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Sinking and Swimming Together: The Dormant Commerce Clause, Extraterritorial Regulation, and Prices in the Generic Drug Market

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SINKING AND SWIMMING TOGETHER: THE DORMANT COMMERCE CLAUSE, EXTRATERRITORIAL REGULATION, AND PRICES IN THE GENERIC DRUG MARKET

I. INTRODUCTION

On a daily basis, people struggle to afford their medications. In recent years, the increase in generic drug prices has created a burden on consumers.[1] One in four people claim they have trouble affording their prescription drugs.[2] From January 2012 to December 2017, the top selling brand-name drugs' median cost increase was 76%.[3] People with Type 1 and Type 2 diabetes are affected by this price increase in insulin.[4] Because people with diabetes do not produce their own insulin, they require the man-made drug version of insulin to regulate their body's blood glucose levels and, essentially, to live.[5] In 2016, Type 1 diabetics spent $5,705 per person on insulin, compared to the only $2,864 that was spent in 2012.[6] In 2017, the price of Insulin glargine (Lantus—a basal insulin) cost almost three-times the price in the United States as it did in Canada, France, and Germany.[7] Diabetics are just one of many groups with pre-existing conditions and diseases that are affected by the increase in drug prices.[8]

According to Justice Cardozo, "[t]he Constitution was created in order to ensure that the 'peoples of the several states [would] sink or swim together.'"[9] But should they have to when the odds are stacked against them? High prices in generic drugs are devastating to patients

1. Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States*, 316 JAMA NETWORK 858, 859 (2016).

2. Rabah Kamal et al., *What are the recent and forecasted trends in prescription drug spending?*, PETERSON-KFF (Feb. 20, 2019), https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-annual-growth-in-rx-drug-spending-and-total-health-spending-per-capita_nhe-projections-2018-27.

3. Nathan E. Wineinger et al., *Trends in Prices of Popular Brand-Name Prescription Drugs in the United States*, 2 JAMA NETWORK 1, 1 (2019).

4. Ken Alltucker, *Struggling to stay alive: Rising insulin prices cause diabetics to go to extremes*, USA TODAY, https://www.usatoday.com/in-depth/news/50-states/2019/03/21/diabetes-insulin-costs-diabetics-drug-prices-increase/3196757002/ (last updated Mar. 27, 2019, 1:31 PM).

5. *Id.*

6. *Id.*

7. Kesselheim, *supra* note 1, at 859.

8. Gerald F. Anderson, *It's Time to Limit Drug Price Increases*, HEALTH AFFAIRS J. (Jan. 25, 2019), https://www.healthaffairs.org/do/10.1377/hblog20190715.557473/full/.

9. Peter C. Felmly, *Beyond the Reach of States: The Dormant Commerce Clause, Extraterritorial State Regulation, and the Concerns of Federalism*, 55 ME. L. REV. 467, 476 (2003).

who need medications to live healthy, normal lives.[10] State legislatures have been attempting to remedy this problem for their citizens.[11] However, the states are prohibited by the Dormant Commerce Clause from creating legislation that impedes interstate commerce.

This Comment discusses the implications of the Dormant Commerce Clause's effect on the generic drug market. Specifically, it discusses whether the Dormant Commerce Clause applies to the generic drug market, which lacks the competitive aspect the Dormant Commerce Clause aims to protect. Part II of this article discusses the background of the generic drug market and attempts to regulate it. Part III of this article analyzes the impact of the Dormant Commerce Clause on state drug-pricing legislation. Part IV of this article discusses the impacts of applying the Dormant Commerce Clause to generic drug pricing legislation.

II. BACKGROUND

A. Why is There an Increase in Drug Prices?

1. Exclusivity in the Market

In the early 1990s, Congress enacted the Drug Price Competition and Patent Term Restoration Act (also known as the Hatch-Waxman Act). It was intended to provide market exclusivity to drug manufacturers.[12] Congress incentivized drug manufacturers to continue producing new drugs by offering (1) 20-year patent protection, (2) extensions on patents, (3) the right to delay U.S. Food and Drug Administration ("FDA") approval of generic drugs, and (4) other rights providing market exclusivity.[13] Generic drugs are therefore delayed from entering the market, allowing for manufacturers to set the initial price of the drug.[14] Congress enacted a second law, the Orphan Drug Act, which provided further market exclusivity incentives for develop-

10. S. REP. NO. 114-429, at 7–8 (2016) [hereinafter Senate Report].

11. Steven Findlay, *States Pass Record Number Of Laws To Reel In Drug Prices*, KAISER HEALTH NEWS (Sept. 9, 2019), https://khn.org/news/states-pass-record-number-of-laws-to-reel-in-drug-prices/.

12. Henry Waxman et al., *Getting to the Root of High Prescription Drug Prices: Drivers and potential solutions*, THE COMMONWEALTH FUND (July 10, 2017), https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_fund_report_2017_jul_waxman_high_drug_prices_drivers_solutions_report.pdf; Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (1984).

13. *Id.* at 3–5.

14. *Id.* at 3.

ing drugs to combat rare diseases and conditions.[15] Both of these laws give manufacturers of generic drugs market exclusivity.[16]

The primary reason for high drug prices is the protection of those prices offered by market exclusivity through the U.S. Patent and Trademark Office ("USPTO") and the FDA.[17] In regards to patent-related exclusivity, when a new drug product is developed, manufacturers receive a patent that lasts up to twenty years or more.[18] On the other hand, a clinical trial and FDA's review process of a new drug can take up to six to eight years, providing for regulatory exclusivity.[19] Further, companies can apply to have this period extended for five more years.[20] Initial regulatory exclusivity and patent-related exclusivity generate government-granted monopolies, which in turn yield market exclusivity and the ability for a producer to set its own price.[21] In other words, companies are able to set such high prices due to the lack of competing manufacturers licensed to market the drug in the United States.[22] Competition for new drugs only emerges after the monopoly period ends.[23] Once the patent runs out, generic drugs enter the market.[24] The caveat is that when a manufacturer develops a small change to its currently patented drug, the USPTO allows for a new patent—extending the market exclusivity period further.[25]

2. *Role of Third Parties*

Ultimately, drug manufacturers have nothing stopping them from setting high prices on generic drugs.[26] The inelastic market of generic drugs that people with pre-existing conditions need and continuously increased prices allows manufacturers to set their own prices.[27] The high demand for a product allows manufacturers to raise and lower prices at their discretion.[28] Further, the market for drugs differs from regular competitive markets because consumers do not choose the

