PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 17-2166

ASSOCIATION FOR ACCESSIBLE MEDICINES,

Plaintiff - Appellant,

v.

BRIAN E. FROSH, in his official capacity as Attorney General for the State of Maryland; DENNIS R. SCHRADER, in his official capacity as Secretary of the Maryland Department of Health,

Defendants - Appellees,

CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA,

Amicus Supporting Appellant,

AARP; AARP FOUNDATION; KNOWLEDGE ECOLOGY INTERNATIONAL; MARYLAND CITIZENS' HEALTH INITIATIVE EDUCATION FUND, INCORPORATED; PUBLIC CITIZEN; PUBLIC JUSTICE CENTER; MARYLAND CITIZENS' HEALTH INITIATIVE EDUCATION FUND, INCORPORATED; DISABILITY RIGHTS MARYLAND,

Amici Supporting Appellee.

Appeal from the United States District Court for the District of Maryland, at Baltimore. Marvin J. Garbis, Senior District Judge. (1:17-cv-01860-MJG)

Argued: January 24, 2018 Decided: April 13, 2018

Before AGEE, WYNN, and THACKER, Circuit Judges.

Reversed and remanded by published opinion. Judge Thacker wrote the majority opinion, in which Judge Agee joined. Judge Wynn wrote a dissenting opinion.

ARGUED: Jay P. Lefkowitz, KIRKLAND & ELLIS LLP, New York, New York, for Appellant. Joshua Neal Auerbach, OFFICE OF THE ATTORNEY GENERAL OF MARYLAND, Baltimore, Maryland, for Appellees. **ON BRIEF:** Jonathan D. Janow, Matthew D. Rowen, KIRKLAND & ELLIS LLP, Washington, D.C., for Appellant. Brian E. Frosh, Attorney General, Leah J. Tulin, Assistant Attorney General, OFFICE OF THE ATTORNEY GENERAL OF MARYLAND, Baltimore, Maryland, for Appellees. Warren Postman, Janet Galeria, UNITED STATES CHAMBER LITIGATION CENTER, Washington, D.C.; William S. Consovoy, Bryan K. Weir, CONSOVOY MCCARTHY PARK PLLC, Arlington, Virginia, for Amicus Chamber of Commerce of the United States of America. William Alvarado Rivera, Iris Y. González, David Edmon, AARP FOUNDATION LITIGATION, Washington, D.C., for Amici AARP, AARP Foundation, Knowledge Ecology International, The Maryland Citizens' Health Initiative Education Fund, and Public Citizen. K'Shaani Smith, Murnaghan Appellate Advocacy Fellow, PUBLIC JUSTICE CENTER, Baltimore, Maryland, for Amici Public Justice Center, Maryland Citizens' Health Initiative Education Fund, Incorporated, and Disability Rights Maryland, Incorporated.

THACKER, Circuit Judge:

The Association for Accessible Medicines ("AAM") appeals the district court's dismissal of its dormant commerce clause challenge to a Maryland statute prohibiting price gouging in the sale of prescription drugs. AAM also appeals the district court's refusal to enjoin enforcement of the statute on the basis that it is unconstitutionally vague. We hold that the statute violates the dormant commerce clause because it directly regulates the price of transactions that occur outside Maryland.[1] Accordingly, we reverse the district court's dismissal of that claim and remand with instructions to enter judgment in favor of AAM.

I.

Factual Background and Procedural History

A.

Maryland's Anti-Price Gouging Statute

In response to reports of price gouging by pharmaceutical manufacturers in the sale of certain prescription medications, Maryland's legislature passed HB 631, "An Act concerning Public Health – Essential Off-Patent or Generic Drugs – Price Gouging – Prohibition" (the "Act"), during the 2017 legislative session. J.A. 42–48.[2] Maryland's

[1] Because we hold that the statute is unconstitutional pursuant to the dormant commerce clause, we need not address whether it is also void for vagueness.

[2] Citations to the "J.A." refer to the Joint Appendix filed by the parties in this appeal.

governor refused to sign the bill, citing constitutional and other concerns, and the bill became law without his signature. The Act went into effect on October 1, 2017.

The Act prohibits "[a] manufacturer or wholesale distributor" from "engag[ing] in price gouging in the sale of an essential off-patent or generic drug." Md. Code Ann., Health–General § 2-802(a). The Act defines "price gouging" as "an unconscionable increase in the price of a prescription drug." *Id.* § 2-801(c). "Unconscionable increase" is further defined as an increase that "[i]s 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" and "[r]esults in consumers . . . having no meaningful choice about whether to purchase the drug at an excessive price" due to the drug's "importance . . . to their health" and "[i]nsufficient competition in the market." *Id.* § 2-801(f). The "essential" medications subject to the law are those "made available for sale in [Maryland]" that either "appear[] on the Model List of Essential Medicines most recently adopted by the World Health Organization" or are "designated . . . as an essential medicine due to [their] 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." *Id.* § 2-801(b)(1).

A manufacturer or wholesale distributor determined to be in violation of the Act may face a number of legal consequences, including a civil penalty of $10,000 per violation or an action to enjoin the sale of the medication at the increased price. *See* Md. Code Ann., Health–General § 2-803(d). To assist the Maryland Attorney General in identifying violations, the Act provides that the Maryland Medical Assistance Program

"may notify the Attorney General" in the event of a particular price increase, including when an increase "[w]ould result in an increase of 50% or more in the wholesale acquisition cost of the drug within the preceding 1-year period" or when a 30-day supply of the drug "would cost more than $80 at the drug's wholesale acquisition cost." *Id.* § 2-803(a).

B.

AAM's Suit Challenging the Act

AAM is a voluntary organization with a membership that consists of prescription drug manufacturers and wholesale distributors and other entities in the pharmaceutical industry. AAM's member-manufacturers, only one of which is based in Maryland, typically sell their products to wholesale pharmaceutical distributors, *none of which are based in Maryland*. The vast majority of these sales occur outside Maryland's borders.

On July 6, 2017, AAM filed this action against Brian Frosh, Maryland's Attorney General, and Dennis R. Schrader, Secretary of the Maryland Department of Health (collectively, "Maryland"). Among other claims, AAM asserts that the Act violates the dormant commerce clause and is unconstitutionally vague. Maryland filed a motion to dismiss AAM's suit, which the district court granted as to the dormant commerce clause claim but denied as to the vagueness claim. The district court also denied AAM's motion for a preliminary injunction. AAM timely appealed.

II.

Dormant Commerce Clause Challenge

AAM argues that the district court improperly dismissed its claim that the Act violates the dormant commerce clause by directly regulating wholly out-of-state commerce. We review the dismissal de novo, "accepting [AAM's] well-pleaded allegations as true and drawing all reasonable inferences in [AAM's] favor." *Schilling v. Schmidt Baking Co.*, 876 F.3d 596, 599 (4th Cir. 2017).

A.

The Dormant Commerce Clause and the Principle Against Extraterritoriality

Implicit in the constitutional allocation of the "Power . . . To regulate Commerce . . . among the several States," U.S. Const. art. I, § 8, cl. 3, to the federal government is a corollary "constraint on the power of the States to enact legislation that interferes with or burdens interstate commerce." *Brown v. Hovatter*, 561 F.3d 357, 362 (4th Cir. 2009). This doctrine, known as the "dormant" commerce clause, "is driven by concern about economic protectionism" and seeks to prevent state "regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors." *Id.* at 363 (quoting *Dep't of Revenue of Ky. v. Davis*, 553 U.S. 328, 337–38 (2008)).

The principle against extraterritoriality as it relates to the dormant commerce clause is derived from the notion that "a State may not regulate commerce occurring wholly outside of its borders." *Star Sci., Inc. v. Beales*, 278 F.3d 339, 355 (4th Cir. 2002) (citing *Healy v. Beer Inst.*, 491 U.S. 324, 335–36 (1989); *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 582–83 (1986); *Edgar v. MITE Corp.*, 457 U.S.

624, 642–43 (1982) (plurality opinion)). The principle "reflect[s] 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." *Healy*, 491 U.S. at 335–36 (footnote omitted). A state law violates the extraterritoriality principle if it either expressly applies to out-of-state commerce, *see Carolina Trucks & Equip., Inc. v. Volvo Trucks of N. Am., Inc.*, 492 F.3d 484, 491–92 (4th Cir. 2007), or has that "practical effect," regardless of the legislature's intent, *Star Sci.*, 492 F.3d at 355.

1.

One of the earliest cases to address the extraterritoriality principle as it relates to the dormant commerce clause is *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935). The New York law at issue in *Baldwin* required milk dealers to pay a minimum amount to milk producers, even when the milk was purchased outside New York. *See id.* at 519. The parties agreed that "New York ha[d] no power to project its legislation into Vermont by regulating the price to be paid in that state for milk acquired there." *Id.* at 521. In holding that the law violated the dormant commerce clause, the Supreme Court observed that the law essentially operated as a duty on milk produced in other states and therefore unlawfully burdened interstate commerce. *See id.* at 521–22.

A plurality of the Court expounded on this concept nearly half a century later in *Edgar v. MITE Corp.*, 457 U.S. 624 (1982) (plurality opinion). The Illinois law challenged in *Edgar* required "any takeover offer for the shares of a target company [to] be registered with the Secretary of State" if Illinois shareholders owned at least 10% of

the company or if the company was organized under Illinois law or headquartered in the state, among other conditions. *Id.* at 626–27 (internal footnote omitted). The Illinois Secretary of State had the authority "to deny registration to a tender offer" under certain circumstances. *Id.* at 627. The plurality held that the Illinois law violated the dormant commerce clause by "directly regulat[ing] transactions which take place across state lines, even if wholly outside the State of Illinois" because it permitted the Illinois Secretary of State to reject a tender offer even as to those shares not owned by Illinois shareholders. *Id.* at 641–42. In other words, the law granted the Illinois Secretary of State the ability to intervene in transactions between an out-of-state acquiring company and out-of-state shareholders of the target company when neither the acquiring company nor the target company's shareholders had connections to Illinois.

The Court favorably referenced both *Baldwin* and *Edgar* in *Brown-Forman Distillers Corp. v. New York State Liquor Authority*, 476 U.S. 573 (1986). The New York law struck down in *Brown-Forman* "requir[ed] distillers to affirm that they will make no sales anywhere in the United States at a price lower than the posted price in New York," which prohibited the distillers from lowering their prices in other states. *Id.* at 579–80. The Court noted that the law regulated commerce in other states by controlling liquor prices in those states, which would "effectively force [the distiller] to abandon its promotional allowance program in States in which that program is legal, or force those other States to alter their own regulatory schemes in order to permit [the distiller] to lower its New York prices without violating the affirmation laws of those States." *Id.* at 583–84. As a result, the law was invalid. *See id.* at 584.

