UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

ASSOCIATION FOR ACCESSIBLE MEDICINES,

Plaintiff-Appellant,

v. No. 17-2166

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,

Defendants-Appellees.

MOTION FOR INJUNCTION PENDING APPEAL

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Absent this Court's intervention, a new, blatantly unconstitutional Maryland law will force the member-manufacturers of Plaintiff-Appellant Association for Accessible Medicines ("AAM") to confront a Hobson's choice: either undertake costly measures to reform their nationwide sales and distribution networks to conform to the uncertain requirements of a vague state statute, or risk seeing their wholly out-of-state commercial arrangements *penalized and enjoined* by Maryland courts as violations of Maryland law. There is no reason to leave AAM's member-manufacturers in that untenable position while this Court resolves the merits of AAM's claims on appeal. Indeed, there is every reason not to—particularly given that this Court has already granted AAM's request to expedite proceedings. *See* Order, Dkt. 10.

The new statute, Maryland House Bill 631 – Public Health – Essential Off-Patent or Generic Drugs – Price Gouging – Prohibition ("HB 631"), broadly prohibits "price gouging" in the sale of certain off-patent and generic prescription drugs. While no one is here to defend the outlier pricing practices of certain brand-name prescription drugs, the fact remains that state legislation, however well intentioned, is subject to the U.S. Constitution. HB 631 violates the Constitution in two respects.

First, HB 631 violates the dormant Commerce Clause to the extent Defendants seek to apply it to sales that take place outside of Maryland. The

Supreme Court has been crystal clear that a state may not regulate the prices paid and received in transactions that occur in other states, "whether or not the commerce has effects within the State." *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989). Yet that is precisely what HB 631 purports to do. The only thing that can violate the statute is the "sale of an essential off-patent or generic drug" by a manufacturer (or a wholesale distributor), and the overwhelming majority of off-patent and generic drug manufacturers' sales take place entirely outside of Maryland. Thus, by its plain terms HB 631 authorizes Maryland courts to impose sweeping liability on prescription drug manufacturers for the terms of their out-of-state transactions. *See* § 2-803(d)(2), (5) (authorizing Maryland courts to enjoin violations and impose $10,000 per-violation penalties).

Second, HB 631 is void for vagueness. HB 631 defines unlawful "price gouging" as any price increase that is "unconscionable," § 2-801(c), and defines an "unconscionable increase" as any price increase that is "excessive," is not "justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug," and will leave consumers with "no meaningful choice" but to buy the drug "at an excessive price," § 2-801(f). The statute does not define what any of those key terms ("excessive," "appropriate," "meaningful") mean in this context, and none of them is sufficiently concrete to be cognizable absent further elaboration. Even the district court acknowledged that the statute "appear[s] to"

lack *any* standards that are "binding on the Attorney General" when it comes to deciding whether to charge a manufacturer with violating the new law. Mem. & Order, Dist. Ct. Dkt. 43, at 27-28.

Despite that clearly correct recognition of the statute's vagueness, the district court denied AAM's motion for a preliminary injunction. That confounding decision stemmed from the district court's fundamentally flawed understanding of the governing law.

With respect to AAM's vagueness challenge, the district court concluded that discovery on the economic, industrial, and regulatory forces that drive prescription drug pricing decisions was necessary. *See id.* at 29-30 & n.11. But the standard for a void-for-vagueness claim is objective; the fundamental inquiry is whether the scope of the challenged law is so unclear as to preclude regulated parties from ordering their affairs, or is so opaque as to invite arbitrary enforcement. *See, e.g.*, *Hill v. Colorado*, 530 U.S. 703, 732 (2000) ("A statute can be impermissibly vague for either of two independent reasons. First, if it fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits. Second, if it authorizes or even encourages arbitrary and discriminatory enforcement."). Which economic, industrial, or regulatory inputs might affect manufacturers' pricing decisions in the abstract should thus have no bearing on whether HB 631 passes muster under the Due Process Clause.

The district court's Commerce Clause analysis was even more off-base. According to the district court, HB 631 may constitutionally be applied even as to sales that take place entirely outside of Maryland. That is not even arguably consistent with longstanding, on-point precedent. The Supreme Court has clearly held that "a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority." *Healy*, 491 U.S. at 336; *see also Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579-81 (1986) (state law violates dormant Commerce Clause where the "'practical effect' of the law is to control … prices in other States"). As applied to out-of-state sales, that is precisely what HB 631 does: it "controls commerce" by authorizing Maryland courts to penalize and enjoin sales agreements deemed to be "unconscionable," even when those transactions "occur[] wholly outside the boundaries of" the State. *Healy*, 491 U.S. at 336.

