No. 17-2166

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

Association for Accessible Medicines,
Plaintiff-Appellant,

v.

Brian E. Frosh, *et al*.,
Defendants-Appellees.

On Appeal from the United States District Court
for the District of Maryland
(Marvin J. Garbis, District Judge)

BRIEF OF AMICI CURIAE AARP, AARP FOUNDATION, KNOWLEDGE ECOLOGY INTERNATIONAL, THE MARYLAND CITIZENS' HEALTH INITIATIVE EDUCATION FUND, AND PUBLIC CITIZEN IN SUPPORT OF DEFENDANTS-APPELLEES AND URGING AFFIRMANCE

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December 6, 2017

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CORPORATE DISCLOSURE STATEMENTS

The Internal Revenue Service has determined that **AARP** is organized and operated exclusively for the promotion of social welfare pursuant to Section 501(c)(4) of the Internal Revenue Code and is exempt from income tax. The Internal Revenue Service has determined that **AARP Foundation** is organized and operated exclusively for charitable purposes pursuant to Section 501(c)(3) of the Internal Revenue Code and is exempt from income tax. AARP and AARP Foundation are also organized and operated as nonprofit corporations under the District of Columbia Nonprofit Corporation Act. Other legal entities related to AARP and AARP Foundation include AARP Services, Inc., and Legal Counsel for the Elderly. Neither AARP nor AARP Foundation has a parent corporation, nor has either issued shares or securities. No publicly held corporation has a direct financial interest in the outcome of the litigation by reason of a franchise, lease, other profit sharing agreement, insurance, or indemnity agreement.

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Maryland Citizens' Health Initiative Education Fund, Inc., is a nonprofit, non-stock, tax-exempt corporation of the State of Maryland. It has no parent company and that its sole affiliate is another nonprofit entity titled Maryland Citizens' Health Initiative, Inc. Neither of these entities has issued shares to the public, or is controlled by any other entity having a financial interest in the outcome of this litigation. No publicly held corporation has a direct financial interest in the outcome of the litigation by reason of a franchise, lease, other profit sharing agreement, insurance, or indemnity agreement.

Public Citizen, under Federal Rule of Appellate Procedure 26.1 & 29(c)(1), amicus curiae Public Citizen, Inc. states that it have no parent corporation and issues no stock; therefore, no publicly held corporation owns 10 percent or more of it. No publicly held corporation has a direct financial interest in the outcome of the litigation by reason of a franchise, lease, other profit sharing agreement, insurance, or indemnity agreement.

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INTERESTS OF AMICI CURIAE[1]

AARP is the nation's largest nonprofit, nonpartisan organization dedicated to empowering Americans 50 and older to choose how they live as they age. With nearly 38 million members and offices in every state, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, AARP works to strengthen communities and advocate for what matters most to families, with a focus on health security, financial stability, and personal fulfillment. Among other things, AARP advocates to contain the costs of healthcare products and services, including prescription drugs, without compromising the quality of care or inappropriately denying access to care.

AARP's charitable affiliate, AARP Foundation, works to ensure that low-income older adults have nutritious food, affordable housing, a steady income, and strong and sustaining bonds. AARP Foundation helps low-income older persons avoid predatory practices and litigates to protect their rights related to housing, food, income, and healthcare. AARP and AARP Foundation's advocacy for affordable prescription drugs includes participation as amici curiae in federal courts. *See, e.g.*, *Sandoz Inc. v. Amgen Inc.*, 137 S.Ct. 1664 (2017); *Amgen Inc. v. Sanofi*, 872 F.3d 1367 (Fed. Cir. 2017).

[1] The parties consented to amici's participation in this case. No party's counsel authored any part of this brief. No party, party's counsel, or any person other than amici, its members, or its counsel contributed money intended to fund preparing or submitting this brief.

Knowledge Ecology International ("KEI") is an international non-profit, non-governmental organization that searches for better outcomes, including new solutions, to the management of knowledge resources, in particular in the context of social justice. KEI is drawn to areas where current business models and practices by businesses, governments or other actors fail to adequately address social needs. KEI has expertise on intellectual property and medical technologies issues, among others, and works extensively on the problem of high drug prices at the state, federal, and international levels.

The Maryland Citizens' Health Initiative Education Fund, Inc. is a non-profit corporation that actively pursues measures to promote and ensure access to quality, affordable healthcare for all Marylanders. Comprised of 1200 Maryland entities—religious, educational, public health and labor groups, small businesses, community organizations, and public interest foundations—the Fund has urged the General Assembly each year to expand the availability of affordable healthcare coverage for all Marylanders. In the 2017 session, the Fund advocated for the anti-price-gouging law challenged in this litigation. The Fund contends that the law is not only constitutional, but that it fills the urgent public need to rein in excess costs of medicine vital to the health and well-being of all Marylanders—especially the indigent.

