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HEALTH LAW & POLICY BRIEF

VOLUME 17 • ISSUE 1 • FALL 2022

ARTICLES

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Acknowledgements:
We would like to thank our advisor, Lewis Grossman, for his support. We are also grateful to the American University Washington College of Law for providing a legal education that empowers us to champion what matters.

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2022 – 2023

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LETTER FROM THE EDITORS

Dear Reader:

On behalf of the Editorial Board and Staff, we proudly present Volume 17, Issue 1 of the *Health Law & Policy Brief.* Since its formation in 2007, the Brief has published articles on an array of topics in health law, food and drug law, and emerging health technologies. In this issue, our authors discuss facets of substance use, treatment, and regulation in the United States. Volume 16.1 features two articles: one examining the perceived failure of hospital price transparency statutes to control the ever-growing monopolistic hospital systems, and one discusses the value in using generic biologics to increase access to medicine.

Our first article, by Maryclaire Farrington, details the United States' history of healthcare and hospital monopolization, and introduces the Federal Price Transparency Bill and explains why it has been ineffective. Ms. Farrington concludes with an in-depth analysis of the existing efforts to achieve healthcare market fairness and price transparency. Our second article, by Alexander Naum, a member of the Brief, compares the generic drug and biosimilarity regulatory frameworks, and argues that umbrella exclusivity should not be applied to biologics. Mr. Naum recommends a pathway to increasing access to affordable biosimilars through agency reinterpretation and additional encouragement of biosimilar production and use.

We would like to thank the authors for their insight, creativity, and cooperation in producing these pieces. We would also like to thank the *Health Law & Policy Brief's* article editors and staff members who worked so diligently on this issue.

To all our readers, we hope you enjoy this issue, that the never-ending complexities of this area of law inspire your own scholarship, and that you continue to anticipate and scrutinize the inevitable challenges that our healthcare system continues to withstand.

Sincerely,

Delaney Hermenau
Editor-in-Chief

Hannah Zuckerman
Executive Editor

* * *

GENERIC BIOLOGICS: A PATHWAY TO INCREASING ACCESS TO LIFESAVING MEDICINE

Alexander Naum

TABLE OF CONTENTS

*J.D. Candidate, American University Washington College of Law (2023); B.S., University of South Florida (2019). Thank you to the entire staff of the Health Law and Policy Brief for their support in editing and publishing this Article. Thank you to the Note and Comment editors at the Administrative Law Review for their support in the early stages of this Article. I would like to specifically thank Professor Lindsay F. Wiley for her support in picking this topic and Professor Lewis A. Grossman for his support and insight while writing this Article. Additionally, I would like to thank the industry and government experts, who requested not to be named, for their perspectives on this topic. This Article is dedicated to my parents, my two brothers, my cousins, my grandparents, my friends, and the mentors throughout my life that have positively guided me— Thank you for the abundance of love and support that has provided me with the knowledge and confidence to advocate for a brighter future.

I. INTRODUCTION

While the United States continues to recover from the COVID-19 public health crisis, it is important for the nation to address other gaps in maintaining the health of its people. Increasing access to affordable prescription pharmaceuticals is a crucial next step to achieving this goal as 62% of the U.S. adult population takes at least one pharmaceutical product for the prevention, mitigation, or treatment of a medical condition.[1] Unfortunately, 26% of U.S. adults have difficulty accessing their prescribed medications due to financial barriers.[2] This financial barrier is the main reason why roughly three in ten of U.S. adults do not take their prescriptions as prescribed by their healthcare provider.[3] Instead, these adults are forced to extend the life of their prescription by cutting pills in half, skipping doses, or failing to fill a prescription for one or more of their prescribed medications.[4] However, this culture of patients engaging in cost-saving techniques is not a safe solution.[5] These cost-saving techniques create the potential for life-threatening health complications due to the improper dosage that the patient is receiving.[6] When reviewing the most expensive pharmaceutical

[1] *See* Liz Hamel et al., *Public Opinion on Prescription Drugs and Their Prices*, KFF (Apr. 5, 2022), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/ (referring to data in figure 1).
[2] *See id.* (referring to data in figure 3).
[3] *See id.*
[4] *See id.* (referring to data in Figure 4).
[5] *See* Cleveland Clinic, *Is It Safe To Split Pills?*, HEALTH ESSENTIALS (Mar. 7, 2022), https://health.clevelandclinic.org/cutting-pills-in-half/.
[6] *See id.*

products, biologics top the charts with a daily dose costing an average of twenty-two times more than a daily dose of a small molecule, chemical-based drug.[7] The high cost of biologics compared to chemical-based drugs is directly correlated to the lack of generic or biosimilar competition in the majority of biologic markets.[8] This market domination allows brand-name biologic manufacturers to engage in unprecedented price gouging of these essential products, the likes of which are not seen in any other consumer market.[9] This creates a conundrum where only a small portion of wealthy individuals can afford to access these essential biologic products, while the remaining patients are either financially crippled by the cost or are unable to access the products altogether.[10]

All biologics are under strict intellectual property guidelines that make it extremely difficult for generic manufacturers to produce affordable biologics for patients who desperately need them.[11] Brand-name or "name-brand" biologics—the first biologic to enter the market—have taken full advantage of these guidelines and monopolized the pharmaceutical market for years, resulting in

[7] *See* Favour Danladi Makurvet, *Biologics vs. small molecules: Drug costs and patient access*, 9 MED. IN DRUG DISCOVERY 1, 4 (Mar. 2021).
[8] *See id.*
[9] *See id.* at 6.
[10] *See id.* at 4-5 (referring to the class dynamics of biologics access and indicating that most patients fall into the "poor majority" category. Additionally, it is worth noting that most biologics are administered by a medical provider, adding to the cost associated with accessing these products).
[11] *See* Ryan Timmis, *The Biologics Price Competition and Innovation Act: Potential Problems in the Biologic-Drug Regulatory Scheme*, 13 NW. J. TECH. & INTELL. PROP. 215, 217 (2015).

unprecedented price-gouging.[12] While The Biologics Price Competition and Innovation Act (BPCIA)[13] sought to pave the way for many biosimilars to obtain Food and Drug Administration (FDA) approval, there are still unsurpassable barriers for many generic manufacturers.[14] Further, there is a debate regarding whether FDA should apply an "umbrella exclusivity" standard for biologics, which would further decrease biosimilar innovation and approval.[15]

Under the Food, Drug, and Cosmetics Act (FDCA), a biologic is defined as a "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings."[16] Biologics account for roughly 20% of all pharmaceuticals available on the U.S. market.[17] The abundance of these products stems from the wide variety

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[12] *See* Joanna M. Shepherd, *Biologic Drugs, Biosimilars, and Barriers to Entry*, 25 HEALTH MATRIX 139, 141 (2015).
[13] *See* The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 7001–03, 124 Stat. 119, 804–23 (2010) (codified in 42 U.S.C. § 262(k)) [Hereinafter the "BPCIA"].
[14] *See* Shepard, supra note 12 at 146-48.
[15] *See* Big Molecule Watch, *Comments and Letters to FDA in Response to Biosimilars Action Plan*, GOODWIN PROCTER LLP (Oct. 1, 2018), https://www.bigmoleculewatch.com/2018/10/01/comments-and-letters-to-fda-in-response-to-biosimilars-action-plan/; *see also* Gregory J. Glover, *The Importance of Umbrella Exclusivity for Biologics*, PHARM. L. GRP. (Oct. 19, 2018), https://www.pharmalawgrp.com/blog/2/the-importance-of-umbrella-exclusivity-for-biologics/ (defining "umbrella exclusivity" as the ability for brand-name biologic manufacturers to receive market exclusivity for subsequent products released to the market that are marginal changes to their approved biological product).
[16] 42 U.S.C. § 262(i)(1).
[17] *See* WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RSCH. SERV., RL33901, FOLLOW-ON BIOLOGICS: INTELLECTUAL PROPERTY AND INNOVATION ISSUES 1 (2009) (referencing Ernst & Young, *Beyond Borders, Global Biotechnology Report 2008*, 30).

of therapeutic benefits that they provide patients, especially those with chronic conditions such as diabetes, anemia, rheumatoid arthritis, Crohn's disease, and various cancers.[18] While the benefits of biologics are vast, biological products are expensive, especially when compared to chemical-based drugs.[19] One factor contributing to the high cost of biologics is the costs associated with the research and development of these products.[20]

Biologics are produced by manipulating living cells from a variety of sources in order to create a therapeutic product that can efficiently and safely interact with a patient's body.[21] This complex task is also why biologic products take an average of 97.7 months from development to market approval compared to an average of 90.3 months for chemical-based drugs.[22] While research and development of a biologic are both expensive and time-consuming, once a product is approved for the market, making a profit is relatively easy.[23] In 2017, pharmaceutical companies made an estimated $120.1 billion from the sale of their biological products to patients in the United States.[24]

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[18] *See id.* at 1–2, 4; *see also infra* note 42.
[19] *See* SCHACHT & THOMAS, *supra* note 17, at 1-2.
[20] *See* ERNST & YOUNG, BEYOND BORDERS, BIOTECHNOLOGY REPORT 18 (2017) (explaining the research and development costs of a new biologic product are estimated to be $1-2.5 billion or more).
[21] *See* SCHACHT & THOMAS , *supra* note 17, at 3.
[22] *See* CONG. RSCH. SERV., R41483, Follow-On Biologics: The Law and Intellectual Property Issues, 4 (Jan. 15, 2014).
[23] *See* SCHACHT & THOMAS , *supra* note 17, at 1.
[24] *See* Avik Roy, *Biologic Medicines: The Biggest Driver Of Rising Drug Prices*, FORBES (Mar. 8, 2019).

