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)

PETITION FOR REHEARING *EN BANC*

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RULE 35(b)(1) STATEMENT

This is an appeal from a district court decision rejecting a dormant Commerce Clause challenge to Maryland's recently-enacted prohibition on price gouging (the imposition of unconscionable price increases) in the sale of certain off-patent medicines in the State. The statute is the first of its kind to protect consumers from the pattern of conduct detailed in a 2016 report of the U.S. Senate Special Committee on Aging, titled *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model That Harms Patients, Taxpayers and the U.S. Health System*. The panel reversed the district court and invalidated the statute insofar as it affects wholesale transactions occurring outside Maryland. Defendants-appellees, the Attorney General of Maryland and the Maryland Secretary of Health (together, "the State"), seek rehearing *en banc*, because the majority decision conflicts with prior decisions of this Court and other circuits, and because this appeal involves questions of exceptional importance. Specifically:

1. In holding that Maryland's statute reaches drugs intended for sale in states other than Maryland, the panel majority failed to observe the well-established principle that, "[i]n construing a state law, [this Court] look[s] to the rules of construction applied by the enacting state's highest court." *Carolina Trucks & Equipment, Inc. v. Volvo Trucks of North America, Inc.*, 492 F.3d 484, 489 (4th Cir. 2007). Nor did the majority apply the doctrine of constitutional avoidance. The

Maryland General Assembly expressly limited the statute at issue to drugs "made available for sale in the State," and the Maryland Court of Appeals has established a presumption against extraterritoriality in statutory interpretation. As the State has acknowledged, as the district court found, and as the plaintiff-appellant Association for Accessible Medicines ("AAM") has conceded, the statute applies only to products sold or intended for sale in Maryland; it does not reach streams of commerce that do not end in Maryland.

2. The majority also departed from this Court's decision in *Star Scientific v. Beales*, 278 F.3d 339 (4th Cir. 2002), by holding that the dormant Commerce Clause prohibits state regulations that affect price increases imposed in wholesale transactions occurring geographically out of state but involving goods intended for sale in the state. In *Star Scientific*, this Court reached essentially the opposite conclusion, holding that Virginia could impose an escrow fee directly on out-of-state cigarette manufacturers whose sole contacts with Virginia occurred through out-of-state wholesale transactions involving cigarettes later sold in Virginia.

3. The majority acknowledged that, in applying the extraterritoriality principle of the dormant Commerce Clause to invalidate Maryland's statute, it has adopted an understanding of that principle more expansive than that of at least two other circuits. As the dissent observed, "neither the Supreme Court nor this Court ever has relied on the extraterritoriality doctrine as the sole basis to invalidate a state

statute regulating products ultimately sold within the state's borders." Slip op. at 50 (Wynn, J., dissenting). Moreover, the majority's understanding of the extraterritoriality principle, the very existence of which is a matter of doctrinal debate, calls into question the well-established application of state antitrust, consumer protection, and public health laws. *See id*. at 47-49.

4. The statute's validity is, by itself, an issue of exceptional importance. Maryland seeks to protect its citizens from a well-documented pattern of unethical conduct that substantially burdens state-funded health insurance programs and disrupts access to essential medicines. This Court's decision will substantially affect how Maryland and other states may address the adverse effects of extraordinary increases in prices charged for life-saving and life-sustaining drugs.

BACKGROUND

In 2017, the Maryland General Assembly, by overwhelming bipartisan majorities, enacted House Bill 631 ("HB 631" or "the Act"). 2017 Md. Laws, ch. 818. The Act prohibits "unconscionable price increases" in the sale of certain essential off-patent or generic medicines to Maryland consumers under circumstances of "insufficient market competition."

The legislature reviewed substantial evidence of extraordinary price hikes for drugs that had long been off patent; the harmful effects of those price increases on patients, families, and health care systems; and the market conditions that permitted

manufacturers to impose such increases. In HB 631, the legislature targeted the pattern of conduct described in the bipartisan report of the U.S. Senate's Special Committee on Aging, led by Senators Susan Collins and Claire McCaskill.

The Act's core is its prohibition on price gouging: "A manufacturer or wholesale distributor may not engage in price gouging in the sale of an essential off-patent or generic drug." Md. Code Ann., Health-Gen. § 2-802(a). The definitions section refines that prohibition, by defining "essential off-patent or generic drug" as "any prescription drug":

> (i) "for which all exclusive marketing rights, if any, granted under [federal law] have expired";
>
> (ii) that either appears on the World Health Organization's most recently adopted Model List of Essential Medicines or "has been designated by the Secretary as an essential medicine due to its efficacy in treating a life-threatening health condition or a chronic health condition that substantially impairs an individual's ability to engage in activities of daily living";
>
> (iii) "that is actively manufactured and marketed for sale in the United States by three or fewer manufacturers"; and
>
> (iv) that is "made available for sale in the State."