The district court waived off that clear conclusion only by distorting *Healy* and *Brown-Forman* beyond recognition. According to the district court, *Healy* and *Brown-Forman*'s anti-extraterritoriality holdings apply only to those state laws that insist on price parity with other states. *See* Mem. & Order, Dist. Ct. Dkt. 43, at 16-18. But a statute that insists on price parity is not problematic only because it may lead to price gridlock. More fundamentally, such laws violate the Commerce Clause because they have the practical effect of controlling the prices of

transactions that occur wholly outside the regulating state. *See Legato Vapors, LLC v. Cook*, 847 F.3d 825, 831-36 (7th Cir. 2017) ("Price-affirmation laws can violate the Commerce Clause because they have ripple effects in other states, effectively setting the price for a commodity in transactions outside the regulating state."). HB 631 has that effect baked into the very face of the statute. No court has *ever* upheld such a nakedly extraterritorial state law, until now.

When the proper legal standards are applied, there can be no question that HB 631 is unconstitutional, or that AAM is highly likely to succeed in its appeal. AAM's members are also certain to suffer irreparable injury absent this Court's swift intervention, as HB 631 will unleash a potentially unlimited number of enforcement actions seeking to punish AAM members—on whose life-sustaining pharmaceutical products many Marylanders rely—for prices charged for drugs "made available" in Maryland, even if the manufacturers do no business in the state at all. The inevitable effect of such a sweeping yet uncertain prohibition—*i.e.*, manufacturers' imposing a no-go zone for Maryland, even in the resale market—will be jarring, and will come to the detriment not just of prescription drug manufacturers, but of patients too.

And all for no good reason. This Court has already recognized the extraordinary nature of the statute in question in granting AAM's request for expedited briefing and argument. *See* Order, Dkt. 10. So even if this Court

disagrees with AAM on the merits, Defendants will have lost no more than a few months. *See id.* (oral argument to be held in January 2018). By contrast, if this Court agrees with AAM that HB 631 is unconstitutional, then prescription drug manufacturers will not have been forced to undertake costly compliance measures today only to take further costly measures to undo them in a few months' time. AAM thus respectfully requests that this Court enjoin Defendants from implementing or enforcing HB 631 pending resolution of this appeal pursuant to Federal Rule of Appellate Procedure 8.[1]

BACKGROUND

AAM represents the leading manufacturers and distributors of generic and biosimilar medicines, manufacturers and distributors of bulk active pharmaceutical ingredients, and suppliers of other goods and services to the generic and biosimilar pharmaceutical industry. Decl. of Chester "Chip" Davis, Jr., Dist. Ct. Dkt. 9-2, at ¶ 2. Such products perform a crucial function in the American healthcare system. Generic medicines account for nearly 90% of all prescriptions dispensed in the United States, but less than 30% of the money spent on prescriptions. Compl. Ex. D, Dist. Ct. Dkt. 1-4, at 19. All told, generic medicines saved Americans $1.67

[1] Consistent with Rule 8(a)(1) of the Federal Rules of Appellate Procedure, AAM initially sought an injunction pending appeal in the court below. *See* Pl.'s Mot. Entry of Partial Final J. and Inj. Pending Appeal, Dist. Ct. Dkt. 46. The district court denied that request on Thursday, October 12, 2017. *See* Mem. & Order Re: Entry of Partial Final J. and Inj. Pending Appeal, Dist. Ct. Dkt. 49.

trillion over the past decade, and $253 billion in 2016 alone—nearly $5 billion every single week last year. *Id.* at 12, 19. The availability of generic drugs like those produced and sold by AAM members is thus critical to ensuring that patients have access to affordable medicine. *See* Compl. Ex. C, Dist. Ct. Dkt. 1-3, at 2.

Like most off-patent and generic prescription drug manufacturers, AAM members sell nearly all of their products to two types of purchasers: (1) large, national wholesale distributors, and (2) national retail pharmacy chains that warehouse the products themselves. With rare exceptions, these transactions take place entirely outside the State of Maryland. Of the twenty largest generic drug manufacturers in the United States, only one is headquartered in Maryland, and none manufactures any pharmaceuticals in the state. Likewise, not one of the "Big Three" wholesaling firms (which collectively account for 90% of the market) has a corporate presence in Maryland, and neither do any of the national retailing chains that warehouse products themselves. So in the overwhelming majority of cases, an off-patent or generic prescription drug manufacturer's sales occur entirely outside of the state. Compl., Dist. Ct. Dkt. 1, at ¶¶ 25-26.

Against that backdrop, Maryland enacted HB 631. HB 631 prohibits "manufacturer[s] or wholesale distributor[s]" from "engag[ing] in price gouging in the sale of an essential off-patent or generic drug," § 2-802(a), which is defined as "unconscionabl[y] increas[ing] the price of a prescription drug," § 2-801(c).

Rather than target "sale[s]" that actually take place *in Maryland* (such as direct-to-patient sales or sales from manufacturers to institutional purchasers like hospitals), HB 631 authorizes the Maryland Attorney General to bring suit against a generic drug manufacturer even if the manufacturer "did not deal directly with a consumer residing in this State," § 2-803(g), and indeed, even if it did no business in Maryland at all.

