



## **Your Generics & Biosimilars Industry**

### **Association for Accessible Medicines Testimony in Opposition to LD 1117 Before the Committee on Health Coverage, Insurance, and Financial Services**

The Association for Accessible Medicines (AAM) is the leading trade association for manufacturers of generic and biosimilar prescription medicines. AAM's core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved generic and biosimilar medicines.

**AAM respectfully opposes LD 1117 as drafted.** LD 1117 seeks to outlaw the imposition of “an excessive price increase, whether directly through a wholesale distributor, pharmacy or similar intermediary or intermediaries, on the sale of any generic or off-patent prescription drug sold, dispensed or delivered to any consumer in this State.” AAM recognizes the vital importance to all Mainers of maintaining access to affordable generic medications. But **LD 1117 is unconstitutional.** By applying in-state consequences to out-of-state prices, the bill's provisions regulate prices charged outside of Maine, in violation of the Commerce Clause, U.S. Const. art. I, § 8, cl. 3.

## **RELEVANT BACKGROUND**

Under LD 1117, “a prescription drug manufacturer may not impose an excessive price increase, whether directly or through [an] ... intermediary ... on the sale of any generic or off-patent prescription drug sold, dispensed, or delivered to any consumer in the state.” § 2036(1). A price increase is defined as “excessive” when it is greater than either 15% of the previous year’s price, 40% of the three-year-average price, or \$30, whichever is lower. § 2036(2). Liability is expressly limited to manufacturers: “it is not a violation of this section for a wholesale distributor or pharmacy to increase the price of a [drug] if the price increase is directly attributable to additional costs for the drug imposed ... by the manufacturer.” § 2306(3). The Attorney General is empowered under the bill not only to request an injunction to conform prices to this cap, but also to seek a court order to “require that all revenues generated in violation of this section be remitted to the State” and “impose a civil penalty of up to \$10,000 per day for each violation of this section.” And once a manufacturer’s drugs are sold in the state, they cannot be withdrawn: “[I]t is a violation of this chapter for any prescription drug manufacturer ... to withdraw [a] prescription drug from sale or distribution within this State, whether directly or through a wholesale distributor, for the purpose of avoiding the prohibition on excessive price increases.” § 2037(1). Violations of this particular prohibition are punishable with a penalty of \$500,000, issuable, it appears, at the absolute discretion of the Attorney General. § 2037(3).

### **S.P. 308 VIOLATES THE DORMANT COMMERCE CLAUSE**

The United States Constitution provides that “Congress shall have [the] Power ... To regulate commerce ... among the several States.” Art. I, § 8, cl. 3. This “negative command, known as the dormant Commerce Clause,” prohibits States from legislating in ways that regulate or discriminate against interstate commerce. *Okla. Tax Comm’n v. Jefferson Lines, Inc.*, 514 U.S. 175, 179 (1995). A State law that “regulat[es] commerce occurring wholly outside [the State’s] borders” is “virtually *per se* invalid under the Commerce Clause,” even if the transactions that a State wants to regulate “ha[ve] effects within the State.” *Healy v. Beer Inst.*, 491 U.S. 324, 332 (1989); *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986). That is true, moreover, even if that extraterritorial reach is not plain from the face of the statute, but rather from “its practical effect and design.” See *C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 394 (1994) (invalidating ordinance that did not “regulate interstate commerce” “in explicit terms” but “nonetheless” did so “by its practical effect and design”).

In other words, “[w]hen a state statute regulates commerce wholly outside the state’s borders or when the statute has a practical effect of controlling conduct outside of the state” by, e.g., “necessarily requir[ing] out-of-state commerce to be conducted according to in-state terms,” “the statute will be invalid under the dormant Commerce Clause.” *PhRMA v. Concannon*, 249 F.3d 66, 79 (1st Cir. 2001), *aff’d sub nom. PhRMA v. Walsh*, 538 U.S. 644 (2003).<sup>1</sup>