15. *Id.*
16. *Id.*
17. Kesselheim, *supra* note 1, at 860.
18. *Id.* at 861.
19. *Id.*
20. *Id.*
21. *Id.*
22. Kesselheim, *supra* note 1, at 860.
23. *Id.* at 861.
24. *Id.*
25. *Id.*
26. Robert Love, *Why Our Drugs Cost So Much*, AARP (May 1, 2017), https://www.aarp.org/health/drugs-supplements/info-2017/rx-prescription-drug-pricing.html.
27. *Id.*
28. *Id.*

product, their healthcare provider does.[29] The separate roles between the patient, prescriber, and payer also undermines competition.[30] In a regular competitive market, consumers will investigate products to decide which product gives them the most bang for their buck.[31] This inquiry into cost-benefit analysis is what drives prices down and creates competition between manufacturers.[32] However, the generic drug price market is different. The prescriber selects the drug, the payer (insurer) approves the drug and pays for it, or the patient pays out of pocket, and pharmacist sells the medications.[33] The prescriber's role in selecting the drug prevents competition that drives down prices.[34]

Another factor contributing to high drug prices is the role of public and private payers.[35] These payers include private healthcare providers, such as doctors, private insurance companies, etc., and public healthcare providers, such as government institutions like Medicare and Medicaid.[36] Medicare covers senior citizens' outpatient and inpatient drug costs, and Medicaid covers low-income individuals' prescription drug costs.[37] The U.S. marketplace for drug prices and federal law prevents public payers from negotiating lower drug prices.[38] Private payers benefit from higher drug prices because their annual fees can sometimes be contingent on a payer's spending on drugs.[39]

Additionally, the United States healthcare system gives manufacturers the power to set their own price for a given product.[40] Other countries, such as the United Kingdom, designate a national organization to consider whether the suggested price of a drug passes a cost-utility threshold.[41] These designated agencies provide for government involvement in price setting, which the United States' free market theory precludes.[42]

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29. Kesselheim, *supra* note 1, at 861.
30. *Id.*
31. Love, *supra* note 26.
32. *Id.*
33. Kesselheim, *supra* note 1, at 861; *see also* Love, *supra* note 26.
34. Love, *supra* note 26.
35. Kesselheim, *supra* note 1, at 862.
36. *Id.*
37. *Id.*
38. *Id.*
39. *Id.*
40. Love, *supra* note 26.
41. Kesselheim, *supra* note 1, at 860.
42. *Id.*

B. Federal Attempts to Regulate

The federal government analyzed the generic drug market in two separate reports.[43] The first report, the Government Accountability Office Report on Generic Drugs Under Medicine, hereinafter "GAO Report," found that about twenty percent of "established drugs experienced an extraordinary price increase—a price increase of at least 100 percent."[44] The GAO Report stated 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.'"[45] The second report, the Senate Report, Sudden Price Spikes in Off-Patient Prescription Drugs: A Monopoly That Harms Patients, Taxpayers, and the U.S. Healthcare System, examined the business model for seven generic drugs and uncovered the monopoly pricing power manufacturers held.[46] The Senate Report exposed four characteristics of a generic drug that allow a company to "exercise de facto monopoly pricing power."[47] Specifically, whether: (1) the company was the only manufacturer of the generic drug; (2) the generic drug was distributed through a "closed distribution system"; (3) the generic drug was the "gold standard"; and (4) the generic drug essential to treating a rare condition."[48]

Lawmakers on both sides of the aisle are pushing for drug pricing regulations; however, they are split on how to achieve their goal.[49] Democrats have previously attempted to push legislation that would allow price negotiations.[50] The Trump Administration has pressed for

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43. *See generally* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-16-706, GENERIC DRUGS UNDER MEDICARE: PART D GENERIC DRUG PRICES DECLINED OVERALL, BUT SOME HAD EXTRAORDINARY PRICE INCREASES (2016) [hereinafter, GAO Report]; *see also* Senate Report, *supra* note 10.

44. GAO Report, *supra* note 43, at 12.

45. Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 676 (4th Cir. 2018) (Wynn, J., dissenting) (quoting GAO Report).

46. *Id. See generally* Senate Report, *supra* note 10.

47. Senate Report, *supra* note 10, at 4.

48. *Id.*

49. Berkeley Lovelace, Jr., *CBO says House Speaker Nancy Pelosi's drug pricing plan saves Medicare $345 billion over decade*, CNBC (Oct. 14, 2019, 10:13 AM), https://www.cnbc.com/2019/10/14/nancy-pelosis-drug-pricing-plan-would-save-medicare-345-billion-cbo.html (last updated Oct. 15, 2019, 8:01 PM).

50. Theodore T. Lee et al., *The Politics of Medicare and Drug-Price Negotiation*, HEALTH NEWS AFFAIRS (Sept. 19, 2016), https://www.healthaffairs.org/do/10.1377/hblog20160919.056632/full/; Robert Graham, *Prescription-drug price gouging must stop*, WASH. TIMES, Sept. 16, 2019, https://www.washingtontimes.com/news/2019/sep/16/prescription-drug-price-gouging-must-stop/.

importation of less-expensive medications from abroad.[51] However, some right-wing lawmakers oppose drug importation.[52] Other critics claim legislative regulations would hinder the market.[53] Moreover, some fear that price caps on drugs would require the manufacturer to "eat the costs" of producing the drugs.[54] This split in Congress has influenced states to resolve the problem on their own.[55]

C. *How Are States Attempting to Solve This Problem?*

In light of this drug pricing epidemic, many states have created various drug pricing regulations in an effort to protect consumers from being extorted.[56] The efforts include creating drug transparency legislation, anti-price gouging legislation, and drug affordability boards.[57]

1. *Drug Transparency Legislation*

Drug transparency legislation requires manufacturers to provide advance notice of increases in drug prices.[58] For example, California enacted a drug transparency law in 2017.[59] This law applies to brand-name and generic drugs with a wholesale "cost of at least $40 when the price of these drugs increases more than 16 percent in the prior 12 months or 32 percent in the preceding 24 months."[60] Among other requirements, the law requires manufacturers to give ninety-days advance notice of drug price increases to public and private purchasers.[61] Vermont enacted similar legislation in 2016 requiring the manufacturer to provide justification for the increase in drug costs.[62] In 2018, Vermont expanded its 2016 legislation to require more extensive inquiries into increased drug prices.[63] Maine,[64] Connecticut,[65] Oregon,[66]

51. Associated Press, *U.S. to set up plan allowing prescription drugs from Canada*, NBC (July 31, 2019, 8:36 AM), https://www.nbcnews.com/health/health-news/us-set-plan-allowing-prescription-drugs-canada-n1037156.

52. Emmarie Huetteman, *GOP Senators Distance Themselves From Grassley And Trump's Efforts to Cut Drug Prices*, KAISER HEALTH NEWS (July 25, 2019), https://khn.org/news/gop-senators-distance-themselves-from-grassley-and-trumps-efforts-to-cut-drug-prices/.

53. *Id.*

54. *Id.*

55. Findlay, *supra* note 11.

56. *See infra*, Part II.C.

57. *See infra*, Part II.C.

58. Findlay, *supra* note 11.

59. CAL. HEALTH & SAFETY CODE § 1367.243 (West 2017).

60. Richard Cauchi, *Recent Approaches and Innovations in State Prescription Drug Laws*, NCSL (May 29, 2019), http://www.ncsl.org/research/health/rx-costs.aspx.

