UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ASSOCIATION FOR ACCESSIBLE MEDICINES,

Plaintiff,

v.

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

Defendants.

Civil Action No. 1:17-cv-1860

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

Pursuant to Federal Rule of Civil Procedure 65(a), Article I, Section 8 of and the Fourteenth Amendment to the United States Constitution, and the Local Rules of the District of Maryland, Plaintiff the Association for Accessible Medicines ("AAM") seeks a preliminary injunction enjoining Brian E. Frosh, in his official capacity as Attorney General of the State of Maryland (the "Attorney General"), and Dennis R. Schrader, in his official capacity as Secretary of the Maryland Department of Health (the "Secretary" and, collectively with the Attorney General, "Defendants"), from implementing or enforcing House Bill 631 – Public Health – Essential Off-Patent or Generic Drugs – Price Gouging – Prohibition ("HB 631"). The requested relief would avert irreparable injury to AAM members and the public

interest during the pendency of this litigation. Because HB 631 is scheduled to go into effect on October 1, 2017, AAM respectfully requests that this Court enter the requested injunction no later than September 30, 2017.

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INTRODUCTION

Though cast as a local economic regulation, HB 631 unambiguously regulates commerce in every corner of the United States, if not beyond. HB 631 prohibits generic prescription drug manufacturers (and wholesale distributors) from "unconscionabl[y]" increasing the price of any "[e]ssential off-patent or generic drug … that is made available for sale in the State" of Maryland, § 2-801(b)(1)(iv), § 2-802(a), *even if* the relevant entities, conduct and transactions occur entirely outside of the state, *see* § 2-803(g). Such nakedly extraterritorial state regulation is always constitutionally suspect, but it is particularly so here.

The bulk of "off-patent and generic drug" manufacturers sell their products to large, national wholesalers or to large retail pharmacy chains that warehouse the products themselves. These transactions, each and every one of which HB 631 purports to regulate, overwhelmingly occur wholly beyond the boundaries of the State of Maryland. Of the twenty largest generic drug manufacturers in the United States, only one is headquartered in Maryland, and *none of them* manufactures pharmaceuticals in Maryland. 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. Thus, in the overwhelming majority of off-patent and generic prescription drug sales between a pharmacy or healthcare provider and a patient in

Maryland, the only involvement a manufacturer or wholesale distributor has is via an upstream sale that occurred entirely outside of the state. The law's extraterritorial scope could hardly be clearer.

Making matters worse, the operative terms of HB 631's sweeping price-control provisions leave the parties subject to the law woefully uncertain as to what it requires, and provide the state officials tasked with implementing and enforcing the law nearly unbounded discretion to interpret and implement it. HB 631 defines "price gouging" as "an unconscionable increase in the price of a prescription drug," § 2-801(c), and keys the meaning of "unconscionable" on a number of expansive adjectives—"excessive," "justified," "appropriate," and "meaningful," just to name a few—with little to no contextual color to cabin their reach. Manufacturers, wholesalers, courts, and—most worryingly—the state officials charged with implementing the law are left with no meaningful direction to determine whether conduct actually falls within the statute's "price gouging" prohibition. HB 631 thus poses the "danger that 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).

But this Court need not take AAM's word for it. HB 631's unconstitutional sweep has already raised serious alarm at the highest levels of state government. 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 allowing HB 631 to become law, Governor Hogan made clear that he harbored deep apprehension regarding the law's terms. Governor Hogan lamented that 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." Compl., ECF No. 1, Ex. B at 1. 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 1-2.

If allowed to go into effect, HB 631 will unleash a potentially unlimited number of enforcement actions seeking to punish AAM members—on whose life-sustaining pharmaceutical products many Marylanders, and many Americans, rely—for prices charged for off-patent and generic drugs "made available" in the State of

Maryland, even if AAM members do no business in the state. Indeed, the private coalition that spearheaded the legislation is already soliciting individuals to "highlight cases of suspected price gouging that the Attorney General may now pursue." Health Care for All, Prescription Drug Affordability Initiative, http://healthcareforall.com/get-involved/prescription-drug-affordability-initiative/. The resulting lawsuits will wreak untold disruptions in the generic pharmaceuticals market, handcuffing manufacturers from making real-time and free-market-driven pricing decisions which may force the withdrawal of generic products from the market, threatening the public health (and consumers' pocketbooks) both in and out of the state and causing AAM members irreparable reputational harm. And at the very least, AAM's sweeping terms and punitive sanctions will force AAM members to hastily attempt to comply with unknown pricing limitations, which will inevitably cause them direct economic damages they will be unable to recoup in light of Defendants' sovereign immunity. The broader public will also suffer from the resulting uncertainty and disruption in the market.

Only the requested relief can fully avert these severe and irreparable harms. AAM thus seeks a preliminary injunction against enforcement and implementation of HB 631 to maintain the status quo while its constitutional challenge proceeds.

STATEMENT OF FACTS

A. Generic Drugs Help Keep American Healthcare Costs Down

Generic prescription drugs play a crucial role in controlling healthcare costs for Americans. 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., ECF No. 1, Ex. C at 34. Indeed, generic medicines saved Americans $1.67 *trillion* over the past decade, and $253 billion in 2016 alone—nearly $5 billion every week. *Id.* at 20, 34. The availability of generic drugs is thus critical to ensuring that patients have access to affordable medicine. *See* Compl., ECF No. 1, Ex. D at 1 ("Generic drugs have for several decades offered relief from rising prescription drug costs.").

Generics were not always so widely available. Throughout most of the twentieth century, federal law required all pharmaceutical drug products, whether branded or generic, to undergo independent clinical testing to prove their safety and efficacy before they could go to market, even if a generic were chemically identical to a patented drug. *See, e.g.*, Laura J. Robinson, *Analysis of Recent Proposals to Reconfigure Hatch-Waxman*, 11 J. Intell. Prop. L. 47, 52 (2003). This regime left patent holders with an unintended boon. Given the significant costs required to perform the testing required to market a drug lawfully, companies had little incentive to duplicate previously approved pharmaceutical products. Hundreds of branded

drugs thus had no off-patent or generic equivalent, which left patients and consumers forced to pay sky-high prices for basic medications long after the patents protecting those drugs had expired. Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 New Eng. J. Med. 1993 (2007).

That all changed in 1984, when Congress enacted the Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in various sections of titles 21, 35 & 42 U.S.C.). The Hatch-Watchman Amendments were intended "to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting); *see also* H.R. Rep. No. 98-857(I) (1984), at 14-15.

