# APPENDIX A

887 F.3d 664

United States Court of Appeals, Fourth Circuit.

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.

No. 17-2166
|
Argued: January 24, 2018
|
Decided: April 13, 2018

## Attorneys and Law Firms

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.

Before AGEE, WYNN, and THACKER, Circuit Judges.

**Opinion**

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

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 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.

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[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.

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, 128 S.Ct. 1801, 170 L.Ed.2d 685 (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, 109 S.Ct. 2491, 105 L.Ed.2d 275 (1989); *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 582–83, 106 S.Ct. 2080, 90 L.Ed.2d 552 (1986); *Edgar v. MITE Corp.*, 457 U.S. 624, 642–43, 102 S.Ct. 2629, 73 L.Ed.2d 269 (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, 109 S.Ct. 2491 (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.*, 278 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, 55 S.Ct. 497, 79 L.Ed. 1032 (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, 55 S.Ct. 497. 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, 55 S.Ct. 497. 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, 55 S.Ct. 497.

A plurality of the Court expounded on this concept nearly half a century later in *Edgar v. MITE Corp.*, 457 U.S. 624, 102 S.Ct. 2629, 73 L.Ed.2d 269 (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, 102 S.Ct. 2629 (internal footnote omitted). The Illinois Secretary of State had the authority "to deny registration to a tender offer" under certain circumstances. *Id.* at 627, 102 S.Ct. 2629. 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, 102 S.Ct. 2629. 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, 106 S.Ct. 2080, 90 L.Ed.2d 552 (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, 106 S.Ct. 2080. 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, 106 S.Ct. 2080. As a result, the law was invalid. *See id.* at 584, 106 S.Ct. 2080.

Just three years later, the Supreme Court considered a similar Connecticut law in *Healy v. Beer Institute*, 491 U.S. 324, 109 S.Ct. 2491, 105 L.Ed.2d 275 (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, 109 S.Ct. 2491. From its "cases concerning the extraterritorial effects of state economic regulation," *id.* at 336, 109 S.Ct. 2491 (citing *Brown-Forman*, 476 U.S. at 579, 581–83, 106 S.Ct. 2080; *Edgar*, 457 U.S. at 642–43, 102 S.Ct. 2629; *Baldwin*, 294 U.S. at 528, 55 S.Ct. 497), 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, 109 S.Ct. 2491. 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, 55 S.Ct. 497).
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> 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.*
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> 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, 109 S.Ct. 2491. 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, 109 S.Ct. 2491.

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, 109 S.Ct. 2491. 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, 123 S.Ct. 1855, 155 L.Ed.2d 889 (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, 123 S.Ct. 1855. The

petitioner challenged the law on the basis "that the rebate requirement constitutes impermissible extraterritorial regulation." *Id.* at 669, 123 S.Ct. 1855. 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, 123 S.Ct. 1855. 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, 102 S.Ct. 2629; *see also*

*Healy*, 491 U.S. at 333 n.9, 109 S.Ct. 2491 (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 residing in [Maryland]."). The district court thus erred in relying on the Act's "made available for sale" language to uphold the Act.

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[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.

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, 106 S.Ct. 2080 ("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]

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[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, 109 S.Ct. 2491 ("[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, 102 S.Ct. 2629)); *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, 123 S.Ct. 1855)).

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, 123 S.Ct. 1855 (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, 109 S.Ct. 2491; *Brown-Forman*, 476 U.S. at 582, 106 S.Ct. 2080. 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, 106 S.Ct. 2080.

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, 123 S.Ct. 1855. 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, 109 S.Ct. 2491 ("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, 106 S.Ct. 2080)). 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, 109 S.Ct. 2491 ("[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, 109 S.Ct. 2491 ("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, 106 S.Ct. 2080. 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, 98 S.Ct. 2207, 57 L.Ed.2d 91 (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, 133 S.Ct. 1709, 185 L.Ed.2d 758 (2013) (quoting *Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794, 806, 96 S.Ct. 2488, 49 L.Ed.2d 220 (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, 109 S.Ct. 2491. 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, 123 S.Ct. 1855.

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 692–93. 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*

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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 671–72. 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, 100 S.Ct. 2009, 64 L.Ed.2d 702 (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, 128 S.Ct. 1801, 170 L.Ed.2d 685 (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.

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[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 [sic] 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 670; *see also id.* at 670–71 ("[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 671 (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 671, 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, 128 S.Ct. 1184, 170 L.Ed.2d 151 (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*, 363 Md. 77, 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, 109 S.Ct. 2491, 105 L.Ed.2d 275 (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, 128 S.Ct. 1801 (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, 109 S.Ct. 2491; *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, 131 S.Ct. 3091, 180 L.Ed.2d 911 (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, 55 S.Ct. 497, 79 L.Ed. 1032 (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, 109 S.Ct. 2491 (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 671 (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, 6 L.Ed. 23 (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, 56 S.Ct. 855, 80 L.Ed. 1160 (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, 56 S.Ct. 855. 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, 56 S.Ct. 855. 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, 56 S.Ct. 855. *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, 52 S.Ct. 559, 76 L.Ed. 1062 (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, 15 S.Ct. 249, 39 L.Ed. 325 (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, 57 S.Ct. 615, 81 L.Ed. 893 (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, 63 S.Ct. 82, 87 L.Ed. 122 (1942)—which held that the growing of wheat for personal consumption constituted commercial activity subject to congressional regulation, *id.* at 128–29, 63 S.Ct. 82—"[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, 63 S.Ct. 82. 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]

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[2] The majority opinion notes that in *Pharmaceutical Research & Manufacturers of America v. Walsh*, 538 U.S. 644, 123 S.Ct. 1855, 155 L.Ed.2d 889 (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 670 (emphasis added) (quoting *Walsh*, 538 U.S. at 669, 123 S.Ct. 1855 (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 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.

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, 15 S.Ct. 249. 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)).

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, 109 S.Ct. 2491, 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, 97 S.Ct. 2061, 52 L.Ed.2d 707 (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. 573 (1986), *ante* at 667–70[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,

[3] The majority opinion also relies on the Supreme Court's decision in *Edgar v. MITE Corp.*, 457 U.S. 624, 102 S.Ct. 2629, 73 L.Ed.2d 269 (1982), which addressed whether a state anti-takeover statute violated the Supremacy and Commerce Clauses of the Constitution. *Ante* at 667–68. 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, 102 S.Ct. 2629 (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, 107 S.Ct. 1637, 95 L.Ed.2d 67 (1987).

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.

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, 55 S.Ct. 497. 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, 55 S.Ct. 497. 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, 55 S.Ct. 497. "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, 106 S.Ct. 2080 (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, 59 S.Ct. 528, 83 L.Ed. 752 (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, 106 S.Ct. 2080. 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, 106 S.Ct. 2080. 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, 106 S.Ct. 2080 ("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, 109 S.Ct. 2491. 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, 109 S.Ct. 2491. 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, 109 S.Ct. 2491. 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, 109 S.Ct. 2491 (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, 109 S.Ct. 2491. 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, 109 S.Ct. 2491 (emphasis added) (quoting *Brown-Forman*, 476 U.S. at 580, 106 S.Ct. 2080). 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, 106 S.Ct. 2080.

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 [sic] 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 669. 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, 20 S.Ct. 788, 44 L.Ed. 899 (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, 100 S.Ct. 2009. "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, 127 S.Ct. 1786, 167 L.Ed.2d 655 (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, 109 S.Ct. 1661, 104 L.Ed.2d 86 (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.*, 49 Cal.4th 758, 111 Cal.Rptr.3d 666, 233 P.3d 1066, 1070 (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 [sic] dictate the price of a good." *Ante* at 673–74. 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, 109 S.Ct. 2491. 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 673 (quoting *Healy*, 491 U.S. at 338, 109 S.Ct. 2491). 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 673, 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 673 (quoting *McBurney v. Young*, 569 U.S. 221, 235, 133 S.Ct. 1709, 185 L.Ed.2d 758 (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]."

[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 673–74. 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.

*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 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 673, 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, 57 S.Ct. 578, 81 L.Ed. 703 (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, 54 S.Ct. 505, 78 L.Ed. 940 (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, 59 S.Ct. 528 (rejecting dormant Commerce Clause challenge to Pennsylvania law establishing minimum prices for milk); *W. Coast Hotel*, 300 U.S. at 398–400, 57 S.Ct. 578 (upholding Washington minimum wage law for female employees); *Nebbia*, 291 U.S. at 515, 539, 54 S.Ct. 505 (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, 54 S.Ct. 505. 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, 127 S.Ct. 1786). Accordingly, I respectfully dissent from the majority opinion's conclusion that HB 631 violates the extraterritoriality doctrine.

## APPENDIX B

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United States District Court,
D. Maryland.

ASSOCIATION FOR ACCESSIBLE MEDICINES,
Plaintiff
v.
FROSH, et al., Defendants

CIVIL ACTION NO. MJG-17-1860

Signed 09/29/2017

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MEMORANDUM AND ORDER RE: MOTION TO DISMISS AND PRELIMINARY INJUNCTION

Marvin J. Garbis, United States District Judge

The Court has before it Defendants' Motion to Dismiss [ECF No. 29], Plaintiff's Motion for Preliminary Injunction [ECF No. 9] and the materials submitted relating thereto. The Court has held a hearing and has had the benefit of the arguments of counsel.

