No. 17-2166

IN THE
UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

ASSOCIATION FOR ACCESSIBLE MEDICINES,

Appellant,

—v.—

BRIAN E. FROSH, in his official capacity as Attorney General for the State of Maryland; DENNIS R. SCHRADER, in his official capacity as Secretary of the Maryland Department of Health

Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
CIVIL ACTION NO. 17-CV-1860 (MCG)

BRIEF *AMICUS CURIAE* OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA IN SUPPORT OF APPELLANT

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INTEREST OF THE *AMICUS CURIAE*[1]

The Chamber of Commerce of the United States of America ("Chamber") submits this *amicus* brief in support of Appellant Association for Accessible Medicines. The Chamber is the world's largest business federation, representing 300,000 direct members and indirectly representing an underlying membership of more than three million U.S. businesses and professional organizations of every size and in every economic sector and geographic region of the country. The Chamber represents the interests of its members in matters before the courts, Congress, and the Executive Branch.

The Chamber has a substantial interest in this case. The Chamber's members transact business in interstate commerce every day. And the free flow of commerce within the United States is at the heart of the Founder's vision of our Union. The movement of goods and services across state boundaries, unimpeded by parochial state interests, is essential to a strong economy, job creation, and consumer welfare. The Chamber's members therefore have an acute interest in the proper application of constitutional principles that promote the flow of commerce across state lines and prevent State and local governments from hindering interstate

[1] In accordance with Federal Rule of Appellate Procedure 29(c)(5), *amicus* affirms that no counsel for a party authored this brief in whole or in part and that no person other than *amicus*, its members, or its counsel made a monetary contribution intended to fund the brief's preparation or submission. All parties have consented to the filing of this brief.

commerce or imposing coercive conditions on out-of-state parties. Furthermore, the Chamber has a strong interest in preventing the proliferation of inconsistent regulations across States and localities given the significant expense and practical difficulty regulations visit upon its members. For all of these reasons, the Chamber regularly files *amicus* briefs in cases that are important to the nation's business community, including those, like this one, that involve potential impediments to the free flow of commerce.

SUMMARY OF ARGUMENT

Appellant is a trade association representing manufacturers and distributors of generic and biosimilar medicines. Virtually all of these member companies manufacture their drugs outside of Maryland. Thereafter, they sell these drugs to national wholesale distributors and national pharmacies, which likewise are located almost exclusively outside of Maryland. At that stage in the chain of commerce, the involvement of Appellant's members ends.

Yet through HB 631 Maryland has arrogated to itself the authority to directly regulate the out-of-state commercial transactions of these out-of-state companies by making it unlawful, among other things, for a retailer to sell certain generic drugs at an "excessive" price in Maryland. Notably, these in-state retailers—*i.e.*, the entities actually conducting business in Maryland—are not subject to HB 631. Maryland instead seeks to impose liability on only the out-of-

state businesses. And it has asserted this power to impose severe sanctions based strictly on the fact that their products ultimately find their way, through the national chain of commerce, to a local retailer.

This is a remarkable exercise of power, and one that violates core federalism principles. In the terms of the dormant Commerce Clause, HB 631 impermissibly regulates "extraterritorial[ly]." *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989). By "directly control[ling] commerce occurring wholly outside [its] boundaries," Maryland has "exceed[ed] the inherent limits" of its power. *Id.* That a prescription drug winds up being sold in Maryland cannot vest the State with regulatory power over every upstream commercial actor. Time and again, the Supreme Court has explained that "whether or not the commerce has effects within the State," the Constitution "precludes the application of a state statute to commerce that takes place wholly outside of the State's borders." *Id.* (quoting *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982) (plurality opinion)).

In upholding HB 631, the district court's decision contravenes these core principles and reaches a result that cannot be squared with controlling precedent. Indeed, more than one federal court has struck down strikingly similar examples of State and local overreaching because of its effect on out-of-state commerce. As the United States District Court for the District of Columbia put it: "Because all of plaintiffs' members who are manufacturers of patented prescription drugs are

found out of state, and because all of the wholesalers to whom they sell their products are also found out of state, it is impossible to contend that this particular application of the D.C. Act does not effect an impermissible extraterritorial reach." *Pharm. Research & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 70 (D.D.C. 2005). So too here.