Id. § 2-801(b)(1)(i)-(iv); *see* Md. Code Ann., Gen. Prov. § 1-115(b) ("When capitalized, 'State' means Maryland.").

The Act defines "price gouging" as an "unconscionable increase in the price of a prescription drug," *id.* § 2-801(c), and further defines "unconscionable increase" as a price increase with two components. First, the increase must be "excessive and

not justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug to promote public health." *Id.* § 2-801(f)(1). Second, the increase must "result[] in consumers for whom the drug has been prescribed having no meaningful choice about whether to purchase the drug at an excessive price because of" *both* the "importance of the drug to their health" *and* "insufficient competition in the market for the drug." *Id.* § 2-801(f)(2)(i)-(ii). These provisions reference the common-law doctrine of unconscionability. *See, e.g.*, *Walther v. Sovereign Bank*, 386 Md. 412, 425-26 (2005) ("An unconscionable bargain or contract has been defined as one characterized by 'extreme unfairness,' which is made evident by '(1) one party's lack of meaningful choice, and (2) contractual terms that unreasonably favor the other party.'" (citation omitted)). Together, they limit HB 631's applicability to circumstances when patients, because of both their health needs and market dysfunction, must submit to an extraordinary increase in the price of an off-patent medicine unjustified by any increase in the cost of producing the medicine.

In July 2017, before the Act's October 1, 2017, effective date, AAM, a trade group of generic pharmaceutical manufacturers and distributors, filed this action. AAM claims both that Maryland exceeded its authority under the Commerce Clause and that the Act's definition of "unconscionable price increase" is unconstitutionally vague because it lacks a numerical threshold.

On September 29, 2017, the district court denied AAM's motion for preliminary injunction and partially granted the State's motion to dismiss. Agreeing with the State's interpretation, the district court construed the statute to be "triggered only when there is a drug . . . made available for sale *within* the state." J.A. 486. With respect to AAM's Commerce Clause claims, the district court recognized that AAM's extraterritoriality theory "was rejected by the Fourth Circuit in *Star Scientific* and must be rejected here." J.A. 485. The court further concluded that none of the relevant factors, including likelihood of success on the merits, supported AAM's request for preliminary injunctive relief with respect to either of AAM's legal theories.

Although the construction of the statute had been a focus of litigation in the district court, AAM conceded on appeal that HB 631 should be construed as the State asserted. For example, AAM stated in its opening brief that the Act "reach[es] 'sale[s]' that take place outside of Maryland, *so long as the objects of those sales are later resold in Maryland*." Appellant's Br. 28 (emphasis added).

A divided panel reversed the district court's decision. Rejecting the construction of the Act upon which the State, AAM, and the district court had agreed, the majority found that the statute "is not triggered by any conduct that takes place within Maryland" and applies even without "a single pill being shipped to Maryland." Slip op. at 12-13. The majority further held, though, that the Act

exceeds the State's authority under the Commerce Clause even to the extent that it affects out-of-state wholesale transactions involving goods later sold to consumers in Maryland. *See id*. at 14-15.

The majority acknowledged adopting a more expansive understanding of the dormant Commerce Clause than have the Ninth and Tenth Circuits. *See id*. at 10. The majority also declined to apply *Star Scientific* and the Second Circuit's similar decision in *Freedom Holdings Inc. v. Spitzer*, 357 F.3d 205, 220 (2d Cir. 2004), both of which recognize the permissibility of state regulation that affects prices charged in out-of-state wholesale transactions involving goods intended for sale in the state. The majority distinguished *Star Scientific* based principally on its mistaken view that the statute at issue here reaches goods intended for sale to consumers in *other* states, *see id*. at 12, but also based on its understanding that Virginia's imposition of an escrow fee on out-of-state cigarette manufacturers had a "natural" impact on those manufacturers' transactions with out-of-state distributors, whereas the price impact here is "artificially imposed." *Id*. at 16.

In dissent, Judge Wynn recognized that a state statute must be interpreted according to the state's rules of construction and, consistent with Maryland Court of Appeals precedent, would have construed the Act to apply only to products sold or intended for sale in Maryland. *See id*. at 29-32. The dissent then explained why, under the Supreme Court's modern jurisprudence, the term "commerce"

"encompass[es] a *stream* of transactions—including those transactions necessary to produce a good . . . and those by virtue of which the good is distributed and sold to end-users." *Id.* at 37 (emphasis added). Thus, properly construed, the Act specifically relates to *in-state* commerce, and regulates only streams of commerce resulting in sales to consumers in Maryland.

