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Association for Accessible Medicines v. Brian E. Frosh: Judicially Created Principles or State Action to Protect Citizens from Unconscionable Drug Prices

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ABSTRACT

This note examines the holding in Association for Accessible Medicines v. Brian E. Frosh which was heard in the United States Court of Appeals for the Fourth Circuit. The Fourth Circuit struck down Maryland's Anti-Price Gouging Statue ("the Act") as a dormant Commerce Clause violation. This note will argue that the Fourth Circuit's holding was incorrect, and the Act should have been upheld under Maryland's great public interest in regulating the price of generic prescription drugs to protect its citizens' health and welfare. This note will begin with an analysis of the legal background concerning the extraterritoriality principle of the dormant Commerce Clause in relation to price control statutes. The note will then argue that the Fourth Circuit incorrectly applied the extraterritoriality principle to find a per se violation of the dormant Commerce Clause, and that the Act should have been upheld because Maryland's consumer protection interests in protecting citizens from unconscionable drug price increases outweighs any burdens the Act would have placed on interstate commerce. Finally, the note will highlight the Supreme Court, the Fourth Circuit, and Sister Courts' conflicting limitations of the extraterritoriality principle in modern commerce.

INTRODUCTION

In *Association for Accessible Medicines v. Brain E. Frosh*,[1] the United States Court of Appeals for the Fourth Circuit addressed whether the District Court for the District

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1. 887 F.3d 664 (decided April 13, 2018).

of Maryland's dismissal of the Association for Accessible Medicines' ("AAM") claim that Maryland's Anti-Price Gouging Statute[2] ("the Act") was unconstitutional under the dormant Commerce Clause ("DCC") was correct.[3] The Court ruled that the Act violated the DCC because it would directly regulate the price of drug transactions that occurred outside Maryland,[4] even though the Act would only be triggered when there was a drug made for sale within Maryland's borders.[5] The Court incorrectly applied the extraterritoriality principle of the DCC to conclude that the Act impacted transactions that occurred entirely outside of Maryland, implicated a price control as opposed to an upstream pricing impact, and burdened the interstate commerce of prescription drugs.[6]

The Court's incorrect application of the extraterritoriality principle can be understood after first examining the case itself, the legal background, and then reviewing both the majority and dissent's reasoning and analyses.[7] It will become clear that the Court's holding was an incorrect application of the extraterritoriality principle, because Maryland's great public interest in regulating the price of generic prescription drugs to protect and promote its citizens health and welfare outweighs any burdens placed on interstate commerce.[8]

I. THE CASE

On May 27, 2017, the Maryland General Assembly passed House Bill No. 631 ("HB 631"), Maryland's Anti-Price Gouging Statute, for the purpose of prohibiting manufacturers and wholesale distributors of pharmaceuticals from engaging in price gouging in the sale of generic drugs.[9] The bill became effective on October 1, 2017,[10] and was codified in MD Code, Health – General §§ 2-801-803.[11]

The Association for Accessible Medicines[12] is a voluntary organization of prescription drug manufacturers, wholesale distributors, and other entities in the

2. MD. CODE ANN., HEALTH §§ 2-801-803.

3. *Frosh*, 887 F.3d at 666.

4. *Id.*

5. Association for Accessible Medicines v. Frosh, No. MJG-17-1860, slip op. at 6 (D. Md. Sep. 29, 2017).

6. *Frosh*, 887 F.3d at 671–75.

7. *See infra*, Parts II, III.

8. *See infra*, Part IV.

9. H.B. 631, 437th Sess. (Md. 2017).

10. *Frosh*, 887 F.3d at 666. The governor of Maryland refused to sign the bill due to constitutional and other concerns. *Id.*

11. MD. CODE ANN., HEALTH §§ 2-801-803.

12. ASSOCIATION FOR ACCESSIBLE MEDICINES, https://accessiblemeds.org/about (last visited Feb. 3, 2019) ("The Association for Accessible Medicines improves access to safe, quality and effective medicine." Additionally, "as manufacturers of 9 out of every 10 prescriptions dispensed in the U.S., members of the Association for Accessible Medicines form an integral, and powerful, part of the healthcare system.") (internal citation omitted).

pharmaceutical industry.[13] On July 6, 2017, AAM challenged the Act in the District Court of Maryland, seeking 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."[14] AAM alleged that the Act's application to the sale of drugs between out-of-state manufacturers and out-of-state wholesale distributors violated the DCC.[15] On September 29, 2017, the district court ultimately dismissed AAM's DCC claims, denying, *inter alia*, its motions for preliminary injunction and dismissal.[16]

Subsequently, AAM filed an appeal with the United States Court of Appeals for the Fourth Circuit, appealing the district court's dismissal of its DCC challenge and refusal to enjoin enforcement of the statute on the basis that it was unconstitutionally vague.[17]

II. THE LEGAL BACKGROUND

A. Pattern and Practice: Industry-Wide Unconscionable Generic Drug Price Increases

The Maryland General Assembly passed HB 631 to protect the people of Maryland from "the imposition of unconscionable price increases" of generic drugs that resulted from market dysfunction or failure.[18] The General Assembly's proposal, passage, and enactment of the Act followed the release of two reports compiled by the federal government.[19] The first report, entitled *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care system*, was released by the Senate's Committee on Aging.[20] The second report, entitled *Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases*, was released by the Government Accountability Office ("GAO").[21]

The Senate's report investigated dramatic price increases in certain generic drugs and examined the circumstances surrounding extraordinary increases.[22] The

13. *Frosh*, 887 F.3d at 667.

14. *Frosh*, slip op. at 1.

15. *Id.*

16. *Frosh*, slip op. at 15.

17. *Frosh*, 887 F.3d at 666.

18. *Frosh*, slip op. at 1.

19. *Frosh*, 887 F.3d at 675.

20. S. REP. NO. 114-429 (2016).

21. 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).

22. *Frosh*, 887 F.3d at 676. The report investigated the price increase of seven generic drugs that did not have patent protection for decades and were sold by four generic pharmaceutical companies. Two of those pharmaceutical companies were formed and managed by the since-convicted investor Martin Shkreli. *Id.*; *see also*, Dan Mangan, *'Pharma bro' Martin Shkreli sentenced to 7 years in prison – says, 'This is my fault'*, CNBC

Senate's report concluded that all four of the companies investigated "followed a common 'business model' in acquiring and marketing" their drugs.[23] In particular, the Senate found that each extraordinary increase involved four common factors: A single-source generic drug; the drug was distributed through a closed distribution system;[24] the drug was essential to, or the "gold standard" for; the treatment of a rare condition.[25] The Senate report determined that the four common factors allowed each company to create a de facto monopoly of the pricing power of their generic drug – allowing them to impose unconscionable price increases.[26]

The GAO's report investigated trends in pricing for Medicare Part D covered generic drugs.[27] The report found that 315 of the 1,441 established drugs they studied experienced an extortionary price increase of at least 100 percent.[28] For example, piroxicam "a nonsteroidal anti-inflammatory drug that can be used to treat rheumatoid arthritis or osteoarthritis, increased by more than 2,000 percent, from $0.09 per capsule in first quarter 2010 to $1.94 per capsule in first quarter 2011."[29] Additionally, the GAO discovered through stakeholder interviews that if a generic drug served a small patient population, it was more susceptible to price increases because there was little financial incentive for competitors to enter the market.[30] Furthermore, the stakeholders reported that "supplier and buyer consolidation can drive price increases" because of difficulties created in manufacturing generic drugs.[31]

As a result of these reports, the Maryland General Assembly pursued legislation to fight and prevent further cases of abusive pricing practices by generic pharmaceutical companies.[32] The following section will discuss the General Assembly's passage of the Act, and the enforcement powers the Act gave the Maryland Attorney General's Office.

