NO. 18-546

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

BRIEF IN OPPOSITION

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QUESTION PRESENTED

In 2016, Maryland enacted House Bill 631, which prohibits making an "unconscionable increase" in the price of certain off-patent and generic prescription drugs. Petitioners conceded that the statute applies to "wholesale transaction[s] that occur[] out of state" and thus penalizes manufacturers based on the prices they charge their wholesale buyers in other states. App.15a (quoting Oral Arg. Tr. at 20:45-55 (4th Cir. Jan. 24, 2018)). The Fourth Circuit accordingly struck down the statute.

The question presented is:

Whether Maryland may regulate the price of goods sold in other states.

PARTIES TO THE PROCEEDING

Petitioners, and defendants below, are Brian E. Frosh, Attorney General of Maryland, and Robert R. Neall, Maryland Secretary of Health. Dennis R. Schrader was previously Maryland Secretary of Health and defendant below; Secretary Neall has been substituted by operation of law.

Respondent, and plaintiff below, is the Association for Accessible Medicines.

CORPORATE DISCLOSURE STATEMENT

The Association for Accessible Medicines (AAM) is a nonprofit, voluntary organization representing the nation's leading manufacturers of generic and biosimilar prescription medicines. There are no parent corporations or publicly held companies that own 10% or more of AAM's stock. A list of AAM's current members may be found at https://www.accessiblemeds.org/our-members.

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INTRODUCTION

In light of the Framers' "special concern both with the maintenance of a national economic union unfettered by state-imposed limitations on interstate commerce and with the autonomy of the individual States within their respective spheres," this Court has long held that no state may "control[] commerce occurring wholly outside [its] boundaries." *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 335-36 (1989) (footnote omitted). Applications of that rule take many forms, but one is first among equals: No state may "project its legislation into [another state] by regulating the price to be paid in that state for [goods] acquired there." *Baldwin v. G. A. F. Seelig, Inc.*, 294 U.S. 511, 521 (1935). Applying this bedrock principle of federalism, the Fourth Circuit struck down Maryland House Bill 631 because it "instructs prescription drug manufacturers that they are prohibited from charging an 'unconscionable' price in the initial sale of a drug, which occurs outside Maryland's borders." App.19a.

Petitioners now ask this Court to cast that rule aside and hold instead that each state may "impos[e] requirements for transactions" *in other states* whenever they deem it necessary "to protect their citizens from harm." Pet.4. Such a rule would be anathema to the Framers. It would also be a novelty in federal law. Every circuit to confront a state law that "impos[ed] requirements" on transactions conducted in other states has reached the same conclusion: Such laws violate the Commerce Clause. Petitioners do not identify a single counterexample, and for good reason—none exists. Petitioners instead cite cases upholding state laws that apply exclusively

in-state, and claim that those cases are inconsistent with the decision below. But cases that treat apples and oranges differently do not reflect "confusion," Pet.13, let alone a circuit split. They simply reflect that a "focus on geographic boundaries" (Pet.26) is fundamental under our constitutional system.

Each state possesses broad authority to regulate conduct in its respective sphere. A state law that "has only indirect effects on interstate commerce," but does not actually apply out of state, will therefore be upheld unless "the burden" it imposes on interstate commerce "clearly exceeds the local benefits." *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986); *see Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). But each state's authority "is not only subordinate to the federal power over interstate commerce, but is also constrained by the need to respect the interests of other States." *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 571 (1996) (internal citation omitted). State laws like HB 631 that impose requirements on transactions in other states are thus "virtually *per se* invalid under the Commerce Clause." *Brown-Forman*, 476 U.S. at 579.

There is no need to grant review simply to confirm longstanding precedent, which every circuit to address the issue correctly applies. But even if this Court were inclined to revisit the doctrine, this case would be a poor vehicle through which to do so, as substantial authority supports the conclusion that HB 631 is unconstitutionally vague. Finally, this case does not present the dire stakes petitioners raise. Maryland retains ample authority to regulate the price of drugs sold *in the state*. The Court should deny the petition.

STATEMENT OF THE CASE

A. Statutory Background

Under HB 631, "[a] manufacturer or wholesale distributor may not engage in price gouging in the sale of an essential off-patent or generic drug." App.118a (§ 2-802(a)).

The statute defines "price gouging" as making "an unconscionable increase in the price of a prescription drug." App.117a (§ 2-801(c)). The statute defines "unconscionable increase" as any "increase in the price of prescription drug" that is "excessive," is "not justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug," and leaves consumers with "no meaningful choice" but to buy the drug "at an excessive price." *Id.* (§ 2-801(f)). And the statute defines as "essential" any off-patent or generic drug that "appears on the Model List of Essential Medicines most recently adopted by the World Health Organization" 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," "is actively manufactured and marketed for sale in the United States by three or fewer manufacturers," and "is made available for sale in the State" of Maryland. App.116a (§ 2-801(b)(1)).[1]

The penalties for violating that price control are severe. HB 631 authorizes the Maryland Attorney

[1] "Essential off-patent or generic drug" also "includes any drug-device combination product used for the delivery of" an "essential" off-patent or generic prescription drug. App.116a (§ 2-801(b)(2)).

General to bring suit in Maryland court to "enjoin[] a violation" of the statute, "[r]estor[e] to any consumer, including a third party payor, any money acquired as a result of a price increase that violates" the statute, and "[i]mpos[e] a civil penalty of up to $10,000 for each violation." App.120a (§ 2-803(d)).

Manufacturers of off-patent and generic drugs are the statute's clear targets. HB 631 does not apply to retailers in any respect. And although HB 631 does apply to wholesale distributors, App.116a (§ 2-802(a)), "[i]t is not a violation" of the statute "for a wholesale distributor to increase the price of an essential off-patent or generic drug if the price increase is directly attributable to additional costs for the drug imposed on the wholesale distributor by the manufacturer of the drug." App.118a (§ 2-802(b)); *see* Pet.22 & n.4.