61. *Id.*

62. VT. STAT. ANN. tit. 18 § 4635(c)(1) (2019).

63. VT. STAT. ANN. tit. 18 § 4606 (2019).

Louisiana,[67] and Nevada[68] have also passed similar drug transparency legislation. Colorado passed legislation requiring drug manufacturers to disclose certain information to drug prescribers in an effort to regulate drug pricing.[69] Maine's legislation seeks to "increase access to low-cost prescription drugs" by establishing a program to import prescription drugs from Canada.[70]

2. *Anti-Price Gouging Legislation*

Price gouging occurs when retailers and manufacturers take advantage of an inelastic market and charge an *unconscionable* price for a good.[71] Unconscionable is defined as unfair or unreasonable.[72] Price gouging is illegal in many jurisdictions, especially when there is an unfair advantage or a sudden increase in demand for a good.[73]

Maryland enacted anti-price gouging legislation[74] after its previous attempt to regulate drug pricing was struck down in federal court as unconstitutional.[75] Essentially, this law prohibits manufacturers of generic drugs from raising prices to "unconscionable" levels.[76] In Maryland's legislation, "unconscionable" was defined as "excessive and not justified by the cost of producing the drug or the cost," which "results in consumers for whom the drug has been prescribed having no meaningful choice about whether to purchase the drug at an excessive price

64. S.P. 350, 129th Me. Leg., 1st Reg. Sess., at 1–6 (Me. 2019) (expanding drug price transparency).

65. Act of Jan. 1, 2020, Pub. Act 18-41, 2018 Conn. Pub. Acts, at 3–16 (concerning prescription drug costs).

66. Prescription Drug Transparency Act, H.R. 4005, 79th Leg. Assemb., 2018 Reg. Sess. (Or. 2018).

67. H.B. 436, 2017 Leg. Assemb., 43d Reg. Sess., at 1–10 (La. 2017) (requiring drug manufactures to provide information regarding prescription drug prices).

68. S.B. 539, 2017 Gen. Assemb., 79th Reg. Sess., at 1–24 (Nev. 2017) (revising provisions relating to prescription drugs).

69. H.R. 19-1131, 72d Gen. Assemb., 1st Reg. Sess. (Colo. 2019) (concerning a requirement to share the wholesale acquisition cost of a drug when sharing information concerning the drug with another party).

70. LEGIS. DOC. NO. 1272, 129th Me. Leg., 1st Reg. Sess. (Me. 2019).

71. *Price Gouging*, LEGAL DICTIONARY, https://legaldictionary.net/price-gouging/ (last visited Feb. 2, 2020).

72. *Unconscionable*, DICTIONARY.COM, https://www.dictionary.com/browse/unconscionable?s=T (last visited Feb. 2, 2020).

73. *Price Gouging*, *supra* note 71.

74. H.R. 631, 2017 Leg., Reg. Sess. (Md. 2017) (concerning public health – essential off-patent or generic drugs – price gouging prohibition).

75. Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 666 (4th Cir. 2018).

76. MD. CODE ANN., HEALTH-GEN. § 2-801 (West 2017).

because of (1) the importance of the drug to their health, and (2) insufficient competition in the market for the drug."[77]

3. *Drug Affordability Boards*

Illinois has also followed this regulatory trend and attempted to enact legislation that sought to regulate generic drug prices by restricting drug manufacturers and wholesalers from engaging in price extortion.[78] Illinois recently introduced the Prescription Drug Affordability Act, which also creates a prescription drug affordability board.[79] The board will be appointed by various elected officials in the state.[80] The board's members must have expertise in healthcare, economics, or clinical medicine.[81] The legislation provides that the board shall identify prescription drug products and decide whether the product should be subject to a cost review.[82] It lays out the factors the board should consider and the steps the board should take in its cost review.[83] The legislation specifically emphasized it does not prevent a manufacturer from marketing the drug product if it has been approved by the FDA.[84] Maine,[85] Nevada,[86] and New Jersey[87] have all considered similar drug pricing measures.

In 2019, Maryland created a Prescription Drug Affordability Board.[88] The Maryland board contains five members with experience in healthcare, economics, or clinical medicine.[89] Elected officials of the state appoint the board members.[90] The Maryland board will perform a cost-review analysis of generic drugs that may create affordability challenges.[91] It considers the cost of creating the drug, the cost to health plans, the impact on customers, and other factors.[92] The

77. MD. CODE ANN., HEALTH-GEN. § 2-801(f)(1)-(2) (West 2017).

78. Illinois Generic Drug Pricing Fairness Act, H.B. 4900, 100th Gen. Assemb., Reg. Sess. (Ill. 2018).

79. Prescription Drug Affordability Act, H.B. 3493 § 10(a)-(c), 101st Gen. Assemb., 1st Reg. Sess. (Ill. 2019).

80. *Id.* § 10(c).

81. *Id.*

82. *Id.* § 30.

83. *Id.*

84. *Id.* § 30(b).

85. S.B. 461, 129th Me. Leg., 1st Reg. Sess., at 1-6 (Me. 2019) (establishing the Maine Prescription Drug Affordability Board).

86. S.B. 378, 2019 Gen. Assemb., 80th Sess. (Nev. 2019).

87. N.J. Assemb. B. 4216, 218th Leg., Reg. Sess. (N.J. 2018).

88. Act of May 25, 2019, ch. 692, 2019 Md. Laws, at 1-29.

89. *Id.* at 6-7.

90. *Id.*

91. *Id.* at 17.

92. *Id.* at 18.

board then sets a price limit for that drug and submits its proposal to the Maryland General Assembly's Legislative Policy Commission for approval.[93]

4. *Recent Insulin Price Capping Regulation*

In January 2020, Illinois became the second state to cap monthly insulin prices.[94] Illinois' stated purpose for the Act was to make insulin affordable for the many diabetics in the state who struggle to afford the drug.[95] The Act provides that "insurers that provide coverage for prescription insulin drugs . . . shall limit the total amount that an insured is required to pay for a thirty-day supply of covered prescription insulin drugs at an amount not to exceed $100, regardless of the quantity or type of covered prescription insulin drug used to fill the insured's prescription."[96] Colorado passed a similar act in 2019.[97] The Colorado act also provides for a thirty-day supply of insulin capped at $100 per month.[98]

D. The Dormant Commerce Clause

The Constitution gives Congress the power to regulate interstate commerce.[99] Under the Dormant Commerce Clause, states shall not discriminate against interstate commerce, nor can they unduly burden interstate commerce.[100] The doctrine is driven by concern about economic protectionism and seeks to deter state regulation designed to benefit in-state economic interests by burdening out-of-state competitors.[101] Courts analyze the Dormant Commerce Clause question under an ad hoc five factor approach.[102] First, courts ask whether the

93. Id. at 29–30.

94. Aila Slisco, *Illinois Becomes Second State to Cap Monthly Insulin Prices, and More States Are Considering It*, NEWSWEEK (Jan. 24, 2020, 10:00 PM), https://www.newsweek.com/illinois-becomes-second-state-cap-monthly-insulin-prices-more-states-are-considering-it-1483987.