(Mar. 9, 2018, 1:56 PM), https://www.cnbc.com/2018/03/09/pharma-bro-martin-shkreli-sentenced-to-7-years-in-prison.html.

23. *Frosh*, 887 F.3d at 676.

24. *Martin Shkreli's drug distribution strategy blocks generic competitors*, CBC NEWS (Mar. 3, 2016, 1:38 PM), https://www.cbc.ca/news/health/drug-generics-distribution-1.3474384) ("Shkreli had the perfect weapon: a tightly-controlled distribution system which would make it virtually impossible for a competitor to obtain enough Daraprim to develop their own version.").

25. *Frosh*, 887 F.3d at 676.

26. *Id.* at 676–77 ("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.'").

27. *Frosh*, 887 F.3d at 675–76.

28. *Id.*

29. *See supra,* note 21, at 17.

30. *Frosh*, 887 F.3d at 676.

31. *Id.*

32. *Id.* at 677.

B. An Act Concerning Public Health: Maryland's Generic Pharmaceutical Anti-Price Gouging Statute

The prohibition against price gouging for essential off-patent or generic drugs became effective on October 1, 2017 and codified in MD Code—Health §§ 2-801-803.[33] Section 2-802 states:

> (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.[34]

Moreover, Maryland's Anti-Price Gouging Statute defined critical terms, such as "essential off-patent or generic drug," "price gouging," and "unconscionable increase."[35] The Act defined essential off-patent or generic drug as: "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 . . . (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*."[36] Price gouging was defined as "an unconscionable increase in the price of a prescription drug."[37] Next, the Act stated that "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 health; and (2) results in a consumer 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."[38]

The Act gave enforcement powers to the Maryland Attorney General's Office.[39] Those powers included: the power to petition the Circuit Court to enter an injunction for violations of the statute; return money to consumers that resulted from violations of the Act; require violating manufacturers to dispense the drug through any state health program at the drug's last permissible price for up to one

33. MD. CODE ANN., HEALTH §§ 2-801-803.
34. MD. CODE ANN., HEALTH § 2-802.
35. MD. CODE ANN., HEALTH § 2-801.
36. *Id.* (emphasis added).
37. *Id.*
38. *Id.*
39. MD. CODE ANN., HEALTH § 2-803.

year; and order civil penalties of up to $10,000.[40] Furthermore, manufacturers alleged to have violated the Act would not be permitted to raise a defense "that the person did not deal directly with a consumer residing in the State."[41]

Through bipartisan support, the Act gave the Attorney General's Office powers to intervene when the market failed to function as expected, such as allowing drug makers to charge hundreds or even thousands of dollars for drugs that were "manufactured for pennies a pill."[42] In passing the Act, the General Assembly passed what was a "first-in-the nation measure" to protect consumers from shocking drug price increases.[43]

C. Extraterritoriality Principle of the Dormant Commerce Clause

As clearly established in the text and structure of the Constitution itself, Congress holds the power to "regulate Commerce with foreign Nations and among the several States."[44] From this explicit power, the implicit power of the judicial doctrine known as the Dormant Commerce Clause arose.[45]

The doctrine came to fruition out of the Court's long recognition that the Commerce Clause holds within it an implicit limitation on states' powers "to enact legislation affecting interstate commerce."[46] Thus, the DCC "prohibits States from legislating in ways that impeded the flow of interstate commerce."[47] Among the ways states could impede the flow of interstate commerce were by passing legislation or regulations aimed at economic protectionism.[48] Economic protectionism is legislation or regulations "designed to benefit in-state economic interests by burdening out-of-state competitors."[49]

Additionally, the Supreme Court developed the extraterritoriality principle of the DCC from its holdings in *Baldwin,*[50] *Brown-Forman,*[51] and *Healy.*[52] The judicially created extraterritoriality principle of the DCC prohibits states from regulating

40. MD. CODE ANN., HEALTH § 2-803; *Frosh*, 887 F.3d at 678.

41. MD. CODE ANN., HEALTH § 2-803; *Frosh*, 887 F.3d at 677.

42. Ian Duncan, *Maryland General Assembly passes bill aimed at 'price gouging'*, THE BALTIMORE SUN (Apr. 10, 2017, 2:55 PM) http://www.baltimoresun.com/news/maryland/politics/bs-md-drug-price-gouging-20170410-story.html) ("During floor debates on the Act, Republicans questioned whether the attorney general's office had sufficient expertise to take on the new role, but ultimately many Republicans in both the House and the Senate voted for the measure.").

43. *Id.*

44. U.S. CONST. art. I § 8, cl. 3.

45. *Frosh*, 887 F.3d at 667.

46. Healy v. Beer Inst., Inc., 491 U.S. 324, 326. n.1 (1989).

47. Star Scientific Inc. v. Beales, 278 F.3d. 339, 355 (4th Cir. 2002).

48. *Frosh*, 887 F.3d at 667.

49. New Energy Co. of Ind. v. Limbach, 486 U.S. 269, 273–74 (1988).

50. Baldwin v. G.A.F. Seelig, Inc. 294 U.S. 511 (1935).

51. Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573 (1986).

52. Healy v. Beer Inst., Inc., 491 U.S. 324 (1989).

commerce that occurs entirely outside of their borders.[53] The Supreme Court has held that the extraterritoriality principle is violated if a state statute or regulation "expressly applies to out-of-state commerce . . . or it has that practical effect, regardless of the [state]'s intent."[54]

In *Baldwin v. G.A.F. Seeling*, the Supreme Court recognized the extraterritoriality doctrine of preventing burdens on interstate commerce.[55] The Supreme Court reasoned that it is an established doctrine that "a state may not, in any form or under any guise, directly burden the prosecution of interstate business."[56] Applying this principle, the Supreme Court affirmed the lower courts' orders granting the relief sought by the plaintiffs from the New York Milk Control Act, which set up a system of minimum prices to be paid by distributors to manufacturers.[57] The Supreme Court further reasoned that New York "ha[d] no power to project its legislation" into other states "by regulating the prices to be paid" in those states.[58] Thus, the Supreme Court concluded that New York could not use either its taxing or police powers to establish "an economic barrier against competition with the products of another state or the labor of its residents."[59]

Fifty-one years later, in *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, the Supreme Court applied the extraterritoriality balancing test to a state's price control legislation to hold that it did not facially discriminate against interstate commerce.[60] Here, the Supreme Court reasoned that when a statute "has only indirect effects on interstate commerce and regulates evenhandedly," the Court must weigh the state's legitimate interest and local benefits against the burdens on interstate commerce.[61] Additionally, the Supreme Court recognized that "the most important issue was whether [a] statute regulated out-of-state transactions."[62] The Supreme Court applied this reasoning to hold that the New York liquor affirmation

53. *Frosh*, 887 F.3d at 667.

54. *Id.* at 668.

55. *Baldwin*, 294 U.S. at 522.