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<sup>1</sup> See also, e.g., *Daniels SharpSmart, Inc. v. Smith*, 889 F.3d 608, 612-16 (9th Cir. 2018) (enjoining a California law that purported to “dictate the method by which” medical-waste companies treated medical waste “outside of California,” because it “reach[ed] beyond the borders of California [to] control transactions that occur wholly outside of the State”); *Legato Vapors, LLC v. Cook*, 847 F.3d 825, 833 (7th Cir. 2017) (invalidating Indiana law that required “commercial relationships between out-of-state manufacturers and their [out-of-state] employees and contractors” to be conducted consistent with Indiana law if the manufacturers sold products in Indiana); *North Dakota v. Heydinger*, 825 F.3d 912, 921-22 (8th Cir. 2016) (invalidating Minnesota laws that “seek to reduce emissions that occur outside Minnesota by prohibiting transactions that originate outside Minnesota,” because “their practical effect is to control activities taking place wholly outside Minnesota”); *Sam Francis Found. v. Christies, Inc.*, 784 F.3d 1320, 1321-24 (9th Cir. 2015) (en banc) (invalidating California’s Resale Royalty Act, which required sellers to pay a 5% premium into an artists’ fund, but which applied to out-of-State transactions only

LD 1117 violates this bedrock rule of constitutional law, as it necessarily requires out-of-state wholesale transactions between manufacturers and distributors to be conducted in accordance with Maine law. For instance, if (1) a Pennsylvania manufacturer sells generic drugs to an Ohio distributor in Ohio, (2) those drugs are later resold at retail in Maine, and (3) Maine decides that the price the manufacturer charged in that wholesale transaction was too high, then the manufacturer will be deemed to have violated Maine law based entirely on the terms of its out-of-state transaction. In that case, S.B. 380 would “regulat[e] the price of an[] out-of-state transaction,” *Walsh*, 538 U.S. at 669, for the simple reason that it would penalize manufacturers based on the wholesale prices they charge out of state. That is a textbook violation of the dormant Commerce Clause.

It makes no difference to the constitutional analysis that LD 1117 does not say explicitly that it seeks to regulate out of state. As the Supreme Court explained in *Brown-Forman* in striking down a New York ABC law, “[t]hat the ABC Law is addressed only to sales of liquor in New York is irrelevant if the ‘practical effect’ of the law is to control liquor prices in other States.” 476 U.S. at 583. That rule traces back to *Baldwin v. G. A. F. Seelig, Inc.*, 294 U.S. 511 (1935), in which the Supreme Court invalidated a statute that spoke only of in-state milk prices because its practical effect was to “regulat[e] the price to be paid” for milk in upstream, wholesale transactions out of state. *Id.* at 521. Furthermore, by affirmatively attempting to exempt (predominantly in-state) pharmacies and wholesalers from liability for passing on price increases from drug manufacturers, there is no question that the object of LD 1117 is the upstream wholesale transaction, not the in-state retail transaction. In sum, LD 1117 will necessarily have the practical effect of directly regulating out-of-state transactions by penalizing price increases made between manufacturers and wholesalers, wherever they occur, instead of regulating transactions that occur in *Maine*. That is unconstitutional.<sup>2</sup>

Indeed, the Fourth Circuit recently struck down a Maryland law that was essentially identical to LD 1117. At issue in *Association for Accessible Medicines v. Frosh*, 887 F.3d 664 (4th Cir. 2018), was Maryland H.B. 631, which prohibited “excessive” “increase[s] in the price of” generic and off-patent prescription drugs. Like LD 1117, the Maryland law exempted wholesalers from liability “if the price increase [was] directly attributable to additional costs ... imposed on the wholesale distributor by the manufacturer.” Also like S.P. 380, the Maryland law applied only to drugs that were “available for sale” in the State of Maryland. And further like LD 1117, the Maryland law reached and regulated out-of-state *sales* that were upstream of in-state retail sales. The “practical effect” of LD 1117 will thus be exactly the same as the practical effect of Maryland’s unconstitutional law—*i.e.*, it will be “to specify the price at which goods may be sold beyond [Maine’s] borders.” *Frosh*, 887 F.3d at 673. That is a *per se* violation of the Dormant Commerce Clause: no state may “project its legislation into [another state] by

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when “the seller resides in California,” with respect to all “sales outside the State”); *Am. Beverage Ass’n v. Snyder*, 735 F.3d 362, 366-76 (6th Cir. 2013) (invalidating Michigan law that imposes “unique-to-Michigan mark designation,” even though it “does not discriminate against interstate commerce,” because it “allows Michigan to dictate where the product can be sold” and thus “control[s] conduct beyond the State of Michigan”); *Am. Booksellers Found. v. Dean*, 342 F.3d 96, 99-104 (2d Cir. 2003) (invalidating Vermont law that prohibited distribution of explicit materials to minors because it regulated what people could distribute in other States and thus “projected ... into other States, and directly regulated commerce therein” (quoting *Brown-Forman*, 476 U.S. at 584)); *Am. Civil Liberties Union v. Johnson*, 194 F.3d 1149, 1161 (10th Cir. 1999) (invalidating New Mexico law that “attempt[ed] to regulate interstate conduct occurring outside New Mexico’s borders”); *In re Brand Name Prescription Drugs Antitrust Litig.*, 123 F.3d 599, 613 (7th Cir. 1997) (“A state cannot regulate sales that take place wholly outside it.”).