In order to achieve these objectives, the Hatch-Watchman Amendments drew sharp distinctions between brand-name drugs and their generic equivalents, based on a simple premise: where two drug products are in all material respects the same, they will share the same safety and efficacy profile. While branded products remained subject to extensive clinical-testing requirements, *see* 21 U.S.C. § 355(b)(1), generic manufacturers whose products are in all material respects the

same as existing drugs no longer must complete a full New Drug Application on their own. Instead, under Hatch-Waxman generic manufacturers may "file an Abbreviated New Drug Application, in which they may 'rely on the clinical studies performed by the pioneer drug manufacturer.'" *Mylan Pharm., Inc. v. FDA*, 594 F. App'x 791, 793 (4th Cir. 2014) (quoting *aaiPharma, Inc. v. Thompson*, 296 F.3d 227, 231 (4th Cir. 2002)); *see* 21 U.S.C. § 355(j)(2)(A)(vii).

In an Abbreviated New Drug Application, a generic manufacturer must show three things. First, the manufacturer must demonstrate that "the proposed generic drug must be chemically equivalent to the approved brand-name drug," *i.e.*, that it has "the same 'active ingredient' or 'active ingredients,' 'route of administration,' 'dosage form,' and 'strength' as its brand-name counterpart." *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013) (quoting 21 U.S.C. § 355(j)(2)(A)(ii)). "Second, a proposed generic must be 'bioequivalent' to an approved brand-name drug," *i.e.*, "it must have the same 'rate and extent of absorption' as the brand-name drug." *Id.*; *see* 21 U.S.C. § 355(j)(2)(A)(iv), (j)(8)(B). And third, the manufacturer must demonstrate that "the labeling proposed for the new drug is the same as the labeling approved for the [approved brand-name] drug." *Bartlett*, 133 S. Ct. at 2471 (alteration in original); *see* 21 U.S.C. § 355(j)(2)(A)(v).

Hatch-Waxman's streamlined process for approving generic drugs has been remarkably successful in achieving Congress' goal of "'get[ting] generic drugs into

the hands of patients at reasonable prices—fast.'" *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (quoting *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)). Today, some 200 companies market generic drugs in the United States, and nearly all of them provide American consumers with access to affordable medicines that sustain millions of lives every day.

Take, for instance, asthma medications. Before its patent expired in August 2012, Merck's Singulair (montelukast) cost patients about $180 a month. The introduction of a generic alternative immediately decreased the price to patients by roughly 50%, and by 2015, the cost of an average 30-day supply was $18, or 10% what it was before generics entered the market. *See* Consumer Reports News, *New generic Singulair could save asthma sufferers big bucks* (Aug. 6, 2012), *available at* http://www.consumerreports.org/cro/news/2012/08/new-generic-singulair-could-save-asthma-sufferers-big-bucks/index.htm; Allison Gilchrist, *5 Drugs That Actually Decreased in Price Last Year*, Pharmacy Times (Jan. 5, 2016), *available at* http://www.pharmacytimes.com/news/5-drugs-that-actually-decreased-in-price-last-year. Other similar examples abound, and lawmakers around the country have taken note. *See, e.g.*, Sen. Susan Collins, *Working to Keep Lifesaving Medications Affordable* (Sep. 2, 2016) ("[O]ne factor that will help drive down costs for patients is ensuring there is a market for generic competitors."), *available at* https://www.collins.senate.gov/newsroom/working-keep-lifesaving-medications-

affordable. Other, similar examples abound. When it comes to the cost of healthcare in America, generic drugs are part of the solution, not the problem.

B. The Generic Prescription Drug Distribution Chain

That off-patent and generic drugs are far less costly for manufacturers to produce—and thus far less costly for patients to purchase—than their branded counterparts does not mean that they are immune from market forces. At the most basic level, generic drug manufacturers are able to charge low prices for their products because of robust competition in the market. Compl., ECF No. 1, Ex. D at 1 ("Generic drugs have for several decades offered relief from rising prescription drug costs. This occurs because there is robust competition among multiple interchangeable products that drive prices for generic drugs to be a fraction of that of the corresponding brand name drug. The result is that decreases in generic drug prices have partially offset large increases in prices for brand drugs.").

Basic macroeconomic forces such as supply and demand undeniably affect pricing conduct, but so too do a myriad other interconnected factors, including the rate at which drugs are prescribed, regulatory requirements, insurance reimbursement rates, supply-chain factors, and so on. *See, e.g.*, *Washtenaw Cty. Emps.' Ret. Sys. v. Walgreen Co.*, No. 15-cv-3187, 2016 WL 5720375, at *1 (N.D. Ill. Sept. 30, 2016) (discussing various factors that affect drug pricing). Indeed, "the price of prescription drugs paid by the consumer is determined by a constellation of

negotiated contracts between manufacturers, PBMs [pharmacy benefit managers], wholesale distributors, pharmacies, and [insurance] plan sponsors." Compl., ECF No. 1, Ex. E at 24. In short, "[t]he pricing of prescription drugs and the flow of money among the various links in the pharmaceutical supply chain is more complex than the physical distribution of drugs through the chain," which itself is an intricate and interconnected system. *Id.*

Moreover, decisions relating to pricing and distribution of off-patent and generic prescription drugs are made at a national, not state-by-state, level. *See id.* at 17-23. Indeed, HB 631 itself acknowledges and refers to *national* pricing benchmarks in connection with its own price monitoring provisions. Under § 2-801(g), the term "wholesale acquisition cost," commonly known as WAC, is given the same meaning as in Title 42 of the U.S. Code. *See* 42 U.S.C. § 1395w-3A(c)(6)(B) (defining "wholesale acquisition cost" to mean "the manufacturer's list price for the drug … to wholesalers or direct purchasers in the United States … as reported in wholesale price guides or other publications of drug or biological pricing data"). This means that laws in any one state imposing artificial price restraints on generic and off-patent pharmaceutical products will inevitably affect commercial transactions, pricing, and commerce in other other states.