The dissent also disagreed with the panel's refusal to adopt the limitations on the extraterritoriality principle recognized by other circuits. *See id.* at 47-50. It found *Star Scientific* to be consistent with the law in these other circuits, as well as broader trends in dormant Commerce Clause jurisprudence and scholarship. *See id.* at 33-35, 45-47.

The dissent expressed concern about the impact of the majority's holding on state antitrust, consumer protection, and public health laws. "[T]he majority opinion's expansive interpretation of the extraterritoriality doctrine," the dissent warned, "substantially intrudes on the States' reserved powers to legislate to protect the health, safety, and welfare of their citizens." *Id.* at 47. Judge Wynn also cautioned that, in striking down a state statute based on the extent of its perceived interference with market conditions, the majority had departed from sound principles of federalism and judicial restraint. *See id.* at 57-58.

REASONS FOR GRANTING REHEARING *EN BANC*

I. IN BROADLY CONSTRUING THE ACT TO APPLY TO OUT-OF-STATE COMMERCE, THE MAJORITY DECISION CONFLICTS WITH THIS COURT'S ESTABLISHED PRINCIPLES OF STATUTORY CONSTRUCTION.

HB 631 prohibits the imposition of unconscionable price increases for certain essential medicines "made available for sale *in* [*Maryland*]." Md. Code Ann., Health-Gen. § 2-801(b)(1)(iv) (emphasis added). This language reflects the legislature's intention to regulate sales to consumers in Maryland. There is no evidence that the Maryland legislature, in limiting HB 631 to drugs "made available for sale in the State," intended to regulate the price of drugs sold to other states' consumers.

This Court has declared that, "[i]n construing a state law, we look to the rules of construction applied by the enacting state's highest court." *Carolina Trucks*, 492 F.3d at 489. The Maryland Court of Appeals has adopted a presumption against extraterritoriality in state statutory interpretation. *See, e.g., Chairman of Board of Trustees of Employees' Retirement Sys. v. Waldron*, 285 Md. 175, 184 (1979). Thus, to the extent that there is any ambiguity concerning whether the Act applies only to products sold or intended for sale in Maryland, precedent required the panel to adopt that narrower interpretation.

Likewise, the canon of constitutional avoidance mandates that "every reasonable construction must be resorted to, in order to save a statute from

unconstitutionality." *Gonzales v. Carhart*, 550 U.S. 124, 153 (2008). In *K-S Pharmacies, Inc. v. Am. Home Products Corp.*, 962 F.2d 728 (7th Cir. 1992), the Seventh Circuit applied that canon in an analogous case, involving a dormant Commerce Clause challenge to a Wisconsin law prohibiting price discrimination in certain drug sales. The plaintiff, a drug reseller, asserted that, although the statute guaranteed "every purchaser *in this state*" the same price as "the most favored purchaser," the statute did not also expressly limit the term "most favored purchaser" to *in-state* purchasers. *Id.* at 730-31 (emphasis added). If the statute had been construed as the drug reseller insisted, it would have been a price-tying statute—requiring sellers to charge the same prices in Wisconsin that they charge in other states—of the type the Supreme Court has found to violate the dormant Commerce Clause. *See id*. at 730. Writing for the court, Judge Easterbrook readily construed the statute to prohibit price discrimination only among in-state purchasers, asking rhetorically "[w]hat sense would it make" to construe it otherwise. *Id*.

Here, the majority nonetheless held that the Act is "not triggered by any conduct that takes place within Maryland" and applies without "a single pill being shipped to Maryland." Slip op. at 12-13. Because that interpretation directly conflicts with this Court's rules of construction, the appeal should be reheard *en banc*.

II. IN HOLDING THAT THE ACT IMPERMISSIBLY REGULATES WHOLESALE TRANSACTIONS UPSTREAM FROM CONSUMER SALES IN MARYLAND, THE MAJORITY DECISION CONFLICTS WITH THIS COURT'S PRIOR DECISION IN *STAR SCIENTIFIC*.

The key question in this case is whether dormant Commerce Clause principles permit a state to protect its citizens from harms arising from in-state consumer sales by imposing regulations that may affect transactions occurring outside state borders but involving goods intended for sale in the state. This Court answered that question in the affirmative in *Star Scientific*, rejecting a Commerce Clause challenge—based on the same theory advanced by AAM here—to a Virginia statute that imposed a per-cigarette fee directly on manufacturers when their cigarettes were sold in Virginia, including in circumstances when the manufacturer was located out of state and dealt exclusively with out-of-state distributors. 278 F.3d at 355-56.