HB 631 also contains reporting requirements. The statute authorizes the Maryland Medical Assistance Program to monitor manufacturers' drug-pricing decisions and "notify the [Maryland] Attorney General of any increase in the price of an essential off-patent or generic drug when," *inter alia*, a price increase "[w]ould result in an increase of 50% or more in the wholesale acquisition cost of the drug." App.118a (§ 2-803(a)). However, that 50% benchmark in the reporting provision is not "binding on the [Maryland] Attorney General" in enforcing the statute's price control. App.92a; *compare* App.120a (§ 2-803(d)), *with* App.118a (§ 2-803(a)). As a result, the state may seek penalties for "price gouging" under HB 631 even for price increases well below the 50% benchmark.

Finally, HB 631's price control applies even when a manufacturer "did not deal directly with a consumer residing in the State." App.121-122a (§ 2-803(g)). That is no small detail: As petitioners acknowledge, nearly every sale a generic drug manufacturer makes is a sale to a national wholesale distributor that takes place outside of Maryland. App.15a; *see* Pet.8-9. HB 631 thus prohibits "price gouging in the sale of an essential off-patent or generic drug," App.118a (§ 2-802(a)), even when the offending "sale" takes place entirely in another state. App.19a.

B. Proceedings Below

1. The Maryland General Assembly passed HB 631 on April 10, 2017. The bill became law without the Governor's signature on May 27, 2017. *See* Md. Const. art. II, § 17(c). In declining to sign the bill, Governor Hogan expressed concern that HB 631 "likely violate[s] the dormant commerce clause" because it "directly regulate[s] interstate commerce and pricing by prohibiting and penalizing manufacturer pricing which may occur outside of Maryland." CA4 JA 50. The Governor also expressed concern that HB 631's "definition of 'unconscionable increase'" is so vague as to "leav[e] the decision" to sue for price gouging "entirely to the interpretation of the [Maryland] Attorney General." CA4 JA 50-51.

AAM filed suit soon after the statute became law. AAM represents the leading manufacturers and distributors of generic and biosimilar medicines, manufacturers and distributors of bulk active pharmaceutical ingredients, and suppliers of other goods and services to the generic and biosimilar pharmaceutical industry. Like most generic

prescription drug manufacturers, AAM's members sell nearly all of their products to wholesale distributors or national pharmacy chains that warehouse products themselves and act as de facto wholesalers. Nearly all of these sales take place outside of Maryland. App.5a.

AAM sought a declaration that HB 631 unconstitutionally regulates transactions that take place outside of Maryland and is void for vagueness, and sought an injunction prohibiting its enforcement. App.5a-6a. The district court denied AAM's motion. App.67a-105a. The court granted petitioners' motion to dismiss the Commerce Clause claim but not the vagueness claim. App.90a-94a. To facilitate appeal, AAM moved for, and the court granted, final judgment on the Commerce Clause claim. Judgment Pursuant to Rule 54(b), *Ass'n for Accessible Meds. v. Frosh*, 1:17-cv-01860-MJG, Dkt. 50 (D. Md. Oct. 12, 2017).

2. The Fourth Circuit reversed, in an opinion by Judge Thacker. The court began with the well-settled principle that "a State may not regulate commerce occurring wholly outside of its borders." App.7a (citation omitted). That principle reflects "the Constitution's special concern both with the maintenance of a national economic union unfettered by state-imposed limitations on interstate commerce and with the autonomy of the individual States within their respective spheres." App.7a (quoting *Healy*, 491 U.S. at 335-36). HB 631 violates that principle for a simple reason: It "controls the prices of transactions that occur outside the state" of Maryland. App.13a.

Although the statute applies only to *drugs* "available for sale" in Maryland, § 2-801(b)(1)(iv), that "language does not limit the Act's application to *sales*

that actually occur within Maryland." App.14a-15a (emphasis added). That is because HB 631 measures "the lawfulness of a price increase … according to the price a manufacturer … charges *in the initial [wholesale] sale of the drug*" out of state, *not* according to the retail prices paid in Maryland. App.16a. The statute thus "seeks to compel manufacturers and wholesalers to act in accordance with Maryland law *outside of Maryland*," which "is precisely the conduct 'the rule that was applied in *Baldwin* and *Healy*' aims to prevent." App.17a (emphasis added) (quoting *Pharm. Research and Mfrs. of Am. v. Walsh*, 538 U.S. 644, 669 (2003)).

Moreover, because HB 631 "targets wholesale rather than retail pricing," manufacturers could find themselves subject "to conflicting state requirements" if another state enacted its own version of the law. App.20a. Yet the Commerce Clause "protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State." *Id.* (quoting *Healy*, 491 U.S. at 336-37). "Therefore, the fundamental problem with the Act is that it 'regulate[s] the price of [an] out-of-state transaction,'" rather than limiting its scope to in-state sales. App.19a (quoting *Walsh*, 538 U.S. at 669). The Fourth Circuit accordingly invalidated the statute. App.22a. The court made clear, however, that its holding in no way undermined states' authority to "enact legislation meant to secure lower prescription drug prices for their citizens. Indeed, the Supreme Court upheld a Maine law with that very aim in *Walsh*." *Id.* (citing *Walsh*, 538 U.S. at 653-54, 669-70).

3. Petitioners requested rehearing en banc. The Fourth Circuit denied that request. App.106a-07a.

REASONS FOR DENYING THE PETITION

There is no conflict among the circuits. Every circuit to confront a state law that purported to dictate the terms of commerce in other states struck down the law under the Commerce Clause, and no circuit has held that "the *Baldwin* line is limited to cases of economic protectionism involving price-tying." Pet.25. In reality, both circuits petitioners identify have invalidated every state law to come before them that regulated the terms of commerce in other states, even when the laws did not involve price-tying. And each of the supposedly contrary cases petitioners trumpet—*none of which involved a law that applied out of state*—recognized that state laws that regulate prices in other states violate the Commerce Clause. There is no "confusion among the circuits." Pet.13, 24-29. All circuits place the same "focus on geographic boundaries," Pet.26, consistent with this Court's instructions.