To be sure, HB 631 does not kick in until a drug is "made available for sale in the State." § 2-801(b)(1)(iv). But once a single package makes its way onto Maryland shelves or a single pill is sold to a Maryland patient, the statute's plain terms authorize Maryland courts to penalize and enjoin manufacturers' decisions to raise the prices in their out-of-state sales agreements with out-of-state wholesalers, *even if those agreements occurred wholly outside of Maryland*, and even if neither the seller nor the buyer was responsible for making the drug available for sale in Maryland. *See* § 2-803(d)(2), (5).

Adding insult to injury, exactly what constitutes an unlawful "unconscionable" price increase under the statute is far from clear. Although the statute elsewhere contains a digestible benchmark—HB 631 authorizes the Maryland Medical Assistance Program to "notify the Attorney General of any increase in the price of an essential off-patent or generic drug when," *inter alia*, a price increase "would result in an increase of 50% or more in the wholesale

acquisition cost of the drug," § 2-803(a)—the actual prohibition in the statute lacks any such clarity.[2] Under § 2-801(f), a prohibited "unconscionable increase" in the price of an essential off-patent or generic prescription drug is defined as a price increase that (1) is "excessive," (2) is "not justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug to promote public health," and (3) leaves consumers with "no meaningful choice about whether to purchase the drug at an excessive price." The statute does not define what any of those key terms ("excessive," "appropriate," "meaningful") mean in this context, and none of them is sufficiently concrete to be cognizable absent further elaboration.[3]

Long before the law went into effect, HB 631's unconstitutional sweep raised serious alarm. On May 26, 2017, Governor Lawrence J. Hogan Jr. announced that he would allow the law to go into effect without his signature. *See* Md. Const. art. II, § 17(c). Yet in doing so, Governor Hogan made clear that he harbored deep apprehension about the law's terms. Governor Hogan lamented that

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[2] Defendants conceded at oral argument below that the Attorney General's authority to bring suit in Maryland court against drug manufacturers is not tied to the reporting requirements in § 2-803(a).

[3] Nor does context provide any helpful clues. Whereas a "lack of meaningful choice" appears in the statutory definition, HB 631 is not limited to monopolists or cases of market dysfunction, but instead applies even when as many as three manufacturers are "actively manufactur[ing] and market[ing]" the same drug, § 2-801(b)(1)(iii), and even when an infinite number of therapeutic substitutes are available.

HB 631's price-control provisions "directly regulate interstate commerce and pricing by prohibiting and penalizing manufacturer pricing which may occur outside of Maryland," and thus "likely violate the dormant commerce clause of the [United States] Constitution." Dist. Ct. Dkt. 1-2, at 2. Governor Hogan expressed further "concern[] that [HB 631's] definition of 'unconscionable increase' and 'excessive'"—"the heart of" the law—is so vague as to make it "very difficult for manufacturers to know whether they are in violation of these provisions"—and perhaps worse yet, "leav[e] the decision entirely to the interpretation of the Attorney General," in violation of the Fourteenth Amendment's Due Process Clause. *Id.* at 2-3.

On Thursday, July 6, 2017, AAM filed a motion for a preliminary injunction to preserve the status quo and prevent Defendants-Appellees from enforcing HB 631 pending resolution of the action. On Friday, September 29, 2017, after holding oral argument on the motion, the Honorable Marvin J. Garbis of the U.S. District Court for the District of Maryland denied AAM's motion in its entirety. In addition, Judge Garbis granted Defendants' motion to dismiss as to AAM's First Cause of Action under the dormant Commerce Clause, but denied Defendants' motion to dismiss as to AAM's void-for-vagueness claim, concluding that the statute's operative terms ("unconscionable," "excessive," and so on) may well lack sufficient clarity to pass constitutional muster. Mem. & Order, Dist. Ct. Dkt. 43.

AAM moved the district court for an injunction pending appeal pursuant to Federal Rule of Civil Procedure 62(c). *See* Pl.'s Mot. Entry of Partial Final J. and Inj. Pending Appeal, Dist. Ct. Dkt. 46.[4] The district court denied the motion for an injunction pending appeal on Thursday, October 12, 2017. Mem. & Order Re: Entry of Partial Final J. and Inj. Pending Appeal, Dist. Ct. Dkt. 49.

ARGUMENT

In determining whether to grant a stay or an injunction pending appeal, this Court considers four factors: (1) whether the movant has made a strong showing of likelihood of success on the merits of its appeal; (2) whether the movant will be irreparably injured absent a stay; (3) whether granting a stay will cause substantial harm to other interested parties; and (4) whether the public interest will be served by granting the stay. *See Nken v. Holder*, 556 U.S. 418, 434 (2009). Each element supports the entry of an injunction pending appeal here.

[4] In conjunction with its motion for an injunction pending appeal, AAM also moved the district court for entry of partial final judgment as to AAM's Commerce Clause claim under Rule 54(b) of the Federal Rules of Civil Procedure. *See* Pl.'s Mot. Entry of Partial Final J. and Inj. Pending Appeal, Dist. Ct. Dkt. 46. The district court granted that request, and entered partial final judgment on AAM's Commerce Clause claim on Thursday, October 12, 2017. *See* Judgment Pursuant to Rule 54(b), Dist. Ct. Dkt. 50. AAM has filed an amended notice of appeal to join its appeal from the Rule 12(b)(6) dismissal of its Commerce Clause claim together with this appeal from the denial of its motion for a preliminary injunction.

