## 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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December 27, 2022

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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.   |
|--------|--|
| Pursi  | uant to FRAP 26.1 and Local Rule 26.1,   |
| City o | of Huntington, WV  |
| (nam   | ne of party/amicus)  |
|        |  |
| who    | is, makes the following disclosure: ellant/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: |

12/01/2019 SCC - 1 -

| 4. | Is there any other publicly held corporation or oth<br>financial interest in the outcome of the litigation?<br>If yes, identify entity and nature of interest:  | · · ·  |    |
|----|---|--|----|
| 5. | Is party a trade association? (amici curiae do not of the second of the proceeding or pursuing in a representative capacity, or state that  | stock or equity value could be affected whose claims the trade association is  | VO |
| 6. | Does this case arise out of a bankruptcy proceeding If yes, the debtor, the trustee, or the appellant (if reparty) must list (1) the members of any creditors' caption), and (3) if a debtor is a corporation, the percorporation that owns 10% or more of the stock of | neither the debtor nor the trustee is a committee, (2) each debtor (if not in the parent corporation and any publicly held | ne |
| 7. | Is this a criminal case in which there was an organ If yes, the United States, absent good cause shown victim of the criminal activity and (2) if an organi parent corporation and any publicly held corporat of victim, to the extent that information can be ob-      | n, must list (1) each organizational izational victim is a corporation, the zion that owns 10% or more of the stock        |    |
|    | ure: /s David C. Frederick el for: Appellant City of Huntington, WV   | Date:December 27, 2022   | _  |

#### UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

#### **DISCLOSURE STATEMENT**

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- 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.  |
|------|---|
| Purs | suant to FRAP 26.1 and Local Rule 26.1,   |
| Cabe | ell County Commission   |
| (nan | ne of party/amicus)   |
|      |   |
| who  | o is, makes the following disclosure: bellant/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: |

12/01/2019 SCC - 1 -

| 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?  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?   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. |
|    | el for: Appellant Cabell County Commission  |

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| 28 U.S.C. § 1407(a)22  |
| West Virginia Uniform Controlled Substances Act, W.Va. Code § 60A-1-101 et seq   |
| Okla. Stat. tit. 50:   |
| § 143  |
| § 243  |
| W.Va. Code:  |
| § 7-1-3kk83  |
| § 8-12-5(23)83   |
| § 53-1-133   |

## 21 C.F.R.: § 1301.37.......10 § 1308.12(b)(1)......5 W.Va. C.S.R.: § 15-2-2 (2017) ......9 § 15-2-3 ......9 W.Va. R.C.P. 1 (1960)......86 OTHER MATERIALS 58 Am. Jur. 2d Nuisances: § 26 (2012)......31 § 29 (1989)......80, 83 1 Dan B. Dobbs, *Law of Remedies* (2d ed. 1993)......86 W. Page Keeton et al., Prosser and Keeton on the Law of Torts (5th ed. 1984)......31

Restatement (Second) of Torts (1979)......31, 36, 39,

Restatement (Third) of Torts: Liability for Economic Harm (2020) .....36, 38, 39, 40

40, 43, 46, 71, 79

### 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." JA\_\_[Op.166]. 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. JA\_\_[Op.131].

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.

JA\_\_\_[HuntingtonDoc.1531]. Huntington and Cabell County timely filed a joint notice of appeal on August 2, 2022. JA - [HuntingtonDoc.1533].

### 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. JA\_\_[Op.97];

JA\_\_[5/4/21Tr.37] (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).

Common prescription opioids include oxycodone and hydrocodone; illicit opioids include heroin. JA\_\_\_\_\_ [5/4/21Tr.80-84] (Waller). Oxycodone is at least 1.5 times as potent as morphine, similar in potency to heroin. JA\_\_\_\_, JA\_\_\_ [MC-WV-1764at2,34]; JA\_\_\_ - \_\_\_, JA\_\_\_ [5/4/21Tr.45-46,75] (Waller). All opioids, including heroin, are chemically similar, with the same biological mechanism and similar effects. JA\_\_ [Op.97]; JA\_\_ - \_\_\_, JA\_\_\_ - \_\_\_ [5/4/21Tr.47-48,71-72] (Waller); JA\_\_ [MC-WV-2079at7]. Addiction to one opioid can be satisfied by another opioid. JA\_\_ - \_\_ [5/4/21Tr.71-72] (Waller) ("the brain doesn't know" the difference between prescription opioids and heroin);

JA\_\_\_, JA\_\_\_[MC-WV-2079at4,7]; JA\_\_\_-\_\_[6/11/21Tr.179-180] (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. JA\_\_\_\_\_ [5/26/21Tr.16-17] (Rafalski); JA\_\_\_\_ [5/13/21Tr.149-151] (Zimmerman); JA\_\_\_ [7/9/21Tr.12] (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%. JA\_\_ [P-898at2]; JA\_\_ - \_\_\_ [5/12/21Tr.159-160] (Zimmerman). Distributors ship prescription opioids to pharmacies, which dispense them to consumers with prescriptions. JA\_\_ [DEF-WV-1598at11]; JA\_\_ - \_\_ [5/12/21Tr.159-160] (Zimmerman); JA\_\_ [5/26/21Tr.17] (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.

