No. 18-_____

In The
Supreme Court of the United States

BRIAN E. FROSH, Attorney General of Maryland, and ROBERT R. NEALL, Maryland Secretary of Health,

Petitioners,

v.

ASSOCIATION FOR ACCESSIBLE MEDICINES,

Respondent.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Does the Commerce Clause prohibit a state from protecting consumer access to essential off-patent and generic prescription drugs by requiring manufacturers to refrain from unconscionably raising the price of those drugs sold in the state?

PARTIES TO THE PROCEEDINGS

The petitioners are Brian E. Frosh, Attorney General of Maryland, and Robert R. Neall, Maryland Secretary of Health. Secretary Neall replaces Dennis R. Schrader, who was Secretary of Health during the proceedings below. Respondent is the Association for Accessible Medicines.

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PETITION FOR A WRIT OF CERTIORARI

Brian E. Frosh, Attorney General of Maryland, and Robert R. Neall, Maryland's Secretary of Health, respectfully petition this Court for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fourth Circuit.

OPINIONS BELOW

The opinion of the Fourth Circuit is reported at 887 F.3d 664. App. 1a. The Fourth Circuit's order denying Maryland's petition for rehearing en banc is available at 2018 WL 3574755. App. 106a. The district court's unreported opinion is available at 2017 WL 4347818. App. 67a.

JURISDICTION

The Fourth Circuit entered judgment on April 13, 2018. Petitioners filed a timely petition for rehearing en banc, which the Fourth Circuit denied on July 24, 2018. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Commerce Clause of the United States Constitution provides:

> The Congress shall have Power . . . To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes. . . .

U.S. Const. art. I, § 8, cl. 3.

The Maryland statutory provisions at issue, Md. Code Ann., Health Gen. §§ 2-802(a), 2-801(b), (c) (LexisNexis Supp. 2018), are reproduced in the appendix. App. 116a.

STATEMENT

This case presents the question whether the states' sovereign power to regulate in-state commerce includes the power to impose consumer-protection requirements on both in-state and out-of-state manufacturers of goods destined for sale in the state. As this case shows, laws like these are increasingly susceptible to attack under the so-called extraterritoriality prong of the dormant Commerce Clause, a judicially created doctrine that has been the subject of repeated criticism.

The law at issue here is consumer-protection legislation enacted by Maryland's General Assembly in response to well-documented instances of certain drug manufacturers exploiting market dysfunction to impose staggering price increases—of as much as several thousand percent—on medicines that had long been off patent and available at a stable, affordable price. Following numerous public reports of extraordinary

price increases and resulting patient hardships, Maryland enacted bipartisan legislation in 2017 to prohibit unconscionable price increases in the sale of essential off-patent or generic drugs. 2017 Md. Laws ch. 818 (the "Anti-Price-Gouging Act").

Maryland's Anti-Price-Gouging Act is facially neutral legislation that prohibits price gouging with respect to certain off-patent and generic prescription drugs sold in Maryland. It requires any manufacturer or distributor of those drugs to refrain from unconscionably increasing the price of medicines sold in Maryland. It applies equally to all companies selling drugs in Maryland, whether they are located in the state or out of state. And it applies only to in-state commerce and is silent as to the price any manufacturer or distributor may charge for drugs sold in other states.

Despite the Act's non-discriminatory language, a divided panel of the Fourth Circuit held that it violates the dormant Commerce Clause to the extent that it imposes requirements on out-of-state manufacturers whose drugs are sold in Maryland. Misconstruing this Court's precedent, and departing from at least two other circuits' application of that precedent, the panel majority concluded that a law setting conditions for the in-state sale of consumer goods is unconstitutional to the extent it affects wholesale transactions occurring geographically out of state, even where those transactions are part of a stream of commerce directed into the state.

But, contrary to the holding below, this Court has never held that the states are unable to protect their citizens from harm by imposing requirements for transactions leading to in-state sales of consumer goods that both in-state and out-of-state manufacturers must follow if they wish their products to be sold in a state. That question is now squarely presented, and the Court should grant the petition and hold that states are not powerless to regulate dangerous, predatory commercial practices that occur in complex interstate markets and will injure people within state borders.

Factual Background

1. In 2017, the Maryland General Assembly enacted legislation to protect Maryland consumers from unconscionable increases in the price of essential, off-patent and generic medicines. 2017 Md. Laws ch. 818 (An Act concerning Public Health—Essential Off-Patent or Generic Drugs—Price Gouging—Prohibition), codified at Md. Code Ann., Health Gen. §§ 2-802(a), 2-801(b), (c) (LexisNexis Supp. 2018).

The State's Anti-Price-Gouging Act targets a business model that exploits market failures to generate windfall profits for drug manufacturers at the expense of patients' well-being. Under this practice, manufacturers capitalize on dysfunction in the market for drugs which have long been off patent, to impose dramatic price increases. The best-documented examples of these exploitative price increases have involved

drugs that are needed by only a small number of patients, are considered the "gold standard" for the conditions they treat, and are available only from limited sources. That is, the targeted drugs have small, captive markets and normal market forces cannot keep their prices in check. *See generally* U.S. Senate Spec. Comm. on Aging, *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System* ("Senate Rep.") 73 (2016).

