Trade and Opioid Diversion: Litigation Strategies and Case Studies
2026 Supplement

CHAPTER 7

The Drug Supply Chain Security Act: A Statutory Tool to Prevent Trade Diversion

B. The Statutory Requirements of the DSCSA

Page 61. Insert at the end of footnote 11:

On August 6, 2026, the FDA, pursuant to its authority under Section 582(a)(3) of the Food, Drug, and Cosmetic Act ("FD&C Act") to grant exemptions to small business dispensers, granted DSCSA exemptions from certain requirements under Section 582 of the FD&C Act until November 27, 2027, representing a one-year extension from November 27, 2026. FDA Doc. at 1. ("For the purpose of this exemption, the FDA continues to define a dispenser as a small business dispenser if the corporate entity that owns the dispenser has a total of 25 or fewer full-time employees licensed as pharmacists or qualified as pharmacy technicians." (A "dispenser" is defined in 21 U.S.C § 360eee (3).)) The FDA noted that significant progress had been made in "*enhanced drug distribution security requirements* … intended to facilitate interoperable, electronic tracing at the package level of products in the U.S. pharmaceutical distribution supply chain." *Id.* However, the FDA determined that the extension was "appropriate to maintain public health and help ensure continued patient access to certain prescription drugs in the United States." (FDA Doc. at 2.) (The document can be found in PDF form at https://www.fda.gov/media/194424/download?attachment/ ("FDA Doc."). *See also* "Exemptions under the Drug Supply Chain Security Act: FDA Grants Exemptions to Small Dispensers" at: https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/exemptions-under-drug-supply-chain-security-act.

CHAPTER 18

The Application of State Public Nuisance Law to Opioid Diversion Claims

F. 2022 MDL Opioid Diversion Trial Track Decisions

(i) Track Two Trial

Page 267. In line 3 of the main text, after the citation to City of Huntington v. AmerisourceBergen Drug Corp., *change the comma after the citation to a period and insert the case history below along with the following paragraphs:*

, *rev'd*, 157 F.4th 547, 2025 U.S. App. LEXIS 28199 (4th Cir. 2025).[52.1]

In this decision by the Fourth Circuit Court of Appeals (the "Appeals Court"), the Court reversed the federal District Court of West Virginia's (the "lower court" or "district court") decision dated July 4, 2022 (the "Decision").[52.1] The lower court in its Decision dismissed the public nuisance claims of the City of Huntington, West Virginia and the County Commission of Cabell County, West Virginia (collectively, the "plaintiffs") against defendant distributors of medical products: Amerisource-Bergen Drug Corporation, Cardinal Health, Inc. and McKesson Corporation (collectively, the "distributors").

The Appeals Court relied upon multiple grounds for reversal. Preliminarily, the Appeals Court reemphasized consistent with the lower court the devastating impact of the opioid epidemic in

[52.1] *See City of Huntington v. AmerisouceBergen Drug Corp.,* Civ. Action No. 3:17-01362 and 01665, 2022 U.S. Dist. LEXIS 117322 (S.D. W. Va. July 4, 2022).

West Virginia. *Id.* at 2-3. The Appeals Court then reviewed the core allegation of plaintiffs' claims against the distributors of public nuisance, *i.e.,*

> … the distributors' conduct of repeatedly shipping opioids to pharmacies in quantities that the distributors allegedly knew or should have known exceeded any legitimate uses for the drugs.

Id. at 4. The lower court had held that the "public nuisance claims failed as a matter of law because West Virginia common law does not permit such a claim based on the distribution of prescription drugs." *Id.*

The Appeals Court held to the contrary: "… under West Virginia common law, the conditions resulting from the over-distribution of opioids can constitute a public nuisance." *Id.* at 5.[52.2] More specifically, the Appeals Court found that "… the district court misconstrued the distributors' duties under the Controlled Substances Act, 21 U.S.C. §§ 801-904." *Id.* (the "Act") As discussed *infra*, the Appeals Court also rejected the lower court's holding that barred plaintiffs' recovery of money damages. *Id.*

In connection with the purpose of the Act, the Appeals Court noted that the rules under the Act seek "… to combat 'diversion,' which is the transfer of legally prescribed controlled substances for illicit purposes. 21 U.S.C. § 823(b)(1)." *Id.* at 7. Under these regulations,

> [o]pioid distributors, including defendants, have a broad obligation under the Act to maintain effective controls against diversion, which includes the exercise of due care to confirm that all pharmacy orders are legitimate before filling those orders. [citation omitted.]

Id. at 8. More specifically, distributors are required to implement systems designed "to identify 'suspicious' orders of controlled substances." [citation omitted.] *Id.* at 9-10. The regulations under the Act categorize as "suspicious" "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id.* at 10.

After reviewing the pertinent regulations under the Act, the Appeals Court determined, based on the lower court record below, that the distributor defendants attempted to work around the regulations "[b]y frequently increasing their pharmacy customers' threshold limits," thus avoiding "having to report many 'suspicious' orders to the DEA." *Id.* 13. This resulted "in the distribution of more and more opioids and in the distributors' ability to avoid the required reporting to the DEA." *Id.* at 15.

Because there was no ruling by the State Supreme Court of West Virginia (the "State Supreme Court") on whether the common law of public nuisance could apply to the sale and distribution of opioids, the lower court had predicted that the State Supreme Court would decline to extend the application of the common law of public nuisance to such sales. *Id.* at 19. The lower court also

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[52.2] In its decision, the Appeals Court reviewed the elements for a claim of public nuisance under West Virginia common law:

> …. A plaintiff must show that the defendants unreasonably interfered with a public right, that the defendants' actions were a proximate cause of the plaintiffs' injury, and that there is a remedy that will abate the nuisance. [citation omitted.]