56. *Id.* (citing International Textbook Co. v. Pigg, 217 U.S. 91, 112 (1910)).

57. *See id.* at 519 (the substance of the provision was that "there shall be no sale within the state of milk bought outside unless the price paid to the producers was one that would be lawful upon a like transaction within the state.").

58. *Id.* at 521.

59. *Baldwin*, 294 U.S. at 527 (the court found New York's legislation to be the "equivalent of rampart customs duties designed to neutralize advantages belonging to the place of origin," and were "thus hostile in conception as well as burdensome in result.").

60. *See Brown-Forman*, 476 U.S. at 579 ("When 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 Court] has generally struck down the statute without further inquiry.").

61. *Id.* at 579 ("The critical consideration is the overall effect of the statute on both local and interstate activity.")

62. *Id.* at 581.

statute regulated out-of-state transactions in violation of the Commerce Clause.[63] In striking down the New York liquor control law, the Court concluded that although "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."[64]

Healy v. Beer Institute, Inc. later reaffirmed the extraterritoriality principle established by the Supreme Court.[65] Justice Blackmun, writing for the Court, reiterated that a state cannot create commerce legislation or regulation that occurs "wholly outside of the State's borders, whether or not the commerce has effects within the State."[66] If the statute on its face directly controls commerce entirely outside of its borders then there is no question that it is invalid, but if this reach is not clear, then the "critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the state."[67] The Supreme Court articulated that the practical effect of a statute is evaluated by considering not only the "consequences of the statute itself, but also . . . how the statute may interact with the legitimate regulatory regimes of other States."[68] Through this reasoning, the Supreme Court concluded that Connecticut's price-affirmation statute had "the undeniable effect of controlling," commercial activity that occurred entirely outside of the state.[69] Additionally, the practical effect of the price affirmation law, along with similar laws enacted throughout the country, was to create "just the kind of competing and interlocking local economic regulation that the Commerce Clause was meant to preclude."[70] Therefore, the Supreme Court reaffirmed that the Commerce Clause precludes states from depriving businesses and consumers in other states of competitive advantages that they possess based on their local interests.[71]

63. *See id.* at 582. (the New York liquor affirmation statute regulated out-of-state transactions by "forcing a merchant to seek regulatory approval in one State before undertaking a transaction in another," thus directly regulating commerce).

64. *Brown-Forman*, 476 U.S. at 580.

65. Healy v. Beer Institute, Inc., 491 U.S. 324 (1989).

66. *Healy*, 491 U.S. at 336. ("Specifically, a State may not adopt legislation that has the practical effect of establishing a 'scale of prices for use in other states.'").

67. *Id.* at 336.

68. *Id.* at 336–37 ("Generally speaking, the Commerce Clause protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State.").

69. *Id.* (Connecticut's statute required out-of-state shippers of beer to affirm that their posted prices for products sold to Connecticut wholesalers be no higher than the prices at which those products were being sold in the bordering States).

70. *Id.* at 337.

71. *Healy*, 491 U.S. at 339.

D. The Supreme Court's Limitation of Extraterritoriality to Price Control and Price Affirmation Statutes

In 2003, the Supreme Court departed from its long-held application of the extraterritoriality principle in *Pharm. Research and Mfrs. of America v. Walsh*.[72] In *Walsh*, the Court reviewed a challenge by an association of "nonresident drug manufacturers" to the Maine Rx program.[73] The Maine Rx program was passed by Maine's legislature in 2003 with the primary intent of "provid[ing] discounted prescription drugs" to Maine citizens.[74]

The association of drug manufacturers challenged the Maine Rx program on two grounds, alleging first that the program was preempted by the Medicaid statute, and second that it violated the Commerce Clause.[75] The drug manufacturers association grounded its preemption challenge on a prior authorization[76] requirement Maine added for prescription drugs.[77] In granting the manufacturers' motion for preliminary injunction, the district court, "without resolving any factual issues," held that "Maine had not just passed a statute that conflicted with federal Medicaid legislation, but it had actually taken the federal Medicaid program and altered it to serve Maine's local purposes."[78]

However, the Court of Appeals for the First Circuit overturned the district court's analysis of the preemption issue, and the Supreme Court ultimately affirmed the holding.[79] The Supreme Court reasoned that the record did not demonstrate "that

72. Pharmaceutical Research and Mfrs. of America v. Walsh, 538 U.S. 644 (2003).

73. *Walsh*, 538 U.S. at 649–50 (after Congress "enacted [a] cost-saving measure in 1990, requir[ing] drug companies to pay rebates to States on their Medicaid purchases," several state legislatures enacted "supplemental rebate programs to achieve additional cost savings on Medicaid purchases as well as for purchases made by other needy citizens," one being the Maine Rx program).

74. *Id.* at 649.

75. *Id.* at 650.

76. *See id.* at 650–51 (when Congress first created the Medicaid program in 1965 it "did not specifically address outpatient prescription drug coverage" . . . instead it established "regulations and guidelines [that] 'set upper limits on each State's aggregate expenditures for drugs.'" Additionally, with approval by the Secretary, states "designed and administrated their own formularies" concerning prescription drugs, including prior authorization programs "that required approval by a state agency to qualify a doctor's prescription for reimbursement.").

77. *See id.* at 656 (before the commencement of the Maine Rx Program, "the Pharmaceutical Research and Manufacturers of America, an association representing manufacturers that 'account for more than 75 percent of brand name drug sales in the United States,'" brought its action in part based off of three affidavits that commented on the "operation of prior authorization programs administered by private managed care organizations, describing their actual and potential adverse impact on both manufacturers and patients.").

78. *Walsh*, 538 U.S. at 658–59. (the District Court reasoned that the prior authorization program amounted to an "alteration [that] served purposes outside the scope of the Medicaid program and created an obstacle to the administration of the federal program [that] was sufficient to establish preemption" . . . because the obstacle was one in which "drugs on the list must be approved by the state Medicaid Medical Director before they can be dispensed.").

79. *Id.* at 668.

prior authorization would have a significant adverse impact on the manufacturers of brand name prescription drugs," but instead would result in some administrative costs to physicians.[80] Ultimately, the Supreme Court held that the question of whether prior authorization by the Secretary must be sought before the Maine Rx program could go into effect was not dispositive, and therefore the Supreme Court "offer[ed] no view as to whether it would be proper for the Secretary to disallow funding for the Maine Medicaid program if Maine fails to seek approval from the Secretary of its Maine Rx Program."[81]

Moreover, the Supreme Court upheld the court of appeals holding that the Maine Rx program did not violate the DCC.[82] The Supreme Court held that the court of appeals correctly distinguished the Maine Rx Program from its DCC jurisprudence concerning price affirmation statutes.[83] The manufacturers' Commerce Clause challenge focused on the potential effects to manufacturers that would result if they complied with the Maine Rx Program.[84] The Supreme Court reasoned that there was no burden placed on commerce by the Maine Rx Program because "the alleged harm to interstate commerce would be the same regardless of whether the manufacturer[s] compliance was voluntary or the product of coercion."[85] Additionally, the Maine Rx Program did not regulate out-of-state transactions by "insisting that manufacturers sell their drugs to a wholesaler for a certain price."[86] Therefore, the Supreme Court found that the extraterritoriality principle that was applied in *Baldwin* and *Healy* did not apply to this case, because "unlike the price control or price affirmation statutes" the Maine Rx program did not expressly or inevitably affect "regulat[ing] the price of any out-of-state transaction."[87]

III. THE COURT'S REASONING

In *Association for Accessible Medicines v. Frosh*, the United States Court of Appeals for the Fourth Circuit reversed and remanded the United States District Court for the District of Maryland's dismissal of AAM's complaint, holding that Maryland's Anti-Price Gouging Statute violated the DCC because it regulated price transactions that occur outside of Maryland.[88] Judge Thacker wrote the majority opinion, in

80. *Id.* ("The impact on the manufacturers is not relevant because any transfer of business to less expensive products will produce savings for the Medicaid program. The impact on doctors may be significant if it produces an administrative burden that affects the quality of their treatment of patients, but no such effect has been proved.").

