No. 18-546

In the Supreme Court of the United States

BRIAN E. FROSH, Attorney General of Maryland, *et al.*,
Petitioners,

v.

ASSOCIATION FOR ACCESSIBLE MEDICINES,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

Brief of *Amici Curiae* National Health Law Program, AARP and AARP Foundation, Disability Rights Maryland, Families USA, Justice in Aging, Knowledge Ecology International, Maryland Citizens' Health Initiative, and Public Citizen in Support of Petitioners

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INTERESTS OF AMICI CURIAE[1]

The *amici curiae* are the National Health Law Program (NHeLP), AARP and AARP Foundation, Disability Rights Maryland, Families USA, Justice in Aging, Knowledge Ecology International, Maryland Citizens' Health Initiative, and Public Citizen (collectively, "NHeLP et al."). All of the *amici* are nongovernmental corporations that do not have parent corporations nor any publicly held company owning 10% or more of the corporation's stock. While each *amicus* has particular interests, together they share the mission of advancing public health and removing barriers to health care for all people. *Amici* NHeLP *et al.* work on behalf of low-income populations in Maryland and throughout the country to advance access to quality health care.

The legislation at issue here seeks to prevent the predatory practice of unconscionably increasing prescription drug prices, a practice that interferes with access to quality health care of low-income and underserved people. *Amici* submit this brief to provide the Court with more information about the impact, magnitude, causes, and persistence of these practices. We urge the Court to grant certiorari on this petition in order to resolve the important legal question presented

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[1] No party's counsel authored this brief in whole or in part. No party or party's counsel contributed money to fund preparation or submission of this brief. No person, other than *amici* and *amici*'s counsel, contributed money intended to fund preparation of submission of this brief. *See* Supreme Court Rule 37.6. Both Petitioners and Respondent have filed blanket consents for amicus briefs with the Clerk. Counsel for all parties received timely notice of the intent to file this brief.

and assure states that they may enact limits on price-gouging practices at the local level.

SUMMARY OF ARGUMENT

Prescription drugs play an essential role in the American health care system. The availability of generic medications should ensure that vital medications are available at an affordable cost. Low-cost generic medications are particularly important for treatment and management of chronic conditions. But when generic prices rise dramatically, individuals often make difficult choices to forgo medication or take lower doses than prescribed, creating serious health risks and even resulting in death. In theory, the generic market should keep costs down through competition. The promise of competition, however, has not prevented price gouging. Barriers to entry, small markets, and consolidation of manufacturers has resulted in market distortions that enable generic drug manufacturers to maintain monopoly power, and monopoly pricing, long after patent rights have expired. Maryland's legislation is an essential protection for all individuals who rely on prescription medications.

ARGUMENT

I. Extraordinary Prescription Drug Price Increases Harm the Health and Well-Being of Low-Income Americans and the Health Care Systems That Serve Them.

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

Prescription drugs are central to American health care, with 60% of Americans taking prescription drugs. U.S. Senate Spec. Comm. on Aging, *Sudden Price Spikes in Off-Patent Prescription Drugs* 12 (2016), https://goo.gl/GQqF5o [hereinafter Senate Report]. Their expense makes up "an estimated 17% of total health care costs" and "19% of employer-based insurance benefits." Aaron Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 859 (2016), https://goo.gl/49ddRK. Americans were expected to "spend more than $328 billion on prescription drugs" in 2016. Senate Report, *supra*, 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*.

Many Americans rely on low-cost generic drugs and drugs whose patents have expired ("off-patent drugs") to help them balance the high overall cost of prescription drugs. Such drugs help ensure affordability and accessibility in the prescription drug market, and their role in containing health care

expenditures will only increase in the coming years. Earlier this year, the federal Centers for Medicaid & Medicare Services projected that in the next decade, spending on prescription drugs in the United States will grow faster than any other medical good or service. *See* Gigi A. Cuckler et al., Ctrs. Medicare & Medicaid Servs., *National Health Expenditure Projections, 2017–26*, 37 Health Aff. 3, 4 (2018), https://goo.gl/Ydizfw. That approximately 90% of dispensed drugs in the United States are now generics reflects a demand 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 & Leigh Purvis, AARP Pub. Pol'y Inst., *Trends in Retail Prices of Generic Prescription Drugs Widely Used by Older Americans, 2006 to 2015* at 2 (2017), https://goo.gl/YJHh31; *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 alternative such as many insulin formulations have also increased dramatically. *See* Jing Luo et al., *Trends in Medicaid Reimbursements for Insulin from 1991 Through 2014*, 175 JAMA Internal Med. 1681, 1682 (2016), https://goo.gl/LUwvmv. "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. Low-Income Americans Are Particularly Vulnerable to the Harms Caused by Extraordinary Increases in Off-Patent and Generic Prescription Drug Prices.