By the time that Maryland enacted its Anti-Price-Gouging Act, there were many documented examples of drug companies engaging in predatory price gouging:

- Valeant Pharmaceuticals International raised the price on two drugs—Cuprамine and Syprine—that treat Wilson disease, a rare condition that inhibits the processing of copper, by 5,785% (from $445 to $26,189) and 3,162% ($652 to $21,267), respectively.
- Turing Pharmaceuticals increased the price of Daraprim, the "gold standard" for treating toxoplasmosis, by more than 5,000% ($13.50 to $750 per pill).
- Rodelis Therapeutics increased the cost of 30 capsules of Sromycin, which treats a life-threatening form of multi-drug resistant tuberculosis, by 2,060% ($500 to $10,800).

- Retrophin, Inc. increased the price of Thiola, one of only two drugs available for a rare condition called cystinuria, by nearly 2,000% ($1.50 to $30 per pill).

Senate Rep. 6.

Price increases like these are devastating to patients and their families. In one case, a 35-year-old father died after going without Syprine because his copay for a single month's supply skyrocketed to $20,000. *Id.* at 101. In another, parents had to face the agonizing and daunting prospect of raising more than a quarter-million dollars to treat their newborn's life-threatening illness, before finally obtaining a life-saving medication from an alternate source. *Id.* at 103. Other families have experienced substantial financial distress in trying to cover the increased costs of essential medications, while the lives of their loved ones hang in the balance. *Id.* at 101. And patients have been forced to adopt riskier or less-effective treatment regimens due to cost constraints. *Id.* at 100.

2. Maryland's Anti-Price-Gouging Act targets a narrow and carefully defined form of commercial conduct: the exploitation of dysfunction in the market for certain essential, off-patent or generic medicines to impose unconscionable price increases for those medicines. It prohibits any drug manufacturer or wholesale distributor from engaging in "price gouging" in the sale of any "essential off-patent or generic drug." Health Gen. § 2-802(a). Maryland's law defines "price gouging" as "an unconscionable increase in the price of a

prescription drug." *Id.* § 2-801(c). An "unconscionable increase" means a price increase that is excessive, and not justified by the cost of producing the drug or expanding access to it, and that results in consumers having no meaningful choice about whether to purchase the drug at an excessive price, because of the importance of the drug to their health, and insufficient competition in the market for the drug. Health Gen. § 2-801(f). An "[e]ssential off-patent or generic drug" is any prescription drug: (i) for which all exclusive marketing rights have expired; (ii) that appears on the World Health Organization's Model List of Essential Medicines or that has been designated an "essential medicine"; (iii) that is manufactured and marketed for sale by three or fewer manufacturers; *and* (iv) that is made available for sale in Maryland. *Id.* § 2-801(b)(1)(i) – (iv). In addition to directly prohibiting price gouging, Maryland's statute grants enforcement authority to the State's Attorney General. *Id.* § 2-803.

Because Maryland's Anti-Price-Gouging Act prohibits price gouging only for a class of drugs "made available for sale in the State," *id.* § 2-801(b)(1)(iv), it is limited on its face to commerce directed into Maryland. The statute's reach is further circumscribed by Maryland law's general presumption against construing state statutes to apply extraterritorially. *See, e.g.*, *Chairman of Bd. of Trs. of Emps.' Ret. Sys. v. Waldron*, 285 Md. 175, 183-84 (1979).

Due to the structure of the modern prescription-drug industry, most drugs sold in Maryland arrive by way of third-party wholesalers or distributors. Drug

manufacturers, most of which are located outside Maryland, set drug price increases, which they then pass along to distributors and ultimately to consumers.

Because Maryland's Anti-Price-Gouging Act requires *any* manufacturer or distributor to refrain from price gouging with respect to drugs sold in Maryland, it applies equally to all unconscionable price increases—whether imposed by in-state actors, out-of-state actors dealing with in-state intermediaries and consumers, or out-of-state actors dealing with out-of-state intermediaries—if the products at issue are intended for sale in the State. But because the statute prescribes conditions only for drugs sold in Maryland, and does not purport to tie the price of drugs sold in Maryland to the price of drugs sold elsewhere, it does not place any restriction on the imposition of price increases for drugs sold anywhere outside the State.

Procedural History

1. Respondent Association for Accessible Medicines ("AAM") is a trade group representing manufacturers of generic prescription drugs. AAM brought a pre-enforcement facial challenge to Maryland's Anti-Price-Gouging Act in the United States District Court for the District of Maryland. As relevant here, AAM alleged that the law violates the Commerce Clause by regulating out-of-state commerce.[1] Specifically, because manufacturers set the prices for their drugs in

[1] AAM also brought a vagueness challenge that is not at issue here.

transactions with wholesalers and distributors that often occur outside Maryland, AAM argued that the statute "penalize[s] out-of-state manufacturers for the prices they charge in out-of-state transactions[.]" Appellant's Br. 5, 8 ("AAM Opening Br."), *AAM v. Frosh*, No. 17-2166, 4th Cir. ECF No. 26. AAM sued petitioners in their official capacities, because they are responsible for enforcing the Anti-Price-Gouging Act.