Just three years later, the Supreme Court considered a similar Connecticut law in *Healy v. Beer Institute*, 491 U.S. 324 (1989). The law, which was aimed at preventing Connecticut residents from crossing state lines to purchase cheaper beer, required beer producers to affirm that their Connecticut prices were, "at the moment of posting, no higher than the prices at which those products are sold in the bordering States." *Id.* at 326. From its "cases concerning the extraterritorial effects of state economic regulation," *id.* at 336 (citing *Brown-Forman*, 476 U.S. at 579, 581–83; *Edgar*, 457 U.S. at 642–43; *Baldwin*, 294 U.S. at 528), the Supreme Court outlined the principle against extraterritoriality:

1) A state statute may not regulate "commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State." *Id.* at 336. Specifically, a state law may not have "the practical effect of establishing 'a scale of prices for use in other states.'" *Id.* (quoting *Baldwin*, 294 U.S. at 528).

2) "A statute that directly controls commerce occurring wholly outside the [legislating state's] boundaries . . . is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature." *Id.* The statute's "practical effect" is the focus of the inquiry. *Id.*

3) In evaluating a statute's "practical effect," the Court considers "not only . . . the consequences of the statute itself, but also . . . how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if . . . every[] State adopted similar legislation." *Id.* at 336. This is because "the Commerce Clause protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State." *Id.* at 336–37.

Applying these three directives, the Court invalidated the Connecticut law due to its "undeniable effect of controlling commercial activity occurring wholly outside the boundary of the State." *Id.* at 337. The Court also emphasized that "the practical effect of this affirmation law, in conjunction with the many other beer-pricing and affirmation laws that have been or might be enacted throughout the country, is to create just the kind of competing and interlocking local economic regulation that the Commerce Clause was meant to preclude." *Id.*

2.

Maryland asserts that in *Pharmaceutical Research & Manufacturers of America v. Walsh*, 538 U.S. 644, 669 (2003), the Supreme Court limited the principle against extraterritoriality in the dormant commerce clause context to price affirmation statutes. The Maine law at issue in *Walsh* established a program through which the state would "attempt to negotiate rebates with drug manufacturers to fund the reduced price for drugs offered to [program] participants." *Id.* at 649. The petitioner challenged the law on the basis "that the rebate requirement constitutes impermissible extraterritorial regulation." *Id.* at 669. The Supreme Court concluded that "[t]he rule that was applied in *Baldwin* and *Healy*" did not apply to the rebate program because "unlike price control or price affirmation statutes, '[the program] does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect.'" *Id.* (quoting *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 81–82 (1st Cir. 2001)).

Maryland's reading of this language, while adopted by two of our sister circuits, is too narrow. The Supreme Court's statement does not suggest that "[t]he rule that was

applied in *Baldwin* and *Healy*" applies *exclusively* to "price control or price affirmation statutes." *See Walsh*, 538 U.S. at 669. Instead, the Court's statement emphasizes that the extraterritoriality principle is violated if the state law at issue "regulate[s] the price of any out-of-state transaction, either by its express terms or by its inevitable effect." *Id.* The Maine program challenged in *Walsh* directly affected only transactions in Maine and did not impact the prices drug manufacturers could charge elsewhere. Further, the Illinois statute at issue in *Edgar*, which permitted the Secretary of State to block the takeover of a target company with certain connections to Illinois, clearly was not a price control or price affirmation statute, but the Court nonetheless concluded that it ran afoul of the principle against extraterritoriality. *See* 457 U.S. at 627, 641–42; *see also Healy*, 491 U.S. at 333 n.9 (stating that *Edgar* "significantly illuminates the contours of the constitutional prohibition on extraterritorial legislation"). We therefore reject Maryland's argument that *Walsh* limited the extraterritoriality principle only to price affirmation statutes.

B.

AAM's Challenge to the Act

We now turn to the merits of AAM's dormant commerce clause challenge. AAM asserts that the Act directly regulates the prices charged for prescription drugs in out-of-state transactions, even though its provisions are triggered only when one of those drugs is available for sale in Maryland. Maryland acknowledges that the Act is intended to reach the manufacturers' conduct in the series of wholesale transactions that occur

"upstream" from consumer retail sales but argues that these indirect effects do not violate the dormant commerce clause's prohibition on direct regulation.

We agree with AAM that the district court erroneously upheld the Act under the dormant commerce clause. First, the Act is not triggered by any conduct that takes place within Maryland. Second, even if it were, the Act controls the prices of transactions that occur outside the state. Finally, the Act, if similarly enacted by other states, would impose a significant burden on interstate commerce involving prescription drugs. All of these factors combine to create a violation of the dormant commerce clause.

1.

The Act is Not Limited to Sales Wholly Within Maryland

In reaching its conclusion, the district court emphasized that the Act's provisions "are triggered only when there is a drug . . . made available for sale *within* the state." J.A. 486 (emphasis in original). The district court likened the Act to the Virginia statute at issue in *Star Scientific*, but this comparison is inapposite. *See id.* at 485–86. The Virginia statute at issue in *Star Scientific* did not apply to sales to distributors, retail chains, or consumers *outside Virginia*. Instead, it specifically required tobacco manufacturers selling cigarettes *in Virginia* to join a nationwide settlement agreement or place into escrow a fee of two cents per cigarette actually sold in the state. *See Star Sci.*, 278 F.3d at 346. The relevant conduct penalized by that statute was the sale of a cigarette *in Virginia*.

In contrast, here, the Act's plain language allows Maryland to enforce the Act against parties to a transaction that did not result in a single pill being shipped to

Maryland. Specifically, the Act prohibits "price gouging in the sale of an essential off-patent or generic drug." Md. Code Ann., Health–General § 2-802(a). "Essential off-patent or generic drug" is defined, in part, as a drug "[t]hat is made available for sale in [Maryland]." *Id.* § 2-801(b)(1)(iv). This "made available for sale" language does not limit the Act's application to sales that actually occur within Maryland, nor does it restrict the Act's operation to the context of a resale transaction with a Maryland consumer. Indeed, Maryland acknowledges that the Act is intended to reach sales upstream from consumer retail sales. *See* Oral Argument at 20:45–55, *Ass'n for Accessible Meds. v. Frosh*, No. 17-2166 (4th Cir. Jan. 24, 2018), http://www.ca4.uscourts.gov/oral-argument/listen-to-oral-arguments ("[T]he conduct that violates the statute could manifest itself in a wholesale transaction that occurs out-of-state.").[3] Such "upstream" sales would occur almost exclusively outside Maryland.

Therefore, the Act targets conduct that occurs entirely outside Maryland's borders, a conclusion supported by the Act's prohibition of a manufacturer's use of the defense that it did not directly sell to a consumer in Maryland. *See* Md. Code Ann., Health–General § 2-803(g) ("[A] person who is alleged to have violated a requirement of this subtitle may not assert as a defense that the person did not deal directly with a consumer

[3] Thus, even if we applied a limiting construction to require a consumer sale in Maryland prior to enforcement of the Act, Maryland's own interpretation of the Act clarifies that it targets not a consumer retail sale but the manufacturer's initial sale of the drug.

residing in [Maryland].”). The district court thus erred in relying on the Act’s “made available for sale” language to uphold the Act.

2.

The Act Impacts Transactions that Occur Wholly Outside Maryland

Even if the Act did require a nexus to an actual sale in Maryland, it is nonetheless invalid because it still controls the price of transactions that occur wholly outside the state. *See Brown-Forman*, 476 U.S. at 580 (“The mere fact that the effects of New York’s ABC Law are triggered only by sales of liquor within the State of New York . . . does not validate the law if it regulates the out-of-state transactions of distillers who sell in-state.”). The Act, by its own terms, is not fixated on the price the Maryland consumer ultimately pays for the drug. Instead, the lawfulness of a price increase is measured according to the price the manufacturer or wholesaler charges *in the initial sale of the drug*. An “unconscionable” price increase is one that “[i]s 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.” Md. Code Ann., Health–General § 2-801(f). Significantly, the retailers that sell the drug directly to the consumer cannot be held liable under the Act; only “[a] manufacturer or wholesale distributor” is prohibited from “engag[ing] in price gouging.” *Id.* § 2-802(a); *see id.* § 2-803(g). This structure makes clear that the conduct the Act targets is the upstream pricing and sale of prescription drugs, and the parties agree that nearly all of these transactions occur outside Maryland.[4]

[4] AAM challenges the Act only as it applies to these out-of-state sales.

Therefore, the Act effectively seeks to compel manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland. This it cannot do. *See Healy*, 491 U.S. at 336 ("[T]he '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' . . . ." (quoting *Edgar*, 457 U.S. at 642–43)); *Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070, 1103 (9th Cir. 2013) (explaining that "[s]tates may not mandate compliance with their preferred policies in wholly out-of-state transactions" (citing *Walsh*, 538 U.S. at 669)).

More importantly, the Act 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. This is precisely the conduct "[t]he rule that was applied in *Baldwin* and *Healy*" aims to prevent. *Walsh*, 538 U.S. at 669 (concluding that the Maine law at issue was valid in part because "Maine does not insist that manufacturers sell their drugs to a wholesaler for a certain price"). We acknowledge that the Act does not establish a price schedule for prescription drugs, nor does it aim to tie the prices charged for prescription drugs in Maryland to the prices at which those drugs are sold in other states. *See Healy*, 491 U.S. at 338; *Brown-Forman*, 476 U.S. at 582. But like the laws struck down in *Healy* and *Brown-Forman*, the Act attempts to dictate the price that may be charged elsewhere for a good. Any legitimate effects the Act may have in Maryland are insufficient to protect the law from invalidation. *See Brown-Forman*, 476 U.S. at 580.

3.