Biologics are extremely profitable because they dominate a niche market with relatively no competition, thereby allowing pharmaceutical companies to charge high rates to patients.[25] In 2005, 17% of all Medicare Part B carrier drug spending went directly to paying for patients' use of two different biologics used for the treatment of anemia.[26] Patients suffering from the debilitating condition known as Crohn's disease pay approximately $51 thousand annually to mitigate their symptoms with the biologic known as Humira.[27] Insurers often pass on the high costs associated with these biologics to patients in the form of high copays, resulting in financial burdens for insured, underinsured, and uninsured patients.[28]

The Biologics Price Competition and Innovation Act (BPCIA) was enacted as part of the Patient Protection and Affordable Care Act of 2010 to create a regulatory framework for FDA to approve generic biologics, labeled as either "biosimilar" or "interchangeable."[29] The BPCIA has a goal similar to the Hatch-Waxman Act of 1983 and creates a regulatory pathway for FDA to approve

[25] *See* SCHACHT & THOMAS, *supra* note 17, at 2.
[26] *See* Pamela Jones Harbour, Commissioner, *The Competitive Implications of Generic Biologics,* Federal Trade Commission (Jun. 14, 2007), http://www.ftc.gov/speeches/harbour/070614genbio.pdf.
(stating that the Centers for Medicare and Medicaid Services (CMS) spends $100,000 per patient annually to administer the biologic Avastin for the treatment of colon cancer).
[27] *See* Timmis, *supra* note 11, at 217; *see also Overview of Crohn's Disease*, CROHN'S & COLITIS FOUND., https://www.crohnscolitisfoundation.org/what-is-crohns-disease/overview (last visited Oct. 26, 2022) (explaining that Crohn's disease is a common condition related to inflammatory bowel diseases; it is estimated to affect three million patients in the U.S).
[28] *See* Timmis, *supra* note 11, at 217; *see generally* Keru Wiginton, *Insurance Coverage and Biologics*, WEBMD (Jan. 27, 2022), https://www.webmd.com/skin-problems-and-treatments/psoriasis/biologic-insurance.
[29] *See supra* note 22, at 1, *see also,* 42 U.S.C. § 262(k).

generic versions of chemical-based drugs.[30] However, differences in the length of exclusivity periods between the BPCIA and Hatch-Waxman make it difficult for generic manufacturers to release affordable biosimilar alternatives into the market.[31]

In 2018, FDA sought stakeholder input on the idea of applying umbrella exclusivity to biological products.[32] Umbrella exclusivity has traditionally been applied to chemical-based drugs, which allows all drug applications—even applications just for a new dosage, administration, or minor formula change to an existing approved drug—to receive the same period of exclusivity protection, expanding the time it takes for generics to enter the market.[33] Stakeholders representing pharmaceutical manufacturers overwhelmingly supported this proposal as an opportunity to increase biologic innovation.[34] However, stakeholders representing consumer advocacy groups and generic manufacturers explained that this proposal would reduce biosimilars entering the market due to

[30] *See* Timmis*, supra* note 11, at 217; *see also* Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. §§ 355, 360(cc) (2000) (commonly known as the "Hatch-Waxman Act").
[31] *See* Preston Atteberry et al., *Biologics Are Natural Monopolies (Part 1): Why Biosimilars Do Not Create Effective Competition,* HEALTH AFFAIRS BLOG (Apr. 15, 2019), https://www.healthaffairs.org/do/10.1377/hblog20190405.396631/full/ (explaining that FDA gives biologics an additional twelve-year exlcusivity period while drugs are only given an additional five years of exclusivity).
[32] *See* Glover, *supra* note 15.
[33] *See id.*
[34] *See id.*

the potential for product-hopping, a tactic maintaining the monopolistic hold brand-name drug companies have on the market.[35]

Rather than allowing further anticompetitive practices to occur in the biologics market, Congress and FDA should work to foster a competitive biologic market and provide patients with more affordable access to these essential medications. Around eighty percent of U.S. adults find the price of prescription pharmaceuticals unreasonable.[36] The public support for lowering the cost of prescription pharmaceuticals, especially biologic products, is overwhelming and bipartisan, as exemplified by the near-unanimous congressional support of The Advancing Education on Biosimilars Act of 2021.[37] The congressional intent of this statute demonstrates Congress' interest in reforming the biologic market by allocating resources to promote biosimilars and increasing access to cheaper alternatives.[38] This goal is mirrored by the Biden Administration's goals to foster

[35] *See id.*
[36] *See* Hamel, s*upra* note 1.
[37] *See* Advancing Education on Biosimilars Act, 42 U.S.C.A. § 263-1 (2021)*; see also* 167 Cong. Rec. 1783-84 (2021); *see generally* Press Release, Off. of Sen. Bill Cassidy, Senate Passes Two Pieces of Cassidy Legislation to Lower Prescription Costs (Mar. 11, 2021), https://www.cassidy.senate.gov/newsroom/press-releases/senate-passes-two-pieces-of-cassidy-legislation-to-lower-prescription-costs.
[38] *See* Advancing Education on Biosimilars Act, 42 U.S.C.A. § 263-1 (2021).; *see also* 167 Cong. Rec. 1754-55; *see generally* Press Release, Off. of Sen. Maggie Hassan, Bipartisan Legislation Introduced by Senators Hassan, Cassidy to Help Lower Drug Costs Heads to President's Desk, (Apr. 14, 2021), https://www.hassan.senate.gov/news/press-releases/president-signs-into-law-bipartisan-legislation-introduced-by-senators-hassan-and-cassidy-to-help-lower-health-care-costs-by-improving-education-about-drug-products; *see generally* Press Release, Off. of Sen. Bill Cassidy, Senate Passes Two Pieces of Cassidy Legislation to Lower Prescription Costs (Mar. 11, 2021), https://www.cassidy.senate.gov/newsroom/press-releases/senate-passes-two-pieces-of-cassidy-legislation-to-lower-prescription-costs.

both a competitive biologics market and a reduction in prescription pharmaceutical pricing for patients.[39] Real reform in the biologic market is possible and is supported by the public – it is up to legislators and regulators to decide whether or not they will use the readily available tools to create this necessary reform.

Part II of this Article reviews the history and regulatory framework of the Hatch-Waxman Amendments to illustrate the current barriers that prevent the BPCIA from producing a market saturation of biosimilars and how umbrella exclusivity is applied to drugs. Part III of this Article reviews the 2018 hearing and comments related to applying umbrella exclusivity to biologics and explains why FDA should not pursue this avenue. Part IV of this Article reviews the need for FDA to reinterpret its stance that the BPCIA grants biologics twelve years of market exclusivity and instead interpret it to mean data exclusivity. Further, Part IV explains why Congress should amend the BPCIA to lower the exclusivity period to five years. Finally, Part IV analyzes how FDA can incentivize public trust in biosimilars and reduce patient costs through their interpretation of the Advancing Education on Biosimilars Act.

[39] *See* Exec. Order No. 14,036, 86 Fed. Reg. 36,987 (July 9, 2021).

II. THE GENERIC DRUG REGULATORY FRAMEWORK VS. BIOSIMILAR REGULATORY FRAMEWORK

Throughout the twentieth century, FDA sought to balance the needs of brand-name drug manufacturers and generic competitors.[40] To maintain this balance, Congress enacted the Hatch-Waxman Amendments, allowing the generic drug market to flourish while providing incentives for brand-name drug manufacturers.[41] Similarly, when Congress enacted the BPCIA under the ACA, lawmakers intended for the statute to have a similar effect on the biosimilar market that the Hatch-Waxman Amendments had on the generic drug market.[42] Unfortunately, this was not achieved as the BPCIA provisions and interpretations by FDA did not lead to a market saturation of affordable biosimilar alternatives.[43]

A. The History That Led to the Hatch-Waxman Amendments

Pharmaceutical innovation boomed in the twentieth century.[44] By the 1950s, pharmaceutical manufacturers were introducing an average of forty-three new drug products per year.[45] Drug patenting was viewed as a crucial protection

[40] *See* Erika Lietzan, *The History and Political Economy of the Hatch-Waxman Amendments*, 49 SETON HALL L. REV. 53, 66-68 (2018).
[41] *See* Martha M. Rumore, *The Hatch-Waxman Act – 25 Years Later: Keeping the Pharmaceutical Scales Balanced*, PHARMACY TIMES (Aug. 7, 2021), https://www.pharmacytimes.com/view/generic-hatchwaxman-0809 (explaining that the term incentive includes certain market protections from encroaching generic competitors).
[42] *See* Kasey E. Koballa, *The Biologics Price Competition and Innovation Act: Is a Generic Market for Biologics Attainable?*, 9 WM. & MARY BUS. L. REV. 479, 516 (2018).
[43] *See id*. at 518.
[44] *See* Lietzan *supra* note 40, at 66.
[45] *See id*.

in order to continue this drug innovation boom.[46] Following this surge in drugs entering the market, Congress enacted laws that established premarket approval, which manufacturers criticized as eroding the life of their patents.[47] To combat this concern, manufacturers advocated for patent incentives, including beginning the life of a patent directly after the approval of a new drug application (NDA).[48]

Before 1962, due to a lack of regulation, generic drug manufacturers operated within a legal grey area. For example, manufacturers showed product safety by piggybacking off of approved NDAs with the same underlying active ingredients.[49] In 1962, Congress increased the regulatory standards required under NDA approval by adding an effectiveness requirement.[50] FDA responded by promulgating rules that allowed generic drug manufacturers to file abbreviated new drug applications (ANDAs) for approved NDAs filed before 1962.[51] However, a regulatory gap for the agency arose as post-1962 drug patents began

[46] *See id*. at 67 (referring to Professor Gabriel's view that drug patenting was "ethically legitimate and even necessary, as a part of the incentive structure").
[47] *See id.* at 67–68 (referencing the Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (21 U.S.C. § 301)).
[48] *See id.* at 71 (referring to a report issued by The National Research Council of the National Academies of Science, that the life of a patent should start "when regulatory approval is granted, thereby restoring the effective patent life to the nominal life of 17 years").
[49] *Compare id.* at 92 (referring to the lack of generic drug approval framework within the Food Drug and Cosmetic Act of 1938), *with* 21 U.S.C. § 355(a) (1938) (only provides that "no person shall introduce. . .into interstate commerce any new drug, unless an approval of an application . . .").
[50] *See* 21 C.F.R. § 314.50 (d)(5)(iv)-(v) (2016).
[51] *See* Lietzan, *supra* note 40 at 92–93 (explaining the easier approval of abbreviated new drug applications (ANDAs) over new drug applications (NDAs) because ANDAs did "not contain clinical safety or effectiveness data").

