IN THE SUPREME COURT FOR
THE STATE OF TENNESSEE

JARED EFFLER ET AL.,	)	
	)	Tennessee Supreme Court
Plaintiffs/Appellees,	)	No. E2018-01994-SC-R11-CV
	)	
v.	)	On Appeal by Permission from
	)	the Court of Appeals
PURDUE PHARMA L.P. ET AL.,	)	
	)	Circuit Court for Campbell
Defendants/Appellants.	)	County, No. 16596
	)	

AMICI CURIAE BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, AND AMERICAN TORT REFORM ASSOCIATION IN SUPPORT OF DEFENDANTS/APPELLANTS

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QUESTIONS PRESENTED

(1) Does § 29-38-116, which allows district attorneys general to "represent" local governments in DDLA suits, authorize district attorneys general to bring claims as plaintiffs—without consent from those local governments?

(2) Does § 29-38-105(a), which provides for liability against a "person who knowingly participates in the illegal drug market," encompass a pharmaceutical company's lawful sale of legal prescription medications to legal, state-licensed distributors because a portion of those medications are ultimately diverted into illegal drug markets by the illegal acts of third parties?

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INTEREST OF *AMICI CURIAE*[1]

Amici are organizations whose members include manufacturers of pharmaceutical and other products that are highly regulated, lawfully manufactured, and sold through licensed distribution channels. Some of these products may be diverted to illegal markets, and *amici* fully support the District Attorneys' efforts to pursue criminals engaging in any such illicit market. This is not such a case. Here, District Attorneys, with unchecked power, are attempting to misuse the Tennessee Drug Dealer Liability Act, which is intended solely to aid their fight against local drug crime. *Amici* are concerned that such actions will undermine state and federal laws designed to regulate the prescription drug market and harm the ability of patients to receive needed medications.

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a nonprofit association representing the country's leading research-based pharmaceutical and biotechnology companies.[2] PhRMA's mission is to advocate for public policies encouraging the discovery of life-saving and life-enhancing new medicines. PhRMA's members are devoted to discovering and developing medicines that enable patients to

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[1] No counsel for any party authored this brief in whole or in part, and no person or entity other than *amici*, their members, or their counsel made a monetary contribution intended to fund its preparation or submission.

[2] A list of PhRMA members is at http://www.phrma.org/about/members.

live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $900 billion in the search for new treatments and cures, including $79.6 billion in 2018 alone. PhRMA remains deeply committed to working collectively to prevent the misuse, abuse, and diversion of prescription drugs.[3]

The American Tort Reform Association ("ATRA") is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled their resources to promote the goal of ensuring fairness, balance, and predictability in civil litigation. ATRA has filed *amicus curiae* briefs in cases before state and federal courts that have addressed important liability issues, including attempts as here to create unprincipled industry-wide liability through misusing state and federal laws never intended for those purposes.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

The Court of Appeals ruling below authorizes a radical departure from the statutory authority of the District Attorney and existing

[3] https://www.phrma.org/en/Advocacy/Safety/Prescription-Misuse-Abuse. In addition, PhRMA has partnered with the Rx Abuse Leadership Initiative (RALI), which convenes national, state, and community leaders to exchange best practices and provide resources that help prevent misuse of prescription medicines. RALI works alongside local and national partners and leaders to engage in education and outreach campaigns to help promote safe disposal efforts, share information about the importance of prevention, and highlight local recovery resources and leadership. *See* https://www.raliusa.org.

Tennessee law in ways that will undermine the vital, highly-regulated market for prescription medicines. Here, the District Attorneys seek to use Tennessee's Drug Dealer Liability Act ("DDLA"), enacted some fifteen years ago in the fight against local street drug crime, to penalize prescription medicine manufacturers because some pain medications they sell through highly-regulated distribution channels were diverted to illicit markets long after the FDA-approved medicines left the manufacturers' control. The allegations rest entirely on abstract, speculative assertions, as the District Attorneys have not identified any order shipped from any manufacturer that was illegal or even improper.