81. *Id.*

82. *Id.* at 660.

83. *Frosh*, 887 F.3d at 669–70; *Walsh*, 538 U.S. at 669.

84. *Walsh*, 538 U.S. at 669.

85. *Id.*

86. *Id.*

87. *Id.*

88. *Frosh*, 887 F.3d at 665–66.

which Judge Agee joined, and supported his holding by applying the extraterritoriality principle of the DCC to the Maryland statute.[89] Judge Wynn dissented on the grounds that the Act was a constitutional application of the State's police powers and authority to protect its citizens from unconscionable generic drug prices, and not a violation of the extraterritoriality principle.[90]

A. The Majority Found A Per Se Violation of the Extraterritoriality Principle

The majority opened its ruling by discussing the legislative and procedural history of the Maryland Anti-Price Gouging Statute.[91] The majority walked through the relevant portions of the statute, including the definitions of key terms, and the proposed enforcement mechanisms.[92] Additionally, the majority discussed the Maryland legislature's passage of the statute in response to the release of the two federal government reports,[93] the governor's refusal to sign the statute, and the July 6, 2017 filing of AAM's DCC challenge.[94]

The majority reviewed the district court's dismissal *de novo*, "accepting [AAM's] well pleaded allegations as true and drawing all reasonable inference in [AAM's] favor."[95] Judge Thacker reiterated the classic DCC jurisprudence, stating that the federal government's power to restrain states from enacting legislation that "interferes or burdens" interstate commerce was driven by the Supreme Court's concerns about economic protectionism.[96] The extraterritoriality principle of the DCC arose out of the principle that states cannot regulate commerce that occurs entirely outside of their borders.[97] Therefore, a state's legislation would violate "the extraterritoriality principle if it either expressly applies to out-of-state commerce . . . or has that 'practical effect,' regardless of the legislature's intent."[98]

First, the majority walked through extraterritoriality principle jurisprudence established in *Brown-Forman*, *Healy*, and *Baldwin*.[99] The Court placed great reliance on the Supreme Court's *Healy* outline of the principle against extraterritoriality.[100] In *Healy*, the Supreme Court reasoned that; (1) a state law cannot regulate commerce that takes place entirely outside of its state; (2) a statute that directly controls out-of-state commerce is invalid regardless of the legislature's intent, and

89. *Id.* at 667.
90. *See infra,* Part III.B.
91. *Frosh*, 887 F.3d at 666–67.
92. *Id.*
93. *See supra* at notes 20, 21.
94. *Frosh*, 887 F.3d at 666–67.
95. *Id.* at 667 (citing *Schiling v. Schmidt Bank Co.*, 876 F.3d 596, 599 (4th Cir. 2017)).
96. *Id.*
97. *Id.*
98. *Id.* at 668.
99. *Frosh*, 887 F.3d at 668–70.
100. *Id.* at 669.

to determine this, courts must look to the practical effect of the legislation; and (3) when weighing the practical effect of the legislation, the court looks to both the consequences of the statute itself and how the statute could affect the legitimate regulatory regimes of states if other states passed similar legislation.[101]

The court then moved on to address Maryland's argument that the Supreme Court limited the extraterritoriality principle to price affirmation statutes in *Walsh*.[102] The majority acknowledged that "the rules that applied in *Baldwin* and *Healy*" were not applicable to the Maine Rx program, because "unlike price control or price affirmation statutes," Maine's program did not directly or inevitably regulate the prices of transactions that occurred outside of Maine's borders.[103] However, the majority reasoned that Maryland's argument that the extraterritoriality principle was limited to only price affirmation statutes was incorrect.[104] The Court reiterated that Maine's Rx program only affected the prices of drug transactions that occurred within Maine, and then pointed to the Supreme Court's holding in *Edger v. MITE Corp.*[105] In *MITE Corp.*, the Supreme Court held a non-price affirmation statute that directly regulated transactions that occurred across state lines, in relation to corporate takeovers of companies in which at least ten percent of the shares were owned by Illinois residents, violated the principle against extraterritoriality.[106] Therefore, the majority concluded that Maryland's interpretation of the Supreme Court's reasoning in *Walsh* was too narrow.[107]

The majority then turned to the "merits of AAM's dormant commerce clause challenge."[108] The majority focused on the "made available for sale" language of the Act's definition of "essential off-patent or generic drug."[109] The majority, reasoned that this language did not limit the Act to sales that occurred within Maryland, and did not restrict the Act's "operation to the context of a resale transaction with a Maryland consumer."[110] Additionally, the majority noted that Maryland acknowledged during oral arguments that the conduct violating the Act was intended to reach "upstream consumer retail sales," which would "occur almost exclusively outside Maryland."[111]

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101. *Id.*

102. *Id.*

103. *Id.* at 669–70.

104. *Frosh*, 887 F.3d at 670.

105. Edgar v. MITE Corp., 457 US 624 (1982).

106. *See* Frosh, 887 F.3d at 668, 670 (the Supreme Court in *Edgar v. MITE Corp.* held that an Illinois law that allowed the Secretary of State to reject a tender offer, even to shares not owned by Illinois shareholders of a corporate takeover of the shares of a target company, violated the extraterritoriality principle of the dormant commerce clause).

107. *Frosh*, 887 F.3d at 670.

108. *Id.*

109. *Id.* at 671.

110. *Id.*

111. *Id.*

Judge Thacker also analyzed the Act's structure.[112] Here, the majority reasoned that the Act was fixated on the "lawfulness of a price increase [that] is measured according to the price the manufacturer or wholesaler charges in the initial sale of the drug," which clearly targeted the "upstream pricing and sale of prescription drugs" that occur outside of Maryland.[113] Thus, the majority concluded that the Act would "compel manufacturers and wholesalers" to comply with the law outside of Maryland.[114]

Through this compulsion to comply with the Maryland Act, the majority found the practical effect of the Act to be the specification of the prices of drugs that could be sold outside Maryland.[115] The majority reasoned that the Act aimed "to override prescription drug manufacturers reaction to the market and to regulate the prices these manufacturers could charge for their products."[116] Therefore, the fundamental problem with the Act was that it would do more than impact upstream pricing.[117]

Next, the majority held that if multiple states enacted similar legislation, it could "subject prescription drug manufacturers to conflicting state requirements."[118] The majority reasoned that manufacturers would have to modify their distribution systems to enter into separate transactions for each state in order to remain in compliance with the different state pricing acts.[119] Therefore, the majority found the possibility of "the kind of competing and interlocking local economic regulation that the Commerce Clause was meant to preclude" significantly realistic.[120]

In sum, the majority found Maryland's Act to be a violation of the DCC because it would control the pricing of transactions that occurred outside of Maryland.[121] However, the majority specifically stated that their holding should not be interpreted as preventing states from enacting legislation to "secure lower prescription drug prices for their citizens."[122] Ultimately, however, the majority reversed the district court's dismissal of AAM's challenge, holding that that Act was "not triggered by any conduct that takes place in Maryland," the Act "control[led] the prices of transactions. . .outside of the state," and if other states began to enact

112. *Frosh*, 887 F.3d at 672.