JA\_\_\_, JA\_\_\_[P-32at5,9]; JA\_\_\_-\_\_[6/7/21Tr.174-178] (former DEA head of

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. JA\_\_\_, JA\_\_\_ - \_\_[5/17/19-30(b)(6)Dep.Tr.982, 997-999] (Prevoznik); JA\_\_\_[5/26/21Tr.195] (Rafalski); JA\_\_\_[6/7/21Tr.170], JA\_\_\_ - \_\_[6/8/21Tr.190-191] (Rannazzisi); JA\_\_\_[5/20/21Tr.104] (Mone); JA\_\_\_[DEF-WV-1598at11]; JA\_\_\_[DEF-WV-1597at8].

The controlled-substance supply chain is made up of millions of registrants and transactions, and DEA's investigative resources are limited.

JA [4/18/19Dep.Tr.625] (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. JA\_\_\_\_\_ [6/7/21Tr.178-180] (Rannazzisi); JA\_\_\_\_ - \_\_\_ [5/17/19-30(b)(6)Dep.Tr.983-985] (Prevoznik); JA\_\_\_ [P-32] (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." JA\_\_\_ [P-629at4]. DEA agreed. JA\_\_\_ - \_\_\_ [5/17/19-30(b)(6)Dep.Tr.900-901] (Prevoznik). As a "choke point" in the supply chain, JA\_\_\_ [P-193at2], 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).

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

<sup>&</sup>lt;sup>1</sup> 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." JA\_\_\_[P-8873at5]. 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." JA\_\_\_-\_[5/17/19-30(b)(6)Dep.Tr.973-974].

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. JA\_\_[Op.19].² "The opioid crisis has taken a considerable toll on the citizens of Cabell County and . . . Huntington." JA\_\_[Op.183]. As of 2017, more than 10% of Huntington residents had been or currently were addicted to opioids. JA\_\_[Op.20]. 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). JA\_\_[DEF-WV-1597at11]; JA\_\_-\_\_[6/11/21Tr.199-202] (Keyes). From 2001 to 2018, the opioid epidemic contributed to 1,002 deaths in Cabell/Huntington. JA\_\_[6/10/21Tr.134] (Smith). Prescription opioids remain "an ongoing and significant cause" of Cabell/Huntington overdose deaths. JA\_\_[Op.23].

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. JA\_\_[Op.20]. In 2016, the rate for

<sup>&</sup>lt;sup>2</sup> Huntington is mostly within Cabell County. JA\_\_[P-44711at10] (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. JA [5/11/21Tr.125] (McCann).

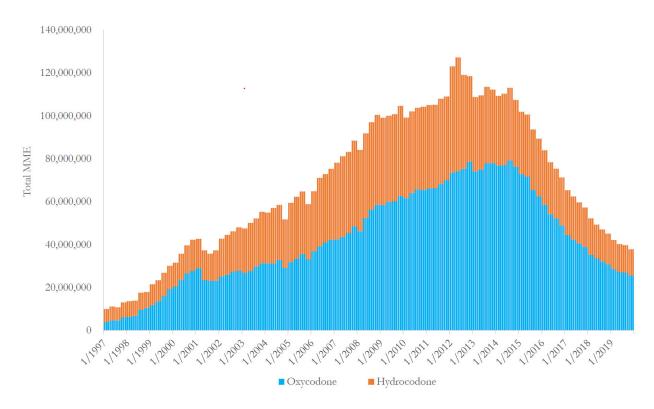
neonatal abstinence syndrome in Cabell was nine times the national rate. JA\_\_\_\_- [6/11/21Tr.202-203] (Keyes).

Crime increased, with drug offenses that occurred in "only a small area of Huntington" in 2004 "engulf[ing] every neighborhood" by 2016. JA\_\_[Op.23]. Placements into foster care doubled, most due to parental substance abuse. JA\_\_[Op.21]. Infectious diseases—including HIV, Hepatitis B, and Hepatitis C—spread rapidly. JA\_\_-[Op.21-22]. Neighborhoods hollowed out. *See* JA\_\_[5/27/21Tr.120] (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." JA [5/27/21Tr.119] (Zerkle).

