.D. Cal. 2020) (holding that 21 U.S.C. § 903 "precludes any argument that Congress intended to preempt state laws that enforce the CSA absent a positive conflict" and that "[n]o such conflict exists" with respect to state-law public nuisance claims); *In re Nat'l Prescription Opiate Litig.*, 2019 WL 4178591, at *12 (N.D. Ohio Sept. 3, 2019) ("The Court has previously rejected this obstacle preemption argument, albeit with respect to the FDA, and now does so with respect to the DEA."); *State of South Dakota v. Purdue Pharma L.P.*, No. 32CIV18-000065, 2021 WL 5873046, at *4 (S.D. Cir. Ct. Jan. 13, 2021) ("In 21 U.S.C. § 903, the [CSA] contemplates that states' traditional enforcement of tort law will supplement the federal enforcement scheme."); *State of New Mexico v. Purdue Pharma L.P.*, No. D-101-CV-2017-02541 (N.M. Dist. Ct. July 1, 2022) at 4 ("[T]he Court rejects the argument that the State's claims are preempted because they purportedly seek to enforce the [CSA] . . . .").

32. The Panel thus holds that the CSA and DEA regulation do not preempt or otherwise preclude the State's WVCCPA and public nuisance claims based on Defendants' alleged diversion-control failures in their distribution and/or dispensing of prescription opioids as controlled substances.

33. Second, the West Virginia Uniform Controlled Substances Act ("WVCSA"), W. Va. Code §§ 60A-1-101 *et seq.*, likewise does not preempt or otherwise preclude the State's WVCCPA and public nuisance claims. Defendants argue that both claims are precluded by the WVCSA's grant of exclusive enforcement authority to the West Virginia Board of Pharmacy. *See, e.g.,* CVS Dispensing MOL at 23, 28. The Panel has rejected this argument as applied to common law negligence claims, as other courts have with respect to WVCCPA and public nuisance claims.

34. In its October 31, 2019, *Order Denying Pharmacy Defendants' Motion to Dismiss Plaintiffs' Complaint*, entered in Civil Action Nos. 18-C-222 MSH and 18-C-233 MSH through 18-C-236 MSH ("Pharmacies Order") (Transaction ID 64374772), the Panel adopted as law of the case the ruling by the Circuit Court of Marshall County rejecting several Pharmacy Defendants' assertion that a claim incorporating WVCSA standards was an impermissible enforcement action. This ruling explained as follows:

> The Court finds and concludes that Plaintiffs are not attempting to assert a private right of action under the WVCSA. Instead, they rely on the WVCSA to help establish a standard of care for their common-law negligence claim, which is permissible under the law.

Id. at Ex. A, p.6 ¶ 15. The Panel adopted and incorporated this ruling as law of the case in this mass litigation. *Id.* at 3.

35. In *State ex rel. Morrisey v. AmerisourceBergen Drug Corp.*, No. 12-C-141, 2014 WL 12814021 (W. Va. Cir. Ct., Boone Cnty Dec. 12, 2014), *writ denied*, *State ex rel. AmerisourceBergen Drug Corp. v. Thompson*, No. 15-1026 (W. Va. Jan. 5, 2016), Judge Thompson ruled that the State may base a WVCCPA unfair practices claim upon defendant opioid distributors' conduct violating their statutory and regulatory duties to maintain effective controls against diversion. While the defendants argued that "not all violations of a statute or

regulation are unfair[,]" *id.* at *14, the court ruled that the "question of 'unfairness' is decided on a case-by-case basis" and denied dismissal of the claim. *Id.*

36. The court in *State v. AmerisourceBergen* ruled correctly that the State may base a WVCCPA unfair practices claim upon a defendant's conduct violating WVCSA statutory and regulatory duties to maintain effective controls against diversion of controlled substances. The WVCCPA declares "unfair or deceptive acts or practices in the conduct of any trade or commerce" to be "unlawful." W. Va. Code § 46A-6-104. The Act provides a non-exclusive definition of what may constitute an unfair practice. W. Va. Code § 46A-6-102(7). The Act further provides that "[i]t is the intent of the Legislature that, in construing this article, the courts be guided by the policies of the Federal Trade Commission [FTC] and interpretations given by the [FTC] and federal courts to [15 U.S.C. § 45(a)(1)], as from time to time amended . . . ." W. Va. Code § 46A-6-101(1). The FTC has considered in assessing whether an act or practice is "unfair" under the federal statute "whether the practice, without necessarily having been previously considered unlawful, offends public policy as it has been established by statutes, common law, or otherwise . . . ." FTC, *Statement of Basis and Purpose of Trade Regulation Rule*, 29 FR 8324, 8355 (1964). Conduct prohibited by the WVCSA thus may be a predicate for a WVCCPA unfair practices claim.

37. So, too, may conduct prohibited by the WVCSA support a public nuisance claim. "A public nuisance is an act or condition that unlawfully operates to hurt or inconvenience an indefinite number of persons." *Duff v. Morgantown Energy Ass'n*, 187 W. Va. 712, 716, 421 S.E.2d 253, 257 (1992) (internal quotation marks and citation omitted). The Supreme Court of Appeals has found that "this definition is consistent with the *Restatement (Second) of Torts* § 821B(1) (1979), which defines a public nuisance as 'an unreasonable interference with a right

common to the general public.'" *Id.* at 716 n.6, 421 S.E.2d at 257 n.6. Under the *Restatement* provision, "[c]ircumstances that may sustain a holding that an interference with a public right is unreasonable include . . . whether the conduct is proscribed by a statute, ordinance or administrative regulation[.]" *Restatement (Second) of Torts* § 821B(2)(b). Although unlawful conduct is not *required*, *see Duff*, 187 W. Va. at 716, 421 S.E.2d at 257 (a "business lawful in itself [may] constitute[] a public nuisance"), this is a permissible way to prove that conduct supports public nuisance liability. *See State v. AmerisourceBergen*, 2014 WL 12814021, at *9 (denying dismissal of State's public nuisance claim alleging that opioid distributor defendants "failed to provide effective controls against the diversion of controlled substances and failed to operate a system that discloses suspicious orders of controlled substances"). Conduct prohibited by the WVCSA thus may be a predicate for a public nuisance claim.

38. The Panel holds that the WVCSA does not preempt or otherwise prohibit the State's WVCCPA and public nuisance claims alleging in part that the Pharmacy Defendants violated their statutory and regulatory duties to maintain effective controls against diversion of the prescription opioids they distributed and dispensed in West Virginia.

39. Third, none of the other state statutory provisions invoked by the Pharmacy Defendants supports dismissal of the State's claims.

40. Defendants contend that W. Va. Code § 30-5-21(a), part of the Larry W. Border Pharmacy Practice Act ("Pharmacy Act"), W. Va. Code §§ 30-5-1 *et seq.*, bars any common-law claim based on prescription drug dispensing. *See, e.g.*, CVS Dispensing MOL at 29. This provision addresses responsibility for the "quality of all drugs, chemicals and medicines" sold. W. Va. Code § 30-5-21(a). The Panel previously rejected the argument that this provision precludes claims based on controlled substances *distribution*. In its *Order Denying the*

Distributor Defendants' Motion to Dismiss Plaintiffs Complaint, entered in Civil Action Nos. 18-C-222 MSH and 18-C-233 MSH through 18-C-236 MSH ("Distributors Order") (Transaction ID 64374611), *writ denied*, *State ex rel. AmerisourceBergen Drug Corp. v. Moats*, No. 19-1051 (W. Va. Jan. 30, 2020), the Panel addressed the Circuit Court of Marshall County's ruling that § 30-5-21(a) "does not apply to the instant claims because claims against Defendants arise out of their duties to prevent diversion as distributors of controlled substances rather than the 'quality' of the drugs sold at retail," *id.* at Ex. A, p. 11 ¶ 27, and incorporated and adopted this ruling as law of the case in this mass litigation. *Id.* at 2-3. Having previously held that this provision does not apply to or prohibit opioid *distribution* claims, the Panel now holds that W. Va. Code § 30-5-21(a) likewise does not apply to or prohibit opioid *dispensing* claims alleging failure to maintain effective controls against diversion because these claims do not involve the "quality" of the opioid drugs sold at retail.

41. Defendants also contend that W. Va. Code § 55-7-23 bars any common-law claim based on prescription drug dispensing. *See, e.g.*, CVS Dispensing MOL at 29-30. This provision addresses liability "to a patient or third party for injuries sustained as a result of the ingestion of a prescription drug . . . ." W. Va. Code § 55-7-23(a). It does not apply to the State's public nuisance claims alleging failure to maintain effective controls against diversion. These claims are not derivative of anyone's injuries sustained from ingesting opioids. Rather, they are based on the need to remediate community harms of an opioid epidemic allegedly triggered and sustained by Defendants' conduct. *See In re Nat'l Prescription Opiate Litig., supra*, 2018 WL 6628898, at *6 (N.D. Ohio Dec. 19, 2018) ("Defendants claim that Plaintiffs' asserted injuries are 'necessarily derivative of harms to individual opioid users . . . .' . . . [However,] Plaintiffs have alleged a plausible claim that their injuries are the direct result of Defendants' creation of

an illicit opioid market within their communities. Plaintiffs' asserted economic injuries are borne by them and not passed-on by any intermediate party . . . ."). W. Va. Code § 55-7-23 does not apply to or prohibit the State's claims.

42. Defendants also contend that W. Va. Code § 55-7-31(b) bars any common-law claim based on prescription drug dispensing. *See, e.g.*, CVS Dispensing MOL at 30. This provision addresses a "product liability action," W. Va. Code § 55-7-31(b), defined as a:

> [C]ivil action brought against a . . . seller of a product, based in whole or in part on the doctrine of strict liability in tort, for or on account of personal injury, death or property damage caused by or resulting from: (A) The manufacture, construction, design, formula, installation, preparation, assembly, testing, packaging, labeling, marketing or sale of a product; (B) The failure to warn or protect against a danger or hazard in the use, misuse or unintended use of a product; or (C) The failure to provide proper instructions for the use of a product.

W. Va. Code § 55-7-31(a)(4). The State does not allege any product defect, failure to warn, or failure to instruct, by Defendants. Rather, the State alleges that Defendants failed to maintain effective controls against diversion of the opioids they distributed and dispensed in West Virginia. W. Va. Code § 55-7-31 does not apply to the State's claims.

43. The Panel thus holds that the CSA, the WVCSA, and state pharmacy practice and product liability statutes do not preempt the State's WVCCPA and public nuisance claims.

C. The State's WVCCPA Public Enforcement Claims

44. The State alleges that the Pharmacy Defendants committed unfair or deceptive acts or practices in violation of the WVCCPA through their failures to maintain effective controls against diversion of the prescription opioid drugs they distributed into West Virginia and dispensed and sold through their West Virginia pharmacy stores. *See, e.g.*, CVS FAC, ¶¶ 178-86. Defendants raise numerous arguments for dismissal of the State's WVCCPA claims.

45. First, Defendants argue that "the [WV]CCPA does not apply to commerce involving prescription medications, because licensed prescribers---not consumers—drive prescription medication purchases." CVS Dispensing MOL at 3 (citing *White v. Wyeth*, 227 W. Va. 131, 141, 705 S.E.2d 828, 838 (2010)); *see also id.* at 12-17 ("Conduct involving prescription drugs is not actionable under the [WV]CCPA."); Rite Aid Dispensing MOL at 16-19 (same substantive argument); Walgreens Dispensing MOL at 9-14 (same); Walmart MOL at 12-17. The Panel rejects this argument as contrary to well-established West Virginia law.

46. The WVCCPA is a remedial statute that, by its express terms, "shall be liberally construed so that its beneficial purposes may be served." W. Va. Code § 46A-6-101(1). The Supreme Court of Appeals and other courts thus have repeatedly addressed WVCCPA public enforcement claims by the State against sellers and distributors of prescription drugs, including Defendants in this and other cases in this mass litigation, without questioning the Act's application. *See State ex rel. McGraw v. Johnson & Johnson*, 226 W. Va. 677, 680 and 684, 704 S.E.2d 677, 680 and 684 (2010) (WVCCPA claim involving deceptive communications to healthcare providers about prescription medications; addressing availability of civil penalties); *State v. CVS, supra*, 646 F.3d at 171 (WVCCPA claim involving unlawful acts in the sale of generic prescription drugs; addressing federal court jurisdictions); *State v. AmerisourceBergen, supra*, 2014 WL 12814021, at *14 ¶ 82 (WVCCPA claim involving improper and illegal distribution of prescription opioid pills without required diversion controls; denying motion to dismiss).

47. The Supreme Court of Appeals' decision in *White v. Wyeth, supra*, is not to the contrary. There, the Court held that "the *private* cause of action afforded consumers under West Virginia Code § 46A-6-106(a) does not extend to prescription drug purchases" because of the

unlikelihood that a private consumer could establish causation of a loss in connection with a prescription drug purchase where "[t]he intervention by a physician in the decision-making process necessitated by his or her exercise of judgment whether or not to prescribe a particular medication . . . protects consumers in ways respecting efficacy that are lacking in advertising campaigns for other products." *Id.* (emphasis added). *White*'s analysis of private consumer claims does not apply to the State's public enforcement claims. The difference between the two types of claims is critical.

48. The State in a public enforcement action like those here does not have to prove loss-causation, reliance, or damages, which was the basis for the ruling in *White*. Instead, when a defendant has committed an unfair or deceptive act or practice prohibited by the WVCCPA, the State, through the Attorney General, "may bring a civil action to restrain [the defendant] from violating [the WVCCPA] and for other appropriate relief." W. Va. Code § 46A-7-108. The phrase "other appropriate relief" in § 108 "indicates that the legislature meant the full array of equitable relief to be available in suits brought by the Attorney General." *State ex rel. McGraw v. Imperial Mktg.*, 203 W. Va. 203, 215-16, 506 S.E.2d 799, 811-12 (1998) ("*Imperial Mktg. II*"). This includes disgorgement of ill-gotten gains. *See, e.g., State v. CVS*, 646 F.3d at 176. It also includes civil penalties for repeated and willful violations. W. Va. Code § 46A-7-111(2). To obtain these remedies, the State must submit proof of the defendant's conduct, and nothing more. *See, e.g., State v. Johnson & Johnson*, 226 W. Va. at 684, 704 S.E.2d at 684 ("If the attorney general can prove that a defendant has engaged in a course of repeated and willful violations of the Act, then a court may assess a civil penalty of no more than five thousand dollars for each violation."). Since the State need not prove loss-causation, reliance, or damages

for its WVCCPA public enforcement claims, *White v. Wyeth* is inapposite, and the State may proceed on its claims involving distribution and dispensing of prescription drugs.

49. Second, Defendants argue that the State's WVCCPA claims must be dismissed for want of a consumer transaction. *See* CVS Dispensing MOL at 21-22; Rite Aid of Maryland MOL at 8-11; Rite Aid of West Virginia MOL at 8-11; Walgreens Distribution MOL at 11-13; Walmart MOL at 21-24. This argument, too, relies upon authority addressing *private* plaintiff claims under the WVCCPA. *See* CVS Dispensing MOL at 21 (citing *Harper v. Jackson Hewitt, Inc.*, 227 W. Va. 142, 145, 706 S.E.2d 63, 66 (2010) (private plaintiff class action); *Cather v. Seneca-Upshur Petroleum, Inc.*, No. 90CV139, 2010 WL 3271965, at *7-8 (N.D. W. Va. Aug. 18, 2010) (same). This authority does not address the requirements for State public enforcement claims under the WVCCPA like those here.

50. Unlike the WVCCPA's private-right-of-action provision, W. Va. Code § 46A-6-106(a), the Act's public enforcement provisions do not on their face require proof of a consumer transaction. *See* W. Va. Code § 46A-7-108 ("The Attorney General may bring a civil action to restrain a person from violating this chapter and for other appropriate relief."); W. Va. Code § 46A-7-111(2) ("The Attorney General may bring a civil action against a creditor or other person to recover a civil penalty for willfully violating this chapter."). Accordingly, courts addressing the State's public enforcement authority under the WVCCPA have held that the Act does not require the State to allege a consumer transaction. *See, e.g. State ex rel. McGraw v. Minn. Mining & Mfg. Co. (3M Co.)*, 354 F. Supp. 2d 660, 667 (S.D. W. Va. 2005 ("Plaintiff's CCPA claims accuse defendants of unfair methods of competition and/or unfair [or] deceptive acts or practices in violation of West Virginia Code section 46A-6-104, as defined in 46A-6-102. The claims do not appear to require the presence of a consumer or a consumer transaction.") (citation

omitted); *State v. AmerisourceBergen*, 2014 WL 12814021, at *15 ("W. Va. Code § 46A-6-104 does not require a consumer or consumer transaction.") (internal quotation marks omitted); *see also State v. CVS*, 646 F.3d at 176 ("[The Attorney General] is authorized to file suit independently of any consumer complaints, as a *parens patriae*, that is, as the legal representative of the State to vindicate the State's sovereign and quasi-sovereign interests . . . ."). The Panel thus holds that the State need not allege or prove a consumer transaction to proceed on a WVCCPA public enforcement claim.

51. Third, certain Defendants argue that the State's WVCCPA claims based on opioid distribution must be dismissed for failure to allege transactions that occur in the scope of trade or commerce. *See* CVS Distribution MOL at 15-16; Walgreens Distribution MOL at 14-17.[6] The WVCCPA requires the occurrence of an unfair method of competition or unfair or deceptive act or practice "in the conduct of any trade or commerce." W. Va. Code § 46A-6-104. The State, however, readily satisfies this requirement for its opioid distribution-based claims.

52. The WVCCPA defines "'Trade' or 'commerce" to encompass "the advertising, offering for sale, sale *or distribution of any goods* or services" and to "include any trade or commerce, directly or indirectly, affecting the people of this state." W. Va. Code § 46A-6-102(6) (emphasis added). Defendants' distribution of opioid pills to their pharmacy stores in West Virginia is, by definition, the distribution of a good affecting the people of West Virginia. CVS nonetheless contends that this definition's inclusion of "advertising" and "offering for sale" must be read to limit the meaning of "distribution" to apply only to "arms-length commercial transactions between third parties, not to CVS's internal transfer of inventory from its own distribution centers to its own pharmacies." CVS Distribution MOL at 16; *see also* Walgreens

[6] These Defendants do not make this argument with respect to the State's claims based on opioid *dispensing*.