The Act Implicates a Price Control as Opposed to an Upstream Pricing Impact

Maryland attempts to justify the Act by arguing that its out-of-state pricing implications are merely "the upstream pricing impact of a state regulation." *Freedom Holdings, Inc. v. Spitzer*, 357 F.3d 205, 220 (2d Cir. 2004). But the Act is unlike the statute at issue in *Freedom Holdings*, which banned the importation of cigarettes manufactured by companies that did not comply with an escrow law similar to the one we upheld in *Star Scientific*. *See id.* at 211–14. The importers in *Freedom Holdings* argued that the New York law regulated out-of-state commerce by requiring manufacturers to sell cigarettes at a higher price "to purchasers in sales transactions that occur wholly outside [New York]." *Id.* at 220. The Second Circuit rejected the argument, holding that "[t]he extraterritorial effect described by [the importers] amounts to no more than the upstream pricing impact of a state regulation" and observing that "a similar pricing impact might result from any state regulation of a product." *Id.* The price change caused by the New York law at issue in *Freedom Holdings* -- unlike that mandated by the Act here -- was the result of natural market forces and was not artificially imposed by the laws of another state. By contrast, the Act aims to override prescription drug manufacturers' reaction to the market and to regulate the prices these manufacturers charge for their products. This is more than an "upstream pricing impact" -- it is a price control.

Therefore, the fundamental problem with the Act is that it "regulate[s] the price of [an] out-of-state transaction." *Walsh*, 538 U.S. at 669. The Act 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. Maryland cannot, even in an effort to protect its consumers from skyrocketing prescription drug costs, impose its preferences in this manner. The "practical effect" of the Act, much like the effect of the statutes struck down in *Brown-Forman* and *Healy*, is to specify the price at which goods may be sold beyond Maryland's borders. *See Healy*, 491 U.S. at 336 ("The critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State." (citing *Brown-Forman*, 476 U.S. at 579)). The district court erred by failing to account for this impact.

4.

The Act Burdens Interstate Commerce in Prescription Drugs

The Act's significant scope is further illuminated by the burden similar legislation would place on interstate commerce. *See Healy*, 491 U.S. at 336 ("[T]he practical effect of the statute must be evaluated not only by considering the consequences of the statute itself, but also by considering how the challenged statute 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."). Because the Act targets wholesale rather than retail pricing, an analogous restriction imposed by a state other than Maryland has the potential to subject prescription drug manufacturers to conflicting state requirements. *See id.* at 336–37 ("Generally speaking, the Commerce Clause protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State."); *Brown-Forman*, 476 U.S. at 583–84. And the Act's relatively

subjective definition of what constitutes an unlawful price increase only exacerbates the problem. If multiple states enacted this type of legislation, then a manufacturer may consummate a transaction in a state where the transaction is fully permissible, yet still be subject to an enforcement action in another state (such as Maryland) wholly unrelated to the transaction.

In upholding the Act, the district court referred to this conundrum as a "practical problem" and suggested that prescription drug manufacturers could simply modify their distribution systems to track the shipments of drugs bound for Maryland and isolate those drugs in order to comply with the Act. J.A. 489–90. It is indeed true that the dormant commerce clause does not "protect[] the particular structure or methods of operation in a retail market." *Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 127 (1978). But the Act requires manufacturers and wholesale distributors to do more than alter their distribution channels. It sets prescription drug prices in a way that "interfere[s] with the natural function of the interstate market" by superseding market forces that dictate the price of a good. *McBurney v. Young*, 569 U.S. 221, 235 (2013) (quoting *Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794, 806 (1976)). If Maryland compels manufacturers to sell prescription drugs in the initial transaction at a particular price, but another state imposes a different price, then manufacturers could not comply with both laws in a single transaction. The manufacturers' compliance would require more than modification of their distribution systems; it would force them to enter into a separate transaction for each state in order to tailor their conduct so as not to violate any state's price restrictions. Even then, if a drug from a transaction addressed to another state were later made

available for sale in Maryland, the Act would permit Maryland to penalize the manufacturer. The potential for "the kind of competing and interlocking local economic regulation that the Commerce Clause was meant to preclude" is therefore both real and significant. *Healy*, 491 U.S. at 337. We are thus pressed to invalidate the Act.

5.

In sum, we hold that the Act is unconstitutional under the dormant commerce clause because it directly regulates transactions that take place *outside Maryland*. We therefore reverse the district court's dismissal of this claim and remand this matter to the district court with instructions to enter judgment in favor of AAM.

To be clear, we in no way mean to suggest that Maryland and other states cannot 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*. *See* 538 U.S. at 653–54, 669–70.

Although we sympathize with the consumers affected by the prescription drug manufacturers' conduct and with Maryland's efforts to curtail prescription drug price gouging, we are constrained to apply the dormant commerce clause to the Act. Our dissenting colleague suggests that by doing so, we imply that prescription drug manufacturers have a constitutional right to engage in price gouging. *See post* at 57–58. This is a sweeping and incorrect conclusion to draw from our holding that Maryland is prohibited from combating prescription drug price gouging *in the manner utilized by the Act*. Prescription drug manufacturers are by no means "constitutionally entitled," *id.* at 57, to engage in abusive prescription drug pricing practices. But Maryland must address

this concern via a statute that complies with the dormant commerce clause of the U.S. Constitution.

III.

Conclusion

For the foregoing reasons, we reverse the district court's dismissal of AAM's dormant commerce clause challenge and remand with instructions to enter judgment in favor of AAM. AAM's request for an injunction pending this appeal is denied as moot.

REVERSED AND REMANDED
WITH INSTRUCTIONS

WYNN, Circuit Judge, dissenting:

After a series of high-profile incidents in which several generic pharmaceutical manufacturers imposed multiple-thousand-fold price increases for single-source generic drugs that treat rare and life-threatening conditions, the Maryland legislature enacted legislation prohibiting "unconscionable" price increases for certain generic drugs "made available for sale" to Maryland consumers. Md. Code Ann. Health-Gen. §§ 2-801 to -803 (2017). But a trade association representing generic pharmaceutical manufacturers—which styles itself the "Association for Accessible Medicines" ("AAM" or "Plaintiff")—brought this action to enjoin the Maryland statute on grounds that it violates the dormant Commerce Clause and is unconstitutionally vague. The district court upheld Maryland's authority under the dormant Commerce Clause to protect its citizens from the abusive pricing practices at issue. I agree with the district court's holding, but my colleagues in the majority hold otherwise.

In particular, the majority opinion holds that the Maryland statute violates the dormant Commerce Clause's "extraterritoriality doctrine" to the extent that it applies to sales of generic drugs between manufacturers and distributors consummated outside of Maryland, even when the generic drugs involved in such out-of-state transactions are subsequently resold to Maryland consumers. *Ante* at 13–15. Put differently, the majority opinion concludes that the Commerce Clause bars Maryland from protecting its citizens against unconscionable pricing practices by out-of-state generic drug manufacturers who distribute their drugs to Maryland's citizens through an out-of-state intermediary. That

conclusion conflicts with the approach taken by several of our sister circuits in deciding whether a state statute's extraterritorial reach violates the dormant Commerce Clause.

Contrary to the majority opinion's conclusion, Maryland is authorized under its "general police powers to regulate matters of legitimate local concern." *Lewis v. BT Inv. Mgrs., Inc.*, 447 U.S. 27, 36 (1980) (internal quotation marks omitted). Here, Maryland legitimately targeted generic drug pricing practices specifically designed to prey on the special vulnerabilities of a defenseless group of Maryland's citizens. Simply put, the Maryland statute—which applies equally to in-state and out-of-state manufacturers and distributors—does not implicate the concerns that lie at the heart of the Supreme Court's dormant Commerce Clause jurisprudence: economic protectionism, discrimination against interstate commerce, and State regulation of streams of transactions that never cross through the State's borders. *See Dep't of Revenue of Ky. v. Davis*, 553 U.S. 328, 337–38 (2008). Accordingly, I respectfully dissent.

I.

Two recent reports by the federal government regarding generic drug pricing gave rise to Maryland taking action to protect its citizens from abusive pricing practices by a subset of generic drug manufacturers. Both reports were prompted by media stories highlighting significant increases in the price of certain generic drugs. *See, e.g.*, Jonathan D. Alpern *et al.*, High-Cost Generic Drugs—Implications for Patients and Policy Makers, 371 N. Engl. J. Med. 1859, 1859–60 (2014); Andrew Pollack, *Once a Neglected Treatment, Now an Expensive Specialty Drug*, N.Y. Times, Sept. 21, 2015, at B1.

The first report, prepared by the Government Accountability Office ("GAO") in response to a request by a bipartisan group of legislators, examined pricing trends for generic drugs covered by the Medicare program's outpatient prescription drug benefit, commonly referred to as "Medicare Part D." *See* U.S. Gov't Accountability Off., GAO-16-706, Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases (2016) [hereinafter, "GAO Report"]. The GAO Report found that for a basket of 1,441 "established generic drugs"—"drugs that were continuously billed under Medicare Part D . . . during [the] study period"—prices fell, on average, 0.7 percent per quarter from the first quarter of 2010 through the second quarter of 2015. *See id.* at 9. Although prices for established generic drugs generally declined during the 2010 to 2015 period, the GAO Report further found that "315 of the 1,441 established drugs experienced an extraordinary price increase—a price increase of at least 100 percent." *Id.* at 12. Notably, the number of established drugs experiencing a price increase of at least 100 percent *increased* during the five-year study period: 45 drugs experienced such an increase between the first quarter of 2010 and the first quarter of 2011, whereas 103 drugs experienced such an increase between the first quarter of 2014 and the first quarter of 2015. *Id.* at 12, 18.

A smaller subset of established generic drugs experienced even more "extraordinary" price increases—48 such drugs experienced a price increase of 500 percent or greater and 15 such drugs experienced a price increase of 1,000 percent or greater. *Id.* at 14. The vast majority of these extraordinary price increases persisted throughout the term of the study. *Id.* at 18.

Most of the established generic drugs experiencing extraordinary price increases were not among the 100 most heavily prescribed established generic drugs covered under Medicare Part D. To that end, stakeholders interviewed by GAO reported that "[i]f a generic drug serves a small [patient] population, . . . it [is] more susceptible to price increases" because "there may be little financial incentive for a [competing] manufacturer to enter the market" and thus less "downward pressure on price." *Id.* at 24. Stakeholders also reported that supplier and buyer consolidation can drive price increases, as can difficulty manufacturing a particular generic drug. *Id.*

The second report, prepared by the United States Senate Special Committee on Aging, investigated and analyzed several "abrupt and dramatic" price increases for certain generic drugs. *See* Senate Special 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* 3 (2016) [hereinafter, "Senate Report"]. The Senate Report examined the circumstances surrounding large price increases for seven generic drugs, all of which had lacked patent protection for decades, sold by four generic pharmaceutical companies—two of which were formed and managed by since-convicted investor Martin Shkreli.[1] *Id.* at 5–6. All seven price increases exceeded 300 percent, with five of the price increases at or exceeding 2,000 percent. *Id.* at 6.