The decision below is correct. HB 631 "instructs manufacturers and wholesale distributors as to the prices they are permitted to charge in transactions that do not take place in Maryland." App.17a. The statute thus violates the rule of *Baldwin* and *Healy* in the most basic way: It "project[s]" one state's policy preferences into other states "by regulating the price to be paid" in wholesale sales that take place wholly in other states. *Baldwin*, 294 U.S. at 521. HB 631's infirmity becomes all the more obvious when one considers "what effect would arise if not one, but many or every, State adopted similar legislation." *Healy*,

491 U.S. at 336. If even one other state enacted its own version of HB 631, the result would be "to create just the kind of competing and interlocking local economic regulation that the Commerce Clause was meant to preclude." *Id.* at 337. Petitioners' contrary view of the Commerce Clause, under which each state may "impos[e] requirements for transactions" *in other states* whenever they deem it necessary "to protect their citizens from harm," Pet.4, would grind interstate commerce to a halt and result in exactly the sort of "economic Balkanization that had plagued relations among the Colonies and later among the States under the Articles of Confederation." *Okla. Tax Comm'n v. Jefferson Lines, Inc.*, 514 U.S. 175, 180 (1995) (emphasis omitted).

The decision below may also be affirmed on an alternate ground. The district court found "that it is at the very least plausible" that the convoluted definition of "price gouging" "renders the statute unconstitutionally vague." App.92a-93a. Substantial authority supports that conclusion. HB 631 does not define any of the broad terms it uses to describe an "unconscionable increase." It expressly departs from a clear quantitative benchmark contained elsewhere in the statute. It is ostensibly limited to cases of "insufficient competition" but applies even in competitive multimember markets. It provides no safe havens and no specification of what it prohibits. It thus violates the "fundamental principle … that laws which regulate persons or entities must give fair notice of [what] is forbidden or required." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012).

Finally, petitioners overstate the consequences of this case. The decision below in no way precludes states from regulating the price of prescription drugs in their respective spheres. All it does is reaffirm what this Court has long held: No state may "project its legislation into [another state] by regulating the price to be paid in that state." *Baldwin*, 294 U.S. at 521.

I. There Is No Conflict Among The Circuits.

A. Every Circuit to Confront a State Law that Controlled Commerce in Other States Struck Down the Law.

Every circuit that has reviewed a state law that actually regulated commerce in other states has invalidated the law as per se inconsistent with the Commerce Clause. *See, e.g.*, *Am. Booksellers Found. v. Dean*, 342 F.3d 96, 99-104 (2d Cir. 2003) (invalidating Vermont law that prohibited distribution of explicit materials to minors because it regulated what people could distribute in other states and thus "'projected … into other States, and *directly regulated* commerce therein'" (quoting *Brown-Forman*, 476 U.S. at 584)); *Am. Beverage Ass'n v. Snyder*, 735 F.3d 362, 366-76 (6th Cir. 2013) (invalidating Michigan law that imposes "unique-to-Michigan mark designation," even though it "does not discriminate against interstate commerce," because it "allows Michigan to dictate where the product can be sold" and thus "control[s] conduct beyond the State of Michigan"); *Legato Vapors, LLC v. Cook*, 847 F.3d 825, 833 (7th Cir. 2017) (invalidating Indiana law that required "commercial relationships between out-of-state manufacturers and their [out-of-state] employees and contractors" to be conducted consistent

with Indiana law if the manufacturers sold products in Indiana); *North Dakota v. Heydinger*, 825 F.3d 912, 921-22 (8th Cir. 2016) (invalidating Minnesota laws that "seek to reduce emissions that occur outside Minnesota by prohibiting transactions that originate outside Minnesota," because "their practical effect is to control activities taking place *wholly* outside Minnesota"); *Am. Civil Liberties Union v. Johnson*, 194 F.3d 1149, 1161 (10th Cir. 1999) (invalidating New Mexico law that "attempt[ed] to regulate interstate conduct occurring outside New Mexico's borders"); *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1358-59 (Fed. Cir. 2013) (vacating California-law injunction that had the effect of "impos[ing]" the requirements of a California statute "on entirely extraterritorial conduct"); *cf. Carolina Trucks & Equip., Inc. v. Volvo Trucks of N. Am., Inc.*, 492 F.3d 484, 489-90 (4th Cir. 2007) (adopting saving construction to avoid invalidating South Carolina law under *Healy*).

Against that "long line of cases holding that states violate the Commerce Clause by regulating or controlling commerce occurring wholly outside their own borders," *Dean Foods Co. v. Brancel*, 187 F.3d 609, 615 (7th Cir. 1999), petitioners do not identity a single case to the contrary. That is because no such case exists.

Petitioners nonetheless insist that "[t]he Fourth Circuit's focus on geographic boundaries" is "inconsistent with the approach" other circuits have taken. Pet.26-27. In reality, every circuit places the same "focus on geographic boundaries." Every circuit holds that a state law that dictates the terms of

commerce in other states violates the Commerce Clause under the per se rule of *Baldwin* and *Healy*. Every circuit also holds that state laws that apply only in-state, but nonetheless may have some indirect effects out of state, are subject to the deferential balancing test of *Pike v. Bruce Church, Inc.*[2]