## I. BACKGROUND

Plaintiff Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing a number of manufacturers and distributors of generic and biosimilar medicines. AAM brings an action for declaratory and injunctive relief under the Commerce Clause and the Fourteenth Amendment Due Process Clause, pursuant to 42 U.S.C. § 1983 and § 1988, against Brian E. Frosh and Dennis R. Schrader in their respective capacities as Attorney General for the State of Maryland and Secretary of the Maryland Department of Health (collectively, "Defendants").

AAM challenges the constitutionality of Maryland's House Bill 631 ("HB 631"), which prohibits manufacturers and wholesale distributors from engaging in price-gouging in the sale of essential off–patent or generic drugs that are made available for sale in Maryland. § 2-802(a). AAM alleges that HB 631 violates the dormant Commerce Clause as applied to the sales of drugs between out-of-state manufacturers and out-of-state wholesale distributors. Additionally, AAM brings a facial challenge to HB 631 as impermissibly vague under the Due Process Clause of the Fourteenth Amendment.

### A. History of HB 631

Defendants state that HB 631 "seeks to protect Marylanders from the imposition of unconscionable price increases for certain off-patent or generic drugs in circumstances of market failure or dysfunction."

Defs.' Mot. Dismiss at 1, ECF No. 29-1. It was enacted in response to two government reports detailing price-gouging of off-patent drugs under specific market conditions. *Id.* at 4.

One of the reports, issued by the U.S. Senate's bipartisan Special Committee on Aging, is entitled "Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System." Defs.' Mot. Dismiss Ex. A ("U.S. Senate Report"). This Report describes a "business model" in which some generic drug companies would choose to produce a drug serving a small market for which there was only one manufacturer, ensure the drug was the "gold standard" for the condition it treats, control access to the drug through a closed distribution system or specialty pharmacy, and engage in "price gouging," or "maximizing profits by jacking up prices as high as possible." U.S. Senate Report at 4. Illustrations provided of this "business model" included:

- Turing's increase of Daraprim (which treats the life-threatening toxoplasmosis) from $13.50 to $750.00 per pill, a more than 5000% increase,
- Retrophin's increase of Thiola (which treats a genetic kidney disease) from $1.50 to $30.00 per pill, a nearly 2000% increase,
- Valeant's increase of Cuprimine and Syphine supplies (which treat Wilson's disease) from a few hundred dollars per

supply to $26,189.00 or $21,267.00 per supply, respectively, corresponding to 5,785% and 3,162% increases; and

- Rodelis's increase of 30 capsules of Seromycin (which treats a life-threatening form of multi-drug resistant tuberculosis) from $500.00 to $10,800.00, an increase of 2060%.

*Id.* at 4–6.

The second report, issued by the Government Accountability Office in August 2016, studied a basket of 1,441 established generic drugs and found that, during the period from 2010 to 2015, manufacturers had imposed at least one "extraordinary price increase" for 315 of those drugs.[1] Defs.' Mot. Dismiss Ex. B at 12 ("GAO Report"). Moreover, "out of the 351 extraordinary price increases, 48 were 500 percent or higher and 15 were 1,000 percent or higher." GAO Report at 14.

HB 631 was introduced in early 2017 and passed both houses of the Maryland General Assembly by large bipartisan majorities. Although it was not signed by Governor Larry Hogan, it is scheduled to go into effect on October 1, 2017.

B. Text of HB 631

Under HB 631, "[a] manufacturer or wholesale distributor may not engage in price gouging in the sale

[1] An "extraordinary price increase" is defined as an increase of more than 100% within a one-year period. GAO Report at 45.

of an essential off-patent or generic drug." § 2-802(a).[2] "Price gouging" is defined as "an unconscionable increase in the price of a prescription drug." § 2-801(c). The term "[u]nconscionable increase" is defined as

> an increase in the price of a prescription drug that:
>
> (1) Is 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) Results in consumers for whom the drug has been prescribed having no meaningful choice about whether to purchase the drug at an excessive price because of:
>
> (i) The importance of the drug to their health; and
>
> (ii) Insufficient competition in the market for the drug.

§ 2-801(f). HB 631 contains a reporting provision that authorizes the Maryland Medical Assistance Program ("MMAP") to notify the Attorney General when there is an increase in a drug price that amounts to an increase of "50% or more in the wholesale acquisition

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[2] "Essential off-patent or generic drug" is defined as any prescription drug that is (1) off-patent, (2) appears on the Model List of Essential Medicines adopted by the World Health Organization or designated by the Secretary as essential, (3) is "actively manufactured and marketed for sale in the United States by three or fewer manufacturers," and (4) is "made available for sale in the State." § 2-801(b)(1).

cost of the drug" within the preceding one year, or if a 30-day supply or full course of treatment would "cost more than $80 at the drug's wholesale acquisition cost."[3] § 2-803(a). If there is such a notification by MMAP, the Attorney General may request the manufacturer to submit a statement to the Attorney General justifying the price increase. § 2-803(b). The Attorney General also has the power to require a manufacturer or distributor to produce records relevant to determining whether a violation has occurred. § 2-803(c).

Finally, HB 631 authorizes Maryland Circuit Courts,[4] on petition of the Attorney General, to issue orders to compel the violating party to produce certain records, to restrain or enjoin a violation, to restore to any consumer money lost as a result of the violation, to require a violating party engaging in price-gouging to make the drug available at the pre-violation price for one year, and to impose a civil penalty of up to $10,000 for each violation. § 2-803(d). Except for compelling parties to produce records, the Attorney General may not bring an action without first giving the violating party an opportunity to justify the price increase. § 2-803(e). It is not a defense that the manufacturer or distributor did not deal directly with a consumer residing in Maryland. § 2-803(g).

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[3] The term "wholesale acquisition cost" is given the same meaning in HB 631 as in 42 U.S.C. § 1395w-3A. § 2-801(g).

[4] At the hearing, counsel for Defendant Frosh confirmed that Frosh's interpretation of HB 631's reference to "circuit court" is that it means "Maryland Circuit Court" only, not the courts of any other jurisdiction.

## II. MOTION TO DISMISS

### A. LEGAL STANDARD

A motion to dismiss filed pursuant to Rule 12(b)(6) tests the legal sufficiency of a complaint. A complaint need only contain "'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citations omitted). When evaluating a 12(b)(6) motion to dismiss, a plaintiff's well-pleaded allegations are accepted as true and the complaint is viewed in the light most favorable to the plaintiff. However, conclusory statements or "a formulaic recitation of the elements of a cause of action will not [suffice]." *Id.* A complaint must allege sufficient facts "to cross 'the line between possibility and plausibility of entitlement to relief.'" *Francis v. Giacomelli*, 588 F.3d 186, 193 (4th Cir. 2009) (quoting *Twombly*, 550 U.S. at 557). Inquiry into whether a complaint states a plausible claim is "'a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.'" *Id.* Thus, if "the well-pleaded facts [contained within a complaint] do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)).

B. DORMANT COMMERCE CLAUSE CHALLENGE

i. Legal Standard

To determine whether a state statute violates the dormant Commerce Clause, the court must conduct a two-tiered analysis. *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 579 (1986); *Star Scientific Inc. v. Beales*, 278 F.3d 339, 355 (4th Cir. 2002).

Under the first tier, "[w]hen a state statute directly regulates or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests," the statute is generally struck down "without further inquiry." *Brown-Forman*, 476 U.S. at 579. Thus, for state statutes that discriminate against interstate commerce, the court applies "a virtually *per se* rule of invalidity." *Philadelphia v. New Jersey*, 437 U.S. 617, 624 (1978), *see also Wyoming v. Oklahoma*, 502 U.S. 437, 454–55 (1992).

When a statute does not discriminate against interstate commerce but "regulates even-handedly" and only incidentally affects interstate commerce, the court conducts a second tier analysis, involving a balancing test first articulated under *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). Under this balancing test, courts look to "whether the State's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits." *Brown-Forman*, 476 U.S. at 579. "A 'less strict scrutiny' applies under [this]

undue burden tier." *Yamaha Motor Corp., U.S.A. v. Jim's Motorcycle, Inc.*, 401 F.3d 560, 567 (4th Cir. 2005) (internal citations omitted).

Based on recent Supreme Court precedent, there may be an emerging "third strand" of analysis that applies to "certain price control and price affirmation laws that control 'extraterritorial' conduct—that is, conduct outside the state's borders." *Energy & Env't Legal Inst. v. Epel*, 793 F.3d 1169, 1172 (10th Cir. 2015), *cert. denied*, 136 S. Ct. 595 (2015). Three Supreme Court decisions illustrate the reasoning under this "third strand," or extraterritoriality principle: *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935), *Brown-Forman*, 476 U.S. 573 (1986), and *Healy v. Beer Inst., Inc.*, 491 U.S. 324 (1989).