2. West Virginia, Cabell, and Huntington did not always have an epidemic of opioid addiction. Historically, opioid abuse was far rarer.

JA\_\_[MC-WV-2079at6] (Appalachia "historically did not have much illicit opioid trade"); JA\_\_-[6/10/21Tr.139-140] (Smith) (overdose rate grew 13-fold from 2001 to 2018). Before 2000, the fatal overdose rate was below the national average. JA\_\_[5/5/21Tr.175] (Gupta); JA\_\_\_[5/6/21Tr.166] (Gupta).

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



JA\_\_\_[P-44711at8].<sup>3</sup> By 2006, prescription opioids were the most abused prescription drug in Appalachia and the most common cause of drug overdoses.

JA\_\_\_[DEF-WF-43at2]. Because oxycodone is so potent, and common forms could be snorted or injected, it became especially widely abused. JA\_\_\_, JA\_\_\_
\_\_[MC-WV-1764at2,7-8]; JA\_\_\_[DEF-WV-1597at8]; JA\_\_\_[MC-WV-2079at6]. Oxycodone was the leading cause of overdose deaths in West Virginia from 2001 to 2015. JA [P-41213at5].

<sup>&</sup>lt;sup>3</sup> 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. JA\_\_[5/4/21Tr.204] (Waller); JA\_\_[MC-WV-2079at7]; JA\_\_-\_[6/17/21Tr.219-220] (Holbrook); JA\_\_[P-41527at8]. The portion of drug abuse cases in Huntington due to heroin and fentanyl soon grew from 10% to 60-70%. JA\_\_-\_[5/27/21Tr.92-93] (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. JA\_\_[6/14/21Tr.175] (Keyes); see also JA\_\_-\_[6/11/21Tr.172-177] (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. JA\_\_\_\_\_\_\_[5/10/21Tr.88-91] (McCann); JA\_\_\_\_\_, JA\_\_\_\_[P-44711at21,24,27]. 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.

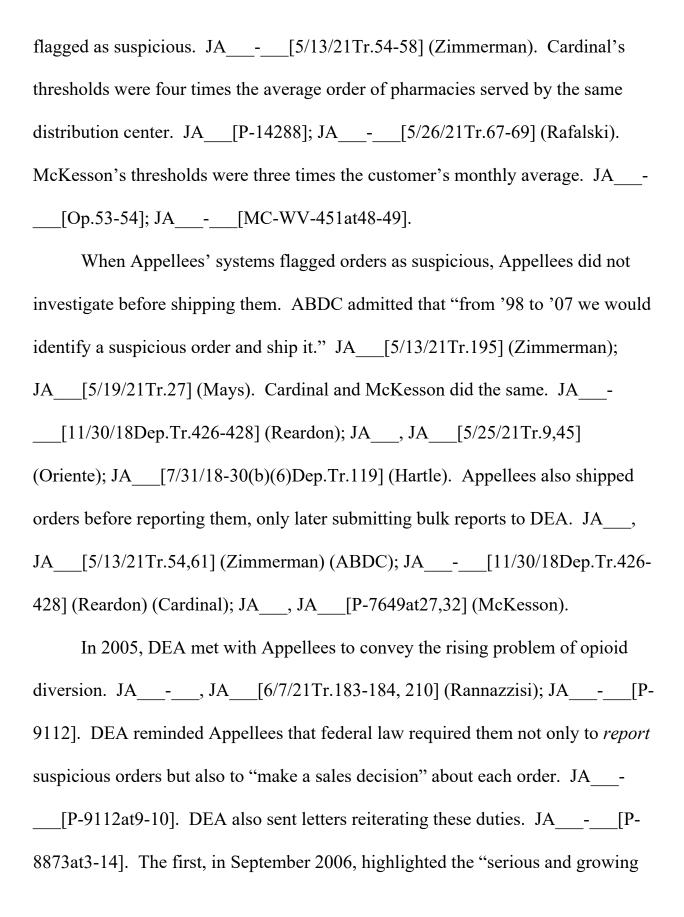
JA [5/10/21Tr.90] (McCann); JA , JA [P-44711at21,27].

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. JA\_\_[P-44711at3] (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. JA\_\_[P-44711at34]. 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. JA\_\_\_[Op.34]. A pharmacy averaging 10,000 oxycodone units per month could order up to 30,000 units the next month without the order being



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." JA\_\_\_-\_[P-8873at11-12].