Id. at 19. *See also id.* at 36.

found that there was no evidence that the distributor defendants "supplied opioids to pharmacies conducting illicit activities," therefore the lower court held that plaintiffs "failed to show that the distributors' conduct was a proximate cause of the harm alleged." *Id.* at 22. The lower court also found that based on the conduct of the doctors and the pharmacies there were,

> … intervening causes that broke the chain of causation between the distributors' conduct in shipping prescription opioids to their pharmacy customers and the harm alleged by the local governments. [citation omitted.]

Id. at 23.

In reviewing the lower court's decision, the Appeals Court noted that in response to the certified question put to the State Supreme Court, the State Supreme Court declined to answer the question but stated that "whether a nuisance exists is a factual issue." *Id.* at 26.

In response to whether a factual issue existed concerning a public nuisance in the record at bar, the Appeals Court observed that public nuisance under West Virginia law is "broadly defined." Public nuisance is,

> … "is an act or condition that unlawfully operates to hurt or inconvenience an indefinite number of persons." [citations omitted.][52.3]

Id. at 27. Under this standard, the Appeals Court rejected the lower court's holding that "product-based harm cannot constitute a public nuisance." *Id.* at 30. Instead, the Appeals Court held that,

> … under West Virginia law, an unreasonable interference with a right common to the general public resulting from the distribution of opioids may qualify as a public nuisance when the evidence establishes that distribution of this product unreasonably "operates to hurt or inconvenience an indefinite number of persons. [citation omitted.]

Id. at 30.

Based on the foregoing, the Appeals Court found that the lower court adopted an impermissibly narrow interpretation of the distributors' duties under the Act. Specifically, the Appeals Court found that,

> The Act directs that distributors develop a system to examine for indicia of diversion the *individual orders* of controlled substances placed by customer pharmacies. [citation omitted.]

Id. at 41. The Appeals Court emphasized that if the lower court's standard were adopted "the Act's purpose to prevent diversion of controlled substances would be substantially undermined." *Id.* at

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[52.3] The Appeals Court distinguished the holding of the Supreme Court of Oklahoma in *State ex rel. Hunter v. Johnson & Johnson,* 499 P. 3d 719 (Okla. 2021), (see case analysis in this chapter on p. 263) by noting that the Oklahoma Supreme Court was "required to interpret Oklahoma's public nuisance statutes" not "an issue of West Virginia common law." *Id.* at 34.

42. Accordingly, the Appeals Court vacated the district court's "finding that the local governments failed to prove that the distributors unreasonably interfered with a public right …" *Id.* at 43.

The Appeals Court also rejected the lower court's analysis of proximate causation, based on "[t]he district court's failure to consider all the duties imposed on the distributors under the Act and corresponding regulations … ." *Id.* at 44. In this connection, the Appeals Court emphasized that, "[t]here may be more than one proximate cause of an injury arising from more than one act by more than one person." [citation omitted.] *Id.* The Appeals Court found that the distributors were obligated to establish, "a system to disclose and to inform the DEA of **individual**, 'suspicious orders.' 21 C.F.R. § 1301.74(b)." [Emphasis added.] *Id.* at 45. Based on the failure of the distributors to do this along with their self-serving pattern of "threshold limit increases" on the quantities of opioids distributed, the Court on remand directed the district court to address in this factual context its finding on proximate cause. *Id.* at 48.

On the issue of "intervening cause," addressed by the lower court in the Decision, the Appeals Court noted that,

> [u]nder West Virginia law, care must be taken not to label a downstream cause of an injury as an intervening cause breaking the chain of causation if that cause was foreseeable by the upstream actor.

Id. at 51. Accordingly, "a trial court must examine the ongoing, repeated nature, if any, of the defendant's acts and the other acts in the chain of causation. [citation omitted.]" In light of the record below, the Appeals Court vacated the district court's holding that "the distributors' acts [were] too remote to be a proximate cause of the alleged harm." *Id.* at 53.

Last, on the issue of abatement, the Appeals Court also took issue with the district court's limitation of abatement "only to eliminate a defendant's wrongful conduct … is not appropriate to address harmful conditions resulting from such conduct," *i.e.,* the payment of money damages. [citation omitted.] *Id.* at 54-55. To the contrary, the Appeals Court concluded that,

> … West Virginia law permits abatement of a public nuisance to include a requirement that a defendant pay money to fund efforts to eliminate the resulting harm to the public.… the goal of abatement in a public nuisance case is to repair a public right that has been damaged by a defendant. [citation omitted.] Courts have broad powers to effect equitable relief.

Id. at 57.

Based on all of the above, the Appeals Court vacated the district court's judgment and remanded "the case for further proceedings consistent with the principles expressed in this opinion." *Id.* at 58-59.

APPENDIX VI

Trade and Opioid Diversion Cases Listed

B. Opioid Diversion Cases

Page 479, insert at the end of citation 10:

, *rev'd*, 157 F.4th 547, 2025 U.S. App. LEXIS 28199 (4th Cir. 2025).

TABLE OF CASES

Page 488, add the following to the end of City of Huntington citation and before the page references:

rev'd, 157 F.4th 547, 2025 U.S. App. LEXIS 28199 (4th Cir. 2025).