Founded in 1971, Public Citizen is a nonprofit consumer advocacy organization with members and supporters in all 50 states. Public Citizen appears before Congress, administrative agencies, and courts on many issues, including access to affordable medicines for consumers both domestically and globally. Through its Access to Medicines program, Public Citizen works with partners worldwide to improve health outcomes and save lives by advancing policies to lower pharmaceutical prices. Many Public Citizen members are older persons and have particularly strong interests in preventing price-gouging for prescription medications. Public Citizen has long supported the Hatch-Waxman Act's policies of decreasing domestic drug prices through generic competition.

Through the legislation at issue, the State of Maryland seeks to prevent the predatory practice of unconscionably increasing prescription drug prices. Price-gouging harms older persons' health and unnecessarily depletes often limited financial assets. Amici submit this brief to provide more information to the Court regarding the magnitude of the problem of drug price-gouging and how it affects older persons to further illustrate how the district court's decision below dismissing Plaintiff's commerce clause claims and denying a preliminary injunction correctly applied the law to the claims.[2]

[2] Amici address considerations that inform the equitable balancing that governs the granting or denial of preliminary relief, as well as the merits of the Plaintiff's vagueness challenge. As to the dismissal of the commerce clause claims, amici

SUMMARY OF ARGUMENT

The rapidly rising cost of prescription drugs is a consistent source of anxiety and privation for older Americans. Even those who had good-paying jobs, such as Janet Huston, a retired attorney living in Des Moines, Iowa, are hit hard by drug prices. *Why Our Drugs Cost So Much*, AARP Bulletin (May 2017), goo.gl/YU6uAo. "[E]specially in the months when income taxes and property taxes come due," she skips doses to afford her drugs, a common and dangerous strategy. *Id.*; *see also* Howard LeWine, *Millions of adults skip medications due to their high cost*, Harvard Health Blog (Jan. 30, 2015), goo.gl/7K3aeN (discussing a study by the National Center for Health Statistics finding that "8% of adult Americans don't take their medicines as prescribed because they can't afford them."). Though the negative health and financial impacts of unconscionably high drug prices are partly caused by brand-name drug manufacturers,[3] they are also caused by manufacturers and wholesalers of generic and off-patent drugs seeking increased profits means including targeted price increases directed at groups too small in number to cause reputational harm, or sometimes even through

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agree with the State's argument that the district court's judgment was correct and do not separately address its merits in this brief.

[3] *See, e.g.*, Aaron Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 860 (2016) (noting that, while "brand-name drugs comprise only 10% of all dispensed prescriptions in the United States, they account for 72% of drug spending.").

anticompetitive price-fixing arrangements.[4] Although some gambits to keep prescription drug prices high have been addressed or at least mitigated by regulators and courts,[5] other schemes and strategies have been largely or entirely unmitigated by mechanisms such as negotiating power of counter-parties or persistent negative media attention.

Several studies show that efforts to raise drug prices in the generic and off-patent markets have been increasing in number and severity over the last several years.[6] More companies have targeted more drugs for the kinds of egregious price-gouging that led to the passage of House Bill 631 (HB 631), codified at §§ 2-801 through 2-803 of Maryland's General Health Article. A Government

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[4] On recent generic price-fixing conspiracies, *see* Karen Freifeld, *U.S. states allege broad generic drug price-fixing collusion*, Reuters (Oct. 31, 2017), goo.gl/WgSu1f.

[5] *See, e.g.*, Kerstin Noelle Vokinger et al., *Strategies that Delay Market Entry for Generic Drugs*, 177 JAMA Internal Med. 1665, at E2-E3 (2017) (discussing pay-for-delay, ruled unlawful in *FTC v. Actavis*, 570 U.S. 136 (2013); "product-hopping," enjoined in *New York v. Actavis*, 787 F.3d 638 (2d Cir. 2015), but still often successful, *see Mylan Pharms. Inc. v. Warner Chilcott Public Ltd. Co.*, 838 F.3d 421 (3d Cir. 2016); and the use of restricted distribution systems as a means to delay generic entry, which has been partially addressed by the FTC, but is still subject to numerous complaints).

[6] Generic drugs are a subset of off-patent drugs. The challenged statute applies to both types of drugs because both present the same kinds of vulnerabilities to exploitation. For example, one of the earliest instances of an unjustified price increase via obtaining a sole-source position in the market was Amedra's albendazole, a "broad-spectrum antiparasitic" with long-expired patents but no generic version. Jonathan Alpern et al., *High-Cost Generic Drugs—Implications for Patients and Policymakers*, 371 New Eng. J. Med. 1859, 1859-60 (2014).