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, JA [P-23733at1], and alleged violations at McKesson facilities in Texas and Colorado, JA - [P-23733at1-2]. In 2007, DEA issued an order immediately suspending an ABDC distribution center in Florida. JA [P-49at1]; JA [6/8/21Tr.59] (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." JA - [P-49at1-2]. 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. JA\_\_\_-\_[P-8873at49-69].

Appellees used consistent policies and practices at their distribution centers, including those supplying Cabell/Huntington. JA\_\_\_[5/12/21Tr.189]

(Zimmerman); JA\_\_\_-\_\_[11/30/18Dep.Tr.455-456] (Reardon); JA\_\_\_
[1/10/19Dep.Tr.130-132] (Walker); JA - [5/24/21Tr.40-41] (Oriente).

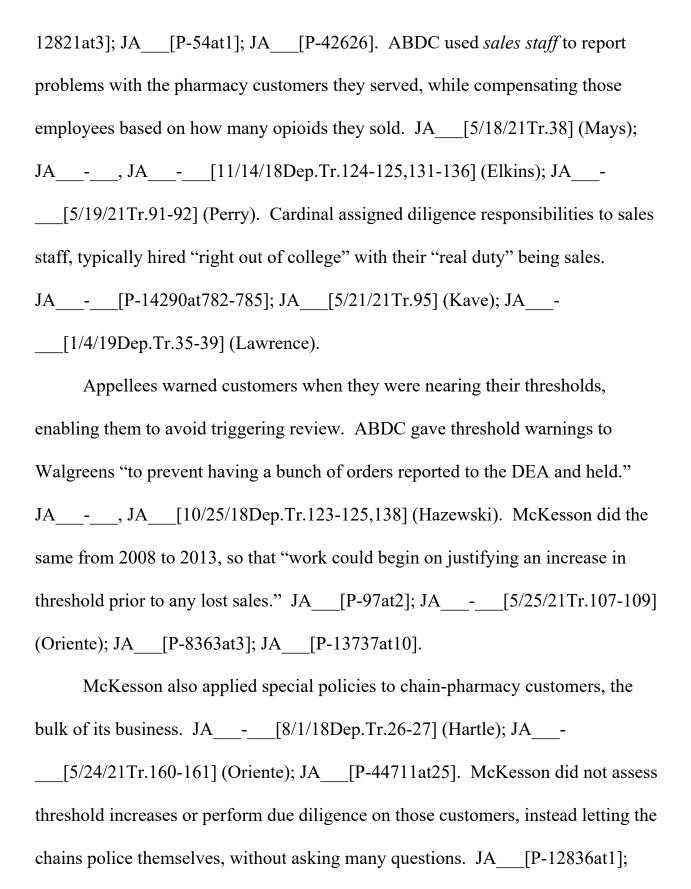
Appellees resolved the enforcement actions by settlement, agreeing to improve diversion controls throughout their nationwide operations. ABDC pledged to review orders flagged as suspicious and ship them only if it determined they were "legitimate following diligent review." JA\_\_[P-877at2]; JA\_\_[P-9at2].

McKesson agreed to pay \$13.25 million. JA\_\_-\_[P-23733at3-5]. Establishing new monthly limits for oxycodone and hydrocodone, McKesson pledged to ship orders exceeding those limits only after completing "a due diligence review."

JA\_\_-\_[P-23845at2-3]. Cardinal agreed to pay \$34 million, JA\_\_-\_[P-8873at34-47], and committed to ship orders flagged as suspicious only if investigation first cleared the suspicion, JA\_\_-\_\_[5/20/21Tr.61-63] (Mone).

Following the settlements, each Appellee adopted new policies and changed its methods for setting thresholds that flagged orders for further review. JA\_\_\_- \_\_\_, JA\_\_\_- \_\_\_, JA\_\_\_- \_\_\_[Op.39-40,47-50,56-57]; JA\_\_\_- \_\_\_, JA\_\_\_- \_\_\_\_ [5/17/21Tr.203-204, 216-218] (Mays) (ABDC); JA\_\_\_- \_\_\_ [5/20/21Tr.59-60] (Mone) (Cardinal); JA\_\_\_- \_\_\_ [5/25/21Tr.62-64] (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. JA [P-



JA\_\_\_[P-12743at3]; JA\_\_\_-\_\_[1/10/19Dep.Tr.201-204] (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." JA\_\_\_-\_[P-8873at28-30]; JA\_\_\_- \_\_\_[6/8/21Tr.89-90] (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." JA\_\_\_-\_[6/8/21Tr.90-94]. Cardinal settled, admitting that "its due diligence efforts" were "inadequate." JA\_\_\_[P-8873at17].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." JA\_\_[P-122at2]. 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. JA\_\_[P-42554].