I. AAM Has A Substantial Possibility Of Success On Appeal.

A. HB 631 Violates the Dormant Commerce Clause as Applied to Wholly Out-of-State Transactions.

"[A]t a minimum," the Supreme Court's dormant Commerce Clause cases "concerning the extraterritorial effects of state economic regulation" stand for two basic principles. *Healy*, 491 U.S. at 336. First, the Commerce Clause "precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State." *Id.* (quoting *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982) (plurality opinion)). "Second, a statute that directly controls commerce occurring wholly outside the boundaries of a state exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature." *Id.* (citing *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935)). "The critical inquiry" for either strand "is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State." *Id.* (citing *Brown-Forman*, 476 U.S. at 579).

Before moving onto the terms of the state statute at issue here, it is important to understand just what those principles mean in practice. *Healy* and the cases on which it built do not require invalidating every state enactment that somehow affects out-of-state commercial behavior; only laws that actually dictate the terms of out-of-state commerce (whether by their terms of their practical effect), and then

penalize actors for noncompliance, run afoul of the anti-extraterritoriality principle. *See Cotto Waxo Co. v. Williams*, 46 F.3d 790, 794 (8th Cir. 1995) ("a statute has extraterritorial reach when it necessarily requires out-of-state commerce to be conducted according to in-state terms"). Nor does *Healy* mandate a hermetically sealed line of demarcation between out-of-state commerce and in-state effects; a state law may be unconstitutionally extraterritorial even if it applies only once a sale is made inside the state. *See, e.g.*, *Legato Vapors*, 847 F.3d at 830 (invalidating an Indiana law as unconstitutionally extraterritorial "because it dictates how out-of-state manufacturers must build and secure their facilities, operate assembly lines, clean their equipment, and contract with security providers, if any of their products are sold in Indiana," even when those transactions and operations occur out of state).

As applied to the statute at issue here, those basic constitutional principles compel a simple outcome: HB 631, which plainly purports to dictate (although via vague terms) the prices drug manufacturers can charge for their products, cannot be applied to sales that take place outside of Maryland—even if the objects of those sales (*i.e.*, the manufacturers' drugs) later end up being resold in separate transactions inside Maryland. Indeed, the two most analogous state laws were both invalidated on extraterritoriality grounds. *See Pharm. Research & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 67-71 (D.D.C. 2005) (striking down

price-gouging law "as applied to sales between out-of-state manufacturers … and other out-of-state entities" under dormant Commerce Clause), *aff'd sub nom., Biotech. Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007) (per curiam); *Pharm. Research & Mfrs. of Am. v. Comm'r, Me. Dep't of Human Servs.*, 2000 WL 34290605, at *1-2, *7 (D. Me. Oct. 26, 2000) ("the interstate Commerce Clause will not permit" a State to "legislate the amounts that out-of-state manufacturers obtain when they sell to pharmaceutical wholesalers or distributors out-of-state"), *rev'd on other grounds, Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 79-84 (1st Cir. 2001) (distinguishing a valid law from one that "insist[s] that manufacturers sell their drugs to a wholesaler for a certain price" even outside of the regulating state), *aff'd, Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644 (2003). And as the Seventh Circuit recently explained, despite "two hundred years of Commerce Clause precedents to draw from," there is simply "no authority" to support upholding a state law that purports to "govern[] the … commercial relationships between out-of-state manufacturers and their" out-of-state counterparts. *Legato Vapors*, 847 F.3d at 833.

The district court nonetheless ruled that Maryland could lawfully hold manufacturers liable under HB 631 for their wholly out-of-state sales so long as the objects of those transactions were later "made available for sale in Maryland."

Mem. & Order, Dist. Ct. Dkt. 43, at 15. Two fundamental errors coalesced to produce this patently incorrect conclusion.

First, the district court read *Healy*, *Brown-Forman*, and *Baldwin* to apply *only* to cases involving "price-parity or price-affirmation statutes." *Id.* at 17. That is wrong both as a matter of precedent and as a matter of principle. As an initial matter, "the Supreme Court has never so limited the doctrine, and indeed has applied it more broadly." *North Dakota v. Heydinger*, 825 F.3d 912, 920 (8th Cir. 2016) (rejecting argument that anti-extraterritoriality doctrine is limited to laws mandating price parity). In *Edgar*, for instance, the Supreme Court struck down the Illinois Business Take-Over Act,[5] which is not even arguably a price-parity provision, in part because it "purport[ed] to regulate directly and to interdict interstate commerce, *including commerce wholly outside the State*." 457 U.S. at 642-43 (plurality opinion) (emphasis added); *see also, e.g.*, *Midwest Title Loans, Inc. v. Mills*, 593 F.3d 660, 669 (7th Cir. 2010) (invalidating an Indiana lending law as applied to an Illinois company's lending to Indiana residents using contracts made and executed entirely in Illinois). And in *West Lynn Creamery*, the Court stressed that its dormant Commerce Clause jurisprudence "is not so rigid as to be

[5] Under the Business Take-Over Act, the Illinois Secretary of State could overrule takeover offers of corporations that had their "principal executive office in Illinois, [were] organized under the laws of Illinois, or ha[d] at least 10% of [their] stated capital … within the State." *Edgar*, 457 U.S. at 627 (opinion of the Court).

controlled by the form by which a State erects barriers to commerce." *W. Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 201 (1994).