If upheld, HB 631's practical effect would be to visit local encumbrances on commercial and distribution activities that are national in scope, take place in other States, and are lawful where they occur. *See Healy*, 491 U.S. at 336, 337 n.14 (deeming a law's practical effects the "critical inquiry" or "critical consideration in determining whether the extraterritorial reach of a statute violates the Commerce Clause"). As Appellants have demonstrated, the costs of trying to comply with HB 631 will be massive. Because the pharmaceuticals market is national in scope, manufacturers have little choice but to avail themselves of the national distribution network that makes its drugs available to local retailers throughout the country. The extraterritoriality doctrine safeguards these channels of interstate commerce, shielding market participants from overlapping and inconsistent regulation. These concerns go to the heart of federalism: the Framers sought to eliminate the "serious interruptions of the public tranquility" that could flow from parochial efforts to burden the free flow of trade among the several States. The Federalist No. 42, at 219 (James Madison) (Gideon ed., 2001).

But even if Maryland could be excised from the national market for generic drugs—a result that would harm both Appellant's members and consumers of these life-saving therapies—it would not improve things. That would just create the type of "economic Balkanization" the Commerce Clause is designed to curtail. *Hughes v. Oklahoma*, 441 U.S. 322, 325 (1979). The Framers shared "the conviction that in order to succeed, the new Union would have to avoid the tendencies toward economic Balkanization that had plagued relations among the Colonies and later among the States under the Articles of Confederation.'" *Okla. Tax Comm'n v. Jefferson Lines*, 514 U.S. 175, 180 (1995) (quoting *Wardair Canada, Inc. v. Fla. Dep't of Rev.*, 477 U.S. 1, 7 (1986)). A State law, like HB 631, that disrupts the national market for prescription drugs not only contradicts important constitutional principles—it violates the public interest.

Nor are the effects of the district court's decision limited to HB 631 or even to the pharmaceutical industry. The decision invites other States to adopt their own price-control regimes. But not just for generic drugs. Any article of commerce could be subjected to this type of regulation given that, under the district court's reasoning, a State may regulate out-of-state manufacturers whose products are sold into national commerce so long as the manufacturer's products ultimately land in that State at the end of the commercial chain. The decision below should be reversed.

ARGUMENT

I. The district court's decision contravenes Commerce Clause precedent and disregards core federalism principles.

HB 631 conflicts with our federal system and violates the Commerce Clause. As the Supreme Court has explained, "the States in the Union are coequal sovereigns under the Constitution." *PPL Mont., LLC v. Montana*, 565 U.S. 576, 591 (2012). The Constitution thus empowers the States to evenhandedly "regulate matters of legitimate local concern." *Maine v. Taylor*, 477 U.S. 131, 138 (1986) (citation and quotations omitted). But that principle necessarily carries a negative implication: "Laws have no force of themselves beyond the jurisdiction of the state which enacts them, and can have extraterritorial effect only by the comity of other states." *Huntington v. Attrill*, 146 U.S. 657, 669 (1892); *see also N.Y. Life Ins. Co. v. Head*, 234 U.S. 149, 160 (1914) (explaining that it is "impossible to permit the statutes of [a State] to operate beyond the jurisdiction of that State … without throwing down the constitutional barriers by which all the States are restricted within the orbits of their lawful authority and upon the preservation of which the Government under the Constitution depends").

Thus, because "[t]he several States are of equal dignity and authority, ... the independence of one implies the exclusion of power from all others." *Pennoyer v. Neff*, 95 U.S. 714, 722 (1877), *overruled in part on other grounds by Shaffer v. Heitner*, 433 U.S. 186 (1977); *see also Bonaparte v. Tax Court*, 104 U.S. 592, 594

(1881) ("No state can legislate except with reference to its own jurisdiction."). In short, "[t]he sovereignty of each State ... implie[s] a limitation on the sovereignty of all of its sister States." *World-Wide Volkswagen v. Woodson*, 444 U.S. 286, 293 (1980); *see also State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003) ("A basic principle of federalism is that each State may make its own reasoned judgment about what conduct is permitted or proscribed within its borders, and each State alone can determine what measure of punishment, if any, to impose on a defendant who acts within its jurisdiction."); Katherine Florey, *State Courts, State Territory*, *State Power*: *Reflections on the Extraterritoriality Principle in Choice of Law & Legislation*, 84 Notre Dame L. Rev. 1057, 1091 (2009) (explaining that the extraterritoriality doctrine "is perhaps best understood as a means of establishing order—and confining each state to its proper sphere of authority—in a federalist system").