113. *Id.* at 671.

114. *Id.* at 672 (the Majority held that any "legitimate effects the Act may have had in Maryland [were] insufficient" to protect the Act, because the Act targeted the "price that may be charged elsewhere for a good.").

115. *Id.* at 673.

116. *Id.* at 672.

117. *Frosh*, 887 F.3d at 672–673.

118. *Id.* at 673.

119. *Id.*

120. *Id.* at 674.

121. *Id.*

122. *Frosh*, 887 F.3d at 674.

similar legislation, it would create a "significant burden on interstate commerce involving prescription drugs."[123]

B. The Dissent Argued That the Act is Not a per se Violation and is a Constitutional Exercise of State Authority

The dissent first argued that Maryland's legislature has the authority to protect its citizens from the unconscionable drug pricing of out-of-state generic drug manufacturers under its general police powers.[124] The dissent reasoned that Maryland's Act was constitutional because the Act "[did] not implicate the concerns that lie at the heart of the Supreme Court's dormant Commerce Clause jurisprudence."[125] The dissent began its analysis of the Act by reiterating the serious concerns outlined in the two federal government reports and reviewing the language of the Act itself.[126]

The dissent then argued that the Act was triggered only by conduct occurring within Maryland. Moreover, the dissent disagreed with that majority's conclusion that the Act did not "require a nexus to an actual sale in Maryland."[127] The dissent pointed to the State's repeated representations that the Act was not meant to "reach any stream of commerce that does not end in Maryland" to conclude that the Act's construction was never intended to reach nonapplicable streams of commerce.[128] The dissent reasoned that Maryland represented that the Act was only triggered when drugs were made available for sale within Maryland, and controlling Maryland law dictated that unless expressly stated otherwise by the legislature, the intent of the legislation "will be presumed not to have any extraterritorial effect."[129]

The dissent further argued that AAM's DCC challenge was without merit for numerous reasons.[130] The dissent began by reminding the majority that the extraterritoriality doctrine is a judicially created doctrine that expresses states prohibition from regulating "commerce occurring wholly outside" of a state's boundaries.[131] Additionally, the dissent noted a concurring opinion from the Sixth Circuit holding that "there has never been a single Supreme Court dormant

123. *Id.* at 670, 674.

124. *Id.* at 675 (Wynn, J., dissenting).

125. *Id.*

126. *Id.* at 675–677.

127. *Frosh*, 887 F.3d at 678.

128. *Id.* at 679. (reasoning that "because Maryland repeatedly represented that the Act 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").

129. *Id.* at 680 (quoting Chairman of Bd. Of Trs. of Emps.' Ret Sys. v. Waldron, 401 A.2d 172, 183-84 (Md. 1979)).

130. *Id.*

131. *Id.* at 680–81.

Commerce Clause holding that relied exclusively on the extraterritoriality doctrine to invalidate a state law."[132] In addition, the dissent reasoned that parallel to a recent trend of sustaining state regulations that might be in conflict with the DCC, the Supreme Court's modern definition of commerce encompasses all transactions in the stream of commerce, and the legislation would only impact commerce negatively if it regulated a transaction in a stream of commerce that never took place in Maryland.[133]

Furthermore, the dissent took the position that the holdings from *Baldwin*, *Healy*, and *Brown-Forman*, which the majority relied on, all turned on the principle concerns of economic protectionism, discrimination against interstate commerce, and state regulation of transactions that never enter the concerned state.[134] Not a single one of those cases held that nondiscriminatory state legislation "regulating an upstream transaction in a stream of transactions that ends in the State" constituted a violation of the extraterritoriality principle of the DCC.[135] Thus, the dissent concluded that the extraterritoriality doctrine applied only to "price control or price affirmation statutes" that connect the prices being charged in-state with those being charged out-of-state that discriminate against interstate commerce.[136]

Finally, the dissent argued that Maryland should be entitled to regulate prices charged for essential generic drugs under their strong public interest and police powers as long as the Act did "not favor in-state transactions at the expense of out-of-state interests or discriminate against interstate commerce."[137] The dissent supported its argument by noting other states' consumer protection laws that regulate the prices of manufacturers of non-pharmaceutical goods that survived extraterritoriality challenges.[138] Ultimately, the heart of the dissent's closing analysis was rooted in the fact that the Act did not "compel manufacturers to sell prescription drugs" at a specific price, but instead, under the legislature's representation of the public interest, "forbid manufacturers from imposing an 'unconscionable' price increase for essential generic drugs."[139]

IV. ANALYSIS

In *Association for Accessible Medicines v. Frosh*, the Fourth Circuit held that Maryland's anti-price gouging statute was an unconstitutional violation of the extraterritoriality principle of the DCC.[140] The Court's judgment was incorrect in this

132. *Frosh*, 887 F.3d at 681.
133. *Id.* at 683.
134. *Id.* at 684.
135. *Id.*
136. *Id.* at 686.
137. *Frosh*, 887 F.3d at 686, 692.
138. *Id.* at 690.
139. *Id.* at 689.
140. *Id.* at 674.

case because it erroneously applied the extraterritoriality principle to find a per se violation of the DCC, and thus failed to weigh Maryland's strong public interest in regulating generic prescription drug manufacturers.[141] Additionally, there has been conflicting applications and limitations of the extraterritoriality principle of the DCC from the Supreme Court and across several circuits.[142] Therefore, the Fourth Circuit should have applied the balancing test of the extraterritoriality principle to find that Maryland's interest in protecting its citizens from unconscionable drug price increases greatly outweighs any burden that might be placed on the interstate commerce of drug manufacturers and distributors.[143]

A. The Majority Incorrectly Applied the Extraterritoriality Principle to the Act

Writing for the majority, Judge Thacker incorrectly held that the Act was a DCC violation merely because "it directly regulates transactions that take place outside of Maryland."[144] The majority's holding failed to properly consider the two-tiered legal standard established in DCC jurisprudence, which was relied on by the district court.[145]

As stated in *Brown-Forman*, the first tier of the test asks the court to inquire whether the "state statute directly regulates or discriminates against interstate commerce, or [is] its effect [] to favor in-state economic interest over out-of-state interest."[146] If either is found, the court should strike down the legislation without further inquiry.[147] However, where a state statute "does not discriminate against interstate commerce but 'regulates even-handedly' and only incidentally affects interstate commerce," then the court moves to the second tier of the DCC analysis.[148] Under this second tier, the court conducts a balancing test, weighing the legitimacy of the state's interests and local benefits against the burden that is placed on interstate commerce by the legislation.[149]

Under the first tier of this legal framework, the Court of Appeals incorrectly held that the Act directly regulated transactions taking place outside of Maryland,

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141. *See infra* Parts IV.A., IV.B.

142. *See infra* Part IV.C.

143. *See infra* Part IV.B.

144. *Frosh*, 887 F.3d at 674.