And save for the local pharmacies that sell the products to patients directly, next to none of the relevant participants in this distribution chain resides in

Maryland. Of the Nation's twenty largest generic drug manufacturers, only *one* is based in Maryland, and *none* manufactures *any* prescription drugs in the state. The overwhelming majority of generic prescription drugs provided to patients in the United States are initially sold by manufacturers to large wholesalers like AmerisourceBergen Corp., McKesson Corp., and Cardinal Health, Inc., or large retail pharmacy chains like CVS or Rite-Aid that warehouse their own drugs. (Generics sold to wholesalers are typically resold to retail pharmacies and healthcare institutions that dispense the drugs directly to patients.) Yet none of the "Big Three" wholesalers—which collectively account for nearly 90% of the wholesale market, *see* Compl., ECF No. 1, Ex. E at 8—resides in Maryland; nor do any of the large, national or regional retail pharmacy chains that warehouse their own drugs.

Thus, in the overwhelming majority of generic drug sales to patients in Maryland, the only involvement a drug manufacturer has to the end transaction is via an upstream sale that occurred wholly outside of the state.

C. HB 631

On April 10, 2017, the Maryland General Assembly passed HB 631, which seeks to add a new subtitle to Title 2 of the Maryland general health statutes concerning the Department of Health and Mental Hygiene, entitled "Prohibition Against Price Gouging For Essential Off-Patent Or Generic Drugs." The bill passed

by overwhelming majorities: 38-7 in the Maryland Senate, and 137-2 in the the Maryland House of Delegates.

The statute broadly 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 it defines as "an unconscionable increase in the price of a prescription drug," § 2-801(c). That key term—"unconscionable increase"—is itself defined as "an increase in the price of a prescription drug that:

> (1) Is excessive and 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
>
> (2) Results in consumers for whom the drug has been prescribed having no meaningful choice about whether to purchase the drug at an excessive price because of:
>
> (i) The importance of the drug to their health; and
>
> (ii) Insufficient competition in the market for the drug."

§ 2-801(f).

HB 631's "price gouging" prohibition applies to all "essential off-patent and generic drug[s]," § 2-801(b)(1), which the statute defines as any prescription drug "for which all exclusive market rights, if any, granted under the federal Food, Drug, And Cosmetic Act, § 351 of the federal Public Health Service Act, and federal patent law have expired," § 2-801(b)(1)(i), which "is actively manufactured and marketed for sale in the United States by three or fewer manufacturers," § 2-801(b)(1)(iii),

which "is made available for sale in the State," § 2-801(b)(1)(iv), and which either (1) appears on the most recent World Health Organization ("WHO") List of Essential Medicines or (2) has been designated by the Maryland Secretary of Health and Mental Hygiene as an essential medicine, § 2-801(b)(1)(ii). HB 631's price restraint also applies to "any drug-device combination product used for the delivery" of a generic prescription drug. § 2-801(b)(2).

In addition to these price-control provisions, HB 631 authorizes the Maryland Medical Assistance Program, a component of the Maryland Department of Human Resources, to engage in broad monitoring of essential off-patent and generic drug pricing, and imposes sweeping reporting requirements on manufacturers of essential off-patent and generic drugs. § 2-803(a). HB 631 requires manufacturers identified by the Maryland Medical Assistance Program to "submit a statement" to the Maryland Attorney General "[i]temizing the components of the cost of producing the drug" in question, "[e]xplaining any improvement in public health associated with" any increased expenditures, and, *inter alia*, "[p]roviding any other information … relevant to a determination of whether a violation of this subtitle has occurred." § 2-803(b). And HB 631 authorizes the Attorney General to launch investigatory inquiries into, and send document requests to, manufacturers and wholesale distributors regarding price increases and potential violations of the statute. § 2-803(c), (d).

HB 631's monitoring provisions are keyed in part off of federal Medicaid provisions. The bill authorizes the Maryland Medical Assistance Program, which administers Maryland's Medicaid 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). And under § 2-801(g), the term "wholesale acquisition cost" is given the same meaning in HB 631 as in Title 42 of the U.S. Code. *See* 42 U.S.C. § 1395w-3A(c)(6)(B) (defining "wholesale acquisition cost" to mean "the manufacturer's list price for the drug … to wholesalers or direct purchasers in the United States … as reported in wholesale price guides or other publications of drug or biological pricing data").

Finally, HB 631 authorizes the Attorney General to petition Maryland Circuit Courts for orders: (1) "[c]ompelling a manufacturer or a wholesale distributor" to produce various documents pursuant to § 2-803(b) & (c); (2) "restraining or enjoining a violation" of the statute; (3) "restoring to any consumer, including a third party payor, any money acquired as a result of a price increase that violates" the statute; (4) "requiring a manufacturer that has engaged in price gouging" in violation of the statute "to make the drug available to participants in any State health plan or State health program for a period of up to 1 year at the price at which the drug was made available to participants in the State health plan or State health program

immediately prior to the manufacturer's violation"; and (5) "[i]mposing a civil penalty of up to $10,000 for each violation" of the statute. § 2-803(d). The Attorney General's authority to initiate civil actions against manufacturers under HB 631 is not tied to the reporting requirements in § 2-803(a). *Compare* § 2-803(d), *with* § 2-803(a).

In any action brought by the Attorney General under § 2-803(d), "a person who is alleged to have violated a requirement of this subtitle may not assert as a defense that the person did not deal directly with a consumer residing in this State." § 2-803(g). Put differently, a manufacturer may be held to have violated HB 631 even though it conducted no business in Maryland or with a Maryland-based entity.

D. Governor Hogan Declines to Sign HB 631 Given Constitutional Concerns

On May 26, 2017, Maryland 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). The law is scheduled to take effect on October 1, 2017. Yet in allowing HB 631 to become law, Governor Hogan expressed deep apprehension regarding the law's sweep.

In acquiescing in the bill's enactment, Governor Hogan lamented that 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

Constitution." Compl., ECF No. 1, Ex. B at 1. The Governor also raised the 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." *Id.* at 1-2.

JURISDICTION

AAM challenges the validity of HB 631 under 42 U.S.C. § 1983 as well as the Commerce Clause of and Fourteenth Amendment to the United States Constitution. The Court thus has jurisdiction over this action under 28 U.S.C. § 1331.[1]

ARGUMENT

In deciding whether to grant a preliminary injunction, this Court considers: (1) the plaintiff's likelihood of success on the merits; (2) whether the plaintiff stands to suffer irreparable harm were an injunction not granted; (3) the balance of equities as between the plaintiff and other interested parties; and (4) whether the requested

[1] That HB 631 has not yet taken effect does not render this motion unripe for adjudication. *See, e.g.*, *Virginia v. Am. Booksellers Ass'n*, 484 U.S. 383, 392-93 (1988) (permitting pre-enforcement challenge where plaintiffs would incur significant costs to comply and where court saw no evidence that law would not be enforced); *Pierce v. Soc'y of Sisters of the Holy Names of Jesus & Mary*, 268 U.S. 510, 536 (1925) (suit ripe even though statute would not take effect until over a year after case was decided).

injunction would further the public interest. *Centro Tepeyac v. Montgomery Cty.*, 722 F.3d 184, 188 (4th Cir. 2013); *see also Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). All four factors weigh heavily in favor of granting injunctive relief here.