[1] On March 9, 2018, the U.S. District Court for the Southern District of New York sentenced Shkreli to seven years' imprisonment for securities fraud and conspiracy to commit securities fraud. Stephanie Clifford, *Citing "Multitude of Lies," Judge Sentences Shkreli to 7 Years in Fraud Case*, N.Y. Times, Mar. 10, 2018, at B2.

The Senate investigation revealed that the four companies followed a common "business model" in acquiring and marketing the seven generic drugs. *Id.* at 4. In particular, each case involved a (1) single-source generic drug (2) distributed through a "closed distribution system" that (3) was essential to—the "gold standard" for—(4) treating a rare condition. *Id.* at 4, 30–31. Each of these four characteristics allowed the company to "exercise de facto monopoly pricing power, and then impose and protect astronomical price increases," the Senate committee found. *Id.* at 4.

For example, single-source drugs distributed through closed-distribution systems—which make it harder for potential entrants to bring to market a competitive product or attract and retain patients—are unlikely to face competition, thereby allowing sellers to charge monopoly prices, notwithstanding the generic drug's lack of patent protection. *Id.* at 4, 30–31. Likewise, when a generic drug is the "gold standard" for treating a particular condition, physicians continue to prescribe the drug, even in the face of substantial price increases. *Id.* at 30; *see also*, *e.g.*, *id.* at 56 (chief executive of one generic firm explaining that it had monopoly "pricing power" for a generic drug that is the standard-of-care for treating a rare and deadly disease because, absent the drug, patients would face "liver failure or a liver transplant or even death"). And because the generic drugs treat a "rare" condition "the patient population dependent upon them [is] too small to organize effective opposition to the price increase." *Id.* at 31.

The Senate Report found that the large price increases "devastated patients . . . across the nation," many of whom were "forced to go without vital medicine[s]" or switch to alternative, potentially less effective, therapies. *Id.* at 7–8. The price increases

also harmed providers. For example, the Johns Hopkins Health System, which is headquartered in Maryland, reported that it lost nearly $1 million in 2015 alone as a result of several-hundred-fold price increases for two of the drugs. *Id.* at 6–8. The price increases also led to increases in spending by governmental health care programs, including state Medicaid programs. *Id.* at 110. The report further concluded that existing federal competition laws were inadequate to prevent the dramatic price increases and suggested several statutory and regulatory remedies. *Id.* at 116–25.

After reviewing these reports, the Maryland legislature decided to enact legislation to combat what it concluded were abusive pricing practices by certain generic drug suppliers. To that end, on May 27, 2017, the Maryland General Assembly passed HB 631. That statute, which went into effect on October 1, 2017, prohibits manufacturers and distributors from engaging in "price gouging" in the sale of an "essential off-patent or generic drug." Md. Code Ann. Health-Gen. § 2-802(a). The statute exempts "wholesale distributors" from liability, however, if they impose a price increase that "is directly attributable to additional costs for the drug imposed on the wholesale distributor by the manufacturer of the drug." *Id.* § 2-802(b).

HB 631 defines "essential off-patent or generic drug" as a drug: (1) "[f]or which all exclusive marketing rights, if any, granted under the federal Food, Drug, and Cosmetic Act, § 351 of the federal Public Health Service Act, and federal patent law have expired"; (2) that is listed on the Model List of Essential Medicines, as adopted by the World Health Organization, or that has been has been designated, according to specified criteria, an "essential medicine" by the Maryland Secretary of Health; (3) "[t]hat is

actively manufactured and marketed for sale in the United States by three or fewer manufacturers"; and (4) that is "made available for sale" in the State of Maryland. *Id.* § 2-801(b)(1). "Essential off-patent or generic drug" also includes any "drug-device combination product used for the delivery of a drug" for which all exclusive marketing rights have expired. *Id.* § 2-801(b)(2). Although HB 631 regulates only those generic drugs "made available for sale" in Maryland, "a person who is alleged to have violated [the statute] may not assert as a defense that the person did not deal directly with a consumer residing in the State." *Id.* §§ 2-801(b)(1), 2-803(g).

The statute defines "price gouging" as an "unconscionable increase in the price of a prescription drug." *Id.* § 2-801(c). Tracking many aspects of the "business model" identified in the Senate Report, the statute provides that an "unconscionable increase" means an increase in price that (1) "[i]s 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"; and (2) "[r]esults in consumers for whom the drug has been prescribed having no meaningful choice about whether to purchase the drug at an excessive price" due to the "importance of the drug to their health" and insufficient market competition. *Id.* § 2-801(f).

HB 631 authorizes the Attorney General to petition a Maryland circuit court to restrain or enjoin violations of the statute; restore money to consumers obtained as a result of violations; require manufacturers that have engaged in "price gouging" to provide the drug to participants in any state health plan or state health program at the

drug's last permissible price for a period of up to one year; and order civil penalties of up to $10,000. *Id.* § 2-803(d).

HB 631 also confers monitoring authority on the State's Medicaid program, the Maryland Medical Assistance Program (the "Medicaid Program"). In particular, the Medicaid Program may notify the Attorney General of certain price increases to an "essential off-patent or generic drug." Specifically, the Medicaid Program may notify the Attorney General if (1) a price increase, either by itself or together with other price increases, would cause a fifty percent or more increase, as measured within a one year time period, to the wholesale acquisition cost or price paid by the Medicaid Program; and (2) it would cost $80 at the wholesale acquisition cost to obtain a thirty day supply of the maximum recommended dosage, a full course of treatment, or if the drug is not made available in such quantities, it would exceed $80 at the wholesale acquisition cost to obtain a thirty day supply or full course of treatment. *Id.* § 2-803(a). After receiving notification of such an increase, the Attorney General may demand that the manufacturer imposing the increase submit documentation that itemizes the cost of production; provides explanation for the price increase, including information related to any expenditures made to "expand access to the drug," as well as the associated benefits to the public health; and any other relevant information. *Id.* § 2-803(b).

II.

On appeal, AAM argues that HB 631, as applied to any transaction consummated outside of Maryland's borders, violates the Commerce Clause, regardless of whether the drugs involved in such transaction later are resold in Maryland. Before addressing the

merits of that claim, it is first necessary to determine what the Maryland legislature intended when it limited HB 631's extraterritorial reach to generic drugs "made available for sale" in Maryland. *Id.* § 2-801(b)(1). The district court held, correctly in my view, that HB 631 is "triggered only when there is a drug . . . made available for sale *within* [Maryland]." *Ass'n for Accessible Meds. v. Frosh*, No. 17-cv-1860, 2017 WL 4347818, at *6 (D. Md. Sept. 29, 2017). The majority opinion, however, concludes that HB 631 "is not triggered by any conduct that takes place within Maryland." *Ante* at 12; *see also id.* at 12-13 ("[Section 2-801(b)(1)'s] plain language allows Maryland to enforce [HB 631] against parties to a transaction that did not result in a single pill being shipped to Maryland."); *id.* at 14 (asserting that HB 631 does not "require a nexus to an actual sale in Maryland"). For several reasons, I disagree with the views of my colleagues in the majority.

To begin, the majority opinion's conclusion that HB 631 requires no "nexus to an actual sale in Maryland," *id.* at 14, runs contrary to the State's representation as to its own statute's extraterritorial reach. Before the district court and this Court, the State repeatedly asserted that HB 631 "*in no way prohibits* any of AAM's members from selling drugs at a conscience-shocking price to distributors, to the extent that those drugs are later sold in California or in any other state." J.A. 291 (emphasis added); *see also* Appellee's Br. 7 (representing that HB 631 "applies only when drugs are sold in Maryland"). Put differently, the State represents that HB 631 "does not reach, or purport to reach, any stream of commerce *that does not end in Maryland*." Mem. In Support of Defs.' Mot. to Dismiss, at 23, *Ass'n for Accessible Meds. v. Frosh*, No. 17-cv-1860 (D.

Md. Aug. 14, 2017), ECF No. 29-1 (emphasis added). Because pre-enforcement constitutional challenges to state statutes—like AAM's dormant Commerce Clause challenge—are disfavored, *see Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 450–51 (2008), and because the State repeatedly has represented that HB 631's reach does not extend to generic drugs that are not later sold in Maryland, principles of federalism and judicial restraint dictate that we construe the statute's reach as not extending to any stream of commerce that does not end in Maryland.

The majority opinion's conclusion that the statute extends to drugs not ultimately sold in Maryland also conflicts with AAM's understanding of the statute's extraterritorial reach. In particular, AAM asserts that HB 631 "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). AAM, therefore, has not challenged the State's representation—and the district court's conclusion—that HB 631 is "triggered only when there is a drug . . . made available for sale *within* [Maryland]." *Frosh*, 2017 WL 4347818, at *6. In such circumstances, the majority opinion errs in reaching out to reject the State's construction of its own statute, and AAM's acquiescence in that construction. *Cf. United States v. Al-Hamdi*, 356 F.3d 564, 571 n.8 (4th Cir. 2004) ("It is a well settled rule that contentions not raised in the argument section of the opening brief are abandoned.").

Even if the parties disagreed as to whether the statute's applicability requires an in-state sale, Maryland rules of statutory construction—which this Court must follow—support rejecting the majority opinion's broad interpretation of the statute's

extraterritorial reach. *See Carolina Trucks & Equip., Inc. v. Volvo Trucks of N. Am., Inc.*, 492 F.3d 484, 489 (4th Cir. 2007) ("In construing a state law, we look to the rules of construction applied by the enacting state's highest court.").

