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

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Association for Accessible Medicines ("AAM") brings this complaint against Brian E. Frosh, in his official capacity as Attorney General for 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"), based on personal knowledge as to all AAM facts, and on information and belief as to all other matters:

NATURE OF THE ACTION

1. In this action, AAM challenges an extraordinary Maryland law, House Bill 631 – Public Health – Essential Off-Patent or Generic Drugs – Price Gouging – Prohibition ("HB 631") (Exhibit A), which broadly prohibits "price gouging" in the

sale of certain off-patent and generic prescription drugs, and which authorizes the Attorney General to petition state courts for injunctive relief restraining any violation of the law as well as for disgorgement and up to $10,000 for each violation.

2. Though cast as a local economic regulation, HB 631's sweeping price control reaches into every corner of the United States, if not beyond. By its terms, HB 631 prohibits 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). Yet manufacturers do not sell their products or make pricing decisions on a state-by-state basis. The bulk of "off-patent and generic drug[s]" manufactured and distributed in the United States are sold either to large national or regional wholesalers for resale to smaller pharmacies or to large national or regional self-warehousing retail pharmacy chains, which subsequently resell the prescription products directly to patients. And next to none of the largest generic drug manufacturers, national pharmaceutical wholesalers, or self-warehousing retail pharmacy chains reside in Maryland, so the only involvement a manufacturer has in the overwhelming majority of off-patent and generic prescription drug sales in Maryland is via an upstream sale that occurred entirely outside of the state. HB 631 thus targets commerce and pricing conduct that occurs wholly outside of Maryland, and at a minimum will have the practical effect of controlling manufacturers'

commercial conduct far beyond the boundaries of the state. The law's extraterritorial scope could hardly be clearer.

3. Making matters worse, the operative terms of HB 631's sweeping price restraint are so vague as to leave the state officials tasked with implementing and enforcing the law nearly unbounded discretion. HB 631 defines "price gouging" as "an unconscionable increase in the price of a prescription drug," 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 or to inform manufacturers how to conform to the law's requirements. *See* § 2-801(c). 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).

4. Because HB 631 regulates commercial activity that occurs wholly outside the boundaries of the State of Maryland, it violates the Commerce Clause of the United States Constitution, U.S. Const. art. I, § 8, cl. 3.

5. Because HB 631's vague prohibition on "price gouging" provides no meaningful description of what its terms prohibit, it violates the Due Process Clause

of the Fourteenth Amendment to the United States Constitution, U.S. Const. amend. XIV, § 1.

6. Indeed, 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 Governor Larry Hogan Announces Additional Legislative Actions*, available at http://governor.maryland.gov/ 2017/05/26/governor-hogan-announces-additional-legislative-actions/; Md. Const. art. II, § 17(c). (HB 631 is currently scheduled to take effect on October 1, 2017.) 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." Letter from Hon. Larry Hogan to Hon. Michael E. Busch, at 1 (May 26, 2017) (Exhibit B). Governor Hogan expressed further concern that "the heart of" the law—*i.e.*, HB 631's "definition of 'unconscionable increase' and 'excessive'"—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[es] the decision entirely to the interpretation of the Attorney General," in violation of the Fourteenth

Amendment's Due Process Clause. *Id.* at 1-2.

7. If allowed to go into effect, HB 631 will unleash a potentially unlimited number of enforcement actions seeking to punish AAM members for prices charged for off-patent and generic drugs simply "made available" in the State of Maryland, even if the bulk of the targeted conduct and commerce occurs outside of the state—and even more strikingly, even if AAM members do no business in the state at all. This is no mere hypothetical. 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 national pharmaceuticals market, limiting the ability of generic drug manufacturers to respond to national market changes and potentially forcing manufacturers to withdraw their less-costly generic products—on which many Marylanders and other Americans rely—from the marketplace entirely. Both AAM members and the public at large thus stand to suffer irreparable harm if HB 631 is implemented or enforced.

8. For these reasons, and as explained below, AAM seeks an injunction against the implementation and enforcement of HB 631, a declaration that HB 631 is unconstitutional and invalid, and any other relief this Court deems appropriate.

JURISDICTION AND VENUE

9. AAM's causes of action arise under 42 U.S.C. § 1983 and the United States Constitution. The Court thus has jurisdiction under 28 U.S.C. § 1331.

10. That HB 631 will not take effect until October 2017 does not render this action unripe. *See, e.g.*, *Pierce v. Soc'y of Sisters of the Holy Names of Jesus & Mary*, 268 U.S. 510, 536 (1925).