<sup>&</sup>lt;sup>4</sup> 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. JA\_\_\_, JA\_\_\_[P-2037at3,5].

### 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. JA\_\_[4/18/19-30(b)(6)Dep.Tr.643] (Prevoznik); JA\_\_[6/7/21Tr.181] (Rannazzisi). Existing measures are insufficient to address these harms in Cabell/Huntington, but they can be addressed with additional measures. JA\_\_-, JA\_\_- \_\_[6/28/21Tr.32-36,110-111] (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. JA\_\_, JA\_\_-, JA\_\_, JA\_\_- \_\_\_[6/28/21Tr.8,18-19,99,129-145] (Alexander):

**Prevention.** Preventing new cases of opioid use disorder and further diversion is a key step. JA\_\_-\_\_, JA\_\_-\_\_[6/28/21Tr.36-38, 45-46] (Alexander). Prevention programs have proven effective at reducing opioid-related harms. JA\_\_[6/28/21Tr.46] (Alexander).

*Treatment.* Treating people with opioid use disorder reduces the risk of death, homelessness, unemployment, and other harms. JA\_\_\_\_, JA\_\_\_\_.

[6/28/21Tr.48-49,51-52] (Alexander). Treatment includes inpatient and outpatient models and connecting individuals with opioid use disorder to treatment.

JA\_\_\_\_\_.

[6/28/21Tr.47-52] (Alexander). Such measures can decrease mortality risks by as much as 50%. JA [6/28/21Tr.53] (Alexander).

**Recovery.** Drug courts, vocational training, and mental health counseling reduce opioid-related crime. JA\_\_\_, JA\_\_\_[6/28/21Tr.29,46] (Alexander). Dr. Alexander testified to their effectiveness: for example, 82% of Cabell drug-court graduates did not re-offend in the next 12 months. JA\_\_\_-\_[6/28/21Tr.63-64] (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." JA\_\_\_, JA\_\_\_-\_\_[6/28/21Tr.64,69-70] (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).

JA\_\_\_, JA\_\_\_-\_\_[6/29/21Tr.106,115-116] (Barrett).

### F. Procedural History

1. Huntington and Cabell filed these suits on January 19, 2017, and March 9, 2017, respectively. JA\_\_\_- [HuntingtonDoc.1]; JA\_\_\_- [CabellDoc.1]. 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); JA\_\_\_-\_ [HuntingtonDoc.45]; JA\_\_-\_ [CabellDoc.117].

On December 31, 2018, the MDL court designated the Cabell/Huntington suits as 
"Track Two" bellwether cases. JA\_\_-\_ [MDLDoc.1218]. 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

The "Track One" bellwether cases, brought by two Ohio counties against Appellees and opioid manufacturers, settled on the eve of trial in 2019. JA\_\_\_- [MDLDoc.2868]. 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. JA\_\_- [MDLDoc.2950at1-3].

Cabell/Huntington pursued only public nuisance claims against Appellees. JA\_\_- \_\_\_, JA\_\_- \_\_ [MDLDocs.2989,2990,3024]. The suits were remanded on January 14, 2020, JA\_\_ - \_ [MDLDoc.3079], and consolidated for trial on February 7, 2020, JA\_\_ - \_ [HuntingtonDoc.155].

Before trial, Appellants twice sought rulings from the district court confirming it would adhere to the MDL court's interpretation of distributors' CSA duties. JA\_\_\_-\_[HuntingtonDoc.189] (Mar. 3, 2020); JA\_\_\_
[HuntingtonDoc.1011] (Sept. 22, 2020). The court summarily denied the motions before trial, stating that the "reasons [would] be placed on the record

forthwith." JA\_\_\_-, JA\_\_\_[HuntingtonDocs.1247,1292]. It did not subsequently provide reasoning for either ruling.

2. Trial ran from May 3, 2021, to July 28, 2021.<sup>5</sup> 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. JA\_\_\_-\_[Op.19-23]; *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. JA\_\_\_\_\_\_\_ [Op.151-159]. 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." JA\_\_\_\_\_ [Op.153-154].

<sup>&</sup>lt;sup>5</sup> The month after trial, Appellees entered into a nationwide settlement (excluding West Virginia). JA\_\_\_-\_[MDLDoc.3823].

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. JA\_\_\_-\_[Op.159-161].

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.

JA\_\_[Op.178].