145. *See Frosh*, slip op. at 3-4; *Star*, 278 F.3d. at 355 (citing Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth. 476 U.S. 573, 578–79 (1986) (when a court is faced with the task of determining "whether a State statute violates the dormant Commerce Clause, [it] conducts a two-tiered analysis."); Environmental Tech. Council v. Sierra Club, 98 F.3d 774, 785 (4th Cir. 1996));

146. *Star*, 278 F.3d. at 355 (quoting Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth. 476 U.S. 573, 579 (1986)).

147. *Brown-Forman,* 476 U.S. at 578–79.

148. *Frosh*, slip op. at 3 (quoting Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970)).

149. *Star*, 278 F.3d. at 355 (quoting Brown-Forman Distillers Corp. v. New York State Liquor Auth. 476 U.S. 573, 579 (1986)).

thereby resulting in "a virtually per se" violation of the DCC.[150] However, a plain language reading of the relevant portions of the Act, supported by the record, warrants a different conclusion. The Act states that "a manufacturer or wholesale distributor may not engage in price gouging of *an essential off-patent or generic drug*."[151] Furthermore, the legislature specifically defined essential off-patent or generic drug, in part, as a drug "that is actively manufactured and marketed for sale in the United States by three or fewer manufacturers , *and that is made available for sale in the State*."[152] This essential language clearly displays that the Act is only triggered when there is a drug made available for sale within Maryland.[153]

Additionally, since the Act would only be applicable to prices of drugs ultimately sold in Maryland, the Act did not "'insist on price parity with drugs sold outside of the state," and therefore would not have the "practical effect of regulating commerce occurring wholly outside of the state."[154] This plain language reading of the Act is further supported by Maryland's repeated assertions on the record that the Act "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 other states.[155] Additionally, Maryland argued that the Act "does not reach, or purport to reach any stream of commerce that does not end in Maryland."[156]

Furthermore, the enforcement provisions of the Act relied on the Maryland Medical Assistance Program[157] notifying the Maryland Attorney General of violating increases in prices of essential off-patent or generic drugs.[158] The Maryland Medical Assistance Program, *inter alia*, provides "medical and other health care services [to] indigent individuals or medically indigent individuals" in Maryland.[159] The Secretary of this program also administers the Medicare Option Prescription Drug Program.[160] Under the Medicare Option Prescription Drug Program, one of the Secretary's duties is to enter into contracts with prescription drug plans to coordinate the Program and Medicare Part D benefits for eligible individuals, of which one of the requirements is to be a resident of Maryland.[161] The structure of the enforcement provisions further displays that the practical effects of the Act would only regulate drugs made available for sale within Maryland.[162] Additionally, the majority and

150. *Frosh*, slip op. at 3.
151. MD. CODE ANN., HEALTH § 2-802(a) (emphasis added).
152. MD. CODE ANN., HEALTH § 2-801(b)(1)(iii)(iv) (emphasis added).
153. *Frosh*, slip op. at 6.
154. *Id.* At 5 (citing Star Scientific Inc. v. Beales, 278 F.3d. 399, 356 (4th Cir. 2002)).
155. *Frosh*, 887 F.3d at 678-79.
156. *Id.*
157. MD. CODE ANN., HEALTH § 15-103.
158. MD. CODE ANN., HEALTH § 2-803(a).
159. MD. CODE ANN., HEALTH § 15-103(a)(2)(i).
160. *Id.*; MD. CODE ANN., HEALTH § 15-124.3.
161. MD. CODE ANN., HEALTH § 15-124.3(e)(1)(i)-(f)(1).
162. *See supra* Part II.B.

AAM cite the extraterritoriality doctrine "without adequately engaging with the fact that [the Act] could only give rise to liability when a drug is made available for sale in Maryland."[163]

Moreover, AAM's true concerns with the Act were rooted in fears about its members' current distribution and business practices.[164] According to AAM, their members do not track where their drugs were ultimately offered for sale, and therefore, do not know which of their drugs would end up for sale in Maryland.[165] Thus, compliance with the Act would require their members to "have to 'rejigger' their business practices," resulting in business conduct wholly outside of Maryland.[166] However, this argument is extremely unpersuasive in light of the fact that many manufacturers of many different goods have to change their business practices to "conform to differing state requirements."[167] Additionally, for a sector of the economy that between 2006 and 2015 increased revenue from $534 billion to $775 billion,[168] the cost of compliance with Maryland's Act and other state regulations appears, on its face, minimal. Furthermore, the Act would not be regulating manufacturers' ability to make profits, but would regulate "the ability of [manufacturers] to extract excessive profits by price-gouging Maryland consumers on essential drugs for which there is limited competition."[169] Therefore, the Act only sought to regulate drug manufacturers' products that were ultimately made available for sale within Maryland[170] in order to protect its citizens from abusive price gouging practices.

B. Maryland Has a Great Public Interest in Regulating Generic Prescription Drug Manufacturers

Under the second tier of the DCC inquiry, Maryland's local benefits in regulating unconscionable prescription drug price increases clearly outweigh any burden imposed on interstate commerce. The undue burden tier of the DCC inquiry states that "where the statute regulates evenhandedly to effectuate a legitimate local

163. *Frosh*, slip op. at 6.

164. *Id.* at 7.

165. *Id.*

166. *Id.*

167. *Id.*

168. *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-40, *DRUG INDUSTRY: Profits, Research and Development Spending, and Merger and Acquisition Deals* (2017); *see generally* Sarah Kliff, *The true story of America's sky-high prescription drug prices*, VOX (May 10, 2018, 9:19 AM), https://www.vox.com/science-and-health/2016/11/30/12945756/prescription-drug-prices-explained) ("The United States is exceptional in that it does not regulate or negotiate the prices of new prescription drugs when they come onto market." However, if the United States started price-regulating drugs people would trade off spending less money on drugs, for less choice of drugs and innovation.).

169. *Frosh*, slip op. at 7.

170. *See id.* at 6. ("Only if those drugs are then made available for sale in Maryland would the provisions of [the Act] apply to the transaction.").

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."[171] When applying this balancing test, the Fourth Circuit held in *Star*[172] that it considers; "(1) the nature of the local benefits advanced by the statute; (2) the burden placed on interstate commerce by the statute; and (3) whether the burden is 'clearly excessive' when weighed against [the] local benefits."[173]

Furthermore, the Supreme Court has long recognized that the limitations on states' regulatory powers created by the DCC "is by no means absolute."[174] The Court's reasoning stems from its recognition that states hold "reserved powers to legislate to protect the health, safety, and welfare of their citizens."[175] In addition, consumer protection legislation has traditionally been subject to state regulation, and therefore "courts should be particularly hesitant to interfere with a State's efforts to protect consumers under the guise of the dormant Commerce Clause."[176]

The Maryland legislature passed the Act "to protect Marylanders from the imposition of unconscionable price increases" for certain generic drugs, which resulted from "market failure and dysfunction."[177] The Act's introduction followed the release of two federal government reports detailing the "price-gouging of off-patent drugs." The Senate report detailed the "substantial burdens" that have been "imposed on patients and their families."[178] Some of those burdens directly affected patients "health, time, emotional well-being, and pocketbooks."[179] For example, the report detailed cases where patients were "forced to go without vital medicine and experienced[ed] dangerous and sometimes life threatening symptoms as a result."[180] Additionally, the GAO report found that "300 of 1,441 established generic drugs analyzed had at least one extraordinary price increase of 100 percent."[181] Furthermore, of the drugs that experienced an extraordinary price increase, "48 of

171. Yamaha Motor Corp., U.S.A. v. Jim's Motorcycle, Inc., 401 F.3d 560, 567 (4th Cir. 2005) (quoting Pike v. Bruce Church, Inc., 3978 U.S. 137, 142 (1970)).