In *Baldwin*, the Supreme Court struck down a New York law that prohibited out-of-state companies from selling milk in the state unless they purchased their milk from dairy farmers at the same price paid to New York dairy farmers. The Court explained that it impermissibly established "a wage scale or a scale of prices for use in other states," and would "bar the sale of the products, whether in the original packages or in others, unless the scale has been observed." *Baldwin*, 294 U.S. at 528.

In *Brown-Forman*, the Supreme Court struck down a provision of the New York Alcoholic Beverage Control Law that required liquor distillers or producers selling to wholesalers within the state to affirm that their prices for products sold to in-state

wholesalers were no higher than the lowest price at which the same product was sold in any other state during that month. The Court found that, although the statute was addressed only to the sale of liquor in New York, it had the impermissible "practical effect" of controlling liquor prices in other states. *Brown-Forman*, 476 U.S. at 583.

Similarly, in *Healy*, the Supreme Court struck down the Connecticut Liquor Control Act, which required out-of-state beer shippers to affirm that the prices of their products sold to Connecticut wholesalers were no higher than the prices of those same products sold in bordering states. The Court reasoned that the statute tied pricing decisions to the regulatory schemes of these bordering states, thus preventing brewers from undertaking competitive pricing in other states. *Healy*, 491 U.S. at 338–39.

The Supreme Court and other courts have stated that this extraterritoriality principle is limited to price-control statutes or price-affirmation statutes which link prices paid in-state with those paid out-of-state. *See Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 669 (2003); *Energy & Env't Legal Inst.*, 793 F.3d at 1175 (explaining that extending the *Baldwin* doctrine to become a "weapon far more powerful than" the two established tiers would be a "novel lawmaking project [the court] decline[s] to take up on [its] own"); *Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937, 951 (9th Cir. 2013) ("[t]he Supreme Court has explained that *Healy* and *Baldwin* involved 'price control or price affirmation statutes' " and

are inapplicable 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.' ").

In *Walsh*, nonresident drug manufacturers challenged a Maine statute that required certain manufacturers selling drugs in Maine to enter into a rebate agreement with the Maine State Commissioner, or else meet a set of prior authorization requirements to dispense drugs in the state. *Walsh*, 538 U.S. at 653–54. The *Walsh* plaintiff argued that "with the exception of sales to two resident distributors, all of their prescription drug sales occur outside of Maine," so the act must be impermissible extraterritorial regulation. *Id.* at 656. The Supreme Court disagreed, explaining that the rule articulated in *Baldwin* and *Healy* "is not applicable to this case" because the Maine Act is not a price-control or price-affirmation statute, does not regulate prices of any out-of-state transaction, and does not tie in-state prices to out-of-state ones. *Id.* at 669.

The Fourth Circuit has also declined to apply the *Baldwin*, *Brown-Forman*, and *Healy* price-parity principle in a situation similar to the context of the instant case involving HB 631. In *Star Scientific*, a cigarette manufacturer challenged the constitutionality of the Master Settlement Agreement ("MSA") between the Commonwealth of Virginia and the major tobacco manufacturers, which assesses an escrow payment amount on each cigarette sold by nonparticipating tobacco manufacturers "within the Commonwealth, whether directly or through a distributor, retailer, or similar intermediary or intermediaries." *Star*

*Scientific*, 278 F.3d at 354. Presenting a "third-strand" extraterritoriality argument, the *Star Scientific* plaintiff contended that the statute required it to "make payments on cigarettes sold by it to independent distributors in other states if the cigarettes are later sold into Virginia," and thus "regulates transactions beyond the Commonwealth's borders." *Id.*

The Fourth Circuit distinguished the *Star Scientific* statute from the laws at issue in *Healy* and *Brown-Forman*, because Virginia's *Star Scientific* statute expressly limited its applicability to the sale of cigarettes "within the Commonwealth." *Star Scientific*, 278 F.3d at 356. Moreover, the court noted that to the extent that the statute may affect the prices charged by out-of-state distributors, the effect would be "applicable only to prices charged on cigarettes sold within Virginia." *Id.* Because the statute did not insist on "price parity" with the prices of cigarettes sold outside of the state, it did not have the "'practical effect' of controlling prices or transactions occurring wholly outside of the boundaries of Virginia, as was the case in *Brown-Forman* and *Healy*." *Id.*

ii. Application to HB 631:
First Tier and Extraterritoriality

Regardless of whether these extraterritoriality cases are construed as a separate line of cases or as applications of the first tier analysis, *Energy & Env't Legal Inst.*, 793 F.3d at 1174–75, this Court must follow *Star Scientific's* reasoning. Like the plaintiff in

*Star Scientific*, AAM argues that HB 631 impermissibly regulates conduct occurring wholly outside the state, because its members are manufacturers and wholesalers of generic drugs who almost all reside outside of Maryland, operate under national contracts, and do not sell directly to actors in Maryland.[5] Pl.'s Opp. Mot. Dismiss at 21, ECF No. 36. Even if that characterization is correct,[6] that argument was rejected by the Fourth Circuit in *Star Scientific* and must be rejected here.

The structure of HB 631 is similar to the challenged statute in *Star Scientific*. HB 631 only regulates drug manufacturers or wholesale distributors engaging in the sale of an essential off-patent or generic drug "made available for sale in the State." § 2-801(b)(1). The Virginia statute in *Star Scientific* regulates tobacco product manufacturers selling cigarettes to consumers within the Commonwealth, "whether directly or through a distributor, retailer or similar intermediary or intermediaries." Va. Code Ann. § 3.2-4200. Therefore, both HB 631 and the *Star Scientific* statute apply only to products being made available for sale *within* the boundaries of the state, and both laws

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[5] AAM's pre-implementation challenge to HB 631 under the dormant Commerce Clause only applies to sales between out-of-state manufacturers and out-of-state distributors. AAM concedes that the statute would not violate the dormant Commerce Clause as applied to manufacturers or wholesalers who sell drugs directly to a person or entity within Maryland's borders.

[6] Defendants note that almost all of AAM's members hold a Maryland wholesale distributor permit. Defs.' Suppl. Statement at 2, ECF No. 34.

place liability on the out-of-state manufacturer whether or not the Maryland sale was direct or through an intermediary.

To the extent that HB 631 may affect the prices charged by out-of-state distributors or producers, the effect would be applicable only to prices charged on drugs to be sold within Maryland. As with the challenged law in *Star Scientific*, HB 631 does not tie the price charged on the sales of in-state drugs with the price charged on the sales of out-of-state drugs. Because HB 631 does not "insist on price parity" with drugs sold outside of the state, it does not have the "practical effect" of regulating commerce occurring wholly outside of the state, as was the case in *Baldwin*, *Brown-Forman*, and *Healy*. *Star Scientific*, 278 F.3d at 356.

AAM tries to distinguish *Star Scientific* by arguing that the punishable act in *Star Scientific* was refusing to pay the required escrow amount on each cigarette sold by nonparticipating tobacco manufacturers within Virginia (which is "in-state"), whereas the punishable act under HB 631 is the sale of drugs at unconscionable prices between an out-of-state manufacturer and an out-of-state distributor. Hearing Rough Tr. at 9:14-24 (Sept. 14, 2017).

AAM's comparison is inaccurate. HB 631 and the *Star Scientific* statute are triggered only when there is a drug or a cigarette made available for sale *within* the state. Whether any subsequent fine or escrow payment is made within Maryland is not relevant to the

analysis. Under HB 631, a sale of drugs between an out-of-state manufacturer and an out-of-state distributor—regardless of the price—does not give rise to liability. Only if those drugs are then made available for sale in Maryland would the provisions of HB 631 apply to the transaction. Indeed, HB 631 is more limited in scope than the law in *Star Scientific*: whereas the *Star Scientific* law applied to each and every sale of tobacco, HB 631 only applies to specific essential drugs made available in the state at an unconscionable price and under certain market conditions.

AAM also points to the language in *Healy* and *Brown-Forman* cautioning against laws that apply to commerce taking place "wholly outside" of the state's borders, or having the "practical effect" of regulating commerce occurring wholly outside that state's borders. *Brown-Forman*, 476 U.S. at 582; *Healy* at [sic] 491 U.S. at 336. However, when read within the decision as a whole, these statements were clearly made in the context of one state attempting to tie the price of a good inside the state with the price charged for the good in another state. *See Brown-Forman*, 476 U.S. 573 at 583 (explaining the practical effect under the New York price-affirmation statute that once a distiller's posted price "is in effect in New York, it must seek the approval of the New York State Liquor Authority" before lowering prices for the same item in other states); *Healy*, 491 U.S. at 332–33 ([T]he Commerce Clause does not permit a state "to establish a wage scale or a scale of prices for use in other states. . . ."), *quoting Baldwin*, 294 U.S. at 528.

AAM repeatedly cites these statements without adequately engaging with the fact that HB 631 could only give rise to liability when the drug is made available for sale in Maryland. These statements from *Brown-Forman*, *Healy*, and *Baldwin* do not stand for the much broader proposition that a regulation that has effects outside the state is *per se* invalid. *C.f. Energy & Env't Legal Inst.*, 793 F.3d at 1175 ("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?").