The district court granted Maryland's motion to dismiss AAM's Commerce Clause claims. The court concluded that, because the Anti-Price-Gouging Act applies only to drugs sold in Maryland and does not require parity between in-state and out-of-state drug prices, the act does not regulate commerce occurring wholly outside Maryland. App. 81a. After the district court entered a final judgment as to AAM's dormant Commerce Clause claims under Federal Rule of Civil Procedure 54(b), AAM noticed an appeal to the United States Court of Appeals for the Fourth Circuit.

2. Over the dissent of Judge Wynn, the Fourth Circuit reversed the district court's judgment. The court of appeals' core holding was that "the fundamental problem with the statute is that it 'regulates the price of an out-of-state transaction.' " App. 19a (quoting *Pharmaceutical Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 669 (2003) (alterations omitted)).

To reach this conclusion, the panel majority found in this Court's precedent three "principles against extraterritoriality": (i) a statute may not regulate commerce that takes place wholly outside a state's borders

whether or not it has in-state effects; (ii) a statute that directly controls commerce wholly outside a state's borders is invalid whether or not its extraterritorial reach was intended; and (iii) in evaluating a statute's "practical effect," a court considers how the statute would interact with the regulatory regimes of other states. App. 10a-11a, 19a. The panel majority drew these anti-extraterritoriality principles from a trilogy of cases in which this Court struck down state laws that *discriminated* against interstate commerce by preventing merchants from offering better prices on their goods in other states. *See Healy v. Beer Inst., Inc.*, 491 U.S. 324 (1989); *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573 (1986); *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935).

Applying the *Baldwin* line of cases, the panel majority held that Maryland's Anti-Price-Gouging Act violates the dormant Commerce Clause. The majority reasoned that, although the Anti-Price-Gouging Act regulates prices of only those drugs "made available for sale in [Maryland]," Health Gen. § 2-801(b)(1)(iv), it affects "conduct that occurs entirely outside Maryland's borders" in the form of "sales upstream from consumer retail sales." App. 15a. The court further held that, even if the Anti-Price-Gouging Act is understood as requiring some nexus to sales in Maryland, "it still controls the price of transactions that occur wholly outside the state." App. 16a. Thus, according to the panel majority, rather than merely effecting an "upstream pricing impact" that is the result of "natural market forces and . . . not artificially imposed by the laws of another state," the Act imposes "a price control" that "aims to

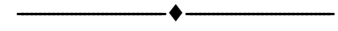
override prescription drug manufacturers' reaction to the market[.]" App. 18a-19a. The panel majority further reasoned that, if analogous restrictions were imposed by other states, there was the "potential" to subject drug manufacturers to conflicting obligations. App. 20a.

The panel majority's opinion rests on a reading of this Court's precedent that would deprive a state of power to protect consumers from predatory commercial practices that originate out of state, even though they are directed into the state and will directly harm its citizens. Although the panel majority acknowledged that states may regulate the price of drugs once they enter the state and seemed to recognize that states may indirectly affect out-of-state commerce when the effect is the result of "natural market forces," App. 18a, the majority's conclusion effectively insulates from state regulation any transaction that occurs outside a state, even when that transaction sets the price that will be borne by consumers for a product sold in the state.

In dissent, Judge Wynn observed that the majority's reading of the Commerce Clause impinges on states' power to protect the health and welfare of their citizens. App. 24a. He explained that this Court's *Baldwin* line of decisions was not concerned with mere extraterritoriality but with preventing "economic protectionism, discrimination against interstate commerce, and State regulation of a stream of transactions that never crosses through the State's borders." App. 46a.

Judge Wynn also disagreed with the panel majority's focus on discrete transactions instead of broader streams of commerce. App. 39a, 43a-44a. Although Maryland's Anti-Price-Gouging Act might affect some *transactions* that occur prior to an in-state sale, it does so only when they are part of a stream of sales that ends in Maryland. In other words, the statute does not regulate wholly out-of-state *commerce* even if it affects the price of some out-of-state *sales*. App. 39a, 44a. And because the Maryland statute does not regulate any streams of commerce that end in other states, it does not truly regulate out-of-state commerce. App. 44a.

3. Following the Fourth Circuit's ruling, the district court stayed AAM's remaining challenges, and Maryland petitioned for rehearing en banc. On July 24, 2018, a divided Fourth Circuit denied rehearing. Once again, Judge Wynn wrote a dissent. In addition to rearticulating his objections to the majority's Commerce Clause holding, Judge Wynn also criticized the majority for failing to reconsider its ruling in light of this Court's decision in *South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080 (2018), decided while Maryland's petition for rehearing was pending. As Judge Wynn observed, *Wayfair* affirmed states' power under the Commerce Clause to tax in-state sales by out-of-state merchants, and thus cast doubt on whether the Commerce Clause prohibits state laws merely because they have an extraterritorial effect. App. 110a-114a.