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[2] *See, e.g.*, *All. of Auto. Mfrs. v. Gwadosky*, 430 F.3d 30, 35 (1st Cir. 2005) ("A state statute that purports to regulate commerce occurring wholly beyond the boundaries of the enacting state outstrips the limits of the enacting state's constitutional authority and, therefore, is per se invalid."); *Entergy Nuclear Vt. Yankee, LLC v. Shumlin*, 733 F.3d 393, 429 (2d Cir. 2013) ("When a statute 'directly controls commerce occurring wholly outside the boundaries of a State,' it is invalid under the dormant Commerce Clause because it 'exceeds the inherent limits of the enacting State's authority.'"); *A.S. Goldmen & Co. v. N.J. Bureau of Sec.*, 163 F.3d 780, 786 (3d Cir. 1999) ("If the transaction to be regulated occurs 'wholly outside' the boundaries of the state, the regulation is unconstitutional."); *Star Sci., Inc. v. Beales*, 278 F.3d 339, 355 (4th Cir. 2002) ("[A] State may not regulate commerce occurring wholly outside of its borders."); *In re Brand Name Prescription Drugs Antitrust Litig.*, 123 F.3d 599, 613 (7th Cir. 1997) ("A state cannot regulate sales that take place wholly outside it."); *Cotto Waxo Co. v. Williams*, 46 F.3d 790, 793 (8th Cir. 1995) ("Under the Commerce Clause, a state regulation is per se invalid when it has an 'extraterritorial reach,' that is, when the statute has the practical effect of controlling conduct beyond the boundaries of the state."); *Greater L.A. Agency on Deafness, Inc. v. Cable News Network, Inc.*, 742 F.3d 414, 432-33 (9th Cir. 2014) ("The dormant Commerce Clause forbids a state from regulating commerce 'that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State.'"); *Quik Payday, Inc. v. Stork*, 549 F.3d 1302, 1307 (10th Cir. 2008) ("[A] statute will be invalid *per se* if it … control[s] commerce occurring entirely outside the boundaries of the state in question."); *Bainbridge v. Turner*, 311 F.3d 1104, 1112 (11th Cir. 2002) (State "laws that directly regulate commerce occurring in other states are invalid.");

Every case petitioners identify reflects that same "focus on geographic boundaries." *International Dairy Foods Association v. Boggs*, 622 F.3d 628 (6th Cir. 2010) (cited at Pet.27), dealt with an Ohio law that requires dairy products sold *in Ohio* to use a particular label. The statute applies only to sales *in Ohio*; by its terms, the statute "has no bearing on how [companies] are required to label their products in other states." *Id.* at 647. The Sixth Circuit thus held that the per se rule of *Baldwin* and *Healy* did not apply, because the Ohio law does not control commerce anywhere but Ohio.[3] *Id.* at 648. But when the Sixth Circuit confronted a different state labeling law that *did* apply in other states, the court did not hesitate to strike it down. Michigan enacted a law that forbade selling bottles and cans *in other states* if they were affixed with a particular mark. The Sixth Circuit invalidated that law because it "control[led] conduct beyond the State of Michigan." *Snyder*, 735 F.3d at 373-76. What explains the different outcomes in the two cases is not "confusion" about the doctrine, but the fact that Michigan's law governed sales outside the state's "geographic boundaries" whereas Ohio's law did not.

Allergan, 738 F.3d at 1359 ("Neither the California courts nor the California legislature are permitted to regulate commerce entirely outside of the state's borders.").

[3] *Boggs* also makes clear that the rule of *Baldwin* and *Healy* is not limited to protectionist legislation. *See Boggs*, 622 F.3d at 645 ("In addition to regulations that are protectionist, the Supreme Court has recognized a second category of regulation that is also virtually per se invalid under the dormant Commerce Clause: a regulation that has the practical effect of controlling commerce that occurs entirely outside of the state in question.").

The story is the same in the Second Circuit. *National Electrical Manufacturers Association v. Sorrell*, 272 F.3d 104 (2d Cir. 2001) (cited at Pet.26), also involved a labeling law. Vermont passed a law under which no manufacturer, wholesaler, or retailer may sell certain mercury-containing products "*in this State*" without a label informing consumers of the presence of mercury. *Id.* at 107 & n.1 (emphasis added). Like the Ohio law in *Boggs*, the Vermont law in *Sorrell* applies only to sales *in Vermont*; "by its terms," it "is 'indifferent' to whether lamps sold anywhere else in the United States are labeled or not." *Id.* at 110. The Second Circuit thus upheld the law. *Id.* at 110-13. By contrast, the Second Circuit struck down a different Vermont law that "project[ed]" Vermont's definition of what is "'harmful to minors'" "onto the rest of the nation," such that "someone in Connecticut" could be held in violation of Vermont law for distributing materials *in Connecticut*, under the per se rule of *Baldwin*, *Brown-Forman*, and *Healy*. *Dean*, 342 F.3d at 99-104. Again, what explains the different outcomes in the two cases is not "confusion," but the basic reality that the law in *Sorrell* regulated commerce only in Vermont, whereas the law in *Dean* regulated commerce *in other states*.

The same is true of the sole case petitioners cite in support of the claim that "similar regulatory initiatives in different states will suffer different fates" absent this Court's review. Pet.28. The California ethanol statute in *Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070 (9th Cir. 2013) (cited at Pet.28-29), "imposes no civil or criminal penalties on non-compliant transactions completed wholly out of state," and "says nothing at all about ethanol

produced, sold, and used outside California." *Id.* at 1102-03. HB 631, by contrast, *does* impose penalties for non-compliant transactions completed wholly out of state, as petitioners admitted. *See* App.15a (citing concession that HB 631 applies to "wholesale transaction[s] that occur[] out-of-state"). "The Ninth Circuit's reasons for upholding the California ethanol statute" (Pet.29) thus do not apply *at all* to HB 631.

B. No Circuit Has Limited the Per Se Rule of *Baldwin* and *Healy* to "Price-Tying."

Petitioners claim that the Ninth and Tenth Circuits "have held" that "the *Baldwin* line is limited to cases of economic protectionism involving price-tying." Pet.25. That is simply false. Both circuits apply the doctrine the same way every circuit does: State laws that dictate the terms of commerce in other states are per se invalid under the Commerce Clause, regardless of how they accomplish that control.