This lawsuit represents an unwise expansion of a disturbing trend of novel, highly-speculative litigation and it should be stopped. As detailed below, contingency fee lawyers are competing to recruit local public officials with pre-packaged, generic lawsuits. *See For Profit or for the Public? The Rise in Contingency-Fee Lawsuits by Local Governments*, Am. Tort Reform Ass'n (2019).[4] As here, the lawsuits often seek to subject businesses to liability over societal problems—regardless of fault, the cause of the harm, whether the elements of a statute or tort are met, or even if the liability will actually address the

[4]https://agsunshine.com/for-profit-or-for-the-public-the-rise-in-contingency-fee-lawsuits-by-local-governments/

issue.[5] To circumvent such regulatory, enforcement, and liability rules, the lawsuits often seek to leverage statutes and, in other cases tort claims, for situations never intended when developed. Further, by recruiting multiple public officials to file claims, the lawyers are trying to leverage the government's ability to file high-stakes lawsuits with lower burdens of proof into lucrative settlements.

The instant action by the District Attorneys is simply a bridge too far. *Amici* fully appreciate the opioid epidemic in Tennessee and in other states must be addressed, but there is a substantial dissonance between the allegations against Defendants and the DDLA's purpose, terms, and remedies. First, the DDLA does not give District Attorneys the authority to file DDLA claims on their own volition; they can file DDLA claims only for government clients. In some claims here, the governments they purport to represent already filed separate lawsuits with separate contingency fee counsel seeking the same costs associated with opioid abuse. This Court should not allow District Attorneys to pursue unauthorized litigation without direction from the governments they purport to represent. District Attorneys are creations of statutory authority and have no authority to bring these cases on their own.

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[5] Richard Scruggs, a renowned former plaintiffs' attorney, explained the tactic of pursuing theories that "do not hinge on fault," but seek relief based on the fact these entities made money selling opioids. *See* Richard Scruggs, *Are Opioids the New Tobacco?*, Law360 (Sept. 18, 2017).

Second, Defendants include prescription medicine manufacturers selling highly beneficial pain medication based on designs and labeling approved by the Federal Food & Drug Administration ("FDA"). There are no allegations Defendants ever engaged in the criminal opioid drug market, which is the DDLA's sole province. They and the distributors to whom they sell the medications are registered with the state and federal governments to sell these medicines, the medicines must be dispensed at licensed pharmacies, and each person must obtain a prescription from a licensed physician to purchase them. Further, there are entire bodies of regulatory regimes, statutes and tort claims that set the rights, responsibilities and remedies for each activity raised in this suit. The DDLA is not one of them, nor is it needed to fill any gaps. If Defendants who manufacture the medications stopped shipping these medicines in Tennessee, which could be the effect of this action, many Tennesseans would be deprived of needed pain relief, such as patients receiving palliative care, living in hospices, or experiencing cancer pain.

Amici respectfully urge the Court to reverse the ruling below to ensure Tennessee courts are not drawn into making national public policy decisions over prescription medicines through plaintiffs and statutes never intended for this purpose. It should apply the DDLA as written and intended, not as the District Attorneys seek to misapply it.

ARGUMENT

I. THE LEGISLATURE DID NOT GIVE DISTRICT ATTORNEYS STANDING TO FILE THESE UNAUTHORIZED DDLA CLAIMS

In Tennessee, the District Attorneys are creations of their statutory authority, which is generally limited to prosecuting "violations of the state criminal statutes" and other activities related to enforcing criminal law. Tenn. Code Ann. § 8-7-103(1)-(7). When the General Assembly enacted the DDLA, it authorized only individuals and entities that suffered losses from the illegal drug trade to sue—not District Attorneys. *See* Tenn. Code Ann. § 29-38-103, 106. Individuals with a right of action under the DDLA are limited to the parent, legal guardian, child, spouse, or sibling of an illegal drug user, a person exposed to an illegal drug in utero, the illegal drug user's employer, and a person injured from the willful, reckless or negligent actions of an illegal drug user. *See* Tenn. Code Ann. § 29-38-106(a). The only government entities authorized to bring a DDLA action are those that "fund a drug treatment program" used by the illegal drug user. *Id.* In these actions, the government entity "may" choose the District Attorney to "represent" it in the action. Tenn. Code Ann. § 29-38-116(a).