Low-income individuals and families 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 due to their financial circumstances, they are particularly sensitive to even small price increases. A 2011 Gallup poll found that "Americans in poverty are more likely than those who are not to struggle with a wide array of chronic health problems," Alyssa Brown, *With Poverty Comes Depression, More Than Other Illnesses*, Gallup (Oct. 30, 2012), https://goo.gl/7THd9A. At the same time, Americans with chronic health conditions are more likely to rely on prescription drugs as treatment, especially those with chronic mental health conditions. *See, e.g.,* Therapeutic Drug Use, Ctrs. Disease Control & Prevention, https://goo.gl/v1VGVX (last visited Dec. 11, 2018) (most frequently prescribed therapeutic classes in physician offices in 2015 were analgesics, which treat pain; antihyperlipidemic agents, which treat high cholesterol, and antidepressants); Thomas J. Moore & Donald R. Mattison, *Adult Utilization of Psychiatric Drugs and Differences by Sex, Age, and Race*, 177 JAMA Int. Med. 274, 274 (2017), https://goo.gl/M1chdF (2013 data suggests that approximately 17% of adults take prescribed medication to treat a mental health condition).

Reliance on prescription drugs as part of a health care regimen correlates to other demographic factors.

For example, black women are more likely than people of other races and genders to have used at least five prescription drugs in the past 30 days. *See* Ctrs. Disease Control & Prevention, *Prescription Drug Use in the Past 30 Days* 1 (2017), https://goo.gl/eeGzjY. Similarly, adults over age 65, and women over 65 in particular, are more likely to have used at least five prescription drugs in the past 30 days. *Id.* at 2.

When individuals absorb the cost of prescription drugs through copays, coinsurance, or deductibles, they often attempt to lessen the impact of those costs by making difficult choices to forgo medication or take lower doses than prescribed. *See* Robin A. Cohen & Maria A. Villarroel, Ctrs. Disease Control & Prevention, *Strategies Used by Adults to Reduce Their Prescription Drug Costs* 1-2 (2015), https://goo.gl/kAEiFB. This is especially true for low-income individuals. *See id.* at 1. These price increases can create near-constant anxiety and fear of possibly losing access to necessary prescription drugs. Senate Report, *supra*, at 98. Moreover, when "forced to go without vital medicine," people "experience dangerous and sometimes life-threatening symptoms." *Id.* In order to pay for their prescriptions, individuals sometimes go without other health care services and treatment, or make difficult choices between their financial stability, quality of life, and the care they need. *See e.g.*, Craig Palosky & Rakesh Singh, *Survey Finds One in Five Working-Age Americans with Health Insurance Report Problems Paying Medical Bills*, Kaiser Family Found. (Jan. 5, 2016), https://goo.gl/PkoNyG. Given their increased need for prescription drugs to treat their health conditions, people with mental health conditions, black women, and older women are

particularly likely to be harmed by increases in prescription drug costs.

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, *supra*, at 7-8, 98-103. For example, the Committee heard from Berna Heyman, a retiree living with Wilson's 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 7-8. Syprine was approved by the FDA in 1985; its active ingredient was developed in 1969. *Id*.[2] Despite having insurance, Mrs. Heyman projected that her copays alone would "exceed $10,000 per year," and her insurance company could expect to pay another $260,000. *Id*. at 6. A young father, Patrick Melvin, was also diagnosed with Wilson's disease, but able to manage its symptoms with Syprine. Then, in 2015, his out-of-pocket costs for the drug skyrocketed to $20,000 for a month's supply, causing him to go without the drug for several weeks, until "he began to have increased tremors and hallucinations, and to slur words, drool, and lose his memory." *Id.* at 101. He became unable to work and his family's income

[2] 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, *supra*, 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.*

declined. Eventually, he was able to obtain disability assistance and regained access to medication, but then suffered a stroke that killed him in September 2015 at the age of 35. *Id.* Treatment adherence is of particular concern for persons living with HIV/AIDS. Interruptions in ant-retroviral therapy can lead to drug resistance. *See e.g.,* Jean B. Nachega, et al. *HIV Treatment Adherence, Drug Resistance, Virologic Failure: Evolving Concepts*, 11 Infect Disord Drug Targets 167 (2011), https://goo.gl/u6DNuE.

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. Senate Report, *supra*, at 102 (describing some insurance companies' response to price hikes of Daraprim by Turing).