1. Every time the Ninth Circuit has confronted a state law that attempted to dictate the terms of out-of-state commerce, the court has struck down the law, even in cases that did not involve price-tying. For instance, in *Daniels Sharpsmart, Inc. v. Smith*, the Ninth Circuit enjoined a California law that purported to "dictate the method by which" medical-waste companies treated medical waste "outside of California," because the statute "reach[ed] beyond the borders of California [to] control transactions that occur wholly outside of the State." 889 F.3d 608, 612-16 (9th Cir. 2018). Similarly, in *National Collegiate Athletic Association v. Miller*, the Ninth Circuit invalidated a Nevada law imposing procedural requirements on NCAA enforcement proceedings

across the country, because the law had "the practical effect" of "requir[ing]" the NCAA to apply Nevada procedural rules "in enforcement proceedings in every state in the union." 10 F.3d 633, 639 (9th Cir. 1993).

Petitioners do not mention either of those cases, neither of which involved price-tying. Petitioners also relegate to a footnote the recent en banc decision that "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," even though it did not involve price-tying. Pet.25 n.7 (citing *Sam Francis Found. v. Christie's, Inc.*, 784 F.3d 1320, 1323 (9th Cir. 2015) (en banc)). That gives the lie to the claim that the Ninth Circuit has limited the doctrine to price-tying cases.[4]

In arguing to the contrary, petitioners offer a single dictum from a single case, *Association des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937 (9th Cir. 2013) (cited at Pet.25). But all *Harris* shows is that "geographic boundaries" really do matter. Unlike in *Sam Francis*, the California statute in *Harris* does not apply to sales in any other state. Rather, it forbids sales "*within California*" of products produced by force-feeding birds. *Id.* at 949 (emphasis added). *That* is why the court held that the statute

[4] Petitioners' use of italics suggests that they think the sales regulated in *Sam Francis* were more "*purely*" out-of-state than the sales that HB 631 regulates. But the statute in *Sam Francis* applies out of state *only as to sales involving Californians*. 784 F.3d at 1323. HB 631, by contrast, applies to out-of-state sales in which neither buyer nor seller is a Marylander, as petitioners recognize. *See* Pet.8 (HB 631 applies to out-of-state sales between "out-of-state actors [and] out-of-state intermediaries").

does not trigger the rule of *Baldwin* and *Healy*—it does not apply "outside the boundaries of California" at all. *Id.* at 951.[5] In sum, the law in the Ninth Circuit is crystal clear (and the same as the law in every other circuit): State laws that purport to dictate the terms of out-of-state commerce are per se invalid, even if they do not involve price-tying.

2. The law in the Tenth Circuit is no different. Petitioners again rely on a single quotation from a single decision, namely *Energy & Environment Legal Institute v. Epel*, 793 F.3d 1169 (10th Cir. 2015) (cited at Pet.15, 25-26). But *Epel* is the same as *Harris*. The Colorado statute in *Epel* "requires electricity generators to ensure that 20% of the electricity they sell to Colorado consumers comes from renewable sources." *Id.* at 1170. The statute thus applies only to sales *in the state*. *Id.* at 1173. Indeed, all the statute does is "regulate[] the quality of a good sold *to in-state residents*." *Id.* (emphasis added). And as the court recognized, "state laws setting non-price standards for products sold in-state" are analyzed under the "*Pike* balancing test," not the rule of *Baldwin* and *Healy*. *Id.*

Epel certainly contains dicta regarding the scope of the doctrine. But because *Epel* did not involve a state law that actually regulated any commerce out of state, it is inapposite. In all events, when the Tenth

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[5] The same is true of the other "*Harris*" case petitioners cite in passing, namely *Chinatown Neighborhood Association v. Harris*, 794 F.3d 1136 (9th Cir. 2015) (cited at Pet.26 n.7). The statute there "makes it 'unlawful for any person to possess, sell, offer for sale, trade, or distribute a shark fin' *in the state*." *Id.* at 1139 (emphasis added). Because it regulates *only in-state commerce*, the rule of *Baldwin* and *Healy* did not apply. *Id.* at 1146.

Circuit confronted a state law that *did* regulate commerce in other states, it held that the law violated the Commerce Clause, *even though the law did not involve price tying*. *American Civil Liberties Union v. Johnson* involved a New Mexico statute that governed what could be distributed to minors on the Internet. 194 F.3d 1149, 1152 (10th Cir. 1999). The statute was obviously not a "price-tying" law, and it just as obviously was not discriminatory, as it applied the same in every state. The Tenth Circuit still struck the statute down as "a per se violation of the Commerce Clause," because it "regulate[d] interstate conduct occurring outside New Mexico's borders." *Id.* at 1161. Petitioners do not mention *Johnson*.

In the end, petitioners have not identified a single case that upheld a state law that regulated commerce in other states. That is because no such case exists. There is no conflict among the circuits.

II. The Decision Below Is Correct.

This Court has long held that no state may "project its legislation into [another state] by regulating the price to be paid in that state." *Baldwin*, 294 U.S. at 521. That is precisely what HB 631 does. Overturning the decision below—and allowing State *A* to regulate the wholesale prices parties can charge in State *B*, merely because the products might end up being resold in State *A*—would require overturning nearly a century of this Court's precedent and would unleash a race to the bottom culminating in "the destruction of commerce among the several states." *Minnesota v. Barber*, 136 U.S. 313, 321 (1890).