Moreover, the policy concerns first raised in *Baldwin* and reiterated in *Healy* and *Brown-Forman* clarify that price-parity or price-affirmation statutes must be treated differently because they are barriers to free trade between states. *See Baldwin*, 294 U.S. at 521 (these statutes "will set a barrier to traffic between one state and another as effective as if customs duties . . . had been laid upon the thing transported"); *Brown-Forman*, 476 U.S. at 580 ("Economic protectionism . . . may include attempts to give local consumers an advantage over consumers in other States"); *Healy*, 491 U.S. at 335–36 (noting the Constitution's "special concern . . . with the maintenance of a national economic union unfettered by state-imposed limitations on interstate commerce"). The concerns about local price gridlock or restricted trade between states are not similarly raised with regard to HB 631, because AAM's

members may still sell drugs to other states at different prices.

The activity regulated under HB 631 is not the ability of AAM members to make profits (which was the concern of the plaintiffs in *Baldwin*, *Brown-Forman*, and *Healy*), but the ability of AAM members to extract excessive profits by price-gouging Maryland consumers on essential drugs for which there is limited competition.[7] Under HB 631, AAM members may raise prices to make profits in other states—even to uncontrolled levels—but not for the drugs made available for sale *in Maryland*. AAM's concern that it faces a "Hobson's choice" in complying with this anti-price-gouging law fails to engage with this reality. Pl.'s Mot. Prelim. Inj. at 32, ECF No. 9-1.

Ultimately, AAM's concern with the law appears to rest in part on a practical problem. It argues that its members do not currently track where the drugs first sold to distributors or intermediaries are ultimately offered for sale to patients, so they do not know which of their drugs end up in Maryland. The practical effect of complying with this regulation, AAM claims, is that their members will have to "rejigger" their business practices. Pl.'s Mot. Prelim. Inj. at 35, ECF No. 9-1.

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[7] Indeed, AAM agrees that "generic drug manufacturers are able to charge low prices for their products because of robust competition in the market." Pl.'s Mot. Prelim. Inj. at 9, ECF No. 9-1. Drugs priced in a competitive marketplace would not be subject to HB 631. § 2-801(b)(1), § 2-801(f)(2).

Thus, AAM argues, HB 631 necessarily regulates conduct wholly outside of the state.

Because many physical consumer products must conform to differing state requirements, this argument is unpersuasive. AAM has not offered a reason for why its members—who are leading manufacturers and distributors of generic drugs in this country—could not apply a tracking system to determine which of their drugs are eventually made available for sale in Maryland. Certainly, the plaintiff in *Star Scientific*—a manufacturer of tobacco products—overcame this practical challenge. *Star Scientific*, 278 F.3d 339 at 357 (explaining that Star Scientific "overstat[ed] its burden" when arguing that because the escrow payments are imposed "on cigarettes sold not only by it, but also by its distributors, even when the distributors purchased the cigarettes outside the state," so it has to "police interstate sales or channel those sales into contractual forms that may be more burdensome to commerce").

Although AAM appears to rest its argument on the extraterritoriality principle, it also alleges that because in-state retailers are not subject to HB 631, the law discriminates against out-of-state actors in favor of in-state actors. Pl.'s Opp. Mot. Dismiss at 10, ECF No. 36. However, this comparison inappropriately compares retailers with wholesalers and distributors. That the legislature chose to regulate some actors in the drug distribution chain instead of all of them is not indicative of discriminatory activity or economic protectionism against upstream out-of-state actors in favor of in-state retailers. Manufacturers and distributors

residing within Maryland (of which there is at least one) would have to comply with the same rules as manufacturers and distributors residing outside of Maryland.[8]

AAM has not alleged a plausible dormant Commerce Clause violation under the first tier or the extraterritoriality principle, because of the Fourth Circuit's *Star Scientific* precedent. Hence, the dormant Commerce Clause analysis must proceed to the second tier.

iii. Application to HB 631: Second Tier Balancing

"Under the undue burden (or *Pike* balancing) tier, '[w]here the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits.'" *Yamaha Motor Corp*, 401 F.3d at 567.

Defendants have explained that their legitimate interest is enforcing HB 631 to prevent price-gouging in Maryland for essential medicines and to protect the safety and health of Maryland residents. Defs.' Opp. Prelim. Inj. at 10, ECF No. 30. This interest has been

[8] The parties have not argued, and the Court declines to address, the question of whether—in case discrimination was found—Defendant has met the burden to justify HB 631 "in terms of the local benefits flowing from the statute and the unavailability of nondiscriminatory alternatives adequate to preserve the local interests at stake." *Wyoming*, 502 U.S. at 456.

reasonably illustrated in Exhibits A and B to its Motion to Dismiss and discussed herein at Section I.A. AAM, on the other hand, does not present an argument that HB 631 should be held unconstitutional under this balancing test.

Given the strength of the state's interest and the requirement that AAM must show that "the burden on interstate commerce would *clearly* exceed the local benefits" (emphasis added), AAM's challenge cannot succeed under this second tier test. *Yamaha Motor Corp.*, 401 F.3d at 567.

Accordingly, because HB 631 is valid under the *Star Scientific* Fourth Circuit precedent, and AAM has not shown that any burden imposed by the law does not clearly exceed the local benefits to Maryland consumers, it has failed to adequately allege a plausible claim that HB 631 violates the dormant Commerce Clause.

## B. DUE PROCESS VAGUENESS CHALLENGE

### i. Legal Standard

A law is not void for vagueness so long as it "(1) establishes 'minimal guidelines to govern law enforcement,' and (2) gives reasonable notice of the proscribed conduct." *Schleifer by Schleifer v. City of Charlottesville*, 159 F.3d 843, 853 (4th Cir. 1998). *See also Greenville Women's Clinic v. Comm'r, S.C. Dep't of Health & Envtl. Control*, 317 F.3d 357, 367 (4th Cir. 2002) ("[A] regulation is not void for vagueness unless

it is so unclear with regard to what conduct is prohibited that it 'may trap the innocent by not providing fair warning,' or it is so standardless that it enables 'arbitrary and discriminatory enforcement.' ").

Judges are cautioned to exercise restraint in facial vagueness challenges. *Schleifer by Schleifer*, 159 F.3d at 853. ("Striking down ordinances . . . as facially void for vagueness is a disfavored judicial exercise."). *See also Washington State Grange v. Washington State Republican Party*, 552 U.S. 442, 450 (2008) (facial challenges are disfavored because they "rest on speculation," "run contrary to the fundamental principle of judicial restraint," and "threaten to short circuit the democratic process").

The precedents do not provide a clear statement of the proper standard to apply in facial vagueness challenges. Under one formulation of the test, "the complainant must demonstrate that the law is impermissibly vague in all of its applications." *Village of Hoffman Estates v. Flipside*, 455 U.S. 489, 497 (1982). In other words, "the challenger must establish that no set of circumstances exists under which the Act would be valid." *United States v. Salerno*, 481 U.S. 739, 745 (1987).

However, in a recent decision involving a criminal statute, the Supreme Court rejected the view that "a statute is void for vagueness only if it is vague in all its applications." *Johnson v. United States*, 135 S. Ct. 2551, 2561 (2015). Instead, the Court explained that "our *holdings* squarely contradict the theory that a

vague provision is constitutional merely because there is some conduct that clearly falls within the provision's grasp" (emphasis in original).[9] *Id. See also United States v. Comstock*, 627 F.3d 513, 518 (4th Cir. 2010) (acknowledging reservations within the Supreme Court in the years since *Salerno* about the stringent "no set of circumstances" test).

At the very least, it appears that a facial challenge cannot succeed if a "statute has a 'plainly legitimate sweep.'" *Comstock*, 627 F.3d at 518; *Washington State Grange*, 552 U.S. at 449 ("While some Members of the Court have criticized the *Salerno* formulation, all agree that a facial challenge must fail where the statute has a 'plainly legitimate sweep.'").

A statute that has a "plainly legitimate sweep" has also been described as having "more than a conceivable application." *Martin v. Lloyd*, 700 F.3d 132, 136–37 (4th Cir. 2012). However, concrete illustrations of what constitutes a "plainly legitimate sweep" for a non-criminal, non-First Amendment statute—such as HB 631—are limited. In *Hightower v. City of Boston*, the plaintiff's facial challenge to Massachusetts's gun licensing statute failed because she did not establish that the statute lacked a "plainly legitimate sweep" of circumstances where an applicant may properly be denied a license on the grounds of unsuitability. 693 F.3d at

[9] There is good reason to question the direct applicability of this sentence in *Johnson* to the instant case. Due to the gravity of criminal penalties, "the [required] standard of certainty is higher" for criminal statutes than it is for civil statutes. *Schleifer by Schleifer*, 159 F.3d at 853.

77–78. In its reasoning, the court pointed to at least one set of circumstances in which the suitability requirement is clearly constitutional—where false information is provided on an application form. *Id.* at 78.