Nor would limiting the anti-extraterritoriality doctrine to price-parity provisions make any sense as a matter of principle. In the district court's telling, price-parity and price-affirmation statutes "must be treated differently because they are barriers to free trade between states." Mem. & Order, Dist. Ct. Dkt. 43, at 17. While that is certainly one concern such statutes raise, *see Baldwin*, 294 U.S. at 521, it is hardly the only one, or even the most pernicious. After all, lots of state laws erect barriers to interstate trade in one form or another, and yet not all such provisions violate the Constitution. *See, e.g.*, *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 568-70 (1996) ("a State may protect its citizens by prohibiting deceptive trade practices," even though such laws may impose roadblocks to interstate trade); *see also Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

What makes state laws that insist on price parity so problematic is not just that they stop the free flow of goods throughout the Nation. Rather, the fundamental problem with such laws is that "they have ripple effects in other states, effectively setting the price for a commodity in transactions outside the regulating state." *Legato Vapors*, 847 F.3d at 831. In other words, they have the "practical effect" of imposing one state's views of what commercial terms are acceptable on conduct that takes place beyond its boundaries. *See Brown-Forman*,

476 U.S. at 583. At bottom, *that* extraterritorial extension of a state's jurisdiction is what violates the Constitution. *See BMW of N. Am.*, 517 U.S. at 571-72.

Second, the district court fundamentally misunderstood how HB 631 works. The district court believed that "a sale of drugs between an out-of-state manufacturer and an out-of-state distributor … does not give rise to liability." Mem. & Order, Dist. Ct. Dkt. 43, at 17. But "a sale of drugs between an out-of-state manufacturer and an out-of-state distributor" is often the *only* thing that will "give rise to liability" under HB 631; not even Defendants have been willing to contest that conclusion.[6] Yet this Court need not take our word for it that, under HB 631, the Maryland Attorney General can haul an out-of-state drug manufacturer into Maryland court on the basis of the prices it charged in an out-of-state sale to an out-of-state wholesaler. All this Court needs to do is read the statute.

[6] In their briefing below, Defendants consistently staked out the position that "the Act does not reach, or purport to reach, any stream of commerce that does not end in Maryland." Mem. in Support of Defs.' Mot. to Dismiss, Dist. Ct. Dkt. 29-1, at 23; *see also, e.g.*, *id.* at 25 (acknowledging that HB 631 may apply to "upstream transactions between out-of-state manufacturers and out-of-state distributors" if the products sold later end up in Maryland). Yet Defendants repeatedly refused to refute the obvious logical consequence of that position: that manufacturers *can* be held liable under HB 631 for their wholly out-of-state transactions if *someone else* later resells the objects of those transactions in (and thus brings the "stream of commerce" to) Maryland. Indeed, at oral argument, Defendants refused to concede that HB 631 could not be constitutionally applied against a manufacturer who does no business in Maryland at all.

HB 631 prohibits "price gouging in the sale of an essential off-patent or generic drug" by manufacturers and wholesale distributors. § 2-802(a). The only thing that can violate the statute is thus the "price" of a "sale" by a manufacturer (or a wholesale distributor). Often (in fact, nearly always) those "sale[s]" take place entirely outside of Maryland, *i.e.*, when an out-of-state manufacturer sells its products to an out-of-state wholesaler in an agreement governed by some other state's laws.[7] (HB 631 clearly recognizes as much. *See, e.g.*, § 2-803(g).) As a result, when HB 631 says that Maryland courts may "restrain[] or enjoin[] a violation of this subtitle" or impose "a civil penalty of up to $10,000 for each violation of this subtitle," § 2-803(d)(2), (5), what it means is that Maryland courts may penalize and enjoin *wholly out-of-state commercial transactions*. After all, if only a manufacturer and only a sale can violate the statute, and a manufacturer's sales all took place outside of Maryland, then the only thing that could possibly be "enjoin[ed]" or "penal[ized]" would be the manufacturer's out-of-state sale.

[7] Given the as-applied nature of AAM's Commerce Clause claim, constitutionally nothing turns on the fact that such sales (*i.e.*, wholly out-of-state ones) are the rule rather than the exception. But precisely because such sales are the norm and not the exception, the Maryland Attorney General will have ample opportunity to apply HB 631 to a wide range of wholly extraterritorial transactions absent this Court's intervention. Indeed, under § 2-803(g), it is "not … a defense" to a price-gouging charge that the manufacturer or distributor "did not deal directly with a consumer residing in [Maryland]." The stakes could hardly be higher for AAM's members.