172. Star Scientific Inc. v. Beales, 278 F.3d. 339 (4th Cir. 2002).

173. *Star*, 278 F.3d. at 357.

174. *Frosh*, 887 F.3d at 687 (quoting Lewis v. BT Inv. Managers, Inc., 447 U.S. 27, 36 (1980)).

175. *Id.*

176. *Frosh*, 887 F.3d at 687-88, (internal quotations and brackets omitted) (citing SPGGC, LLC v. Blumenthal, 505 F.3d 183, 194 (2d. Cir. 2007) (quoting United Hauler Ass'n v. Oneida-Herkimer Solid Waste Mgmt. Auth., 550 U.S. 330, 344 (2007)).

177. *Frosh*, slip op. at 1.

178. *See supra*, note 20, at 98.

179. *Id.*

180. *See Id.* (some patients and their physicians have "reported having to skip doses or hoard pills out of fear that their next refill would not be available or would be unaffordable." Additionally, even patients covered by health insurance "reported watching anxiously as prices climbed, knowing that they could lose access without warning…").

181. *See supra,* note 21.

those drugs had a price increase of 500 percent, and 15 of the drugs had a price increase of 1,000 percent or higher."[182] In addition, those extraordinary price increases generally lasted for at least one year with most having no downward pricing movement after this increase.[183] For example, methazolmide, a drug used to treat glaucoma "experienced a price increase of approximately 454 percent from about $0.33 per tablet…to $1.85 per tablet" in 2011, and by 2015 "the drug's price had further increased… [to] $5.47 per tablet."[184]

When applying the *Star* balancing test, it is clear that the Act's local benefits outweigh possible burdens on interstate commerce. For example, in 2014, Maryland had 891,411 Medicare beneficiaries[185] and spent $10,857,000 in total on Medicare.[186] Additionally, in 2018 Maryland spent $11,496,573,841[187] on Medicaid and had a total Medicaid enrollment of 1,165,777.[188] By preventing companies from unconscionably raising the price of generic drugs, the Act would have likely saved the state and consumers money by preventing abusive pricing to continue. Furthermore, before the Act was passed, a 2016 poll showed that 84 percent of Maryland voters were in favor of prescription drug price transparency and legal action by the Office of the Attorney General.[189]

Moreover, some of the drugs covered by the Act's prohibition on unconscionable price increases are essential life-saving generics, such as EpiPen and Naloxone.[190] EpiPen, a life-saving medication used to treat allergic reactions, had a price increase

182. *See supra,* note 21, at 14.

183. *See supra,* note 21.

184. *See supra,* note 21, at 18.

185. *Total Number of Medicare Beneficiaries,* HENRY K KAISER FAMILY FOUNDATION, https://www.kff.org/medicare/state-indicator/total-medicare-beneficiaries/?currentTimeframe=0&selectedRows=%7B%22states%22:%7B%22maryland%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited Feb. 2, 2019).

186. *Total Medicare Spending by State (in millions)*, HENRY K KAISER FAMILY FOUNDATION, https://www.kff.org/medicare/state-indicator/medicare-spending-by-residence/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited Feb. 2, 2019).

187. *Total Medicaid Spending*, HENRY K KAISER FAMILY FOUNDATION, https://www.kff.org/medicaid/state-indicator/total-medicaid-spending/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited Oct. 17, 2019).

188. *October 2018 Medicaid & CHIP Enrollment Data* Highlights, MEDICAID.GOV, https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html (last visited Oct. 17, 2019).

189. *Maryland Voter Poll on Prescription Drug Affordability,* MARYLAND CITIZEN'S HEALTH INITIATIVE: HEALTHCARE FOR ALL, http://healthcareforall.com/wp-content/uploads/2016/09/Prescription-Drug-Affordability-Poll-Memo-090816-FINAL.pdf (last visited Feb. 2, 2019).

190. *Key Facts on Prescription Drug Price Affordability,* MARYLAND CITIZEN'S HEALTH INITIATIVE: HEALTHCARE FOR ALL, http://healthcareforall.com/wp-content/uploads/2016/12/Prescription-Drug-Affordability-Key-Facts-12.1.pdf (last visited Feb. 2, 2019).

of 508 percent.[191] The Naloxone auto-injector, a life-saving drug that is preferred by first responders to treat opioid overdoses, had a price increase of 553 percent.[192] Prescription drug costs in 2015 hit a record high of $57 billion, and according to some projections, could surpass $600 billion by 2020.[193] Furthermore, in 2015, the top 50 pharmaceutical companies spent 558 percent more on sales, marketing, and administration then on research and development.[194]

Out of control drug prices are not limited to Maryland, and other states have sought legislation to address this abusive industry pattern and practice. According to the National Conference of State Legislatures, more than a dozen other states have filed legislation for a state law similar to Maryland's Anti-Price Gouging Act that could block or restrict generic drug price gouging.[195] The Connecticut Attorney General's office even launched an investigation that has culminated in a coalition of forty-five states filing a suit alleging that generic pharmaceutical companies engaged in price-fixing.[196]

Moreover, the district court noted that when faced with the second tier of the DCC analysis, AAM did not even present an argument that the Act was unconstitutional.[197] The nature of the Act is to protect Marylanders and their families from the ramifications of unconscionable generic prescription drug price increases that appear entirely outside of their control. The burden on the manufacturers, which gross billions of dollars in profits each year, to comply with the regulation remains unpersuasive, and supported by AAM's lack of argument as to the balancing test, the local benefits clearly appear to outweigh any burden placed on interstate commerce. Therefore, the district court correctly held that the Act was a constitutional exercise of Maryland's police powers to protect its citizens from greed and systemic failures, and the Fourth Circuit was incorrect to find a violation of the DCC.[198]

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191. *HB631: Prohibition Of Price Gouging In The Sale Of Essential Off-patent Or Generic Drugs,* MARYLAND CITIZEN'S HEALTH INITIATIVE: HEALTHCARE FOR ALL, http://healthcareforall.com/wp-content/uploads/2017/05/Price-Gouging-One-Page-Graphic-Summary.pdf (last visited Feb. 2, 2019).

192. *Id*.

193. *Why Transparency Matters In Drug Pricing,* MARYLAND CITIZEN'S HEALTH INITIATIVE: HEALTHCARE FOR ALL, http://healthcareforall.com/wp-content/uploads/2017/05/Why-Transparency-Matters-In-Drug-Pricing.pdf (last visited Feb. 2, 2019).

194. *Id.*

195. See Colorado, Illinois, Louisiana, Maine, Massachusetts, Minnesota, Mississippi, New Hampshire, New Jersey, New York, Rhode Island, Tennessee, Vermont, Virginia, Washington, and Wisconsin. *State Actions to Halt Price Gouging for Generic Drugs*, National Conference of State Legislatures: Prescription Drug Resource Center (last updated Jul. 20, 2018), www.ncsl.org/Portals/1/Documents/Health/Generic_drug_antiprice_gouging_Maryland_31894.pdf.