Accountability Office study found "that more than 300 of the 1,441 established generic drugs analyzed had at least one extraordinary price increase of 100% or more between 2010 and 2015 and that the extraordinary price increases generally persisted for at least one year with no downward movement after the extraordinary price increase." 2017 Legis. Bill Hist. MD HB 631. Although pharmaceutical companies have offered putative justifications for extraordinary price increases of off-patent and generic drugs, those claims, like the ones that the Association for Accessible Medicines (AAM) has offered for supposed irreparable harm, Mem. Law Supp. Pl.'s Mot. Prelim. Inj. 32-35, ECF No. 9-1, have been advanced without empirical support. For example, Martin Shkreli, the founder and chief executive of Turing responsible for increasing Daraprim's price by 5,555%, claimed "that the impact on the health system would be miniscule and that Turing would use the money it earns to develop better treatments," but doctors questioned the need for a better drug. *See* Andrew Pollack, *Drug Goes From $13.59 a Tablet to $750, Overnight*, N.Y. Times, Sept. 20, 2015. The reality is that the public has no way of knowing how companies set their launch prices or decide to make subsequent price increases, although what little information we have gleaned from various congressional investigations indicates that "what the market will bear" is an apt description. S. Rep. No. 114-429 ("Senate Report"), at 13-14, 123-124 (2016). Maryland's HB 631 addresses the negative impact that drug price-gouging and

lack of pricing transparency have on the public health and on the individual well-being of its residents by requiring that manufacturers and wholesalers provide information to justify extraordinary price increases.

The drug price-gouging trend that animated nearly unanimous bipartisan support for HB 631, the harms of price-gouging to the public health and coffers, and the plainly legitimate sweep of HB 631 along with its narrow scope and high thresholds for liability, make it evident that the district court was correct in its judgment that the balance of equities and the public interest required denying AAM a preliminary injunction. AAM has fallen well short of the considerable burden of establishing that the Constitution precludes Maryland's enforcement of HB 631.

ARGUMENT

I. Extraordinary Price Increases to Prescription Drugs, and Particularly to Off-Patent and Generic Drugs, Harm the Health and Well-Being of Older Adults and the Health Insurance Programs and Healthcare Systems That Serve Them.

A. Prescription Drugs Account for a Significant Portion of the Cost of Healthcare, and Low-Cost Generic and Off-Patent Drugs are Essential to Reducing Those Costs.

Prescription drugs are central to American healthcare, with 60% of Americans and 90% of seniors taking prescription drugs, Senate Report at 12, and their expense making up "an estimated 17% of total health care costs" and "19% of employer-based insurance benefits," Kesselheim et al., *supra*, at 859. Americans

were expected to "spend more than $328 billion on prescription drugs" in 2016. Senate Report at 12. "Of this amount, individuals [were expected to] pay about $50 billion out of pocket," with the federal government paying another $126 billion. *Id*.

Reliance on low-cost generic and off-patent drugs is the primary method of balancing the high overall cost of prescription drugs with the need to ensure affordability and accessibility, and their role in containing healthcare expenditures will only increase in the coming years. Between 2001 and 2011, prescription drug costs represented "the fastest growing segment of healthcare expenditures in the United States." Kesselheim et al., *supra*, at 860. "Many policy-makers view generic drug competition as the principal method to contain the rapid growth in drug costs." Luke Olson and Brett Wendling, FTC Bureau of Economics Working Paper No. 317, *The Effect of Generic Drug Competition on Generic Drug Prices During the Hatch-Waxman 180-Day Exclusivity Period*, at 1 (2013). That approximately 90% of dispensed drugs in the United States are now generics reflects a preference for these lower-cost alternatives. *See* Kesselheim et al., *supra*, at 860. The "availability of economically competitive and lower-cost generic drugs will take on added importance as an escalating number of brand name drugs and biologicals enter the market with unusually high prices." Stephen W. Schondelmeyer and Leigh Purvis, AARP Public Policy Institute, *Trends in*

Retail Prices of Generic Prescription Drugs Widely Used by Older Americans, 2006 to 2015, 2 (2017); *see also* Kesselheim et al., *supra*, at 860 (noting the increasing prevalence of drugs with annual treatment prices exceeding $100,000). Prices of widely used off-patent drugs with no generic such as many insulin formulations have also increased, leading to "an increase in out-of-pocket expenditures for those with private health insurance" and "strain[ing] the budgets of government payors such as Medicaid." Jing Luo et al., *Trends in Medicaid Reimbursements for Insulin from 1991 through 2014*, 175 JAMA Internal Med. 1681, 1682 (2016). "Between 1991 and 2014," Luo and his coauthors found "a near-exponential upward trend in Medicaid payments for a wide variety of insulin products regardless of formulation, duration of action, and whether or not the product was patented." *Id.* at 1685.

B. Older Adults Are Particularly Vulnerable to the Harms Caused by Extraordinary Increases in Off-Patent and Generic Prescription Drug Prices.