The General Assembly's decision to allow government entities the option to retain a District Attorney as counsel in a DDLA case makes sense. Municipal attorneys generally act as legal advisors and defenders in suits brought against their governments and likely would not have the expertise in the criminal drug trafficking laws and activities that

form the bases for DDLA claims. *See* Sara L. Swain, *Plaintiff Cities*, 71:4 Vanderbilt L. Rev. 1227, 1229 (2018). Also, the District Attorneys may be pursuing criminal sanctions for the drug trafficking crimes at the center of the DDLA claims, thereby creating prosecutorial efficiencies. However, when a District Attorney has not been retained by an authorized government entity to file a DDLA claim, as is the situation at bar, the District Attorney has no standing to file the claim. Here, the District Attorneys are actually competing with lawsuits three of their would-be clients—Fentress, Scott and Campbell Counties—have filed seeking recoveries for the same funds for the same alleged acts.[6]

The predicament caused by overlapping government litigation, even when each entity arguably has standing to file the claims, has already become a controversial issue in opioid litigation. States, counties, and municipalities—often for the same population—have filed lawsuits against manufacturers, distributors, and pharmacies seeking money for themselves and their residents for wide-ranging harms they attribute to opioid abuse. *See* Victor E. Schwartz, Phil Goldberg & Christopher E. Appel, *Deep Pocket Jurisprudence: Where Tort Law Should Draw the Line*, 70 Okla. L. Rev. 359, 382-387 (2018) (discussing

[6] *See Fentress Cty. v. AmerisourceBergen Drug Corp.*, No. 2:18-cv-00028 (M.D. Tenn. Mar. 27, 2018); *Scott Cty. v. Purdue Pharma L.P.*, No. 3:18-cv-00083 (E.D. Tenn. Mar. 2, 2018); *Campbell Cty. v. Amerisource-Bergen Drug Corp.*, No. 3:18-cv-00006 (E.D. Tenn. Jan. 4, 2018).

the origins and scope of government opioid lawsuits). This litigation, which is estimated to now include more than 2,000 locality lawsuits, even without the District Attorney cases, already pits the local governments against the state attorneys general in a race to obtain a recovery for a county or municipality before the state obtains a recovery that would be shared among all of the state's inhabitants.[7]

Ohio Attorney General David Yost expressed this concern when he sought dismissal of lawsuits by local municipalities alleging harm related to opioid use. *See* Pet. for Writ of Mandamus of State of Ohio, *In re: State of Ohio*, No. 19-3827 (6th Cir. Aug. 30, 2019). His petition was supported by 14 state attorneys general, including a rare combination of state attorneys general whose affiliations ran the gamut of liberal to conservative politics. *See* Brief of *Amici Curiae* States of Michigan, Alaska, Arizona, Connecticut, Hawaii, Indiana, Kansas, Montana, Nebraska, North Dakota, South Dakota, Tennessee, Texas, and District of Columbia in Support of the State of Ohio's Petition for Writ of Mandamus*, In re: State of Ohio*, No. 19-3827 (6th Cir. Sept. 6, 2019), *at* 2019 WL 4390968. These attorneys general recognized that lo cal

[7] The U.S. Chamber Institute for Legal Reform has explained that each government leader may be motivated to make up a budget shortfall, fill a perceived gap in enforcement, or "enhance their own public profiles" while seeing "little risk or cost" to the suit. *Mitigating Municipality Litigation*, U.S. Chamber Inst. for Legal Reform (Mar. 2019), at 1.

government suits like this one seek to usurp the authority of the state attorneys general, which, in turn, "undermine" and "impede" any statewide resolution. *Id.* at *14. Further, this recent wave of overlapping lawsuits creates a "structural issue that could severely undermine the authority" of government entities charged to protect its populace. Victor Schwartz & Markus Green, *'Locality Lawsuits' Threaten the Civil Justice System*, Law360, Dec. 17, 2019.