95. Jackson Danbeck, *Illinois governor signs law capping insulin costs at $100 per month*, NBC15 (Jan. 24, 2020, 7:45 PM), https://www.nbc15.com/content/news/Illinois-governor-signs-law-capping-insulin-costs-at-100-per-month-567282431.html; Pub. Act 101-0625, 101st Gen. Assemb., Reg. Sess. (Ill. 2019).

96. 215 ILL. COMP. STAT. 5/356z.41(c) (2020).

97. H.R. 19-1216, 2019 Leg., 1st Reg. Sess., at 1–5 (Colo. 2019) (concerning measures to reduce a patient's cost of prescription insulin drugs and, in connection therewith, making an appropriation).

98. *Id.*

99. U.S. CONST. art. I, § 8, cl. 3.

100. Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511, 523 (1935).

101. *Id.*

102. Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 579 (1986).

law is rationally related to a legitimate state purpose.[103] Second, the court asks if the law will have extraterritorial regulatory effects, in other words, when applied, will the law have the effect of regulating out-of-state transactions.[104] Third, the court will look at whether the state law discriminates against interstate commerce; if so, does the law represent the least discriminatory means for the state to achieve its purpose?[105] Fourth, whether the law places burdens on interstate commerce that are obviously excessive in relation to the benefits that the law affords to the state[106] Finally, does the law represent the least burdensome means for the state to achieve its goal?[107]

Analyzing extraterritorial regulatory effects is at issue in this Comment. The dormant Commerce Clause presents an obstacle for state regulation of generic drug prices because courts have previously held that this type of regulation violates the extraterritoriality principle of the Dormant Commerce Clause.[108]

1. Extraterritoriality Principle History

The extraterritoriality principle of the Dormant Commerce Clause prohibits states from enacting legislation which "has the practical effect of establishing a scale of prices for use in other states."[109] While the extraterritoriality "principle ensures that a state will not overstep its bounds and unreasonably trample upon the authority of another [state],"[110] it is also meant to ensure free market competition.[111]

In *Edgar v. MITE Corporation*, the Supreme Court invalidated an Illinois antitakeover statute.[112] The plurality in *Edgar* reasoned that the statute was "a direct restraint on interstate commerce and that it has a sweeping extraterritorial effect."[113] The Court was concerned

103. Lainie Rutkow et al., *Law and the Public's Health*, 126 PUBLIC HEALTH REPORTS 750, 751 (2011).

104. *Brown-Forman*, 476 U.S. at 579.

105. C & A Carbone, Inc. v. Town of Clarkstown, 511 U.S. 383, 392 (1994); *see also* S.D. Farm Bureau, Inc. v. Hazeltine, 340 F.3d 583, 596 (8th Cir. 2003), *cert. denied*, 541 U.S. 1037 (2004).

106. Dean Milk Co. v. City of Madison, 340 U.S. 349, 356 (1951); *see also* S. Pacific Co. v. Arizona, 325 U.S. 761, 770–71 (1945).

107. Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970); *see also* Minnesota v. Clover Leaf Creamery Co., 449 U.S. 456, 473 (1981).

108. *See generally* Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 674 (4th Cir. 2018).

109. Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511, 528 (1935).

110. Felmly, *supra* note 9, at 509.

111. *Baldwin*, 249 U.S. at 524. ("Commerce between the states is burdened unduly when one state regulates by indirection the prices paid to be producers in another." This ensures states do not interfere with competition of prices in markets that reach other states.); CTS Corp. v. Dynamics Corp. of America, 481 U.S. 69, 90 (1987).

112. Edgar v. MITE Corp., 457 U.S. 624, 642 (1982) (plurality opinion).

113. *Id.*

that if Illinois imposed such a regulation, other states would do so as well, and interstate commerce (and the market) would be stifled.[114] Justice Powell, in his concurrence, alluded to the extraterritoriality principle's purpose being to protect the market.[115]

The Supreme Court again addressed the purpose of the extraterritoriality principle in *CTS Corp. v. Dynamics Corp. of America*.[116] In *CTS Corp.*, the state statute at issue conditioned "acquisition of control of a corporation on approval of a majority of the pre-existing disinterested shareholders."[117] The Court explained that the Dormant Commerce Clause scrutinizes statutes that discriminate against interstate commerce.[118] However, just because there is a burden on interstate commerce does not mean it is discriminatory.[119] The Court further explained that to determine whether a statute is discriminatory, the statute must impose a greater burden on out-of-state participants than it does on similarly situated in-state participants.[120] The Court further established the connection between the extraterritoriality principle and inconsistent regulations by stating that because the Indiana Business Corporation Law did not create inconsistent regulation between states, the extraterritoriality principle was not at issue.[121] The Dormant Commerce Clause prohibits states from enacting laws that regulate transactions that affect certain aspects of interstate commerce.[122] One of the aspects the Court is referring to is the free market system.[123] According to the Court, the free market system depends on the fact that a corporation is organized under and governed by the law of a single jurisdiction.[124] The Court is concerned that multiple laws governing one good will hinder the market.[125] Thus, if there are inconsistent regulations among states in the market, the market will be adversely affected.[126]

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114. *Id.* ("Furthermore, if Illinois may impose such regulations, so many other States; and interstate commerce in securities transactions generated by tender offers would be thoroughly stifled.").

115. *Id.* at 646 (Powell, J., concurring).

116. *CTS Corp.*, 481 U.S. at 90.

117. *Id.* at 73–74.

118. *Id.* at 87.

119. *Id.* at 88.

120. *Id.*

121. *Id.* at 89–90; IND. CODE § 23-1-17 (2017).

122. *CTS Corp.*, 481 U.S. at 89–90.

123. *Id.* at 90.

124. *Id.*

125. *Id.*

126. *Id.*

a. Price Affirmation Cases

Price affirmation statutes followed the enactment of the Twenty-First Amendment.[127] States enforced regulations to be able to monitor the sale of alcohol products within each state.[128] Price affirmation statutes require manufacturers and retailers to announce the price of a good to affirm that the price will not be lower or higher than the price in another state.[129]

In *Brown-Forman Distillers Corp. v. New York State Liquor Authority*, the Court invalidated a New York price affirmation statute.[130] The statute required distillers to post monthly wholesale prices for sales within the state and also affirm those prices were not lower or higher than prices in other states.[131] The statute prohibited distillers from reducing their price in either New York or in other states.[132] Further, it proscribed out-of-state prices to dip below the price posted in New York.[133] The Court concluded that because the statute regulated commerce in other states, it was prohibited by the Dormant Commerce Clause.[134]

In *Healy v. The Beer Institute*, the Supreme Court invalidated a Connecticut price affirmation statute, which applied to beer sales in three bordering states.[135] The Court reaffirmed *Brown-Forman* by holding that a state may not adopt legislation that has the practical effect of establishing the price of a good in another state.[136] Further, the Court stated that the practical effect must be evaluated by considering the consequences of the statute itself, as well as the effect the legislation would have on interstate commerce if other states adopted similar legislation.[137] Ultimately, the Court struck down the statute on the grounds that it created inconsistent legislation among other states.[138]

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127. Anne-Kathryn Claassen, *Retroactivity—Though Subsequent Case Found Price Affirmation Statutes Unconstitutional, Prior Opinion Would Be Applied:* Stroh Brewery Co. v. Director of the New Mexico Department of Alcoholic Beverage Control, 23 N.M. L. REV. 341, 343 (1993) (citing U.S. CONST. amend. XXI, §§ 1–2).