Distribution MOL at 16 (same in substance). This argument fails because the Act includes the distribution of goods in the disjunctive, separate and apart from advertising or sales, and further provides that the covered distribution of goods may "directly or indirectly[] affect[] the people of this state." W. Va. Code § 46A-6-102(6). This definition does not require direct advertising or sales. The State therefore satisfies the WVCCPA's "trade or commerce" requirement for its claims based on Defendants' distribution of opioid pills in West Virginia.

53. Fourth, Defendants argue that the State does not adequately allege an unfair or deceptive act or practice violating the WVCCPA. *See* CVS Dispensing MOL at 17-21; Rite Aid Dispensing MOL at 19-22; Walgreens Dispensing MOL at 14-17; Walmart MOL at 18-21. This argument, too, has no merit.

54. The WVCCPA declares "unfair or deceptive acts or practices in the conduct of any trade or commerce" to be "unlawful." W. Va. Code § 46A-6-104. The Act provides a non-exclusive definition of what may constitute an unfair practice. W. Va. Code § 46A-6-102(7). The Act further provides that "[i]t is the intent of the Legislature that, in construing this article, the courts be guided by the policies of the [FTC] and interpretations given by the [FTC] and federal courts to [15 U.S.C. § 45(a)(1)], as from time to time amended . . . ." W. Va. Code § 46A-6-101(1). The federal statute assesses unfairness based on whether "the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition." 15 U.S.C. § 45(n). The FTC may "consider established public policies as evidence to be considered with all other evidence[,]" although these "may not serve as a primary basis for such determination." *Id.* The "likely . . . consumer injury" that supports finding unfairness may include "[u]nawarranted health and safety risks[.]" FTC, *Statement of Policy,*

supra, 104 F.T.C. 949, 1984 WL 565290, at *97. The FTC also has considered "whether the practice, without necessarily having been previously considered unlawful, offends public policy as it has been established by statutes, common law, or otherwise . . . ." FTC, *Statement of Basis, supra*, 29 FR at 8355.

55. Based on the foregoing, Judge Thompson in *State v. AmerisourceBergen, supra*, held that the State's allegation of a failure to maintain effective controls against diversion in the distribution of prescription opioids supported an unfair practices claim under the WVCCPA. 2014 WL 12814021 at *14 ("The State has pled that Defendants have profited off the prescription drug epidemic by ignoring state-law anti-diversion regulations, thereby supplying Pill Mills. That meets the pleading requirement of unfairness at this stage.").

56. This Panel ruled similarly in this litigation in denying motions by Manufacturer Defendants to dismiss the State's WVCCPA claims alleging in part their failure to maintain effective controls against diversion. *See* Order Denying Allergan and Teva Defendants' Motions to Dismiss State's First Amended Complaint ("Teva Order") (Transaction ID 65887418) at 3; Order Denying Janssen Defendants' Motion to Dismiss State's Complaint ("Janssen Order") (Transaction ID 65899715) at 4.

57. In urging a contrary ruling here, Defendants contend that the common thread running through the WVCCPA's enumerated examples of "unfair or deceptive acts or practices" is that the conduct deceives, misleads, or confuses a consumer. *See, e.g.,* CVS Dispensing MOL at 18 (citing W. Va. Code § 46A-6-102(7)), 20 ("[T]here is no support for the proposition that the quantity of a lawful product, in itself, is deceptive."). This argument fails because the WVCCPA expressly provides with respect to these enumerated examples of "unfair or deceptive acts or practices" that this concept "means and includes, *but is not limited to*, any one or more of

the following[.]" W. Va. Code § 46A-6-102(7) (emphasis added); *see also State v. AmerisourceBergen*, 2014 WL 12814021 at *14 ("This language indicates the list is not exclusive, and other conduct can constitute unfair or deceptive acts or practices.").

58. The Panel therefore holds that the State sufficiently pleads an "unfair practices" claim under the WVCCPA based on its allegations that the Pharmacy Defendants failed to maintain effective controls against diversion in their distribution and dispensing of prescription opioid pills in West Virginia.

59. Fifth, Defendants seek dismissal of the State's WVCCPA claims for failure to plead with particularity as required by W. Va. R. Civ. P. 9(b) for claims sounding in fraud. *See, e.g.*, CVS Dispensing MOL at 22-23. A WVCCPA public enforcement claim by the State does not sound in fraud. *Compare* W. Va. Code § 46A-6-102(7)(M) (misrepresentation or concealment of material facts can be an unfair or deceptive act or practice "whether or not any person has in fact been misled, deceived or damaged thereby"), *with Sneberger v. Morrison*, 235 W. Va. 654, 670, 776 S.E.2d 156, 172 (2015) ("essential elements" of fraud include "that plaintiff relied on [material and false representation] and was justified under the circumstances in relying on it" and that plaintiff "was damaged because he relied on it") (internal quotation marks and citation omitted). The Panel thus has ruled in this litigation that Rule 9(b) does not apply to the State's WVCCPA claims against other Defendants. *See* Teva Order (Transaction ID 65887418) at 3. Other courts have ruled likewise that Rule 9(b) does not apply to statutory unfair practices claims. *See, e.g., Moore v. RoundPoint Mortg. Serv. Corp.*, No. 2:18-cv-01222, 2018 WL 4964362, at *3 (S.D. W. Va. Oct. 15, 2018) ("The court finds, however, that [Federal] Rule 9(b) does not apply to the plaintiffs' allegation that RoundPoint violated Section 46A-2-128, as the plaintiffs allege only that RoundPoint used unfair or unconscionable means to collect

a debt, which does not require a showing of fraud."); *see also FTC v. Kitco of Nevada, Inc.*, 612 F. Supp. 1282, 1293 (D. Minn. 1985) (fraud elements do not apply to FTC action). The Panel thus holds that Rule 9(b) does not apply to the State's WVCCPA public enforcement claims against the Pharmacy Defendants.

60. Moreover, even if Rule 9(b) did apply, the State's detailed allegations of how Defendants failed to maintain effective controls against diversion of the opioids they distributed and dispensed provide more than sufficient detail of the circumstances of the alleged unlawful conduct to give Defendants notice of the claims against them. *See, e.g.*, CVS FAC, ¶¶ 44-154 (systematic failures to maintain effective controls against diversion in distribution and dispensing of prescription opioids), ¶¶ 167-72 (failures in West Virginia). These allegations would readily satisfy Rule 9(b) if it did apply, which it does not.

61. The Panel thus holds that the State pleads viable WVCCPA public enforcement claims against the Pharmacy Defendants.

D. The State's Public Nuisance Claims

62. The State alleges that the Pharmacy Defendants contributed to a public nuisance because their failures to maintain effective controls against diversion in their distribution and dispensing of prescription opioid pills helped to trigger and sustain the oversupply and diversion of these highly addictive drugs that have fueled the public health and safety harms of the opioid epidemic in West Virginia. *See, e.g.*, CVS FAC, ¶¶ 187-199.

63. West Virginia defines public nuisance as "'an act or condition that unlawfully operates to hurt or inconvenience an indefinite number of persons.'" *Duff, supra*, 187 W. Va. at 716, 421 S.E.2d at 257 (quoting *Hark v. Mountain Fork Lumber Co.*, 127 W. Va. 586, 595-96, 34 S.E.2d 348, 354 (1945)). The Supreme Court of Appeals has found that "this definition is

consistent with the *Restatement (Second) of Torts* § 821B(1) (1979), which defines a public nuisance as 'an unreasonable interference with a right common to the general public.'" *Duff*, 187 W. Va. at 716 n.6, 421 S.E.2d at 257 n.6. Under the *Restatement (Second)*:

> Circumstances that may sustain a holding that an interference with a public right is unreasonable include the following:
>
> (a) Whether the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, or
>
> (b) whether the conduct is proscribed by a statute, ordinance or administrative regulation, or
>
> (c) whether the conduct is of a continuing nature or has produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect upon the public right.

Restatement (Second) of Torts § 821B(2). Although unlawful conduct is not *required* to establish public nuisance, *see Duff*, 187 W. Va. at 716, 421 S.E.2d at 257 (a "business lawful in itself [may] constitute[] a public nuisance"), this is one of the permissible ways to prove that an interference is unreasonable in support of public nuisance liability.

64. The Panel has issued orders in this mass litigation denying motions by the Pharmacy, Distributor, and Manufacturer Defendants for dismissal of or summary judgment on the State's or City and County Plaintiffs' public nuisance claims. *See* Pharmacies Order, *supra*, at 3 and Ex. A pp. 11-12; Distributors Order, *supra*, at 3 and Ex. A pp. 13-14; *Order Denying Manufacturer Defendants' Joint Motion to Dismiss Plaintiffs' Complaint* ("Manufacturers Order") (Transaction ID 64374079) at 2-3 and Ex. A p. 12; Teva Order, *supra*, at 2-3; Janssen Order, *supra*, at 1-4; *Amended Order Regarding Rulings Issued During March 25, 2022, Pretrial Conference* ("Manufacturers MSJ Order") (Transaction ID 67650385) at 4 (denying summary judgment for Manufacturer Defendants on State's public nuisance claims).

65. The Panel recently set forth comprehensive findings and legal conclusions concerning the application of public nuisance to governmental opioid claims. *See Findings of Fact and Conclusions of Law and Order Denying Defendants' Motion for Summary Judgment re "Factual Issue #2"* ("Distributors MSJ Order 2") (Transaction ID 67786397) at 1-9 (denying summary judgment for Distributor Defendants on City and County Plaintiffs' public nuisance claims). That decision outlined the historical background of public nuisance claims in West Virginia and in nationwide opioid litigation and explained why contrary decisions are unpersuasive. *Id.* at 1-6. The Panel reaffirms those conclusions and incorporates them here.

66. The Pharmacy Defendants nonetheless raise numerous arguments for dismissal of the State's public nuisance claims. The Panel addresses each of these arguments in turn.

67. First, Defendants seek dismissal on the ground that the State does not allege harm to real property. *See, e.g.*, CVS Distribution MOL at 24-25; CVS Dispensing MOL at 27 ("This public nuisance claim . . . amounts to nothing more than an attempt to stretch the doctrine of public nuisance far beyond its property-based roots to third party abuse or misuse of lawful products."). This argument fails first as a factual matter because the State *does* allege damage to public property and resources caused by Defendants' conduct. *See, e.g.*, CVS FAC, ¶ 176 (harms suffered by State include "children placed in foster care, babies born addicted to opioids, criminal behavior, poverty, [and] property damage"), ¶ 192 ("The greater demand for emergency services, law enforcement, addiction treatment, and other social services places an unreasonable burden on governmental resources."). These allegations show that the State may be able to demonstrate that an oversupply and the diversion of prescription opioids and an epidemic of opioid misuse and addiction have contributed to public harms that include loss of the use of public space, property, and resources due to drug abuse and related criminal behavior. *Cf. In re*

Opioid Litigation: Manufacturer Cases, No. 21-C-9000-MFR (April 5, 2022 Transcript of Proceedings) at 447 17-21 ("We also had people that were deliberately injecting themselves in shopping mall bathrooms, gas stations, other places . . . ."), at 489:8-12 ("As part of the Department of Health and Human Resources, we are also responsible for foster care, and we found that a substantial portion of foster care was – was being driven – increases being driven by [the] substance use crisis . . . .") (testimony Rahul Gupta, M.D.). Based on the foregoing, the Panel finds that the State alleges harm to public property and resources. These allegations must be evaluated on a fuller factual record.

68. Moreover, even if the State had not alleged property damage as one of its harms, it need not do so to state a claim for public nuisance. The Panel has repeatedly so held. *See* Pharmacies Order at Ex. A p.11 ("The Court finds and concludes that public nuisance is not limited to property disputes and that West Virginia courts have applied the public nuisance doctrine in numerous contexts, including in opioids cases like this."); Distributors Order at Ex. A p. 13 (same); Manufacturers MSJ Order at 4 ("The Court further notes that at least 22 states have found public nuisance claims based on the marketing of prescription opioids to be viable."); Distributors MSJ Order 2 at 1-6 (rejecting argument that "governmental public nuisance claims are limited to claims arising out of the use of property"). So, too, have other courts. *See Lemongello v. Will Co., Inc.*, No. 02-cv-2952, 2003 WL 21488208, at *2 (W. Va. Cir. Ct. June 19, 2003) ("This Court finds that West Virginia law does not necessarily involve interference with use and enjoyment of land."); *State v. AmerisourceBergen*, 2014 WL 12814021, at *9 (denying dismissal of State's public nuisance claim based on same public health and safety harms as State alleges herein); *see also Restatement (Second) of Torts* § 821B cmt. h ("Unlike a private nuisance, a public nuisance does not necessarily involve interference with use and

enjoyment of land."). These rulings and authority are consistent with the Supreme Court of Appeals' recognition that "nuisance is a flexible area of the law that is adaptable to a wide variety of factual situations." *Sharon Steel Corp. v. City of Fairmont*, 175 W. Va. 479, 483, 334 S.E.2d 616, 621 (1985).

69. The decision in *City of Huntington, supra*, does not warrant reconsideration of the Panel's rulings that public nuisance does not require harm to real property or of the authority on which they are based. In *City of Huntington,* the court found that "the West Virginia Supreme Court has only applied public nuisance law in the context of conduct that interferes with public property or resources" and the "extension of the law of nuisance to cover the marketing and sale of opioids is inconsistent with the history and traditional notions of nuisance." 2022 WL 2399876 at *57. The Panel is not persuaded by this finding.

70. The *City of Huntington's* placement of an artificial external constraint on the common law cause of action for public nuisance is inconsistent with the Supreme Court of Appeals' longstanding recognition that a public nuisance is *any* act or condition that "'operates to hurt or inconvenience an indefinite number of persons[,]'" *Duff*, 18 W. Va. at 716, 421 S.E.2d at 257 (quoting *Hark*, 127 W. Va. at 595-96, 34 S.E.2d at 354), and that "nuisance is a flexible area of the law that is adaptable to a wide variety of factual situations." *Sharon Steel*, 175 W. Va. at 483, 334 S.E.2d at 621.

71. In any event, even under the *City of Huntington* court's reformulation of public nuisance to require "conduct that interferes with public property or resources," the State sufficiently alleges interference with public property or resources. *See, e.g.*, CVS FAC, ¶¶ 12-15, 173-77, 192. Thus, the decision does not support dismissal of the State's public nuisance claims even on its own terms.

72. Second, Defendants also seek dismissal on the ground that the State does not identify a public right recognized by West Virginia law with which they interfered. *See, e.g.*, CVS Distribution MOL at 25; CVS Dispensing MOL at 33 n.15. The Panel repeatedly has rejected this argument in this mass litigation, as have other courts addressing the same type of claim. *See* Distributors MSJ Order 2 at 7; Pharmacies Order at Ex. A p. 11 ("The Court further finds and concludes that Plaintiffs have adequately alleged that Defendants interfered with a public right."); Distributors Order at Ex. A p. 13(same); *State v. AmerisourceBergen*, 2014 WL 12814021, at *9 (allegations that failure to maintain effective controls against diversion of opioids "injuriously affects the safety, health, or morals of the public, or works some substantial annoyance, inconvenience, or injury to the public" are held to "fit squarely within the definition of a public nuisance under West Virginia law").

73. These rulings align with the Supreme Court of Appeals' recognition that a public nuisance is an act or condition that "'operates to hurt or inconvenience an indefinite number of persons[,]'" *Duff*, 18 W. Va. at 716, 421 S.E.2d at 257 (quoting *Hark*, 127 W. Va. at 595-96, 34 S.E.2d at 354), and that "[a] public nuisance action usually seeks to have some harm which affects the public health and safety abated." *Kermit Lumber, supra*, 200 W. Va. at 245, 488 S.E.2d at 925.

74. The Panel thus holds that the State pleads viable public nuisance claims based on unreasonable interference with public health, safety, peace, comfort, and/or convenience, and that the State's separate allegations of harm to public property and resources are sufficient though not necessary to support these claims.

75. Third, Defendants also seek dismissal because they contend that the State does not sufficiently allege proximate causation of the public nuisance. *See, e.g.*, CVS Distribution

MOL at 21-24; CVS Dispensing MOL at 30-33. This argument fails as grounds for dismissal on the pleadings. "The question of proximate causation is ordinarily a factual one" that is "within the province of the jury." *Anderson v. Moulder*, 183 W. Va. 77, 89-90, 394 S.E.2d 61, 73-74 (1990) (internal quotation marks and citation omitted).

76. The Panel repeatedly has rejected this argument for dismissal or summary judgment in this mass litigation. *See* Pharmacies Order at Ex. A pp. 4-6; Distributors Order at Ex. A pp. 11-13; Manufacturers Order at Ex. A pp. 6-7; *see also* Findings of Fact and Conclusions of Law and Order Denying Distributor Defendants' Motion for Summary Judgement re "Factual Issue #1" (Distributors MSJ Order 1) (Transaction ID 67786183) at 11-13 ("An allegedly 'intervening act,' even an illegal act, does not sever causation if it is foreseeable.").

77. These rulings also are consistent with the Supreme Court of Appeals' recognition that "not every intervening event wipes out another's preceding negligence. In fact, 'a tortfeasor whose negligence is a substantial factor in bringing about injuries is not relieved from liability by the intervening acts of third persons if those acts were reasonably foreseeable by the original tortfeasor at the time of his negligent conduct.'" *Wal-Mart Stores East, L.P. v. Ankrom*, 244 W. Va. 437, 450,854 S.E.2d 257, 270 (2020) (quoting Syl. Pt. 13, *Anderson v. Moulder, supra*).

78. The State's pleading of proximate causation satisfies the West Virginia standard. *See, e.g.,* CVS FAC, ¶ 74 ("CVS's failure to exercise appropriate controls foreseeably harms the public health and welfare."); ¶ 196 ("[A] reasonable person in CVS's position would foresee the widespread problems of opioid addiction and abuse that resulted from the drastic oversupply of opioids in this state."). The Panel finds persuasive in this setting the court's recognition in *City and County of San Francisco*, *supra*, that the "very existence of the duties to maintain effective

controls supports the notion that opioid misuse is foreseeable. 'A lack of reasonable care in the handling, distribution, and administration of controlled substances can foreseeably harm the individuals who take them. That's why they're 'controlled' in the first place—overuse or misuse can lead to addictions and long-term health problems.'" 491 F. Supp. 3d at 680 (quoting *Dent v. NFL*, 902 F.3d 1109, 1119 (9th Cir. 2018)). Against this backdrop, the State sufficiently pleads public nuisance proximate causation.