Moreover, when considering phrases or words within a statute, those phrases or words should be considered in the context of the statute as a whole. *The Real Truth About Abortion, Inc. v. Fed. Election Comm'n*, 681 F.3d 544, 554 (4th Cir. 2012); *Martin*, 700 F.3d at 136. In doing so, a court is "not confined to the plain language of the contested statute." *Martin*, 700 F.3d at 136.

Finally, these standards "should not . . . be mechanically applied." *Village of Hoffman Estates*, 455 U.S. at 498. Rather, "[t]he degree of vagueness that the Constitution tolerates—as well as the relative importance of fair notice and fair enforcement—depends in part on the nature of the enactment." *Id.* Indeed, "economic regulation is subject to a less strict vagueness test because its subject matter is often more narrow, and because businesses, which face economic demands to plan behavior carefully, can be expected to consult relevant legislation in advance of action." *Id.* The Supreme Court "has also expressed greater tolerance of enactments with civil rather than criminal penalties because the consequences of imprecision are qualitatively less severe." *Id.* at 498–99.

ii. Application to HB 631

HB 631 prohibits price gouging, which is defined as "an unconscionable increase in the price of a prescription drug." § 2-801(c). The term "[u]nconscionable increase" is defined as

> an increase in the price of a prescription drug that:
>
> (1) Is 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) Results in consumers for whom the drug has been prescribed having no meaningful choice about whether to purchase the drug at an excessive price because of:
>
> (i) The importance of the drug to their health; and
>
> (ii) Insufficient competition in the market for the drug.

§ 2-801(f). AAM argues that "HB 631 falls well short of any reasonable standard of clarity," and contends that several terms within the statute are vague.[10] Pl.'s Mot. Prelim. Inj. at 26, ECF No. 9-1. The Court will address each in turn.

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[10] Although AAC brought an as-applied challenge to HB 631 under the dormant Commerce Clause, its challenge under the Fourteenth Amendment Due Process Clause is facial.

- "Unconscionable increase"

AAM argues that the definition of "unconscionable increase" is keyed on a number of "expansive adjectives," including "excessive," "justified," "appropriate," and "meaningful." Pl.'s Mot. Prelim. Inj. at 2, ECF No. 9-1. Defendants argue that "HB 631 closely tracks both the 'procedural' and 'substantive' components of the common law doctrine of unconscionability" which is "centuries-old." Defs.' Opp. Prelim. Inj. at 4, ECF No. 30.

Although the term "unconscionability" itself has been defined by judges in the contracts context, those judicial interpretations may not be directly applicable to non-contracts cases. *See, e.g.*, *Williams v. Walker-Thomas Furniture Co.*, 350 F.2d 445 (D.C. Cir. 1965). Ultimately, the question of whether the body of common law unconscionability doctrine is incorporated into the statute is not determinative because the term "unconscionable increase" is defined in the statute. The Court will address the sub-components of the definition.

- "Excessive," "not justified," and "appropriate"

AAM relies on Governor Hogan's statements that the term "excessive" is at "the heart of" the law and renders it unconstitutionally vague. Pl.'s Mot. Prelim. Inj. at 3, ECF No. 9-1. AAM argues that because the statute does not define "excessive," it is not "sufficiently concrete to be cognizable absent further

elaboration." Pl.'s Opp. Mot. Dismiss at 12, ECF No. 36. Defendants argue that courts have rejected vagueness challenges to civil statutes based on the imprecision of words such as "excessive," and based on "qualitative standards rooted in common law." Def. Mot. Dismiss at 32–33, ECF No. 29-1.

It is true that statutes often use broad terms, and that courts have upheld some of these statutes under a vagueness challenge. *See, e.g.*, *Grayned v. City of Rockford*, 408 U.S. 104, 110 (1972) (upholding an anti-noise regulation that used the phrase "tends to disturb"); *United Companies Lending Corp. v. Sargeant*, 20 F. Supp. 2d 192, 205 (D. Mass. 1998) (rejecting vagueness challenge where the phrase "otherwise unconscionable" was used but undefined). However, each phrase is context specific and must be examined within its own statutory framework.

Here, "excessive" is a comparative term—a price must be "excessive" *in relation to* a benchmark. Although HB 631's reporting provision could serve as a benchmark, it does not appear to be binding on the Attorney General. *See* § 2-803(a) (allowing the MMAP to notify the Attorney General when there is, *inter alia*, an increase in drug price that amounts to an increase of "50% or more in the wholesale acquisition cost of the drug" within the preceding one year). Even though "excessive" is joined with another provision (*i.e.*, "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 . . . ") (emphasis added), AAM argues that "justified" and "appropriate"

are also modifiers that cannot be readily defined absent meaningful contextual distillation. Pl.'s Mot. Prelim. Inj. at 27, ECF No. 9-1.

The Court finds that it is at the very least plausible that the combination of these broader words renders the statute unconstitutionally vague. A complaint must allege sufficient facts "to cross 'the line between possibility and plausibility of entitlement to relief.'" *Francis v. Giacomelli*, 588 F.3d 186, 193 (4th Cir. 2009).

- "No meaningful choice"

AAM also argues that the term "meaningful" is unconstitutionally vague. Pl.'s Mot. Prelim. Inj. at 27, ECF No. 9-1. However, in the context of the whole statute, it becomes apparent that this standard is more than sufficient. The phrase is qualified by two subprovisions: "(i) The importance of the drug to their health; *and* (ii) insufficient competition in the market for the drug" (emphasis added). AAM does not allege that either of these sub-provisions is vague.

On the current state of the record, AAM has alleged at least a plausible basis to challenge some of the HB 631 provisions discussed above as unconstitutionally vague. However, the Court finds that the parties have not presented a record adequate to enable a final decision as to the alleged vagueness of HB 631, and cannot now determine whether the statute would pass constitutional muster on a more complete record which

includes evidence regarding pricing decisions made by drug manufacturers and/or distributors.[11]

It is also possible that the relevant state agencies may issue additional guidance or regulations, which this Court must then consider. *Village of Hoffman Estates*, 455 U.S. at 495 n.5 ("In evaluating a facial challenge to a state law, a federal court must, of course, consider any limiting construction that a state court or enforcement agency has proffered.").

The Court recognizes that there are reasonable—though not necessarily prevailing—contentions asserted by the Plaintiff. Accordingly, AAM has presented a plausible claim that HB 631 may be void for vagueness and shall not grant Defendants' motion seeking dismissal of the vagueness claims.

## III. PRELIMINARY INJUNCTION

### A. LEGAL STANDARD

"A preliminary injunction is an extraordinary remedy, to be granted only if the moving party clearly establishes entitlement to the relief sought." *Manning v. Hunt*, 119 F.3d 254, 263 (4th Cir. 1997). *See also MicroStrategy Inc. v. Motorola, Inc.*, 245 F.3d 335, 339 (4th Cir. 2001) ("preliminary injunctions are extraordinary remedies involving the exercise of very

[11] For example, AAM contends that "[b]asic macroeconomic forces" as well as "other interconnected factors," including regulatory requirements, affect pricing decisions. Compl. ¶ 23, ECF No. 1.

far-reaching power to be granted only sparingly and in limited circumstances.").

To obtain a preliminary injunction, the Plaintiff must make a clear showing:

1. That it will likely succeed on the merits;

2. That it is likely to suffer irreparable harm absent preliminary relief;

3. That the balance of equities tips in its favor; and

4. That an injunction is in the public interest.

*Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 20 (2008); *Centro Tepeye v. Montgomery County*, 722 F.3d 184, 188 (4th Cir. 2013). The plaintiff has the burden of establishing that it meets the *Winter* factors. *Dewhurst v. Century Aluminum Co.*, 649 F.3d 287, 293 (4th Cir. 2011) ("[Plaintiffs], who 'must establish' that they meet the *Winter* standard in order to be awarded a preliminary injunction, fail to do so.").

B. DISCUSSION

i. Likelihood of Success on the Merits

First, AAM must make a clear showing that it will likely succeed on the merits at trial. *Winter*, 555 U.S. at 20.

As discussed in the preceding sections, the Court does not find that AAM has shown that it is likely to prevail on the as-applied dormant Commerce Clause

challenge. Moreover, the factual record at the moment does not support its likelihood of prevailing on the facial Due Process Clause challenge. Accordingly, this factor weighs in favor of denying a preliminary injunction.

ii. Likelihood of Irreparable Harm

Second, AAM must make a clear showing that it is likely to be irreparably harmed absent preliminary relief. *Id.*

This showing must not be speculative. The Court in *Winter* rejected a standard where issuing a preliminary injunction is "based only on a possibility of irreparable harm," because such standard is "inconsistent with our characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter*, 555 U.S. at 22.

AAM claims that its members would suffer irreparable harm for three reasons: (1) they will need to conform their conduct to the law's "sweeping terms" and face a barrage of investigations, (2) they would suffer "irreparable reputational and economic harm," and (3) the mere fact that the law violates the Constitution will subject AAM members to irreparable injury. Pl.'s Mot. Prelim. Inj. at 32–37, ECF No. 9-1.