to expire.[52] Several solutions were attempted by the agency, but none seemed to produce an equitable outcome for either generic or brand-name drug manufacturers.[53] In response to the confusion, Congress had to balance the brand-name drug manufacturers' interest in innovation protections and patients' and generic manufacturers' interest in the ability to buy and sell cheaper generic drug products.[54] These motivations ultimately lead to the 1984 enactment of the Hatch-Waxman Amendments.[55]

B. Regulatory Framework of Hatch-Waxman and Umbrella Exclusivity of Drugs

The Hatch-Waxman Amendments revolutionized the generic drug market; its effects are still seen today as generic drugs make up more than 70% of all prescriptions.[56] The United States healthcare system saved $2.2 trillion between 2009 and 2019 due to generic drug sales.[57] Patients typically save 85% of the price of brand-name drugs when multiple generic drugs are available.[58] The

[52] *See id.* at 93.
[53] *See id.* at 93–9 (referring to the failed "paper NDA" strategy, that only required the submission of published literature to prove efficiency and safety); *see also Drug Legislation: Hearings on H.R. 1554, H.R. 3605, H.R. 1055 and H.R. 1097*: *Before the Subcomm. on Health & the Env't of the Comm. on Energy and Com.*, 98th Cong. 133 (1983) (statement of PMA comparing these policies of allowing generic manufacturers to use their research to gain approval for a "free ride").
[54] *See* Lietzan, *supra* note 40 at 83–85.
[55] *See* id. at 83.
[56] *See* Rumore, *supra* note 41.
[57] *See Generic Drug Facts*, U.S. FOOD & DRUG ADMIN. (Nov. 1, 2021), https://www.fda.gov/drugs/generic-drugs/generic-drug-facts (citing data released by IMS Health Institute).
[58] *See id.* (patients typically save 30% of the price of a brand-name drug when a single generic competitor is present).

brand-name drug manufacturers also benefited from these Amendments as FDA granted them various patent protections for their innovations.[59]

Under the Hatch-Waxman Amendments, generic drug manufacturers' ability to file ANDAs expanded to all approved NDAs, even those approved after 1962; however, this new regulatory scheme presented different ANDA requirements.[60] ANDAs now must show that the generic has the same active ingredient, route of administration, dosage form, strength, and intended use as the brand-name drug.[61] ANDAs must also establish "bioequivalence," meaning that the generic interacts with the body in the same fashion as the brand-name drug.[62] A key difference that makes an ANDA easier to file than an NDA is that preclinical animal trials and clinical human trials are generally not required for approval.[63]

Brand-name drug manufacturers were awarded several patent protections under the Amendments.[64] Most notably, FDA granted brand-name drug manufacturers patent extensions that added an extra five years of exclusivity in addition to the twenty-year term granted by the U.S. Patent and Trademark Office.[65] During this exclusivity period, generic manufacturers face patent

[59] *See* Lietzan, *supra* note 40, at 55-56.
[60] *See id.* at 63.
[61] *See id.* (explaining the requirements of 21 U.S.C. § 355).
[62] *See Abbreviated New Drug Application (ANDA)*, U.S. FOOD & DRUG ADMIN. (Aug. 10, 2021), https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda.
[63] *See id.*
[64] *See Generic Drug Facts, supra* note 57.
[65] *See id.*

infringement if they market or sell their generic versions of the brand-name drug.[66]

In 2013, several brand-name drug manufacturers petitioned FDA to revise its stance on exclusivity provisions, specifically as it related to its umbrella exclusivity policy.[67] At that time, FDA viewed umbrella exclusivity as a five-year term granted to the originally approved drug and the manufacturer's other products that contain the same active moiety as the approved drug.[68] The new product(s) would be under the same five-year exclusivity timeline as the original drug; however, if the original drug was at the end of the initial exclusivity period then the new product(s) would receive an additional five years.[69] In this framework, FDA interpreted the word "drug" to mean "drug product," which is the product as a whole.[70] The brand name manufacturers argued that this regulatory framework decreases drug innovation and incentivizes "suboptimal drug development," especially relating to the continuously changing treatment of complex diseases like HIV and cancer.[71] In response to this concern, FDA revised its interpretation of "drug" to mean "drug substance."[72] This allowed

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[66] *See id.*
[67] *See* U.S. FOOD & DRUG ADMIN., NEW CHEMICAL ENTITY EXCLUSIVITY DETERMINATIONS FOR CERTAIN FIXED-COMBINATION DRUG PRODUCTS: GUIDANCE FOR INDUSTRY (2014) [hereinafter NEW CHEMICAL ENTITY EXCLUSIVITY].
[68] *See id*.
[69] *See id.*
[70] *See id.*
[71] *See id*.
[72] *See* NEW CHEMICAL ENTITY EXCLUSIVITY, *supra* note 67, at 2 (defining "drug substance" as each active ingredient approved in the original product).

drug manufacturers to release new products protected under a new five-year exclusivity as long as it contains at least one new substance with a new active moiety or chemical structure.[73] Critics attribute the FDA's decision to revise the interpretation to the growing practice of "product hopping." Product hopping is an anti-competitive tactic, when a brand-name drug manufacturer marginally reformulates its product so it receives a longer exclusivity period and blocks generic entry indefinitely.[74]

C. Difficulties in Biosimilar Approval

Before a generic manufacturer can submit an application to FDA for biosimilar approval, the application must provide scientific evidence of similarity between the proposed product and the reference biologic.[75] The application must prove that the proposed product and reference biologic "utilize the same mechanism . . . of action for the condition . . . of use prescribed, recommended, or suggested in the proposed labeling."[76] The application must also show that the recommended use on the proposed labeling was "previously approved for the reference product."[77] Next, the application must show that "the route of administration, the dosage form, and the strength" of the proposed product are the

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[73] *See id.*
[74] *See* Samantha McGrail, *Brand Drug Product Hopping Costs US $4.7B Annually*, PHARMA NEWS INTELLIGENCE (Aug. 10, 2021), https://pharmanewsintel.com/news/brand-drug-product-hopping-costs-us-4.7b-annually; *see also infra* Part II (explaining the harmful effects of "product hopping").
[75] *See* 42 U.S.C. § 262(k)(2)(A)(i)(I).
[76] 42 U.S.C. § 262(k)(2)(A)(i)(II).
[77] 42 U.S.C. § 262(k)(2)(A)(i)(III).

same as the reference biologic or brand-name biologic.[78] Further, the application must demonstrate that the manufacturing facility meets FDA's standards to assure continuous production of a "safe, pure, and potent" product.[79] Additionally, the FDA Commissioner has the discretion to determine how the manufacturer of the proposed product can provide data to show that it is biosimilar to the referenced biologic.[80] Accepted data includes analytical studies, animal studies, and clinical studies "that are sufficient to demonstrate safety, purity, and potency" for the product's intended use.[81]

Conversely, an applicant seeking approval for a generic biologic can choose an alternative approval path by showing that their proposed product is "interchangeable" with the referenced biologic.[82] Similar to achieving biosimilar status, an interchangeable application requires evidence that the proposed product is biosimilar to the referenced product, as supported by submitted data.[83] Unlike achieving biosimilar approval, an interchangeable application must also show that "the same clinical result" will occur between the proposed product and referenced biologic in "any given patient."[84] Lastly, interchangeable applications submitted for products that are administered multiple times must show that switching to the

[78] *See* 42 U.S.C. § 262(k)(2)(A)(i)(IV).
[79] 42 U.S.C. § 262(k)(2)(A)(i)(V).
[80] *See* 42 U.S.C. § 262(k)(2)(A)(ii).
[81] 42 U.S.C. § 262(k)(2)(A)(i)(I).
[82] *See* 42 U.S.C. § 262(k)(4).
[83] *See* 42 U.S.C. § 262(k)(4)(A)(i).
[84] *See* 42 U.S.C. § 262(k)(4)(A)(ii).

proposed product does not create a greater risk for the patient than "the risk of using the reference product without such alternation or switch."[85] Thus, proving interchangeability is more difficult than obtaining biosimilar approval because showing "the same clinical result" in "any given patient" is a difficult standard to achieve.[86]

The differences in the regulatory framework between the generic forms of biologics (biosimilar and interchangeable applications) and generic drugs also extend to their exclusivity.[87] Under FDA's interpretation of the BPCIA, biologics are awarded twelve years of exclusivity during which no biosimilar can be marketed or approved.[88] However, a generic manufacturer can submit a 351(k) application to FDA to begin the biosimilar or interchangeable review process four years into the twelve-year exclusivity period.[89] This caused confusion in the courts because BPCIA's safe harbor provision was intended to apply to biologics

[85] *See* 42 U.S.C. § 262(k)(4)(B).
[86] *See* 42 U.S.C. § 262(k)(4)(A)(ii); *see also FDA Approves Cyltezo, the First Interchangeable Biosimilar to Humira, Second Interchangeable Biosimilar Product Approved by Agency*, U.S. FOOD AND DRUG ADMIN. [Press Release] (18 Oct. 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-cyltezo-first-interchangeable-biosimilar-humira (displaying the difficulty to approve interchangeable biologics because only two interchangeable biologics have been approved compared to 31 biosimilar biologics as of 2021).
[87] *See* U.S. FOOD AND DRUG ADMIN., REFERENCE PRODUCT EXCLUSIVITY FOR BIOLOGICAL PRODUCTS FILED UNDER SECTION 351(A) OF THE PHS ACT (2014) [hereinafter REFERENCE PRODUCT EXCLUSIVITY].
[88] *See id*. at 1.
[89] *See id.* (this four-year period in which no biosimilar or interchangeable applications can be submitted is known as the "reference product exclusivity period").

broadly.[90] To further this confusion, generic manufacturers must publicly disclose their biosimilar applications, often leading to a barrage of legal disputes from brand-name manufacturers that delay market entry and increase costs for biosimilar manufacturers.[91]