Older adults are particularly vulnerable to the harms caused by drug price-gouging because they frequently experience high rates of chronic conditions requiring long-term treatment and often live on low, fixed incomes. In 2005, more than "70 million Americans ages 50 and older—four out of five older adults—suffer[ed] from at least one chronic condition," *Chronic Care: A Call to Action for Health Reform*, at 10, goo.gl/HGSv9Y, and the CDC noted recently that "two of

three older Americans have multiple chronic conditions," *The State of Aging and Health in America 2013*, at 6, goo.gl/uRWgwJ. Additionally, low-income adults have higher rates of certain chronic illnesses, including heart disease and diabetes, than do middle/higher-income older adults. *See Chronic Care*, *supra*, at 15. Unsurprisingly, adults age 65 and older take an average of "4.5 prescription drugs every month." Schondelmeyer and Purvis, *supra*, at 1. AARP's study of the prices of the most widely used generic drugs among older adults revealed that this population's average annual generic drug bill doubled from 2006 to 2015. *Id*. Two-thirds of the generic drugs that were evaluated in this price study are typically used for chronic conditions. *Id*. at 9. If older adults used 4.5 different drugs every month, their average annual cost for generic drug therapy would have been $2,355—about nine percent of the median income for Medicare beneficiaries in 2015. *Id*.

Many were already having trouble paying for prescription drugs in 2015, Kesselheim et al., *supra*, at 864 (citing a 2015 Kaiser tracking poll), and older adults are among those who can least afford extraordinary increases in prescription drug prices. AARP's Public Policy Institute (PPI) reports that the median income of a person 50 or older in America in 2016 was $28,267. *Total Person-Level Income 50+, CPS, national*, (last visited Nov. 24, 2017), goo.gl/SykfA7. The median income for a person 65 or older was $22,376. *Total Person-Level Income*

65+, CPS, national, (last visited Nov. 24, 2017), goo.gl/v6mJ9v. Among those 65 and older, 44.93% of rely on Social Security for at least half of their family income and 21.8% rely on Social Security for 90% or more of their family income. *Reliance on Social Security for Persons 65+ by state, CPS*, (last visited Nov. 24, 2017), goo.gl/DUXkf7. The vast majority of people over 65 receive Social Security income (85%) and have other sources of income that are fixed (*e.g.*, pensions, public assistance, and veterans' benefits), while only 24% have income from work earnings. *See* Pension Rights Center, *Sources of Income for Older Adults*, Table 7, (last visited Nov. 26, 2017), goo.gl/giyqnV. This means that when faced with extraordinarily high increases in prescription drug prices—whether they are generics such as statins to manage heart disease or off-patent drugs such as insulin to manage diabetes—many older adults must regularly make a very difficult choice: take care of their health or pay for basic necessities like groceries or utility bills; their incomes will not grow to meet all of their needs. *See Why Our Drugs Cost So Much*, *supra*.

C. Extraordinary Increases in Off-Patent and Generic Prescription Drug Prices Cause Economic Harm to Health Insurers and the Healthcare System in General, Which, in Turn, Harms Patients and Communities.

The impact of drug price-gouging on older adults is just one aspect of the negative clinical and economic consequences of extraordinary prescription drug price increases for individuals, health insurers, hospitals and the healthcare system

in general. When "forced to go without vital medicine," patients "experience dangerous and sometimes life-threatening symptoms." Senate Report at 98. In addition to the human health toll, including the constant anxiety and fear of possibly losing access to necessary prescription drugs, *id*., nonadherence to drug treatment protocols resulting in part from high drug prices increases healthcare costs by an estimated $105 billion annually. Kesselheim et al., *supra*, at 864.

While the Senate Report on sudden price hikes in off-patent drugs details how thoroughly price increases have upended the lives of many individuals, Senate Report at 98-103, it also elucidates the harm of price-gouging to the broader healthcare system, *id*. at 103-110. For example, the Committee heard from Berna Heyman, a retiree living with Wilson disease, a chronic condition the rarity of which made it easy for Valeant, maker of Syprine (the standard-of-care treatment for the disease), to increase the price by 3,162% without much reputational damage. *Id*. at 6-8. Syprine was approved by the FDA in 1985; its active ingredient was developed in 1969. *Id*.[7] Despite having good insurance, Mrs. Heyman projected that her co-pays alone would "exceed $10,000 per year," and

[7] As the Senate Report makes clear, Valeant's pricing strategy bore no relationship to any events affecting its costs of production, research and development, or changing conditions such as demand suddenly outstripping supply. Senate Report at 47-63. The "Orphan Drug Pricing Strategy" was adopted to facilitate the company executives' ability to increase their compensation, which was tied to performance, and to continue meeting the expectations of Wall Street analysts. *Id.*

her insurance company could expect to pay another $260,000. *Id.* Another retiree, Bruce Mannes, "had been managing his Wilson disease well for 55 years with Cuprimine [another off-patent drug owned by Valeant], until the summer of 2015, when his monthly co-pay skyrocketed from about $366 to $1,800." *Id.* at 101. Following significant media coverage of this price-gouging, and after his wife had to take a second part-time job to keep Mr. Mannes alive, Valeant provided the drug to him free of charge. *Id.* However, Valeant made no change to the price of either Cuprimine or Syprine, and insurers continue to pay extraordinarily high prices for these off-patent drugs, *id.*, costs that are passed on to other consumers of health insurance through increased deductibles and cost-sharing, *id.* at110. The sudden and extraordinary price hikes of off-patent drugs have even led some insurance companies to limit or eliminate beneficiaries' access to these drugs. *Id.* at 102 (describing some insurance companies' response to price hikes of Daraprim by Turing).