128. *Id.*

129. Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 575–76 (1986).

130. *Id.* at 585.

131. *Id.* at 576.

132. *Id.* at 576, 579–80.

133. *Id.* at 582–83 (quoting Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511, 521 (1935)).

134. *Id.* at 582.

135. Healy v. Beer Inst., 491 U.S. 324, 343 (1989).

136. *Id.* at 336.

137. *Id.*

138. *Id.* at 337.

In 2003, the Supreme Court upheld a Maine statute aimed at securing lower drug prices.[139] The Maine law created a program that would allow the state to negotiate rebates with drug manufacturers to decrease its prices for drugs offered to the program's participants.[140] The Supreme Court held the state law did not constitute impermissible extraterritorial regulation.[141] The Court reasoned that the program did not regulate any out-of-state transaction "either by its express terms or by its inevitable effect."[142] Thus, the extraterritorial analysis failed to invalidate the statute.[143]

2. Association for Accessible Medicines v. Frosh

In 2017, the Association for Accessible Medicines brought a dormant Commerce Clause challenge against a Maryland statute prohibiting "a manufacturer or wholesale distributor from engaging in price gouging in the sale of an essential off-patent or generic drug."[144] "Price gouging" was defined as "an unconscionable increase in the price of a prescription drug."[145] The District Court initially held the statute was only triggered when the drug was made available for sale within Maryland.[146] However, the Fourth Circuit reversed the trial court's decision and concluded Maryland's statute prohibiting price gouging in the sale of prescription drugs violated the Dormant Commerce Clause.[147]

First, the Fourth Circuit determined that the statute did not trigger any conduct that took place within Maryland.[148] However, the Fourth Circuit found the language of the act indicated that its application was not limited to sales within Maryland.[149] The Fourth Circuit struck the statute down on the grounds that it might create inconsistencies in the market among other states.[150] The Court was concerned the "statute

139. Pharm. Research & Mfrs. of America v. Walsh, 538 U.S 644, 649, 670 (2003).

140. *Id.* at 649.

141. *Id.* at 669.

142. *Id.*

143. *Id.*

144. Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 666–67 (4th Cir. 2018) (quoting MD. CODE ANN., HEALTH-GEN § 2-802(a) (West 2017)).

145. *Id.* at 666 (quoting MD. CODE ANN., HEALTH-GEN. § 2-801(c) (West 2017)).

146. *Id.* at 670.

147. *Id.*

148. *Id.*

149. *Id.* at 671 (citing MD. CODE. ANN., HEALTH-GEN. § 2-801(b)(1)(iv) (West 2017)).

150. *Ass'n for Accessible Meds.*, 887 F.3d at 671, 673–74 (citing MD. CODE ANN., HEALTH-GEN. § 2-801(b)(1)(iv) (West 2017)).

could manifest itself in a wholesale transaction that occurs out-of-state," creating inconsistent prices across state lines.[151]

Second, the Court held that even if the statute triggered activity that took place in Maryland, it might still affect the prices of transactions that occur outside of the state.[152] The court reasoned the statute was essentially a price control act that affected prices outside of Maryland's borders.[153]

Finally, the statute, if similarly enacted by other states, would impose a significant burden on interstate commerce involving prescription drugs.[154] The majority stated that the act would set drug prices in a way that would "'interfere with the natural function of the interstate market' by superseding market forces that dictate the price of a good."[155] The majority was concerned the statute may burden manufacturers by requiring them to modify their distribution and tailor their agreements with other states so as to not violate Maryland's restrictions.[156] The Fourth Circuit explicitly stated its holding did not limit states to enact legislation intended to lower drug prices; the Maryland statute went just beyond the state's police power.[157]

The dissent argued that the Maryland statute did not violate the Dormant Commerce Clause because it did "not implicate the concerns that lie at the heart" of the doctrine.[158] The dissent stated that Maryland had the authority to regulate drug pricing under its general police powers.[159] Further, the dissent agreed with the District Court's initial finding that the statute is "triggered only when there is a drug . . . made available for sale *within* [Maryland]."[160] Maryland asserted that its statute "does not reach, or purport to reach, any stream of commerce *that does not end in Maryland.*"[161] Therefore, according to the dissent, the statute did not violate the extraterritorial principle.[162] The dissent further argued that the majority's extension of the extra-

151. *Id.*

152. *Id.* at 670–71 (citing MD. CODE. ANN., HEALTH-GEN. § 2-801(b)(1)(iv) (West 2017)).

153. *Id.* at 672.

154. *Id.* at 670.

155. *Id.* at 673 (citing McBurney v. Young, 569 U.S. 221, 235 (2013) (quoting Hughes v. Alexandria Scrap Corp., 426 U.S. 794, 806 (1976))).

156. *Ass'n for Accessible Meds.*, 887 F.3d at 673–74.

157. *Id.* at 674.

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

159. *Id.* (Wynn, J., dissenting).

160. *Id.* at 678 (Wynn, J., dissenting).

161. *Id.* at 679 (Wynn, J., dissenting).

162. *Ass'n for Accessible Meds.*, 887 F.3d at 686 (Wynn, J., dissenting).

territoriality principle goes beyond the Supreme Court's application of it.[163]

III. ANALYSIS

The Dormant Commerce Clause stems from a line of price affirmation statute cases and statutes that link in-state prices with out-of-state prices.[164] There are two theories that support the Dormant Commerce Clause: the political theory and the economic theory.[165] The political theory is that if one state ("State A") is regulating in a way that affects another state ("State B"), at some point the regulation in State A will affect the people of State B.[166] However, the people of State B are not represented in State A, thus, the Dormant Commerce Clause remedies this by prohibiting State A from imposing its regulations on State B.[167] On the other hand, the economic theory is that regulations of interstate commerce will adversely affect the free market system in the United States.[168] While both economic and political theories support the Dormant Commerce Clause, the economic theory goes a step further to support an the Dormant Commerce Clause's extraterritoriality principle that states "may not regulate commerce occurring wholly outside its boundaries."[169]

At the heart of the Dormant Commerce Clause lies apprehension of economic protectionism and the extraterritoriality principle.[170] The extraterritoriality principle is the notion that states may not engage in setting legislation which has the practical effect of establishing "a scale of prices for use in other states."[171] Economic protectionism is aimed at preventing states from insulating interstate competition,[172] in other words, states trying to favor in-state economic interests over out-of-state economic interests.[173] The extraterritoriality principle and economic protectionism are meant to ensure that the free market sys-

163. *Id.* at 687 (Wynn, J., dissenting).