As the attorneys general recognized, there are several adverse consequences with overlapping litigation applicable to the case at bar. First, it incentivizes every government actor, including the District Attorneys here, to sue so as not to "miss out" on the ability to get a piece of the action. Second, which is of significant concern here, it prevents the political leaders from determining what is in the collective best interests of their entire citizenry. Third, it clogs a state's courts and exhausts limited judicial resources over the same issues. Fourth, it can trample on the parties' rights, as some of the lawsuits like the one here stretch the law beyond traditional recognition in an effort to join the fray. Fifth, it may result in conflicting outcomes, as judges in different parts of a state may reach widely different conclusions on the merits of what are essentially the same claims. Finally, settlements that address the plaintiffs' alleged harms while providing defendants with finality are much more difficult to achieve.

These concerns are magnified here, where there is no political accountability or even guiding principles from the District Attorneys' "clients" or their citizenry. In this case, seven District Attorneys assert they are suing for more than 100 counties and municipalities, and the same law firm is representing eight other District Attorneys in materially identical DDLA lawsuits for 50 other Tennessee counties and municipalities.[8] Some localities that have not brought their own suits may have decided these lawsuits are inappropriate for them and their constituents. As courts in other states have held in such opioid cases, "it might be tempting to wink at this whole thing and add pressure on parties who are presumed to have lots of money and moral responsibility. . . . But it's bad law." *City of New Haven v. Purdue Pharma, L.P.*, 2019 WL 423990 (Conn. Super. Ct., Jan. 8, 2019); *see also North Dakota ex rel. Stenehjem v. Purdue Pharma L.P.*, 2019 WL 2245743, at *11 (N.D. Dist. Ct. May 10, 2019) (finding manufacturers do not control how opioids are prescribed or used).

Instead of looking to their would-be clients, as the law requires, these District Attorneys are taking direction from private, profit-motivated contingency fee lawyers. Opioid litigation, in particular, has

[8] *See Staubus v. Purdue Pharma L.P.*, No. C-41916 (Tenn. Cir. Ct. Sullivan Cty. Feb. 15, 2018); *Dunaway v. Purdue Pharma, L.P.*, No. CC1-2018-cv-6347 (Tenn. Cir. Ct. Cumberland Cty. Jan. 10, 2018).

been marred by District Attorneys and other leaders being inundated with pitches from law firms pressuring them to file claims in a "race to the courthouse." Marissa Evans, *In 'Race to the Courthouse,' Lawyers Urge Texas Counties to Sue Over Opioids*," Texas Trib., Mar. 13, 2018. Private lawyers here seek to leverage the DDLA to aggregate claims without class or mass action safeguards and sue for product-based harms without proving defect or affording product liability defenses. Also, by cloaking claims in the State's police power, they are seeking to take advantage of the belief that participation of District Attorneys brings credibility to a lawsuit. *See* Walter Olson, *Tort Travesty*, Wall St. J., May 18, 2007 ("Even aside from the chance to rack up stupendous fees, they confer a mantle of legitimacy and state endorsement on lawsuit crusades whose merits might otherwise appear chancy.").