79. The Pharmacy Defendants nonetheless challenge the State's pleading of proximate causation, arguing that the State fails to allege how their "purportedly insufficient suspicious order monitoring system and anti-diversion efforts caused the nuisance when the Board of Pharmacy independently receives extensive information about controlled-substance prescriptions and thereby knows about each opioid prescription." CVS Dispensing MOL at 31. This fact-based argument is not grounds for Rule 12(b)(6) dismissal. Moreover, any act or omission of the Board of Pharmacy does not relieve Defendants of their own duties to maintain effective controls against diversion, including by operating systems to identify and report suspicious orders and block their shipment pending investigation, and to identify and block medically illegitimate prescriptions. *See* 21 C.F.R. §§ 1301.71(a), 1301.74(b), 1306.04(a); W. Va. C.S.R. §§ 15-2-5.1.1, 15-2-5.3, 15-2-8.4.1; Order Granting City/County Plaintiffs' Motion for Partial Summary Judgment Regarding Duties Arising Out of the Controlled Substances Act (Transaction ID 67706109) at 7-8 (duty to maintain effective controls against diversion includes requirement to "stop shipment of suspicious orders, and hold orders of a similar drug class, pending investigation and due diligence").

80. The decision in *City of Huntington, supra*, does not warrant reconsideration of the Panel's rulings that the Plaintiffs in this litigation have sufficiently pleaded public nuisance

proximate causation. The *Huntington* decision was based on a voluminous factual record from an eight-week bench trial. *See* 2022 WL 2399876, at *1-8 (describing proceedings and listing 70 fact and expert witnesses). Moreover, the court's statement that "oversupply and diversion were made possible, beyond the supply of opioids by [distributor] defendants, by overprescribing by doctors, *dispensing by pharmacists of the excessive prescriptions*, and diversion of the drugs to illegal usage—all effective intervening causes beyond the control of defendants[,]" *id.* at *67 (emphasis added), was made after the court had ruled that the plaintiffs "fail[ed] to prove unreasonable conduct by the defendants. *Id.* at *35.

81. Those statements addressing the role of wholesale distributors in the opioid supply chain also are inapposite to the role of Pharmacy Defendants here. The *City of Huntington* court expressly distinguished and singled out pharmacies as having additional duties:

> Distributors also are not pharmacists with expertise in assessing red flags that may be present in a prescription.
>
> Indeed, the CSA 'imposes duties on [pharmacies] to maintain systems, policies, or procedures to identify prescriptions that bear indicia ("red flags") that the prescription is invalid, or that the prescribed drugs may be diverted for illegitimate use. There is no question that dispensers of controlled substances are obligated to check for and conclusively resolve red flags of possible diversion prior to dispensing those substances.'
>
> Pharmacies are obviously best equipped to decide whether to fill prescriptions.

Id. at *65 (quoting *In re Nat'l Prescription Opiate Litig.*, 477 F. Supp. 3d 613, 629 (N.D. Ohio 2020)). Because of the explicit differentiation between the roles of wholesale distributors and pharmacies, the *City of Huntington* court's discussion of proximate causation does not bear on the State's claims against Pharmacy Defendants here even putting aside the different procedural postures of these cases. The State sufficiently pleads public nuisance proximate causation.

82. In sum, based on the foregoing authority and analysis, the Panel holds that the State pleads viable public nuisance claims against the Pharmacy Defendants.

E. Pleading of Right to Equitable Relief

83. The State pleads that it has a right to "[e]quitable relief, including, but not limited to, restitution and disgorgement[.]" CVS FAC, Prayer for Relief ¶ c. The WVCCPA provides the State with the right to this relief in a public enforcement action.

84. The WVCCPA provides that "[t]he attorney general may bring a civil action to restrain a person from violating this chapter and for other appropriate relief." W. Va. Code § 46A-7-108. The Supreme Court of Appeals has held that the Act's "use of the phrase 'other appropriate relief' indicates that the legislature meant the full array of equitable relief to be available in suits brought by the Attorney General." *Imperial Mktg. II*, 203 W. Va. At 215-16, 506 S.E.2d at 811-12. This includes disgorgement of ill-gotten gains. *See State v. Imperial Mktg.*, 196 W. Va. 346, 352 n.7, 472 S.E.2d 792, 798 n.7 (1996) ("*Imperial Mktg. I*") ("The Attorney General is seeking additional relief beyond preliminarily enjoining SCI from engaging in violations of the Consumer Credit and Protection Act . . . , including . . . a disgorgement of funds illegally obtained . . . ").

85. Defendants seek to dismiss the State's WVCCPA claims for disgorgement and other equitable relief, arguing that this is barred by laches. *See* CVS Dispensing MOL at 34; Walgreens Dispensing MOL at 24-25 (applying argument to claim for disgorgement and attorneys' fees and costs); Walmart MOL at 36-37. This argument does not have merit for at least three independent reasons.

86. First, laches does not apply where the State is acting within its police powers, as it is here in bringing this WVCCPA enforcement action. *See* Syl. P.t 7, *State v. Sponaugle*, 45 W.

Va. 415, 32 S.E. 283 (1898) ("Laches is not imputable to the state."). Even in cases where laches has been invoked against state-*sponsored* entities (as opposed to the State itself), it is applied narrowly and conservatively so that the interests of the State and the public may be given substantial consideration. *State ex rel Webb v. W. Va. Bd. Of Medicine*, 203 W. Va. 234, 237-38, 506 S.E.2d 830, 833-34 (1998). These principles are consistent with the Supreme Court of Appeals' holding that actions seeking equitable relief are not subject to statutes of limitation. *See* Syl. P.t 2, *Dunn v. Rockwell*, 225 W. Va. 43, 689 S.E.2d 255 (2009).

87. Second, Defendants do not demonstrate prejudice, as required for laches to apply, Syl. Pt. 3, *Kinsinger v. Pethel*, 234 W. Va. 463, 766 S.E.2d 410 (2014), given the recent nature of their conduct, their denial of liability, and the fact that their conduct is alleged to have created harms that are as-of-yet unabated. *See* Syl. Pt. 2, *Mundy v. Arcuri*, 165 W. Va. 128, 267 S.E.2d 454 (1980) ("Where a party knows his rights or is cognizant of his interest in a particular subject-matter, but takes no steps to enforce the same until the condition of the other party has, in good faith, become so changed, that he cannot be restored to his former state if the right be then enforced, delay becomes inequitable, and operates as an estoppel against the assertion of the right.").

88. Third, Defendants' arguments also fail because their own actions helped shield their misconduct. By continuing to distribute and dispense opioids in West Virginia while operating systematically deficient suspicious order monitoring systems and having duties to stop unresolved suspicious orders and flagged prescriptions, Defendants created an inaccurate appearance that they were filling legitimate orders and prescriptions. *See, e.g.*, CVS FAC, ¶ 139 ("Before 2009, CVS lacked any meaningful suspicious order monitoring ('SOM'). Instead, CVS relied on gut instincts of 'Pickers and Packers' of the drugs in the distribution center to identify

'really big' orders that they believed were simply too large. This was not an effective or legally compliant SOM system – or a system at all.") (citing deposition testimony); ¶ 141 ("CVS did not even begin to design a rudimentary SOM program until 2007."); *see generally W. Va. Bd. of Med.*, 203 W. Va. at 240 n.2506 S.E.2d at 836 n.2 (Workman, J. concurring in part and dissenting in part) ("An element of the equitable defense of laches dictates that the defendant may not obtain the benefit of the defense where his own actions have created the inequity. Thus, where an individual asserting the doctrine of laches has caused or contributed to the delay, laches is inapplicable.").

89. For each of these reasons, the Panel holds that the doctrine of laches does not apply to support dismissal on the pleadings of the State's WVCCPA claims for equitable relief.

90. Defendants also seek dismissal of the State's request for equitable relief on the ground that the State does not allege that it paid money to Defendants. *See, e.g.*, CVS Dispensing MOL at 34 n.16. This argument also does not have merit. The WVCCPA does not require the State to prove its own payment of money in a public enforcement action seeking equitable relief. *See State v. CVS*, 646 F.3d at 173 ("As authorized by these Acts, the West Virginia Attorney General is, in this action, seeking . . . equitable relief, including but not limited to restitution and disgorgement of moneys obtained as a result of the overcharges . . . ."). To the extent Defendants obtained monies as a result of their wrongful distribution and dispensing practices, *see, e.g.*, CVS FAC, ¶¶ 160-72 (from 2006 to 2014, CVS dispensed over 2.4 billion morphine milligram equivalents of opioids in West Virginia), they may be ordered to disgorge these monies.

91. The Panel holds that the State pleads viable claims for equitable disgorgement and other appropriate equitable relief under the WVCCPA.

F. Timely Service of Complaints

92. Rite Aid and CVS also sought dismissal without prejudice of the State's Complaints on the grounds of allegedly untimely service pursuant to W. Va. R. Civ. P. 12(b)(4). *See* Rite Aid of Maryland Distribution MOL at 29-30; Rite Aid of West Virginia Distribution MOL at 29-30; CVS Distribution MOL at 29 n.9. These arguments, too, do not have merit.

93. The State provided service on Rite Aid to the Secretary of State's Office on September 30, 2020, which is within 120 days of the Rite Aid Complaint's filing on June 3, 2020. The State thus has complied with W. Va. R. Civ. P. 4(k). Under West Virginia's "long arm" statute, the State completed service by "leaving the original and two copies of both the summons and the Complaint, and the fee required by § 59-1-2 of this code with the Secretary of State, or in his or her office . . . ." W. Va. Code § 56-3-33(c). The State provided the required copies of the Complaint and summons in person to the Secretary of State's Office on September 30, 2020, which was within 120 days of the Complaint's June 3, 2020 filing date, thus satisfying the State's obligation under Rule 4(k) and under the "long arm" statute. The State's service of the Complaint and summons on Rite Aid was timely.

94. The State provided service on CVS to the Secretary of State's Office on December 15, 2020, which is within 120 days of the CVS Complaint's filing on August 18, 2020. The State thus has complied with W. Va. R. Civ. P. 4(k). Under West Virginia's "long arm" statute, the State completed service by "leaving the original and two copies of both the summons and the Complaint, and the fee required by § 59-1-2 of this code with the Secretary of State, or in his or her office . . . ." W. Va. Code § 56-3-33(c). The State provided the required copies of the Complaint and summons in person to the Secretary of State's Office on December 15, 2020, which was within 120 days of the Complaint's August 18, 2020, filing date, thus

satisfying the State's obligation under Rule 4(k) and under the "long arm" statute. The State's service of the Complaint and summons on CVS was timely.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, the Motions to Dismiss Complaints and Amended Complaints filed by Pharmacy Defendants CVS, Walgreens, and Walmart (Transaction IDs 66812516, 67074618, 66816944, 67074136, and 66979844) are **DENIED.** These proceedings are stayed as to Pharmacy Defendant Rite Aid to permit the parties to finalize settlement. *See* Footnote 4 *Supra*.

The Pharmacy Defendants' objections are noted for the record.

A copy of this Order has this day been electronically served on al counsel of record via File & Serve*Xpress*.

It is so **ORDERED.**

ENTERED: August 3, 2022.

/s/ Alan D. Moats
Lead Presiding Judge
Opioid Litigation

/s/ Derek C. Swope
Presiding Judge
Opioid Litigation

STATE OF WEST VIRGINIA

At a Regular Term of the Supreme Court of Appeals, continued and held at Charleston, Kanawha County, on September 8, 2022, the following order was made and entered:

SCA EFiled: Sep 08 2022
03:58PM EDT
Transaction ID 68065888

State of West Virginia ex rel.
CVS Pharmacy, Inc.,
CVS Indiana, LLC,
CVS Rx Services, Inc.,
CVS TN Distribution, LLC,
West Virginia CVS Pharmacy, LLC,
Walmart, Inc.,
Walgreens Boots Alliance, Inc.,
Walgreen Co., and
Walgreen Eastern Co., Inc.,
Petitioners

vs) No. 22-635

Honorable Alan D. Moats, Lead Presiding Judge,
Opioid Litigation, Mass Litigation Panel,
Honorable Derek C. Swope, Presiding Judge,
Opioid Litigation, Mass Litigation Panel, and
Patrick Morrisey, Attorney General of West Virginia,
Respondents

ORDER

On August 12, 2022, the petitioners, CVS Pharmacy, et al., by counsel Carte P. Goodwin, Mary Claire Davis, and Alex J. Zurbuch, Frost Brown Todd, LLC; Alexander Macia and Tia Shadrick Kluemper, Spilman Thomas & Battle, PLLC; and Bryant J. Spann and Robert H. Akers, Thomas Combs & Spann, PLLC, filed a petition praying for a writ of prohibition against the respondents, along with a motion for expedited relief.

On August 15, 2022, the respondent, Patrick Morrisey, Attorney General, by Ann L. Haight, Deputy Attorney General; Vaughn T. Sizemore, Deputy Attorney General; and Abby G. Cunningham, Assistant Attorney General, filed a response to the motion for expedited relief. The respondent, by counsel, filed a response to the petition for writ of prohibition on September 2, 2022.

Upon consideration and review, the Court is of the opinion that a rule should not be awarded, and the writ prayed for by the petitioners is refused. Justice Armstead would issue a rule to show cause. The motion for expedited relief is refused as moot.

A True Copy

Attest: /s/Edythe Nash Gaiser
Clerk of Court

EFiled: Oct 18 2022 11:19AM
EDT Transaction ID 68267633

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

IN RE: OPIOID LITIGATION **CIVIL ACTION NO. 19-C-9000**

THIS DOCUMENT APPLIES TO:

THE CITY OF BECKLEY, WEST VIRGINIA,

Plaintiff,

v. **Civil Action No. 20-C-34 MSH**

ALLERGAN PLC F/K/A ACTAVIS PLC F/K/A ALLERGAN INC., et al.,

Defendants.

FINDINGS OF FACT AND CONCLUSIONS OF LAW ON ORDER DENYING DEFENDANTS BYPASS PHARMACY, INC.'S AND RHONDA'S PHARMACY, L.L.C.'S MOTIONS TO DISMISS

The Mass Litigation Panel ("Panel") previously entered an Order (Transaction ID 68171315) which denied Defendants Bypass Pharmacy, Inc.'s and Rhonda's Pharmacy, L.L.C.'S motions to dismiss (Transaction IDs 66005900 and) and directed the City of Beckley to file and serve a detailed proposed Order with findings of fact and conclusions of law, consistent with the Panel's August 3, 2022, *Findings of Fact and Conclusions of Law on Order Denying Pharmacy Defendants' Motions to Dismiss Complaints and Amended Complaints* (Transaction ID 67895252). Having reviewed the submission and objections thereto, the Panel hereby makes the following findings of fact and conclusions of law:

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. The City of Beckley is one of several West Virginia political subdivisions which have brought public nuisance actions against the manufacturers, distributors and dispensers of prescription opioids now pending before the Panel. Plaintiff alleges that Bypass Pharmacy and Rhonda's Pharmacy engaged in unlawful and/or unreasonable conduct which contributed to the opioid epidemic within the City of Beckley.

2. The Panel notes at the outset that the City of Beckley has dismissed all claims for relief with the express exception of its equitable claims for public nuisance. *Order Granting Plaintiffs' Rule 41(a)(2) Motion to Dismiss Certain Claims* (Transaction ID 66942534).

3. Defendants move to dismiss pursuant to Rules 12(b)(l) and 12(b)(6) of the West Virginia Rules of Civil Procedure. Defendants argue the Panel lacks subject matter jurisdiction over the City of Beckley's claims based on opioid dispensing because the claims are governed by the Medical Professional Liability Act ("MPLA"), W. Va. Code §§ 55-7B-1 et seq., and the City of Beckley has not complied with the MPLA's pre-suit notification requirement. Further, Defendants argue that Plaintiff's public nuisance claims fail as a matter of law and are barred by the Pharmacy Immunity Statute. As set forth below, the Panel concludes that the MPLA does not apply to the City of Beckley's claims of public nuisance, the complaint states a claim for relief under West Virginia public nuisance law, and the Defendants are not immune from liability.

The Legal Standard

4. As explained by the Court in *John W. Lodge Distributing Co., Inc. v. Texaco, Inc.*, 161 W. Va. 603, 604-606, 245 S.E.2d 157, 158-159 (1978):

> The purpose of a motion under Rule l 2(b)(6) of the West Virginia Rules of Civil Procedure is to test the formal sufficiency of the complaint. For purposes of the motion to dismiss, the complaint is construed in the light most favorable to plaintiff, and its allegations are to be taken as true. Since common law demurrers have been abolished, pleadings are now liberally construed so as to do substantial justice. W.Va. R.C.P. 8(f). The policy of the rule is thus to decide cases upon their merits, and if the complaint states a claim upon which relief can be granted under any legal theory, a motion under Rule 12(b)(6) must be denied.
>
> ***
>
> In view of the liberal policy of the rules of pleading with regard to the construction of plaintiff's complaint, and in view of the policy of the rules favoring the determination of actions on the merits, the motion to dismiss for failure to state a claim should be viewed

> with disfavor and rarely granted. The standard which plaintiff must meet to overcome a Rule 12(b)(6) motion is a liberal standard, and few complaints fail to meet it. The plaintiff's burden in resisting a motion to dismiss is a relatively light one. *Williams v. Wheeling Steel Corp.*, 266 F.Supp. 651 (N.D.W.Va.1967).

5. A trial court considering a motion to dismiss under Rule 12(b)(6) must "liberally construe the complaint so as to do substantial justice." *Cantley v. Lincoln Co. Comm 'n.*, 221 W. Va. 468, 470, 655 S.E.2d 490, 492 (2007) and West Virginia Rule of Civil Procedure, Rule 8(f), "The trial court, in appraising the sufficiency of a complaint on a Rule 12(b)(6) motion, should not dismiss the complaint unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Id.* at Syl. pt. 2, quoting Syl. pt. 3, *Chapman v. Kane Transfer Company*, W.Va., 236 S.E.2d 207 (1977).

Application of Standard

A. Medical Professional Liability Act and Opioid Dispensing-Based Claims

6. The MPLA's prerequisites to suit apply only to a "medical professional liability action." W. Va. Code § 55-7B-6(a). "Medical professional liability" is a defined term:

> "Medical professional liability" means any liability for damages resulting from the death or injury of a person for any tort or breach of contract based on health care services rendered, or which should have been rendered, by a health care provider or health care facility to a patient. It also means other claims that may be contemporaneous to or related to the alleged tort or breach of contract or otherwise provided, all in the context of rendering health care services.