While this foundational principle underlies several constitutional doctrines, it has special purchase when it comes to commerce between the states. After all, the main point of forming the Union was to create a separate government that, though limited in power, would have the exclusive authority to regulate on a national scale. Many of the Framers saw, for example, a critical need for a unified system regulating truly interstate commerce. *See Gibbons v. Ogden*, 22 U.S. 1, 100 (1824). As Alexander Hamilton warned, commercial relations between the states

would remain "fettered, interrupted, and narrowed by a multiplicity of causes" so long as local laws could infringe on commerce among the states. The Federalist No. 11, at 54 (Alexander Hamilton) (Gideon ed., 2001); *see* James Madison, *Preface to Debates in the Convention of 1787*, *in* 3 Records of the Federal Convention of 1787, 547 (Max Farrand ed., 1911); 1 Laurence H. Tribe, *American Constitutional Law* § 6-12, at 1098 (3d ed. 2000) (discussing "the *per se* principle against extraterritorial state regulation"). As a consequence, no State may regulate commercial activity elsewhere in the nation under the guise of "policing its own concerns." *Pac. Coast Diary v. Dep't of Agric. of Cal.*, 318 U.S. 285, 295 (1943). Such out-of-state commercial matters are "none of her concern." *Osborn v. Ozlin*, 310 U.S. 53, 62 (1940).

Controlling precedent captures this settled understanding. Although "a literal reading evinces a grant of power to Congress, the Commerce Clause also directly limits the power of the States." *Wyoming v. Oklahoma*, 502 U.S. 437, 454 (1992). This negative, or dormant, aspect of the Commerce Clause prohibits extraterritorial regulation; a State may not regulate "commerce that takes place wholly outside of the State's borders." *Healy*, 491 U.S. at 336 (citation omitted). The Constitution is "framed upon the theory that the peoples of the several States must sink or swim together, and in the long run prosperity and salvation are in union and not division." *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 523 (1935).

It is thus immaterial whether those commercial transactions have "effects within the State." *Healy*, 491 U.S. at 336 (citation omitted). If the "practical effect" of the law is "to control conduct beyond the boundaries of the State," it "exceeds the inherent limits of the enacting State's authority and is invalid." *Id*. Extraterritoriality, for that reason, has been invoked to invalidate an array of state laws, including: price-affirmation statutes, *see Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 585 (1986); laws restricting corporate takeovers, *see Edgar*, 457 U.S. at 641-42 (plurality opinion); rules governing athletic-association hearings, *see NCAA v. Miller*, 10 F.3d 633, 637 (9th Cir. 1993); and waste-disposal regulations, *see Nat'l Solid Wastes Mgmt. Ass'n v. Meyer*, 165 F.3d 1151, 1152-53 (7th Cir. 1999) (per curiam).[2]

HB 631 should be added to this list. Among other things, the law prohibits "excessive" pricing on "essential" generic drugs "made available" in Maryland. Section 2-801(b)(1)(iv), (f); JA 370.[3] But HB 631 does not in fact regulate sales in

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[2] As these cases show, the district court's conclusion that the extraterritoriality doctrine applies narrowly to price-tying and price-affirmation laws was misplaced. *See also* Appellant's Br. 29-37. It has been extended far beyond those categories—and rightly so.

[3] As Appellant explains, *see* Appellant's Br. 37-43, HB 631 also is hopelessly vague. "A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012). None of HB 631's key terms afford regulated entities the guidance to which the Due Process Clause entitles them. HB 631 is unconstitutional for this reason too.

Maryland. The statute does not apply to retailers, *see* Appellant's Br. 5, and it does not violate HB 631 for "a wholesale distributor to increase the price of an essential off-patent or generic drug if the price increase is directly attributable to additional costs for the drug imposed on the wholesale distributor by the manufacturer of the drug." Section 2-802(b); JA 372. Rather than regulating sales or distribution in Maryland, HB 631 regulates out-of-state manufacturers and distributors, even though they "did not deal directly with a consumer residing in the State." Section 2-803(g); JA 374-75. Thus, HB 631's purpose and effect are plain: Maryland seeks to control the price at which out-of-state manufacturers may sell "essential" generic drugs to out-of-state distributors and pharmacy chains. *See* Appellant's Br. 8-9.