REASONS FOR GRANTING THE PETITION

This Court's review is necessary to clarify the scope of states' power to protect their citizens from the abusive commercial practices of out-of-state actors operating upstream of in-state consumer transactions. The Fourth Circuit's decision relied on a line of anti-protectionism cases that this Court has never applied—and should not apply—to consumer-protection laws whose regulatory objectives fall well within the ambit of traditional state police powers, and which do not require parity between in-state and out-of-state pricing.

In misinterpreting the reach of this Court's *Baldwin* line of cases, the Fourth Circuit departed from two other circuits on the fundamental question of whether the extraterritoriality principle continues to exist under the Court's modern precedent. This reading of the Court's decisions deepens the existing confusion among the circuits, which differ with respect to states' power to impose requirements for out-of-state manufacturers' sale of goods in a state, and on the role rigid geographic boundaries play in answering that question.

Not only does the decision below prevent Maryland and other states from reining in abusive prescription-drug prices that harm their consumers and the public health, but it could call into question other important state regulatory efforts. As a result, the ruling could leave states with diminished power to protect their citizens from injuries that occur in complex

commercial markets. The Court should grant the petition and affirm that a state may require out-of-state entities to follow the same requirements as in-state entities if they wish to lawfully sell goods in that state.

I. This Court's Review Is Necessary to Resolve an Important Question of Federalism and to Clarify the Scope of States' Sovereign Police Powers Under the Commerce Clause.

The decision below calls into question states' longstanding and fundamental power to promote public welfare by establishing requirements for selling consumer products in the state. To reach its holding, the Fourth Circuit applied this Court's Commerce Clause decisions more broadly than this Court has done, due to the panel majority's mistaken belief that this Court's dormant Commerce Clause jurisprudence categorically prohibits states from enacting regulations that might affect transactions occurring outside the boundaries of the state, even where those transactions are a necessary antecedent to in-state sales that are within states' regulatory power. To the contrary, this Court has not squarely addressed whether states can pass laws that obligate out-of-state manufacturers to respect state-law requirements on the in-state sale of products. The question presented goes to the heart of states' sovereign police powers, and the Court should answer this important question now.

A. This Case Presents an Important and Unresolved Question of State Sovereignty.

This Court has never directly examined whether the dormant Commerce Clause limits states' sovereign powers to enact non-discriminatory consumer-protection legislation when out-of-state commercial actors seek to target the state's consumers for predatory practices. Nothing in the Court's holdings supports the conclusion that an extraterritorial effect, standing alone, is forbidden. To the contrary, Maryland's Anti-Price-Gouging Act is consistent with the Court's prior Commerce Clause decisions.

1. The Court's Prior Extraterritoriality Cases Concerned Discriminatory Economic Protectionism, Not State Efforts to Protect Consumers from Predatory Commercial Practices in Interstate Markets.

The decision below misapplies this Court's Commerce Clause holdings, which are "driven by a concern about economic protectionism—that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors." *McBurney v. Young*, 569 U.S. 221, 235 (2013) (internal quotation marks omitted). Indeed, "a careful look at" this Court's extraterritoriality jurisprudence "suggests a concern with preventing discrimination against out-of-state rivals or consumers." *Energy & Env't Legal Inst. v. Epel*, 793 F.3d 1169, 1173 (10th Cir. 2015) (Gorsuch, J.). Jettisoning this touchstone, the Fourth Circuit over-read

a series of cases in which this Court struck down specific, discriminatory extraterritorial regulations.

In *Baldwin*, the Court invalidated a New York law that prohibited the sale of milk if it had been sold by a producer to a distributor out of state at a price lower than the minimum price that could be charged in New York. 294 U.S. at 519. In *Brown-Forman*, the Court struck down a New York law that made it illegal for liquor distillers to sell alcohol outside New York at prices lower than they charged in the state. 476 U.S. at 579-80. And in *Healy*, the Court overturned a Connecticut law that prohibited distributors from selling beer to Connecticut wholesalers at prices higher than they charged in neighboring states. 491 U.S. at 326. In each of these cases, the Court did not strike down state laws solely because of their extraterritorial effects. *Baldwin*, as this Court later explained, involved clear discrimination against interstate commerce by imposing a "tariff[] by other means." *West Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 193 (1994). Through the price-tying mechanisms at issue in *Brown-Forman* and *Healy*, states interfered with the price that could be charged to consumers in *other* states. Maryland's statute, by contrast, does not discriminate against interstate commerce and has no effect on the price charged to consumers in other states.