In *Carolina Trucks*, this Court considered a dormant Commerce Clause challenge to a South Carolina statute that prohibited motor vehicle manufacturers from "sell[ing], directly or indirectly, a motor vehicle to a consumer in this State, except through a new motor vehicle dealer." *Id.* at 488. The plaintiff argued that the phrase "in this State" modified only the term "consumer," meaning the statute prohibited "manufacturer-to-consumer sales to South Carolina buyers without regard to the state in which the sales took place"—including sales consummated outside of South Carolina's borders. *Id.* Noting that "[t]he statute is ambiguous as to what 'in this State' modifies," this Court rejected the plaintiff's proposed broad construction of the statute's extraterritorial reach. *Id* at 488–89. In reaching that conclusion, we emphasized that broadly construing the ambiguous statutory language would run contrary to South Carolina rules of statutory construction, which "provide that statutes must not be read to operate outside the state's borders." *Id.*

Like the statute at issue in *Carolina Trucks*, Section 2-801(b)(1)'s limitation of HB 631's reach to essential generic drugs "made available for sale" in Maryland is at least ambiguous as to the statute's extraterritorial reach. In particular, this Court reasonably could interpret the statute as applying only to those specific unconscionably priced pills that are sold or resold in Maryland—as the State represents and the district court concluded—or as extending to any unconscionably priced generic drug, some pills

of which are "made available for sale" in Maryland, regardless of whether the particular pills subject to an enforcement action actually are sold or resold in Maryland—as the majority concludes. And like South Carolina law, Maryland law dictates that "unless an intent to the contrary is *expressly* stated, acts of the legislature will be presumed not to have any extraterritorial effect." *Chairman of Bd. of Trs. of Emps.' Ret. Sys. v. Waldron*, 401 A.2d 172, 183–84 (Md. 1979) (emphasis added). *Carolina Trucks*, therefore, requires that we reject a "broader interpretation" of Section 2-801(b)(1)'s extraterritorial reach, like that adopted by the majority opinion.

Additionally, the majority opinion's broad construction of the statute's extraterritorial reach conflicts with the rule of construction, applied by Maryland courts, requiring a court "whenever reasonably possible, [to] construe and apply a statute to avoid casting serious doubt upon its constitutionality." *R.A. Ponte Architects, Ltd. v. Invs.' Alert, Inc.*, 857 A.2d 1, 18 (Md. 2004) (quoting *Becker v. State*, 767 A.2d 816, 824 (Md. 2001)). To be sure, a State statute that regulated sales in streams of commerce not ending in that State would raise significant concerns under the dormant Commerce Clause. But that is not a concern here because Maryland law obliges that we interpret the law narrowly—and in accordance with the State's own construction—as applying only to sales in streams of commerce ending in Maryland.

III.

Because HB 631 regulates, at most, sales of essential generic drugs in streams of commerce that end in Maryland, AAM's Commerce Clause challenge is without merit.

The Commerce Clause entrusts Congress with the authority "[t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes." U.S. Const. art. I, § 8, cl. 3. The Supreme Court "has long recognized that this affirmative grant of authority to Congress also encompasses an implicit or 'dormant' limitation on the authority of the States to enact legislation affecting interstate commerce." *Healy v. Beer Inst.*, 491 U.S. 324, 326 n.1 (1989). To that end, the "dormant" Commerce Clause "prohibits States from legislating in ways that impede the flow of interstate commerce." *Star Sci., Inc. v. Beales*, 278 F.3d 339, 355 (4th Cir. 2002). Although some earlier Supreme Court decisions broadly applied the dormant Commerce Clause to invalidate state laws, "modern" dormant Commerce Clause jurisprudence "is driven by concern about economic protectionism—that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors," *Davis*, 553 U.S. at 337–38 (internal quotation marks omitted).

AAM does not argue that HB 631 implicates either of these concerns underlying the Supreme Court's modern dormant Commerce Cause jurisprudence: discrimination against interstate commerce or favoring in-state economic interests over out-of-state economic interests. Rather, AAM contends—and the majority opinion agrees—that HB 631 violates the "extraterritoriality doctrine."

The extraterritoriality doctrine—a judge-made doctrine which states that a State may not regulate "commerce occurring wholly outside [its] boundaries," *Healy*, 491 U.S. at 336; *see also Star Sci.*, 278 F.3d at 355—has been characterized by our sister circuits as the "the most dormant" of the Supreme Court's dormant Commerce Clause

jurisprudence, *Energy & Envtl. Legal Inst. v. Epel* (*EELI*), 793 F.3d 1169, 1172 (10th Cir. 2015) (Gorsuch, J.); *IMS Health Inc. v. Mills*, 616 F.3d 7, 29 n.27 (1st Cir. 2010) ("Extraterritoriality has been the dormant branch of the dormant Commerce Clause."), *vacated sub nom. on other grounds IMS Health, Inc. v. Schneider*, 564 U.S. 1051 (2011). Indeed, several circuits have questioned the continuing vitality of the extraterritoriality doctrine following the Supreme Court's decision in *Pharmaceutical Research & Manufacturers of America v. Walsh*, which "pointedly referred to [the extraterritoriality doctrine] as 'the rule that was applied in *Baldwin* [*v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935),] and *Healy*.'" *IMS Health*, 616 F.3d at 29 n.27; *EELI*, 793 F.3d at 1174–75; *see also Am. Beverage Ass'n v. Snyder*, 735 F.3d 362, 381 (6th Cir. 2013) (Sutton, J., concurring) (noting that there never has been "a single Supreme Court dormant Commerce Clause holding that relied exclusively on the extraterritoriality doctrine to invalidate a state law").

Not only have courts questioned the extraterritoriality doctrine's continuing vitality, judges and commentators also have questioned the constitutional rationale underlying the doctrine, in light of new and expanded modes of interstate commerce, changes to the Supreme Court's interpretation of the Commerce Clause, and the availability of potentially more appropriate constitutional provisions, like the Due Process Clause, to ensure that States do not unduly extend their regulatory authority beyond their borders. *See Am. Beverage*, 735 F.3d at 377–80 (describing the extraterritoriality doctrine as "a relic of the old world with no useful role to play in the new"); Brandon P. Denning, *Extraterritoriality and the Dormant Commerce Clause: A*

Doctrinal Post-Mortem, 73 La. L. Rev. 979, 998 (2013); Jack L. Goldsmith & Alan O. Sykes, *The Internet and the Dormant Commerce Clause*, 110 Yale L.J. 785, 788–90, 806 (2001). Nevertheless, unless and until the Supreme Court repudiates the extraterritoriality doctrine as a separate line of dormant Commerce Clause jurisprudence, we are constrained to determine whether HB 631, as applied to out-of-state transactions involving essential generic drugs later sold in Maryland, amounts to a regulation of "commerce occurring wholly outside [Maryland's] borders," as the Supreme Court used that phrase in *Healy*.

The majority opinion concludes that HB 631 regulates "*commerce* occurring wholly outside the boundaries of [Maryland]," *Healy*, 491 U.S. at 336 (emphasis added)—and therefore violates the dormant Commerce Clause—because it "controls the price of *transactions* that occur wholly outside of the state," *ante* at 14 (emphasis added). I, however, conclude that the Supreme Court's Commerce Clause jurisprudence—including its decisions applying the extraterritoriality doctrine, in particular—and this Court's decisions applying that jurisprudence do not support equating a single "transaction" with "commerce," as the majority opinion does in striking down HB 631.

The Supreme Court first defined "commerce," as that term is used in the Commerce Clause, in *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1 (1824) (Marshall, J.). There, the appellee argued that the meaning of commerce is "limit[ed] to traffic, to buying and selling, or the interchange of commodities." *Id.* at 189. Writing for the Court, Chief Justice Marshall rejected the appellee's narrow definition—which sought to limit the meaning of commerce to a single exchange of goods—stating that "[c]ommerce,

undoubtedly, is traffic, but it is something more: it is intercourse. It describes the commercial intercourse between nations, and parts of nations, in all its branches . . ." *Id.* at 189–90.

Notwithstanding Chief Justice Marshall's expansive definition of commerce in *Gibbons*, between the late Nineteenth Century and the New Deal the Supreme Court narrowly interpreted the term, treating each distinct transaction within a single stream of economic activity as a piece of "commerce." For example, in *Carter v. Carter Coal Co.*, 298 U.S. 238 (1936), the Supreme Court struck down a federal law establishing boards responsible for determining the wages, hours, and working conditions of coal mine employees, *id.* at 280–84. The Court concluded that Congress lacked power under the Commerce Clause to regulate coal mine workers' terms of employment because "the relation of employer and employee . . . in all producing occupations is purely local in character." *Id.* at 303. In reaching this conclusion, the Court rejected the argument that the subsequent sale of the mined coal rendered the terms of the miners' employment in "commerce," and therefore subject to congressional regulation. *Id.* "Mining brings the subject-matter of commerce into existence. Commerce disposes of it," the Court held. *Id.* at 304. *Carter* is one example of a series of cases excluding "production" and "manufacturing" from the definition of "commerce." *See also, e.g.*, *Champlin Ref. Co. v. Corp. Comm'n of State of Okl.*, 286 U.S. 210, 235 (1932) ("[Oil] production is essentially a mining operation, and therefore is not a part of interstate commerce, even though the product obtained is intended to be and in fact is immediately shipped in such

commerce."); *United States v. E.C. Knight Co.*, 156 U.S. 1, 12 (1895) ("Commerce succeeds to manufacture, and is not a part of it.").

The Supreme Court abandoned the production-commerce distinction in a series of cases beginning with *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1, 40 (1937) ("[T]he fact that the employees here concerned were engaged in production is not determinative."). As Justice Jackson explained in *Wickard v. Filburn*, 317 U.S. 111 (1942)—which held that the growing of wheat for personal consumption constituted commercial activity subject to congressional regulation, *id.* at 128–29—"[w]hether the subject of the regulation in question was 'production,' 'consumption,' or 'marketing,' is . . . not material for purposes of deciding the question of federal power" to regulate commerce under the Commerce Clause, *id.* at 124. Accordingly, in cases involving the scope of the federal government's power under the Commerce Clause, the Supreme Court now interprets the term "commerce" as encompassing a stream of transactions—including those transactions necessary to produce a good, such as labor contracts, and those by virtue of which the good is distributed and sold to end-users.[2]

[2] The majority opinion notes that in *Pharmaceutical Research & Manufacturers of America v. Walsh*, 538 U.S. 644 (2003), the Supreme Court agreed with the First Circuit's conclusion that a statute did not violate the extraterritoriality doctrine because "unlike price control or price affirmation statutes, '[the program] does not regulate the price of any out-of-state *transaction*, either by its express terms or by its inevitable effect,'" *ante* at 10 (emphasis added) (quoting *Walsh*, 538 U.S. at 669 (quoting *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 81–82 (1st Cir. 2001))). But if a statute does not regulate the price in *any* out-of-state transaction, it certainly does not regulate prices in out-of-state "commerce," a term which the Supreme Court has defined more broadly. Accordingly, *Walsh* did not consider, much less decide, the relevant issue (Continued)

The now-abandoned production-commerce distinction reflected an effort by the Supreme Court to draw a bright line between the regulatory powers of the States and those of the federal government, each of which the Court viewed as "exclusive." *E.C. Knight*, 156 U.S. at 11. The Supreme Court's more expansive interpretation of the meaning of commerce in cases like *Jones & Laughlin* and *Wickard*—which returned to Chief Justice Marshall's expansive definition of the term set forth in *Gibbons*—necessarily entailed a narrowing of the restrictions on state regulatory authority imposed by the dormant Commerce Clause. To that end, at the same time as the Court authorized the federal government to exercise "power over traditionally 'local' activities," a separate line of Supreme Court decisions empowered the States to "share regulatory authority" in areas previously reserved to the federal government by, in appropriate circumstances, "regulat[ing] commerce that eventually would cross state lines." *Am. Beverage*, 735 F.3d at 377–78 (collecting cases). As one commentator explained, "[j]ust as . . . the permissive scope for congressional commerce action has broadened . . . the prohibitive effect of the clause has been progressively narrowed. The trend has been toward sustaining state regulation formerly regarded as inconsistent with Congress' unexercised power over commerce." *Id.* at 378 (quoting Wiley Rutledge, A Declaration of Legal Faith 68 (1947)).