W. Va. Code § 55-7B-2(i).

7. The MPLA defines "Plaintiff" as "a patient or representative of a patient who brings an action for medical professional liability under this article," W. Va. Code § 55-7B-2(n), and "Patient" as "a natural person who receives or should have received health care from a licensed health care provider under a contract, express or implied." W. Va. Code § 55-7B-2(m).

8. The MPLA also defines "health care" services to include, in relevant part, "[a]ny

act, service or treatment provided under, pursuant to or in the furtherance of a physician's care, a health care facility's plan of care, medical diagnosis or treatment[.]" W. Va. Code § 55-7B-2(e)(1).

9. Thus, for the MPLA to apply, the plaintiff must be a "patient or representative of a patient" who is or was a "natural person" who suffered "death or injury" from the provision of or failure to provide "health care services" that are in furtherance of medical treatment, for which the plaintiff seeks tort or breach of contract damages and related relief. The City of Beckley is not such a plaintiff covered by the MPLA for at least three independent reasons.

10. First, the City of Beckley is not a patient, or a representative of a patient as required by the MPLA for its provisions to apply. W.Va. Code§ 55-7B-2(n). Rather, the City of Beckley is a political subdivision and filed this lawsuit as proper public officials to vindicate the rights of the public and to provide for the elimination of hazards to public health and safety and to abate or cause to be abated a public nuisance. W.Va. Code § 8-12-5(13), (23) and (44). Since the City of Beckley brings its public nuisance claim as a political subdivision vindicating the interests of the public, not as an injured patient or representative of an injured patient, the MPLA does not apply to this claim.

11. Second, the City of Beckley does not seek damages as required under the MPLA. W.Va. Code § 55-7B-2(i). The City of Beckley has dismissed all claims for relief with the express exception of its equitable claims for abatement of a public nuisance. *Order Granting Plaintiffs' Rule 41(a)(2) Motion to Dismiss Certain Claims* (Transaction ID 66942534). This Panel has consistently held that the public nuisance remedy of prospective, equitable abatement is not damages. *Order Granting Plaintiffs' Motion to Strike Defendants' Notices of Non-Party Fault* ("Cities-Counties NNPF Order") (Transaction ID 65807300) at 4-5 ("[T]he 'distinction

between abatement of nuisances and recovery of damages for injuries occasioned by wrongful acts constituting nuisances' is both 'apparent' and 'vast.'") (quoting *McMechen v. Hitchman-Glendale Consol Coal Co.*, 88 W. Va. 633, 107 S.E. 480, 482 (1921)).

12. The Panel finds the discussions by the court in the federal multidistrict litigation (MDL) and in the Restatement (Second) of Torts' regarding the nature and scope of public nuisance abatement persuasive and applicable to this case. See *In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804, 2019 WL 4043938, at *2 (N.D. Ohio Aug. 26, 2019) ("Thus, the Court, exercising its equitable powers, has the discretion to craft a remedy that will require Defendants, if they are found liable, to pay the prospective costs that will allow Plaintiffs to abate the opioid crisis."); *id.*, ___ F. Supp. 3d ___, 2022 WL 671219, at *27 (N.D. Ohio March 7, 2022) ("Even if as Defendants assert, they discontinued the conduct that led to the existence of the nuisance, they are still subject to liability for abatement of any ongoing consequential effects of the nuisance."); RESTATEMENT (SECOND) OF TORTS (1979), § 834 cmt. e ("[I]f the activity has resulted in the creation of a physical condition that is of itself harmful after the activity that created it has ceased, a person who carried on the activity that created the condition or who participated to a substantial extent in the activity is subject to the liability for a nuisance, for the continuing harm."). The remedy the City of Beckley seeks here is not damages, but equitable abatement to which the MPLA does not apply. The recent decision, holding to the contrary, in *City of Huntington v. AmerisourceBergen Drug. Corp.*, No. 3:17-01362, ___ F. Supp. 3d ___, 2022 WL 2399876 (S.D. W. Va. July 4, 2022) is neither predictive nor consistent with West Virginia law and, therefore, does not warrant reconsideration of the Panel's prior rulings.

13. Third, the City of Beckley's public nuisance claims are not based on health care services rendered in furtherance of a physician or health care facility's plan of care, medical

diagnosis, or treatment. W.Va. Code§ 55-7B-2(i) and 2(e)(l). The City of Beckley's claims are based on Bypass Pharmacy's and Rhonda's Pharmacy's alleged failure to discharge their duties as DEA registrants under the federal and West Virginia Controlled Substances Acts to maintain "effective controls against diversion of controlled substances into *other than* legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1) (emphasis added); see also W. Va. Code § 60A-3-303(a)(1) (same), 21 C.F.R. § 1301.71(a), W. Va. C.S.R. § 15-2-5.1.1. This includes the requirement that dispensing pharmacies operate systems to detect and block medically *illegitimate* prescribing. *See* 21 C.F.R. § 1306.04(a), W. Va. C.S.R. § 15-2-8.4.1. The City of Beckley alleges that Defendants violated these duties by, *inter alia*, failing to use their own dispensing data to identify doctors with prescribing patterns that present red flags for diversion and *nonmedical* use.

14. The federal and state regulations that the City of Beckley alleges Defendants failed to comply with provide specifically that:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription . . .

21 C.F.R. § 1306.04(a); *see also* W. Va. C.S.R. § 15-2-8.4.1 (same). The alleged failure of Defendants to prevent diversion by failing to investigate red flags of diversion and illegitimate prescribing does not fall under the MPLA's protections. *Cf. East Main St. Pharmacy; Affirmance of Suspension Order*, 75 FR 66149-01, 66157, 2010 WL 4218766 (D.E.A. Oct. 27, 2010) ("'[A] pharmacist can know that prescriptions are issued for no legitimate medical purpose without his needing to know anything about medical science.'") (quoting *U.S. v. Hayes*, 595 F.2d 258, 261

n.6 (5th Cir. 1979)). Since the duties underpinning the City of Beckley's public nuisance claims are not performed in furtherance of patient treatment, but pursuant to registrants' duties to prevent diversion outside of legitimate patient care, the MPLA does not apply to these claims.

15. Finally, the Panel adopts herein the holdings in its August 3, 2022, *Findings of Fact and Conclusions of Law on Order Denying Pharmacy Defendants' Motions to Dismiss Complaints and Amended Complaints* (Transaction ID 67895252) related to the MPLA and notes the Supreme Court of Appeals of West Virginia refused a petition for writ of prohibition challenging the same. *See State of West Virginia ex rel. CVS Pharmacy, Inc., et al v. Hon. Alan D. Moats, et al,* No. 22-635 (W.Va. Sept. 8, 2022) (Transaction ID 68065888).

16. The Panel holds that the MPLA does not apply to the City of Beckley's public nuisance claims for equitable abatement because these claims are not brought by or on behalf of a patient and do not seek damages for a patient's death or injury in receiving medical services.

B. West Virginia public nuisance law applies to the manufacture, distribution and dispensing of prescription opioids.

17. Defendants argue that "the West Virginia Supreme Court of Appeals has never recognized a public nuisance claim arising out of a defendant's distribution of a lawful product. Public nuisance law was designed to protect the public's rights to use and enjoy public lands. The West Virginia Supreme Court of Appeals has never upheld a common law public nuisance claim that sought to vindicate anything other than an interest in property or the environment." *See* Defendants' Memo. at pp. 13-14. Defendants move this Panel to dismiss the public nuisance claim as a matter of law for failure to state a claim for relief under W.V.R. Civ. Proc. 12(b)(6).

18. The Panel has consistently issued orders in this mass litigation denying motions by the Pharmacy, Distributor, and Manufacturer Defendants for dismissal of or

summary judgment on the State's or City and County Plaintiffs' public nuisance claims. *See* October 31, 2019, *Order Denying Pharmacy Defendants' Motion to Dismiss Plaintiffs' Complaint,* Civil Action Nos. 18-C-222 MSH and 18-C-233 through 18-C-236 MSH ("Pharmacies Order") (Transaction ID 64374772), at 3 and Ex. A pp. 11-12; October 31, 2019, *Order Denying the Distributor Defendants' Motion to Dismiss Plaintiffs Complaint,* Civil Action Nos. 18-C-222 MSH and 18-C-233 MSH through 18-C-236 MSH ("Distributors Order") (Transaction ID 64374611) at 3 and Ex. A pp. 13-14, *writ refused, State ex. rel. AmerisourceBergen Drug Corp. v. Hon. Alan D. Moats*, No. 19-1051 (W. Va. Jan. 30, 2020); October 31, 2019, *Order Denying Manufacturer Defendants' Joint Motion to Dismiss Plaintiffs' Complaint* ("Manufacturers Order") (Transaction ID 64374079) at 2-3 and Ex. A p. 12; August 31, 2020, *Order Denying Allergan and Teva Defendants' Motions to Dismiss State's First Amended Complaint* ("Teva Order") (Transaction ID 65887418) at 2-3; September 2, 2020, *Order Denying Janssen Defendants' Motion to Dismiss State's Complaint* ("Janssen Order")(Transaction ID 65899715) at 1-4; and May 23, 2022, *Amended Order Regarding Rulings Issued During March 25, 2022, Pretrial Conference* ("Manufacturers MSJ Order") (Transaction ID 67650385) at 4 (denying summary judgment for Manufacturer Defendants on State's public nuisance claims).

19. The Panel recently set forth comprehensive findings and legal conclusions concerning the application of public nuisance to governmental opioid claims. *See Findings of Fact and Conclusions of Law and Order Denying Defendants' Motion for Summary Judgment re "Factual Issue #2"* ("Distributors MSJ Order 2") (Transaction ID 67786397) at 1-9 (denying summary judgment for Distributor Defendants on City and County Plaintiffs' public nuisance claims). That decision outlined the historical background of

public nuisance claims in West Virginia and in nationwide opioid litigation and explained why contrary decisions are unpersuasive. *Id.* at 1-6. The Panel reaffirmed those conclusions in its August 3, 2022, *Findings of Fact and Conclusions of Law on Order Denying Pharmacy Defendants' Motions to Dismiss Complaints and Amended Complaints* (Transaction ID 67895252) *writ refused, State of West Virginia ex rel. CVS Pharmacy, Inc., et al v. Hon. Alan D. Moats, et al,* No. 22-635 (W.Va. Sept. 8, 2022) (Transaction ID 68065888), and does so again here.

20. The decision in *City of Huntington*, *supra*, does not warrant reconsideration of the Panel's rulings that public nuisance does not require harm to real property or of the authority on which they are based. In *City of Huntington*, the court found that "the West Virginia Supreme Court has only applied public nuisance law in the context of conduct that interferes with public property or resources" and the "extension of the law of nuisance to cover the marketing and sale of opioids is inconsistent with the history and traditional notions of nuisance." 2022 WL 2399876 at *57. The Panel is not persuaded by this finding.

21. The *City of Huntington*'s placement of an artificial external constraint on the common law cause of action for public nuisance is inconsistent with the Supreme Court of Appeals' longstanding recognition that a public nuisance is any act or condition that "'operates to hurt or inconvenience an indefinite number of persons[,]'" *Duff*, 18 W. Va. at 716, 421 S.E.2d at 257 (quoting *Hark*, 127 W. Va. at 595-96, 34 S.E.2d at 354), and that "nuisance is a flexible area of the law that is adaptable to a wide variety of factual situations." *Sharon Steel*, 175 W. Va. at 483, 334 S.E.2d at 621. The holding in *City of Huntington* is neither predictive nor consistent with West Virginia law on public nuisance and, therefore, does not warrant reconsideration of the Panel's prior rulings.

C. Plaintiff's claims are not barred by the Pharmacy Immunity Statute.

22. Defendants argue they are immune from liability under W. Va. Code § 30-5-2l(a) ("All persons, whether licensed pharmacists or not, shall be responsible for the quality of all drugs, chemicals and medicines they may sell or dispense, with the exception of those sold in or dispensed unchanged from the original retail package of the manufacturer, in which event the manufacturer shall be responsible.").

23. This Panel has rejected the argument that the Pharmacy Act bars common law claims addressing prescription opioid distribution, holding that the Act's provision addressing responsibility for dispensed drugs focuses on the quality of drugs, but says nothing about duties to prevent their diversion. *See* "Distributors Order", *supra*, at 3 and Ex. A at 11 (adopting and incorporating as law of the case *Brooke County Commission et al v. Purdue Pharma L.P.*, Civil Action No. 17-C-248, *Order Denying AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation's Motion to Dismiss,* (Marshall Cty. December 28, 2018 – "West Virginia Code §30-5-21(a) does not apply to the instant claims because [the] claims against Defendants arise out of their duties to prevent diversion as distributors of controlled substances rather than the 'quality' of the drugs sold at retail."). The same analysis applies here. Beckley bases its claims on the pharmacies' duty to prevent diversion, not the quality of the drugs they dispensed. The Pharmacy Act thus does not preclude these claims.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, and in accordance with this Panel's previously entered Order (Transaction ID 68171315), the Motions to Dismiss

filed by Defendants Bypass Pharmacy, Inc.'s And Rhonda's Pharmacy, L.L.C.'S motions to dismiss (Transaction IDs 66005900 and 67235324) are **DENIED**.

The objections of Defendants Bypass Pharmacy, Inc. and Rhonda's Pharmacy, L.L.C. are noted for the record.

A copy of this Order has this day been electronically served on all counsel of record via File & Serve*Xpress*.

It is so **ORDERED.**

ENTERED: October 18, 2022.

/s/ Alan D. Moats
Lead Presiding Judge
Opioid Litigation

/s/ Derek C. Swope
Presiding Judge
Opioid Litigation

3768, which enacted sections 801a, 830, and 852 of this title, amended sections 352, 802, 811, 812, 823, 827, 841 to 843, 872, 881, 952, 953, and 965 of this title and section 242a of Title 42, The Public Health and Welfare, repealed section 830 of this title effective Jan. 1, 1981, and enacted provisions set out as notes under sections 801, 801a, 812, and 830 of this title. For complete classification of this Act to the Code, see Short Title of 1978 Amendment note set out under section 801 of this title and Tables.

This subchapter and subchapter II of this chapter, referred to in subsec. (g)(1), was in the original ''titles II and III of the Comprehensive Drug Abuse Prevention and Control Act'', which was translated as meaning titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, 1285, as amended, to reflect the probable intent of Congress. Title II is classified principally to this subchapter and part A of title III comprises subchapter II of this chapter. For complete classification of this Act to the Code, see Short Title notes set out under section 801 of this title and Tables.

AMENDMENTS

2004—Subsec. (g)(1). Pub. L. 108–358, § 2(b)(1), substituted ''drug which contains a controlled substance from the application of this subchapter and subchapter II of this chapter if such drug'' for ''substance from a schedule if such substance''.

Subsec. (g)(3)(C). Pub. L. 108–358, § 2(b)(2), added subpar. (C).

1984—Subsec. (g)(3). Pub. L. 98–473, § 509(a), added par. (3).

Subsec. (h). Pub. L. 98–473, § 508, added subsec. (h).

1978—Subsec. (d). Pub. L. 95–633 designated existing provisions as par. (1) and added pars. (2) to (5).

CHANGE OF NAME

''Secretary of Health and Human Services'' substituted for ''Secretary of Health, Education, and Welfare'' in subsec. (d)(2), (3), (4)(A), (B), (5) pursuant to section 509(b) of Pub. L. 96–88 which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 2004 AMENDMENT

Amendment by Pub. L. 108–358 effective 90 days after Oct. 22, 2004, see section 2(d) of Pub. L. 108–358, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

§ 812. Schedules of controlled substances

(a) Establishment

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) SCHEDULE I.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) SCHEDULE II.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) SCHEDULE III.—

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) SCHEDULE IV.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) SCHEDULE V.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

(c) Initial schedules of controlled substances

Schedules I, II, III, IV, and V shall, unless and until amended[1] pursuant to section 811 of this title, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

SCHEDULE I

(a) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers,

[1] Revised schedules are published in the Code of Federal Regulations, Part 1308 of Title 21, Food and Drugs.

salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol.
(2) Allylprodine.
(3) Alphacetylmathadol.[2]
(4) Alphameprodine.
(5) Alphamethadol.
(6) Benzethidine.
(7) Betacetylmethadol.
(8) Betameprodine.
(9) Betamethadol.
(10) Betaprodine.
(11) Clonitazene.
(12) Dextromoramide.
(13) Dextrorphan.
(14) Diampromide.
(15) Diethylthiambutene.
(16) Dimenoxadol.
(17) Dimepheptanol.
(18) Dimethylthiambutene.
(19) Dioxaphetyl butyrate.
(20) Dipipanone.
(21) Ethylmethylthiambutene.
(22) Etonitazene.
(23) Etoxeridine.
(24) Furethidine.
(25) Hydroxypethidine.
(26) Ketobemidone.
(27) Levomoramide.
(28) Levophenacylmorphan.
(29) Morpheridine.
(30) Noracymethadol.
(31) Norlevorphanol.
(32) Normethadone.
(33) Norpipanone.
(34) Phenadoxone.
(35) Phenampromide.
(36) Phenomorphan.
(37) Phenoperidine.
(38) Piritramide.
(39) Propheptazine.
(40) Properidine.
(41) Racemoramide.
(42) Trimeperidine.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine.
(2) Acetyldihydrocodeine.
(3) Benzylmorphine.
(4) Codeine methylbromide.
(5) Codeine-N-Oxide.
(6) Cyprenorphine.
(7) Desomorphine.
(8) Dihydromorphine.
(9) Etorphine.
(10) Heroin.
(11) Hydromorphinol.
(12) Methyldesorphine.
(13) Methylhydromorphine.
(14) Morphine methylbromide.
(15) Morphine methylsulfonate.
(16) Morphine-N-Oxide.
(17) Myrophine.
(18) Nicocodeine.
(19) Nicomorphine.
(20) Normorphine.
(21) Pholcodine.
(22) Thebacon.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 3,4-methylenedioxy amphetamine.
(2) 5-methoxy-3,4-methylenedioxy amphetamine.
(3) 3,4,5-trimethoxy amphetamine.
(4) Bufotenine.
(5) Diethyltryptamine.
(6) Dimethyltryptamine.
(7) 4-methyl-2,5-diamethoxyamphetamine.
(8) Ibogaine.
(9) Lysergic acid diethylamide.
(10) Marihuana.
(11) Mescaline.
(12) Peyote.
(13) N-ethyl-3-piperidyl benzilate.
(14) N-methyl-3-piperidyl benzilate.
(15) Psilocybin.
(16) Psilocyn.
(17) Tetrahydrocannabinols.