More recently, this Court itself confirmed that *Baldwin* and its progeny simply do not address regulations, like the Anti-Price-Gouging Act, that do not involve discrimination against interstate commerce or economic protectionism. The Court explained that

"[t]he rule that was applied in *Baldwin* and *Healy* . . . is not applicable" in a case that did not involve price-tying and price-affirmation statutes. *Walsh*, 538 U.S. at 669. In *Walsh*, the Court upheld a Maine statute that required any manufacturer selling drugs in Maine through a public financial assistance program to enter into a rebate agreement with the state. *Id.* at 654. The statute resulted in lower in-state prescription drug prices for qualified Maine residents. *Id.* Although a drug manufacturers' association argued that the statute violated the extraterritoriality principle of the dormant Commerce Clause by regulating the terms of out-of-state transactions, the Court rejected that argument because "Maine does not insist that manufacturers sell their drugs to a wholesaler for a certain price"[2] or "t[ie] the price of its in-state products to out-of-state prices." *Id.* at 669 (quoting *Concannon*, 249 F.3d at 82).

This Court has never held that states may not protect their citizens from harmful commercial practices by requiring all manufacturers to adhere to the same consumer protection regulations for in-state sales, just because some abusive practices targeted at the state's consumers are implemented outside the state's

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[2] This language does not suggest that a price *cap*, as opposed to a price-tying requirement, would violate the Constitution. The First Circuit decision upheld in *Walsh*—which this Court cited favorably—clarified that the reason that the Maine statute was constitutional was that "[t]here is nothing within the Act that requires the rebate to be a certain amount dependent on the price of prescription drugs *in other states*." *Pharmaceutical Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 81-82 (1st Cir. 2001) (emphasis added).

borders. On the contrary, "innumerable valid state laws affect pricing decisions in other States—even so rudimentary a law as a maximum price regulation." *Healy*, 491 U.S. at 345 (Scalia, J., concurring). No one disputes that in passing the Anti-Price-Gouging Act, Maryland's General Assembly sought to protect Marylanders from a predatory business practice, not to give Marylanders an unfair commercial advantage over residents of other states.[3] The Fourth Circuit therefore misapplied the *Baldwin* line of cases in which this Court invalidated *protectionist* state laws that imposed de facto tariffs on interstate commerce or effectively regulated consumer transactions in other states.

2. Maryland's Price-Gouging Ban Is Consistent with this Court's Precedent.

This Court's prior cases support allowing states to require out-of-state manufacturers to follow consumer-protection requirements in order to sell their goods in the state, even when those manufacturers principally

[3] In its opposition to Maryland's petition for rehearing en banc, AAM relied on an argument it had failed to raise previously: That Maryland's Anti-Price-Gouging Act "plainly *do[es]* implicate 'economic protectionism,'" because "lowering prices exclusively for in-state residents is perhaps the most common form of economic protectionism." Resp. to Pet. for Reh'g en Banc at 15, *AAM v. Frosh*, No. 17-2166, 4th Cir. ECF No. 50 (emphasis in original). But this Court has held that "a State may seek lower prices for its consumers." *Brown-Forman*, 476 U.S. at 580. Moreover, AAM admits that "a State may protect its citizens by prohibiting deceptive trade practices" even if doing so affects some interstate commerce. AAM Opening Br. 32 (quoting *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 568-70 (1996)).

sell their goods through intermediaries. Maryland's Anti-Price-Gouging Act lacks all of the attributes of the statutes the Court struck down in the *Baldwin* line: It does not involve price tying or price affirmation, it does not discriminate against interstate commerce, and it leaves drug manufacturers and distributors completely free to impose price increases on drugs intended for sale in other states.

Contrary to the holding below, Maryland's statute resembles the kind of in-state regulation this Court has *affirmed*, despite an incidental effect on out-of-state actors. In *Walsh*, drug manufacturers argued, as they have argued in this case, that "[v]irtually all manufacturers' sales of prescription drugs occur outside of Maine in transactions with wholesalers and distributors[.]" Pet'r's Br., *Pharmaceutical Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644 (2003), 2002 WL 31120844, at *29. The Maine statute's extraterritorial effect was thus no different from the extraterritorial effect that AAM alleges here: According to the pharmaceutical manufacturers, the Maine statute required them to follow certain requirements "even if they are complete strangers to the instate pharmacy sales transaction, and even if the manufacturer never engaged in *any* sales transaction in Maine leading up to that retail purchase." *Id.* at *10 (emphasis in original). The Court nevertheless rejected the manufacturers' dormant Commerce Clause challenge and held that because Maine did not "insist that manufacturers sell their drugs to a wholesaler for a certain price," and "was not tying the price of its in-state products to its out-of-state

prices," "[t]he rule that was applied in *Baldwin* and *Healy* accordingly is not applicable[.]" 538 U.S. at 669.

The Court reached a similar result in *Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456 (1981), which upheld a Minnesota law prohibiting the sale of milk in certain containers. 449 U.S. at 458-59. The law had the practical effect of regulating how milk producers, including those located out of state, packaged milk destined for sale in Minnesota, but the Court held that the statute did not violate the dormant Commerce Clause. As in *Walsh*, the Court distinguished between "simple protectionism" and "regulat[ing] evenhandedly" the sale of all milk in prohibited containers "without regard to whether the milk, the containers, or the sellers are from outside the State." *Id.* at 471-72 (internal quotation marks omitted).