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in the instant case—whether a State may regulate an out-of-state "transaction," if that transaction is a component of "commerce," part of which occurs in the State.

Therefore, under the modern definition of "commerce"—which encompasses a stream of transactions—a State regulates "commerce occurring wholly outside of [its borders]," *Healy*, 491 U.S. at 336, if no transactions in that stream take place within the State's borders. Put differently, "State *A* cannot use its [consumer protection] law to make a seller in State *B* charge a lower price to a buyer in *C*." *In re Brand Name Prescription Drugs Antitrust Litig.*, 123 F.3d 599, 613 (7th Cir. 1997) (Posner, J.). When viewed in that light, HB 631 does not regulate "commerce"—as the Supreme Court has used that term in Commerce Clause cases—occurring wholly outside of Maryland's borders. In particular, HB 631 applies only to upstream sales in streams of transactions that end in Maryland, *see supra* Part II, and therefore does not regulate any stream of economic activity that does not enter Maryland's borders.

That is precisely the conclusion the Seventh Circuit reached in *Brand Name Prescription Drugs*. There, a group of pharmacies alleged that certain prescription drug manufacturers were engaged in a price-fixing conspiracy. 123 F.3d at 602–03. Like the consumers protected by HB 631, the pharmacies did not purchase the drugs directly from the manufacturers. *Id.* at 603. Rather, the manufacturers sold the drugs to wholesalers, which in turn sold the drugs to the pharmacies. *Id.* Because the Supreme Court has barred "indirect purchasers," like the pharmacies, from seeking relief under the Sherman Act, *see Ill. Brick Co. v. Illinois*, 431 U.S. 720, 736 (1977), the pharmacies sought relief under Alabama's antitrust statute, *Brand Name Prescription Drugs*, 123 F.3d at 612. Notwithstanding that the sales between manufacturers and wholesalers were consummated outside of Alabama, the Seventh Circuit held that Alabama pharmacies—

but not pharmacies in other States—could seek relief under the Alabama statute without violating the extraterritoriality doctrine. *Id.* at 613; *see also K-S Pharmacies, Inc. v. Am. Home Prods. Corp.*, 962 F.2d 728, 731 (7th Cir. 1992) (Easterbrook, J.) (holding that Wisconsin statute did not violate extraterritoriality doctrine because statute did not regulate "sales outside Wisconsin for *resale outside Wisconsin*" (emphasis added)).

In accordance with the meaning of "commerce" adopted in *Jones & Laughlin* and *Wickard* and applied in *Brand Name Prescription Drugs*, none of the three dormant Commerce Clause cases upon which the majority opinion relies—*Baldwin*, *Healy*, and *Brown-Forman Distillers v. N.Y. State Liquor Auth.*, 476 U.S. 592 (1986), *ante* at 7–10[3]—holds that a nondiscriminatory State law regulating an upstream transaction in a stream of transactions that ends in the State—like HB 631—constitutes an unconstitutional regulation of "wholly" out-of-state "commerce." Rather, each of the three cases turns on the principle concerns animating the Supreme Court's dormant Commerce Clause jurisprudence: economic protectionism, discrimination against interstate commerce, and State regulation of a stream of transactions that never crosses through the State's borders.

[3] The majority opinion also relies on the Supreme Court's decision in *Edgar v. MITE Corp.*, 457 U.S. 624 (1982), which addressed whether a state anti-takeover statute violated the Supremacy and Commerce Clauses of the Constitution. *Ante* at 7–8. The extraterritoriality analysis in Justice White's opinion in *Edgar*, however, did not receive support from a majority of the Court. *Id.* at 626, 641–43 (opinion of White, J.). And the Court subsequently rejected a dormant Commerce Clause challenge to a similar, but not identical, state anti-takeover statute. *See CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 87–88 (1987).

In *Baldwin*, the Supreme Court considered a New York statute setting minimum prices that New York distributors of milk had to pay to New York dairies. 294 U.S. at 519. The statute further provided that "there shall be no sale within [New York] of milk bought outside [of New York] unless the price paid to the producers was one that would be lawful upon a like transaction within [New York]." *Id.* The Court concluded that the latter aspect of the statute violated the dormant Commerce Clause, explaining "New York has no power to project its legislation into[, for example,] Vermont by regulating the price to be paid in that state for milk acquired there." *Id.* at 521. The Court further held that the statute violated the dormant Commerce Clause because it had the purpose of "suppress[ing] or mitigat[ing] the consequences of competition between the states." *Id.* at 522. "If New York, in order to promote the economic welfare of her farmers, may guard them against competition with the cheaper prices of Vermont, the door has been opened to rivalries and reprisals that were meant to be averted by subjecting commerce between the states to the power of the nation," the Court explained. *Id.*; *Brown-Forman*, 476 U.S. at 580 (explaining that *Baldwin* stood for the proposition that "[w]hile a State may seek lower prices for its consumers, it may not insist that producers or consumers in other States surrender whatever competitive advantages they may possess"); *Milk Control Bd. of Pa. v. Eisenberg Farm Prods.*, 306 U.S. 346, 353 (1939) (explaining that *Baldwin* struck down the New York law because it "amounted in effect to a tariff barrier set up against milk imported into [New York]."). Accordingly, concerns about economic protectionism—that the New York law was intended to favor in-state interests at the expense of out-of-state producers and consumers—undergirded *Baldwin*.

Likewise, in *Brown-Forman*, the Court struck down a New York "price-affirmation" statute that "requir[ed] every liquor distiller or producer that sells liquor to wholesalers within [New York] to sell at a price that is no higher than the lowest price the distiller charges wholesalers anywhere else in the United States." 476 U.S. at 575. In the event a distiller desired to lower its posted price in another State, it had to seek approval of a New York regulator. *Id.* at 583. The Court held that the price-affirmation statute violated the Commerce Clause because it had the effect of "regulat[ing] out-of-state transactions" by controlling the prices out-of-state distillers could charge to *out-of-state customers*—i.e., for liquor that would *never* be sold in New York. *Id.* at 582 ("Once a distiller has posted prices in New York, it is not free to change its prices *elsewhere in the United States* during the relevant month." (emphasis added)). *Brown-Forman*, therefore, struck down the New York statute because it had the effect of regulating the price charged in streams of commerce that *never* entered New York's borders.

Healy also involved a "price-affirmation" statute, pursuant to which Connecticut "require[d] out-of-state shippers of beer to affirm that their posted prices for products sold to Connecticut wholesalers are, as of the moment of the posting, no higher than the prices at which those products are sold in . . . bordering states." 491 U.S. at 326. The Court concluded that the statute violated the dormant Commerce Clause for several reasons. First, the Connecticut statute—like the New York statute at issue in *Brown-Forman*—had the effect of controlling the prices of beer in States other than Connecticut. *Id.* at 337-38. In particular, Connecticut's affirmation and posting requirements, effectively locked in the prices brewers could charge in other States because if they

changed their prices in those States as a result of "prevailing market conditions," they would violate the Connecticut statute. *Id.* at 338. Furthermore, the posting and affirmation requirements effectively barred brewers from providing retroactive discounts, like promotional and volume discounts, outside of Connecticut, allowing Connecticut to exert further "control" over prices charged in neighboring states. *Id.* The "Connecticut Statute, like the New York law struck down in *Brown-Forman*," the Court explained, "requires out-of-state shippers to forgo the implementation of competitive pricing schemes in *out-of-state markets* because those pricing decisions are imported by statute into the Connecticut market regardless of local competitive conditions." *Id.* at 339 (emphasis added); *see also Freedom Holdings, Inc. v. Spitzer*, 357 F.3d 205, 221 n.16 (2d Cir. 2004) ("The [*Healy*] Court held the statute to be unconstitutional because it had the effect of *controlling prices in neighboring states* . . . ." (emphasis added)).

Additionally, the Connecticut statute "discriminate[d] against brewers and shippers of beer engaged in interstate commerce" because such brewers faced greater restraints on their pricing than brewers that operated solely within Connecticut. *Id.* at 340–41. Finally, the Court asserted that the statute impermissibly favored in-state interests at the expense of out-of-state interests by "depriv[ing] businesses and consumers *in other States* of 'whatever competitive advantages they may possess' based on conditions of the local market." *Id.* at 339 (emphasis added) (quoting *Brown-Forman*, 476 U.S. at 580). Therefore, like *Baldwin*, concerns about economic protectionism were at the heart of *Healy*.

As then-Judge, now-Justice Gorsuch explained after closely analyzing the Court's opinions in *Baldwin*, *Brown-Forman*, and *Healy*, "[i]n all three cases, then, the Court . . . faced (1) a price control or price affirmation regulation, (2) linking in-state prices to those charged elsewhere, with (3) the effect of raising costs for out-of-state consumers or rival businesses." *EELI*, 793 F.3d at 1172–73; *see also Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 81 (1st Cir. 2001) ("The statutes in [*Baldwin*, *Brown-Forman*, and *Healy*] involved regulating the prices charged in the home state and those charged in other states in order to benefit the buyers and sellers in the home state, resulting in a direct burden on the buyers and sellers in the other states."). In other words, "a careful look at the holdings in [*Baldwin*, *Brown-Forman*, and *Healy*] suggests a concern with preventing discrimination against out-of-state rivals or consumers"—the concern over economic protectionism underlying the Supreme Court's dormant Commerce Clause jurisprudence, generally. *EELI*, 793 F.3d at 1173. The extraterritoriality doctrine, therefore, as explicated in *Baldwin*, *Brown-Forman*, and *Healy*, applies "*only* [to] price control or price affirmation statutes that link in-state prices with those charged elsewhere and discriminate against out-of-staters." *Id.* at 1174 (emphasis added).