164. *Id.* at 686 (Wynn, J., dissenting) (quoting Energy & Envtl. Legal Inst. v. Epel, 793 F.3d 1169, 1172 (10th Cir. 2015)).

165. *See generally* S.C. State Highway Dep't v. Barnwell Bros., 303 U.S. 177, 184 (1938).

166. *Id.*

167. *Id.*

168. CTS Corp. v. Dynamics Corp. of America, 481 U.S. 69, 90 (1987).

169. *Ass'n for Accessible Meds.*, 887 F.3d at 680–81 (Wynn, J., dissenting) (quoting Healy v. Beer Inst., 491 U.S. 324, 336 (1989)).

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

171. Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511, 528 (1935).

172. *Id.* at 523.

173. Donald H. Regan, *The Supreme Court and State Protectionism: Making Sense of the Dormant Commerce Clause*, 84 MICH. L. REV. 1091, 1096 (1986).

tem's price competition is not affected by out-of-state regulations.[174] But what if there is no price competition in a specific marketplace?

As discussed above, the generic drug market lacks the competitive aspect that most markets exhibit due to the third-party involvement of healthcare providers and the manufacturers' ability to set prices for their own drugs. In *Association for Accessible Medicines*, the Fourth Circuit misapplied the extraterritoriality principle in holding the state statute at issue was invalid according to the Dormant Commerce Clause.[175] Further, courts should set aside the Dormant Commerce Clause analysis due to the unnatural function of the generic drug market.[176]

A. The Fourth Circuit's Flaws

The Fourth Circuit focused on strictly applying the extraterritoriality principle to the Maryland price-gouging prohibition statute at issue in the case.[177] The Fourth Circuit's sole justification for disabling the price-gouging prohibition is based on the Supreme Court's principle against extraterritoriality.[178] The majority suggested that "[a] state law violates the extraterritoriality principle if it either expressly applies to out-of-state commerce or has that 'practical effect,' regardless of the legislature's intent."[179] The Court concluded that the Maryland statute violates the Dormant Commerce Clause because it "controls the price of transactions that occur wholly outside of the state."[180] The Court's approach is flawed for the following reasons.

1. First Flaw: Misapplication of The Extraterritoriality Doctrine

The Fourth Circuit misapplied the Dormant Commerce Clause doctrine because the Dormant Commerce Clause only applies to a regulation that fixes the price of a product and links the price of out-of-state products to its in-state product's price.[181] The majority held that since the regulation "directly regulates transactions that take place outside

174. *Id.* at 1092, 1094–96.

175. *Ass'n for Accessible Meds.*, 887 F.3d at 692–93 (Wynn, J., dissenting).

176. *See infra* Part IV.B.

177. *Ass'n for Accessible Meds.*, 887 F.3d at 674.

178. *Id.* at 669–70. *See generally* Healy v. Beer Inst., 491 U.S. 324, 336 (1989) (explaining the Supreme Court's extraterritoriality principle).

179. *Ass'n for Accessible Meds.*, 887 F.3d at 668 (quoting Star Sci., Inc. v. Beales, 278 F.3d 339, 355 (4th Cir. 2002)).

180. *Id.* at 671. *See* Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 580 (1986) ("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.").

181. *Id.* at 681 (Wynn, J., dissenting).

Maryland," the Dormant Commerce Clause invalidates the regulation.[182]

The majority's opinion relies on three Supreme Court cases—*Healy, Baldwin, and Brown-Forman*—all of which concern economic protectionism and the extraterritoriality principle.[183] Under all three cases, the majority held that "a non-discriminatory State law regulating an upstream transaction in a stream of transactions that ends in the State. . . constitutes an unconstitutional regulation of 'wholly' out of state 'commerce.'"[184] However, the three cases which the majority relies on only apply to "price control or price affirmation statutes that link in-state prices with those charges elsewhere and discriminate against out-of-staters."[185] In other words, the extraterritoriality analysis should only be applied to 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.[186] The Maryland statute at issue here was neither a price affirmation statute, nor did it link in-state prices to out-of-state prices.[187]

Accordingly, the majority misapplied *Healy, Baldwin, and Brown-Forman* because those cases and the extraterritoriality principle only apply to a statute that (1) prescribes the price of a product and (2) ties the price of out-of-state prices to its in-state product's price.[188] The Supreme Court has only struck down those two types of statutes on extraterritoriality grounds.[189] In *Association for Accessible Medicines,* the Maryland statute regulated upstream sales in streams of transactions that end in Maryland.[190] In other words, it regulated transactions beginning in other states, but ending in Maryland. Therefore, it "does not regulate any stream of economic activity that does not enter Maryland's borders."[191] The Maryland statute also did not dictate the prices that manufacturers were required to charge in other states.[192] Nor did the Maryland statute regulate commerce occurring "wholly outside" of Maryland's borders (i.e., tie in-state products to out-of-

182. *Id.* at 674.

183. *Id.* at 667–70.

184. *Id.* at 684 (Wynn, J., dissenting).

185. Energy & Envtl. Legal Inst. v. Epel, 793 F.3d 1169, 1174 (10th Cir. 2015).

186. *Ass'n for Accessible Meds.*, 887 F.3d at 686 (Wynn, J., dissenting).

187. *Id.*

188. *Id.* at 684–85.

189. *Id.*

190. *Id.* at 683.

191. *Id.*

192. *Ass'n for Accessible Meds.*, 887 F.3d at 686 (Wynn, J., dissenting).

state prices, or vice versa).[193] Thus, the majority failed to accurately base its holding on extraterritorial grounds.

Further, the Fourth Circuit erroneously based its entire Dormant Commerce Clause analysis on the extraterritoriality principle. As Professor Donald Regan has explained, "[i]t is clear that the Court cannot flatly prohibit all state laws that have extraterritorial effects, or even all state laws that have substantial extraterritorial effects. Such a prohibition would invalidate much too much legislation. If extraterritorial effects are to have any constitutional relevance, the most the Court can possibly say is that extraterritorial effects count against a piece of state legislation."[194] The extraterritoriality analysis is only a piece of the Dormant Commerce Clause analysis, thus, it should not be the only basis for the majority's holding in this case.[195]

2. *Second Flaw: A Decision Based on Fear*

Second, the majority's holding was a result of its fear of inconsistent regulations, which is another driving force behind the extraterritoriality doctrine.[196] The majority stated, "[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."[197] However, this statement is flawed because the Maryland statute does not "*compel* manufacturers to sell . . . at a *particular price*," rather, it forbids unconscionable price increases.[198] The manufacturers are still able to set their own prices within broad limits.