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," JA\_\_\_-\_\_, JA\_\_\_-\_\_[Op.178-179,182-183], and the remedy Appellants sought constituted damages, not abatement, JA\_\_\_[Op.181].

Cabell County and Huntington timely appealed. JA\_\_\_[HuntingtonDoc.1533].

#### **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. 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).

<sup>&</sup>lt;sup>6</sup> 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.<sup>7</sup> Many, like West Virginia's courts, grounded

<sup>&</sup>lt;sup>7</sup> 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).<sup>8</sup>

#### 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."

JA\_\_[Op.153]. 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

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.).

<sup>&</sup>lt;sup>8</sup> 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).

adopted; 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." JA [Op.154]. 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. JA - [Op.153-154] (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." JA\_\_\_[Op.153] (citing Restatement (Third) § 8 cmt. g). It

<sup>&</sup>lt;sup>9</sup> 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.

reasoned that 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

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)).

<sup>&</sup>lt;sup>11</sup> 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." JA\_\_[Op.154]. 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," JA\_\_\_[Op.155], 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]." JA\_\_[Op.155]. *See supra* pp. 38-40. And it ignored *Lemongello*, cited in both *Brooke County* and Appellants' briefing, JA\_\_\_
[HuntingtonDoc.1493PCOL¶25n.1110,26n.1112]. Instead, it cited out-of-state decisions reaching the opposite conclusion. JA\_\_--\_[Op.158-159] (citing *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099 (III. 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-ofstate 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. JA\_\_\_\_\_ [Op.155-158]; *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." JA\_\_\_\_\_\_\_[Op.155-156]. But policy preference cannot justify a

federal court sitting in diversity disregarding a consistent line of applicable statecourt 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." JA\_\_[Op.19]. More than 10% of Cabell/Huntington residents are or have been addicted to opioids, including more than 600 pregnant women in 2018. JA\_\_[Op.20]. 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. JA\_\_\_[Op.21]. The court found the opioid

epidemic increased crime rates. JA\_\_\_[Op.23]. 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*JA\_\_[Op.161], 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." JA\_\_[Op.166]. 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

\*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." JA\_\_\_[5/13/21Tr.195] (Zimmerman). Cardinal and McKesson admitted doing the same. JA\_\_\_-

\_\_\_[11/30/18Dep.Tr.451-452] (Reardon); JA\_\_\_-\_[5/25/21Tr.42-45] (Oriente); JA\_\_\_[7/31/18-30(b)(6)Dep.Tr.119] (Hartle).

Those actions violated Appellees' duties under the CSA and occurred repeatedly as Appellees shipped increasingly vast quantities of opioids to Cabell/Huntington pharmacies. JA\_\_\_[P-44711\_00029]. 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. JA\_\_\_[P-43225at1] (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. JA\_\_\_, JA\_\_\_[P-43225at7,13].

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. JA\_\_\_[P-877at2]; 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. JA\_\_\_\_\_ [P-43225at1-2] (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. JA\_\_\_[P-43225at1].

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.

JA\_\_[5/19/21Tr.145] (Perry); JA\_\_[P-16643at7]. 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.

JA\_\_-[HuntingtonDoc.1493PFOF¶148,150&nn.200-201]; JA\_\_[P-44766];

JA\_\_[P-43225at1]. 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." JA [P-16655at2].

Despite repeatedly raising SafeScript's ordering limits, ABDC still flagged 775 SafeScript orders as suspicious from 2007 to 2011.

JA\_\_\_[HuntingtonDoc.1493PFOF¶157]; JA\_\_\_[P-44765]. 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. JA\_\_[HuntingtonDoc.1493PFOF¶152]; JA\_\_[P-44765]; JA\_\_[P-44766]. ABDC's sales representative requested another threshold increase, citing SafeScript's "issues" with "exceeding the thresholds." JA\_\_[P-16651at3]. 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* JA\_\_[P-16642]. 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. JA\_\_[P-16642]; JA\_\_[P-432].

#### 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. JA\_\_\_-\_[P-43225at7-8]. 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. JA\_\_\_-\_[P-43225at11-12].

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. JA\_\_\_,

JA\_\_[HuntingtonDoc.1493PFOF¶232, 236]; JA\_\_--\_[P-42116]. Cardinal's file for CVS stores in Cabell/Huntington contained no indication that it ever reviewed a single suspicious order. JA\_\_-\_[P-42123].

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.

JA\_\_\_[HuntingtonDoc.1493PFOF¶232]; JA\_\_\_[5/21/21Tr.77] (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. JA\_\_\_[5/10/21Tr.135] (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. JA\_\_[HuntingtonDoc.1493PFOF¶229]; JA\_\_[P-44275] (rows 13, 47); JA\_\_\_-\_\_[P-42100].