Other circuits also have recognized the limited scope of the extraterritoriality doctrine, as the Supreme Court applied that doctrine in *Baldwin*, *Brown-Forman*, and *Healy*. *See Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937, 951 (9th Cir. 2013) ("*Healy* and *Baldwin* are not applicable to a statute that does not dictate the price of a product and does not 't[ie]' the price of its in-state products to out-of-state prices."); *IMS Health*, 616 F.3d at 30 (recognizing that the Supreme Court "has

only struck down two related types of statutes on extraterritoriality grounds"—price affirmation statutes and "statutes that force an out-of-state merchant to seek regulatory approval in one State before undertaking a transaction in another" (internal quotation marks omitted)).

Here, HB 631 is not a price affirmation statute, nor does it link in-state prices to out-of-state prices. HB 631 also does not dictate the prices that manufacturers or distributors charge to downstream purchasers in States other than Maryland. Additionally, it is undisputed that HB 631 does not favor in-state interests at the expense of out-of-state interests—it subjects out-of-state and in-state manufacturers and distributors to the same unconscionability limitation. And it is undisputed that HB 631 does not discriminate against interstate commerce—manufacturers and distributors remain free to engage in interstate commerce, they just may not charge unconscionable prices for essential generic drugs later sold to Maryland consumers. HB 631, therefore, does not violate the extraterritoriality doctrine, as that doctrine was applied in *Baldwin*, *Brown-Forman*, and *Healy*. Indeed, *Brown-Forman* expressly recognized that "a State may seek lower prices for its consumers"—precisely what HB 631 does—without violating the Commerce Clause. 476 U.S. at 580.

This Court reached a similar conclusion in *Star Scientific*, which involved a Virginia statute that imposed a per-cigarette escrow obligation on manufacturers of cigarettes sold in Virginia. 278 F.3d at 346. Any manufacturer that failed to put the money in escrow was subject to civil fines and barred from selling cigarettes to Virginia consumers. *Id.* Like AAM, Star Scientific argued that the escrow statute violated the

extraterritoriality doctrine as applied to cigarette manufacturers located outside of Virginia such as Star Scientific, because the statute "require[d] [Star Scientific] to make payments on cigarettes sold by it to *independent distributors in other states* if the cigarettes are later sold into Virginia." *Id.* at 354 (emphasis added). Also like AAM, Star Scientific asserted that *Healy*'s prohibition on a State's regulation of "commerce occurring wholly outside of its borders" barred States from "attempt[ing] to regulate *aspects of the stream of commerce*"—*i.e.*, transactions—"that occur upstream, outside the State's borders." *Id.* at 355 (emphasis added). This Court rejected that argument, holding that the Virginia statute did not violate the dormant Commerce Clause because the statute's applicability—like that of HB 631—was limited "to the sale of cigarettes 'within the Commonwealth.'" *Id.* at 356 (quoting Va. Code. Ann. § 3.1-336.2.A). This Court further distinguished *Brown-Forman* and *Healy* on grounds that the Virginia statute (1) was not "aiming at or reacting to *commerce outside of Virginia*," (2) "ha[d] no effect on transactions undertaken by out-of-state distributors *in other States*," and (3) "does not insist on price parity with cigarettes sold *outside of the State*." *Id.* (emphasis added).

Like the statute in *Star Scientific*, HB 631 applies only to essential generics drugs sold in Maryland. *See supra* Part II. And like the statute in *Star Scientific*, HB 631 is not "aim[ed]" at "commerce" outside of Maryland, has no effect on transactions undertaken by out-of-state distributors with consumers outside of Maryland, and does not insist on "price parity" with essential generic drugs sold outside of Maryland. *Id.* Accordingly,

HB 631 implicates none of the extraterritoriality concerns this Court recognized in *Star Scientific*.

In striking down HB 631, therefore, the majority opinion extends the extraterritoriality doctrine beyond the contexts in which the Supreme Court and this Court previously have applied it. The majority opinion acknowledges that in doing so, it diverges from the approach taken by several of our sister circuits, which interpret the extraterritoriality doctrine far more narrowly. *Ante* at 10. For several reasons, I do not believe such an expansion is warranted.

To begin, the majority opinion's expansive interpretation of the extraterritoriality doctrine substantially intrudes on the States' reserved powers to legislate to protect the health, safety, and welfare of their citizens. *See, e.g.*, *L'Hote v. City of New Orleans*, 177 U.S. 587, 596 (1900). The Supreme Court long has recognized that the limitation on state regulatory power imposed by the dormant Commerce Clause "is by no means absolute." *Lewis*, 447 U.S. at 36. "Rather, [i]n the absence of conflicting federal legislation, the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected." *Id.* "And because consumer protection is a field traditionally subject to state regulation, '[courts] should be particularly hesitant to interfere with [a] State's efforts [to protect consumers] under the guise of the [dormant] Commerce Clause.'" *SPGGC, LLC v. Blumenthal*, 505 F.3d 183, 194 (2d Cir. 2007) (quoting *United Haulers Ass'n v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 344 (2007)). Yet that is precisely what the majority opinion does in striking down HB 631, which amounts to an effort by

the Maryland legislature to protect some of the State's most vulnerable citizens from the abusive pricing practices detailed in the GAO and Senate Reports.

Additionally, the majority opinion's broad construction of the extraterritoriality doctrine also calls into question the constitutionality of numerous state antitrust and consumer protection statutes. For example, many States allow indirect purchasers to seek relief under their state antitrust laws against manufacturers which engage in an antitrust conspiracy, notwithstanding that such indirect purchasers did not purchase the allegedly price-fixed product directly from the manufacturer. *See California v. ARC Am. Corp.*, 490 U.S. 93, 99–100 (1989) (holding that the Sherman Act, which does not allow indirect purchaser actions, does not preempt state laws that allow indirect purchasers to obtain relief); *see also, e.g.*, *Brand Name Prescription Drugs*, 123 F.3d at 613 (applying Alabama antitrust law in indirect purchaser action by Alabama pharmacies against out-of-state drug manufacturers); *Clayworth v. Pfizer, Inc.*, 233 P.3d 1066, 1070 (Cal. 2010) (applying California antitrust law in indirect purchaser action by California pharmacies against out-of-state drug manufacturers). Yet under the majority opinion, all such laws would be unconstitutional to the extent they allow an in-state consumer to seek relief against an upstream out-of-state seller which sold the price-fixed product in an out-of-state transaction.

Likewise, numerous States impose safety, quality, and labeling restrictions on goods sold by out-of-state manufacturers through out-of-state distributors to in-state consumers. Courts consistently uphold such statutes in the face of Commerce Clause challenges as legitimate exercises of such States' police powers. *See, e.g.*, *Rocky*

Mountain Farmers Union v. Corey, 730 F.3d 1070, 1103–04 (9th Cir. 2013) (upholding California environmental regulation governing the composition of gasoline, which applied to out-of-state producers that distributed gasoline through out-of-state distributors, and explaining that "California may regulate with reference to local harms, structuring its internal markets to set incentives for firms to produce less harmful products *for sale in California*" (emphasis added)); *Int'l Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 647–48 (6th Cir. 2010) (rejecting dormant Commerce Clause challenge to state milk labeling law); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 110–12 (2d Cir. 2001) (rejecting dormant Commerce Clause challenge to state labeling law for lightbulbs). Yet under the broad construction of the extraterritoriality doctrine in the majority opinion, none of these statutes would pass constitutional muster because they regulate wholly out-of-state "transactions." *See EELI*, 793 F.3d at 1175 (rejecting broader construction of extraterritorial doctrine because "if any state regulation that 'control[s] . . . conduct' out of state is *per se* unconstitutional, wouldn't we have to strike down state health and safety regulations that require out-of-state manufacturers to alter their designs or labels"). None of the Supreme Court's extraterritoriality doctrine opinions provides any indication that the Court intended for the doctrine to invalidate such a broad swath of state statutes.

* * * * *

In sum, the Supreme Court's Commerce Clause jurisprudence does not support equating a single out-of-state transaction with "commerce" for purposes of the extraterritoriality doctrine. And contrary to the majority opinion's holding, 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. The majority opinion's application of the extraterritoriality doctrine also conflicts with the approach taken by several of our sister circuits, including in factually indistinguishable cases. And the majority opinion's expansion of the extraterritoriality doctrine significantly incurs on the States' reserved police powers and would render numerous longstanding state laws unconstitutional. In such circumstances, I cannot join the majority opinion's conclusion that HB 631 violates the extraterritoriality doctrine.

IV.

The majority opinion concludes that HB 631 violates the dormant Commerce Clause for two additional reasons: (1) "an analogous restriction imposed by a state other than Maryland has the potential to subject prescription drug manufacturers to conflicting state requirements" and (2) it "interferes with the natural function of the interstate market by superseding market forces that the dictate the price of a good." *Ante* at 17-18. I conclude that neither argument warrants barring Maryland—or any other State—from protecting its citizens from the abusive generic drug pricing practices the legislature sought to address.

Regarding the first reason, *Healy* directed courts confronted with extraterritoriality challenges to consider "how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect if not one, but many or every, State adopted similar legislation." 491 U.S. at 336. According to the majority opinion, HB 631 poses a risk of subjecting manufacturers to "'the kind of competing and interlocking

local regulation that the Commerce Clause was meant to preclude'" because "[i]f Maryland compels manufacturers to sell prescription drugs in the initial transaction at a particular price, but another state imposes a different price, then manufacturers could not comply with both laws in a single transaction." *Ante* at 18 (quoting *Healy*, 491 U.S. at 338). This contention is wrong as a matter of both fact and law.

As a matter of fact, HB 631 does not "compel[] manufacturers to sell prescription drugs . . . *at a particular price*." *Id.* (emphasis added). Rather, it forbids manufacturers from imposing an "unconscionable" price increase for essential generic drugs. § 2-801(c). Generic drug manufacturers, therefore, retain broad discretion to set prices for essential generic drugs and to increase the prices of such drugs, even if another state adopted a similar law. Accordingly, the majority opinion's contention that a manufacturer could not comply with two such laws in a single transaction is speculative, at best, and therefore does not offer a basis for striking down a state statute on extraterritoriality grounds, particularly when AAM identifies no State which has adopted, or intends to adopt, a potentially conflicting regulation. *See Rocky Mountain*, 730 F.3d at 1104–05 ("To show the threat of inconsistent regulation, Plaintiffs must either present evidence that conflicting, legitimate legislation is already in place or that the threat of such legislation is both actual and imminent." (internal quotation marks omitted)); *Sorrell*, 272 F.3d at 112 ("It is not enough to point to a risk of conflicting regulatory regimes in multiple states; there must be an actual conflict between the challenged regulation and those in place in other states.").