As explained, this is precisely what the Commerce Clause forbids Maryland from doing. It makes no difference that HB 631 regulates only those manufacturers whose drugs eventually enter Maryland. The Constitution precludes the direct application of a State's law to commerce occurring wholly outside its jurisdictional boundaries irrespective of whether there is some in-state effect. *Healy*, 491 U.S. at 336; *cf. Daimler AG v. Bauman*, 134 S. Ct. 746, 757 (2014)

Indeed, a similar law seeking to regulate out-of-state drug companies was invalidated based on its extraterritorial reach. Under the District of Columbia's now-defunct "Prescription Drug Excessive Pricing Act," D.C. Code § 28-4551 *et*

seq., it was "unlawful for any drug manufacturer or licensee thereof, excluding a point of sale retail seller, to sell or supply for sale … a patented prescription drug that results in the prescription drug being sold in the District for an excessive price." *Id.* § 28-4553. In other words, the ordinance exposed any manufacturer whose prescription drug is sold at an "excessive price" in the District to potentially significant liability.

The D.C. law was invalidated for the same reasons Appellant presses here. "[T]he D.C. Act, as applied to sales between out-of-state manufacturers ... and other out-of-state entities [had] a *per se* invalid extraterritorial reach in violation of the Commerce Clause." *PhRMA*, 406 F. Supp. 2d at 71. Like Appellant, the manufacturers in *PhRMA* sold the overwhelming bulk of their prescription drugs "in out-of-state transactions to wholesalers or large retail chains that maintain their own warehousing and retail distribution system[s]," which were also located out-of-state. *Id.* at 68. Because the D.C. law targeted the manufacturers based on those sales, the court reasoned, "the Act effectively [sought] to regulate transactions that occur[red] wholly out of state." *Id.*

There is no principled distinction between the D.C. law and HB 631. Like the D.C. law, HB 631 is formally triggered by an in-state "hook" that Maryland then exploits to regulate out-of-state conduct. *See id.* at 69 (citing *Baldwin*, 294 U.S. at 518-21); *see also id.* (noting that "as soon as [a] drug is sold in the District,

the manufacturer's out-of-state sale becomes the Act's primary target."). Because the Plaintiffs' members are found almost entirely outside of Maryland, and nearly "all of the wholesalers to whom they sell their products are also found" outside of Maryland, HB 631 "effect[s] an impermissible extraterritorial reach." *Id.* at 70. This is wholly "'interstate business'" that Maryland may not directly burden "'in any form or under any guise.'" *Baldwin*, 294 U.S. at 522 (quoting *Int'l Textbook Co. v. Pigg*, 217 U.S. 91, 112 (1910)). By doing so, Maryland invades the authority of the other States.

But even if Maryland did not seek to impose nationwide price controls, that is the "practical effect" of the regulation. *Healy*, 491 U.S. at 336. The only way a manufacturer could avoid liability under HB 631 is to take steps to ensure that its drugs are not resold into Maryland. As a general matter, however, manufacturers have little control over where their products are ultimately sold after they transfer them to distributors. And, it is far from clear that manufacturers would be able to do so even if they engaged in the enormously time-consuming and costly effort of trying. *See* Appellant's Br. 43-45. If manufacturers are not certain that HB 631 can be avoided, they may have to tailor their national policies to Maryland's price-control regime. In effect, then, Maryland would be regulating generic-drug prices for every state in the Union. But the Supreme Court has rejected efforts by one state to encourage the other 49 states to adopt similar policies by discriminating

against interstate commerce. *See*, *e.g.*, *New Energy Co. v. Limbach*, 486 U.S. 269, 274 (1988).

Just as New York has no constitutional authority to pass a law that "has the practical effect of controlling Massachusetts [beer] prices," *Healy*, 491 U.S. at 338, Maryland cannot, as it did here, control the prices for generic drugs in Massachusetts or any other State. Regulation of the pharmaceutical industry can have significant (and sometimes unintended negative) public health consequences. *See* Appellant's Br. 3-4, 44; *see also* John E. Calfee, *Pharmaceutical Price Controls and Patient Welfare,* 134 Ann. Intern. Med. 1060 (2001). The "sovereign prerogative[]" to regulate drug prices resides with each State or is "lodged in the Federal Government." *Massachusetts v. EPA*, 549 U.S. 497, 519 (2007). Maryland does not get to force her sister States "into a common, uniform mold." *Addington v. Texas*, 441 U.S. 418, 431 (1979).