C. Extraordinary Increases in Off-Patent and Generic Prescription Drug Prices Cause Economic Harm to the Health Care System.

In addition to the human health toll, nonadherence to drug treatment protocols resulting in part from high drug prices increases health care costs by an estimated $105 billion annually. Kesselheim et al., *supra*, at 864.

The Senate Report elucidates the harm of price-gouging to the broader health care system. *See* Senate Report, *supra,* at 103-110. Valeant implemented extraordinary price increases on two other drugs, Nitropress and Isuprel, which are both used in "emergency cardiac cases" and lost patent protections

many years ago.[3] *Id.* These price increases 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 health care 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. *See* U.S. Dep't Health & Hum. Servs., *Observations on Trends in Prescription Drug Spending* 2 (2016), goo.gl/9G58dT.

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

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, "increased from less than $100,000 per year in 2008 . . . to more than $7.5 million in 2013." Jonathan Alpern et al., *High-Cost Generic Drugs—Implications for Patients and Policymakers*, 371 New. Eng. J. Med. 1859, 1859-60 (2014), https://goo.gl/xCXkUa. Based on these trends, prescription drug spending for government-funded programs is projected to continue to rise. *See* U.S. Dep't Health & Hum. Servs., *supra*, at 3.

The State of Maryland devotes almost a third of its budget to health care, with health care expenditures steadily increasing in the last several years. *See* Maryland, *Budget Highlights FY 2017*, at 7 (2016), goo.gl/6BcCwU. 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 a strong interest in 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 Has Increased in Frequency and Severity in Recent Years.

Pharmaceutical companies have enormous leeway to set whatever prices they choose for prescription

drugs. Cases of price gouging have frequently appeared in the news, often occurring after a company acquires a new drug and wants to profit. In 2015, Martin Shkreli infamously increased the price of Daraprim, a drug that treats a life-threatening parasitic infection, from $13.50 to $750 per tablet. Andrew Pollack, *Drug Goes From $13.59 a Tablet to $750, Overnight*, N.Y. Times, Sept. 20, 2015, at B1, https://goo.gl/U9cDK6. This overnight change meant that the total cost of treatment for some patients would cost hundreds of thousands of dollars. *Id.* Likewise, Cycloserine, a drug that treats multi-resistant tuberculosis, increased in price to $10,800 for 30 pills from $500 after its acquisition by Rodelis Therapeutics. Doxycycline, an antibiotic, went from $20 a bottle to $1,849 in less than 6 months. *Id.*

These are not isolated examples. A GAO study examined 1,441 "established" generic drugs—that is, drugs that were billed under Medicare Part D each quarter of the study period—and found that 315 (22%) had at least one extraordinary price increase of 100 percent or more between the first quarter of 2010 and the first quarter of 2015. U.S. Gov't Accountability Office, *Generic Drugs under Medicare Part D: Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases* at 12 (2016), https://goo.gl/UTRM6N. 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 percent or higher and 15 of the increases were 1,000 percent or higher. *Id.* at 14; s*ee also* Kesselehim at 860 (describing "[s]ignificant increases in the prices of . . . older drugs including isoproterenol (2500%), nitroprusside (1700%), and digoxin (637%)"); Schondelmeyer & Purvis, *supra*, at 1 (identifying 47 of 399 generic drugs widely used by older adults that, between 2006 and 2015, had an extraordinary price increase of more than 100 percent at a single point in time, including 15 with an increase of more than 250 percent). In short, efforts to raise drug prices in the generic and off-patent markets have been increasing in number and severity in recent years.

B. Market Forces, Existing Regulation, and Negative Media Attention Have Not Been Able to Stop Off-Patent and Generic Drug Price Gouging.

Although the problem of price gouging is becoming both more frequent and more severe, current market forces and regulation are insufficient to stop the practice. In fact, the sharp increase in price gouging since 2010 has occurred despite a significant decline in generic drug prices generally. U.S. Gov't Accountability Office, *supra,* at 9-11. Rather than respond to these general market trends, "most extraordinary price increases" between 2010 and 2015 "had no downward movement in the subsequent years" following the increase. *Id.* at 18.

The nature of the generic drug market in the United States creates distortions that enable drug

manufacturers to set their own prices. In the multi-payer health care system, pharmaceutical companies hold far more negotiating power than providers and patients. Even group purchasing organizations that pool their buying power to obtain better rates have been unable to stem the rising tide of drug prices. Senate Report, *supra*, at 13-21. Likewise, self-insured employer plans at multinational companies and America's largest insurance companies have been unable to negotiate lower rates. *Id.* Pharmacy benefit managers (PBMs), whose putative role is to negotiate with manufacturers, have also 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. As a result of the imbalance in negotiating positions, even strong consumer backlash and negative media attention have not caused drug companies to change their practices. *See, e.g.*, Senate Report, *supra*, at 3 n.2 (after Retrophin ousted Mr. Shkreli, the company did not lower the price of Thiola).