As a matter of law, the majority opinion does not cite any authority—nor have I found any—holding that the dormant Commerce Clause entitles manufacturers to consummate all sales to a distributor in "a single transaction." On the contrary, as the majority opinion acknowledges, *ante* at 18, courts have recognized that a State can adopt a consumer protection law that may require a manufacturer to sell different products or versions of products for resale in the State than it sells in other States. For example, in *Sorrell*, the Second Circuit considered an extraterritoriality challenge to a Vermont statute that required special labeling on all mercury-containing light bulbs sold in Vermont. 272 F.3d at 107. A trade group representing light bulb manufacturers challenged the statute on extraterritoriality grounds, asserting that "[g]iven the manufacturing and distribution systems used by its members . . . if its members continue selling in Vermont, they would also be forced as a practical matter to label lamps sold in every other state." *Id.* at 110. The court rejected that argument, explaining that, by its terms, the statute did "not inescapably require manufacturers to label" lamps sold outside of Vermont and that "[t]o avoid the statute's alleged impact on other states, lamp manufacturers could arrange their production and distribution processes to produce labeled lamps solely for the Vermont market." *Id.*

Likewise, in *International Dairy*, the Sixth Circuit considered an extraterritoriality challenge by milk processors to an Ohio law regulating milk products on grounds that "due to the complex national distribution channels through which milk products are delivered" and the costs associated with altering the nationwide distribution system, milk processors would be "forced" to comply with the Ohio law "nationwide." 622 F.3d at

647. The court rejected that argument, emphasizing that the Ohio law did not require processors to sell milk in other States in conformance with the Ohio regulation, nor did it preclude other States from regulating milk in a different manner. *Id.* at 647–48; *see also SPGGC*, 505 F.3d at 194 (concluding that state consumer protection law regulating the terms and conditions of gift cards did not violate extraterritoriality doctrine because the law did not "directly regulate sales of gift cards in other states" and did not "prevent other states from regulating gift card sales differently within their own territories").

Like the statutes at issue in *Sorrell* and *International Dairy*, HB 631 does not require generic drug manufacturers to sell drugs destined for resale outside of Maryland at conscionable prices. On the contrary, HB 631 does not purport to regulate the price of essential generic drugs that do not enter Maryland's borders, nor does it bar other States from regulating differently the price of essential generic drugs sold to consumers within their borders. And AAM has not argued—much less proven—that its members could not restructure their distribution processes and contracts to ensure that distributors do not resell unconscionably priced generic drugs into Maryland. Again to the contrary, there would seem to be no obstacle to a generic drug manufacturer entering into a single contract with a distributor for an essential generic drug, under which the manufacturer imposes a conscience-shocking price increase for those pills the distributor resells outside of Maryland and a non-conscience-shocking price increase for the pills the distributor resells in Maryland. The contract could further require the distributor to indemnify the manufacturer against any liability resulting from any unconscionably priced pills that make their way into the Maryland market, unintentionally or otherwise. Accordingly,

"[t]o the extent [HB 631] may be said to 'require' [conscionable pricing for drugs] sold outside [Maryland], then, it is only because the manufacturers are unwilling to modify their production and distribution systems to differentiate between [Maryland]-bound and non-[Maryland]-bound [drugs]." *Sorrell*, 272 F.3d at 110. That is not a basis for relying on the dormant Commerce Clause to invalidate a state consumer protection statute, like HB 631.[4] *Id.* at 110–11.

The majority opinion's assertion that HB 631 violates the dormant Commerce Clause because it "'interferes with the natural function of the interstate market' by superseding market forces that dictate the price of a good" fares no better. *Ante* at 18 (quoting *McBurney v. Young*, 569 U.S. 221, 235 (2013)). As a matter of fact, the market at issue—like many markets for health care goods and services—is not one that "natural[ly] function[s]." *See generally* Erin C. Fuse Brown, *Resurrecting Health Care Rate Regulation*, 67 Hastings L.J. 85, 92-103 (2015) (describing a variety of market failures in the health care system). On the contrary, the essential generic drugs at issue in this case present classic examples of market failure. The "business model" detailed in the Senate Report—which HB 631 targets—shows that the generic drug manufacturers that

[4] The majority opinion further maintains that complying with HB 631 "would require more than modification of [manufacturers'] distribution systems; it would force them to enter into a separate transaction for each state in order to tailor their conduct so as not to violate any state's price restrictions." *Ante* at 18. But at this preliminary juncture of the litigation, AAM has put forward no evidence that other States intend to impose similar statutes regulating the pricing of generic drugs, let alone evidence that its members would have to enter into "separate transaction[s]" to comply with multiple such laws, rather than by simply modifying their distribution systems and contracts.

imposed conscience-shocking price increases exploited patients who were at a gross disadvantage in terms of bargaining power. That disadvantage derived from a lack of alternative manufacturers of the drugs—such increases were generally imposed for single-source generic drugs distributed through a "closed distribution system"—and from the fact that the drugs were essential to treating rare and life-threatening conditions. Senate Report at 4, 30–31. Because such patients lack alternatives and face a debilitating illness or even death absent these drugs, they must accept whatever price a manufacturer charges.

The Senate Report reveals that the generic manufacturers recognized and sought to exploit this bargaining inequality by imposing dramatic price increases. For example, Retrophin CEO Shkreli stated in an email explaining a 1,900 percent increase for one generic drug, which was the "only treatment for a rare disease called cystinuria," that "[t]he next generation of pharma guys (or the smart ones) understand the inelasticity of certain products. The insurers really don't care. They just pass [the price increase] through [to patients]." *Id.* at 41, 44–45. Likewise, Valeant CEO J. Michael Pearson explained that Valeant had monopoly "pricing power" for another generic drug that is the standard-of-care for treating a rare and deadly disease—and therefore was able to impose a multiple-thousand-fold price increase—because, absent the drug, patients would face "liver failure or a liver transplant or even death." *Id.* at 6, 56.

By analogy to the issue in this case, the Supreme Court long has recognized that States may "supersede market forces," *ante* at 18, by imposing wage and price restrictions when gross inequality in bargaining power leads to market failure, *see, e.g.*,

W. Coast Hotel Co. v. Parrish, 300 U.S. 379, 399 (1937) (upholding state minimum wage law because, in part, "[t]he exploitation of a class of workers who are in unequal position with respect to bargaining power and are thus relatively defenseless against the denial of a living wage is not only detrimental to their health and well being, but casts a direct burden for their support on the community.").

As a matter of law, since the demise of the *Lochner* doctrine, the Supreme Court has held that "[t]he Constitution does not guarantee the unrestricted privilege to engage in a business or conduct it as one pleases," and therefore that "statutes prescribing the terms upon which those conducting certain businesses may contract, or imposing terms if they do enter into agreements, are within the state's competency." *Nebbia v. New York*, 291 U.S. 502, 527–28 (1934). To that end, the Supreme Court and lower courts have rejected numerous constitutional challenges to nondiscriminatory state statutes that control the price of goods or services, or otherwise interfere with "market forces that dictate the price of a good" or service. *See, e.g.*, *Milk Control Bd.*, 306 U.S. at 351–53 (rejecting dormant Commerce Clause challenge to Pennsylvania law establishing minimum prices for milk); *W. Coast Hotel*, 300 U.S. at 398–400 (upholding Washington minimum wage law for female employees); *Nebbia*, 291 U.S. at 515, 539 (upholding New York law which established a "Milk Control Board" to fix minimum and maximum retail prices for milk); *All. of Auto. Mfrs. v. Gwadosky*, 430 F.3d 30, 32–33 (1st Cir. 2005) (rejecting dormant Commerce Clause challenge to Maine law prohibiting motor vehicle manufacturers from "adding state-specific surcharges to wholesale motor vehicle prices in order to recoup the costs of their compliance with [state] retail-reimbursement laws"); *Grant's Dairy—*

Maine, LLC v. Comm'r of Me. Dep't of Agric., Food & Rural Res., 232 F.3d 8, 19–24 (1st Cir. 2000) (rejecting dormant Commerce Clause challenge to Maine law establishing minimum price for milk). Accordingly, even if the markets for essential generic drugs were "natural[ly] function[ing]"—which they are not—Maryland would be entitled to regulate prices charged in those markets for the public interest, so long as the regulation did not favor in-state interests at the expense of out-of-state interests or discriminate against interstate commerce.

V.

In striking down HB 631—legislation enacted to restrain abusive generic drug pricing practices specifically designed to prey on the special vulnerabilities of a defenseless group of Maryland citizens—the majority opinion "empower[s] the judiciary and leave[s] . . . state legislatures and everyone else on the sidelines." *Kolbe v. Hogan*, 849 F.3d 114, 150 (4th Cir. 2017) (Wilkinson, J., concurring). To begin, the majority opinion ignores basic principles of federalism and judicial restraint to reject the State's own interpretation of the statute's extraterritorial reach. Then, relying on its own expansive interpretation of HB 631's reach, the majority opinion extends the extraterritoriality doctrine beyond the contexts in which the Supreme Court and this Court previously have applied it, and in a manner contrary to the approach taken by several other circuits. The majority opinion's expansive conception of the extraterritoriality doctrine renders numerous state consumer protection statutes unconstitutional, and significantly expands federal courts' authority to second-guess

States' efforts to protect their citizens. I do not believe that either the Framers or the Supreme Court intended for the Commerce Clause to serve such a purpose.

At the end of the day, AAM argues—and the majority opinion concludes—that, absent federal regulation, its members are *constitutionally entitled* to impose conscience-shocking price increases on Maryland consumers, so long as AAM's members sell their essential generic drugs to Maryland consumers through out-of-state intermediaries. But "[t]he Constitution does not secure to any one liberty to conduct his business in such fashion as to inflict injury upon the public at large, or upon any substantial group of the people." *Nebbia*, 291 U.S. at 538–39. And the dormant Commerce Clause is not a "roving license" for federal courts to strike down non-discriminatory state consumer protection laws, like HB 631. *SPGGC*, 505 F.3d at 194 (quoting *United Haulers*, 550 U.S. at 343). Accordingly, I respectfully dissent from the majority opinion's conclusion that HB 631 violates the extraterritoriality doctrine.