#### c) McKesson

After McKesson's 2008 DEA settlement, its per-capita oxycodone shipments to Cabell/Huntington grew steadily. JA\_\_\_-\_[P-43225at13-14]. 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. JA\_\_-\_\_[5/10/21Tr.177-178] (McCann); JA\_\_- [P-44747at5-6].

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." JA\_\_\_\_\_[5/25/21Tr.141-142] (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 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.

JA\_\_[P-13712]; JA\_\_\_-\_[5/24/21Tr.31-34] (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." JA [P-13714].

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. JA\_\_\_[P-8873at5]; *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.

JA\_\_[6/15/21Tr.66] (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. JA\_\_, JA\_\_-\_[6/15/21Tr.123,134-136] (Keller). Before

losing their licenses, Drs. Webb and Fisher combined to prescribe more than 24 million dosage units of opioids in Cabell/Huntington. JA\_\_\_\_\_,

JA\_\_\_[6/15/21Tr.117-118, 120] (Keller); JA\_\_\_[HuntingtonDoc.1493PFOF¶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. JA\_\_\_[5/19/21Tr.131] (Perry); JA\_\_\_[P-16642]. Likewise, McKesson knew that Custom Script aggressively marketed to Dr. Fisher and included Dr. Webb among its top prescribers. JA\_\_\_[P-13714]; JA\_\_\_[P-13284at8]. More than 70% of Dr. Webb's prescriptions filled at Drug Emporium #1 were for opioids, JA\_\_\_[6/15/21Tr.130] (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. JA\_\_\_ - \_\_[6/15/21Tr.76-77] (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, JA\_\_-\_[Op.124-125], nor the changing standard of care for prescription opioids, JA\_\_-\_[Op.103-126], 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, JA\_\_[Op.32], 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." JA\_\_[Op.166]. 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." JA \_[Op.173].

JA\_\_[Op.169], pharmacies with "suspicious customers," JA\_\_-\_[Op.167-168], or pharmacies filling prescriptions from "doctors who may be intentionally or unintentionally violating medical standards," JA\_\_[Op.172].

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, JA\_\_\_
[HuntingtonDoc.189] (Mar. 3, 2020); JA\_\_\_- [HuntingtonDoc.1011] (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. JA\_\_\_-\_[Op.166-167] (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." JA\_\_\_[Op.171]. 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, JA\_\_\_[Op.166], 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. JA\_\_\_-\_[Op.83-85]. 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. JA\_\_\_-\_[Op.73-78]. 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.*, JA\_\_\_-\_[Op.81-83] (ABDC), JA\_\_\_\_\_[Op.86-88] (Cardinal), JA\_\_\_-\_[Op.89-90] (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. JA\_\_-\_\_, JA\_\_-\_\_, JA\_\_-\_\_[Op.83-86,87-88,90-91].

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." JA\_\_\_[Op.84]. 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.

JA\_\_\_[Op.85]. 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 credited Cardinal for visiting Medicine Shoppe in August 2012, JA\_\_\_[Op.88], 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. JA\_\_\_[P-28038at1]. Cardinal's post-visit report records that growth but no inquiry into the nature of SafeScript's business or the reasons for its closure. JA\_\_\_[CAH-WV-00770]. The report also records Medicine Shoppe's explanation that 15-mg and 30-mg oxycodone were area prescribers' preference. JA\_\_\_[Op.88]. The court thought this innocuous. *Id.* But former DEA official Rannazzisi testified that these were among the most-diverted opioids nationwide, JA\_\_\_[6/8/21Tr.25], and Cardinal's own training materials identified them as such, JA\_\_\_\_\_[5/21/21Tr.91-92] (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. JA\_\_\_\_\_[Op.90-91]. It cited a McKesson employee's testimony that "Rite Aid was conducting [its] due diligence," JA\_\_\_[Op.91];

JA\_\_\_[5/25/21Tr.141] (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." JA\_\_\_[Op.92]. 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. JA\_\_\_[Op.80] ("[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.

JA\_\_[P-42116]. 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., JA [Op.46] ("Reardon understood from those conversations that the DEA thought Cardinal Health was headed in the right direction"); JA - [Op.63-64]. And it described the (superficial) changes in Appellees' systems without acknowledging that DEA enforcement prompted those changes. JA - [Op.47-57]. 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. JA\_\_[Op.37]. 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. JA\_\_\_[P-42554at8]. It even ignored Appellees' admissions of unlawful conduct. In 2012, Cardinal admitted "that its due diligence efforts for some pharmacy customers" were "inadequate." JA\_\_\_[P-8873at17]. In 2017, McKesson admitted that "it did not identify or report to DEA certain orders" it should have detected as suspicious. JA\_\_\_[P-42554at3].