That leaves just one final coda on this issue. The district court concluded that this Court's decision in *Star Scientific, Inc. v. Beales*, 278 F.3d 339 (4th Cir. 2002), supported the outcome reached below. Perhaps if the district court were right that an out-of-state sale could not constitute a violation of HB 631, that conclusion might follow. In reality, however, precisely the opposite is true. The statute at issue in *Star Scientific* imposed a two-cent levy to each cigarette sold in Virginia, which was to be paid into an escrow account for potential future use to satisfy any tobacco-litigation-related judgments. Cigarette manufacturers were required to pay the fee even if they did not directly sell the cigarettes in the state. *See id.* at 344-46.

The district court homed in on that indirect-sale provision, and concluded that it made the *Star Scientific* statute materially indistinguishable from HB 631. *See* Mem. & Order, Dist. Ct. Dkt. 43, at 15-16. But the district court overlooked the critical distinction between the two statutes. The only thing that could violate the statute in *Star Scientific* was refusal to pay the levy. As a result, the Virginia statute did not directly regulate *any* transactions at all, let alone any out-of-state transactions. All it did was create a new, *wholly in-state* transaction (paying two cents into a state-controlled escrow account), participation in which Virginia made a condition of selling cigarettes in the state. *See Star Scientific*, 278 F.3d at 356 (concluding that the Virginia law does "not have the 'practical effect' of controlling

prices or transactions occurring wholly outside of the boundaries of Virginia, as was the case in *Brown-Forman* and *Healy*"). That could not be more *unlike* HB 631, which, again, authorizes Maryland courts to penalize prescription drug manufacturers for the terms of their transactions even when those transactions take place entirely outside of Maryland. Under binding precedent, HB 631 violates the Commerce Clause as applied to such transactions.

B. HB 631 Is Void for Vagueness.

HB 631 provides precisely zero meaningful guidance on how to interpret or apply any of the law's key terms, leaving courts without a reliable basis to craft a narrower construction—as even the district court recognized. *See* Mem. & Order, Dist. Ct. Dkt. 43 at 27-28. The district court declined to enjoin enforcement of the statute on the basis of its mistaken view that the economic and regulatory inputs that affect manufacturers' pricing decisions were somehow relevant to whether a statute that authorizes the Maryland Attorney General to bring suit is unconstitutionally vague. This Court is highly likely to rectify that error.

Under § 2-801(f), HB 631 defines as "unconscionable" any price increase that is "excessive," is not "justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug," and will leave consumers with no "meaningful choice" but to buy the drug at an "excessive price." Not a single one of § 2-801(f)'s keys terms ("excessive," "justified," "meaningful," "appropriate")

has a sufficiently definite meaning to be cognizable absent further elaboration, and yet not a single one of them is defined in the statute. *See* Mem. & Order, Dist. Ct. Dkt. 43 at 27-28 (HB 631 "appear[s] to" lack *any* standards that are "binding on the Attorney General").

To be sure, not all laws that rely on similarly broad terms to define their scope are invalid; "courts at times uphold the use of [vague] terms by relying on narrowing judicial constructions or on the clarifying effects of other statutory elements." M. Sean Royall, *Constitutionally Regulating Telephone Harassment: An Exercise in Statutory Precision*, 56 U. Chi. L. Rev. 1403, 1413 (1989). But HB 631 leaves a number of basic questions about its scope entirely unanswered. Take the term "lack of meaningful choice." That phrase might make some sense had the Maryland General Assembly actually limited the statute to sole-source drugs. But HB 631 is not limited to monopolists or cases of market dysfunction; it instead applies even when as many as three manufacturers are "actively manufactur[ing] and market[ing]" the same drug, § 2-801(b)(1)(iii), and even when an infinite number of therapeutic substitutes are available. And, to state the obvious, it is nearly impossible to understand how such a competitive market could leave a consumer without a "meaningful choice" of which product to purchase.

The statute's foundational criterion for unlawful conduct—"excessive"—is even less tethered to anything concrete or readily cognizable. As written, an

increase from ten cents per pill to twenty cents per pill for a generic prescription drug might lead to a $10,000 penalty. So, too, might a 5% increase from $75 per month to $82 per month. Or maybe only one of them, or neither, will be sanctionable. The important point is not which of these conjectures is correct, but rather a more basic one: *the statute says nothing to help manufacturers figure that out*. Indeed, despite prodding both by AAM and the district court, at oral argument on the preliminary injunction motion the Attorney General repeatedly refused to accept that even a 10% price increase could not be "unconscionable" under the statute.