A. HB 631 Regulates Prices in Other States.

HB 631 is a price control. The statute prohibits "engag[ing] in price gouging in the sale of an essential off-patent or generic drug," App.118a (§ 2-802(a)), which it defines as making "an unconscionable increase in the price of a prescription drug," App.117a (§ 2-801(c)). Violations of that price control trigger severe penalties. HB 631 authorizes Maryland courts to "enjoin[] a violation" of the statute, "[r]estor[e] to any consumer, including a third party payor, any money acquired as a result of a price increase that violates" the statute, and "[i]mpos[e] a civil penalty of up to $10,000 for each violation" of the statute. App.120a-121a (§ 2-803(d)). Crucially, neither HB 631's price-gouging prohibition nor the penalties for violating it are limited "to sales that actually occur within Maryland." App.14a-15a. Rather, HB 631 "instructs prescription drug manufacturers that they are prohibited from charging an 'unconscionable' price in the initial sale of a drug, which occurs *outside Maryland's borders*." App.19a (emphasis added).

That is clear from the text and structure of the statute. HB 631 does not apply to retailers, *see* App.118a (§ 2-802(a)), even though they make the overwhelming majority of drug sales in the state. HB 631 does apply to wholesale distributors, but "[i]t is not a violation" of the statute "for a wholesale distributor to increase the price of an essential off-patent or generic drug if the price increase is directly attributable to additional costs for the drug imposed on the wholesale distributor by the manufacturer of the drug." *Id.* (§ 2-802(b)). Manufacturers are thus the statute's clear targets. Yet as petitioners

acknowledge, nearly every sale a generic drug manufacturer makes is a sale to a national wholesale distributor that takes place outside Maryland. Pet.8-9. HB 631 is clear, however, that the price-gouging prohibition applies to out-of-state wholesale sales. Under § 2-803(g), manufacturers "alleged to have violated [the statute] may not assert as a defense that [they] did not deal directly with a consumer residing in the State." App.121a-122a. HB 631 thus directly regulates the prices manufacturers may charge in "transaction[s] that occur[] out-of-state," as petitioners themselves admitted below. App.15a (quoting Oral Arg. Tr. at 20:45-55 (4th Cir. Jan. 24, 2018)).

Notwithstanding that concession, petitioners now claim that HB 631 *actually* applies only to sales in Maryland. Petitioners routinely refer to HB 631's price control as an "in-state regulation," Pet.19, 20, 27 n.8, and even go so far as to claim that it "applies only to in-state commerce," Pet.3. But petitioners cannot change what the statute says, or what the statute's text and structure correctly led them to admit: Under HB 631's plain terms, manufacturers can be held in violation of Maryland law (and face significant state-law penalties) based on the prices they charged in "transaction[s] that occurs out-of-state." App.15a.

Nor was petitioners' concession at oral argument a singular slip of the tongue. Despite their attempts to recast the statute, petitioners often describe HB 631 correctly, albeit perhaps unknowingly. *See, e.g.*, Pet.4 (HB 631 "impos[es] requirements for transactions *leading to in-state sales*"); Pet.8 (HB 631 "applies equally to all unconscionable price increases,"

including those "imposed by … out-of-state actors dealing with out-of-state intermediaries"); Pet.13 (HB 631 targets "commercial practices of out-of-state actors operating *upstream of in-state consumer transactions*"); Pet.14 (HB 631 applies to sales "*antecedent to in-state sales*"); Br. of Appellees 14 (4th Cir. Nov. 29, 2017) ("technically accurate" that HB 631 "regulates" "wholesale transactions situated upstream from" sales in Maryland). (Emphases added). And, of course, a transaction that "lead[s] to in-state sales" (Pet.4) or that is "upstream of" (Pet.13) or "antecedent to in-state sales" (Pet.14) is an *out-of-state transaction*. Otherwise it would just be an in-state sale.

In short, petitioners cannot change the facts. HB 631 "is effectively a price control statute that instructs manufacturers and wholesale distributors as to the prices they are permitted to charge in transactions that do not take place in Maryland." App.17a. And as discussed below, that is "precisely the conduct '[t]he rule that was applied in *Baldwin* and *Healy*' aims to prevent." App.17a (quoting *Walsh*, 538 U.S. at 669).

B. HB 631 Violates the Commerce Clause Under a Straightforward Application of this Court's Precedent.

1. The decision below follows directly from *Baldwin* and *Healy*. *Baldwin* arose after a Vermont "creamery" (manufacturer) sold milk wholesale to a New York "milk dealer" (wholesale distributor) at a price New York's Milk Control Act deemed too low. 294 U.S. at 518. "By concession," that transaction occurred in Vermont, *id.*, and the milk sold in the transaction was, in petitioners' verbiage, "intended for sale" to New Yorkers. Pet.8; *see Baldwin*, 294 U.S. at

518. Indeed, the Act "applied only to milk that would eventually be sold to New York consumers." *Carolina Trucks*, 492 F.3d at 491 (discussing *Baldwin*). Even though the Act reached only transactions "leading to," "antecedent to," and "upstream of in-state consumer transactions" in New York, Pet.4, 13-14, the Court still struck it down, and for a simple reason: Under the Commerce Clause, "New York has no power to project its legislation into Vermont by regulating the price to be paid in that state for milk acquired there," even if the milk may later be resold in a downstream consumer sale in New York. *Baldwin*, 294 U.S. at 521.

The situation here is practically identical. A state (New York there, Maryland here) enacts a statute that regulates prices parties may charge in out-of-state wholesale sales. *Baldwin*, 294 U.S. at 518, 521; App.13a-19a. The statute is intended to protect in-state consumers. *Baldwin*, 294 U.S. at 523 ("The end to be served [by the Milk Control Act] is the maintenance of a regular and adequate supply of pure and wholesome milk."); Pet.29 (HB 631 is intended "to protect in-state consumers against harms originating out of state"). The statute applies only to products available for sale in the enacting state. *See Carolina Trucks*, 492 F.3d at 491 (discussing *Baldwin*); App.116a (§ 2-801(b)(1)(iv)). The statute nonetheless violates the Constitution because it regulates the terms of sales *in other states* and "the 'Commerce Clause … precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, *whether or not the commerce has effects within the State*.'" *Healy*, 491 U.S. at 336 (emphasis added) (quoting *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982) (plurality opinion)). As it was

there, so it is here. Maryland "has no power to project its legislation into Vermont [or Florida, etc.] by regulating the price to be paid in that state for [drugs] acquired there," *Baldwin*, 294 U.S. at 521, even if the drugs may later be resold in downstream consumer sales in Maryland, and even if the prices paid by wholesalers out of state affect the price paid by consumers in Maryland.