Star Scientific explained that, even if Virginia's escrow fee statute "affect[ed] the prices charged by out-of-state distributors," it did not have any impermissible extraterritorial impact, because it imposed a fee only on cigarettes sold within the state and did not "insist on price parity with cigarettes sold outside of the State." 278 F.3d at 354. The Court declined to apply the Supreme Court's extraterritoriality decisions, because it recognized that, like HB 631 here, Virginia's statute had "no effect on transactions undertaken by out-of-state distributors [on products sold] in other States." *Id*. at 356. Thus, this Court recognized that the statute did not offend extraterritoriality principles because it was not analogous to a price-tying or price-

affirmation statute. The Second Circuit reached the same conclusion regarding New York's escrow fee statute, holding that the extraterritorial effects described by the manufacturers "amount[ed] to no more than the *upstream pricing impact* of a state regulation," the effects of which "do[] not rise to the level of a constitutionally impermissible act." *Freedom Holdings*, 357 F.3d at 220 (emphasis added).

The panel majority here identified two bases for distinguishing *Star Scientific*. Neither is valid. First, the majority relied on its broad construction of HB 631, emphasizing that Virginia's escrow fee applied only when cigarettes were sold "*in Virginia*" and "did not apply to distributors, retail chains, or consumers *outside Virginia*." Slip op. at 12 (emphasis in original). As discussed above, however, under a correct construction, HB 631's impact on out-of-state manufacturers is the same as in *Star Scientific*, because it affects only manufacturers selling products *in Maryland* "directly or through . . . [an] intermediary." *See Star Scientific*, 278 F.3d at 354 (quoting Va. Code Ann. § 3.1-336.2A); *compare* Md. Code Ann., Health-Gen. § 2-803(g) ("did not deal directly with a consumer residing in the State").

Second, the majority reasoned, incorrectly, that the undisputed impact of Virginia's statute on the price term of wholesale transactions between out-of-state manufacturers and distributors "was the result of natural market forces and was not artificially imposed by the" escrow fee statutes themselves. Slip op. at 16. But the *Star Scientific* statute imposed a fee *directly* on out-of-state manufacturers, even

those who engaged in *no* commercial transactions within Virginia's borders. And contrary to the panel majority's analysis, the impact of that fee on wholesale transactions was neither more "natural" nor more market-driven than the impact of HB 631.

In any event, the economic impact of HB 631 is, in at least two respects, far more limited than that of the statute challenged in *Star Scientific*. HB 631 applies only in the rare instances when a manufacturer or distributor imposes an increase in the price for an essential medicine that *shocks the conscience*, and otherwise not at all. Moreover, by its plain terms, the Act applies only in circumstances of "insufficient market competition," and therefore has no application in normally-functioning markets.

III. IN EMBRACING A NOVEL APPLICATION OF THE DORMANT COMMERCE CLAUSE, THE PANEL MAJORITY DIVERGED FROM OTHER CIRCUITS ON A QUESTION OF DOCTRINAL AND PRACTICAL SIGNIFICANCE.

The majority decision would unmoor dormant Commerce Clause jurisprudence from its function as a check on economic protectionism and discrimination against interstate commerce. Those concerns, which have animated both the judicial recognition of the dormant Commerce Clause and its application in the overwhelming majority of cases, are wholly absent here. Moreover, as the dissent explained, the trend over the past two decades has been consistent with *Star Scientific* in sharply limiting the application of the extraterritoriality principle. At

least three other circuits have indicated that, under the Supreme Court's decision in *Pharmaceutical Research & Manufacturers of America v. Walsh*, 538 U.S. 644 (2003), the extraterritoriality principle applies *exclusively* in the context of price-tying and price-affirmation cases. *See Energy & Environment Legal Institute v. Epel ("EELI")*, 793 F.3d 1169, 1175 (10th Cir. 2015); *Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937, 951 (9th Cir. 2013); *IMS Health, Inc. v. Mills*, 616 F.3d 7, 30 (1st Cir. 2010). Indeed, the price-tying and price-affirmation cases implicate the core concerns of the dormant Commerce Clause, and it is therefore open for discussion, as then-Judge Gorsuch has explained, whether the extraterritoriality principle even represents a distinct branch of dormant Commerce Clause jurisprudence. *See EELI*, 793 F.3d at 1173.