11. Venue is appropriate in this district pursuant to 28 U.S.C. § 1391(b).

THE PARTIES

12. AAM is a nonprofit, voluntary association representing 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. AAM's members provide American consumers with generic drugs that are just as safe and effective as their brand-name counterparts, but substantially less expensive. AAM members include manufacturers whose products appear on the Model List for Medicines most recently adopted by the World Health Organization, and many of the drugs produced and sold by AAM members are thus directly regulated by HB 631. As a result, AAM members will likely face a significant risk of litigation if HB 631 is allowed to go into effect. AAM is authorized by its Board of Directors to bring this suit on its members' behalf.

13. Brian E. Frosh is the Attorney General for the State of Maryland. In that capacity, he has the authority to investigate and prosecute violations of the laws of Maryland, including HB 631. *See* Md. Const. art. V, § 3. HB 631 also specifically vests the Attorney General with authority to file suit to, *inter alia*, "restrain[] or enjoin[] a violation" of the statute, and further authorizes the Attorney General to investigate generic drug manufacturers and wholesale distributors for potential violations of the statute. § 2-803(C), (D).

14. Dennis R. Schrader is the Secretary of the Maryland Department of Health. In that capacity, he oversees the Maryland Medical Assistance Program, which HB 631 authorizes to engage in broad monitoring of off-patent and generic drug pricing. § 2-803(a), (b).

BACKGROUND

Generic Drugs Help Keep American Healthcare Costs Down

15. 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. *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 windfall. Given the significant costs of performing the required tests, drug manufacturers had little incentive to duplicate previously approved

pharmaceutical products, since it would be difficult to recoup their initial investment. Hundreds of branded drugs thus had no off-patent or generic equivalent, which left patients with little choice but to pay sky-high prices for basic medications long after the patents protecting those drugs had expired. *See* Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 New Eng. J. Med. 1993 (2007).

16. 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 (summarizing the purpose of the law).

17. 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 remain 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 of 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).

18. 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) and (iii)). "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).

19. The Hatch-Waxman Amendments' 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)). As a result of that landmark legislation, "[g]eneric drugs have for several decades offered relief from rising prescription drug costs." U.S. Dep't of Health and Human Servs., Office of the Assistant Sec'y for Planning and Evaluation, *Understanding Recent Trends in Generic Drug Prices* at 1 (Jan. 27, 2016) (Exhibit C); *see also id.* ("[G]eneric drug prices are not an important part of the drug cost problem facing the nation.").

20. Today, some 200 companies market generic drugs in the United States, and generic 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 prescription drugs. Ass'n for Accessible Medicine, *2017 Generic Drug Access & Savings in the U.S.* at 34 (Exhibit D). Indeed, generic medicines saved Americans $1.67 *trillion* over the past decade, including $253 billion in 2016 alone. *Id.* at 20. The availability of generic drugs is thus critical to ensuring that patients have access to affordable medicine, and that the American healthcare system works for the benefit of all Americans.

21. Recent history makes this clear. For instance, before its patent expired

in August 2012, Merck's Singulair (montelukast), a treatment for chronic asthma used by thousands of Americans every day, 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), 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), http://www.pharmacytimes.com/news/5-drugs-that-actually-decreased-in-price-last-year. And that is just one example; similar instances abound. When it comes to the cost of healthcare in America, generic drugs are part of the solution, not the problem.

The Generic Prescription Drug Distribution Chain

22. 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. Exhibit C 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.").

23. Basic macroeconomic forces such as supply and demand undeniably affect pricing decisions, but so too do a myriad other interconnected factors, including the rate at which drugs are prescribed, regulatory requirements, insurance reimbursement rates, national supply-chain factors, and more. *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." The Henry J. Kaiser Family Foundation, *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain* at 24 (Mar. 2005) (Exhibit E). As a result, "[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.*

24. Moreover, decisions relating to pricing and distribution of off-patent

and generic prescription drugs are made at a national, not state-by-state, level. 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 states.

25. 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 of them* manufactures 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* Exhibit E at 8—resides in Maryland; nor do any of the large, national or regional retail pharmacy chains that warehouse their own drugs.

26. Thus, in the overwhelming majority of off-patent and 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.

Constitutional Limitations on Extraterritorial State Regulation

27. The Framers who drafted the Constitution 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). Our Constitution, "framed upon the theory that the peoples of the several states must sink or swim together," *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 523 (1935), thus embodies a "special concern both with the maintenance of national economic union unfettered by state-imposed limitations on interstate commerce and with the autonomy of the individual States within their respective spheres," *Healy v. Beer Inst.*, 491 U.S. 324, 335-36 (1989).