The majority does not justify invalidating the statute on the extraterritoriality principle's inconsistency grounds. In order "[t]o show the threat of inconsistent regulation, [p]laintiffs must either present evidence that conflicting, legitimate legislation is already in place or that the threat of legislation is both actual and imminent."[199] Here, the majority did not cite any inconsistent legislation from another state.[200] The error in the majority's reasoning here is that this is an if/then-

193. *Id.*

194. Donald H. Regan, *Siamese Essays: (I)* CTS Corp. v. Dynamics Corp. of America *and Dormant Commerce Clause Doctrine; (II) Extraterritorial State Legislation*, 85 MICH. L. REV. 1865, 1878 (1987).

195. *Id.*

196. *Ass'n for Accessible Meds.*, 887 F.3d at 673–74.

197. *Id.* at 673.

198. *Id.* at 689 (Wynn, J., dissenting) (emphasis added).

199. Rocky Mountain Farmers Union v. Corey, 730 F.3d 1070, 1104–05 (9th Cir. 2013) (quoting S.D. Myers, Inc. v. City & Cty. of S.F., 253 F.3d 461, 469–70 (9th Cir. 2001)).

200. *Ass'n for Accessible Meds.*, 887 F.3d at 689.

hypothetical. The potential legislation is not already in place. That is not to say this potential legislation is not imminent; however, since it has not occurred the majority cannot base its reasoning on this theory.

Lastly, the majority fears a regulation of this nature will interfere with the market.[201] This fear stems from the majority's prohibition against inconsistent regulations.[202]

3. *Third Flaw: Rejecting the Dormant Commerce Clause Application*

Even if the Fourth Circuit's application of the extraterritorial analysis were accurately applied, the circumstances surrounding the regulations themselves do not implicate the dormant Commerce Clause. As the dissent suggested, the Maryland statute at issue in *Association for Accessible Medicines* does not implicate the issues that lie at the heart of the Dormant Commerce Clause.[203] The majority stated the statute "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."[204] However, the generic drug price market is not a "naturally functioning" market.[205] Thus, states should be allowed to regulate the drug price market under the states' general police powers.[206]

a. Generic Drug Price Market Function

The generic drug market lacks the competitive aspect that most markets exhibit.[207] The noncompetitive aspect of the market supports the claim that the generic drug market functions unnaturally.[208] This is a result of the third-party involvement of healthcare providers, such as hospitals, doctors, insurance companies, and the manufacturers' ability to set prices for their own drugs.[209] In a typical market, such as electronics, consumers scout out the best price for a new television, which in turn drives down the price, and thus, drives competition.[210] As explained in Part III, physicians make decisions for their patients

201. *Id.* at 673–74.
202. *Id.*
203. *Id.* at 675 (Wynn, J., dissenting).
204. *Id.* at 673.
205. *See generally* Erin C. Fuse Brown, *Resurrecting Health Care Rate Regulation*, 67 HASTINGS L.J. 85, 94–103 (2015) (describing the loss of competition and failures in the healthcare system).
206. *Ass'n for Accessible Meds.*, 887 F.3d at 675.
207. Fuse Brown, *supra* note 205, at 94.
208. *Id.*
209. *See generally id.* at 94–103.
210. Love, *supra* note 26.

about which medications their patients should take.[211] Thus, the information given to consumers-patients is trivial compared to consumers in markets such as the electronics market.[212] Physicians prescribe patients medications the physician is most familiar with–this information typically comes from the drug manufacturers.[213] Unlike the electronics market, consumers in the drug market lack the opportunity to make informed decisions about their medications.[214] Thus, the drug market does not function the same way other markets function.[215] On the other end of the market, manufacturers have the luxury of setting prices to almost whatever they want.[216] This price setting power comes from patenting, insurance providers, and physicians.[217] Consequently, the issue with the generic drug market is that there is not a *functioning* competitive marketplace.[218]

4. *The Fourth Circuit's Final Flaw*

The final flaw in the majority's reasoning is that because the Maryland statute sets prescription drug prices, the natural function of the market will be obstructed and the overall market will be affected.[219] However, the generic drug price market is not a "naturally functioning" market.[220] The interference of third parties in the generic drug market and the monopoly power vested in drug manufacturing companies challenge any aspect of the market's "natural function."[221] The majority's fear of third party interference stems from its fear of inconsistent prices placing undue burdens not only on interstate commerce, but on the market as a whole.[222] The Fourth Circuit allows this fear to override the state's police power to regulate on behalf of its citizens by striking down the Maryland statute.[223]

Whether or not states have the power to regulate on behalf of their citizens has been a struggle for courts to decide.[224] The Supreme

211. Fuse Brown, *supra* note 205, at 98; Love, *supra* note 26.
212. Love, *supra* note 26.
213. Fuse Brown, *supra* note 205, at 98–99.
214. *Id.* at 98.
215. *Id.*
216. Love, *supra* note 26.
217. *Id.*
218. Fuse Brown, *supra* note 205, at 103.
219. Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 673 (4th Cir. 2018).
220. *See generally* Fuse Brown, *supra* note 205, at 94–103 (describing the loss of competition and failures in the healthcare system).
221. *Ass'n for Accessible Meds.*, 887 F.3d at 691.
222. *Id.* at 673.
223. *Id.* at 675 (Wynn, J., dissenting).
224. Felmly, *supra* note 9, at 468.

Court has recognized that states may supersede market forces by imposing wage and price restrictions when gross inequality in bargaining power leads to market failure.[225] On the other hand, the Court has stated, "[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."[226]

Specifically, the Court has grappled with this question: when a competitive market is virtually nonexistent, should the Dormant Commerce Clause apply in full force?[227] The answer is no. The Supreme Court previously explained that where there is actual competition in the marketplace, the Dormant Commerce Clause's objective is to protect that competition.[228] Justice Scalia wrote, "[i]n the absence of actual or prospective competition between supposedly favored and disfavored entities in a single market there can be no local preference, whether by express discrimination against interstate commerce or undue burden upon it, to which the dormant Commerce Clause may apply."[229] In other words, when there is an absence of actual competition, the possibility for state discrimination or burden on competition is nonexistent.

By adopting the theory that the Dormant Commerce Clause should not apply to a noncompetitive market, courts will likely conclude that the Dormant Commerce Clause does not apply to the generic drug market.[230] The majority's reasoning for striking down the Maryland statute is not justified on Dormant Commerce Clause grounds, specifically extraterritorial grounds. In the generic drug price market, states are not trying to favor their drug manufacturers over others; the states are attempting to remedy an obstacle for their citizens.[231] Due to the scarcity in competition, the extraterritorial prohibition and economic protectionism concerns that drive the Dormant Commerce Clause are not implicated in the generic drug market, nor state statutes regulating

225. W. Coast Hotel Co. v. Parrish, 300 U.S. 379, 399 (1937) (upholding state minimum wage law because a class of workers were in an unequal position to bargain and thus were defenseless).

226. Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 580 (1986).

227. Felmly, *supra* note 9, at 468.

228. Gen. Motors Corp. v. Tracy, 519 U.S. 278, 300 (1997).

229. *Id.*

230. CTS Corp. v. Dynamics Corp. of America, 481 U.S. 69, 90 (1987) (because the generic drug market lacks the competitive aspect which the dormant Commerce Clause seeks to protect).

231. Anna Zaret & Darien Shanske, *The Dormant Commerce Clause: What Impact Does It Have on the Regulation of Pharmaceutical Costs?*, NAT'L ACAD. ST. HEALTH POL'Y (Nov. 2017), https://nashp.org/wp-content/uploads/2017/11/DCC-White-Paper.pdf.

the market.[232] Thus, contrary to the Fourth Circuit's approach, the unnatural function of the generic drug price market precludes the Dormant Commerce Clause's extraterritorial analysis.[233]

IV. IMPACT

The Fourth Circuit's approach broadens the extraterritoriality principle. The court's holding in *Association for Accessible Medicines* essentially strikes down any legislation that directly limits or prohibits unreasonably high generic drug prices. It applies Dormant Commerce Clause analysis to a market that does not possess the same competitive functions other markets do.

What does this mean for consumers in the generic drug market? Due to this decision, consumers–patients will be forced to sink, rather than swim. If other courts follow the Fourth Circuit's approach, many state consumer protection statutes would be rendered unconstitutional.[234] People will continue to struggle with affording life-preserving medications. Further, the Fourth Circuit's approach prevents states from protecting their consumers and its decision enhances "federal courts' authority to second guess states' efforts to protect their citizens."[235] For example, anti-price-gouging statutes, like the one in *Association for Accessible Medicines*, would be prohibited on Dormant Commerce Clause grounds due to the potential extraterritorial effect the regulation might have.[236] However, there are three other types of legislation that would pass the Fourth Circuit's approach. Drug transparency legislation, drug affordability boards, and recent insulin price capping legislation can pass Dormant Commerce Clause analysis.

A. Drug Transparency Legislation

Drug transparency legislation would be upheld if it were scrutinized under the Fourth Circuit's approach because the legislation does not control drug prices, it merely requires transparency and notification of higher prices. If the legislation is fashioned with regard for administrative costs, (i.e., manufacturers' profits, costs of producing the drug, etc.), then the Dormant Commerce Clause will not prohibit it.[237] The Dormant Commerce Clause is concerned with regulations that ad-

232. Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 675 (4th Cir. 2018).
233. *Gen. Motors Corp.*, 519 U.S. at 300.
234. *Ass'n for Accessible Meds.*, 887 F.3d at 692–93.
235. *Id.*
236. *Id.* at 673–74.
237. Zaret & Shanske, *supra* note 231.

versely affect or discriminate against interstate commerce. Drug transparency legislation simply requires manufacturers to be honest and up front with the public about the prices they are setting. The drug transparency legislation does not invoke the Dormant Commerce Clause because it does not proscribe certain prices.

B. Drug Affordability Boards

Another type of legislation that would likely pass the Fourth Circuit's analysis are the implementation of drug affordability boards. Similar to drug transparency legislation, these boards do not prevent the marketing of products, they merely require cost review for pricing of products.[238] Since drug transparency legislation and drug affordability boards do not involve setting prices, they would not be subject to extraterritoriality scrutiny.[239] The extraterritoriality principle scrutinizes legislation that ultimately affects interstate commerce. Here, drug affordability boards are merely analyzing and approving prices of products. Thus, Dormant Commerce Clause analysis is not invoked.

C. Insulin Price Capping Legislation

Insulin price capping legislation will also pass the Dormant Commerce Clause analysis. For example, the Illinois statute capping insulin prices imposes a price limit on the insurer, rather than the manufacturer.[240] Consequently, other states are excluded from the transaction. Thus, the Fourth Circuit's concern that the regulation will impact transactions that occur wholly outside the state is not a concern here.[241] Further, because the effect of the capped price falls on transactions that happen within the state enacting the legislation, the Dormant Commerce Clause will not invalidate the statute.

D. Positive Impact from Legislation

The positive impacts of these three types of legislation will hold drug manufacturer's accountable, aiding in creating affordable medications. Thus, drug pricing legislation will allow people to afford the drugs they need to live, rather than be forced to pay unconscionable prices for medications.

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238. Love, *supra* note 26.
239. *Ass'n for Accessible Meds.*, 887 F.3d at 673; *see also* Zaret & Shanske, *supra* note 231.
240. Pub. Act 101-0625, 101st Gen. Assemb., Reg. Sess. (Ill. 2019).
241. *Ass'n for Accessible Meds.*, 887 F.3d at 671.

One cannot fault the Fourth Circuit's majority for its conclusion because it was based on a traditional approach in an unresolved issue. On the other hand, when considering the noncompetitive characteristic of the generic drug market, applying the Dormant Commerce Clause would be erroneous. The Dormant Commerce Clause analysis does not function properly in the generic drug market because the market lacks the competitive aspect that the Dormant Commerce Clause is meant to protect. If the courts follow the approach of abandoning the Dormant Commerce Clause analysis when there is no competition to protect, then most legislation regarding drug prices will pass.

V. CONCLUSION

Not being able to afford insulin, EpiPens, or other life-enhancing medications is a genuine fear for many Americans. Twenty-five percent of people claim obtaining their prescription drugs is difficult.[242] The feeling when you are down to your last vial of insulin, or have run out completely, is alarming. Many Americans ration their medicines and supplies, some going as far as to travel overseas for their medications, because an international flight is cheaper than the alternative.[243]

People should not be forced to pay extremely high prices for their medication. Not only is the Fourth Circuit's application of the Dormant Commerce Clause flawed, the Dormant Commerce Clause should not have applied in the first place. The purpose of the Dormant Commerce Clause and its extraterritorial principle is to ensure the market is not superseded by extraterritorial forces and competition is not adversely impacted. Nevertheless, the noncompetitive feature of the generic drug market does not require Dormant Commerce Clause analysis. In a recent Court of Appeals case in Maryland, the court briefly addressed the topic of competition in a marketplace.[244] The court mentions that the Dormant Commerce Clause focuses on markets with actual or prospective competition in them.[245] Furthermore, the 2020 election will likely be impactful on the generic drug market and the healthcare system as a whole. If true and actual competition is brought back into the marketplace, it is possible the Dor-

242. Kamal et al., *supra* note 2.

243. Rachel Roberts, *Big Ticket Drug: The Cost of Staying Alive*, HILL MAG. (Sept. 6, 2019), https://hillmag.uark.edu/big-ticket-drug-the-cost-of-staying-alive/.

244. Wynne v. Comptroller, 228 A.3d 1129, 1142 (Md. 2020).

245. *Id.*

mant Commerce Clause will be applicable, but until then, it should not be.

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