I. AAM Is Highly Likely To Succeed On The Merits.

To be entitled to a preliminary injunction, plaintiffs must "make a 'clear showing'" that they are "likely to succeed" on the merits of their claims, but they "need not show a certainty of success." *Pashby v. Delia*, 709 F.3d 307, 321 (4th Cir. 2013). AAM is highly likely to succeed on each of the constitutional challenges it asserts.

A. HB 631 Directly Regulates Commerce Wholly Outside of Maryland, in Violation of the Commerce Clause.

Despite being framed as a price regulation only for drugs that are "made available for sale in the State" of Maryland, § 2-801(b)(1)(iv), HB 631 does not target in-state commerce. Indeed, it regulates almost no in-state pricing decisions or transactions at all. To the contrary, HB 631 directly regulates commerce that takes place almost exclusively outside the state. The Constitution does not tolerate such naked efforts by one of "the several States" to regulate interstate commerce.

The Constitution vests Congress, and Congress alone, with the "Power … to regulate Commerce among the several States." U.S. Const. art. I, § 8, cl. 3. "Despite th[at] express grant to Congress," the Supreme Court has "consistently held this

language to contain a further, negative command, known as the dormant Commerce Clause," *Okla. Tax Comm'n v. Jefferson Lines, Inc.*, 514 U.S. 175, 179-80 (1995), which functions as "a limitation on state regulatory powers," *Fulton Corp. v. Faulkner*, 516 U.S. 325, 330 (1996). This negative construction of the Commerce Clause "prevent[s] a State from retreating into economic isolation or jeopardizing the welfare of the Nation as a whole, as it would do if it were free to place burdens on the flow of commerce across its borders that commerce wholly within those borders would not bear," *Jefferson Lines*, 514 U.S. at 179-80, and thus serves the fundamental "purpose of the Commerce Clause": "to create an area of free trade among the several States." *McLeod v. J. E. Dilworth Co.*, 322 U.S. 327, 330 (1944) (Rutledge, J., dissenting); *see also Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 6 (1824) (Marshall, C.J.) ("The entire purpose for which the delegates assembled at Annapolis, was to devise means for the uniform regulation of trade.").

"The modern law of … the dormant Commerce Clause is driven by concern about 'economic protectionism, that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors." *Dep't of Revenue of Ky. v. Davis*, 553 U.S. 328, 338 (2008) (quoting *New Energy Co. of Ind. v. Limbach*, 486 U.S. 269, 273-74 (1988)). Thus, in interpreting a state law that regulates commerce, "the practical effect of the statute must be evaluated not only by considering the consequences of the statute itself, but also by considering how

the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation." *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989).

"Under the resulting protocol for dormant Commerce Clause analysis," a law that "discriminates against interstate commerce … is 'virtually *per se* invalid.'" *Davis*, 533 U.S. at 337-38 (quoting *Or. Waste Sys., Inc. v. Dep't of Envtl. Quality of Or.*, 511 U.S. 93, 99 (1994)). In short, a state may not attempt to control the in-state price of a good by regulating the price of transactions occurring outside the state. *See Healy*, 491 U.S. at 336 ("[A] State may not adopt legislation that has the practical effect of establishing 'a scale of prices for use in other states.'" (quoting *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 523 (1935))). Yet that is precisely what HB 631 purports to accomplish. By its terms, HB 631 operates solely against manufacturers and wholesale distributors—the overwhelming majority of whom have no presence in Maryland and do no business directly in Maryland—and purports to apply to *every* pricing decision such out-of-state actors make for *every* "essential off-patent or generic drug" that is made available for purchase in the state, regardless of in which state the relevant transactions occurred. *See* §§ 2-801(b)(1), 2-802(a).

Consider the following. A New Jersey-based generic drug manufacturer with no production facilities or other presence in Maryland sells some of its product, which is listed on the World Health Organization's list of essential medicines, *see*

§ 2-801(a)(1)(ii), to a wholesaler located in Pennsylvania. The Pennsylvania-based wholesaler, which has no warehouses or other presence in Maryland, resells some of what it bought from the manufacturer to a local pharmacy in Maryland, which in turn fills a prescription for a patient (a purchase which may be paid for in whole or in part by insurance). Or instead, consider an initial sale from a generic manufacturer to a national retail pharmacy chain, which is incorporated in Delaware and has its principal place of business in New York. The retailer initially warehouses the product in New York, and then transports a portion of what it bought from the wholesaler to one of its retail pharmacies in Maryland, where it fills a prescription for the drug for a patient.

Even though none of the business conduct between the manufacturer and its direct customers involved Maryland entities or occurred within the State of Maryland, HB 631 still governs each transaction between them. But remarkably, it does not apply to the very *intra*-state sale to the patient. *See* § 2-801(c)(iii), (d) (HB 631 applies where essential off-patent or generic drug is merely "made available for sale in the State"). In other words, HB 631 governs *every* transaction *outside* of Maryland, but does *not* govern the primary transactions inside its borders. The statute's extraterritorial scope could hardly be clearer.

And to be clear, this hypothetical is far from a flight of fancy. In fact, it is *de rigueur*. As explained above, *see supra* 10-11, the vast majority of generic

prescription drugs provided to patients in the United States are not sold directly by manufacturers to consumers or healthcare institutions, but rather to large national (or regional) entities, next to none of whom has any direct relationship to Maryland. The overwhelming majority of off-patent and generic prescription drugs sold in the United States are supplied by the companies that comprise AAM's membership rolls, and yet just *one* of AAM's regular members is headquartered in Maryland, and *zero* of them actually manufacture any drugs in the state. Decl. of Chester "Chip" Davis, Jr., on behalf of AAM (Ex. 1) ¶ 7; *see* Decl. of Sean Moriarty on behalf of Lupin Pharmaceuticals, Inc. (Ex. 2) ¶¶ 2, 4-6. Similarly, generic drug manufacturers typically sell to large wholesalers or to large retail pharmacy chains that warehouse their own drugs, but *none* of these national companies—not one of the three national wholesalers that collectively account for nearly 90% of the wholesale market (AmerisourceBergen Corp., McKesson Corp., and Cardinal Health, Inc.), nor any of the major corner-store retail chain that warehouse their goods (like CVS, Rite-Aid, and so on)—is incorporated in, or has its principal place of business, in Maryland. Ex. 1 ¶ 7; Decl. of Don Bullock on behalf of Sagent Pharmaceuticals (Ex. 3) ¶ 5; Decl. of Lisa Graver on behalf of Alvogen Group, Inc. (Ex. 4) ¶ 5; Decl. of Michael Keenley on behalf of Zydus Pharmaceuticals USA Inc. (Ex. 5) ¶ 5. The vast majority of off-patent and generic prescription drugs are therefore not even arguably "made available for sale in the State" of Maryland unless, long after a manufacturer sells