Among the small handful of biologics that gained biosimilar approval, Zarxio is notable because its approval survived a patent dispute in the Supreme Court.[92] Zarxio gained biosimilar status to the reference product known as Neupogen, which is used to "stimulate the production of white blood cells."[93] While Zarxio's approval was a significant win for the future of biosimilar approval, it did not provide patients with an option that was affordable enough to persuade most physicians to prescribe Zarixo, which was only being sold at a discount of 15% compared to the brand-name drug Neupogen.[94] Similarly, another approved biosimilar known as Inflectra received a similar market response – it was sold at only a 15% discount.[95] These limited discounts are

[90] *See Biosimilars and the safe harbor provision*, GENERICS AND BIOSIMILARS INITIATIVE (Oct. 4, 2020), https://www.gabionline.net/biosimilars/general/Biosimilars-and-the-safe-harbor-provision (referring to the safe harbor language under 35 U.S.C. §271(e)(1), "to make ... a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs").
[91] See *id.* (explaining the "patent dance," which requires biosimilar applicants to list their process patents publicly within the Orange book, something not required for generic drugs).
[92] *See* Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664, 1678 (2017).
[93] *See id.* at 1672–73.
[94] *See* Koballa, *supra* note 42, at 514.
[95] *See id.*

directly related to the time and costs associated with biosimilar research and litigation from patent challenges.[96]

III. UMBRELLA EXCLUSIVITY SHOULD NOT BE APPLIED TO BIOLOGICS

Lobbying groups that represent brand-name biologic manufacturers have the monetary incentive to pressure FDA to apply umbrella exclusivity to approved biologics.[97] The ramifications of such a policy change would create an environment ripe for brand-name biologic manufacturers to deploy additional monopolistic tactics to prevent biosimilar competition.[98] This action would fail a *Chevron* review because it would violate the congressional intent and construction of the BPCIA; along with failing other forms of judicial review.[99]

A. Debate on Umbrella Exclusivity in Biologics

In July 2018, then-FDA Commissioner, Scott Gottlieb, announced that the agency would work harder to increase the number of biosimilars on the market.[100] In the statement, Gottlieb mentioned that while less than "2 percent of Americans use biologics, they represent 40 percent of total spending on prescription

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[96] *See id.* at 516.
[97] *See* Glover, *supra* note 15.
[98] *See Facilitating Competition and Innovation in the Biological Marketplace Part 15 Public Hearing,* U.S. FOOD AND DRUG ADMIN., 176-77 (Sept. 4, 2018).
[99] *See* Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, 467 U.S. 837, 837-38 (1984), W. Virginia v. Envtl. Protection Agency, 142 S. Ct. 2587 (2022); *.see also infra* Part III(c).
[100] *See Remarks from FDA Commissioner Scott Gottlieb, M.D., as prepared for delivery at the Brookings Institution on the release of FDA's Biosimilars Action Plan,* U.S. FOOD AND DRUG ADMIN. (Jul. 18, 2018), https://www.fda.gov/news-events/press-announcements/remarks-fda-commissioner-scott-gottlieb-md-prepared-delivery-brookings-institution-release-fdas.

drugs."[101] The agency also informed the public that it would hold a hearing within the year about whether umbrella exclusivity should apply to biologics.[102]

The September 4, 2018, hearing overwhelmingly attracted stakeholders representing the interests of brand-name biologic pharmaceutical manufacturers.[103] The lobbying group Pharmaceutical Research and Manufacturers of America (PhRMA) and Janssen Pharmaceutical Companies (a subsidiary of Johnson & Johnson) were among the stakeholders representing major pharmaceutical entities.[104] PhRMA argued that umbrella exclusivity would incentivize investments into the research and development of biologics, including improving already approved biologics and expanding treatment options.[105] Janssen Pharmaceutical Companies similarly argued in support of expanding umbrella exclusivity to biosimilars.[106]

The Biosimilars Council Division of the Association for Accessible Medicines (AAM), a lobbying organization representing the U.S. generic pharmaceutical companies, also attended the hearing.[107] The AAM overemphasized the barriers that prevent biosimilar market saturation, including

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[101] *See id.*
[102] *See Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; Request for Comments*, FOOD AND DRUG ADMIN. (July 25, 2018).
[103] *See* Glover, *supra* note 15.
[104] *See id.*
[105] *See id.*
[106] *See id.*
[107] *See Facilitating Competition and Innovation in the Biological Marketplace Part 15 Public Hearing, supra* note 98.

referencing the Commissioner's statement that the lack of biosimilar market saturation cost the U.S. $4.5 billion in 2017 alone.[108] The AAM addressed the barrier as being a result of brand-name pharmaceutical companies' "shenanigans."[109] To illustrate this point, the AAM described manipulative tactics such as "patent thickets"[110] as the main reason why patients do not have access to affordable biosimilars.[111] These thickets include methods like umbrella exclusivity which allow brand-name drug companies to block competition and "game the system."[112]

B. Product Hopping Encourages Monopolistic Behavior

Product hopping is a tactic used by brand-name drug manufacturers to maintain their monopolistic hold on the market.[113] A manufacturer engages in product hopping by marginally reformulating a drug that is near the end of its exclusivity period, then releasing the reformulation as a new product with a new

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[108] *See id*. at 174.
[109] *See id*. at 176–7.
[110] *See* Lisa Orucevic, *A Machete for the Patent Thicket: Using Noerr-Pennington Doctrine's Sham Exception to Challenge Abusive Patent Tactics by Pharmaceutical Companies*, 75 VAND. L. REV. 277, 277 (2022) (defining "patent thickets" as, "dense webs of overlapping patents surrounding one drug, which have artificially extended the companies' monopolies for years or even decades after a drug's initial patent expires").
[111] *See Facilitating Competition and Innovation, supra* note 105, at 176–77.
[112] *See id.* at 125, 126, 130 (quoting Bruce Leicher, Senior Vice President and General Counsel at Momenta Pharmaceuticals, a manufacturer engaged in biosimilar production and member of the AAM).
[113] *See* Alex Brill, *The Cost of Brand Drug Product Hopping*, MATRIX GLOBAL ADVISORS (Sep. 2020), https://www.affordableprescriptiondrugs.org/app/uploads/2020/09/CostofProductHoppingSept2020-1.pdf.

exclusivity period.[114] In 2020, Matrix Global Advisors, LLC released a report that found that pharmaceutical companies' product hopping tactics of five specific products cost the U.S. healthcare system $4.7 billion annually.[115]

Prilosec, manufactured by AstraZeneca, imposed the largest burden on the U.S. healthcare system among the five drugs reviewed.[116] Many patients relied on Prilosec for the prevention of ulcers, a demand that once placed the product as the highest-selling drug in the U.S.[117] Toward the end of Prilosec's exclusivity, AstraZeneca introduced the drug Nexium in 2002, a marginally reformulated version of Prilosec.[118] AstraZeneca aggressively incentivized providers to prescribe Nexium, which had thirteen years of patent exclusivity, over Prilosec.[119] Several companies, including Walgreens and Rite Aid, challenged AstraZeneca's market manipulative actions in federal district court.[120] The alleged manipulative actions included aggressively promoting Nexium to providers while ending the promotion of Prilosec.[121] As a result of this promotion, characterized as a soft-

[114] *See id.* at 3 (providing that pharmaceutical manufacturers will often pull their original product from the market, "hard switch;" or incentivize providers to use their new product over their old product, "soft switch").
[115] *See id.* at 2 (reviewing the tactics used by manufacturers for the brand-name pharmaceuticals Prilosec, TriCor, Suboxone, Doryx, and Namenda).
[116] *See id.* at 4 (referencing the graphic showing that the product hopping of Prilosec cost the U.S. Healthcare system $2.36 billion annually since 2001).
[117] *See id.* (demonstrating that AstraZeneca earned $4.1 billion in sales for Prilosec in 2001).
[118] *See id.*
[119] *See id.* at 3-4 (explaining that this would be characterized as a "soft switch" since the original product remained on the market, but the new product was aggressively promoted to providers over the original product).
[120] *See* Walgreen Co. v. AstraZeneca Pharm. L.P., 534 F. Supp. 2d 146, 147 (D.D.C. 2008).
[121] *See id*. at 149.

switch, one-third of the Prilosec prescriptions were switched to Nexium.[122] The plaintiffs' complaint projected that patients would collectively lose $11.5 billion in savings by the end of 2006 from the lack of generic competition resulting from AstraZeneca's product hopping.[123] However, the district court dismissed the antitrust claims on the basis that the plaintiffs could still compete with the drug Prilosec since it was still available on the market for patients.[124] This opinion was heavily based on consumer choice in other markets, but it did not reflect the "realities of drug markets" where a patient's choice of prescription is mainly controlled by physician preference.[125]

The 2020 report also reviewed the product hoping tactics of the brand-name manufacturer Forest Laboratories (a subsidiary of Actavis) for their Alzheimer's drug Namedia IR, which had the second largest burden on the U.S. healthcare system among the five drugs reviewed.[126] While preparing for generic competition against Namedia IR, Forest Laboratories created an extended-release version of the drug with a new name "Namedia XR."[127] Namedia XR provided

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[122] *See id.*
[123] *See id.*
[124] *See id*. at 152-3.
[125] *See* Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 195 (2016); *see also* Geoffrey F. Joyce et al., *Physician Prescribing Behavior and Its Impact on Patient-Level Outcomes*, 17 THE AM. J. OF MANAGED CARE. 1, 3 (Dec. 1, 2011) (reviewing pharmaceutical and medical data spanning from 2003 to 2007 from twenty-nine companies around the U.S.).
[126] *See* Brill, *supra* note 113, at 4 (showing that the product hopping tactics of Namenda cost the U.S. Healthcare System $1.04 billion annually).
[127] *See id*. at 6.

patients with the same type of treatment and efficiency as Namedia IR; however, Namedia XR was designed as a single daily dose rather than a double dose.[128] With this minuscule change in the dosage frequency, coupled with Namedia IR being voluntarily pulled from the market, Forest Laboratories intended to extend their exclusivity beyond what was previously given.[129] This allowed the brand-name manufacturer to ensure the continuation of their market dominance of Namedia IR, a drug with U.S. sales totaling $1.8 billion in 2013.[130]