It would have been fairly simple to give even a hint of guidance. HB 631 authorizes the Maryland Medical Assistance Program to "notify the Attorney General of any increase in the price of an essential off-patent or generic drug when," *inter alia*, a price increase "would result in an increase of 50% or more in the wholesale acquisition cost of the drug." § 2-803(a). Such a benchmark could have been added to § 2-801(f), but none was. The Attorney General's authority to bring suit in Maryland court against drug manufacturers is not tied to the reporting requirements in § 2-803(a). *Compare* § 2-803(d), *with* § 2-803(a). The Attorney General therefore enjoys what amounts to a blank check to go after the major players in the generic market as he sees fit. So long as HB 631 remains on the

books, manufacturers can thus rely on neither benchmarks nor common sense to keep them out of Maryland state court.

Despite acknowledging that fundamental flaw in the statute, *see* Mem. & Order, Dist. Ct. Dkt. 43, at 27-28 (statute lacks standards that are "binding on the Attorney General"), the district court nonetheless refused to enjoin HB 631 based on the mistaken premise that discovery on the economic and industrial forces that drive prescription drug pricing decisions was necessary, *see id.* at 29-30. But the standard for a void-for-vagueness claim is objective. At bottom, what matters is whether the challenged law is so unclear as to preclude regulated parties from ordering their affairs or to invite arbitrary enforcement. *See, e.g.*, *Hill*, 530 U.S. at 732 ("A statute can be impermissibly vague for either of two independent reasons. First, if it fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits. Second, if it authorizes or even encourages arbitrary and discriminatory enforcement."); *Ledezma-Cosino v. Sessions*, 857 F.3d 1042, 1047 (9th Cir. 2017) (dispositive inquiry is whether a statute "lends itself to an objective factual inquiry"), *pet. for cert. filed*, No. 17-313 (Aug. 25, 2017). Which economic, industrial, or regulatory inputs might affect manufacturers' pricing decisions in the abstract are thus entirely irrelevant to whether HB 631 passes muster under the Due Process Clause.

Absent this Court's intervention, Maryland will be able to enforce a concededly standardless law. The consequences of leaving the decision below intact thus could hardly be more obvious: "the state will get away with more inhibitory regulation than it has a constitutional right to impose, because persons at the fringes of amenability to regulation will rather obey than run the risk of erroneous constitutional judgment." Anthony G. Amsterdam, *The Void-For-Vagueness Doctrine in the Supreme Court*, 109 U. Pa. L. Rev. 67, 80 (1960). Given the fundamental errors underlying the district court's decision, there is no reason for this Court to abide that state of affairs.

II. AAM Members Will Suffer Irreparable Harm If No Injunction Issues.

AAM's member-manufacturers sell the overwhelming majority of their products to national wholesalers in bulk agreements outside of Maryland. Yet in light of the district court's conclusion that manufacturers' sales that take place *wholly outside of Maryland* may still be deemed to violate HB 631 so long as someone else later resells the objects of those sales in the state, the only way a manufacturer can reliably ensure that it will not be subject to massive penalties and crippling injunctions under the new Maryland law is to take costly steps to keep its drugs out of the state entirely. Instituting such a no-resale-to-Maryland policy will not be easy or costless; like most drug manufacturers, AAM's members generally do not track their sales "downstream" or even have an infrastructure in place to

ensure that their products are kept out of this state or that. *See, e.g.*, Dkt. 7-2 at Ex. 3 ¶¶ 4-7; Ex. 5 ¶¶ 7-9; Ex. 7 ¶¶ 4-7; Ex. 8 ¶¶ 4-6.

The most obvious costs of such efforts will come in the form of money spent developing ways to track already-sold products, plus money lost in the form of renegotiated sales agreements with wholesalers. But arguably the more onerous costs will come in the form of reputational injury; Maryland patients are unlikely to take kindly to having their favored medicines removed from their local pharmacies' shelves, and nationwide distributors are even less likely to forget manufacturers' insistence on reworking dozens of nationwide agreements long after the fact. *See, e.g.*, *PBM Prod., LLC v. Mead Johnson & Co.*, 639 F.3d 111, 127 (4th Cir. 2011) (damage to manufacturer's reputation constitutes irreparable harm). And in all events, regardless of what shape these efforts take, any and all costs manufacturers are forced to bear in response to the new statute will be irreparable by definition; after all, the State enjoys sovereign immunity from damages claims. *See generally Chamber of Commerce of the U.S. v. Edmondson*, 594 F.3d 742, 770-71 (10th Cir. 2010); *see also, e.g.*, *Ohio Oil Co. v. Conway*, 279 U.S. 813, 814 (1929) (per curiam).

More broadly, AAM members will suffer irreparable harm in the form of the loss of constitutional freedoms, *i.e.*, being subjected to unconstitutional state action. *See, e.g.*, *Davis v. District of Columbia*, 158 F.3d 1342, 1346 (D.C. Cir.