The settlements cannot be written off as inapplicable to West Virginia.

Appellees employ centralized policies nationwide. JA\_\_[5/12/21Tr.189]

(Zimmerman) (ABDC); JA\_\_[5/20/21Tr.53] (Mone) (Cardinal); JA\_\_
\_[5/24/21Tr.40-41] (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. JA\_\_
\_[P-8873at34-35]. McKesson's 2017 settlement resolved allegations concerning distribution centers in 11 States, including at the facility serving

Cabell/Huntington. JA\_\_- \_[P-42554at3-4]. 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."

JA\_\_\_\_\_[Op.159-160] (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," JA\_\_\_[Op.161] (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

<sup>&</sup>lt;sup>12</sup> The district court cited the correct standard in its summary-judgment ruling. JA\_\_\_[HuntingtonDoc.1294at5].

<sup>&</sup>lt;sup>13</sup> 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]." JA\_\_[Op.160]. In support, the court cited the testimony of DEA officials Rannazzisi and Prevoznik that 99% of doctors were prescribing opioids responsibly. JA\_\_-\_\_[Op.136-137]. 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." JA\_\_[Op.161].

That opinion ignores Rannazzisi's further testimony that "only a few untrained or unscrupulous physicians" can create "large pockets of addicts."

JA\_\_\_-\_[6/10/21Tr.84-85]; JA\_\_\_-\_[5/17/19-30(b)(6)Dep.Tr.982-983]

(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. JA\_\_[6/15/21Tr.61] (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.

<sup>&</sup>lt;sup>14</sup> 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. JA\_\_\_, JA\_\_\_[PrevoznikPlfsDesig; PrevoznikDefsDesig].

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; JA\_\_\_, JA\_\_\_, JA\_\_\_, JA\_\_\_, JA\_\_\_[P-44711at17,21,24,27,34]. The myriad harms from the massive oversupply of prescription opioids in Cabell/Huntington were undisputed. See JA - [Op.19-23]; 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

 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.*, JA\_\_\_[Op.131] ("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."); JA\_\_\_[Op.132] ("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 JA\_\_\_[6/14/21Tr.81] (Keyes). As the court found, overprescribing and overdispensing created demand, and Appellees met that demand with "almost perfect[]" precision. JA [Op.131].

#### 2. The district court failed to analyze foreseeability

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." JA\_\_\_[4/18/19-30(b)(6)Dep.Tr.642] (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.*, JA\_\_\_, JA\_\_\_[7/31/18-30(b)(6)Dep.Tr.268,364] (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."). <sup>15</sup>

<sup>&</sup>lt;sup>15</sup> 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. JA\_\_\_, JA\_\_\_\_\_[Op.148,181-183]. 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. JA\_\_\_[Op.178]. Second, it miscast Appellants' requested abatement remedy as damages. JA\_\_\_[Op.181].

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.<sup>16</sup>

## 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

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

<sup>&</sup>lt;sup>16</sup> 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." JA\_\_\_[Op.178] (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 JA\_\_\_\_\_[Op.179-181)] 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." JA - [Op.180-

181]. It erroneously limited abatement to "'seek[ing] court intervention to require one party to stop doing something that affects another.'" JA\_\_\_[Op.180] (quoting *Moats*, 859 S.E.2d at 389-90 (Armstead, J., concurring in part and dissenting in part)).<sup>17</sup>

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

<sup>&</sup>lt;sup>17</sup> 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. JA\_\_[Op.180] (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." JA [Op.183] (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. JA , JA [6/28/21Tr.48, 75] (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. JA\_\_\_[Op.181]. 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*. JA\_\_[Op.181] (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. JA\_\_[Op.181]. 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.

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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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| (s) David C. Frederick   |  |   |                         |  |
| Party Name City of Huntington & Cabell Cnty. Co  |  |   |                         |  |
| Dated: December 27, 2022   |  |   |                         |  |

## ATTACHMENT TO CERTIFICATE OF COMPLIANCE

- 1. The foregoing Page-Proof 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 17,634 words, excluding the parts of the Brief exempted by Federal Rule of Appellate Procedure 32(f).
- 2. The foregoing Page-Proof 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: December 27, 2022 By: /s/ David C. Frederick

David C. Frederick

**CERTIFICATE OF SERVICE** 

I hereby certify that, on December 27, 2022, I electronically filed the

foregoing Page-Proof 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