196. Seth Whitelaw et al., *Drug Pricing—The Next Compliance Waterloo*, 44 MITCHELL HAMLINE L. REV. 1165, 1192–93 (2019).

197. *Frosh*, slip op. at 8.

198. *Id.*

C. The Supreme Court, the 4th Circuit, and Sister Circuits have limited the Extraterritoriality Principle in Modern Commerce

Various courts have delivered more stringent holdings that limit the reach of the DCC's extraterritoriality principle when challenged by various state regulations. Arguably one of the most relevant of those holdings in relation to AAM's challenge of the Maryland Anti-Price Gouging Statute is the Supreme Court's holding in *Pharma Research & Mfrs. of Am. v. Walsh*.[199] The Court held that the extraterritoriality principle was not applicable, because "unlike control or affirmation statutes, 'the Maine Act [did] not regulate the price of any out-of-state transaction'" expressly or by inevitable effect.[200] In upholding the Maine Rx program, the Court emphasized that Maine was not "tying the price of its in-state products to out-of-state prices," and was not insisting manufacturers "sell their drugs to wholesalers for a certain price."[201] Thus, the Supreme Court concluded that the rule from *Brown-Forman*, *Healy*, and *Baldwin* did not apply because those cases dealt with regulations seeking pricing parity with out-of-state goods.[202]

Although the majority held Maryland's reading of *Walsh* as too narrow,[203] the extraterritoriality principle has also been limited across the circuits.[204] In the Tenth Circuit, when faced with a DCC challenge to Colorado's renewable energy mandate,[205] now Justice Gorsuch stated that when assessing *Brown-Forman*, *Healy*, and *Baldwin*, all three cases presented "(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 business."[206] Ultimately, the Tenth Circuit upheld Colorado's regulation and ruled against the extraterritoriality principle, stating that the regulation "just didn't share any of the three essential characteristics that mark those cases: it isn't a price control statute, it doesn't link prices paid [in-state] with those paid out-of-state, and it does not discriminate against out-of-staters."[207]

Similarly, in *Ass'n Des Eleverus De Canards Et D'Oies Du Quebec v. Harris*,[208] the Ninth Circuit ruled against another extraterritorial DCC challenge. In *Harris*, producers of foie gras challenged a California statute "banning the sale of products that are the result of force feeding birds to enlarge their livers beyond normal

199. *Walsh*, 538 U.S. at 644.

200. *Id.* at 669.

201. *Id.*

202. *Id.*

203. *Frosh*, 887 F.3d at 670.

204. *Id.*; *see e.g.*, Energy & Evtl. Legal Inst. v. Epel (EELI), 793 F.3d 1169 (10th Cir. 2015).

205. *EELI*, 793 F.3d at 1170.

206. *Id.* at 1172–73.

207. *Id.* at 1173 (a careful look at the holdings from Baldwin, Brown-Forman, and Healy "suggest concern with preventing discrimination against out-of-state rivals or consumers.").

208. 729 F.3d 937, 941–42 (9th Cir. 2013).

size."[209] The Ninth Circuit applied the Supreme Court's holding from *Walsh*, to conclude that "*Healy* and *Baldwin* are not applicable to a statute that does not dictate the price of a product and does not 'tie the price of its in-state products to out-of-state prices.'"[210]

Additionally, the Second Circuit struck down another DCC challenge based on the extraterritoriality principle in *Nat'l Elec. Mfrs. Ass'n. v. Sorrell*.[211] In *Sorrell*, an association of lamp-manufacturers challenged the constitutionality of Vermont's legislation requiring "manufacturers of some mercury-containing products to label their products and packaging to inform consumers that the products contain mercury, and on disposal, should be recycled or disposed of as hazardous waste."[212] The Second Circuit ultimately held that the association's extraterritoriality challenge failed "because the statute [did] not inescapably require manufacturers to label all lamps wherever distributed."[213] In coming to its holding, the Second Circuit reasoned that Vermont's statute does not mention any other states for any purpose, "unlike the restrictions involved in the Supreme Court's price-regulation cases."[214]

Furthermore, the Fourth Circuit in *Star* refused to uphold an extraterritoriality challenge.[215] In *Star*, a cigarette manufacturer challenged the constitutionality of the Master Settlement Agreement between forty-six states and major tobacco manufacturers, as well as a Virginia statute that imposed a pre-cigarette escrow obligation on those manufacturers.[216] The manufacturer in *Star* argued that the statute would require it to make payments on cigarettes sold to independent distributors in other states, therefore violating the extraterritoriality doctrine against placing burdens on interstate commerce through transactions occurring outside of Virginia.[217] Additionally, the manufacturer rested its argument on the extraterritoriality doctrine that "a statute that directly controls commerce occurring wholly outside the boundaries of a state exceeds the inherent limits" of the state's authority, despite the state legislature's intent.[218] The Fourth Circuit rejected these

209. Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris 729 F.3d 937, 941–42 (9th Cir. 2013).

210. *Harris*, 729 F.3d at 951 (the California Statute "does not impose any prices for duck liver products and does not tie prices for California liver products to out-of-state prices.").

211. 272 F.3d 104, 110 (2d Cir. 2001).

212. National Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 107–08 (2d Cir. 2001).

213. *Id.* at 110 ("To the extent the statute may be said to 'require' labels on lamps sold outside Vermont, then, it is only because the manufacturers are unwilling to modify their production and distribution systems to differentiate between Vermont-bound and non-Vermont-bound lamps. To 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 . . .").

214. *Id.*

215. *Star*, 278 F.3d. at 362.

216. *Id.* at 345.

217. *Id.* at 354

218. *Id.* at 355–56 (citing Healy v. Beer Inst., Inc., 491 U.S. 324, 336. (1989)).

arguments, holding that the Virginia statute "specifically limits its applicability to the sale of cigarettes" within Virginia, and did not regulate upstream transactions because a fee would only be placed on cigarettes actually sold within the State.[219] Furthermore, the Fourth Circuit held that Virginia's statute was not a *per se* violation of the DCC, because any effects of the law were not applicable to out-of-state distributors that did not sell cigarettes in Virginia.[220] Lastly, the statute did not have any "practical effect of controlling prices or transactions occurring wholly outside" of Virginia because the statute did not insist on "price parity" with out-of-state distributors.[221]

CONCLUSION

In *Association for Accessible Medicines v. Frosh*, the Fourth Circuit held the Act was unconstitutional because it was a per se violation of the extraterritoriality principle of the dormant Commerce Clause.[222] The Fourth Circuit incorrectly decided the case because it failed to apply its own precedent and the extraterritoriality principle in full to weigh the local benefits of the Act against any burdens that might be placed on interstate commerce.[223] The Fourth Circuit should have held under the balancing test that the local benefits of the Act far outweigh the abusive and exploitative practices of the pharmaceutical industry to unconscionably raise the prices of essential and life-saving drugs on Maryland consumers.[224] As a result of this opinion, Marylander's who are in the most dire need of affordable medication will still face issues acquiring these medications, and pharmaceutical profits will still supersede consumers' protections.

219. *Id.* at 356.
220. *Id.*
221. *Star*, 278 F.3d. at 356.
222. *Frosh*, 887 F.3d at 674.
223. *See supra* Parts IV.A., IV.B.
224. *See supra* Part IV.B.