1998) ("Although a plaintiff seeking equitable relief must show a threat of substantial and immediate irreparable injury, a prospective violation of a constitutional right constitutes irreparable injury for these purposes."); 11A Charles Alan Wright et al., *Federal Practice & Procedure* § 2948.1, at 161 (2d ed. 1995) ("When an alleged deprivation of a constitutional right is involved, most courts hold that no further showing of irreparable injury is necessary."). Consistent with that general principle, this Court has recognized that "violations of [a plaintiff's] First, Fourth, and Sixth Amendment rights" may properly form the basis of a finding of irreparable harm, full stop. *A Helping Hand, LLC v. Baltimore Cty.*, 355 F. App'x 773, 777 (4th Cir. 2009) (discussing *Ross v. Meese*, 818 F.2d 1132, 1135 (4th Cir. 1987)). And while this Court has not yet extended that holding to the constitutional violations alleged here, there is no reason why the same would not be true of the constitutional invasions alleged here. Indeed, numerous courts have recognized that the principle applies with full force to violations of the Due Process Clause and the Commerce Clause. *See, e.g.*, *Whole Woman's Health v. Hellerstedt*, 231 F. Supp. 3d 218, 232 (W.D. Tex. 2017) ("In light of the likely deprivation of" plaintiff's due process rights, "'no further showing of irreparable injury is necessary.'"); *Am. Libraries Ass'n v. Pataki*, 969 F. Supp. 160, 168 (S.D.N.Y. 1997) ("Deprivation of the rights guaranteed under the Commerce Clause constitutes irreparable injury.").

Yet this Court need not reach that question to grant the request injunction. Even Defendants have never contested that AAM members will be forced to suffer both direct and indirect costs in trying to comply with HB 631's vague terms. Nor could anyone argue that Defendants' Eleventh Amendment immunity will render such costs unrecoverable even if this Court later holds HB 631 unconstitutional. It is difficult to imagine a more paradigmatically irreparable injury.

III. An Injunction Would Not Unduly Burden The State, And The Public Interest Favors An Injunction.

As this Court recently explained, "the State of Maryland is in no way harmed by issuance of an injunction that prevents the state from enforcing unconstitutional restrictions." *Legend Night Club v. Miller*, 637 F.3d 291, 302-03 (4th Cir. 2011). "If anything, the system is improved by such an injunction.'" *Giovani Carandola, Ltd. v. Bason*, 303 F.3d 507, 521 (4th Cir. 2002); *cf. Joelner v. Vill. of Wash. Park*, 378 F.3d 613, 620 (7th Cir. 2004) ("[T]here can be no irreparable harm to a municipality when it is prevented from enforcing an unconstitutional statute."); *Gordon v. Holder*, 826 F. Supp. 2d 279, 297 (D.D.C. 2011) ("a potential deprivation of [a plaintiff's] constitutional right to due process ... outweighs the possible injury to defendants from enjoining enforcement until the merits of [the plaintiff's] claim can be determined"), *aff'd*, 721 F.3d 638 (D.C. Cir. 2013). Compared to the substantial and irreparable harm AAM members will

suffer if HB 631 is allowed to take effect, Defendants will suffer no meaningful injury from the relief sought.

With regard to the public interest, AAM readily acknowledges that the stated purposes underlying the statute are valid and perhaps even noble. But the public interest is never served by allowing an unconstitutional state action to remain in effect. *See, e.g.*, *Int'l Refugee Assistance Project v. Trump*, 857 F.3d 554, 591 (4th Cir. 2017) (affirming injunction against executive order the "purpose" of which is "to protect the Nation from terrorist activities"). To the contrary, "upholding constitutional rights is in the public interest," period. *Miller*, 637 F.3d at 303.

This Court could rest its public interest analysis on that ground alone. But it need not. In light of its sweeping terms, HB 631 exposes generic drug manufacturers to a significant risk of liability, though on terms that are far from certain. HB 631 has thus introduced enormous uncertainty and business risk for generic drug manufacturers. The inevitable effect of that risk will be that some manufacturers will take drastic measures to keep their medicines out of Maryland. *See* ECF No. 7-2 at Ex. 1 ¶¶ 9-10; Ex. 3 ¶¶ 9-10; Ex. 4 ¶¶ 11-12; Ex. 5 ¶¶ 11-12; Ex. 7 ¶¶ 7-8; Ex. 8 ¶¶ 7-8; Ex. 9 ¶¶ 8-9. Such retrenchment will be worse for patients' health (as they may be forced to go without life-saving medicines or to switch to uncertain alternatives), worse for patients' pocketbooks (as decreased competition will drive up prices for those manufacturers who continue to allow

their products to be made available for sale in Maryland), and worse for Maryland. Enjoining the law's enforcement pending appeal is in the public interest.

CONCLUSION

For the foregoing reasons, Plaintiff-Appellant respectfully requests that this Court enjoin Defendants from enforcing HB 631 pending the resolution of this appeal. Pursuant to Fourth Circuit Local Rule 27(a), counsel for Defendants have been informed of the intended filing of the motion and have indicated that they intend to file a response in opposition.

Respectfully submitted,

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October 12, 2017

CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of October, 2017, I electronically filed the foregoing Motion for Injunction Pending Appeal with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit using the CM/ECF system.

/s/
JONATHAN D. JANOW