drugs to a wholesaler, a wholesaler later resells units to a retail pharmacy or healthcare institution in the state (or to a warehousing retail chain that takes possession of the drugs outside the state and transports units to the state) who fills a prescription for an in-state patient.

A District of Columbia law that similarly regulated out-of-state pricing of patented prescription drugs—and that ultimately was invalidated—is instructive. Like HB 631, the D.C. law made it "unlawful for any drug manufacturer … to sell or supply for sale or impose minimum resale requirements for … a patented prescription drug that results in the prescription drug being sold … for an excessive price." D.C. Act § 28-4553. Also like HB 631, the D.C. law was triggered by an in-state (or in-District) sale. *See id.* (price constraint applies only to drugs "sold in the District"). Yet despite its in-District hook, the D.C. law was held to "effect an impermissible extraterritorial reach," and thus violate the dormant Commerce Clause, for two reasons. *Pharm. Research & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 70 (D.D.C. 2005), *aff'd sub nom. Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007) ("*PhRMA*"). First, "the overwhelming majority of" patented prescription drug transactions "occur entirely outside the District of Columbia between out-of-state manufacturers and out-of-state wholesalers." *Id.* at 68. And second, the D.C. law expressly exempted from its reach the only local transaction in the distribution chain: the one between the retailer and

the patient. *See id.* at 69 (noting that the law "specifically exclud[ed] 'point of sale retail seller[s]' in the District from its reach") (second alteration in original).

So too here. Just as in *PhRMA*, "the overwhelming majority of" generic prescription drug transactions "occur entirely outside [of Maryland] between out-of-state manufacturers and out-of-state wholesalers." *Id.* at 68; *see supra* 10-11. And just as in *PhRMA*, the only in-state transaction in the chain—the one between the retailer and the patient—does not fall within HB 631's reach. Thus, just as in *PhRMA*, "as applied to sales between out-of-state manufacturers—like [AAM's] members—and other out-of-state entities," HB 631 "has a *per se* invalid extraterritorial reach in violation of the Commerce Clause and must therefore be … struck down as unconstitutional." *See* 406 F. Supp. 2d at 71.

Indeed, HB 631 is arguably even more egregious than the D.C. law struck down in *PhRMA*. Unlike the invalidated D.C. statute, HB 631 expressly denies to manufacturers and distributors alleged to have violated the law's price control provisions the ability to "assert as a defense that [they] did not deal directly with a consumer residing in this state." § 2-803(g). Thus, "the provisions at issue here are not close calls—they clearly discriminate against out-of-state" commerce. *Envtl. Tech. Council v. Sierra Club*, 98 F.3d 774, 785 (4th Cir. 1996). HB 631 should accordingly be subject to the same fate as the D.C. law, which Judge Leon enjoined before the District had begun to enforce the law. *See PhRMA*, 406 F. Supp. 2d at 62,

72 (granting "plaintiffs' motion for an injunction prohibiting defendants from enforcing D.C. Act 16-171").

Nor would HB 631 be any less offensive to the Constitution if this extraterritorial sweep were somehow unintentional. The Framers held "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." *Hughes v. Oklahoma*, 441 U.S. 322, 325 (1979); *see also Baldwin*, 294 U.S. at 523 (our Constitution was "framed upon the theory that the peoples of the several states must sink or swim together"). State laws that have "the practical effect of regulating commerce occurring wholly outside the State's borders'" are thus unconstitutional "regardless of whether the statute's extraterritorial reach was intended by the legislature." *Healy*, 491 U.S. at 336.

Furthermore, courts must evaluate "the practical effect of the [challenged] statute … by considering … what effect would arise if not one, but many or every, State adopted similar legislation." *Id.* at 336. And here, as in *PhRMA*, "it takes little imagination to envision the harm to interstate commerce that could be caused by the domino effect of similar legislation [to HB 631] being adopted in many, or every, state." 406 F. Supp. 2d at 70. Such a "race[] to the bottom of the marketplace can be as dangerous to the interstate market as any other type of market failure, such as

a monopoly or price-tying measures." *Id.*; *see also Nat'l Ass'n of Home Builders v. Babbitt*, 130 F.3d 1041, 1049 (D.C. Cir. 1997) (characterizing a "race to the bottom" as having a "substantial harmful effect on interstate commerce"). That is precisely the sort of the "dangerous" interstate effect the Commerce Clause was intended to prevent. *See Jefferson Lines*, 514 U.S. at 180.

In sum: HB 631 is the very definition of a state enactment that directly regulates interstate commerce in violation of the Constitution. It directly regulates transactions and pricing decisions that take place "wholly outside" the boundaries of the State of Maryland. *See Healy*, 491 U.S. at 336. Indeed, it expressly targets commercial conduct at the manufacturer-wholesale level, which occurs largely, if not exclusively, outside of the state, and yet does *not* apply to the retail transactions that occur within the state. The extraterritorial reach of HB 631 is thus both astounding and astoundingly transparent. It is also transparently unconstitutional. Lest the "very purpose of the Commerce Clause" be jettisoned altogether, *McLeod*, 322 U.S. at 330, HB 631 cannot stand.

B. HB 631's Vague Provisions Fail to Provide Fair Notice of What its Terms Require or to Meaningfully Restrain Executive Discretion, in Violation of Due Process.

The Supreme Court has long held that "a statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application, violates the first

essential of due process of law." *Connally v. General Constr. Co.*, 269 U.S. 385, 391 (1926); *see also FCC v. Fox Television Stations, Inc.*, 132 S. Ct. 2307, 2317 (2012) ("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."). "This requirement of clarity in regulation is essential to the protections provided by the Due Process Clause," *id.*, since "[v]ague laws may trap the innocent by not providing fair warning," *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972).