Therefore, in these cases, contingency fees are not facilitating access to courts for those who cannot afford counsel, but spurring speculative and duplicative lawsuits that otherwise would not make sense, financially or legally, to bring. *See* Joe Palazzolo, *More Cities Suit up for Legal Action*, Wall St. J., May 3, 2016. "These contracts also create the potential for outrageous windfalls or even outright corruption for political supporters of the officials who negotiated the contracts." William H. Pryor, Jr., *Government "Regulation by Litigation" Must Be Terminated*, Legal Backgrounder (Wash. Legal Found. May 18, 2001), at 4. Removing any such appearance for financial impropriety is the

reason the District Attorneys themselves are prohibited from engaging in the private practice of law. *See* Tenn. Code Ann. § 8-7-104. Prosecutors must retain their impartial judgment, not pursue litigation—or have litigation pursued in their names—intended to drive profit. *See* Martin H. Redish, *Private Contingent Fee Lawyers and Public Power: Constitutional and Political Implications*, 18 Sup. Ct. Econ. Rev. 77, 103 (2010) (stating that for-profit motive distorts claims where the public interest is furthered "not by continued litigation, not by gaining damage awards, but either by cessation of litigation or accepting of a form of non-monetary relief").

For these reasons, the Court should find the District Attorneys do not have standing to bring this DDLA case. The Legislature did not provide District Attorneys authority to file them on their own volition, and these claims would not be brought without a profit motive.

II. THE DDLA IMPOSES LIABILITY ON CRIMINAL DRUG DEALERS, NOT MANUFACTURERS SELLING LAWFUL MEDICINES IN THE LAWFUL DISTRIBUTION CHAIN

A. The DDLA's Purpose, Terms, and Remedies Were Intended to Target Only Dealers and Users in the Criminal Drug Market

Nationally, the DDLA was a response to the "war on drugs" over crack cocaine use in the 1980s and 1990s. In 1992, the American Legislative Exchange Council adopted model legislation supporting the DDLA's reforms, leading several states to adopt the DDLA, including Tennessee in 2005. *See* S.B. 222, 104th Gen. Assemb., Reg. Sess. (Tenn.

2005). The DDLA's purpose was to give family members, employers and governments that spent money on a person's criminal drug use a right of action they otherwise did not have to recoup these costs from criminal drug dealers. *See Schafer v. Shopko Stores, Inc.*, 741 N.W.2d 758, 761 (S.D. 2007) (finding "common law effectively barred family members of drug users from filing suits against illegal drug dealers"). It did so by relaxing longstanding rules fundamental to traditional liability law. The DDLA never intended to impose these relaxed standards on *non-criminal* conduct. *See id.* at 763 ("To interpret and apply the [DDLA] . . . would make [defendant] liable for a legal act. Such an interpretation is strained and would cause an absurd result.").

The contingency fee counsel who pitched this litigation to the District Attorneys published a revealing discussion on the use of the DDLA in this case. *See* Tricia Herzfeld, Gerald Stranch & Zack Buck, *The Opioid Epidemic: Regulation Responsibility and Remedies*, 13 Tenn. J.L. & Pol'y 317 (2018). The attorneys fully acknowledged this law was always intended for cocaine and other illegal drugs; it gave people who spent money treating a user of illegal drugs the ability to "go after the higher-level drug dealer chain" beyond the "person at the drug house." *Id.* at 320. The DDLA's liability shortcuts, particularly eliminating causation, made it easy to subject that drug dealer to liability. The attorneys explained that these shortcuts made the DDLA attractive to them here: "One of them we really like is, there's not that

level of causation. . . . that's why we chose that cause of action" and recruited the District Attorneys. *Id.* at 321. They admittedly were never seeking to enforce the DDLA against drug dealers, but deliberately using the DDLA to circumvent the liability laws that apply in a case against prescription drug manufacturers.