Generally, economic harms do not by themselves constitute irreparable injury. *Sampson v. Murray*, 415 U.S. 61, 90 (1974) ("the temporary loss of income,

ultimately to be recovered, does not usually constitute irreparable injury."). However, several circuit courts have held that the inability to recover monetary damages because of sovereign immunity renders the harm suffered irreparable for preliminary injunction purposes. *See, e.g.*, *Odebrecht Const., Inc. v. Sec'y, Florida Dep't of Transp.*, 715 F.3d 1268, 1289 (11th Cir. 2013) (noting that "numerous courts have held that the inability to recover monetary damages because of sovereign immunity renders the harm suffered irreparable"); *Chamber of Commerce of U.S. v. Edmondson*, 594 F.3d 742, 770–71 (10th Cir. 2010) (holding that "monetary damages that cannot later be recovered for reasons such as sovereign immunity constitute irreparable injury"). *But see Otsuka Pharm. Co. v. Burwell*, No. GJH-15-852, 2015 WL 1962240, at *11 (D. Md. Apr. 29, 2015) ("That Otsuka is unable to recover monetary damages from FDA or Defendant–Intervenors does not, however, automatically make its harm irreparable.").

It is possible that AAM cannot recover potential losses it would suffer from the Maryland government if HB 631 were applied and later found to be unconstitutional. However, AAM's actual claims of irreparable harm are unconvincing.

AAM's concern that it will "face a barrage of investigations and lawsuits" is entirely speculative and supported by no evidence in the record. Pl.'s Mot. Prelim. Inj. at 32, ECF No. 9-1. It also provides little to no support for how its members "will need to conform their conduct" to the law's terms or how much those

individual actions would cost. *Id.* Although AAM refers generally to "multiple, costly steps to restructure their pricing, distribution, and other business practices," it does not specify what those "multiple, costly" steps would involve. *Id.* It is insufficient to state in a conclusory manner that AAM members would have to "rejigger" their own business models, which would cost "time and money." *Id.* at 35.

Moreover, AAM claims that the implementation of the law would force its members to discontinue marking [sic] certain medicines in Maryland or in the United States as a whole. Compl. ¶ 7, ECF No. 1. They imply that patients and customers would be left with no generic medication choices and would "simply perceive manufacturers as making life tougher on them," causing alleged reputational harm. Pl.'s Mot. Prelim. Inj. at 35, ECF No. 9-1. *See also* Hearing Rough Tr. at 64:1-3 (Sept. 14, 2017) (Counsel for Plaintiff: "So we actually, I don't think, have the ability in any way at all, to control whether our drugs end up in Maryland, except by not selling them."). No support is provided for the dramatic statement that AAM members would shut down parts of their businesses in order to comply with HB 631.

AAM's submitted declarations are conclusory:

- Chester Davis, President and CEO of AAM, states that AAM members would need to take "nontrivial steps to modify [their] pricing, distribution, or other business practices." ECF No. 9-2 ¶ 9. However, he does not explain what those

nontrivial steps are and how much money those modifications would cost.

- Sean Moriarty, Secretary of Lupin Pharmaceuticals, states that "Lupin will be forced to expend unnecessary resources attempting to achieve compliance with an uncertain target." ECF No. 9-3 ¶ 10. However, he does not explain what resources would be expended in this process. The same or similar conclusory sentence appears in the Declarations of Don Bullock of Sagent Pharmaceuticals (ECF No. 9-4 ¶ 9), Lisa Graver of Alvogen Group (ECF No. 9-5 ¶ 11), Michael Keenley of Zydus USA (ECF No. 9-6 ¶ 11), Andrew Bower of Teva Pharmaceutical (ECF No. 9-7 ¶ 11), Jeffrey Hampton of Apotex Corp. (ECF No. 9-9 ¶ 7), Jim Luce of Amneal Pharmaceuticals(ECF No. 9-10 ¶ 8), and Michael Raya of West-Ward Pharmaceuticals Corp. (ECF No. 9-11 ¶ 9).

- Don Bullock, Executive VP of Sales for Sageant [sic] Pharmaceuticals, states that Sagent will be "injured" both "directly and reputationally" if it changes its pricing or distribution practices, but provides no rationale for how those injuries might occur. ECF No. 9-4 ¶ 10. He also states that "HB 631 exposes Sagent to a level of risk that will require it to evaluate whether to continue to market certain medicines within Maryland, or in the U.S. market as a whole," but does not provide support for this dramatic statement. The

> same or similar conclusory statements appear in the Declarations of Lisa Graver of Alvogen Group (ECF No. 9-5 at ¶ 12), Michael Keenley of Zydus USA (ECF No. 9-6 ¶ 12), Andrew Bower of Teva Pharmaceuticals (ECF No. 9-7 ¶ 12), Jeffrey Hampton of Apotex Corp. (ECF No. 9-9 ¶ 8), Jim Luce of Amneal Pharmaceuticals(ECF No. 9-10 ¶ 9), and Michael Raya of West-Ward Pharmaceuticals Corp. (ECF No. 9-11 ¶ 10).

These statements are insufficient to meet the "clear showing" standard in *Winter*, 555 U.S. at 22.

AAM also argues that simply being held to unconstitutional state action "constitutes irreparable injury for purposes of obtaining a preliminary injunction." *Id.* at 37. However, the controlling cases that contain this reasoning may be limited to deprivations of individual rights (*e.g.*, First Amendment rights, Fourth Amendment rights, voting rights). *See, e.g.*, *Elrod v. Burns*, 427 U.S. 347, 373 (1976) ("The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury."); *League of Women Voters of N. Carolina v. North Carolina*, 769 F.3d 224, 247 (4th Cir. 2014) ("Courts routinely deem restrictions on fundamental voting rights irreparable injury," noting that this makes sense because "once the election occurs, there can be no do-over and no redress."); *Ross v. Meese*, 818 F.2d 1132, 1135 (4th Cir. 1987) (Courts may "order injunctive relief to remedy constitutional violations which are based on the plaintiff's right to privacy in her home and her person

which the Fourth Amendment protects against unreasonable government search and seizure"). Regardless, with the current record the Court does not find that HB 631 would cause a deprivation of rights under the dormant Commerce Clause. There is an insufficient record to make a determination as to the Due Process Clause of the Fourteenth Amendment.

AAM has not provided support for its speculative claims of irreparable economic and reputational harm. Accordingly, this factor weighs in favor of denying a preliminary injunction.

iii. Balance of the Equities

Third, AAM must make a clear showing that the balance of equities tips in its favor. *Winter*, 555 U.S. at 20. In examining this third factor, courts "must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief." *Id.* at 24.

AAM simply argues that there is no substantial harm in not enforcing a likely unconstitutional statute, and that the Defendants will "suffer little, if any, injury from the relief sought." Pl.'s Mot. Prelim. Inj. at 38, ECF No. 9-1. However, as discussed above, the Court does not find AAM to have shown that HB 631 is substantially likely to be held unconstitutional. Moreover, the Court finds that an erroneous grant of a preliminary injunction would cause substantial harm by permitting the sale of essential drugs to Maryland

residents at unconscionable prices. Defs.' Opp. Prelim. Inj. at 10, ECF No. 30.

Accordingly, this factor weighs in favor of denying a preliminary injunction.

iv. Public Interest

Finally, AAM must make a clear showing that the requested injunction is in the public interest. *Winter*, 555 U.S. at 20. *See also id.* at 24 ("[C]ourts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction.").

AAM makes two main public interest arguments: (1) that upholding AAM's constitutional rights is in the public interest and (2) that HB 631 will introduce enough uncertainty and business risk for generic drug manufacturers that some will discontinue marketing their medicines in Maryland or in the United States as a whole and "decline altogether to enter the market of developing new, low cost generic alternatives to expensive brand products." Pl.'s Mot. Prelim. Inj. at 38–39, ECF No. 9-1. They claim that this "retrenchment" will result in decreased competition, fewer treatment options, and higher costs for patients and taxpayers. *Id.*

Defendants argue that this law is meant to prohibit unconscionable price increases for essential medicines, and that there is ample evidence that this type of conduct is presently causing public harm, and will continue to do so in the future absent legislative

change. Defs.' Opp. Prelim. Inj. at 11–14, ECF No. 30. They explain that disempowering Maryland from implementing this bill would "signal to the pharmaceutical industry that state governments lack the authority to protect their citizens from even unconscionable increases in the prices of essential medicines" and encourage future abuses. *Id.* at 16.

As discussed above, AAM's claim that its members may stop marketing their drugs completely in response to HB 631 (essentially, shutting down parts of their businesses), which would result in decreased competition, fewer treatment options, and higher costs for patients and taxpayers, is entirely speculative. Litigants may not, without adequate factual support, hold courts hostage by resorting to these kinds of hypothetical scenarios. *C.f. Martin v. Lloyd*, 700 F.3d at 137 (in the context of a vagueness challenge, "[a]ppellants made a tactical decision to bring a facial challenge to this law—that decision does not allow them to lean on extravagant hypothetical scenarios that bear no resemblance to their own conduct . . . ").