Contrary to this Court's decisions in cases like *Walsh* and *Clover Leaf Creamery*, AAM disputes that the extraterritoriality doctrine is narrowly concerned with preventing economic protectionism. AAM argued below that in *Edgar v. MITE Corp.*, 457 U.S. 624 (1982), a plurality of this Court invalidated a statute on extraterritoriality grounds even though it was not a price-tying statute. But *Edgar* does not answer the question presented here because it did not involve in-state regulation but a law that regulated commerce occurring entirely outside the regulating state. In *Edgar*, a plurality of this Court concluded that an Illinois statute allowing the state to block tender offers of companies with minimal ties to Illinois was an unconstitutional extraterritorial regulation because it applied "even if"

the regulated transactions occurred "wholly outside the State of Illinois." 457 U.S. at 641 (plurality opinion). Regardless of what *Edgar* means for the broader extraterritoriality doctrine, it does not mean that states are powerless to place reasonable requirements on manufacturers whose goods are sold in the state. The Court should grant the petition and hold that the Commerce Clause is not violated by requiring manufacturers to observe consumer-protection regulations if they want to sell their goods in a state.

B. The Holding Below Impedes States' Exercise of Their Sovereign Police Powers to Protect Their Citizens from Injuries Caused by Harmful Practices in Interstate Markets.

The Fourth Circuit's unjustified expansion of this Court's extraterritoriality holdings has potentially serious consequences for state sovereignty. For nearly two centuries this Court has recognized that "the power to regulate commerce in some circumstances was held by the States and Congress concurrently." *Wayfair*, 138 S. Ct. at 2090 (citing *Wilson v. Black-Bird Creek Marsh Co.*, 27 U.S. 245 (1829)). Indisputably, Maryland possesses the power to protect the health and safety of its consumers, *see, e.g.*, *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), but the theory of extraterritoriality applied below would undermine Maryland's ability to do so where harmful products enter the State from elsewhere. This Court recently recognized that "[i]f it becomes apparent that the Court's

Commerce Clause decisions prohibit the States from exercising their lawful sovereign powers in our federal system, the Court should be vigilant in correcting the error." *Wayfair*, 138 S. Ct. at 2096. Such vigilance is needed here: If states cannot prevent harm to consumers within their territory from sales made within their territory simply because the source of the harm resides out of state, they lose the ability to protect consumers in an important category of cases.

For example, in the context of the prescription-drug industry, the documented instances of price-gouging principally involve manufacturers located outside of Maryland. Once a manufacturer has unconscionably raised a drug's price, subsequent transactions may just pass along the unreasonable price set by the manufacturer.[4] Limiting states' regulatory power to those secondary transactions effectively prevents the state from addressing the underlying unconscionable and harmful price increase. This is especially true where normal market forces cannot be expected to correct upstream prices which, by definition, is the case with any drugs that Maryland's statute regulates.

Many important state prerogatives, including safety and consumer-protection laws, require that states be able to place conditions on in-state activity even when it involves out-of-state actors. As Judge

[4] Maryland's Anti-Price-Gouging Act accounts for this fact by providing that a *distributor* does not violate the statute if it increases a drug's price to pass through a price increase that the distributor itself is forced to pay manufacturers. Health Gen. § 2-802(b).

Wynn pointed out in his dissent, the holding below threatens state consumer-protection laws that "impose safety, quality, and labeling restrictions on goods sold by out-of-state manufacturers through out-of-state distributors to in-state consumers." App. 55a (Wynn, J., dissenting). Similarly, under the panel majority's reasoning, state antitrust laws that allow indirect purchasers to seek relief from manufacturers who conspire to fix prices could come under attack where they authorize suit "against an upstream out-of-state seller which sold the price-fixed product in an out-of-state transaction." App. 55a (Wynn, J., dissenting).[5]

The Court should grant the petition and hold that states do not lose the power to promote the public welfare just because consumer goods sold in the State arrive from outside state boundaries.

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[5] Several cases pending before the Court this Term further illustrate how laws within traditional areas of state sovereignty become susceptible to Commerce Clause attack simply because the goods they regulate are distributed through interstate markets. *See Indiana v. Massachusetts*, Orig. No. 149; *Missouri v. California*, Orig. No. 148. These laws address the quality of food sold in the state, but because the markets for that food involve out-of-state producers selling food in the state, the challenged laws necessarily require out-of-state producers to follow certain requirements in order to sell their goods in the state, just as Maryland's Anti-Price-Gouging Act does.

II. There Is Considerable Confusion Among the Circuits over the Existence and Scope of any Extraterritoriality Principle in the Court's Dormant Commerce Clause Jurisprudence.