It is abundantly clear that the DDLA's terms and remedies do not fit the lawful prescription drug market. The DDLA targets sellers of "illegal drugs" and those who "illegally profit" from the illicit drug market. Tenn. Code Ann. § 29-38-102. When Defendants sold the FDA-approved medications at issue here, they were engaged solely in legal sales of legal drugs in a highly regulated distribution chain. The District Attorneys' allegations are only that some legal medicines were diverted by others after they left the manufacturers' control into an illegal drug market. A physician may have improperly prescribed a medication, a consumer sold a lawfully obtained medicine, or a person stole lawful medicine from a friend or family member. *See Policy Impact: Prescription Painkiller Overdoses*, Nat'l Ctr. for Injury Prevention and Control (Nov. 2011) (finding seventy percent of the people who abuse prescription pain relievers obtain them from friends or relatives who purchased them legally).[9] The manufacturer has no visibility at the time of sale which of these medications will end up in

lawful, beneficial uses and which will be diverted to an illegal market. To the extent the DDLA can apply to the opioid crisis, it is only to those who deal drugs *during or after* its diversion to the illegal drug market.

To this end, the people the DDLA seeks to punish are "those persons in the community who have joined the illegal drug market," not national manufacturers of products explicitly approved by federal regulators and sold pursuant to state and federal licenses. Tenn. Code Ann. § 29-38-102. The law expressly states that its focus is on the small drug dealer who "markets illegal drugs at the workplace, who encourages friends to become users, among others, [and] is likely to decide that the added cost of entering the market is not worth the benefit." Tenn. Code Ann. § 29-38-103(3)-(4). The plaintiff can pursue others up the chain in the illegal drug trade, but again, not those who engaged in the medicine's lawful commerce *before* its diversion. Otherwise, any entity or person in the chain of commerce, without a limiting principle, could be targeted with DDLA litigation. And, as Defendants point out, the DDLA could be applied to the unlawful use of other products or other lawful medicines. This case is the proverbial camel's nose under the tent of broader DDLA abuse.

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[9] https://www.cdc.gov/drugoverdose/pdf/PolicyImpact-PrescriptionPainkillerOD-a.pdf.

The reason the DDLA eliminates traditional causation requirements, setting aside whether that treatment of causation is constitutional, is to give plaintiffs the ability to expose the illicit chain of distribution. *See* Tenn. Code Ann. § 29-38-103(8) (stating the intent is for the "illegal drug market in a community [to] ultimately be fully revealed"). The problem the legislation seeks to overcome is that users of illicit drugs often do not know the identity of drug dealers up the chain, and those dealers generally do not have records of who uses their drugs after passing through middlemen. *See* Tenn. Code Ann. § 29-38-103(9). These dynamics are inapposite to the prescription drug market, which is highly-regulated with detailed record-keeping. Indeed, in the few other instances where causation—which is the bedrock principle for all liability—has been circumscribed, the goal has not been to create a Cuisinart of industry-wide liability, as sought here, but to reverse the burden of proof under the belief that a defendant is better positioned to exonerate itself. *See City of St. Louis v. Benjamin Moore & Co.*, 226 S.W.3d 110, 115 (Mo. 2007) (rejecting such theories as "unfair, unworkable . . . as well as unsound public policy" (internal quotation and citations omitted)). Here, manufacturers are not better positioned to alter anyone's illegal drug dealing or use. Thus, the rationale for the DDLA's legal shortcuts for pursuing criminals does not apply here.