Moreover, the Senate Report makes clear how leaving the status quo undisturbed will exacerbate the existing harms to hospital systems and state health programs. Extraordinary price increases on two other Valeant drugs, Nitropress and Isuprel, both used in "emergency cardiac cases" and both having lost patent

protections many years ago,[8] have hit many large hospital systems hard, with the Ascension Health System (the nation's largest non-profit health system) reporting "a $12 million budgetary impact in 2015 from pharmaceutical price increases, with Nitropress and Isuprel ranking first and second" among drugs contributing to costs. *Id*. at 8. "Non-profit hospitals, in particular, reported that the price increases led to cuts in different departments, and impinged on programs that help the low-income and vulnerable." *Id*. at 107. Reduced budgets will impact programs like St. Vincent's Hospital's "Rural and Urban Access to Health initiative," which, among other things, provides access to healthcare services to vulnerable, low-income people. *Id*. at 105. As hospitals implement new strategies to attempt to mitigate budgetary effects, new policies, protocols, and training take time and resources away from patients. *Id*. at 108. If price-gouging is left unchecked, these effects will be exacerbated, and some community hospitals may be forced to close. *Id*. at 105.

D. Extraordinary Increases in Off-Patent and Generic Prescription Drug Prices Unduly Burden Government Budgets and Taxpayers.

In 2015, prescription drug spending for government-funded programs, including the federal-state Medicaid program, increased to its highest level—$457 billion. *See* HHS Office of the Assistant Secretary for Planning and Evaluation,

[8] Isuprel was patented in 1965; the active ingredient in Nitropress was isolated in the nineteenth century. Senate Report at 6.

Issue Brief, Observations on Trends in Prescription Drug Spending, 2 (Mar. 8, 2016), goo.gl/9G58dT (last visited Nov. 27, 2017) ("Observations on Trends"). Thirty percent of this increase is attributable to price changes in excess of general inflation, *id*. at 5, and some may be attributable to extraordinary price increases in off-patent drugs. For example, Medicaid spending on off-patent albendazole, *see* Alpern et al., *supra*, at 1859, "increased from less than $100,000 per year in 2008 . . . to more than $7.5 million in 2013." *Id*. at 1860. Based on these trends, prescription drug spending for government-funded programs is projected to continue to rise. *See* Observations on Trends at 3.

The State of Maryland devotes almost a third of its budget to healthcare, with healthcare expenditures steadily increasing in the last several years. *See* Maryland Budget Highlights FY 2017, at 7, goo.gl/6BcCwU (last visited Nov. 27, 2017). Maryland's budget for fiscal year 2017 included $10 billion for its Medicaid program and "$18 million to provide prescription drug assistance to about 28,700 income-eligible Medicare Part D recipients." *Id*. at 16. The State has an obligation to ensure that these funds are used wisely and benefit the largest number of residents possible—including taking measures to prevent drug price-gouging, the effects of which will be partially borne by its Medicaid and prescription drug assistance programs.

II. Price-Gouging in the Off-Patent and Generic Drug Markets is an Increasing and Persistent Problem That Has Largely Gone Unaddressed.

A. Drug Price-Gouging in the Off-Patent and Generic Drug Market Has Increased in Frequency and Severity in Recent Years, Subverting the Purpose of the Federal Regulatory Scheme Designed to Decrease Prices Through Patent Expirations and the Entry of Generic Drugs to the Market.

The effects of price-gouging in the off-patent and generic market have been accruing since at least 2011 and getting worse. "After relatively modest growth after the expiration of patents on many widely used medications from 2010 to 2012, medication expenditures have begun to increase again, punctuated by… sharp increases in the prices of some older [generic or off-patent] ones." Kesselheim et al., *supra*, at 859.

When it passed the bipartisan Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), Congress envisioned that older drugs would get progressively less expensive, with very few or no exceptions. *See* Jeremy Greene, *For 30 years, generic medications helped make health care cheaper. Why is their cost surging?*, Slate (Nov. 20, 2014) (discussing the "two-phase model" after Hatch-Waxman, in which drug costs begin very high until market exclusivity expires, at which point they decline dramatically), goo.gl/bKZifN (last visited Nov. 27, 2017); Jeremy Greene, *Generic: The Unbranding of Modern Medicine* (2014) (explaining in greater detail the history of the Hatch-Waxman Act). However, when a recent

study broke drugs out into groups based on whether they went off-patent before or during the study period, the GAO discovered very serious problems in the current regulatory scheme. Of the 1,441 older or "established" generics studied by GAO, 315 had at least one extraordinary price increase (an increase of at least 100 percent) during the study period. U.S. Gov't Accountability Office, GAO-16-706, *Generic Drugs under Medicare Part D: Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases* ("GAO Report"), at 12 (2016). Two-hundred and eighty of the 315 drugs had one extraordinary increase, another 34 had two separate extraordinary increases during the study, and one drug had three extraordinary increases. *Id.* at 14. The frequency of such price increases went up over time, with 45 occurring between the first quarter of 2010 and the first quarter of 2011 and 103 occurring between the first quarter of 2014 and the first quarter of 2015. *Id.* at 12. And although "most extraordinary price increases were between 100 and 200 percent, a small number of the increases were substantially higher": 48 of the increases were 500% or higher and 15 of the increases were 1,000% or higher. *Id.* at 14.