In contrast, the Defendants have provided ample support for their position that HB 631 targets a narrow set of conduct that is intended to protect Maryland consumers from unconscionable price increases in the drugs that are essential to their health. See *supra*, Section I.A.

* * *

In summary, *Winter* factors 1, 2, 3, and 4 all weigh in favor of denying a preliminary injunction. The Court shall deny Plaintiff the preliminary injunction it seeks.

## IV. 42 U.S.C. § 1983 and § 1988

AAM's claims presented under 42 U.S.C. § 1983 and § 1988 are dependent on its dormant Commerce Clause and Due Process Clause challenges. As held, the Court is allowing Plaintiff's vagueness contentions to proceed further but dismissing their other claims and denying the requested preliminary injunction.

## V. CONCLUSION

For the foregoing reasons:

1. Plaintiff's Motion for Preliminary Injunction [ECF No. 9] is DENIED.

2. Defendants' Motion to Dismiss [ECF No. 29] is GRANTED IN PART and DENIED IN PART.

    a. The Motion is GRANTED as to the First Cause of Action under the dormant Commerce Clause.

    b. The Motion is DENIED as to the Second Cause of Action under the Fourteenth Amendment Due Process Clause.

    c. The Motion is GRANTED as to the Third Cause of Action under 42 U.S.C. § 1983 and § 1988 to the extent it is

dependent on the dormant Commerce Clause challenge.

3. Plaintiff shall arrange a telephone conference to be held by October 6, 2017 to discuss the scheduling of further proceedings herein.

SO ORDERED, on Friday, September 29, 2017.

## APPENDIX C

2018 WL 3574755
See Fed. Rule of Appellate Procedure 32.1
generally governing citation of judicial
decisions issued on or after Jan. 1, 2007.
See also U.S.Ct. of Appeals 4th Cir. Rule 32.1.
United States Court of Appeals, Fourth Circuit.

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.

No. 17-2166
|
Filed: July 24, 2018

117-cv-01860-MJG

ORDER

The petition for rehearing en banc was circulated to the full court. Judge Wilkinson, Judge Niemeyer, Judge Traxler, Judge King, Judge Duncan, Judge Agee, Judge Diaz, Judge Floyd and Judge Thacker voted to deny rehearing en banc. Chief Judge Gregory, Judge Wynn and Judge Harris voted to grant rehearing en banc. Judge Motz and Judge Keenan did not participate in the poll. The court denies the petition for rehearing en banc.

Entered at the direction of Judge Thacker.

WYNN, Circuit Judge, dissenting from the denial of rehearing en banc:

With respect, I must dissent from my colleagues' refusal to grant en banc rehearing in this case. The right of a State to protect the health, safety, and welfare of its citizens should not be denied by the judicial expansion of a judge-made doctrine with a name that aptly describes what it should be, the dormant Commerce Clause's "extraterritoriality doctrine."

In expanding the extraterritoriality doctrine beyond the contexts in which the Supreme Court and this Court previously have applied it—and in a manner that the panel majority concedes conflicts with the approach taken by other circuits—the majority opinion materially encroaches upon 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, 20 S.Ct. 788, 44 L.Ed. 899 (1900). By

doing so, the majority opinion errantly turns the dormant Commerce Clause into a "weapon" for federal judges to second-guess efforts by state legislatures to protect the health and welfare of their citizens, *Energy & Envtl. Legal Inst. v. Epel (EELI)*, 793 F.3d 1169, 1175 (10th Cir. 2015) (Gorsuch, J.), even when such efforts do not implicate the two concerns underlying the Supreme Court's "[m]odern" dormant Commerce Clause jurisprudence: state regulations that "discriminate against interstate commerce" or "impose undue burdens on interstate commerce," *South Dakota v. Wayfair*, ___ U.S. ___, 138 S.Ct. 2080, 2090–91, ___ L.Ed.2d ___ (2018). As then-Judge, now-Justice Gorsuch has explained, federal courts should not embark on such an "audacious" and "novel lawmaking project" absent clear instruction from the Supreme Court. *EELI*, 793 F.3d at 1175. At a minimum, the careful deliberation of this entire Court is warranted before we choose a path that diverges from our sister circuits and raises serious federalism concerns.

At issue is a Maryland law ("HB 631") that prohibits "unconscionable" price increases for certain generic drugs "made available for sale" to Maryland consumers. Md. Code Ann., Health-Gen. §§ 2-801-803 (2017). 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 HB 631 to restrain what it viewed as abusive pricing practices specifically designed to prey on the special

vulnerabilities of a defenseless group of Maryland citizens.

The majority opinion holds that the statute when applied to any sale of covered drugs consummated outside of Maryland—*even when the drugs are later resold to Maryland consumers*—violates the extraterritoriality doctrine by regulating "commerce occurring wholly outside [Maryland's] boundaries." *Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664, 681 (4th Cir. 2018) (quoting *Healy v. Beer Inst.*, 491 U.S. 324, 336, 109 S.Ct. 2491, 105 L.Ed.2d 275 (1989)). That doctrine—which the Supreme Court has not applied in nearly 30 years—has been characterized by our sister circuits as the "the most dormant" of the Supreme Court's dormant Commerce Clause jurisprudence. *See, e.g.*, *EELI*, 793 F.3d at 1172. More significantly, to date, the extraterritoriality doctrine has been applied "*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), and there *never* has been "a single Supreme Court dormant Commerce Clause holding that relied exclusively on the extraterritoriality doctrine to invalidate a state law," *Am. Beverage Ass'n v. Snyder*, 735 F.3d 362, 381 (6th Cir. 2013) (Sutton, J., concurring), as the majority opinion does here.

My dissenting opinion details several ways in which the majority opinion errs in adopting and applying its novel approach to the extraterritoriality doctrine. 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 *before the State had sought to enforce the statute against any generic manufacturer. Frosh*, 887 F.3d at 678–80 (Wynn, J., dissenting). 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. *Id.* at 680–87. Notably, the majority opinion concedes that its expansive construction of the extraterritoriality doctrine conflicts with the approach taken by other circuits. *See Frosh*, 887 F.3d at 670 (majority op.); *see also EELI*, 793 F.3d at 1174; *Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937, 951 (9th Cir. 2013); *IMS Health, Inc. v. Mills*, 616 F.3d 7, 30 (1st Cir. 2010).

The Maryland statute's constitutionality finds further support in the Supreme Court's most recent opinion dealing with the dormant Commerce Clause—*South Dakota v. Wayfair*, ___ U.S. ___, 138 S.Ct. 2080, ___ L.Ed.2d ___ (2018)—which the Court issued after the panel decided this case. In *Wayfair*, the Court considered a South Dakota statute that requires out-of-state sellers who deliver, on an annual basis, "more than $100,000 of goods or services into the State or engage in 200 or more separate transactions for the delivery of goods into the state" to collect and remit sales tax, *regardless of whether the seller has a physical presence in South Dakota*. *Id.* at 2088–89. South Dakota sought to collect sales taxes from Wayfair, an online retailer who made substantial sales to South Dakota residents but lacked a physical presence in the state. *Id.*

at 2089. The South Dakota Supreme Court held that the statute was unconstitutional as-applied to out-of-state sellers who lacked a physical presence in the state, like Wayfair, under the Supreme Court's decisions in *Quill Corp. v. North Dakota*, 504 U.S. 298, 112 S.Ct. 1904, 119 L.Ed.2d 91 (1992), and *National Bellas Hess, Inc. v. Department of Revenue of Ill.*, 386 U.S. 753, 87 S.Ct. 1389, 18 L.Ed.2d 505 (1967). Those decisions held that a State could not require a seller to collect and remit sales tax unless it had a "physical presence such as 'retail outlets, solicitors, or property within the State.'" *Wayfair*, 138 S.Ct. at 2091 (quoting *Bellas Hess*, 386 U.S. at 758, 87 S.Ct. 1389).

*Wayfair* overruled the "physical presence" rule set forth in *Quill* and *Bellas Hess*. *Id.* at 2099. The Court reached this conclusion for several reasons relevant to the dormant Commerce Clause challenge to the Maryland price-gouging statute. To begin, the Court reaffirmed both Justice Marshall's "broad definition of commerce" as "'the interchange of commodities' and 'commercial intercourse' . . . *and* the concurrent regulatory power of the States." *Id.* at 2090 (emphasis added) (quoting *Gibbons v. Ogden*, 22 U.S. 1, 9 Wheat. 1, 6, 6 L.Ed. 23 (1824)). As my dissenting opinion more fully explains, the majority opinion fails to adhere to that "broad" definition of commerce by equating "commerce" with a single "transaction" and usurps the States' concurrent regulatory authority. *Frosh*, 887 F.3d at 683 (Wynn, J., dissenting).