In *New York v. Actavis PLC*,[131] the state of New York brought an antitrust action against Actavis and their subsidiary, Forest Laboratories, due to their manipulative tactics that prevented generic competition.[132] In their complaint, New York alleged that Actavis engaged in a hard switch from Namenda IR to Namenda XR to move the exclusivity period from ending in 2015 to 2029.[133] Actavis disagreed and alleged that patients could still receive Namenda IR using a mail-order-only pharmacy known as Foundation Care if a physician deemed it medically necessary for the patient to continue using Namenda IR.[134] However, it was estimated that less than 3% of patients could receive Namenda IR from Foundation Care, meaning that Namenda IR was essentially removed from the

[128] *See id*.
[129] *See id*. (providing that this is considered a "hard switch" because the original product was pulled from the market and replaced by the new product).
[130] *See id*.
[131] *See* New York v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015).
[132] *See id*. at 642.
[133] *See id*. at 642, 648.
[134] *See id*. at 648.

market.[135] The Second Circuit ruled in favor of New York, affirming the trial court's preliminary injunction and barring Actavis from restricting access to Namenda IR prior to generic entry.[136] In doing so, the court upheld the Ninth Circuit's view that "changes in product design are not immune from antitrust scrutiny and in certain cases may constitute an unlawful means of maintaining a monopoly."[137]

When comparing the D.C. District Court's ruling on Nexium, the Second Circuit's ruling on Namenda IR, and other relevant jurisprudence, it's clear that courts prevent product hopping only in clearly defined hard switches when the original product is pulled from the market.[138] However, brand-name manufacturers engage in various product hopping tactics that create a tremendous burden both on patients and the U.S. healthcare system as a whole, especially the soft switch of Nexium that resulted in billions of lost savings.[139] The United States Judiciary is failing to understand the anticompetitive realities of the pharmaceutical market; thus, policies and regulations are needed to fill in these gaps without inadvertently making anticompetitive practices easier.[140]

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[135] *See id*.
[136] *See* New York v. Actavis PLC, 787 F.3d 638, 663. (2d Cir. 2015).
[137] *See id*. at 660 (quoting Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP, 592 F.3d 991, 998 (9th Cir. 2010)).
[138] *See* Walgreen Co. v. AstraZeneca Pharm. L.P., 534 F. Supp. 2d 146, 147 (D. D.C. 2008); *see also* New York v. Actavis PLC, 787 F.3d 638, 642 (2d Cir. 2015).
[139] *See* Brill, *supra* note 113.
[140] *See* Carrier & Shadowen, *supra* note 125, at 195.

C. Chevron and Major Questions Review of Applying Umbrella Exclusivity to Biologics

The landmark case of *Chevron v. Natural Resource Defense Council* established the principles of agency deference and administrative judicial review.[141] During a *Chevron* review, the court is tasked with reviewing the congressional intent of the statute that governs the agency's decision.[142] If the congressional intent is unclear, the court must determine if the agency's actions are based on a "permissible construction of the statute."[143] The agency's action will be nullified upon review if its decision differs from the congressional intent and is deemed an impermissible interpretation of the governing statute.[144] It is also important to acknowledge the Supreme Court's recent holding in *West Virginia v. Environmental Protection Agency*.[145] In that case, the Court applied the "Major Questions Doctrine" rather than *Chevron*, distancing itself from the *Chevron* precedent.[146] A Major Questions review involves a two-step analysis.[147] First, the court must determine whether an agency's action falls outside of the agency's "history and breadth of authority" and whether the action has "economic

[141] *See Chevron*, 104 S. Ct 2778, 2781-2 (1984).
[142] *See id.*
[143] *See id.*
[144] *See id*. (explaining that regulations are favored unless they're "arbitrary, capricious, or manifestly contrary to the statute)
[145] *See* W. Virginia v. Envtl. Protection Agency, 142 S. Ct. 2587 (2022). [hereinafter "WV v. EPA"].
[146] *See id.* at 2634-5 (KAGAN, J., dissent) (explaining that the majority purposely chose to ignore the long-held precedent established under *Chevron*).
[147] *See id*. at 2608.

and political significance."[148] If the agency's action falls within those categories, the court will then require the agency to provide "clear congressional authorization" for its action.[149] The agency's action will then be nullified if it cannot provide this authorization.[150]

Although FDA has not yet expanded umbrella exclusivity to biologics, brand-name pharmaceutical manufacturers have a monetary incentive to continue pressuring FDA to grant umbrella exclusivity to biologics.[151] The evolving nature of the COVID-19 pandemic will likely revitalize the question of whether granting umbrella exclusivity to biologics is necessary.[152] In addressing the rise of COVID-19 variants, the pharmaceutical industry has engaged in modifications of existing COVID-19 vaccines already on the market.[153] As a result of these

[148] *See id*.
[149] *See id*. at 2609.
[150] *See* WV v. EPA, *supra* note 145 at 2620 (2022) (GORSUCH, J., concurring) ("when an agency action involves a major question… clear congressional authority is required").
[151] *Compare* Tom Wilbur, *The latest: What they are saying: Intellectual property protections vital to COVID-19 research, development and manufacturing*, PHRMA (Feb 12, 2021), https://catalyst.phrma.org/the-latest-what-they-are-saying-intellectual-property-protections-vital-to-covid-19-research-development-and-manufacturing (defending the idea of increasing patent protections for pharmaceuticals), *with* David Korn, *Balancing innovation and competition in the biologics marketplace*, PHRMA (Oct 11, 2018), https://catalyst.phrma.org/balancing-innovation-and-competition-in-the-biologics-marketplace (statement by Vice President, Intellectual Property and Law, PhRMA) (defending the idea of expanding umbrella exclusivity to biologics following the September 4th hearing), *and* 83 Fed. Reg. 35154 (July 25, 2018).
[152] *Compare* Wilbur, *supra* note 151 and Korn, *supra* note 151 *with* Mike Ybarra, *Setting the record straight: Addressing common misconceptions about the COVID-19 vaccine,* PHRMA (Aug 4, 2021).
[153] *Id*.

modifications, it is inevitable that the pharmaceutical industry will again push for FDA to adopt umbrella exclusivity patent protections for biologics.[154]

By promulgating rules that extend umbrella exclusivity to biologics, FDA would be misconstruing the congressional intent of the authors of BPCIA.[155] On December 21, 2010, three principal authors of the BPCIA submitted a letter to FDA addressing the congressional intent of BPCIA.[156] In the letter, they explained that the intent of BPCIA "is clear that no product, under any circumstances, can be granted 'bonus' years of data exclusivity for mere improvements on a product."[157] The authors of the BPCIA further explained that any attempt to grant additional exclusivity to mere improvements of an approved biologic would have negative ramifications on both pharmaceutical innovation and the lives of patients.[158]

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[154] *See generally* Willbur, *supra* note 151; Korn, *supra* note 151; Ybarra, *supra* note 152 (inferring that pharmaceutical manufacturers would desire to have an exclusivity period to modify their vaccine product).
[155] *See* Carrier & Shadowen, *supra* note 125; *see also* Kurt R. Karst, *BPCIA's Principal Authors Seek to Clarify Congressional Intent With Respect to 12-Year Exclusivity Period; PhRMA/BIO Request "Umbrella Exclusivity",* HYMAN, PHELPS & MCNAMARA (Jan. 5, 2011), https://www.thefdalawblog.com/2011/01/bpcias-principal-authors-seek-to-clarify-congressional-intent-with-respect-to-12-year-exclusivity-pe/; *see also* Letter from Representative Anna G. Eshoo, et al., to U.S. Food & Drug Admin. (Dec. 21, 2010) (signed by Democratic Representatives, Eshoo and Inslee, along with Republican Representative Barton).
[156] *See* Letter from Representative Anna G. Eshoo, et al., *supra* note 155.
[157] *Id.* (quoting the letter to FDA describing proposals that would grant biologics umbrella exclusivity).
[158] *See id*.

When applying *Chevron*, the congressional intent of the BPCIA is clear that umbrella exclusivity should not be applied to biologics.[159] Further, the language of the BPCIA directly contradicts the notion of applying umbrella exclusivity to biologics.[160] The text states that the twelve years of exclusivity does not apply to applications that are a "supplement for the biological product that is the reference product," nor does it apply to products by the same manufacturer or related entity "of the biological product that is the reference product."[161] The text further describes tactics used by brand-name manufacturers that would fail to extend their exclusivity, including changes in the "indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength," along with any "modification to the structure of the biological product that does not result in a change in safety, purity, or potency."[162] Any attempt by FDA to grant umbrella exclusivity to biologics would fail a *Chevron* review because it would both ignore the congressional intent of the authors of the BPCIA and be an impermissible interpretation of the statute.[163]

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[159] *See id*.; *see also* 42 U.S.C. § 262(i)(2)(B); *see also Chevron*, 467 U.S. 837 (implying that any decision by FDA to grant umbrella exclusivity to biologics would be an impermissible interpretation of BPCIA).
[160] *See* 42 U.S.C. § 262(k)(7)(C).
[161] *See id.*; *see also* Elizabeth Richardson, *Biosimilars*, HEALTH POLICY BRIEF (Oct. 10, 2013), https://www.healthaffairs.org/do/10.1377/hpb20131010.6409/full/ (explaining that the term "reference product" is another way of saying "original", "innovator", or "pioneer" product, which is defined in the same manner as my use of "brand-name biologic").
[162] *See* 42 U.S.C. § 262 (k)(7)(C).
[163] *See id*.; *see also Chevron, supra* note 141; *see also* Letter from Representative Anna G. Eshoo, et al., *supra* note 155.