HB 631's core infirmity becomes all the more obvious when it is "evaluated not only by considering the consequences of the statute itself, but also by considering how [it] may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation." *Healy*, 491 U.S. at 336. Imagine that Pennsylvania enacts the same law. If Pennsylvania officials have a different view as to what makes a price increase "unconscionable"—which is entirely likely given the indeterminacy of the statutory standard, *see infra* Part III—a manufacturer could find itself in violation of Maryland law based on the terms of a wholesale transaction in Pennsylvania that is perfectly lawful under Pennsylvania law. App.20a. That "sounds absurd, because it is." *Sekhar v. United States*, 570 U.S. 729, 738 (2013). More importantly, it is absurd in a way the Commerce Clause specifically defends against. "[T]he Commerce Clause protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State." *Healy*, 491 U.S. at 336-37.

2. Petitioners contend that *Baldwin* and *Healy* must be read more narrowly in light of subsequent

decisions. Specifically, petitioners claim that this Court "explained" in *Walsh* "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." Pet.16-17 (alteration and ellipsis in original) (quoting *Walsh*, 538 U.S. at 669). In reality, *Walsh* "explained" exactly the opposite.

Here is the relevant passage:

> [U]nlike price control or price affirmation statutes, 'the Maine Act does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect. Maine does not insist that manufacturers sell their drugs to a wholesaler for a certain price. Similarly, Maine is not tying the price of its in-state products to out-of-state prices.' 249 F.3d at 81-82. The rule that was applied in *Baldwin* and *Healy* accordingly is not applicable to this case.

538 U.S. at 669 (quoting *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 81-82 (1st Cir. 2001)). The obvious takeaway is that the "rule that was applied in *Baldwin* and *Healy*" *is* applicable to a state law (like HB 631) that *does* "regulate the price of an[] out-of-state transaction" specifically by "insist[ing] that manufacturers sell their drugs to a wholesaler for a certain price" regardless of where those sales occur.

Indeed, the portion of the First Circuit opinion that *Walsh* quotes expressly distinguished the Maine Act's "anti-profiteering provision," which declared it unlawful "for a manufacturer to 'exact[] or demand[] an unconscionable price'" in the sale of a prescription drug, *Concannon*, 249 F.3d at 72 n.2, 81-82 n.10

(alterations in original) (quoting Me. Rev. Stat. Ann. tit. 22, § 2697(2)), and which "*was held unconstitutional*" precisely because it "regulate[d] the price of … out-of-state transaction[s]" between manufacturers and their wholesale buyers. *Id.* at 81-82 & n.10 (emphasis added). That anti-profiteering provision is nearly identical to HB 631's price-gouging prohibition. *Walsh* thus confirms that *Baldwin* and *Healy* control here. Petitioners try to evade that conclusion by arguing that *Walsh* referred "to a price-tying requirement," not "a price *cap*." Pet.17 n.2. But *Walsh* speaks for itself, and it makes clear that the rule of *Baldwin* and *Healy* applies equally to laws that "insist that manufacturers sell their drugs to a wholesaler for a certain price" and those "tying the price of its in-state products to out-of-state prices." *Walsh*, 538 U.S. at 669.

3. Petitioners alternatively argue that "[n]othing in the Court's holdings supports the conclusion that an extraterritorial effect, standing alone, is forbidden." Pet.15. That is true; it is also entirely irrelevant. HB 631 "instructs manufacturers and wholesale distributors as to the prices they are permitted to charge *in transactions that do not take place in Maryland*." App.17a (emphasis added). The problem with HB 631 is not that it has *effects* on out-of-state prices. The problem is that it actually *regulates* out-of-state prices (and imposes significant penalties for violating its terms). "This is more than an 'upstream pricing impact'—it is a price control." App.19a. And as *Walsh* makes clear, a price control that "insists that manufacturers sell their drugs to a wholesaler for a certain price" *in other states* violates the Commerce Clause. 538 U.S. at 669.

* * *

It is no hyperbole to say that adopting petitioners' view would not only upend longstanding, well-established precedent, but also fundamentally alter interstate commerce as we know it. If Maryland may directly regulate out-of-state wholesale sales of consumer products whenever they might later be resold in Maryland, then every other state may do the same. That was worrisome enough at the Founding or even at the time of *Baldwin*; it is beyond the pale today, as the market for nearly every major product is now national in scope. Simply put, the interstate market could not function if every state were allowed to impose its own rules on commerce that applied coast to coast; "the enactment of a similar statute by each one of the States composing the Union would result in the destruction of commerce among the several states." *Barber*, 136 U.S. at 321. That is why this Court has long explained that "whether or not [out of state] commerce has effects within the State," the Constitution "precludes the application of a state statute to commerce that takes place wholly outside of the State's borders." *Healy*, 491 U.S. at 336 (quoting *Edgar*, 457 U.S. at 642-43 (plurality opinion)). Any other rule would produce the sort of "economic Balkanization" that the Constitution was designed to prevent. *Jefferson Lines*, 514 U.S. at 180.

III. The Alternative Ground To Support The Judgment Is Further Reason To Deny.

Under HB 631, a price increase is unlawful ("unconscionable") if it is "excessive," is not "justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug," and will

leave consumers with no "meaningful choice" but to buy the drug at an "excessive price." App.117a (§ 2-801(f)). The district court found "that it is at the very least plausible" that that "combination" of open-ended terms "renders the statute unconstitutionally vague." App.92a-93a. The Fourth Circuit did not reach the issue, App.3a n.1, but substantial authority supports the conclusion that the statute is void for vagueness.