Nor can states like Maryland rely on competition to prevent price gouging. The practice of price gouging occurs primarily in non-competitive generic markets. One 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. Chintan Dave et al., *High Generic Drug Prices and Market Competition: A Retrospective Cohort Study*, 167 Annals of Internal Med. 145, 148 (2017), https://goo.gl/ih5deS. The longer the market is noncompetitive, the greater the price

increases: Generic markets that had high competition levels in 2008 and then became monopolies experienced an average price increase of approximately 20%. But generic markets that already had low competition levels in 2008 and became or remained monopolies experienced an average price increase of approximately 90%. *Id.* at 150.

In a non-competitive market, drug manufacturers essentially maintain monopoly power, even though the patent rights have expired. Non-competitive markets are prevalent. 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), https://goo.gl/QTmNkY. A separate analysis of data from Medicare Part D, which covers almost all pharmaceuticals, showed that 2,009 drugs (71 percent) have just one manufacturer. Benjamin Isgur et al., Price Waterhouse Coopers, *The FDA is Approving More Generic Drugs Than Ever Before, Faster Than Ever Before* 6 (2018), https://goo.gl/xYPmkt.

There are several reasons for low competition in these markets. First, there are barriers to generic manufactures entering the market. Generic companies must still obtain FDA approval, which requires investment in staff, processes, and technological capabilities. One recent analysis revealed that more than 80 percent of generic drug companies failed to obtain approval during their first review cycle. *Id.* at 4.

The number of generic manufacturers depends on several other factors as well, including the size of the market, the availability of raw ingredients, the production costs and complexity of the production process, and mergers in the industry. Kesselheim at 862; Isgur et al., *supra*, at 5. For instance, "[i]n the case of [Daraprim], the small number of patients with toxoplasmosis in the United States did not attract other potential generic competitors, leaving Turing with a monopoly that it was able to exploit with a 50-fold price increase." Kesselheim et al., *supra*, at 862.

Drug manufacturers also take deliberate steps to maintain their monopolies. Brand name prescription drug companies and generic firms often enter into patent settlements, called "pay for delay," in which the brand name companies will pay generic firms not to bring generic versions for a period of time. Henry Waxman et al., The Commonwealth Fund, *Getting to the Root of High Prescription Drug Prices: Drivers and Potential Solutions* 27 (2017), https://goo.gl/ZQV5LL. Further, certain pharmaceutical companies abuse the risk evaluation and mitigation strategy (REMS) requirements by denying manufacturers of generics and biosimilars access to the product samples they need for FDA approval and market entry. *Id.* at 22. These methods delay the entry of generics into the market and stifle drug competition, preserving companies' drug monopolies and price-setting power.

Finally, as the Senate Report described, price gouging is a deliberate "business model" to "impose and protect astronomical price increases." Senate Report, *supra*, at 4; *see also id.* at 57 (documenting Valeant's deliberate strategy of exploiting the lack of

substitutability between two treatments for Wilson's disease).

While competition can help bring down prices, it is insufficient on its own to prevent price gouging. For instance, research shows that even where there is competition between two or more manufacturers selling drugs in the same class, it "does not usually result in substantial price reductions." Kesselheim et al., *supra*, at 861. Rather, prices only drop when there are several competitors of the same drug. Dave et al., *supra*, at 150.[4] Finally, even when successful, competition often takes years to realize price drops, due to years-long delays for an initial competitor to obtain approval, and even longer for sufficient competition to develop to actually lower prices. *See* Kesselheim, et al., *supra*, at 861.

When competition fails to materialize, or competition does not prevent price gouging, laws like HB 631 are essential to protect the public. Indeed, given the rampant and intractable problem of price gouging, several states are now considering similar laws targeting the practice. *See, e.g.*, State Legislative Action on Pharmaceutical Prices, Nat'l Academy State Health Policy (Oct. 4, 2018), https://goo.gl/5HXo2B (identifying 12 states considering price gouging legislation in 2018).

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[4] Findings like these justify the Maryland 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.").

Maryland's HB 631 addresses the negative impacts of price gouging on the public's health and financial well-being by requiring that manufacturers and wholesalers provide information to justify extraordinary price increases.

CONCLUSION

For the above reasons, and those described in the State's petition, *amici* urge the Court to grant Maryland's petition for a writ of certiorari.

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