When applying the Major Question Doctrine, it is clear that FDA never extended umbrella exclusivity to biologics in the twelve years following BPCIA's enactment, defying how FDA has historically interpreted BPCIA.[164] Furthermore, the authors of BPCIA explained that extending umbrella exclusivity to biologics would have negative economic and political implications on the healthcare system, affecting both patients and biological innovation.[165] Finally, FDA would fail to provide any provision within the text of BPCIA that allows them to apply umbrella exclusivity to biological products.[166] On the contrary, Congress clearly stated in BPCIA that applications that are a "supplement for the biological product that is the reference product" would not receive twelve years of exclusivity.[167] Thus, no matter what test is used by a court, extending umbrella exclusivity to biologics is outside of the scope of FDA's authority.

IV. A PATHWAY TO INCREASING ACCESS TO AFFORDABLE BIOSIMILARS

As it stands, the BPCIA's language and FDA's interpretation of it prevent the statute's intent to produce a market saturated with affordable biosimilar alternatives for patients.[168] In 2021, the Biden Administration enacted the Advancing Education on Biosimilars Act (Advancing Education Act), which

[164] *See* WV v. EPA, *supra* note 145 at 2608-9, 2620.
[165] *See* Letter from Representative Anna G. Eshoo, et al., *supra* note 155.
[166] *See* 42 U.S.C. § 262 (k)(7)(C).
[167] *See id*.
[168] *See supra* Part I.

presents FDA with tools to promote the biosimilar market.[169] FDA, with the help of Congress, must act now to stimulate the biosimilar market. First, FDA should reinterpret the twelve-year exclusivity provisions under BPCIA to mean data exclusivity, rather than market exclusivity. Second, Congress should amend the twelve-year exclusivity period under BPCIA to five years. Third, FDA should use the Advancing Education Act as a tool to educate the public on the safety and efficiency of available biosimilar products. To achieve the goals of educating the public and increasing the affordability of available biosimilars, FDA should establish a public-private partnership with participating biosimilar manufacturers that provides publicly-funded advertising in exchange for reduced biosimilar pricing for patients.

A. An Agency Reinterpretation & Congressional Action

The seven-year difference in exclusivity between generic drug approval and biosimilar approval is a major factor why there are more generic drugs than biosimilars on the market.[170] In the 2018 hearing, AAM representatives identified patent lengths and exclusivity extension tactics as the primary barriers that prevent the market from becoming saturated with biosimilars.[171] FDA can address this issue by adjusting its interpretation of the twelve-year exclusivity

[169] *See* Advancing Education on Biosimilars Act, 42 U.S.C.A. § 263-1 (2021).
[170] *See supra* Part I.
[171] *See supra* note 98 at 174, 176-7.

period for biologics to mean data exclusivity rather than market exclusivity.[172] Congress can also address this issue by amending the BPICA and reducing the data exclusivity period from twelve years to five years.[173]

FDA misinterpreted the congressional intent of the BPCIA in its interpretation of the twelve-year exclusivity period awarded to brand-name biologics.[174] In the 2010 letter to FDA, the authors of the BPCIA explained that the agency's misinterpretation comes from their application of the twelve years of exclusivity as market exclusivity.[175] The authors emphasized that, rather than market exclusivity, the BPCIA "provides data exclusivity for 12 years."[176] FDA can correct this misinterpretation by promulgating a rule clearly identifying the agency's reformed view that the twelve-year exclusivity period only applies to data exclusivity.[177] Notably, FDA can issue this reinterpretation without the need for notice-and-comment rulemaking because it would be an interpretive rule.[178] This difference in interpretation will inevitably allow for more biosimilars to enter

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[172] *See* Letter from Representative Anna G. Eshoo, et al., *supra* note 155 (explaining that "market exclusivity" prevents generic manufacturers from developing data to get their completive biosimilar approved within the 12 years following the brand-name biologics approval; however, "data exclusivity" only prevents generic manufacturers from relying on the data used for the approval of the brand-name biologic to get their competitive biosimilar approved within the 12-year period).
[173] *Compare* 42 U.S.C.A. § 262(k)(7) (referring to the 12-year exclusivity period for biologics), *with* 21 U.S.C.A. § 355 (c)(3) (referring to the 5-year exclusivity period for drugs).
[174] *See* Letter from Representative Anna G. Eshoo, et al., *supra* note 155.
[175] *See id*.
[176] *See id*.
[177] *See id.*
[178] *See id.*; *see also* Perez v. Mortg. Bankers Ass'n, 575 U.S. 92, 95 (2015) (finding that administrative reinterpretations are "interpretive rules," which do not require additional notice and comment).

the market because generic manufacturers can begin gathering data to obtain FDA approval within the twelve-year data exclusivity period.[179]

While an agency reinterpretation of the meaning of exclusivity will lead to more biosimilars on the market, it may be difficult for generic manufacturers to provide patients with significant savings unless Congress also amends the twelve-year data exclusivity period to five years.[180] By keeping the twelve years of data exclusivity, generic manufacturers of biosimilars are prohibited from accessing data from an approved brand-name biologic to support the approval of their biosimilar product within that period of exclusivity.[181] When adding the twenty years of exclusivity already provided by the U.S. Patent and Trademark Office, generic manufacturers are barred from competing with the brand-name biologic for 32 years.[182] Amending the BPCIA by lowering the data exclusivity period to five years for biologics will allow generic manufacturers to enter the market more quickly and bypass much of the cost associated with the research and development of a new biologic.[183]

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[179] *See* Letter from Representative Anna G. Eshoo, et al., *supra* note 155.
[180] *See* Zachary Brennan, New Study Questions the Need for 12 Years of Market Exclusivity for Biologics, Regulatory Focus (Jun. 21, 2019), https://www.raps.org/news-and-articles/news-articles/2019/6/new-study-questions-the-need-for-12-years-of-marke (quoting researchers from the Program On Regulation, Therapeutics, And Law (PORTAL), Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School) ("although biologics are often thought to be more time-consuming to develop than small-molecule drugs, development times for biologics are similar to, or possibly somewhat shorter than, for small-molecule drugs").
[181] *See* Letter from Representative Anna G. Eshoo, et al*., supra* note 155.
[182] *See* 42 U.S.C. § 262 (k)(7)(A); *see also* SCHACHT & THOMAS, *supra* note 17 at 11.
[183] *See* Brennan, *supra* note 180.

The U.S. grants biologics the longest exclusivity period compared to all other nations.[184] Most nations grant drugs and biologics the same period of exclusivity.[185] For example, the exclusivity period for both biologics and drugs in Australia and New Zealand is five years.[186] While certain pharmaceutical manufacturers in the U.S. allege that an equal exclusivity period for both drugs and biologics would hurt biologic innovation, data from the Australian Department of Industry, Innovation and Science suggests otherwise.[187] A report from September 2015, released by the Australian Department of Industry, showed that most pharmaceutical applications were for biologics rather than drugs.[188] Comparatively, data from other nations demonstrate that drugs make up most of the applications submitted for approval, as opposed to biologics.[189]

Some critics also argue that lowering FDA exclusivity period for biologic products will deter brand-name manufacturers from taking on risks related to

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[184] *See* Zachary Zalewski & Nick Diamond, *USMCA Compromise Drops Key Biologics Exclusivity Provisions*, AVALERE (2019), https://avalere.com/insights/usmca-compromise-drops-key-biologics-exclusivity-provisions.
[185] *See id.*
[186] *See* Jenny Wong, *Data Protection for Biologics – Should the Data Exclusivity Period Be Increased to 12 Years?*, UNIV. OF NEW SOUTH WALES L. J. (2016), http://classic.austlii.edu.au/au/journals/UNSWLawJlStuS/2016/7.html (further explaining that Japan and South Korea have exclusivity periods of up to 6 years).
[187] *See id*. (referencing data collected by the Australian Government); *see also* AUSTL. GOV., DEPT. OF INDUSTRY, INNOVATION AND SCIENCE, A PATENT ANALYTICS STUDY ON THE AUSTRALIAN PHARMACEUTICAL INDUSTRY, (2015) [hereinafter AUSTRALIAN PHARMACEUTICAL INDUSTRY] (The department was consolidated into the Department of Industry, Science, Energy and Resources in Feb. of 2020).
[188] *See* AUSTRALIAN PHARMACEUTICAL INDUSTRY*, id.* (finding in Australia, biologics make up 43% of applications, while drugs make up 37% of applications).
[189] *See id.* (finding worldwide that drugs on average, make up 49% of applications, while biologics on average, only make up 29% of applications).

producing new products, as excess profits are allegedly used to pay off failed attempts at producing new products.[190] However, yearly financial statements of brand-name manufacturers show that much of their expenses are allocated toward other areas.[191] For example, in 2011 Pfizer reported over $67 billion in gross revenue but spent roughly $9 billion on the research and development of new pharmaceutical products.[192] While $9 billion is a substantial amount of money, Pfizer also spent $19 billion on marketing in 2011.[193] Even Pfizer's net profit of $10 billion was $1 billion more than what it spent on research and development in 2011.[194] This trend is reflected in the financial reports for twelve of the leading brand-name manufacturers, which show that these manufacturers spend an average of 60% more on marketing compared to what's spent on research and development.[195]

While the biopharmaceutical industry represents a large portion of the U.S. economy, changes to FDA interpretation of exclusivity and decreased

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[190] *See Research and Development in the Pharmaceutical Industry*, CONGRESSIONAL BUDGET OFFICE (Apr. 2021), https://www.cbo.gov/publication/57126 (explaining that only about 12% of new drug applications are approved by FDA).
[191] *See* David Belk MD & Paul Belk PhD, *The Pharmaceutical Industry*, TRUE COST OF HEALTH-CARE (Dec. 2014) at 5, https://truecostofhealthcare.org/wp-content/uploads/2014/12/The-pharmaceutical-industry.pdf.
[192] *See id*.
[193] *See id*.
[194] *See id*.
[195] *See id*.; *see generally* David Belk MD, *Composite Analysis of the Finances for Thirteen of the World's Largest Pharmaceutical Companies from 2011-2018*, TRUE COST OF HEALTH-CARE (Mar. 2019) (explaining that companies reviewed include: "AbbVie, Amgen, AstraZeneca, Bristol-Myer Squibb, Eli Lilly, Gilead Sciences, GlaxoSmithKline, Johnson & Johnson, Merck, Novartis, Pfizer, Roche and Sanofi").

exclusivity periods will have minuscule impacts on the profit-making potential of brand-name biologic manufacturers.[196] The U.S. Patent and Trademark Office (USPTO) awards brand-name, biologics manufacturers with patents lasting twenty years, with an average of six to seven years of that time spent on the clinical development of the product.[197] This means that manufacturers are given roughly thirteen to fourteen years of market dominance in addition to the twelve years that FDA awards them.[198] Even with this seven-year reduction of exclusivity, brand-name manufacturers will likely still produce substantial profits to support the U.S. economy.