SCHEDULE II

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.
(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium.
(3) Opium poppy and poppy straw.
(4) coca[3] leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed; cocaine, its salts, optical and geometric isomers, and salts of isomers; ecgonine, its derivatives, their salts, isomers, and salts of isomers; or any compound, mixture, or preparation which contains any quantity of any of the substances referred to in this paragraph.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

[2] So in original. Probably should be ''Alphacetylmethadol.''

[3] So in original. Probably should be capitalized.

(1) Alphaprodine.
(2) Anileridine.
(3) Bezitramide.
(4) Dihydrocodeine.
(5) Diphenoxylate.
(6) Fentanyl.
(7) Isomethadone.
(8) Levomethorphan.
(9) Levorphanol.
(10) Metazocine.
(11) Methadone.
(12) Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenyl butane.
(13) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.
(14) Pethidine.
(15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.
(16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.
(17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.
(18) Phenazocine.
(19) Piminodine.
(20) Racemethorphan.
(21) Racemorphan.

(c) Unless specifically excepted or unless listed in another schedule, any injectable liquid which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

SCHEDULE III

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:
(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.
(2) Phenmetrazine and its salts.
(3) Any substance (except an injectable liquid) which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.
(4) Methylphenidate.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:
(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.
(2) Chorhexadol.
(3) Glutethimide.
(4) Lysergic acid.
(5) Lysergic acid amide.
(6) Methyprylon.
(7) Phencyclidine.
(8) Sulfondiethylmethane.
(9) Sulfonethylmethane.
(10) Sulfonmethane.

(c) Nalorphine.
(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:
(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.
(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.
(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(e) Anabolic steroids.

SCHEDULE IV

(1) Barbital.
(2) Chloral betaine.
(3) Chloral hydrate.
(4) Ethchlorvynol.
(5) Ethinamate.
(6) Methohexital.
(7) Meprobamate.
(8) Methylphenobarbital.
(9) Paraldehyde.
(10) Petrichloral.
(11) Phenobarbital.

SCHEDULE V

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:
(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.
(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.
(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.
(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(Pub. L. 91–513, title II, §202, Oct. 27, 1970, 84 Stat. 1247; Pub. L. 95–633, title I, §103, Nov. 10, 1978, 92 Stat. 3772; Pub. L. 98–473, title II, §§507(c), 509(b), Oct. 12, 1984, 98 Stat. 2071, 2072; Pub. L. 99–570, title I, §1867, Oct. 27, 1986, 100 Stat. 3207–55; Pub. L. 99–646, §84, Nov. 10, 1986, 100 Stat. 3619; Pub. L. 101–647, title XIX, §1902(a), Nov. 29, 1990, 104 Stat. 4851.)

AMENDMENTS

1990—Subsec. (c). Pub. L. 101–647 added item (e) at end of schedule III.

1986—Subsec. (c). Pub. L. 99–646 amended schedule II(a)(4) generally. Prior to amendment, schedule II(a)(4) read as follows: ''Coca leaves (except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed); cocaine, its salts, optical and geometric isomers, and salts of isomers; and ecgonine, its derivatives, their salts, isomers, and salts of isomers.''

Pub. L. 99–570 amended schedule II(a)(4) generally. Prior to amendment, schedule II(a)(4) read as follows: ''Coca leaves and any salt, compound, derivative, or preparation of coca leaves (including cocaine and ecgonine and their salts, isomers, derivatives, and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.''

1984—Subsec. (c). Pub. L. 98–473, §507(c), in schedule II(a)(4) added applicability to cocaine and ecgonine and their salts, isomers, etc.

Subsec. (d). Pub. L. 98–473, §509(b), struck out subsec. (d) which related to authority of Attorney General to except stimulants or depressants containing active medicinal ingredients.

1978—Subsec. (d)(3). Pub. L. 95–633 added cl. (3).

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–647 effective 90 days after Nov. 29, 1990, see section 1902(d) of Pub. L. 101–647, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

CONGRESSIONAL FINDING; EMERGENCY SCHEDULING OF GHB IN CONTROLLED SUBSTANCES ACT

Pub. L. 106–172, §§2, 3(a), Feb. 18, 2000, 114 Stat. 7, 8, provided that:

''SEC. 2. FINDINGS.

''Congress finds as follows:

''(1) Gamma hydroxybutyric acid (also called G, Liquid X, Liquid Ecstasy, Grievous Bodily Harm, Georgia Home Boy, Scoop) has become a significant and growing problem in law enforcement. At least 20 States have scheduled such drug in their drug laws and law enforcement officials have been experiencing an increased presence of the drug in driving under the influence, sexual assault, and overdose cases especially at night clubs and parties.

''(2) A behavioral depressant and a hypnotic, gamma hydroxybutyric acid ('GHB') is being used in conjunction with alcohol and other drugs with detrimental effects in an increasing number of cases. It is difficult to isolate the impact of such drug's ingestion since it is so typically taken with an ever-changing array of other drugs and especially alcohol which potentiates its impact.

''(3) GHB takes the same path as alcohol, processes via alcohol dehydrogenase, and its symptoms at high levels of intake and as impact builds are comparable to alcohol ingestion/intoxication. Thus, aggression and violence can be expected in some individuals who use such drug.

''(4) If taken for human consumption, common industrial chemicals such as gamma butyrolactone and 1.4-butanediol are swiftly converted by the body into GHB. Illicit use of these and other GHB analogues and precursor chemicals is a significant and growing law enforcement problem.

''(5) A human pharmaceutical formulation of gamma hydroxybutyric acid is being developed as a treatment for cataplexy, a serious and debilitating disease. Cataplexy, which causes sudden and total loss of muscle control, affects about 65 percent of the estimated 180,000 Americans with narcolepsy, a sleep disorder. People with cataplexy often are unable to work, drive a car, hold their children or live a normal life.

''(6) Abuse of illicit GHB is an imminent hazard to public safety that requires immediate regulatory action under the Controlled Substances Act (21 U.S.C. 801 et seq.).

''SEC. 3. EMERGENCY SCHEDULING OF GAMMA HYDROXYBUTYRIC ACID AND LISTING OF GAMMA BUTYROLACTONE AS LIST I CHEMICAL.

''(a) EMERGENCY SCHEDULING OF GHB.—

''(1) IN GENERAL.—The Congress finds that the abuse of illicit gamma hydroxybutyric acid is an imminent hazard to the public safety. Accordingly, the Attorney General, notwithstanding sections 201(a), 201(b), 201(c), and 202 of the Controlled Substances Act [21 U.S.C. 811(a)–(c), 812], shall issue, not later than 60 days after the date of the enactment of this Act [Feb. 18, 2000], a final order that schedules such drug (together with its salts, isomers, and salts of isomers) in the same schedule under section 202(c) of the Controlled Substances Act as would apply to a scheduling of a substance by the Attorney General under section 201(h)(1) of such Act (relating to imminent hazards to the public safety), except as follows:

''(A) For purposes of any requirements that relate to the physical security of registered manufacturers and registered distributors, the final order shall treat such drug, when the drug is manufactured, distributed, or possessed in accordance with an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(i)] (whether the exemption involved is authorized before, on, or after the date of the enactment of this Act [Feb. 18, 2000]), as being in the same schedule as that recommended by the Secretary of Health and Human Services for the drug when the drug is the subject of an authorized investigational new drug application (relating to such section 505(i)). The recommendation referred to in the preceding sentence is contained in the first paragraph of the letter transmitted on May 19, 1999, by such Secretary (acting through the Assistant Secretary for Health) to the Attorney General (acting through the Deputy Administrator of the Drug Enforcement Administration), which letter was in response to the letter transmitted by the Attorney General (acting through such Deputy Administrator) on September 16, 1997. In publishing the final order in the Federal Register, the Attorney General shall publish a copy of the letter that was transmitted by the Secretary of Health and Human Services.

''(B) In the case of gamma hydroxybutyric acid that is contained in a drug product for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355] (whether the application involved is approved before, on, or after the date of the enactment of this Act [Feb. 18, 2000]), the final order shall schedule such drug in the same schedule as that recommended by the Secretary of Health and Human

Services for authorized formulations of the drug. The recommendation referred to in the preceding sentence is contained in the last sentence of the fourth paragraph of the letter referred to in subparagraph (A) with respect to May 19, 1999.

''(2) FAILURE TO ISSUE ORDER.—If the final order is not issued within the period specified in paragraph (1), gamma hydroxybutyric acid (together with its salts, isomers, and salts of isomers) is deemed to be scheduled under section 202(c) of the Controlled Substances Act [21 U.S.C. 812(c)] in accordance with the policies described in paragraph (1), as if the Attorney General had issued a final order in accordance with such paragraph.''

PLACEMENT OF PIPRADROL AND SPA IN SCHEDULE IV TO CARRY OUT OBLIGATION UNDER CONVENTION ON PSYCHOTROPIC SUBSTANCES

Section 102(c) of Pub. L. 95–633 provided that: ''For the purpose of carrying out the minimum United States obligations under paragraph 7 of article 2 of the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, with respect to pipradrol and SPA (also known as (-)-1-dimethylamino-1,2-diphenylethane), the Attorney General shall by order, made without regard to sections 201 and 202 of the Controlled Substances Act [this section and section 811 of this title], place such drugs in schedule IV of such Act [see subsec. (c) of this section].''

Provision of section 102(c) of Pub. L. 95–633, set out above, effective on the date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

§ 813. Treatment of controlled substance analogues

A controlled substance analogue shall, to the extent intended for human consumption, be treated, for the purposes of any Federal law as a controlled substance in schedule I.

(Pub. L. 91–513, title II, § 203, as added Pub. L. 99–570, title I, § 1202, Oct. 27, 1986, 100 Stat. 3207–13; amended Pub. L. 100–690, title VI, § 6470(c), Nov. 18, 1988, 102 Stat. 4378.)

REFERENCES IN TEXT

Schedule I, referred to in text, is set out in section 812(c) of this title.

AMENDMENTS

1988—Pub. L. 100–690 substituted ''any Federal law'' for ''this subchapter and subchapter II of this chapter''.

§ 814. Removal of exemption of certain drugs

(a) Removal of exemption

The Attorney General shall by regulation remove from exemption under section 802(39)(A)(iv) of this title a drug or group of drugs that the Attorney General finds is being diverted to obtain a listed chemical for use in the illicit production of a controlled substance.

(b) Factors to be considered

In removing a drug or group of drugs from exemption under subsection (a) of this section, the Attorney General shall consider, with respect to a drug or group of drugs that is proposed to be removed from exemption—

(1) the scope, duration, and significance of the diversion;

(2) whether the drug or group of drugs is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and

(3) whether the listed chemical can be readily recovered from the drug or group of drugs.

(c) Specificity of designation

The Attorney General shall limit the designation of a drug or a group of drugs removed from exemption under subsection (a) of this section to the most particularly identifiable type of drug or group of drugs for which evidence of diversion exists unless there is evidence, based on the pattern of diversion and other relevant factors, that the diversion will not be limited to that particular drug or group of drugs.

(d) Reinstatement of exemption with respect to particular drug products

(1) Reinstatement

On application by a manufacturer of a particular drug product that has been removed from exemption under subsection (a) of this section, the Attorney General shall by regulation reinstate the exemption with respect to that particular drug product if the Attorney General determines that the particular drug product is manufactured and distributed in a manner that prevents diversion.

(2) Factors to be considered

In deciding whether to reinstate the exemption with respect to a particular drug product under paragraph (1), the Attorney General shall consider—

(A) the package sizes and manner of packaging of the drug product;

(B) the manner of distribution and advertising of the drug product;

(C) evidence of diversion of the drug product;

(D) any actions taken by the manufacturer to prevent diversion of the drug product; and

(E) such other factors as are relevant to and consistent with the public health and safety, including the factors described in subsection (b) of this section as applied to the drug product.

(3) Status pending application for reinstatement

A transaction involving a particular drug product that is the subject of a bona fide pending application for reinstatement of exemption filed with the Attorney General not later than 60 days after a regulation removing the exemption is issued pursuant to subsection (a) of this section shall not be considered to be a regulated transaction if the transaction occurs during the pendency of the application and, if the Attorney General denies the application, during the period of 60 days following the date on which the Attorney General denies the application, unless—

(A) the Attorney General has evidence that, applying the factors described in subsection (b) of this section to the drug product, the drug product is being diverted; and

(B) the Attorney General so notifies the applicant.

(4) Amendment and modification

A regulation reinstating an exemption under paragraph (1) may be modified or revoked with

''(2) such date as may be prescribed by the Attorney General for registration of manufacturers, distributors, or dispensers, as the case may be,

whichever occurs first.''

§ 822a. Prescription drug take back expansion

(a) Definition of covered entity

In this section, the term ''covered entity'' means—

(1) a State, local, or tribal law enforcement agency;

(2) a manufacturer, distributor, or reverse distributor of prescription medications;

(3) a retail pharmacy;

(4) a registered narcotic treatment program;

(5) a hospital or clinic with an onsite pharmacy;

(6) an eligible long-term care facility; or

(7) any other entity authorized by the Drug Enforcement Administration to dispose of prescription medications.

(b) Program authorized

The Attorney General, in coordination with the Administrator of the Drug Enforcement Administration, the Secretary of Health and Human Services, and the Director of the Office of National Drug Control Policy, shall coordinate with covered entities in expanding or making available disposal sites for unwanted prescription medications.

(Pub. L. 114–198, title II, § 203, July 22, 2016, 130 Stat. 717.)

Editorial Notes

CODIFICATION

Section was enacted as part of the Comprehensive Addiction and Recovery Act of 2016, and not as part of the Controlled Substances Act which comprises this subchapter.

Statutory Notes and Related Subsidiaries

ACCESS TO INCREASED DRUG DISPOSAL

Pub. L. 115–271, title III, subtitle B, ch. 6, Oct. 24, 2018, 132 Stat. 3950, provided that:

''SEC. 3251. SHORT TITLE.

''This chapter may be cited as the 'Access to Increased Drug Disposal Act of 2018'.

''SEC. 3252. DEFINITIONS.

''In this chapter—

''(1) the term 'Attorney General' means the Attorney General, acting through the Assistant Attorney General for the Office of Justice Programs;

''(2) the term 'authorized collector' means a narcotic treatment program, a hospital or clinic with an on-site pharmacy, a retail pharmacy, or a reverse distributor, that is authorized as a collector under section 1317.40 of title 21, Code of Federal Regulations (or any successor regulation);

''(3) the term 'covered grant' means a grant awarded under section 3003 [probably means section 3253; no section 3003 of Pub. L. 115–271 has been enacted]; and

''(4) the term 'eligible collector' means a person who is eligible to be an authorized collector.

''SEC. 3253. AUTHORITY TO MAKE GRANTS.

''The Attorney General shall award grants to States to enable the States to increase the participation of eligible collectors as authorized collectors.

''SEC. 3254. APPLICATION.

''A State desiring a covered grant shall submit to the Attorney General an application that, at a minimum—

''(1) identifies the single State agency that oversees pharmaceutical care and will be responsible for complying with the requirements of the grant;

''(2) details a plan to increase participation rates of eligible collectors as authorized collectors; and

''(3) describes how the State will select eligible collectors to be served under the grant.

''SEC. 3255. USE OF GRANT FUNDS.

''A State that receives a covered grant, and any subrecipient of the grant, may use the grant amounts only for the costs of installation, maintenance, training, purchasing, and disposal of controlled substances associated with the participation of eligible collectors as authorized collectors.

''SEC. 3256. ELIGIBILITY FOR GRANT.

''The Attorney General shall award a covered grant to 5 States, not less than 3 of which shall be States in the lowest quartile of States based on the participation rate of eligible collectors as authorized collectors, as determined by the Attorney General.

''SEC. 3257. DURATION OF GRANTS.

''The Attorney General shall determine the period of years for which a covered grant is made to a State.

''SEC. 3258. ACCOUNTABILITY AND OVERSIGHT.

''A State that receives a covered grant shall submit to the Attorney General a report, at such time and in such manner as the Attorney General may reasonably require, that—

''(1) lists the ultimate recipients of the grant amounts;

''(2) describes the activities undertaken by the State using the grant amounts; and

''(3) contains performance measures relating to the effectiveness of the grant, including changes in the participation rate of eligible collectors as authorized collectors.

''SEC. 3259. DURATION OF PROGRAM.

''The Attorney General may award covered grants for each of the first 5 fiscal years beginning after the date of enactment of this Act [Oct. 24, 2018].

''SEC. 3260. AUTHORIZATION OF APPROPRIATIONS.

''There is authorized to be appropriated to the Attorney General such sums as may be necessary to carry out this chapter.''

§ 823. Registration requirements

(a) Manufacturers of controlled substances in schedule I or II

The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) Distributors of controlled substances in schedule I or II

The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(c) Limits of authorized activities

Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 826 of this title.

(d) Manufacturers of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(e) Distributors of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances

The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration or such modification of registration if the Attorney General determines that the issuance of such registration or modification would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled

substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this subchapter.

(g) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications; waiver

(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)

(A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 827 of this title) on such drugs; and

(C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

(i) The practitioner is a qualifying practitioner (as defined in subparagraph (G)).

(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to provide directly, by referral, or in such other manner as determined by the Secretary—

(I) all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including for maintenance, detoxification, overdose reversal, and relapse prevention; and

(II) appropriate counseling and other appropriate ancillary services.

(iii)(I) The total number of such patients of the practitioner at any one time will not exceed the applicable number. Except as provided in subclause (II), the applicable number is 30.

(II) The applicable number is—

(aa) 100 if, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients;

(bb) 100 if the practitioner holds additional credentialing, as defined in section 8.2 of title 42, Code of Federal Regulations (or successor regulations);

(cc) 100 if the practitioner provides medication-assisted treatment (MAT) using covered medications (as such terms are defined in section 8.2 of title 42, Code of Federal Regulations (or successor regulations)) in a qualified practice setting (as described in section 8.615 of title 42, Code of Federal Regulations (or successor regulations)); or

(dd) 275 if the practitioner meets the requirements specified in sections 8.610 through 8.655 of title 42, Code of Federal Regulations (or successor regulations).

(III) The Secretary may by regulation change such applicable number.

(IV) The Secretary may exclude from the applicable number patients to whom such drugs or combinations of drugs are directly administered by the qualifying practitioner in the office setting.

(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V or combinations of such drugs are as follows:

(i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or section 262 of title 42, been approved for use in maintenance or detoxification treatment.