<sup>2</sup> And even if the bill did not regulate upstream manufacturer-wholesaler prices, this bill would also burden interstate commerce, by imposing Maine price regulation on drugs sold nationwide, in violation of another strand of Dormant Commerce Clause doctrine. See *McBurney v. Young*, 569 U.S. 221, 235 (2013).

regulating the price to be paid in that state,” even when the goods sold in that out-of-state transaction are destined for resale in the state. *Baldwin*, 294 U.S. at 521.<sup>3</sup>

*Frosh* is not the only case to invalidate a provision like this. The U.S. District Court for the District of Maine struck down as unconstitutional a strikingly similar “anti-profiteering” drug pricing law twenty years ago in *PhRMA v. Commissioner*, CIV. 00-157-B-H, 2000 WL 34290605, at \*2 (D. Me. Oct. 26, 2000). Notably, the State of Maine itself determined that this part of the District Court’s ruling was so obviously correct that it would not appeal it, despite pursuing and prevailing on an appeal of the remaining parts of the ruling. See *Concannon*, 249 F.3d at 72 n.2.

The anti-“profiteering” provision struck down by the District Court, like the “excessive price” regulations proposed here, barred manufacturers from “extracting or demanding an unconscionable price” for drugs. But because the “drug manufacturers” affected by this law were based outside of Maine, and, more important, all regulated sales by those manufacturers took place outside of Maine (with certain immaterial exceptions), the statute was invalid. “Where the manufacturers’ sales occur outside of Maine,” the District Court explained, “Maine has no authority to regulate the revenues obtained by the manufacturers. Maine’s statutory prohibition on profiteering or excess pricing in such transactions is simply unenforceable.... Maine may have power over what pharmacists later do here in Maine, or over the few distributors who transact business in Maine, but it has no power to regulate the prices paid earlier in transactions in other states.” 2000 WL 34290605, at \*2, \*4.

The State was right not to appeal the District Court’s opinion barring an extraterritorial “profiteering” law in 2000, and no development in Supreme Court case law has occurred in the intervening decades to make what was unconstitutional in 2000—indeed, what was unconstitutional in 1935—any more constitutional in 2021. A state cannot regulate the prices charged in out-of-state transactions just because those transactions will have an impact on the prices charged in in-state transactions. See *Baldwin*, 294 U.S. at 521-23.

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In short, LD 1117 seeks to regulate the prices charged by out-of-state manufacturers to out-of-state wholesalers in the teeth of the State’s own recognition, twenty years ago, that doing precisely this was unconstitutional. Efforts to expand the availability of affordable medicines are a good idea, but the implementation proposed here is not. We respectfully oppose it as written.

Sincerely,

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<sup>3</sup> It is true that the bill contains some trivial alterations from the Maryland law struck down in *Frosh*. For example, it includes a requirement for wholesalers to maintain a registered agent and office within the state, § 2598(3), presumably on the theory that if a manufacturer can be compelled to render itself amenable to the personal jurisdiction of a state’s courts, regulation applied to such an enterprise will no longer be extraterritorial. Not so. Nothing in *Frosh* turned on whether or to what extent the regulated manufacturers had an in-state presence. The constitutional problem was, and is, not an absence of connection between the regulation and in-state actors; the problem is the regulation of *out-of-state upstream transactions*. The problem with Maryland’s law was that it necessarily regulated “the upstream pricing and sale of prescription drugs” outside of Maryland. *Frosh*, 887 F.3d at 671. “This [the state] cannot do.” *Id.* at 672. The same is true here. Just like the Maryland law, LD 1117 penalizes manufacturers for the prices they charge their distributors in sales that take place out of state whenever the drugs sold in those transactions wind up being resold in the state. Maine can only regulate prices charged to Mainers, not prices charged upstream of in-state sales. Because LD 1117 does the latter, it is unconstitutional.

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