The majority correctly noted that, in *Edgar v. MITE Corp.*, 457 U.S. 624, 641-43 (1982), a case that elicited six different opinions, four Supreme Court justices would have applied the extraterritoriality principle to a statute that was neither a price-tying nor a price-affirmation law. But the statute in *Edgar* was so *overwhelmingly* extraterritorial in its focus that it exemplifies, by contrast to HB 631, how greatly the panel majority has expanded the extraterritoriality principle from its doctrinal and precedential foundations. In *Edgar*, Illinois purported to authorize its Secretary of State to block any corporate takeover, occurring anywhere in the country, as long as at least 10% of the shareholders of the company subject to the

tender offer were Illinois residents. *See id*. at 626-27. In its sweeping national focus, the statute in *Edgar* could hardly be further from HB 631, which protects Maryland consumers (and only Maryland consumers) from price gouging in the sale to them of certain essential medicines under circumstances of market dysfunction. Even then, a majority of the *Edgar* Court declined to apply the extraterritoriality principle to the Illinois statute.

Judge Wynn was correct that "neither the Supreme Court nor this Court ever has relied on the extraterritoriality doctrine as the sole basis to invalidate a state statute regulating products ultimately sold within the state's borders," and that "[t]he majority opinion also conflicts with the approach taken by several of our sister circuits, including in factually indistinguishable cases." Slip op. at 50. That circumstance makes this appeal worthy of rehearing *en banc*.

The dissent also explains the troubling practical implications of the majority's decision. No appellate court has previously suggested that the Commerce Clause restricts states from regulating the conduct of manufacturers who wish to sell products in the state simply because that conduct takes place before the products arrive within state borders, or because they sell the products through out-of-state intermediaries. Indeed, it has been clear that, as in *Star Scientific* and *Freedom Holdings*, states may impose fees directly on out-of-state manufacturers arising from transactions with out-of-state distributors to compensate for harms arising from the

later sale of those products to in-state consumers; that states may impose labeling requirements on out-of-state manufacturers when they sell products to out-of-state distributors intended for later sale to in-state consumers, *see Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 110 (2d Cir. 2001); *Int'l Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 647-49 (6th Cir. 2010); and that states may prohibit anti-competitive conduct in transactions between out-of-state manufacturers and out-of-state distributors that increases prices later charged to in-state consumers, *see, e.g.*, *In re Brand Name Prescription Drugs Antitrust Litig.*, 123 F.3d 599, 612-14 (7th Cir. 1997). The panel majority would invalidate the statute at issue here based on its asserted impact on the "natural" price term in certain wholesale transactions, slip op. at 16, but all of the above-referenced state laws had a comparable effect, and, in any event, nothing in dormant Commerce Clause jurisprudence permits courts to invalidate economic regulations for substantive reasons unrelated to their impact on interstate commerce. The majority's emphasis on "artificial[]" interference with "natural" markets recalls a long-held concern that "Commerce Clause jurisprudence [might] degenerate into disputes over degree of economic effect." *Healy v. Beer Institute, Inc.*, 491 U.S. 324, 345 (1989) (Scalia, J., concurring).

AAM has invited this Court to embrace a novel application of the extraterritoriality principle—where the very existence of that principle is in question, where several other circuits have refused to expand that principle in the absence of

discrimination against interstate commerce or economic protectionism, and where the proposed new application of the principle raises a host of doctrinal questions. As such, this appeal presents a question of exceptional importance that the full Court should consider.

IV. THE CASE HAS SUBSTANTIAL IMPLICATIONS FOR STATE EFFORTS TO ADDRESS RISING PRESCRIPTION DRUG COSTS.

The resolution of this appeal will substantially affect the responses of state governments to a problem with both fiscal and public health dimensions: the rapidly-rising cost of prescription drugs. HB 631 addresses conduct that, as documented by the Senate's Special Committee on Aging, has the capacity to inflict severe harm on state governments, state-funded health insurance programs, and state residents who buy and depend upon prescription drugs for life and health. The statute's validity is, by itself, a question of exceptional importance, since its invalidation would disempower Maryland and other states in addressing conduct in wholesale markets that disrupts access to life-saving and life-sustaining medicines.

CONCLUSION

This Court should grant rehearing *en banc*.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME AND TYPEFACE REQUIREMENTS

1. This petition complies with the type-volume limitations of Fed. R. App. P. 35(b)(2)(A), because this brief contains 3,890 words.

2. 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 in Fourteen point, Times New Roman.

/s/ Joshua N. Auerbach
Joshua N. Auerbach

CERTIFICATE OF SERVICE

I hereby certify that, on this 27th day of April, 2018, I electronically filed with the Clerk of the Court via the CM/ECF System the foregoing Petition for Rehearing *En Banc*, which will cause the petition to be delivered electronically to all counsel of record.

/s/ Joshua N. Auerbach
Joshua N. Auerbach