28. In accordance with that understanding, the Supreme Court has "long interpreted the Commerce Clause as an implicit restraint on state authority, even in

the absence of a conflicting federal statute." *United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 338 (2007); *see also* U.S. Const. art. I, § 8, cl. 3 ("The Congress shall have Power ... [t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes."). Indeed, "[t]he very purpose of the Commerce Clause was to create an area of free trade among the several States." *McLeod v. J. E. Dilworth Co.*, 322 U.S. 327, 330 (1944) (Rutledge, J., dissenting).

29. Under this "negative command" implicit in the Commerce Clause, *Okla. Tax Comm'n v. Jefferson Lines, Inc.*, 514 U.S. 175, 179 (1995), the Constitution prohibits each of the "several States," U.S. Const. art. I, § 8, cl. 3, including the State of Maryland, from regulating extraterritorial economic activity. A state law that regulates commerce occurring "wholly outside of the State's borders … exceeds the inherent limits of the enacting State's authority," and will generally be struck down "whether or not the regulated commerce has effects within the State." *Healy*, 491 U.S. at 336 (citation omitted).

30. Under this framework, 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 id.* ("[A] State may not adopt legislation that has the practical effect of establishing 'a scale of prices for use in other states.'" (quoting *Baldwin*, 294 U.S. at 523). State laws that discriminate against interstate commerce are thus routinely

invalidated, "regardless of whether the statute's extraterritorial reach was intended by the legislature." *Id*.

31. "Nor may a State pass laws that have 'the practical effect of regulating commerce occurring wholly outside the State's borders.'" *Star Sci., Inc. v. Beales*, 278 F.3d 339, 355 (4th Cir. 2002) (quoting *Healy*, 491 U.S. at 332)). And in reviewing a state law that regulates commercial activity, "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*, 491 U.S. at 336.

Constitutional Limitations on Vague Legislation

32. 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. Gen. 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).

33. In light of "the attendant dangers of arbitrary and discriminatory application" that such vague regulation entails, the Supreme Court has also held that a law that "impermissibly delegates basic policy matters to policemen, judges, and juries for resolution on an ad hoc and subjective basis" is likewise void for vagueness. *Id.* at 108-09; *see also* 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 notice of what is prohibited, or is so standardless that it authorizes or encourages seriously discriminatory enforcement").

34. No rigid rule governs determinations of a vague law's permissibility. "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." *Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498 (1982). "[B]ecause the consequences of imprecision" in civil laws "are less qualitatively severe" than is true of criminal laws, *id.*, "[a] civil statute is generally deemed unconstitutionally vague only if it commands compliance in terms 'so vague and indefinite as really to be no rule or standard at all,'" *Advance Pharm., Inc. v. United States*, 391 F.3d 377, 396 (2d Cir. 2004) (quoting *Ass'n of Int'l Auto.*

Mfrs. v. Abrams, 84 F.3d 602, 614 (2d Cir. 1996)).

35. Under that standard, an economic regulation is invalid if it does not "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).

HB 631

36. As passed by the Maryland General Assembly, HB 631 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."

37. HB 631 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).

38. HB 631 further defines "an unconscionable increase" 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).

39. HB 631's "price gouging" prohibition applies to all "essential off-patent and generic drug[s]." § 2-801(b)(1). The statute defines an "essential off-patent and generic drug" 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 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).

40. 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 submit document requests to, generic drug manufacturers and wholesale distributors regarding potential violations of the statute. § 2-803(c), (d).

41. HB 631's monitoring provisions are keyed in part off of federal Medicaid provisions. The bill authorizes the Maryland Medical Assistance Program, which administers the state'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").

42. 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).

43. 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.

44. HB 631, which was passed by the General Assembly (38-7 in the Senate and 137-2 in the House of Delegates) on April 10, 2017, is scheduled to take effect on October 1, 2017.

Governor Hogan Declines to Sign HB 631 Due to Constitutional Concerns

45. 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). Yet in allowing HB 631 to become law, Governor Hogan expressed deep apprehension regarding the law's sweep.

46. 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." Exhibit 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.

PLAINTIFF'S CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION
(Declaratory/Injunctive Relief—Unconstitutionality of HB 631 under the Commerce Clause, U.S. Const. art. I, § 8, cl. 3)

47. AAM re-alleges and incorporates herein by reference the allegations of the preceding paragraphs of this Complaint.

48. The Commerce Clause not only vests Congress with "Power ... [t]o regulate Commerce with foreign Nations, and among the several States," U.S. Const. art. I, § 8, cl. 3, but also prohibits states from discriminating against interstate commerce. "The critical inquiry" under this "dormant" aspect of the Commerce Clause "is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State." *Healy*, 491 U.S. at 336.