Though vagueness cannot be measured in precise mathematical terms, *see Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498 (1982) ("The degree of vagueness that the Constitution tolerates—as well as the relative importance of fair notice and fair enforcement—depends in part on the nature of the enactment."), HB 631 falls well short of any reasonable standard of clarity. HB 631 broadly prohibits manufacturers and wholesale distributors from "engag[ing] in price gouging in the sale of an essential off-patent or generic drug," § 2-802(a), which the law defines as a manufacturer or distributor's effectuating "an increase in the price of a prescription drug" that is "excessive" and not "justified by … the cost of appropriate expansion of access to the drug," and which will leave consumers

with no "meaningful choice" about whether to purchase the drug at an "excessive price," § 2-801(f).[2]

Like the adjectives "credible," "reliable," or "unreasonable," *see, e.g.*, *Kolender v. Lawson*, 461 U.S. 352, 359-61 (1983) (holding unconstitutionally vague a California statute requiring loiterers to present "credible and reliable" identification); *Langford v. City of Omaha*, 755 F. Supp. 1460, 1461-63 (D. Neb. 1989) (finding a city ordinance that prohibited "unreasonable" noise was unconstitutional because the term is too vague absent additional guidelines), few if any of the key modifiers in HB 631's operative provisions—"excessive," "meaningful," "justified," and so on—may be readily defined absent meaningful contextual distillation. *See* § 2-801(f). To be sure, not all laws that use such broad terms are invalid; "courts at times uphold the use of [vague] terms by relying on

[2] "'Price gouging'" in HB 631 "means an unconscionable increase in the price of a prescription drug." § 2-801(c). "'Unconscionable increase'" in HB 631 "means an increase in the price of a prescription drug that:

> (1) Is excessive and 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
>
> (2) Results in consumers for whom the drug has been prescribed having no meaningful choice about whether to purchase the drug at an excessive price because of:
>
> > (i) The importance of the drug to their health; and
> >
> > (ii) Insufficient competition in the market for the drug."

§ 2-801(f).

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 provides no such meaningful guidance on how to interpret or apply *any* of these "terms [that] are the heart of" the law, Compl., ECF No. 1, Ex. B at 1, leaving courts without a reliable basis to craft a narrower construction.

Indeed, HB 631 leaves a number of basic questions about its scope entirely unanswered. As written, an increase from ten cents per pill to twenty cents per pill for a generic prescription drug may 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 key point is that manufacturers and distributors have no way of knowing what will lead to potentially crippling liability under HB 631—and instead, the Attorney General has a blank check to go after the major players in the generic market as he sees fit. *See id.* at 1-2 (HB 631's vague provisions "leav[e] the decision" to file potentially crippling lawsuits against manufacturers and distributors for violation of the law's terms "entirely to the interpretation of the Attorney General.").

And make no mistake, the sanctions HB 631 imposes are far from trivial. In addition to allowing a state agency to monitor private entities' pricing decisions, HB 631 authorizes the Attorney General to bring suit for violation of its broad

provisions, and such civil actions may result in disgorgement of monies earned "as a result of a price increase that violates" the statute, the sanction of "a civil penalty of up to $10,000 *for each violation*," or the imposition of sweeping injunctions that stand to impact pricing decisions nationwide. § 2-803(a), (d) (emphasis added). And yet HB 631 contains no standards to cabin the discretion of the Maryland Attorney General to launch potentially crippling civil litigation. HB 631 thus leaves the decision of what constitutes an "egregious case" entirely to the discretion of the Attorney General.

That is especially problematic here. The Attorney General was one of the major proponents of HB 631. In advocating on behalf of the bill's passage, the Attorney General frequently counseled legislators that his enforcement authority was cabined by the reporting requirements applicable to the Maryland Medical Assistance Program. The Attorney General has likewise publicly stated that his office "can only focus on the most egregious cases because of how the bill is written and because of limited resources." FamiliesUSA, *Prescription Drug Price Gouging: Maryland's Landmark Law Protects Consumers* (May 30, 2017), *available at* http://familiesusa.org/blog/2017/05/prescription-drug-price-gouging-maryland-landmark-law-protects-consumers. At the same time, however, a representative of the Attorney General's Office testified before the Finance Committee of the General Assembly to argue not only *that* the definitions of "unconscionable" and "price

gouging [are] not defined by th[e] standard" in § 2-803(a), but that they *should not be*. Indeed, the Attorney General's Office maintained that the mere existence of such provisions in the bill could hamstring the Attorney General's authority to file suit against manufacturers that raise prices, for instance, "only … 20 percent … in one year." Similarly, the Attorney General's public statements regarding his authority under HB 631 have conspicuously omitted any reference to the thresholds that apply to the Maryland Medical Assistance Program.[3]

Ultimately, what matters is not that the Attorney General has engaged in doublespeak regarding the meaning of the law. The point is that what HB 631's price gouging prohibition actually means is anyone's guess—and that the entities subject to its terms are held captive to the whim of an elected official to do as he so chooses. *See* Amsterdam, *supra*, at 104 ("The wider and more undefined is the discretion … the more probable becomes the incidence of erratic regulation…."); *cf. United States v. Williams*, 553 U.S. 285, 304 (2008) (criminal conviction cannot stand where law violated "fails to provide a person of ordinary intelligence fair

[3] That omission is all the more conspicuous given that the private coalition that co-sponsored the legislative effort has continually referred to the Attorney General as "a new sheriff in town" who will assiduously enforce the bill. *See, e.g.*, Michael Dresser, "Hogan lets drug price-gouging bill, dozens of others become law without signature," BALTIMORE SUN, May 26, 2017, *available at* http://www.baltimoresun.com/news/maryland/politics/bs-md-hogan-bill-decisions-20170526-story.html.

notice of what is prohibited, or is so standardless that it authorizes or encourages seriously discriminatory enforcement").

This lack of clarity—and the concomitant lack of direction to rein in the Attorney General's enforcement discretion—is of particular concern for two further reasons. First is HB 631's extraterritorial sweep. Because the overwhelming majority of off-patent and generic drug transactions occur outside of Maryland, and because "uncertain meanings" in a regulation or statute will "inevitably lead citizens to steer far wider of the unlawful zone than [they would] if the boundaries of the forbidden areas were clearly marked," the threat of any sanctions will have an equally sweeping (and equally invalid) prophylactic effect. *Grayned*, 408 U.S. at 109 (quotations omitted). Second, HB 631 does far more than simply allow a state agency to monitor private entities' pricing decisions. Penalties for violating HB 631's broad provisions include disgorgement of monies earned "as a result of a price increase that violates" the statute, money damages of "up to $10,000 for each violation," and imposition of sweeping injunctions that stand to impact manufacturers' and distributors' pricing decisions nationwide. § 2-803(d)(2), (3) & (5). Leaving enforcement decisions entirely up to the "new sheriff" thus leaves manufacturers in an untenable situation.