Similarly, of the 399 generic drugs widely used by older adults studied for AARP's *Rx Price Watch* series, forty-seven "had an extraordinary price increase that exceeded 100 percent at a single point in time" between 2006 and 2015.

Schondelmeyer and Purvis, *supra*, at 1. Moreover, fifteen of these drugs experienced an increase of more than "250 percent." *Id.*[9]

B. Negative Media Attention, Market Forces, and State or Federal Legislation Have Not Been Able to Stop Off-Patent and Generic Drug Price-Gouging.

It is shocking to arrive to pick up an off-patent medication in use for years and learn that the price has increased 5,000% since the previous month's refill. *See* Senate Report at 3. Even when patients in such situations manage to get their stories out to the world, media exposure of these devastating price increases, *see, e.g.*, Pollack, *supra*, has done nothing to stop the practice. *See, e.g.*, Senate Report, *supra*, at 3 n. 2 (after Retrophin ousted Mr. Shkreli, the company did not lower the price of Thiola). "[M]ost extraordinary price increases" between 2010 and 2015 "had no downward movement in the subsequent years" following the increase. GAO Report at 18. High-profile congressional investigations have yielded much to be outraged about but no new federal legislation or behavior change on the part of manufacturers.

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[9] That these increases occurred and persisted for years despite a significant decline in generic drug prices generally, GAO Report at 9-11, and greater and faster market penetration by generics than ever before, Murray Aitken et al., NBER Working Paper 19487, *The Regulation of Prescription Drug Competition and Market Responses: Patterns in Prices and Sales Following Loss of Exclusivity*, at 1 and 7 (2013), http://www.nber.org/papers/w19487, suggests that the problem targeted by HB 631 is tenacious.

"[H]ealth care spending in 2011 amounted to $2.7 trillion and 18 percent of GDP." Martin Gaynor et al., *The Industrial Organization of Health-Care Markets*, 53 J. of Econ. Lit. 235, 235 (2015). Yet the players in this industry have not responded effectively to price-gouging. No doubt part of the reason is that the pharmaceutical industry, as the Senate Report put it, "consists of an opaque and complex network of entities engaged in multiple distribution and payment structures." Senate Report at 13. Group purchasing organizations that pool their buying power to obtain better rates have been unable to stem the rising tide of drug prices, and similar stories can be told about self-insured employer plans at multinational companies and America's largest insurance companies. *Id.* at 13-21; *see also* Gaynor, et al., *supra*, at 236 (effects of drug price increases on employer insurance plans will be passed on to employees through higher premiums, lower wages and fringe benefits, or eliminating health insurance altogether). Pharmacy benefit managers (PBMs), whose putative role is to negotiate with manufacturers, have been unable to stop price-gouging, likely because the standard PBM business model involves getting paid more when prices are higher. *See, e.g.*, Kesselheim et al., *supra*, at 861. Finally, no federal or state law other than HB 631 and analogs that are beginning to be adopted in other states appears able to address the increasingly severe problem of extraordinary price increases on generic and off-patent drugs.

C. Preexisting Public and Private Mechanisms Will Not Solve the Problem of Drug Price-Gouging in Under- or Non-Competitive Generic and Off-Patent Markets.

Several recent studies illuminate yet another dimension to the problem addressed by HB 631 and highlight why current regulatory structures are inadequate to address these issues: pharmaceutical drug companies price-gouge because they can. Though a great improvement over the predecessor system, the Hatch-Waxman Act's regulatory scheme did not adequately address the problem of generic markets that do not attract sufficient competition. A recent review found that, among "417 novel therapeutics" approved since Hatch-Waxman's passage in 1984, "210 were eligible for generic competition" but a full thirty-six (or 17%) "had no generic drugs approved" and another forty-one (20%) had fewer than four generic competitors. Ravi Gupta et al., *Generic Drug Approvals Since the 1984 Hatch-Waxman Act*, 176 JAMA Internal Med. 1391, 1393 (2016).

Moreover, a recent comprehensive study analyzing "1.08 billion prescription drug claims for 57.3 million patients" found that generic drug markets with low competition in 2008 experienced much greater price increases between 2008 and 2013 than did generic drug markets with high competition levels in 2008, often even when the number of competitors in one of these markets became the same during the study period. Chintan Dave et al., *High Generic Drug Prices and Market Competition: A Retrospective Cohort Study*, 167 Annals of Internal Med.