(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in

the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

(I) The notification under subparagraph (B) is in writing and states the name of the practitioner.

(II) The notification identifies the registration issued for the practitioner pursuant to subsection (f).

(III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (f).

(ii) Upon receiving a determination from the Secretary under clause (iii) finding that a practitioner meets all requirements for a waiver under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the registration issued for the practitioner pursuant to subsection (f). The identification number so assigned shall be appropriate to preserve the confidentiality of patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).

(iii) Not later than 45 days after the date on which the Secretary receives a notification under subparagraph (B), the Secretary shall make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B) and shall forward such determination to the Attorney General. If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the practitioner an identification number described in clause (ii) at the end of such period.

(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 824(a)(4) of this title, consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) to be inconsistent with the public interest.

(ii)(I) Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

(F)(i) With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

(G) For purposes of this paragraph:

(i) The term ''group practice'' has the meaning given such term in section 1395nn(h)(4) of title 42.

(ii) The term ''qualifying physician'' means a physician who is licensed under State law and who meets one or more of the following conditions:

(I) The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.

(II) The physician holds an addiction certification or board certification from the American Society of Addiction Medicine or the American Board of Addiction Medicine.

(III) The physician holds a board certification in addiction medicine from the American Osteopathic Association.

(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause. Such training shall include—

(aa) opioid maintenance and detoxification;

(bb) appropriate clinical use of all drugs approved by the Food and Drug Adminis-

tration for the treatment of opioid use disorder;

(cc) initial and periodic patient assessments (including substance use monitoring);

(dd) individualized treatment planning, overdose reversal, and relapse prevention;

(ee) counseling and recovery support services;

(ff) staffing roles and considerations;

(gg) diversion control; and

(hh) other best practices, as identified by the Secretary.

(V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

(VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

(VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

(VIII) The physician graduated in good standing from an accredited school of allopathic medicine or osteopathic medicine in the United States during the 5-year period immediately preceding the date on which the physician submits to the Secretary a written notification under subparagraph (B) and successfully completed a comprehensive allopathic or osteopathic medicine curriculum or accredited medical residency that—

(aa) included not less than 8 hours of training on treating and managing opioid-dependent patients; and

(bb) included, at a minimum—

(AA) the training described in items (aa) through (gg) of subclause (IV); and

(BB) training with respect to any other best practice the Secretary determines should be included in the curriculum, which may include training on pain management, including assessment and appropriate use of opioid and non-opioid alternatives.

(iii) The term ''qualifying practitioner'' means—

(I) a qualifying physician, as defined in clause (ii);

(II) a qualifying other practitioner, as defined in clause (iv), who is a nurse practitioner or physician assistant; or

(III) for the period beginning on October 1, 2018, and ending on October 1, 2023, a qualifying other practitioner, as defined in clause (iv), who is a clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife.

(iv) The term ''qualifying other practitioner'' means a nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant who satisfies each of the following:

(I) The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain.

(II) The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant has—

(aa) completed not fewer than 24 hours of initial training addressing each of the topics listed in clause (ii)(IV) (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Assistants, or any other organization that the Secretary determines is appropriate for purposes of this subclause; or

(bb) has such other training or experience as the Secretary determines will demonstrate the ability of the nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant to treat and manage opiate-dependent patients.

(III) The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is supervised by, or works in collaboration with, a qualifying physician, if the nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is required by State law to prescribe medications for the treatment of opioid use disorder in collaboration with or under the supervision of a physician.

The Secretary may, by regulation, revise the requirements for being a qualifying other practitioner under this clause.

(H)(i) In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Men-

tal Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

(I) Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.

(II) Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

(III) Such other elements of the requirements under this paragraph as the Secretary determines necessary for purposes of implementing such requirements.

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

(ii) Not later than 18 months after the date of enactment of the Opioid Use Disorder Treatment Expansion and Modernization Act,[1] the Secretary shall update the treatment improvement protocol containing best practice guidelines for the treatment of opioid-dependent patients in office-based settings. The Secretary shall update such protocol in consultation with experts in opioid use disorder research and treatment.

(I) Notwithstanding section 903 of this title, nothing in this paragraph shall be construed to preempt any State law that—

(i) permits a qualifying practitioner to dispense narcotic drugs in schedule III, IV, or V, or combinations of such drugs, for maintenance or detoxification treatment in accordance with this paragraph to a total number of patients that is more than 30 or less than the total number applicable to the qualifying practitioner under subparagraph (B)(iii)(II) if a State enacts a law modifying such total number and the Attorney General is notified by the State of such modification; or

(ii) requires a qualifying practitioner to comply with additional requirements relating to the dispensing of narcotic drugs in schedule III, IV, or V, or combinations of such drugs, including requirements relating to the practice setting in which the qualifying practitioner practices and education, training, and reporting requirements.

(h) Applicants for distribution of list I chemicals

The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under clause (iv) or (v) of section 802(39)(A) of this title. In determining the public interest for the purposes of this subsection, the Attorney General shall consider—

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

(i) Registration to manufacture certain controlled substances for use only in a clinical trial

(1) For purposes of registration to manufacture a controlled substance under subsection (d) for use only in a clinical trial, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 824(c) of this title, not later than 180 days after the date on which the application is accepted for filing.

(2) For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 824(c) of this title, unless the Attorney General has granted a hearing on the application under section 958(i) of this title.

(j) Emergency medical services that administer controlled substances

(1) Registration

For the purpose of enabling emergency medical services professionals to administer controlled substances in schedule II, III, IV, or V to ultimate users receiving emergency medical services in accordance with the requirements of this subsection, the Attorney General—

(A) shall register an emergency medical services agency if the agency submits an application demonstrating it is authorized to conduct such activity under the laws of each State in which the agency practices; and

(B) may deny an application for such registration if the Attorney General determines that the issuance of such registration would be inconsistent with the requirements of this subsection or the public interest based on the factors listed in subsection (f).

(2) Option for single registration

In registering an emergency medical services agency pursuant to paragraph (1), the Attorney General shall allow such agency the option of a single registration in each State where the agency administers controlled substances in lieu of requiring a separate registration for each location of the emergency medical services agency.

(3) Hospital-based agency

If a hospital-based emergency medical services agency is registered under subsection (f),

[1] See References in Text note below.

the agency may use the registration of the hospital to administer controlled substances in accordance with this subsection without being registered under this subsection.

(4) Administration outside physical presence of medical director or authorizing medical professional

Emergency medical services professionals of a registered emergency medical services agency may administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services if the administration is—

(A) authorized by the law of the State in which it occurs; and

(B) pursuant to—

(i) a standing order that is issued and adopted by one or more medical directors of the agency, including any such order that may be developed by a specific State authority; or

(ii) a verbal order that is—

(I) issued in accordance with a policy of the agency; and

(II) provided by a medical director or authorizing medical professional in response to a request by the emergency medical services professional with respect to a specific patient—

(aa) in the case of a mass casualty incident; or

(bb) to ensure the proper care and treatment of a specific patient.

(5) Delivery

A registered emergency medical services agency may deliver controlled substances from a registered location of the agency to an unregistered location of the agency only if the agency—

(A) designates the unregistered location for such delivery; and

(B) notifies the Attorney General at least 30 days prior to first delivering controlled substances to the unregistered location.

(6) Storage

A registered emergency medical services agency may store controlled substances—

(A) at a registered location of the agency;

(B) at any designated location of the agency or in an emergency services vehicle situated at a registered or designated location of the agency; or

(C) in an emergency medical services vehicle used by the agency that is—

(i) traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency; or

(ii) otherwise actively in use by the agency under circumstances that provide for security of the controlled substances consistent with the requirements established by regulations of the Attorney General.

(7) No treatment as distribution

The delivery of controlled substances by a registered emergency medical services agency pursuant to this subsection shall not be treated as distribution for purposes of section 828 of this title.

(8) Restocking of emergency medical services vehicles at a hospital

Notwithstanding paragraph (13)(J), a registered emergency medical services agency may receive controlled substances from a hospital for purposes of restocking an emergency medical services vehicle following an emergency response, and without being subject to the requirements of section 828 of this title, provided all of the following conditions are satisfied:

(A) The registered or designated location of the agency where the vehicle is primarily situated maintains a record of such receipt in accordance with paragraph (9).

(B) The hospital maintains a record of such delivery to the agency in accordance with section 827 of this title.

(C) If the vehicle is primarily situated at a designated location, such location notifies the registered location of the agency within 72 hours of the vehicle receiving the controlled substances.

(9) Maintenance of records

(A) In general

A registered emergency medical services agency shall maintain records in accordance with subsections (a) and (b) of section 827 of this title of all controlled substances that are received, administered, or otherwise disposed of pursuant to the agency's registration, without regard to subsection 827(c)(1)(B) of this title.

(B) Requirements

Such records—

(i) shall include records of deliveries of controlled substances between all locations of the agency; and

(ii) shall be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of.

(10) Other requirements

A registered emergency medical services agency, under the supervision of a medical director, shall be responsible for ensuring that—

(A) all emergency medical services professionals who administer controlled substances using the agency's registration act in accordance with the requirements of this subsection;

(B) the recordkeeping requirements of paragraph (9) are met with respect to a registered location and each designated location of the agency;

(C) the applicable physical security requirements established by regulation of the Attorney General are complied with wherever controlled substances are stored by the agency in accordance with paragraph (6); and

(D) the agency maintains, at a registered location of the agency, a record of the stand-

ing orders issued or adopted in accordance with paragraph (9).

(11) Regulations

The Attorney General may issue regulations—

(A) specifying, with regard to delivery of controlled substances under paragraph (5)—

(i) the types of locations that may be designated under such paragraph; and

(ii) the manner in which a notification under paragraph (5)(B) must be made;

(B) specifying, with regard to the storage of controlled substances under paragraph (6), the manner in which such substances must be stored at registered and designated locations, including in emergency medical service vehicles; and

(C) addressing the ability of hospitals, emergency medical services agencies, registered locations, and designated locations to deliver controlled substances to each other in the event of—

(i) shortages of such substances;

(ii) a public health emergency; or

(iii) a mass casualty event.

(12) Rule of construction

Nothing in this subsection shall be construed—

(A) to limit the authority vested in the Attorney General by other provisions of this subchapter to take measures to prevent diversion of controlled substances; or

(B) to override the authority of any State to regulate the provision of emergency medical services consistent with this subsection.

(13) Definitions

In this section:

(A) The term ''authorizing medical professional'' means an emergency or other physician, or another medical professional (including an advanced practice registered nurse or physician assistant)—

(i) who is registered under this chapter;

(ii) who is acting within the scope of the registration; and

(iii) whose scope of practice under a State license or certification includes the ability to provide verbal orders.

(B) The term ''designated location'' means a location designated by an emergency medical services agency under paragraph (5).

(C) The term ''emergency medical services'' means emergency medical response and emergency mobile medical services provided outside of a fixed medical facility.

(D) The term ''emergency medical services agency'' means an organization providing emergency medical services, including such an organization that—

(i) is governmental (including fire-based and hospital-based agencies), nongovernmental (including hospital-based agencies), private, or volunteer-based;

(ii) provides emergency medical services by ground, air, or otherwise; and

(iii) is authorized by the State in which the organization is providing such services to provide emergency medical care, including the administering of controlled substances, to members of the general public on an emergency basis.

(E) The term ''emergency medical services professional'' means a health care professional (including a nurse, paramedic, or emergency medical technician) licensed or certified by the State in which the professional practices and credentialed by a medical director of the respective emergency medical services agency to provide emergency medical services within the scope of the professional's State license or certification.

(F) The term ''emergency medical services vehicle'' means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an emergency medical services agency for the purpose of providing or facilitating emergency medical care and transport or transporting controlled substances to and from the registered and designated locations.

(G) The term ''hospital-based'' means, with respect to an agency, owned or operated by a hospital.

(H) The term ''medical director'' means a physician who is registered under subsection (f) and provides medical oversight for an emergency medical services agency.

(I) The term ''medical oversight'' means supervision of the provision of medical care by an emergency medical services agency.

(J) The term ''registered emergency medical services agency'' means—

(i) an emergency medical services agency that is registered pursuant to this subsection; or

(ii) a hospital-based emergency medical services agency that is covered by the registration of the hospital under subsection (f).

(K) The term ''registered location'' means a location that appears on the certificate of registration issued to an emergency medical services agency under this subsection or subsection (f), which shall be where the agency receives controlled substances from distributors.

(L) The term ''specific State authority'' means a governmental agency or other such authority, including a regional oversight and coordinating body, that, pursuant to State law or regulation, develops clinical protocols regarding the delivery of emergency medical services in the geographic jurisdiction of such agency or authority within the State that may be adopted by medical directors.

(M) The term ''standing order'' means a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services.

(N) The term ''verbal order'' means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously

administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

(k) "Factors as may be relevant to and consistent with the public health and safety" defined

In this section, the phrase ''factors as may be relevant to and consistent with the public health and safety'' means factors that are relevant to and consistent with the findings contained in section 801 of this title.

(Pub. L. 91–513, title II, §303, Oct. 27, 1970, 84 Stat. 1253; Pub. L. 93–281, §3, May 14, 1974, 88 Stat. 124; Pub. L. 95–633, title I, §109, Nov. 10, 1978, 92 Stat. 3773; Pub. L. 98–473, title II, §511, Oct. 12, 1984, 98 Stat. 2073; Pub. L. 103–200, §3(c), Dec. 17, 1993, 107 Stat. 2336; Pub. L. 106–310, div. B, title XXXV, §3502(a), Oct. 17, 2000, 114 Stat. 1222; Pub. L. 107–273, div. B, title II, §2501, Nov. 2, 2002, 116 Stat. 1803; Pub. L. 109–56, §1(a), (b), Aug. 2, 2005, 119 Stat. 591; Pub. L. 109–177, title VII, §712(a)(3), Mar. 9, 2006, 120 Stat. 263; Pub. L. 109–469, title XI, §1102, Dec. 29, 2006, 120 Stat. 3540; Pub. L. 110–425, §3(b), Oct. 15, 2008, 122 Stat. 4824; Pub. L. 114–89, §3, Nov. 25, 2015, 129 Stat. 701; Pub. L. 114–145, §2(a)(1), Apr. 19, 2016, 130 Stat. 354; Pub. L. 114–198, title III, §303(a)(1), (b), July 22, 2016, 130 Stat. 720, 723; Pub. L. 115–83, §2, Nov. 17, 2017, 131 Stat. 1267; Pub. L. 115–271, title III, §§3201(a)–(d), 3202(a), Oct. 24, 2018, 132 Stat. 3943, 3944.)

Editorial Notes

REFERENCES IN TEXT

Schedules I, II, III, IV, and V, referred to in subsecs. (a) to (f), (g)(2), and (j)(1), (4), are set out in section 812(c) of this title.

This subchapter, referred to in subsecs. (f) and (j)(12)(A), was in the original ''this title'', meaning title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, and is popularly known as the ''Controlled Substances Act''. For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (g)(2)(C)(i), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

The date of enactment of the Opioid Use Disorder Treatment Expansion and Modernization Act, referred to in subsec. (g)(2)(H)(ii), probably means the date of enactment of Pub. L. 114–198, known as the Comprehensive Addiction and Recovery Act of 2016, which was approved July 22, 2016. The Opioid Use Disorder Treatment Expansion and Modernization Act was H.R. 4981 of the 114th Congress, as introduced on Apr. 18, 2016. Amendatory provisions of H.R. 4981 were incorporated into Pub. L. 114–198, but no such Short Title was enacted.

This chapter, referred to in subsec. (j)(13)(A)(i), was in the original ''this Act'', meaning Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1236. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

AMENDMENTS

2018—Subsec. (g)(2)(B)(iii)(II). Pub. L. 115–271, §3201(a), amended subcl. (II) generally. Prior to amendment, subcl. (II) read as follows: ''The applicable number is 100 if, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients.''

Subsec. (g)(2)(G)(ii)(VIII). Pub. L. 115–271, §3202(a), added subcl. (VIII).

Subsec. (g)(2)(G)(iii)(II). Pub. L. 115–271, §3201(b), amended subcl. (II) generally. Prior to amendment, subcl. (II) read as follows: ''during the period beginning on July 22, 2016, and ending on October 1, 2021, a qualifying other practitioner, as defined in clause (iv).''

Subsec. (g)(2)(G)(iii)(III). Pub. L. 115–271, §3201(b)(1), (c), added subcl. (III).

Subsec. (g)(2)(G)(iv). Pub. L. 115–271, §3201(d), substituted ''nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant'' for ''nurse practitioner or physician assistant'' wherever appearing.

2017—Subsecs. (j), (k). Pub. L. 115–83 added subsec. (j) and redesignated former subsec. (j) as (k).

2016—Subsec. (g)(2)(B). Pub. L. 114–198, §303(a)(1)(A), added cls. (i) to (iii) and struck out former cls. (i) to (iii) which read as follows:

''(i) The practitioner is a qualifying physician (as defined in subparagraph (G)).

''(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to refer the patients for appropriate counseling and other appropriate ancillary services.

''(iii) The total number of such patients of the practitioner at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, unless, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients. A second notification under this clause shall contain the certifications required by clauses (i) and (ii) of this subparagraph. The Secretary may by regulation change such total number.''

Subsec. (g)(2)(D)(ii). Pub. L. 114–198, §303(a)(1)(B)(i), substituted ''Upon receiving a determination from the Secretary under clause (iii) finding that a practitioner meets all requirements for a waiver under subparagraph (B)'' for ''Upon receiving a notification under subparagraph (B)''.

Subsec. (g)(2)(D)(iii). Pub. L. 114–198, §303(a)(1)(B)(ii), inserted ''and shall forward such determination to the Attorney General'' after ''a waiver under subparagraph (B)'' and substituted ''assign the practitioner'' for ''assign the physician''.

Subsec. (g)(2)(G)(ii)(I). Pub. L. 114–198, §303(a)(1)(C)(i), amended subcl. (I) generally. Prior to amendment, subcl. (I) read as follows: ''The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.''

Subsec. (g)(2)(G)(ii)(II). Pub. L. 114–198, §303(a)(1)(C)(ii), amended subcl. (II) generally. Prior to amendment, subcl. (II) read as follows: ''The physician holds an addiction certification from the American Society of Addiction Medicine.''

Subsec. (g)(2)(G)(ii)(III). Pub. L. 114–198, §303(a)(1)(C)(iii), struck out ''subspecialty'' before ''board certification''.