The decision below deepens the confusion among the circuits over the breadth and scope of the extraterritoriality principle, the existence of which this Court called into serious question in *Walsh*. The Fourth Circuit acknowledged that, in applying *Baldwin* and its progeny to strike down the Anti-Price-Gouging Act, it was departing from other circuits' reading of this Court's decisions. App. 12a. Whereas the Fourth Circuit understood the extraterritoriality doctrine to be a robust constitutional principle, decisions in other circuits have questioned whether, in light of *Walsh*, it even exists. *See, e.g.*, *Epel*, 793 F.3d at 1172, 1173 (Gorsuch, J.) (describing extraterritoriality doctrine as "the most dormant" "strand[] of dormant commerce clause jurisprudence" and questioning "whether the *Baldwin* line of cases is really a distinct line of dormant commerce clause jurisprudence at all"); *American Beverage Ass'n v. Snyder*, 735 F.3d 362, 378 (6th Cir. 2013) (Sutton, J., concurring) ("Is it possible that the extraterritoriality doctrine, at least as a freestanding branch of the dormant Commerce Clause, is a relic of the old world with no useful role to play in the new? I am inclined to think so.").

Only this Court can harmonize these discordant approaches to a fundamental question of federalism. The decision below demonstrates that without guidance

from this Court, the lower courts will continue to reach conflicting conclusions about state power to regulate goods sold in complex interstate markets. Thus, this Court's review is necessary to ensure uniformity among the circuits.[6]

A. The Fourth Circuit Departed from Other Circuits in the Application of this Court's Extraterritoriality Cases.

The decision below departs from several other circuits on whether the *Baldwin* line is limited to cases of economic protectionism involving price-tying. At least two circuits—the Ninth and Tenth—have held that it is so limited, at least following this Court's decision in *Walsh*. The Ninth Circuit has stated that "*Healy* and *Baldwin* are not applicable to a statute that does not dictate the price of a product and does not tie the price of its in-state products to out-of-state prices." *Association des Éleveurs de Canards et d'Oies du Québec v. Harris*, 729 F.3d 937, 951 (9th Cir. 2013) (citing *Walsh*, 538 U.S. at 669).[7] Reaching the same conclusion, the

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[6] Although it is not necessary for the Court to reevaluate whether the concept of the dormant Commerce Clause itself is a constitutionally valid doctrine, this case presents an appropriate vehicle for the Court to do so if it desires.

[7] Citing *Sam Francis Foundation v. Christie's, Inc.*, 784 F.3d 1320 (9th Cir. 2015), AAM has argued that the Ninth Circuit has not limited the extraterritoriality doctrine to price-tying cases. In that case, as this Court did in *Edgar*, the Ninth Circuit struck down a statute that regulated *purely* out-of-state transactions by requiring any California resident to pay a royalty for art sales wherever the sales took place. 784 F.3d at 1321. But the Ninth Circuit distinguished that statute from "state laws that

Tenth Circuit explained that "the Supreme Court has emphasized as we do that the *Baldwin* line of cases concerns only 'price control or price affirmation statutes' that involve 'tying the price of . . . in-state products to out-of-state prices.'" *Epel*, 793 F.3d at 1174-75 (alteration in original) (quoting *Walsh*, 538 U.S. at 669). The Fourth Circuit recognized these courts' holdings but rejected them because it found their reading of *Walsh* "too narrow." App. 12a ("Maryland's reading of [*Walsh*], while adopted by two of our sister circuits, is too narrow.").

The Fourth Circuit's focus on geographic boundaries is also inconsistent with the approach of the Second Circuit, which has upheld state laws requiring out-of-state manufacturers to follow the same conditions as in-state manufacturers whose goods are sold in a state. In *National Electrical Manufacturers Association v. Sorrell*, 272 F.3d 104 (2d Cir. 2001), the Second Circuit vacated a preliminary injunction against the enforcement of a Vermont statute that imposed labeling requirements on manufacturers of certain mercury-containing products. *Id.* at 107, 116. In so doing, the court rejected the plaintiffs' argument that the statute had an impermissible extraterritorial effect "because the statute [did] not inescapably require manufacturers to label all [affected products] wherever

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regulate[ ] *in-state conduct* with allegedly significant out-of-state practical effects," *id.* at 1324 (emphasis in original), and in a subsequent decision, the court reaffirmed its holding that "even when state law has significant extraterritorial effects, it passes Commerce Clause muster when . . . those effects result from the regulation of in-state conduct." *Chinatown Neighborhood Ass'n v. Harris*, 794 F.3d 1136, 1145 (9th Cir. 2015).

distributed." *Id.* at 110. Like Maryland's statute, only products sold into Vermont were subject to the requirement, which made "no mention of other states for any purpose."[8] *Id.* The Sixth Circuit has reached a similar result in upholding state laws that require out-of-state manufacturers to follow conditions on the in-state sale of goods. *See International Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 646-48 (6th Cir. 2010) (holding that Ohio labeling requirements for dairy products did not have impermissible extraterritorial effect, where the requirements "ha[d] no direct effect on the [plaintiffs'] out-of-state labeling conduct").