II. Maryland's regulation of wholly out-of-state commercial transactions will disrupt interstate commerce.

In upholding HB 631, the district court's decision threatens to impose serious financial and administrative burdens on nationwide commercial activity by pharmaceutical companies. "The very purpose of the Commerce Clause was to create an area of free trade among the several States." *McLeod v. J.E. Dilworth Co.*, 322 U.S. 327, 330 (1944). HB 631 turns that foundational principle on its head. "[B]ecause of the potential liability they will face in" Maryland for sales

made elsewhere, Appellant's members are decidedly not "free to conduct commerce on their own terms elsewhere." *PhRMA*, 406 F. Supp. 2d at 70 (citations and internal quotation marks omitted). As noted above, every drug manufacturer and national distributor will find itself subject to HB 631 merely because they sell products to national distributors. If the statute is upheld, the prudent manufacturer thus will need to bear millions of dollars in costs trying to comply with it in one way or another. *See* Appellant's Br. 44-45. These costs alone will impermissibly disrupt the free flow of goods.

The decision also will have a domino effect. It will not be long before other States follow suit, recognizing that they too can champion cheaper generic drug prices within their jurisdictions. Indeed, the District of Columbia and Maine have already tried to assert this authority over drug manufacturers and distributors. It took judicial intervention to rebuffs their efforts. *See PhRMA*, 406 F. Supp. 2d at 67-71; *Pharm. Research & Mfrs. of Am v. Comm'r, Me. Dep't of Human Servs*., No. 00-cv-157, 2000 WL 34290605, at **2-5 (D. Me. Oct. 26, 2000); *see also Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 72 n.2 (1st Cir. 2001) (noting that Maine did not appeal this ruling).

Of course, the burden on manufacturers and distributors would increase dramatically if "not one, but many or every, State adopted similar legislation." *Healy*, 491 U.S. at 336. As here, manufacturers could be subject to fines and

penalties if a retailer with no direct connection to the manufacturer sold its products within that State, even if neither the out-of-state manufacturer nor the out-of-state distributor deliberately made the product available in that State. Tracing individual products and monitoring their entry into all these States long after the manufacturer's wholesale transaction has concluded would be difficult enough. But manufacturers and distributors eventually would be subject to competing, overlapping, and likely irreconcilable regimes. That is untenable. Appellant's members would face "just the kind of competing and interlocking local economic regulation that the Commerce Clause was meant to preclude." *Id.* at 337. This Court should not permit Maryland to trigger the kind of "economic Balkanization that had plagued relations among the Colonies and later among the States under the Articles of Confederation." *Hughes*, 441 U.S. at 325.

Worse yet, the potential for schemes like HB 631 to create a nationwide system of overlapping and conflicting price-regulation regimes extends not just across jurisdictions, but across industries. No article of commerce is immune from this type of regulation. Under the district court's reasoning, after all, state laws may regulate *any* out-of-state manufacturer whose products eventually flow into national commerce so long as the product is resold in-state. It is unrealistic to think that States will not use this decision as a roadmap for how to control product pricing in other industries.

Finally, HB 631's vagueness, *see supra* n.3, only intensifies the problem. One of the chief problems with vague statutes is that they "inhibit the exercise of constitutionally protected rights." *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 499 (1982). Drug manufacturers and distributors have the constitutional right to engage in interstate commerce free from parochial regulation by States where they are not actually selling a product. But given HB 631's draconian penalties, they will need to do everything within their power to avoid liability. *See* Appellant's Br. 48-49. Inevitably, that will lead manufacturers and distributors to steer far wide of the vague line the law draws if not withdraw from certain markets altogether. HB 631's failure to afford regulated entities fair notice therefore will further deter interstate transactions that Maryland has no right under the Constitution to prohibit.

CONCLUSION

For these reasons, the judgment of the district court should be reversed.

Dated: November 3, 2017

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), I certify the following:

This brief complies with the length limitations of Fed. R. App. P. 29(d) because it contains no more than one-half the maximum length authorized by this Court's rules for a party's principal brief, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). The brief contains 3,783 words.

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman 14-point font.

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CERTIFICATE OF SERVICE

I hereby certify that on this 3rd day of November, 2017, a true and correct copy of the foregoing was filed with the Clerk of the United States Court of Appeals for the Fourth Circuit via the Court's CM/ECF system, which will send notice of such filing to all counsel who are registered CM/ECF users.

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