B. State and Federal Regulatory Regimes for Prescription Drugs Balance Patient Needs, Not Give Rise to DDLA Liability

In contrast to the criminal drug market for which the DDLA was enacted, manufacturers of prescription medicines are selling FDA-approved medicines to licensed distributors, all of whom are subject to a regulatory structure that is highly detailed and nuanced. *See* 21 U.S.C. § 821 *et seq.*; Tenn. Code Ann. § 53-11-301 *et seq.* In addition to a lengthy, rigorous approval process, the FDA requires labeling to include information on the safe and effective use of a drug so practitioners can prescribe drugs in ways that maximize effectiveness and minimize risk. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) (codified at 21 C.F.R. §§ 201, 314, and 601). With respect to opioids, federal and state regulators are particularly aware of the need to continually balance the ability of deserving patients to access pain relief with making it more difficult for medicines to be diverted for unlawful uses. *See*, *e.g.*, Tenn. Code Ann. § 53-11-302(a) (providing registrations only to entities with "effective controls against diversion of controlled substances"); 21 C.F.R. § 1303.11(a) (establishing quotas for controlled substances). Further, the FDA has worked on collaborative risk management plans based on improved surveillance, better education, and stronger warnings calling attention to opioid diversion. *See* Opioid Medications, U.S. Food & Drug Admin. ("One of the highest

priorities of the FDA is advancing efforts to address the crisis of misuse and abuse of opioid drugs.").[10]

The Court of Appeals' ruling to allow District Attorneys to use the blunt tool of the DDLA to supplant or second-guess these federal and state policy decisions will undermine the pharmaceutical regulatory regime. This regime already has enforcement mechanisms tailored to each violation, including those the District Attorneys allege as an excuse to invoke the DDLA here. Specifically, the Controlled Substance Act ("CSA") establishes surveillance and reporting requirements, including its own enforcement mechanisms. *See* 21 U.S.C. § 821 *et seq*. Its reporting standards are purposefully vague and flexible, for example, requiring companies to report "suspicious" orders or orders of "unusual" size or frequency. 21 C.F.R. 1301.74(b). The Drug Enforcement Agency "cannot provide more specific suspicious orders guidance because the variables that indicate a suspicious order differ among distributors and their customers." *Prescription Drugs: More DEA Information About Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access*, Food Drug Cosm. L. Rep. (CCH) ¶ 400,076, at 28-29, 67 (June 25, 2016).

Courts have found these and other CSA terms are not sufficiently defined to be standards for liability. *See*, *e.g.*, *Talley v. Danek Med.,*

[10] https://www.fda.gov/drugs/information-drug-class/opioid-medications

Inc., 179 F.3d 154, 159 (4th Cir. 1999) (stating requirements do not "articulate a standard of care but rather requires only . . . a report for the administration of a more general underlying standard"). Congress did not create a right of action for private litigants, local governments, or District Attorneys to sue companies for allegedly violating the CSA or other FDA regulations. *See Astra USA Inc. v. Santa Clara Cty.*, 563 U.S. 110, 117-18 (2011) (explaining no right of action exists for enforcing statutes or regulations unless expressly created by Congress). Violating the CSA may give rise only to a government enforcement action by the relevant regulators. Therefore, there is no basis for converting the DDLA into a tool for creating liability for all opioid addiction on the basis of alleged CSA violations.

The District Attorneys should not be allowed to circumvent regulatory and liability rules by deliberately misapplying the DDLA to create a backdoor right of action. There is a sharp distinction between statutory or regulatory compliance matters and drug dealer liability. This case finds no support in the DDLA and does not resemble any claim Congress had in mind when enacting the Food Drug & Cosmetic Act and CSA, or the Tennessee General Assembly with the DDLA. The obligation to pay for injuries caused by the diversion of lawful drugs into the criminal drug market should remain with criminal wrongdoers. The cost of criminal wrongdoer misdeeds should not be shifted to others, even if those others are believed to have deeper pockets.

CONCLUSION

For these reasons, the Court should reverse and remand with instructions to dismiss this DDLA action against the manufacturer defendants in its entirety.

Respectfully submitted,

/s/ Elizabeth G. Hart

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CERTIFICATE OF COMPLIANCE

I certify that the foregoing complies with the requirements set forth in Section 3, Rule 3.02 of Tennessee Supreme Court Rule 46. Excluding the Certificate of Compliance and Certificate of Service, the foregoing contains 4,166 words.

/s/ Elizabeth G. Hart
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CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing was served through the Court's e-filing system and/or through regular U.S. mail upon the following:

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This 27th day of May, 2020.

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