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[8] The Second Circuit has also noted that "the upstream pricing impact of a state regulation" does not render a law invalid under the dormant Commerce Clause and that "mere upstream pricing impact is not a violation of the dormant Commerce Clause, even if the impact is felt out-of-state where the stream originates." *Freedom Holdings, Inc. v. Cuomo* ("*Freedom Holdings II*"), 624 F.3d 38, 67 (2d Cir. 2010) (quoting *Freedom Holdings, Inc. v. Cuomo*, 592 F. Supp. 2d 684, 707 (S.D.N.Y. 2009)); *Freedom Holdings, Inc. v. Spitzer* ("*Freedom Holdings I*"), 357 F.3d 205, 220 (2d Cir. 2004) (internal quotation marks and alterations omitted). The panel majority attempted to distinguish this case from *Freedom Holdings I* by reasoning that the upstream pricing effect of the New York statute was the result of "natural market forces and was not artificially imposed by the laws of another state." App. 18a-19a. But the panel majority failed to explain why it should be regarded as impermissible for a state to affect upstream pricing through the inevitable economic consequences of in-state regulations, or why the escrow-fee statute at issue in *Freedom Holdings* was any less artificial than the law at issue here. And, most importantly, the court failed to fully grapple with the Second Circuit's emphasis on streams of commerce directed into a state as opposed to geographic boundaries.

B. The Lower Courts' Confusion Will Lead to Inconsistent Outcomes.

The divergence among the circuits over the fundamental question of *Baldwin*'s scope means that similar regulatory initiatives in different states will suffer different fates. States outside the Fourth Circuit now have greater power to protect their consumers from harmful commercial practices than those states within the circuit. For example, in *Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070 (9th Cir. 2013), the Ninth Circuit rejected a dormant Commerce Clause challenge to a California statute with an extraterritorial effect similar to that of Maryland's Anti-Price-Gouging Act. The California law limited the average carbon intensity of ethanol fuel sold in California, and because a significant portion of ethanol's carbon emissions occurs before the fuel enters a car's gas tank, the statute measured carbon intensity over the entire "lifecycle" of the fuel, including stages of production that occurred outside California. 730 F.3d at 1080. By making it illegal to sell ethanol whose average carbon footprint exceeded a threshold, California necessarily required out-of-state ethanol producers to adjust their operations if they wanted to produce ethanol that could be sold in California.

Despite this extraterritorial effect, the Ninth Circuit held that the statute did not violate the Commerce Clause because it was silent about "ethanol produced, *sold, and used* outside California"; did not require other jurisdictions to adopt reciprocal price standards; made no effort to ensure ethanol prices were lower in

California than in other states; and did not impose penalties on non-compliant transactions "completed wholly out of state." *Id.* at 1102-03. Indeed, the court found no fault with California's desire to "regulate with reference to local harms" and concluded that California "properly based its regulation on the harmful properties of fuel." *Id.* at 1104. The Ninth Circuit's reasons for upholding the California ethanol statute apply with equal force to Maryland's Anti-Price-Gouging Act.

The Court should grant the petition and ensure that all states have the power to protect in-state consumers against harms originating out of state.

III. The Question Presented Is One of Exceptional Importance.

The question presented is of exceptional importance because it affects Maryland's ability to protect its citizens from an abusive and potentially life-threatening commercial practice that impedes access to essential medicine. Prescription-drug price gouging extracts monopolist-level profits from vulnerable patients by exploiting their "gross disadvantage in terms of bargaining power." App. 62a (Wynn, J., dissenting). Staggering price hikes "are affecting [patients'] health, time, emotional well-being, and pocketbooks." Senate Rep. 98. Patients suffer anxiety at the prospect of losing—quite literally—their lifelines, and their health suffers as they are unable to maintain proper dosages of their medicines. *Id.*

Price gouging also wreaks havoc with healthcare providers and governments. Doctors lose treating time trying to find affordable medicines for patients and incur financial and administrative burdens in dealing with dropped insurance coverage after price spikes. *Id.* at 105-06. Hospital budgets take multi-million-dollar hits from dramatic rises in drug prices. *Id.* at 106. Insurance companies must raise deductibles, premiums, and co-pays to make up for the increased cost of providing coverage. *Id.* at 110. And price gouging contributes to an increase in federal spending, including a 17% increase in Medicare Part D spending from 2013 to 2014. *Id.*

The effects of price gouging are hard-felt by a nation already in the throes of an opioid epidemic. In 2016, the price of Naloxone, an antidote to prescription painkiller overdoses, increased by 1,000%. *Id.* at 27. To cover the rising costs of critical medicines, hospitals have diverted resources away from their efforts to combat the opioid epidemic. *Id.* at 105, 107.

There is also reason to suspect that prescription-drug price gouging will become more common if states cannot limit it. Between 2010 and 2015, manufacturers imposed extraordinary price increases—defined as an increase of more than 100% within a year—on 315 drugs, out of 1,441 studied. Forty-eight of those 315 increases exceeded 500%, and fifteen exceeded 1,000%. United States Dep't of Gen. Servs., *Generic Drugs Under Medicare, Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases* 12-14 (2016).

States must be able to combat these direct threats to public health, safety, and well-being. The question presented is of surpassing public importance, and the Court should grant certiorari.

CONCLUSION

The Court should grant the petition for a writ of certiorari.

Respectfully submitted,

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