A statute is void for vagueness if "it fails to give ordinary people fair notice of the conduct it punishes, or [is] so standardless that it invites arbitrary enforcement." *Johnson v. United States*, 135 S. Ct. 2551, 2556 (2015); *see Sessions v. Dimaya*, 138 S. Ct. 1204, 1213 (2018) (plurality opinion). The only thing clear about HB 631 is that it flunks that test.

None of the terms that describe the scope of the statute's price control has anything approaching a cognizable meaning. Take the word "excessive." As the district court explained, "'excessive' is a comparative term." App.92a. A common real-world comparator is the price of similar products. But that cannot work under HB 631, because the statute's price control applies even in cases where only one manufacturer produces the drug at issue. App.117a (§ 2-801(f)). Another common comparator is the price of the product before it changed. But that cannot be the standard under HB 631 either, because HB 631 uses "excessive" to modify *both* the ultimate price *and* the magnitude of the price increase. Nor does "excessive" stand alone in the statute. In order to be unlawful ("unconscionable") under HB 631, a price increase must also not be "justified by the cost of producing the drug or the cost of appropriate

expansion of access to the drug." *Id.* But who is to say what level of "expansion of access" is "appropriate"? HB 631 requires participants in the market to read the minds of state elected officials whose perspectives on what level of "access" is "appropriate" are likely quite different than their own (and may change over time as new officials are elected), lest they run afoul of the law.

Moreover, although the statute contains an easily digestible benchmark, it expressly does *not* link that benchmark to the price control. HB 631 authorizes a state agency to "notify the [Maryland] Attorney General of any increase in the price of an essential off-patent or generic drug when" a price increase "[w]ould result in an increase of 50% or more in the wholesale acquisition cost of the drug." App.118a (§ 2-803(a)). But that easy-to-follow standard applies *only* in the context of data-collection. It does *not* limit the scope of Maryland officials' discretion under the price control. App.92a. That is likely why, at oral argument in the district court, petitioners were unable to accept that even a 10% price increase would be immune from liability under the statute. *See* Tr. of Proceedings Before the Honorable Marvin J. Garbis at 57:4-19 (D. Md. Sept. 14, 2017).

Nor is HB 631 limited to a context (like true cases of market dysfunction) that might clarify the scope of its application. Despite an ostensible limitation to "insufficient competition," App.117a (§ 2-801(f)(2)(ii)), HB 631 applies even when as many as three manufacturers are "actively manufactur[ing] and market[ing]" the same drug. App.116a (§ 2-801(b)(1)(iii)). And it is basic economic doctrine that two- or three-member markets are just as competitive

as twenty- or thirty-member markets. "[C]ompetition can be as effective in constraining prices in markets with two, three, or four sellers as in markets with a large number of sellers." Richard J. Pierce, *Reconsidering the Roles of Regulation and Competition in the Natural Gas Industry*, 97 HARV. L. REV. 345, 380 (1983). So even if one could ascertain a coherent standard for "meaningful choice" (or its absence), one still would be left stupefied in trying to determine whether a price increase in a competitive two- or three-member market could nonetheless leave consumers with "no meaningful choice" due to "[i]nsufficient competition." App.117a (§ 2-801(f)(2)).

The statute's indeterminacy is all the more troubling given the sweeping penalties it imposes. HB 631 authorizes Maryland courts to "enjoin[] a violation" of the statute, "[r]estor[e] to any consumer, including a third party payor, any money acquired as a result of a price increase that violates" the statute, and "[i]mpos[e] a civil penalty of up to $10,000 for each violation" of the statute. App.120a-121a (§ 2-803(d)). Manufacturers will thus be compelled to forego even trivial-seeming price increases lest they run afoul of the statute's unknowable scope. *See Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 499 (1982) (vague laws "inhibit the exercise of constitutionally protected rights"). HB 631 violates due process, which further supports denying review.

IV. Petitioners Overstate The Consequences Of This Case.

The decision below in no way undermines states' authority to protect their citizens from the burdens of high prescription drug prices. If Maryland wishes to

regulate the price of prescription drugs in the state, it has a number of options—including options this Court has already allowed.

As an initial matter, there is an institution with authority to regulate wholesale sales regardless of where they occur. That institution is Congress. And true to form, Congress recently enacted a bipartisan bill designed to "improve[] generic drug access" for all Americans by "incentivizing competitive generic drug development," which will help bring drug prices down in every state. FDA Reauthorization Act of 2017, Pub. L. No. 115-52, 131 Stat. 1005, 1068-76 (Aug. 18, 2017).

Nor is Maryland devoid of options to regulate drug prices in its own sphere. Maryland could regulate in-state retail prices, which HB 631 does not do. Maryland could prohibit price gouging for sales *in Maryland* (assuming it did so in a way that is not unconstitutionally vague). Or Maryland could look to the law that this Court upheld in *Walsh*. *See* 538 U.S. at 649-50, 669-70 (upholding Maine law that required manufacturers to pay a supplemental rebate for drugs sold in Maine or else face a "prior authorization" requirement for in-state Medicaid prescriptions).

Every one of those measures could result in lower prices *in Maryland* even if no manufacturer ever itself made a sale in the state. Every one of them would also likely have an effect on out-of-state commerce. Yet that effect alone would not make such measures unconstitutional. The Commerce Clause does not forbid states from enacting laws that cause ripple effects beyond their borders.

But the Commerce Clause *does* forbid states from "regulat[ing] the price of an[] out-of-state transaction"

by "insist[ing] that manufacturers sell their drugs to a wholesaler for a certain price." *Id.* at 669. Maine's law in *Walsh* "does not" do either of those things. *Id.* Maryland's HB 631 does both. If Maryland justifiably wishes to make prescription drugs more affordable for its citizens, it has ample tools at its disposal. It simply must choose an option that complies with the Constitution.

CONCLUSION

For the foregoing reasons, the Court should deny the petition for certiorari.

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