49. HB 631 violates the Commerce Clause because it directly regulates commerce and prices beyond the boundaries of the State of Maryland—and indeed, expressly targets pricing and conduct at the manufacturer-wholesaler level, which occurs largely, if not exclusively, outside of the state.

50. HB 631's extraterritorial scope could not be clearer. HB 631 is not limited to commerce that occurs within the State of Maryland, or even to sales that occur between an entity outside of Maryland and an entity within it. Rather, HB 631 prohibits generic prescription drug manufacturers and wholesale distributors from "unconscionabl[y]" increasing the price of any essential off-patent or generic drug

that is "made available for sale in the State," § 2-801(b)(1)(iv), *even if* the manufacturer or wholesale distributor "did not deal directly with a consumer residing in the State," § 2-803(g).

51. HB 631's extraterritorial reach is particularly apparent given the nature of the generic pharmaceutical drug market. As is true of their patented counterparts, the overwhelming majority of off-patent and generic prescription drugs sold by manufacturers are sold either to large wholesalers or to large retail pharmacy chains that warehouse their own drugs. Yet *not one* of the "Big Three" wholesalers—AmerisourceBergen Corp., McKesson Corp., and Cardinal Health, Inc., which collectively account for nearly 90% of the national wholesale market, *see* RxCommercial Research International, Inc., *Investing into BioPharma Products in the USA (Color): A Reference Guide* 156 (2012)—resides in the State of Maryland, and neither do *any* of the large retail pharmacy chains that warehouse products. Moreover, of the Nation's twenty largest generic drug manufacturers, only *one* is headquartered in Maryland, and *zero* of them manufacture drugs in the state.

52. Thus, the vast majority of off-patent and generic prescription drugs are not even arguably "made available for sale in the State" of Maryland unless and until a wholesaler sells a drug to a retail pharmacy or healthcare institution in the state, or a warehousing retail chain that takes possession of the drugs outside the state transports them to the state and fills a prescription for an in-state patient.

53. Indeed, HB 631 is arguably even more egregious than a D.C. law that purported to govern in-District prices of patented prescription drugs, and which was invalidated on dormant Commerce Clause grounds. *See Pharm. Research & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 69-70 (D.D.C. 2005) ("*PhRMA*") (holding that the law "effect[ed] an impermissible extraterritorial reach" even though its application was "triggered by an in-state sale"), *aff'd sub nom. Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007). As with HB 631 and generic drugs, a "drug manufacturer" violated the D.C. law whenever one of its patented prescription drugs was sold in the District for "an excessive price." *Id.* Yet under HB 631, unlike the D.C. law, manufacturers and distributors alleged to have violated the law's price-control provisions are expressly denied the ability to "assert as a defense that [they] did not deal directly with a consumer residing in this state." § 2-803(g).

54. HB 631 could not be clearer: the statute is not limited to commerce that occurs within Maryland, or even to sales that occur between an entity outside of Maryland and an entity within it. Manufacturers and wholesalers distributors may violate its terms even if they engage in *no* direct commercial activity in Maryland *at all*. 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). Moreover, as in *PhRMA*, where Judge Leon entered a pre-

enforcement injunction against the D.C. law, here AAM members will not "'remain free to conduct commerce on their own terms'" outside of the state, "because of the potential liability they will face in [Maryland]," even for sales that occur far outside the state's confines. 406 F. Supp. 2d at 70.

55. 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," *Healy*, 491 U.S. at 336, and "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," *PhRMA*, 406 F. Supp. 2d at 70. "Such races 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 Okla. Tax Comm'n v. Jefferson Lines, Inc.*, 514 U.S. 175, 180 (1995).

56. Because HB 631 regulates conduct occurring entirely outside of the State of Maryland and "has the practical effect of establishing 'a scale of prices for use in other states,'" *Healy*, 491 U.S. at 336 (quoting *Baldwin v. G.A.F. Seelig, Inc.*,

294 U.S. 511, 528 (1935)), it violates the Commerce Clause, and is void.

SECOND CAUSE OF ACTION
(Declaratory/Injunctive Relief—Unconstitutionality of HB 631 under the Fourteenth Amendment, U.S. Const. amend. XIV, § 1)

57. AAM re-alleges and incorporates herein by reference the allegations of the preceding paragraphs of this Complaint.

58. The Fourteenth Amendment provides that "[n]o State shall … deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV, § 1. Laws that fail to "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited" violate this requirement of due process, and are void for vagueness. *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). A law that "impermissibly delegates basic policy matters to policemen, judges, and juries for resolution on an ad hoc and subjective basis" is likewise void for vagueness in light of "the attendant dangers of arbitrary and discriminatory application" that such sweeping delegation entails. *Id.* at 108-09.