Subsec. (g)(2)(G)(ii)(IV). Pub. L. 114–198, §303(a)(1)(C)(iv), amended subcl. (IV) generally. Prior to amendment, subcl. (IV) read as follows: ''The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause.''

Subsec. (g)(2)(G)(iii), (iv). Pub. L. 114–198, §303(a)(1)(C)(v), added cls. (iii) and (iv).

Subsec. (g)(2)(H)(i)(III). Pub. L. 114–198, § 303(a)(1)(D)(i), added subcl. (III).

Subsec. (g)(2)(H)(ii). Pub. L. 114–198, § 303(a)(1)(D)(ii), amended cl. (ii) generally. Prior to amendment, cl. (ii) read as follows: ''Not later than 120 days after October 17, 2000, the Secretary shall issue a treatment improvement protocol containing best practice guidelines for the treatment and maintenance of opiate-dependent patients. The Secretary shall develop the protocol in consultation with the Director of the National Institute on Drug Abuse, the Administrator of the Drug Enforcement Administration, the Commissioner of Food and Drugs, the Administrator of the Substance Abuse and Mental Health Services Administration and other substance abuse disorder professionals. The protocol shall be guided by science.''

Subsec. (g)(2)(I), (J). Pub. L. 114–198, § 303(b), added subpar. (I) and struck out former subpars. (I) and (J) which limited a State's ability to preclude a practitioner from dispensing or prescribing certain approved drugs and provided the effective date of the paragraph and authorized the Secretary and the Attorney General to make certain determinations.

Subsec. (j). Pub. L. 114–145 added subsec. (j).

2015—Subsec. (i). Pub. L. 114–89 added subsec. (i).

2008—Subsec. (f). Pub. L. 110–425, in introductory provisions, inserted ''and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet'' after ''schedule II, III, IV, or V'' and substituted ''or such modification of registration if the Attorney General determines that the issuance of such registration or modification'' for ''if he determines that the issuance of such registration''.

2006—Subsec. (g)(2)(B)(iii). Pub. L. 109–469, § 1102(1), substituted ''unless, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients. A second notification under this clause shall contain the certifications required by clauses (i) and (ii) of this subparagraph. The'' for ''except that the''.

Subsec. (g)(2)(J)(i). Pub. L. 109–469, § 1102(2)(A), substituted ''thereafter.'' for ''thereafter except as provided in clause (iii) (relating to a decision by the Secretary or the Attorney General that this paragraph should not remain in effect).''

Subsec. (g)(2)(J)(ii). Pub. L. 109–469, § 1102(2)(B), substituted ''December 29, 2006'' for ''October 17, 2000'' in introductory provisions.

Subsec. (g)(2)(J)(iii). Pub. L. 109–469, § 1102(2)(C), substituted ''subparagraph (B)(iii) should be applied by limiting the total number of patients a practitioner may treat to 30, then the provisions in such subparagraph (B)(iii) permitting more than 30 patients shall not apply, effective'' for ''this paragraph should not remain in effect, this paragraph ceases to be in effect''.

Subsec. (h). Pub. L. 109–177 substituted ''clause (iv) or (v) of section 802(39)(A) of this title'' for ''section 802(39)(A)(iv) of this title'' in introductory provisions.

2005—Subsec. (g)(2)(B)(iii). Pub. L. 109–56, § 1(b), substituted ''The total'' for ''In any case in which the practitioner is not in a group practice, the total''.

Subsec. (g)(2)(B)(iv). Pub. L. 109–56, § 1(a), struck out cl. (iv) which read as follows: ''In any case in which the practitioner is in a group practice, the total number of such patients of the group practice at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, except that the Secretary may by regulation change such total number, and the Secretary for such purposes may by regulation establish different categories on the basis of the number of practitioners in a group practice and establish for the various categories different numerical limitations on the number of such patients that the group practice may have.''

2002—Subsec. (g)(2)(I). Pub. L. 107–273, § 2501(1), which directed the substitution of ''on the date of approval by the Food and Drug Administration of a drug in schedule III, IV, or V, a State may not preclude a practitioner from dispensing or prescribing such drug, or combination of such drugs,'' for ''on October 17, 2000, a State may not preclude a practitioner from dispensing or prescribing drugs in schedule III, IV, or V, or combinations of such drugs,'', was executed by making the substitution for the phrase which in the original began with ''on the date of the enactment of the Drug Addiction Treatment Act of 2000,'' rather than the editorial translation ''on October 17, 2000,'' to reflect the probable intent of Congress.

Subsec. (g)(2)(J)(i). Pub. L. 107–273, § 2501(2), which directed the substitution of ''the date referred to in subparagraph (I),'' for ''October 17, 2000,'' was executed by making the substitution for text which in the original read ''the date of the enactment of the Drug Addiction Treatment Act of 2000,'' rather than the editorial translation ''October 17, 2000,'' to reflect the probable intent of Congress.

2000—Subsec. (g). Pub. L. 106–310 designated existing provisions as par. (1), substituted ''Except as provided in paragraph (2), practitioners who dispense'' for ''Practitioners who dispense'', redesignated former pars. (1) to (3) as subpars. (A) to (C), respectively, of par. (1) and redesignated former subpars. (A) and (B) of former par. (2) as cls. (i) and (ii), respectively, of subpar. (B) of par. (1), and added par. (2).

1993—Subsec. (h). Pub. L. 103–200 added subsec. (h).

1984—Subsec. (f). Pub. L. 98–473 amended subsec. (f) generally, substituting provisions relating to registration authority of Attorney General respecting dispensation or conduct of research with controlled research, and separate authority of Secretary respecting registration, for provisions relating to general registration requirements respecting dispensation or conduct of research with controlled or nonnarcotic controlled substances.

1978—Subsec. (f). Pub. L. 95–633 inserted provision relating to the construction of the Convention on Psychotropic Substances.

1974—Subsec. (g). Pub. L. 93–281 added subsec. (g).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110–425 effective 180 days after Oct. 15, 2008, except as otherwise provided, see section 3(j) of Pub. L. 110–425, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 2005 AMENDMENT

Pub. L. 109–56, § 1(c), Aug. 2, 2005, 119 Stat. 591, provided that: ''This section [amending this section] shall take effect on the date of enactment of this Act [Aug. 2, 2005].''

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

EFFECTIVE DATE

Section effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91–513, set out as a note under section 801 of this title.

UPDATE REGULATIONS

Pub. L. 114–198, title III, § 303(c), July 22, 2016, 130 Stat. 723, provided that: ''Not later than 18 months after the date of enactment of this Act [July 22, 2016],

the Attorney General and the Secretary of Health and Human Services, as appropriate, shall update regulations regarding practitioners described in subsection (a)(3)(B)(vii) (as amended by this section) [probably means subsec. (a)(3)(B)(vii) ''of this section'', set out as a note below] to include nurse practitioners and physician assistants to ensure the quality of patient care and prevent diversion.''

TREATMENT FOR CHILDREN

Pub. L. 115–271, title III, §3202(b), Oct. 24, 2018, 132 Stat. 3945, provided that: ''The Secretary of Health and Human Services shall consider ways to ensure that an adequate number of qualified practitioners, as defined in subparagraph (G)(ii) of section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)), who have a specialty in pediatrics or the treatment of children or adolescents, are granted a waiver under such section 303(g)(2) to treat children and adolescents with substance use disorders.''

GRANTS TO ENHANCE ACCESS TO SUBSTANCE USE DISORDER TREATMENT

Pub. L. 115–271, title III, §3203, Oct. 24, 2018, 132 Stat. 3945, provided that:

''(a) IN GENERAL.—The Secretary of Health and Human Services shall establish a grant program under which the Secretary may make grants to accredited schools of allopathic medicine or osteopathic medicine and teaching hospitals located in the United States to support the development of curricula that meet the requirements under subclause (VIII) of section 303(g)(2)(G)(ii) of the Controlled Substances Act [21 U.S.C. 823(g)(2)(G)(ii)], as added by section 3202(a) of this Act.

''(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, for grants under subsection (a), $4,000,000 for each of fiscal years 2019 through 2023.''

REPORTS TO CONGRESS

Pub. L. 114–198, title III, §303(a)(3), July 22, 2016, 130 Stat. 722, provided that:

''(A) IN GENERAL.—Not later than 3 years after the date of enactment of this Act [July 22, 2016] and not later than 3 years thereafter, the Secretary of Health and Human Services, in consultation with the Drug Enforcement Administration and experts in opioid use disorder research and treatment, shall—

''(i) perform a thorough review of the provision of opioid use disorder treatment services in the United States, including services provided in opioid treatment programs and other specialty and nonspecialty settings; and

''(ii) submit a report to the Congress on the findings and conclusions of such review.

''(B) CONTENTS.—Each report under subparagraph (A) shall include an assessment of—

''(i) compliance with the requirements of section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)), as amended by this section;

''(ii) the measures taken by the Secretary of Health and Human Services to ensure such compliance;

''(iii) whether there is further need to increase or decrease the number of patients a practitioner, pursuant to a waiver under section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)), is permitted to treat;

''(iv) the extent to which, and proportions with which, the full range of Food and Drug Administration-approved treatments for opioid use disorder are used in routine health care settings and specialty substance use disorder treatment settings;

''(v) access to, and use of, counseling and recovery support services, including the percentage of patients receiving such services;

''(vi) changes in State or local policies and legislation relating to opioid use disorder treatment;

''(vii) the use of prescription drug monitoring programs by practitioners who are permitted to dispense narcotic drugs to individuals pursuant to a waiver described in clause (iii);

''(viii) the findings resulting from inspections by the Drug Enforcement Administration of practitioners described in clause (vii); and

''(ix) the effectiveness of cross-agency collaboration between [the] Department of Health and Human Services and the Drug Enforcement Administration for expanding effective opioid use disorder treatment.''

PROVISIONAL REGISTRATION

For provisional registration of persons engaged in manufacturing, distributing, or dispensing of controlled substances on the day before the effective date of section 822 of this title who are registered on such date under section 360 of this title or section 4722 of Title 26, Internal Revenue Code, see section 703 of Pub. L. 91–513, set out as a note under section 822 of this title.

§ 824. Denial, revocation, or suspension of registration

(a) Grounds

A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

(1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II;

(2) has been convicted of a felony under this subchapter or subchapter II or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of title 42.

A registration pursuant to section 823(g)(1) of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 823(g)(1) of this title.

(b) Limits of revocation or suspension

The Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist.

(c) Service of show cause order; proceedings

(1) Before taking action pursuant to this section, or pursuant to a denial of registration under section 823 of this title, the Attorney General shall serve upon the applicant or registrant

demonstrate, in and of itself, that adequate competition among them does not exist.

[62 FR 13953, Mar. 24, 1997, as amended at 81 FR 97019, Dec. 30, 2016]

§ 1301.35 Certificate of registration; denial of registration.

(a) The Administrator shall issue a Certificate of Registration (DEA Form 223) to an applicant if the issuance of registration or reregistration is required under the applicable provisions of sections 303 or 1008 of the Act (21 U.S.C. 823 and 958). In the event that the issuance of registration or reregistration is not required, the Administrator shall deny the application. Before denying any application, the Administrator shall issue an order to show cause pursuant to §1301.37 and, if requested by the applicant, shall hold a hearing on the application pursuant to §1301.41.

(b) If in response to a show cause order a hearing is requested by an applicant for registration or reregistration to manufacture in bulk a basic class of controlled substance listed in Schedule I or II, notice that a hearing has been requested shall be published in the FEDERAL REGISTER and shall be mailed simultaneously to the applicant and to all persons to whom notice of the application was mailed. Any person entitled to file comments or objections to the issuance of the proposed registration pursuant to §1301.33(a) may participate in the hearing by filing notice of appearance in accordance with §1301.43. Such persons shall have 30 days to file a notice of appearance after the date of publication of the notice of a request for a hearing in the FEDERAL REGISTER.

(c) The Certificate of Registration (DEA Form 223) shall contain the name, address, and registration number of the registrant, the activity authorized by the registration, the schedules and/or Administration Controlled Substances Code Number (as set forth in part 1308 of this chapter) of the controlled substances which the registrant is authorized to handle, the amount of fee paid (or exemption), and the expiration date of the registration. The registrant shall maintain the certificate of registration at the registered location in a readily retrievable manner and shall permit inspection of the certificate by any official, agent or employee of the Administration or of any Federal, State, or local agency engaged in enforcement of laws relating to controlled substances.

[62 FR 13954, Mar. 24, 1997]

§ 1301.36 Suspension or revocation of registration; suspension of registration pending final order; extension of registration pending final order.

(a) For any registration issued under section 303 of the Act (21 U.S.C. 823), the Administrator may:

(1) Suspend the registration pursuant to section 304(a) of the Act (21 U.S.C. 824(a)) for any period of time.

(2) Revoke the registration pursuant to section 304(a) of the Act (21 U.S.C. 824(a)).

(b) For any registration issued under section 1008 of the Act (21 U.S.C. 958), the Administrator may:

(1) Suspend the registration pursuant to section 1008(d) of the Act (21 U.S.C. 958(d)) for any period of time.

(2) Revoke the registration pursuant to section 1008(d) of the Act (21 U.S.C. 958(d)) if he/she determines that such registration is inconsistent with the public interest as defined in section 1008 or with the United States obligations under international treaties, conventions, or protocols in effect on October 12, 1984.

(c) The Administrator may limit the revocation or suspension of a registration to the particular controlled substance, or substances, with respect to which grounds for revocation or suspension exist.

(d) Before revoking or suspending any registration, the Administrator shall issue an order to show cause pursuant to §1301.37 and, if requested by the registrant, shall hold a hearing pursuant to §1301.41.

(e) The Administrator may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended, in any case where he/she finds that there is an imminent danger to the public health or safety. If the Administrator so suspends, he/she shall serve with the

order to show cause pursuant to §1301.37 an order of immediate suspension which shall contain a statement of his findings regarding the danger to public health or safety.

(f) Upon service of the order of the Administrator suspending or revoking registration, the registrant shall immediately deliver his/her Certificate of Registration, any order forms, and any import or export permits in his/her possession to the nearest office of the Administration. The suspension or revocation of a registration shall suspend or revoke any individual manufacturing or procurement quota fixed for the registrant pursuant to part 1303 of this chapter and any import or export permits issued to the registrant pursuant to part 1312 of this chapter. Also, upon service of the order of the Administrator revoking or suspending registration, the registrant shall, as instructed by the Administrator:

(1) Deliver all controlled substances in his/her possession to the nearest office of the Administration or to authorized agents of the Administration; or

(2) Place all controlled substances in his/her possession under seal as described in sections 304(f) or 1008(d)(6) of the Act (21 U.S.C. 824(f) or 958(d)(6)).

(g) In the event that revocation or suspension is limited to a particular controlled substance or substances, the registrant shall be given a new Certificate of Registration for all substances not affected by such revocation or suspension; no fee shall be required to be paid for the new Certificate of Registration. The registrant shall deliver the old Certificate of Registration and, if appropriate, any order forms in his/her possession to the nearest office of the Administration. The suspension or revocation of a registration, when limited to a particular basic class or classes of controlled substances, shall suspend or revoke any individual manufacturing or procurement quota fixed for the registrant for such class or classes pursuant to part 1303 of this chapter and any import or export permits issued to the registrant for such class or classes pursuant to part 1312 of this chapter. Also, upon service of the order of the Administrator revoking or suspending registration, the registrant shall, as instructed by the Administrator:

(1) Deliver to the nearest office of the Administration or to authorized agents of the Administration all of the particular controlled substance or substances affected by the revocation or suspension which are in his/her possession; or

(2) Place all of such substances under seal as described in sections 304(f) or 958(d)(6) of the Act (21 U.S.C. 824(f) or 958(d)(6)).

(h) Any suspension shall continue in effect until the conclusion of all proceedings upon the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the Administrator or dissolved by a court of competent jurisdiction. Any registrant whose registration is suspended under paragraph (e) of this section may request a hearing on the revocation or suspension of his/her registration at a time earlier than specified in the order to show cause pursuant to §1301.37. This request shall be granted by the Administrator, who shall fix a date for such hearing as early as reasonably possible.

(i) In the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at least 45 days before the date on which the existing registration is due to expire, and the Administrator has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Administrator so issues his/her order. The Administrator may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for reregistration at least 45 days before expiration of the existing registration, with or without request by the registrant, if the Administrator finds that such extension is not inconsistent with the public health and safety.

[62 FR 13955, Mar. 24, 1997]

§ 1301.37 Order to show cause.

(a) If, upon examination of the application for registration from any applicant and other information gathered by the Administration regarding the applicant, the Administrator is unable to make the determinations required by the applicable provisions of section 303 and/or section 1008 of the Act (21 U.S.C. 823 and 958) to register the applicant, the Administrator shall serve upon the applicant an order to show cause why the registration should not be denied.

(b) If, upon information gathered by the Administration regarding any registrant, the Administrator determines that the registration of such registrant is subject to suspension or revocation pursuant to section 304 or section 1008 of the Act (21 U.S.C. 824 and 958), the Administrator shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

(c) The order to show cause shall call upon the applicant or registrant to appear before the Administrator at a time and place stated in the order, which shall not be less than 30 days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

(d) Upon receipt of an order to show cause, the applicant or registrant must, if he/she desires a hearing, file a request for a hearing pursuant to §1301.43. If a hearing is requested, the Administrator shall hold a hearing at the time and place stated in the order, pursuant to §1301.41.

(e) When authorized by the Administrator, any agent of the Administration may serve the order to show cause.

[62 FR 13955, Mar. 24, 1997]

HEARINGS

§ 1301.41 Hearings generally.

(a) In any case where the Administrator shall hold a hearing on any registration or application therefor, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by sections 303, 304, and 1008 of the Act (21 U.S.C. 823–824 and 958), by §§1301.42–1301.46 of this part, and by the procedures for administrative hearings under the Act set forth in §§1316.41–1316.67 of this chapter.

(b) Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act or any other law of the United States.

[62 FR 13956, Mar. 24, 1997]

§ 1301.42 Purpose of hearing.

If requested by a person entitled to a hearing, the Administrator shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the denial, revocation, or suspension of any registration, and the granting of any application for registration to import or to manufacture in bulk a basic class of controlled substance listed in Schedule I or II. Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

[62 FR 13956, Mar. 24, 1997]

§ 1301.43 Request for hearing or appearance; waiver.