A federal statute lowering FDA data exclusivity period from twelve years to five years could lead to due process challenges from brand-name manufacturers; however, these challenges are not likely to survive judicial review. In *Nebbia v. New York*,[199] a New York law established a Milk Control Board with the power to fix maximum and minimum retail prices for milk.[200] A grocery store

[196] *See* Nick McGee, *New Report: America's biopharmaceutical industry supports 4.7 million jobs*, PHRMA (Mar. 1, 2018), https://catalyst.phrma.org/4.7-million-goboldly-to-cure-the-incurable (noting that the biopharmaceutical industry, directly and indirectly, supports 4.7 million workers).
[197] *See* SCHACHT & THOMAS, *supra* note 17 at 11, *see also Pharmaceutical Research & Development: The Process Behind New Medicines*, PhRMA, 10 (2015), chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf ("clinical development" refers to the studies manufacturers must engage in to demonstrate that their product is safe and effective to obtain FDA approval).
[198] *See* SCHACHT & THOMAS, *id*. at 11; *see also Pharmaceutical Research*, *id*. at 6, 10.
[199] *See* Nebbia v. New York, 291 U.S. 502, 506 (1934) (holding that it does not violate due process rights to set minimum and maximum retail prices).
[200] *Id*. at 506-7.

challenged the statute and alleged it violated their Constitutional due process rights by impeding on their private right to control the prices of the milk it sold.[201] After applying the rational basis test, the Supreme Court disagreed with the petitioners and held that due process demands only that the law is not unreasonable, arbitrary, or capricious.[202] An amendment to BIPCIA that lowers the exclusivity period for biologics to five years is not unreasonable, arbitrary, or capricious.[203] This policy change would support the goal of increasing the number of biosimilars approved without unduly burdening brand-name manufacturers because they will still have a total of eighteen to nineteen years of market dominance when factoring in the exclusivity already awarded to their product by the USPTO.[204]

Thus, FDA should promulgate a rule that reinterprets brand-name biologic exclusivity to refer to data exclusivity rather than market exclusivity, and Congress should amend BPCIA to lower the data exclusivity period from twelve years to five years.

B. Encouraging Biosimilar Production and Use

The Biden Administration signaled its willingness to foster a competitive biologic market through several actions, including legislation and executive

[201] *Id.* at 515.
[202] *Id*. at 530-1.
[203] *Id*. at 525, 530.
[204] *See supra* note 197, *see also* supra note 198.

orders.[205] In April 2021, the Biden Administration signed the Advancing Education Act, which allocates funds to FDA to increase public awareness of biosimilars and gives the Commissioner discretion regarding how to achieve such goals.[206] Additionally, the Biden Administration signed Executive Order 14036 in July 2021, which tasks HHS and other agencies with encouraging greater competition within the U.S. economy.[207] To support this order, FDA should promulgate rules to establish a nationwide awareness campaign on biosimilars to increase public knowledge on health outcomes for biosimilars, provide transparency on the prices of available biologics compared to their biosimilar alternatives, and provide grants to participating biosimilar manufacturers to assist in their marketing and function as a price reduction incentive.[208]

The University of Chicago released a study in 2021 that found that 61% of physician respondents reported that few or none of their patients knew of the existence of biosimilars.[209] Further, the study showed that 2020 had the "lowest number of biosimilar approvals since 2016," likely due to the COVID-19

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[205] *See* Advancing Education on Biosimilars Act, 42 U.S.C.A. § 263-1 (2021); *see also* Exec. Order. No. 14036, 86 Fed. Reg. 132, 36987-36988 (July 9, 2021).
[206] *See* Advancing Education on Biosimilars Act, 42 U.S.C.A. § 263-1 (2021).
[207] *See* Exec. Order. No. 14036, 86 Fed. Reg. 132, 36987-36988 (July 9, 2021).
[208] *See id*.; *see also* Shelby Wilde et al., *Understanding Stakeholder Perception of Biosimilars*, NAT'L OP. RSCH. CTR. (NORC) (2021), https://www.norc.org/PDFs/Biosimilars/20210405_AV%20-%20NORC%20Biosimilars%20Final%20Report.pdf (applying the NORC study data to an FDA rule recommendation).
[209] *See* Wilde et al., *id*.

pandemic.[210] The study also uncovered issues that FDA rulemaking could address, including the lack of FDA guidance on product outcomes for biosimilars, the lack of incentives that promote lower pricing of biosimilars, and the lack of transparency to providers and patients relating to the actual price of biosimilars compared to biologics.[211]

The Biden Administration has repeatedly emphasized its support for increasing competition in all sectors of the U.S. economy, especially related to biologic pharmaceuticals.[212] In an Executive Order from July 2021, the Administration outlined its plan to support this competition.[213] Particularly, the Administration's plan includes tasking FDA with making the approval of biosimilars "more transparent, efficient, and predictable."[214] Additionally, the plan includes using the Advancing Education Act to assist biosimilar product adoption through the disbursement of "effective educational materials and communications…among healthcare providers, patients, and caregivers."[215] The overall intent of these actions would be to reduce delays in biosimilar entry while continuing to foster biological innovation in the U.S.[216]

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[210] *See id.*
[211] *See id.*
[212] *See* Exec. Order. No. 14036, 86 Fed. Reg. 132, 36987-36988 (July 9, 2021).
[213] *See id.*
[214] *Id*.
[215] *Id*.
[216] *See id*.

The congressional intent of the Advancing Education Act is clear: increase the number of biosimilars on the market and provide better savings for patients who depend on lifesaving biologics by providing education on the efficiency, safety, and price of biosimilars to providers and patients.[217] In assessing the congressional intent of a statute, courts often review the legislative history surrounding the transition from a bill to a statute.[218] On March 3, 2021, the Advancing Education bill passed unanimously in the Senate roughly one month before it passed in the House.[219] On April 14, 2021, the intent of the bill was explained during a House floor debate before the floor voted to pass the bill.[220] In the debate, Democratic Representative Frank Pallone explained that the bill's purpose was to increase the utilization of cheaper options by ensuring families

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[217] *See* Advancing Education on Biosimilars Act*, supra* note 207; *and* 167 Cong. Rec. H1754-01; *see generally* Press Release, Office of Senator Maggie Hassan, Bipartisan Legislation Introduced by Senators Hassan, Cassidy to Help Lower Drug Costs Heads to President's Desk, (Apr. 14, 2021), https://www.hassan.senate.gov/news/press-releases/bipartisan-legislation-introduced-by-senators-hassan-cassidy-to-help-lower-drug-costs-heads-to-presidents-desk; *see also* Press Release, Office of Senator Bill Cassidy, Senate Passes Two Pieces of Cassidy Legislation to Lower (Mar. 11, 2021), https://www.cassidy.senate.gov/newsroom/press-releases/senate-passes-two-pieces-of-cassidy-legislation-to-lower-prescription-costs.

[218] *See*, Stephen Breyer, *On the Uses of Legislative History in Interpreting Statutes*, 65 S. CAL. L. REV. 845, 845, 864 (1992) (explaining that judges review the legislative history by reviewing "congressional floor debates, committee reports, hearing testimony, and presidential messages in an effort to determine what Congress really "meant" by particular statutory language." Additionally dispelling disputes against this form of judicial review by stating, "nothing about it makes a court's reference to legislative history seem *constitutionally* suspect"); *see generally*, United Steelworkers of Am., AFL-CIO-CLC v. Weber, 443 U.S. 193, 2726-7 (1979) (here the Court assessed "Congress' primary concern in enacting" a disputed statute by assessing the congressional record, also known as "legislative history").

[219] *See* Alexandra Lu, *Senate Passes Bill on Advancing Education on Biosimilars*, GOODWIN PROCTOR LLP (Mar. 16, 2021), https://www.bigmoleculewatch.com/2021/03/16/senate-passes-bill-on-advancing-education-on-biosimilars/; *see also* 167 Cong. Rec. H1783-03.

[220] *See* 167 Cong. Rec. H1754-01; *see also* 167 Cong. Rec. H1783-03.