Second, *Wayfair* emphasized the "significant parallels" between the Due Process Clause "minimum

contacts" standard for personal jurisdiction and the restrictions on state regulation imposed by the Commerce Clause. *Wayfair*, 138 S.Ct. at 2093. Noting that "physical presence" is not required to satisfy the minimum contacts test, the Court stated that physical presence is likewise a "poor proxy" in the dormant Commerce Clause context. *Id.* The Court further explained that the physical presence rule is particularly inappropriate when considered in light of the "day-to-day functions of marketing and distribution in the modern economy." *Id.* at 2095. Here, the majority opinion strikes down the Maryland price-gouging statute because it "controls the prices of transactions that occur outside the state," regardless of whether the drugs conveyed by those out-of-state transactions are later resold in Maryland. *Frosh*, 887 F.3d at 670 (majority op.). The majority's myopic focus on the *location* of the transaction is precisely the "physical presence" approach *Wayfair* rejected as "artificial in its entirety." *Wayfair*, 138 S.Ct. at 2095. Likewise, just as e-commerce and nationwide distribution chains rendered the physical presence rule outmoded, so too do the modern nationwide distribution and reimbursement systems for generic pharmaceuticals counsel against the location-focused approach of the majority opinion.

Third, *Wayfair* held that the bright-line physical presence rule ran contrary to the Court's dormant Commerce Clause jurisprudence, which has "eschewed formalism for a sensitive, case-by-case analysis of purposes and effects." *Id.* at 2094 (quoting *West Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 201, 114 S.Ct.

2205, 129 L.Ed.2d 157 (1994)). The majority opinion's rule—that a State is categorically barred from regulating any transaction consummated outside of the State's borders regardless of whether the subject of that transaction is ultimately sold or resold in the State—embraces the same formalism that *Wayfair* rejected, rather than following the case-by-case approach the Court has prescribed. Thus, the majority opinion's pre-enforcement invalidation of the Maryland statute is antithetical to the Court's case-by-case approach to dormant Commerce Clause questions.

Fourth, *Wayfair* stated that the physical presence rule amounted to "an extraordinary imposition by the Judiciary on States' authority to collect taxes and perform critical public functions." *Id.* at 2095. As explained more fully in my dissent, "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," calling into question the constitutionality of numerous state antitrust and consumer protection statutes. *Frosh*, 887 F.3d at 687–88 (Wynn, J., dissenting). Accordingly, like the physical presence rule overruled in *Wayfair*, the majority opinion's expansive interpretation of the extraterritoriality doctrine—an interpretation that the majority opinion concedes is in conflict with that of other circuits—interferes with "States' authority to . . . perform critical public functions." *Wayfair*, 138 S.Ct. at 2095.

Finally, *Wayfair* replaced *Bellas Hess* and *Quill*'s physical presence rule with a "substantial nexus" test

that has its genesis in Due Process Clause jurisprudence. *Id.* at 2091. Applying that test, the Court held that North Dakota could require Wayfair and the other defendant on-line retailers to collect and remit sales tax because of their "economic and virtual contacts" with the State. *Id.* at 2099. Likewise, under governing Due Process Clause jurisprudence, at a minimum, generic drug manufacturers that "targeted" Maryland consumers—by, for example, marketing their drugs to Maryland consumers or physicians—lawfully would be subject to the Maryland statute, even if they sold their drugs through out-of-state intermediaries, *see J. McIntyre Machinery, Ltd. v. Nicastro*, 564 U.S. 873, 882, 131 S.Ct. 2780, 180 L.Ed.2d 765 (2011) (opinion of Kennedy, J.), meaning that the majority's pre-enforcement invalidation of the Maryland statute was all-the-more improper.

In sum, the majority opinion's expansive (re)interpretation of the extraterritoriality doctrine expressly diverges from the approach taken by the other circuits and is in significant tension—if not outright conflict—with the Supreme Court's most recent exposition of the limitations on state action imposed by the dormant Commerce Clause. More significantly, the majority opinion's expansive interpretation of the extraterritoriality doctrine significantly incurs on the States' reserved powers to enact legislation to protect the health, safety, and welfare of their citizens. The division between this Court and our sister circuits and the significant federalism concerns posed by the majority opinion's expansion of the long-dormant

extraterritoriality doctrine make this a case ripe for rehearing en banc as a matter of exceptional importance.

With respect, I dissent.

## APPENDIX D

Md. Code Ann., Health-Gen. §2–801.

(a) In this subtitle the following words have the meanings indicated.

(b) (1) "Essential off–patent or generic drug" means any prescription drug:

(i) For 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;

(ii) 1. That appears on the Model List of Essential Medicines most recently adopted by the World Health Organization; or

2. That has been designated by the Secretary as an essential medicine due to its efficacy in treating a life–threatening health condition or a chronic health condition that substantially impairs an individual's ability to engage in activities of daily living;

(iii) That is actively manufactured and marketed for sale in the United States by three or fewer manufacturers; and

(iv) That is made available for sale in the State.

(2) "Essential off–patent or generic drug" includes any drug–device combination product used for the delivery of a drug for 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.

(c) "Price gouging" means an unconscionable increase in the price of a prescription drug.

(d) "State health plan" has the meaning stated in § 2–601 of this title.

(e) "State health program" has the meaning stated in § 2–601 of this title.

(f) "Unconscionable increase" means an increase in the price of a prescription drug that:

(1) Is 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) Results in consumers for whom the drug has been prescribed having no meaningful choice about whether to purchase the drug at an excessive price because of:

(i) The importance of the drug to their health; and

(ii) Insufficient competition in the market for the drug.

(g) "Wholesale acquisition cost" has the meaning stated in 42 U.S.C. § 1395w–3a.

Md. Code Ann., Health-Gen. §2–802.

(a) A manufacturer or wholesale distributor may not engage in price gouging in the sale of an essential off–patent or generic drug.

(b) It is not a violation of subsection (a) of this section for a wholesale distributor to increase the price of an essential off–patent or generic drug if the price increase is directly attributable to additional costs for the drug imposed on the wholesale distributor by the manufacturer of the drug.

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Md. Code Ann., Health-Gen. §2–803.

(a) The Maryland Medical Assistance Program may notify the Attorney General of any increase in the price of an essential off–patent or generic drug when:

(1) The price increase, by itself or in combination with other price increases:

(i) Would result in an increase of 50% or more in the wholesale acquisition cost of the drug within the preceding 1–year period; or

(ii) Would result in an increase of 50% or more in the price paid by the Maryland Medical Assistance Program for the drug within the preceding 1–year period; and

(2) (i) A 30–day supply of the maximum recommended dosage of the drug for any indication,

according to the label for the drug approved under the federal Food, Drug, and Cosmetic Act, would cost more than $80 at the drug's wholesale acquisition cost;

(ii) A full course of treatment with the drug, according to the label for the drug approved under the federal Food, Drug, and Cosmetic Act, would cost more than $80 at the drug's wholesale acquisition cost; or

(iii) If the drug is made available to consumers only in quantities that do not correspond to a 30–day supply, a full course of treatment, or a single dose, it would cost more than $80 at the drug's wholesale acquisition cost to obtain a 30–day supply or a full course of treatment.

(b) On request of the Attorney General, the manufacturer of an essential off–patent or generic drug identified in a notice under subsection (a) of this section, within 45 days after the request, shall submit a statement to the Attorney General:

(1) (i) Itemizing the components of the cost of producing the drug; and

(ii) Identifying the circumstances and timing of any increase in materials or manufacturing costs that caused any increase in the price of the drug within the 1–year period preceding the date of the price increase;

(2) (i) Identifying the circumstances and timing of any expenditures made by the manufacturer to expand access to the drug; and

(ii) Explaining any improvement in public health associated with those expenditures; and

(3) Providing any other information that the manufacturer believes to be relevant to a determination of whether a violation of this subtitle has occurred.

(c) The Attorney General may require a manufacturer or a wholesale distributor to produce any records or other documents that may be relevant to a determination of whether a violation of this subtitle has occurred.

(d) On petition of the Attorney General and subject to subsection (e) of this section, a circuit court may issue an order:

(1) Compelling a manufacturer or a wholesale distributor:

(i) To provide the statement required under subsection (b) of this section; and

(ii) To produce specific records or other documents requested by the Attorney General under subsection (c) of this section that may be relevant to a determination of whether a violation of this subtitle has occurred;

(2) Restraining or enjoining a violation of this subtitle;

(3) Restoring to any consumer, including a third party payor, any money acquired as a result of a price increase that violates this subtitle;

(4) Requiring a manufacturer that has engaged in price gouging in the sale of an essential off–patent or generic drug to make the drug available to participants in any State health plan or State health program for a period of up to 1 year at the price at which the drug was made available to participants in the State health plan or State health program immediately prior to the manufacturer's violation of this subtitle; and

(5) Imposing a civil penalty of up to $10,000 for each violation of this subtitle.

(e) The Attorney General may not bring an action for a remedy under subsection (d)(2) through (5) of this section unless the Attorney General has provided the manufacturer or wholesale distributor an opportunity to meet with the Attorney General to offer a justification for the increase in the price of the essential off–patent or generic drug.

(f) Any information provided by a manufacturer or a wholesale distributor to the Attorney General under subsections (b) and (c) of this section shall be considered confidential commercial information for purposes of § 4–335 of the General Provisions Article unless the confidentiality of the information is waived by the manufacturer or wholesale distributor.

(g) In any action brought by the Attorney General under subsection (d) of this section, 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 residing in the State.