145, 148 (2017). That is, while generic markets that had high competition levels in 2008 but became monopolies experienced an average price increase of approximately 20%, generic markets that had low competition levels in 2008 and became or remained monopolies experienced an average price increase of approximately 90%. *Id.* at 150. Even transitioning from a low level of competition in 2008 to a duopoly (with two manufacturers with roughly equal market shares) ended up merely keeping the price at its original non-competitive level. *Id.*[10] Studies like this bring home the importance of laws like HB 631 because even when competition can eventually help control prices, policymakers should expect years-long delays not only for an initial competitor to get approval to enter, *see* Kesselheim, et al., *supra*, at 861 (discussing delays in obtaining marketing approval), but also for prices to do more than simply plateau after entry finally does occur.

When competition either fails to materialize or is subverted through price-fixing conspiracies or other means, laws like HB 631 can help to protect the public

[10] Findings like these are what justify the legislature's inclusion of markets that have more than one manufacturer in the statute's ambit. *See also* Kesselheim et al., *supra*, at 861 ("Drug prices decline to approximately 55% of brand-name drug prices with 2 generic manufacturers . . . 33% with 5 manufacturers, and 13% with 15 manufacturers.").

health.[11] The industry, whether brand-name, generic, or off-patent, is fond of declaring the absolute need for every price it charges, and some small price increases have, indeed, been tied to events like shortages, *see*, *e.g.*, Alpern et al., *supra*, at 1860. However, the GAO and Senate Report findings suggest that price-increase decisions in non-competitive markets reflect not increases in production or development costs but instead what the Senate Report styles a deliberate "business model" to "impose and protect astronomical price increases." Senate Report at 4; *see also id.* at 57 (documenting Valeant's deliberate strategy of exploiting the lack of substitutability between these two treatments for Wilson disease). AAM and amicus Chamber of Commerce suggest that industry's implementation of a price-gouging strategy is simply not Maryland's business, *see, e.g.*, AAM Brief 3-8, but nothing in the Constitution prohibits Maryland from responding just because it is not the only state targeted and systematically threatened by these practices. Maryland is entitled to put the industry's declarations to the test: if AAM's members need a 5,000% increase in prices, let them prove it.

[11] Many other states have or are considering laws targeting similar problems, such as statutes aimed at PBM transparency, *see, e.g.*, *Current State Maximum Allowable Cost Legislation*, PBM Watch (last visited Nov. 27, 2017), goo.gl/35s9og, or at specific drugs such as insulin, *see, e.g.*, Emily Kopp, *Daylight On Diabetes Drugs: Nevada Bill Would Track Insulin Makers' Profits*, Kaiser Health News (June 7, 2017), goo.gl/cQRi6Z.

III. AAM Failed to Meet the Extraordinary Standards for Preliminary Relief in its Constitutional Due Process Challenge, as HB 631 is a Clearly Circumscribed Response to a Well-Defined, Specific Problem.

The bar for AAM in this case is very high. Not only must it meet the "clear showing" standard applicable to any application for preliminary injunctive relief, but it must justify a *facial* constitutional challenge to a statute. *See Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 450 (2008) (laying out several reasons why facial challenges are "disfavored": they "rest on speculation," they "run contrary to the fundamental principle of judicial restraint," and they "threaten to short circuit the democratic process") (citations omitted). Moreover, HB 631 has never been enforced, increasing the difficulty AAM faces in trying to ground the challenge in more than just speculation "regarding a worst-case scenario." *Greenville Women's Clinic v. Comm'r, S.C. Dep't of Health*, 317 F.3d 357, 367 (4th Cir. 2002) (holding such speculation "inappropriate"). Finally, AAM is pursuing a void-for-vagueness challenge against a law that prescribes no criminal penalties, thus decreasing the standard of certainty required of its text and increasing AAM's already high burden. *See Schleifer v. City of Charlottesville*, 159 F.3d 843, 853 (4th Cir. 1998) (citing *Kolender v. Lawson*, 461 U.S. 352, 359 n.8 (1983) ("where a statute imposes criminal penalties, the standard of certainty is higher")). AAM did not provide the substantial amount of evidence necessary to obtain preliminary relief.

AAM's facial vagueness challenge fails because, as the State of Maryland has demonstrated, AAM failed to show that HB 631 lacks a "'plainly legitimate sweep,'" Br. Appellees 51 (quoting *Wash. State Grange*, 552 U.S. at 449), and because the text and historical context of the statute preclude a successful vagueness challenge, *id*. at 35-50. HB 631 did not arrive *ex nihilo*. It was precipitated by a history of market and regulatory failures, *see* Part II., *supra*, and the judgment that neglecting to address those failures would imperil the health and well-being of Marylanders.

AAM challenges HB 631 as so vague that it cannot be enforced without running afoul of its members' Constitutional rights to due process, but HB 631 offers clear guidance for drug manufacturers and wholesalers to determine how to conform their conduct to the plainly legitimate sweep of the law. They must first determine whether a particular drug under consideration is an "essential off-patent or generic drug," Md. Code Ann., Health—General § 2-801(b)(1)(i) and (ii) (LexisNexis 2017), then whether it is "actively manufactured and marketed for sale in the United States by three or fewer manufacturers," *id.* § 2-801(b)(1)(iii), and whether it is currently made available for sale in Maryland, *id.* § 2-801(b)(1)(iv). Wholesalers must then ask whether the contemplated price increase is attributable to the increased price charged by the manufacturer, in which case the wholesaler is not liable. *Id.* § 2-802(b).