HB 631 fails to "establish[] minimal guidelines to govern" officials or "give[] reasonable notice of the proscribed conduct." *Schleifer by Schleifer v. City of*

Charlottesville, 159 F.3d 843, 853 (4th Cir. 1998). It thus violates the Due Process Clause, and is void for vagueness.

II. AAM Members Will Suffer Irreparable Harm Absent An Injunction.

As explained below, allowing HB 631 to go into effect would force AAM members to make sweeping adjustments to their business practices, cause them to suffer economic damages incapable of precise calculation, and at the very least cause them to cope with a torrent of investigations and lawsuits from the Maryland Medical Assistance Program and Maryland Attorney General that would lead to additional undue costs. Moreover, AAM members would suffer irreparable injury simply by being subject to HB 631, as the law exceeds Maryland's authority under the Constitution, and AAM and its members have an interest in being free from such unconstitutional regulation.

A. AAM Members Would Suffer Irreparable Injury Because They Will Need to Conform Their Conduct to the Law's Sweeping Terms or Face a Barrage of Investigations and Lawsuits.

If allowed to go into effect, HB 631 would force AAM members to confront a Hobson's choice: either take multiple, costly steps to restructure their pricing, distribution, and other business practices in an attempt to conform to the vague and extraterritorial requirements of the law, or else face incessant investigations and all-but-inevitable lawsuits from the Attorney General for allegedly violating the law's sweeping terms.

Courts have consistently held that being put to such an untenable decision—*i.e.*, comply with an unconstitutional command or suffer massive cost—constitutes irreparable injury. *See, e.g.*, *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992) (finding irreparable injury where plaintiffs faced "choice" to either "continually violate the [challenged] law and expose themselves to potentially huge liability; or violate the law once as a test case and suffer the injury of obeying the law during the pendency of the proceedings and any further review"). There is no reason to adopt another rule here.

B. AAM Members Would Suffer Irreparable Reputational and Economic Harm if HB 631 Goes Into Effect.

The harm to AAM members from being put to such a "choice" would be particularly acute. To avoid the sweeping reach of HB 631, AAM members would be forced to adjust their pricing conduct to conform not to free-market factors, but rather to the hazy contours of what might be viewed as "unconscionable"—a target that will be crystallized only through the Attorney General's post hoc exercise of discretion. *See* Amsterdam, *supra*, at 80 (Vague laws pose the "danger that 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.").

The scale and suddenness of any such efforts to conform their conduct to the law's uncertain requirements would likely cause AAM members to suffer economic

and reputational harm that could disadvantage them in the marketplace going forward—some of which may never be undone. *See, e.g.*, *PBM Prods., LLC v. Mead Johnson & Co.*, 639 F.3d 111, 127 (4th Cir. 2011) (affirming finding of irreparable harm where evidence demonstrated that movant's "reputation was, and potentially continues to be, damaged"); *see also Wells Am. Corp. v. Ziff-Davis Publ'g Co., a Div. of Ziff Commc'ns Co.*, 900 F.2d 258 (4th Cir. 1990) (noting that "courts have been willing to find irreparable harm to plaintiffs' goodwill, its business reputation, business opportunities, or its continued existence" in cases that "involve a dispute between competitors; a manufacturer threatening to terminate a dealership, a manufacturer threatening to terminate a distributor, or a manufacturer/wholesaler threatening to terminate sales to a retailer"). Indeed, AAM members may well be forced to discontinue marketing their medicines in Maryland (or in the U.S. as a whole), lest they face punitive sanctions.[4] *See* Ex. 1 ¶¶ 9-10; Ex. 3 ¶¶ 9-10; Ex. 4 ¶¶ 11-12; Ex. 5 ¶¶ 11-12; Decl. of Andrew Boyer on behalf of Teva Pharmaceuticals USA, Inc. (Ex. 6) ¶¶ 11-12; Decl. of John Ducker on behalf of Fresenius Kabi USA, LLC (Ex. 7) ¶¶ 7-8; Decl. of Jeff Hampton on behalf of Apotex Corp. (Ex. 8) ¶¶ 7-

[4] And yet it could all be for naught. In light of HB 631's vague commands, AAM members and other entities affected by the law's terms could *still* find themselves subject to the law's uncertain proscriptions. Forcing AAM members to suffer through this potentially Pyrrhic reputational and financial pain serves no plausible public purpose.

8; Decl. of Jim Luce on behalf of Amneal Pharmaceuticals LLC (Ex. 9) ¶¶ 8-9; Decl. of Michael Raya on behalf of West-Ward Pharmaceuticals Corp. (Ex. 10) ¶¶ 9-10. Yet rather than sympathize with manufacturers' plight, patients and business partners alike will likely simply perceive manufacturers as making life tougher on them.

Finally, forcing AAM members to undergo such rapid and widespread renegotiation—or even forcing them to rejigger their own business models to avoid being subject to suit under HB 631—would unquestionably cost AAM members time and money today. *See* Ex. 3 ¶¶ 8-10; Ex. 4 ¶¶ 10-12; Ex. 5 ¶¶ 10-12; Ex. 6 ¶¶ 10-12; Ex. 7 ¶¶ 7-8; Ex. 8 ¶¶ 6-8; Ex. 9 ¶¶ 8-9; Ex. 10 ¶¶ 8-10. To be sure, pure economic harm is ordinarily not irreparable, because money damages "typically may be granted as easily at judgment as at a preliminary injunction hearing, and a party does not normally suffer irreparable harm simply because it has to win a final judgment on the merits to obtain monetary relief." *Hughes Network Sys., Inc. v. InterDigital Commc'ns Corp.*, 17 F.3d 691, 694 (4th Cir. 1994). But that is not always the case. "Even if a loss can be compensated by money damages at judgment, … extraordinary circumstances may give rise to the irreparable harm required for a preliminary injunction." *Id.* And this case presents the paradigmatic example of

such an "extraordinary circumstance": where damages are *per se* unobtainable from the defendants.[5]

Although "the Eleventh Amendment permits suits for prospective injunctive relief against state officials acting in violation of federal law," private parties may *not* sue state officials for backward-looking remedies such as money damages or the equivalent. *Frew ex rel. Frew v. Hawkins*, 540 U.S. 431, 437 (2004). And courts have long held that "[i]mposition of monetary damages that cannot later be recovered for reasons such as sovereign immunity constitutes irreparable injury." *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) (holding that paying an allegedly unconstitutional tax when state law did not provide a remedy for its return constituted irreparable injury in the event that the statute were ultimately adjudged invalid). Indeed, unlike in cases where the defendant was insolvent, here no remedy short of an injunction barring enforcement of the statute can fully account for the likely harms, since there is no way to "preserve the plaintiff's opportunity to receive an award of money damages at judgment." *Hughes*, 17 F.3d at 694. There should thus be no question that AAM members will suffer irreparable harm absent the requested injunction.