59. HB 631 violates the Due Process Clause of the Fourteenth Amendment because it fails to provide a meaningful description of what its terms proscribe. 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 it defines as "increas[ing] the price of a prescription drug that" in a manner that is "excessive" and not cost-"justified," and that leaves consumers with no

"meaningful choice" about whether to purchase the drug at an "excessive price." § 2-801(f).

60. Each of the key terms in these provisions—"terms [that] are the heart of" the law—is itself expansive. Exhibit B at 1. Yet HB 631 provides no guidance to courts or to the generic drug manufacturers and distributors within the law's ambit on how to interpret or apply *any* of these provisions. Manufacturers and distributors have no way to determine whether a given price is "excessive," whether a given market expansion is "appropriate," or whether a given consumer's option set is "meaningful." *See id.* ("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"). AAM members thus lack the necessary clarity to determine whether certain price increases they may consider in the future would be considered "unconscionable." *See id.*

61. Perhaps worse still, HB 631's vague provisions "leav[e] the decision" to launch an investigation or lawsuit "entirely to the interpretation of the Attorney General." *Id.* at 1-2. HB 631 contains no standards to cabin the discretion of the Maryland Medical Assistance Program's decisions to launch costly and cumbersome investigations into manufacturers' and distributors' pricing decisions, or—far more worryingly—of the Maryland Attorney General to launch potentially crippling civil litigation. The meaning of terms as capacious as "justified," "appropriate," "excessive," and "meaningful" are left entirely to the broad discretion of the

Attorney General. HB 631 thus leaves the decision of what constitutes an "egregious case" entirely to the discretion of the Attorney General. Such a lack of direction stands to multiply "the incidence of erratic regulation" of the law nearly *ad infinitum*. Amsterdam, *supra*, at 104 ("The wider and more undefined is the discretion … the more probable becomes the incidence of erratic regulation….").

62. That is particularly 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), http://familiesusa.org/blog/2017/05/prescription-drug-price-gouging-maryland-landmark-law-protects-consumers. At the same time, however, the Attorney General's Office has *also* put forward *exactly the opposite* view of the law. For instance, a representative of the Attorney General's Office testified before the Finance Committee of the General Assembly while the bill was still being debated 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 by, say, "only … 20 percent … in one year," far less than would trigger the reporting provisions. Similarly, the private coalition that co-sponsored the legislative effort along with the Attorney General's Office has referred to the Attorney General as "a new sheriff in town" who will assiduously enforce the bill—and, notably, 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. *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.

63. This lack of clarity and lack of direction to rein in the Attorney General's enforcement discretion is of even greater concern because 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).

64. Because HB 631 fails to provide reasonable notice of what conduct is proscribed and fails to establish minimal guidelines to govern officials' exercise of discretion in implementing and enforcing it, it violates the Due Process Clause of the Fourteenth Amendment, and is therefore void.

THIRD CAUSE OF ACTION
(42 U.S.C. § 1983 and 42 U.S.C. § 1988)

65. AAM re-alleges and incorporates herein by reference the allegations of the preceding paragraphs of this Complaint.

66. By seeking to implement and threatening to enforce HB 631, Defendants, acting under color of state law, have violated and, unless enjoined by this Court, will continue to violate the rights of AAM members to engage in interstate commerce free from unconstitutional state discrimination in violation of the dormant Commerce Clause as well as AAM members' rights to due process of law under the Fourteenth Amendment.

67. An actual "Case or Controversy" exists because HB 631's various unconstitutional requirements create a genuine, credible, and immediate threat that Defendants—acting in their official capacities under color of state law—will violate Plaintiff's constitutionally protected rights.

68. Plaintiff accordingly seeks a declaration that Defendants' implementation or enforcement of HB 631 would violate 42 U.S.C. § 1983. Plaintiff

also seeks reasonable attorney's fees pursuant to 42 U.S.C. § 1988.

RELIEF REQUESTED

WHEREFORE, AAM prays:

A. For a declaration, pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, that HB 631 violates the United States Constitution, including but not limited to the dormant Commerce Clause and the Fourteenth Amendment, and is therefore void and unenforceable;

B. For a preliminary injunction prohibiting Defendants from implementing or enforcing HB 631;

C. For a permanent injunction prohibiting Defendants from implementing or enforcing HB 631;

D. For such costs and reasonable attorney's fees to which it might be entitled by law; and

E. For any other relief that the Court deems just and proper.

Respectfully submitted,

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