(a) Any person entitled to a hearing pursuant to §1301.32 or §§1301.34–1301.36 and desiring a hearing shall, within 30 days after the date of receipt of the order to show cause (or the date of publication of notice of the application for registration in the FEDERAL REGISTER in the case of §1301.34), file with the Administrator a written request for a hearing in the form prescribed in §1316.47 of this chapter.

(b) Any person entitled to participate in a hearing pursuant to §1301.34 or §1301.35(b) and desiring to do so shall, within 30 days of the date of publication of notice of the request for a hearing in the FEDERAL REGISTER, file with the Administrator a written notice of intent to participate in such hearing in the form prescribed in §1316.48 of this chapter. Any person filing a request for

substances for which a report is required; no additional report will be required from him, if no further transactions involving controlled substances are consummated by him. The initial report of the registrant-transferee shall account for transactions beginning with the day next succeeding the date of discontinuance or transfer of business by the transferor-registrant and the substances transferred to him shall be reported as receipts in his/her initial report.

(f) Any registrant that has been authorized as a collector and desires to discontinue its collection of controlled substances from ultimate users shall notify the Administration of its intent by submitting a written notification to the Registration Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. Additionally, such notice may be submitted on-line at *www.DEAdiversion.usdoj.gov*. When ceasing collection activities of an authorized mail-back program, the registrant shall provide the Administration with the name, registered address, and registration number of the collector that will receive the remaining mail-back packages in accordance with §1317.70(e)(3) of this chapter.

[62 FR 13957, Mar. 24, 1997, as amended at 74 FR 15623, Apr. 6, 2009; 75 FR 10676, Mar. 9, 2010; 76 FR 61564, Oct. 5, 2011; 79 FR 53561, Sept. 9, 2014]

SECURITY REQUIREMENTS

§1301.71 Security requirements generally.

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§1301.72–1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in §§1301.72, 1301.73 and 1301.75 may be used in lieu of the materials and construction described in those sections.

(b) Substantial compliance with the standards set forth in §§1301.72–1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Administrator may consider any of the following factors as he may deem relevant to the need for strict compliance with security requirements:

(1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);

(2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or nonusable powders);

(3) The quantity of controlled substances handled;

(4) The location of the premises and the relationship such location bears on security needs;

(5) The type of building construction comprising the facility and the general characteristics of the building or buildings;

(6) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;

(7) The type of closures on vaults, safes, and secure enclosures;

(8) The adequacy of key control systems and/or combination lock control systems;

(9) The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;

(10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

(11) The adequacy of supervision over employees having access to manufacturing and storage areas;

(12) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;

(13) The availability of local police protection or of the registrant's or applicant's security personnel;

(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations; and

(15) The applicability of the security requirements contained in all Federal, State, and local laws and regulations governing the management of waste.

(c) When physical security controls become inadequate as a result of a controlled substance being transferred to a different schedule, or as a result of a noncontrolled substance being listed on any schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in §§ 1301.72–1301.76 when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business operations.

(d) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in §§ 1301.72–1301.76 may submit any plans, blueprints, sketches or other materials regarding the proposed security system either to the Special Agent in Charge in the region in which the system will be used, or to the Regulatory Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(e) Physical security controls of locations registered under the Harrison Narcotic Act or the Narcotics Manufacturing Act of 1960 on April 30, 1971, shall be deemed to comply substantially with the standards set forth in §§ 1301.72, 1301.73 and 1301.75. Any new facilities or work or storage areas constructed or utilized for controlled substances, which facilities or work or storage areas have not been previously approved by the Administration, shall not necessarily be deemed to comply substantially with the standards set forth in §§ 1301.72, 1301.73 and 1301.75, notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved by the Administration.

(f) A collector shall not employ, as an agent or employee who has access to or influence over controlled substances acquired by collection, any person who has been convicted of any felony offense relating to controlled substances or who, at any time, had an application for registration with DEA denied, had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause. For purposes of this subsection, ''for cause'' means in lieu of, or as a consequence of, any Federal or State administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

[36 FR 18729, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 46 FR 28841, May 29, 1981; 47 FR 41735, Sept. 22, 1982; 51 FR 5319, Feb. 13, 1986; 68 FR 41228, July 11, 2003; 75 FR 10677, Mar. 9, 2010; 79 FR 53561, Sept. 9, 2014]

§ 1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; mobile narcotic treatment programs; storage areas.

(a) *Schedules I and II.* Raw material, bulk materials awaiting further processing, finished products which are controlled substances listed in Schedule I or II (except GHB that is manufactured or distributed in accordance with an exemption under section 505(i) of the Federal Food Drug and Cosmetic Act which shall be subject to the requirements of paragraph (b) of this section), and sealed mail-back packages and inner liners acquired in accordance with part 1317 of this chapter, shall be stored in one of the following secured areas:

(1) Where small quantities permit, a safe or steel cabinet;

(i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes

central station protection company, or local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant.

(b) Manufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access which is under surveillance by an employee or employees designated in writing as responsible for the area. ''Limited access'' may be provided, in the absence of physical dividers such as walls or partitions, by traffic control lines or restricted space designation. The employee designated as responsible for the area may be engaged in the particular manufacturing operation being conducted: *Provided*, That he is able to provide continuous surveillance of the area in order that unauthorized persons may not enter or leave the area without his knowledge.

(c) During the production of controlled substances, the manufacturing areas shall be accessible to only those employees required for efficient operation. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through manufacturing areas during production of controlled substances, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

[36 FR 18731, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 and amended at 39 FR 37984, Oct. 25, 1974]

§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; mobile narcotic treatment programs.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant must notify the Field Division Office of the Administration in his or her area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss. Unless the theft or loss occurs during an import or export transaction, the supplier is responsible for reporting all in-transit losses of controlled substances by their agent or the common or contract carrier selected pursuant to paragraph (e) of this section, within one business day of discovery of such theft or loss. In an import transaction, once a shipment has been released by the customs officer at the port of entry, the importer is responsible for reporting all in-transit losses of controlled substances by their agent or the common or contract carrier selected pursuant to paragraph (e) of this section, within one business day of discovery of such theft or loss. In an export transaction, the exporter is responsible for reporting all in-transit losses of controlled substances by their agent or the common or contract carrier selected pursuant to paragraph (e) of this section within one business day of discovery of such theft or loss, until the shipment has been released by the customs officer at the port of export. The registrant must also complete, and submit to the Field Division Office in his or her area, DEA Form 106 regarding the theft or loss. Thefts and significant losses must be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

(1) The actual quantity of controlled substances lost in relation to the type of business;

(2) The specific controlled substances lost;

(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;

(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,

(5) Whether the specific controlled substances are likely candidates for diversion;

(6) Local trends and other indicators of the diversion potential of the missing controlled substance.

(d) The registrant shall not distribute any controlled substance listed in Schedules II through V as a complimentary sample to any potential or current customer (1) without the prior written request of the customer, (2) to be used only for satisfying the legitimate medical needs of patients of the customer, and (3) only in reasonable quantities. Such request must contain the name, address, and registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of part 1305 of the chapter shall be complied with for any distribution of a controlled substance listed in Schedule II. For purposes of this paragraph, the term ''customer'' includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the person.

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in §1301.72. In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.

(f) When distributing controlled substances through agents (e.g., detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

(g) Before the initial distribution of thiafentanil, carfentanil, etorphine hydrochloride and/or diprenorphine to any person, the registrant must verify that the person is authorized to handle the substance(s) by contacting the Drug Enforcement Administration.

(h) The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual designated in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

(i) Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either (1) the licensed practitioner, (2) a registered nurse under the direction of the licensed practitioner, (3) a licensed practical nurse under the direction of the licensed practitioner, or (4) a pharmacist under the direction of the licensed practitioner.

(j) Persons enrolled in any narcotic treatment program (NTP), including those receiving treatment at a mobile NTP, will be required to wait in an area that is physically separated from the narcotic storage and dispensing area by a physical entrance such as a door or other entryway. Patients must wait outside of a mobile NTP component if that conveyance does not have

seating or a reception area that is separated from the narcotic storage and dispensing area. This requirement will be enforced by the program practitioner and NTP employees.

(k) All NTPs, including mobile NTPs, must comply with standards established by the Secretary of Health and Human Services (after consultation with the Administration) respecting the quantities of narcotic drugs which may be provided to persons enrolled in a NTP or mobile NTP for unsupervised use (*e.g.*, take home or non-directly observed therapy).

(l) DEA may exercise discretion regarding the degree of security required in NTPs, including mobile NTPs, based on such factors as the location of a program, the number of patients enrolled in a program, and the number of practitioners, staff members, and security guards. Personnel that are authorized to dispense controlled substances for narcotic treatment must ensure proper security measures and patient dosage. Similarly, DEA will consider such factors when evaluating existing security or requiring new security at a narcotic treatment program or mobile NTP.

(m) Any controlled substances being transported for disposal from the dispensing location of a mobile NTP shall be secured and disposed of in compliance with part 1317, and all other applicable Federal, State, tribal, and local laws and regulations.

(n) A conveyance used as part of a mobile NTP may only be supplied with narcotic drugs by the registered NTP that operates such conveyance. Persons permitted to dispense controlled substances to mobile NTPs shall not:

(1) Receive controlled substances from other mobile NTPs or any other entity;

(2) Deliver controlled substances to other mobile NTPs or any other entity; or

(3) Conduct reverse distribution of controlled substances on a mobile NTP.

(o) A reverse distributor shall not employ, as an agent or employee who has access to or influence over controlled substances, any person who has been convicted of any felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause. For purposes of this subsection, ''for cause'' means in lieu of, or as a consequence of, any Federal or State administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

[36 FR 7778, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 1301.74, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 1301.75 Physical security controls for practitioners.

(a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.

(b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

(c) Sealed mail-back packages and inner liners collected in accordance with part 1317 of this chapter shall only be stored at the registered location in a securely locked, substantially constructed cabinet or a securely locked room with controlled access, except as authorized by § 1317.80(d).

(d) This section shall also apply to nonpractitioners authorized to conduct research or chemical analysis under another registration.

(e) Thiafentanil, carfentanil, etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.

[39 FR 3674, Jan. 29, 1974, as amended at 39 FR 17838, May 21, 1974; 54 FR 33674, Aug. 16, 1989; 62 FR 13957, Mar. 24, 1997; 79 FR 53562, Sept. 9, 2014; 81 FR 58839, Aug. 26, 2016]

(46) *alpha*-Pyrrolidinoheptaphenone, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: PV8; 1-phenyl-2-(pyrrolidin-1-yl)heptan-1-one) 7548
(47) 4′-Chloro-*alpha*-pyrrolidinovalerophenone, its optical, positional, and geometric isomers, salts and salts of isomers (Other names: 4-chloro-α-PVP; 4′-chloro-*alpha*-pyrrolidinopentiophenone; 1-(4-chlorophenyl)-2-(pyrrolidin-1-yl)pentan-1-one) 7443
(48)[Reserved].
(49) 1-(1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)-1,3-dihydro-2*H*-benzo[*d*]imidazol-2-one, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other names: brorphine; 1-[1-[1-(4-bromophenyl)ethyl]-4-piperidinyl]-1,3-dihydro-2*H*-benzimidazol-2-one) 9098

[39 FR 22141, June 20, 1974]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §1308.11, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

EFFECTIVE DATE NOTES: 1. At 84 FR 15511, Apr. 16, 2019, §1308.11 was amended by adding paragraphs (h)(37) through (h)(41) effective Apr. 16, 2019, through Apr. 16, 2021. At 86 FR 16669, Mar. 31, 2021, the effective period was extended to Apr. 16, 2022.

2. At 84 FR 34297, July 17, 2019, §1308.11 was amended by adding paragraphs (h)(42) through (h)(47) effective July 18, 2019, through July 18, 2021. At 86 FR 37672, July 16, 2021, the effective period was extended to July 18, 2022.

3.At 83 FR 5191, Feb. 6, 2018, §1308.11 was amended by adding paragraph (h)(30), effective Feb. 6, 2018, through Feb. 6, 2020. Effective Feb. 6, 2020, Congress extended the effective period for paragraph (h)(30) until May 6, 2021, by Public Law 116–114. Effective May 4, 2021, Congress extended the effective period for paragraph (h)(30) until October 22, 2021, by Public Law 117-12. Effective Sept. 30, 2021, Congress extended the effective period for paragraph (h)(30) until Jan. 28, 2022, by Public Law 117-43. Effective Jan. 13, 2022, Congress extended the effective period for paragraph (h)(30) until Feb. 18, 2022, by Public Law 117-70. Effective Feb. 18, 2022, Congress extended the effective period for paragraph (h)(30) until Mar. 11, 2022, by Public Law 117-86. Effective Mar. 11, 2022, Congress extended the effective period for paragraph (h)(30) until Mar. 15, 2022 by Public Law 117-95. Effective Mar. 15, 2022, Congress extended the effective period for paragraph (h)(30) until Dec. 31, 2022 by Public Law No. 117-103.

4. At 86 FR 11866, Mar. 1, 2021, §1308.11 was amended by adding paragraph (h)(49), effective Mar. 1, 2021 through Mar. 1, 2023.

§ 1308.12 Schedule II.

(a) Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the Controlled Substances Code Number set forth opposite it.

(b) *Substances, vegetable origin or chemical synthesis.* Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, naldemedine, nalmefene, naloxegol, naloxone, 6β-naltrexol, naltrexone, and samidorphan, and their respective salts, but including the following:

(i) Codeine 9050
(ii) Dihydroetorphine 9334
(iii) Ethylmorphine 9190
(iv) Etorphine hydrochloride 9059
(v) Granulated opium 9640
(vi) Hydrocodone 9193
(vii) Hydromorphone 9150
(viii) Metopon 9260
(ix) Morphine 9300
(x) Noroxymorphone 9668
(xi) Opium extracts 9610
(xii) Opium fluid 9620
(xiii) Oripavine 9330
(xiv) Oxycodone 9143
(xv) Oxymorphone 9652
(xvi) Powdered opium 9639
(xvii) Raw opium 9600
(xviii) Thebaine 9333
(xix) Tincture of opium 9630

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (b) (1) of this section, except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves (9040) and any salt, compound, derivative or preparation of coca leaves (including cocaine (9041) and ecgonine (9180) and their salts, isomers, derivatives and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include:

(i) Decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine; or

(ii) [^{123}I]ioflupane.

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrene alkaloids of the opium poppy), 9670.

(c) *Opiates.* Unless specifically excepted or unless in another schedule any of the following opiates, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:

(1) Alfentanil 9737
(2) Alphaprodine 9010
(3) Anileridine 9020
(4) Bezitramide 9800
(5) Bulk dextropropoxyphene (non-dosage forms) 9273
(6) Carfentanil 9743
(7) Dihydrocodeine 9120
(8) Diphenoxylate 9170
(9) Fentanyl 9801
(10) Isomethadone 9226
(11) Levo-alphacetylmethadol 9648
[Some other names: levo-alpha-acetylmethadol, levomethadyl acetate, LAAM]
(12) Levomethorphan 9210
(13) Levorphanol 9220
(14) Metazocine 9240
(15) Methadone 9250
(16) Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenyl butane 9254
(17) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid 9802
(18) Oliceridine (*N*-[(3-methoxythiophen-2-yl)methyl]({2-[(9*R*)-9-(pyridin-2-yl)-6-oxaspiro[4.5]decan-9-yl]ethyl})amine) 9245
(19) Pethidine (meperidine) 9230
(20) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine 9232
(21) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate 9233
(22) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid 9234
(23) Phenazocine 9715
(24) Piminodine 9730
(25) Racemethorphan 9732
(26) Racemorphan 9733
(27) Remifentanil 9739
(28) Sufentanil 9740
(29) Tapentadol 9780
(30) Thiafentanil 9729

(d) *Stimulants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers 1100
(2) Methamphetamine, its salts, isomers, and salts of its isomers 1105
(3) Phenmetrazine and its salts 1631
(4) Methylphenidate 1724
(5) Lisdexamfetamine, its salts, isomers, and salts of its isomers ..... 1205.

(e) *Depressants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible

within the specific chemical designation:

(1) Amobarbital 2125
(2) Glutethimide 2550
(3) Pentobarbital 2270
(4) Phencyclidine 7471
(5) Secobarbital 2315

(f) *Hallucinogenic substances.*

(1) Nabilone 7379
[Another name for nabilone: (±)-*trans*-3-(1,1-dimethylheptyl)-6,6a,7,8,10,10a-hexahydro-1-hydroxy-6,6-dimethyl-9H-dibenzo[b,d]pyran-9-one]
(2) Dronabinol [(-)-delta-9-*trans* tetrahydrocannabinol] in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration ..... (7365)

(g) *Immediate precursors.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

(1) Immediate precursor to amphetamine and methamphetamine:

(i) Phenylacetone 8501
Some trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone;

(2) Immediate precursors to phencyclidine (PCP):

(i) 1-phenylcyclohexylamine 7460
(ii) 1-piperidinocyclohexanecarbonitrile (PCC) 8603

(3) Immediate precursor to fentanyl:

(i) 4-anilino-N-phenethylpiperidine (ANPP) ... 8333
(ii) *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl) 8366

[39 FR 22142, June 20, 1974]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 1308.12, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov.*

§ 1308.13 Schedule III.

(a) Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

(b) *Stimulants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, positional, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under § 1308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances 1405
(2) Benzphetamine 1228
(3) Chlorphentermine 1645
(4) Clortermine 1647
(5) Phendimetrazine 1615

(c) *Depressants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any compound, mixture or preparation containing:
(i) Amobarbital 2126
(ii) Secobarbital 2316
(iii) Pentobarbital 2271

West Virginia Code of State Rules
Title 15. West Virginia Board of Pharmacy
Legislative Rule (Ser. 2)
Series 2. Rules of the Board of Pharmacy for the Uniform Controlled Substances Act

W. Va. Code St. R. § 15-2-3

§ 15-2-3. Adoption of Federal Law.

Currentness

<Emergency action effective Aug. 4, 2021.>

3.1. The requirements of the federal regulations, Drug Enforcement Administration, Department of Justice, 21 CFR Parts 1300-1321 (2020), and the federal Controlled Substances Act, 21 U.S.C. 801, as revised, are adopted by reference.

3.2. The federal regulations are available on the internet at http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR.

Credits
History: Filed 4-1-20, eff. 4-1-20 (emergency); Filed 5-11-21, eff. 6-11-21; Filed 6-23-21, eff. 8-4-21 (emergency).

Current through register dated August 5, 2022. Some sections may be more current. See credits for details.

W. Va. C.S.R. § 15-2-3, WV ADC § 15-2-3

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