[5] *See, e.g.*, *Hoxworth v. Blinder, Robinson & Co., Inc.*, 903 F.2d 186, 206 (3d Cir. 1990) ("the unsatisfiability of a money judgment can constitute irreparable injury").

C. In All Events, Simply Subjecting AAM Members to a Law that Violates the Constitution Will Cause Them Irreparable Injury.

Courts have long held that simply being subject to unconstitutional state action constitutes irreparable injury for purposes of obtaining a preliminary injunction. *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 (2005) ("When an alleged deprivation of a constitutional right is involved, … most courts hold that no further showing of irreparable injury is necessary."). That is no less true of the constitutional violations asserted here. *See, e.g.*, *Whole Woman's Health v. Hellerstedt*, --- F. Supp. 3d ---, 2017 WL 462400, at *10 (W.D. Tex. Jan. 27, 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."). HB 631 purports to regulate wholly out-of-state conduct (in violation of the Commerce Clause) via sweeping terms that fail to provide people of ordinary intelligence reasonable notice of what it proscribe (in violation of the Due Process Clause). Allowing it to go into effect

would thus irreparably injure AAM members, who without question fall within its terms.

III. The Balance Of Hardships Tilts Heavily In Favor Of The Injunction.

Compared to the substantial and irreparable harm AAM members will suffer if HB 631 is allowed to take effect, the State of Maryland, Defendants, and other state officials will suffer little, if any, injury from the relief sought. Indeed, as the Fourth Circuit has 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, Ill.*, 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.").

That is no less true of state officers like Defendants here. "[I]f the plaintiff shows a substantial likelihood that the challenged law is unconstitutional, no substantial harm to others can be said to inhere in its enjoinment." *Deja Vu of Nashville, Inc. v. Metro. Gov't of Nashville & Davidson Cty., Tenn.*, 274 F.3d 377, 400 (6th Cir. 2001); *see also, e.g.*, *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). The balance of hardships strongly favors granting the injunction.

IV. The Requested Injunction Will Further The Public Interest.

The public interest favors granting the requested injunction for a simple reason: "upholding constitutional rights is in the public interest," period. *Miller*, 637 F.3d at 303; *see also, e.g.*, *Newsom v. Albemarle Cty. Sch. Bd.*, 354 F.3d 249, 261 (4th Cir. 2003) ("Surely, upholding constitutional rights serves the public interest."); *Steakhouse, Inc. v. City of Raleigh, N.C.*, 166 F.3d 634, 642 (4th Cir. 1999) ("Steakhouse simply states that it is in the public interest to enjoin an unconstitutional statute. That is true.").

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 will thus introduce enormous uncertainty and business risk for generic drug manufacturers if allowed to go into effect, which will inevitably lead some manufacturers to discontinue marketing their medicines in Maryland (or in the U.S. as a whole), or even to decline altogether to enter the market of developing new, low cost generic alternatives to expensive brand products. *See* 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. The inevitable result of such retrenchment will be decreased prescription drug

competition, fewer treatment options for patients, and higher costs for patients and taxpayers.

That is no small problem. Not taking medicines as prescribed has significant repercussions on people's health and on our country's economic well-being more generally. According to the latest available research, patients' lack of adherence (*i.e.*, not taking drugs as prescribed) is responsible for approximately 125,000 deaths in the United States, at least 10% of hospitalizations, and a substantial increase in morbidity and mortality. The economic impact translates to system costs of between $100 billion and $289 billion annually. And while sticker shock is a primary reason patients stop taking their drugs as prescribed the availability of generic drugs sharply improves rates of adherence. Patients are three times more likely to adhere to their prescribed medicine regimens when they are prescribed a generic drug than when they are prescribed a costly branded product, which makes sense, given that 90% of generic copays are under $20. *See* Compl., ECF No. 1, Ex. C at 26-29.

By driving generic drug manufacturers out of the market, HB 631 may thus have exactly the opposite effect of what was intended: raising, not lowering, generic drug prices, and decreasing the drug choices available to Marylanders. *See, e.g.*, Sen. Susan Collins, *Working to Keep Lifesaving Medications Affordable* (Sep. 2, 2016) ("[O]ne factor that will help drive down costs for patients is ensuring there is a market for generic competitors."), *available at*

https://www.collins.senate.gov/newsroom/working-keep-lifesaving-medications-affordable; Tom Moriarty, Chief Health Strategy Officer and General Counsel, CVS Health, *Addressing Rising Drug Prices in the Changing Health Care Landscape* (Dec. 16, 2016) ("bringing more competition to the market needs to be a top priority"), *available at* https://cvshealth.com/thought-leadership/addressing-rising-drug-prices-in-the-changing-health-care-landscape. Enjoining the law's enforcement is clearly in the public interest.[6]

CONCLUSION

For the foregoing reasons, Plaintiff's motion for a preliminary injunction should be granted.

[6] Granting a preliminary injunction would also preserve the distribution chains AAM members and other manufacturers and wholesalers have successfully used to provide low-cost prescription drugs to American patients for decades. *Cf. Advisory Info. & Mgmt. Sys., Inc. v. Prime Comput., Inc.*, 598 F. Supp. 76, 89 (M.D. Tenn. 1984) (public interest favored non-movant where non-movant's longstanding "distribution system would be greatly disrupted" if injunction were granted).

Respectfully submitted,

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July 6, 2017

CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of July, 2017, I electronically filed the foregoing Memorandum of Law in Support of Plaintiff's Motion for Preliminary Injunction with the Clerk of the Court for the United States District Court for Maryland using the CM/ECF system. This document has been served by hand to the following:

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