At this point, the manufacturer or, if applicable, the wholesaler, must ask whether the contemplated increase is attributable to the costs of production or to the cost of a program to expand access to the drug. *Id.* § 2-801(f)(1). A court considering a case brought under the statute would evaluate evidence presented by the wholesaler or manufacturer as to what constitutes a cost of production or a program to expand access and apply the evidentiary and statutory construction principles it would apply in any other case. In AAM's rush to condemn the many worst-case scenarios it concocts, the role of the courts somehow shrinks to nothing but a rubber stamp. But statutory interpretation and evidence evaluation have always been mainstays of the judiciary's oversight role as a coequal branch of government, and nothing about HB 631 suggests that events will play out differently here.

Further, even if a manufacturer or wholesaler determines that costs of production or expansion of access played little or no role in the decision to increase prices, it must still determine whether consumers in Maryland will have a "meaningful choice" of alternatives. *Id.* § 2-801(f)(2). Although it may not be possible, using information about sales data, formularies, the FDA's Orange Book, treatment alternatives, and so forth, to predict with complete certainty whether the Attorney General and a court would find that consumers would lack a meaningful

choice, complete certainty is not the standard.[12] The statute and its legislative history provide textual guidance and many examples of egregious behavior that precipitated its passage. If the purpose of statutory construction is "the ascertainment of meaning, nothing that is logically relevant should be excluded." Felix Frankfurter, *Some Reflections on the Reading of Statutes*, 47 Colum. L. Rev. 527, 541 (1947); *see also U.S. v. Fisher*, 6 U.S. 358, 386 (1805) (Marshall, C.J.) ("Where the mind labours to discover the design of the legislature, it seizes everything from which aid can be derived."). The court must consider the statute's context in determining its meaning.

In addition, no rule of law requires the statute to supply a numerical threshold for unconscionable price increases. *See* AAM Br. at 39. The reason that the notification provision, Md. Code Ann., Health—General § 2-803(a), does not establish a minimum threshold for price-gouging is simple: to avoid "compounded price increases and perverse incentives." Jeremy Greene and William Padula, *Targeting Unconscionable Prescription-Drug Prices—Maryland's Anti-Price-*

[12] The district court was correct to find AAM's record on its members' asserted inability to implement procedures to conform to this law "unconvincing," "insufficient," "conclusory," and "speculative." *Ass'n for Accessible Meds. v. Frosh*, No. MJG-17-1860, 2017 U.S. Dist. LEXIS 161168, *33-36 (D. Md. Sep. 29, 2017).

Gouging Law, 377 New Eng. J. Med. 101, 102 (2017). "[I]f a 50% increase per year were set as a threshold . . . a manufacturer could simply raise the price of a noncompetitive medicine by 49% each year": "a pill that cost $30 per month in 2017 would cost $44.70 per month after 1 year, $66.60 per month after 2 years, $99.24 per month after 3 years, and nearly $150 per month (a roughly 500% increase) after 4 years." *Id.* Given the schemes that this law is attempting to address, a numerical threshold would likely subvert the legislative intent.

Speculation about the theoretical possibility of frivolous lawsuits, AAM Br. at 40—a possibility inherent in every law—does not strip the law of its plainly legitimate sweep, clear textual guidance, and rich legislative history and purpose. In addition, concern that the Attorney General will seek the maximum penalty for any infraction, AAM Br. at 39, is a matter for the Eighth Amendment or a statutory limit on our system of prosecutorial discretion, *see, e.g.*, *U.S. v. Armstrong*, 517 U.S. 456, 464 (1996) (discussing the presumption of regularity applied to actions of government prosecutors); neither of these has any bearing on AAM's facial void-for-vagueness challenge.

If AAM members are unsure how to draft a contract provision to sell non-exorbitantly-priced generic or off-patent drugs in this state while gouging the rest of the country, it is not too much for Maryland to ask them to learn. If AAM's members cannot conceive of a business model that does not involve acquisition of

"de facto monopoly pricing power" in order to "impose and protect astronomical price increases," Senate Report at 4, the Constitution does not forbid the state of Maryland from making them figure it out.

CONCLUSION

For the above reasons and those described in the State's brief, this Court should affirm the order of the district court.

Dated: December 6, 2017

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMIT

Pursuant to Fed. R. App. P. 29(a)(4)(G), I certify that this brief contains 6,459 words and, therefore, complies with type-volume limits of Fed. R. App. P. 32(g)(1), as exempted by Fed. R. App. P. 32(f). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 for Windows in Times New Roman 14 point font.

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Dated: December 6, 2017

CERTIFICATE OF SERVICE

I hereby certify that on December 6, 2017, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ William Alvarado Rivera
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