"are aware of more affordable options, like biosimilars and generics."[221] Republican Representative Gus Bilirakis supported this and stated that the bill will require HHS "to develop continuing education programs," in addition to the planned biosimilar educational website operated by FDA.[222] Representative Bilirakis further stated that these programs will increase the use of lower-cost biosimilar alternatives by increasing "awareness about available biosimilar products and providing educational resources for physicians and patients about their benefits."[223] The debate concluded with Republican Representative Larry Bucshon emphasizing the importance of patient and provider access to biosimilar information by stating that when new "biosimilar products become available, it is important that physicians have current information."[224] However, the statute is ambiguous regarding how FDA can use these allocated funds to achieve "continuing education" goals and ensure access to information on new biosimilar products to "lower the cost of these important drugs for patients."[225] This ambiguity can be resolved through agency interpretation.[226] In *Morton*, the Supreme Court held that the, "power of an administrative agency to administer a congressionally created and funded program necessarily requires the formulation

[221] *See* 167 Cong. Rec. H1754-01.
[222] *See id*.
[223] *See id*.
[224] *See id*.
[225] See *id*. (quoting in part Representative Gus Bilirakis and Representative Larry Bucshon).
[226] *See* Advancing Education on Biosimilars Act*, supra* note 207, 167 Cong. Rec. H1754-01; *see also* Morton v. Ruiz, 415 U.S. 199, 231 (1974), *Chevron*, *supra* note 141 at 2782, City of Arlington v. F.C.C., 569 U.S. 290, 307 (2013).

of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress".[227] Later in *Chevron*, the Court acknowledged that agency legislative delegation is often "implicit rather than explicit," and that agencies can clear these ambiguities through a "reasonable interpretation" of the statute.[228] More recently, in *City of Arlington*, the Court further explained that when interpreting ambiguous congressional statutes, "the agency can go no further than the ambiguity will fairly allow."[229]

FDA can fairly use the allocated funds from the Advancing Education Act to establish a nationwide campaign to educate the public on biosimilars.[230] This campaign would address multiple concerns surrounding biosimilars for both patients and providers, including educating the public on the safety and efficiency of biosimilars.[231] Further, the campaign would disclose the savings that patients can receive by using a cheaper biosimilar version of a high-cost, brand-name

[227] *See* 415 U.S. 199, *id*. at 231.
[228] *See Chevron*, *supra* note 141 at 2782.
[229] *See* City of Arlington*,* 569 U.S. 290, 307 (2013).
[230] *See* Advancing Education on Biosimilars Act*, supra* note 207 (within the "Continuing Education" section, the text states, "The Secretary shall advance education and awareness among health care providers regarding…biosimilar biological products and interchangeable biosimilar biological products, as appropriate, including by developing or improving continuing education programs). *See generally id*.; *supra* note 228 (relating to agency authority to resolve statutory ambiguity to administer programs).
[231] *See* Advancing Education on Biosimilars Act, *id*. (within the "Continuing Education" section, the text states, "advance the education of such providers on the prescribing of, and relevant clinical considerations with respect to…biosimilar biological products and interchangeable biosimilar biological products").

biologic.[232] This nationwide campaign would involve creating a joint public-private relationship with participating generic manufacturers that functions as a tool to advertise approved biosimilar products.[233] Part of this joint public-private relationship should be contingent on generic manufacturers passing on the savings from this publicly-funded marketing directly to patients.[234] One way that the agency can ensure that these savings are passed onto consumers is by setting price ceilings on biosimilar products advertised by participating manufacturers.[235] The agency can also ensure that these savings are passed to consumers by establishing a minimum percentage in price reduction between the biosimilar and brand-name biologics.[236] As previously mentioned, pharmaceutical marketing accounts for the bulk of the research and development costs of pharmaceutical products.[237] This subsidized marketing, subject to price controls, will provide consumers with

[232] *See Id*. (within the "Content" section, the text states, "Educational materials…may include… information related to development programs for biological products, including biosimilar biological products and interchangeable biosimilar biological products… which may include… information related to the comparability of such biological products").
[233] *See generally* Public-Private Partnerships for Transportation and Water Infrastructure, Congressional Budget Office (Jan. 2020), https://www.cbo.gov/publication/56044 (describing how similar public-private partnerships are often used in high-cost infrastructure projects, including the creation of water purification and energy production facilities. As well as highlighting the importance of these partnerships in reducing monopolies and regulating prices charged to consumers).
[234] *Id*.
[235] *See generally* Fixed Price Contracts, 48 C.F.R § 16.201 (describing how contracts between public and private entities can establish price ceilings or fixed prices with economic price adjustments).
[236] *Id.*
[237] *See supra* Part III (A).

better savings and allow the participating biosimilar manufacturers to maintain profits.

An important question to consider is: would this agency interpretation survive *Chevron* or the Major Questions Doctrine if challenged in court? Regarding *Chevron,* Congress expressed its intent to create a continuing education program that informs providers and patients about the benefits of biosimilar products; this advertising partnership for approved biosimilar products would achieve this goal.[238] Additionally, Congress expressed that the statute's purpose is to lower the cost of biosimilars, but it is ambiguous how that goal will be reached.[239] By providing publicly-funded advertising that is contingent on price controls to keep the cost of participating biosimilars low, FDA would be acting under a "permissible construction of the statute."[240] Regarding the Major Questions Doctrine, it is important to emphasize that the Advancing Education Act is new and thus there is not a long history of the statute being used by FDA differently.[241] Additionally, this interpretation of the statute would not have a major impact on the political landscape, as both Democrats and Republicans want to achieve the goals that this program would provide.[242] Further, this

[238] *See Chevron, supra* note 141, WV v. EPA, *supra* note 145 at 2608-9, 2620; *see also* Advancing Education on Biosimilars Act*, supra* note 207.
[239] *See* Advancing Education on Biosimilars Act*, supra* note 207; *See also* 167 Cong. Rec. H1754-01.
[240] *See Chevron*, 467 U.S. at 843.
[241] *See* Advancing Education on Biosimilars Act*, supra* note 207 ; *see also* WV v. EPA, *supra* note 145 at 2608-9, 2620.
[242] *See* 167 Cong. Rec. H1754-01; *see also id*.

interpretation would have only positive impacts on the economy, as patients and payers (both public and private) will pay less for these essential products.[243] This interpretation by FDA would survive *Chevron* and not draw the Major Questions Doctrine into question. Thus, the Advancing Education Act grants FDA the authority to fully revolutionize how biosimilars are perceived by patients and providers in addition to the ability to provide participating biosimilar manufacturers with publicly-funded advertising that will lead to cheaper biosimilars.

V. CONCLUSION

Biologics are an essential form of medicine responsible for the prevention, mitigation, and treatment of diseases for millions of Americans.[244] However, the high cost of biologics presents a heavy financial burden on both patients and the U.S. healthcare system as a whole.[245] Oftentimes, the financial burden places an unsurpassable obstacle that limits many patients' access to biologics.[246] The high cost of biologics is attributed to brand-name manufacturers' monopolistic hold on the biologics market, thereby preventing competition from affordable biosimilar alternatives.[247] Like the purpose of the Hatch-Waxman Amendments', Congress

[243] *See* Advancing Education on Biosimilars Act*, supra* note 207; *see also* W. Virginia v. Envtl. Protection Agency, 142 S. Ct. 2587 (2022) (this would not create negative economic implications under the Major Questions Doctrine).
[244] *See supra* note 16, *see also* SCHACHT & THOMAS , s*upra* note 17.
[245] *See* ERNST & YOUNG, *supra* note 20.
[246] *See supra* note 7 at 4-5.
[247] *See* Glover, *supra* note 15.

enacted BPCIA with the intent to increase access to affordable biosimilars while also balancing the needs of brand-name biologic manufacturers.[248] However, the twelve-year exclusivity period awarded to biologics and FDA's interpretation of it to mean market exclusivity, as opposed to data exclusivity, makes it difficult for affordable biosimilar alternatives to enter the market.[249]

Brand-name biologic manufacturers are reformulating their COVID-19 vaccines as new variants continue to emerge[250] This will ultimately lead to a resurgence of pressure on FDA to apply umbrella exclusivity to biologics.[251] However, FDA must avoid applying umbrella exclusivity to biologics because it would lead to further monopolistic practices in the biologic market, like product hopping.[252] If FDA applies umbrella exclusivity to biologics, its decision would likely fail either a *Chevron* or Major Questions judicial review.[253]

FDA and Congress must encourage market competition in the biologic market to ensure affordable biologics are available to patients. To achieve this, FDA must first reinterpret the twelve-year exclusivity period awarded to biologics to mean data exclusivity, rather than market exclusivity. Second, Congress must amend the BPCIA exclusivity period by lowering it from twelve years to five

[248] *See supra* Part II.
[249] *See supra* Part IV.
[250] *See supra* Part III.
[251] *See supra* Part III.
[252] *See supra* Part III.
[253] *See supra* Part III.

years. Third, FDA must use the Advancing Education Act to increase public awareness about the safety and efficiency of biosimilar products. To increase public awareness, FDA should establish a public-private partnership with biosimilar manufacturers that provides publicly-funded advertising contingent on biosimilar price reductions. These recommendations will have a significant impact on the U.S. healthcare system by reducing the financial burden that these products place on the system and increasing their availability to low-income patients. The tools to better ensure the health and well-being of patients across the nation are readily available to both legislators and regulators—they must act now to ensure this future.

STUCK BETWEEN A DOC AND A HARD PLACE: HOW HOSPITAL PRICE TRANSPARENCY AND OTHER REGULATORY STATUTES FAIL AGAINST EVER-GROWING MONOPOLISTIC HOSPITAL SYSTEMS

*Maryclaire M. Farrington**

"If we're going to treat something that's precious and lifesaving like a business, then the marketplace for health care must be vibrant and competitive so that the best in the business can rise to the top."
–Xavier Becerra[1]

** First and foremost, I want to thank my dad, Dr. Cecil Murray Farrington, Jr. for being my greatest hero and inspiring this piece – he retires this year after practicing family medicine for 50 years. Thank you to my partner, Drew, my mother, Monica, and Mona Lisa Wallace, for their unyielding support. To Vin, Michaela, and Jacob, for going through law school by my side (for better or for worse). And of course, to Sully, my four-legged associate.*

[1] Katie Thomas, *Sutter Health to Pay $575 Million to Settle Antitrust Lawsuit*, N.Y. TIMES (Dec. 20, 2019), https://www.nytimes.com/2019/12/20/health/sutter-health-settlement-california.html.

Introduction

Americans are undoubtedly more polarized today than ever before. However, Americans overwhelmingly agree that medical bills are growing rapidly, "stunting" families and their economic abilities.[2] Healthcare debt affects over half of the United States population and reached an estimated $140 billion.[3] Today, 90% of Americans support hospital price transparency.[4] This Comment will explain that, despite such a consensus of the American population, the battle for hospital price transparency is not straightforward. More than ever, the monopolistic powers of American hospitals are apparent and the system is crippling transparency and market fairness efforts.

This Comment begins by discussing the history of price transparency and the federal price transparency bill in Part I. Part II explains the status of the Federal Rule, the willful non-compliance of hospital systems during the first year after its passage, and the likely motivations for non-compliance. Part III discusses

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[2] *See* Press Release, North Carolina Department of State Treasurer, Treasurer Folwell Condemns Hospitals' "Pattern of Deceit" on Price Transparency: Calls on Attorney General Josh Stein to Protect Consumers, (Mar. 31, 2021), https://www.nctreasurer.com/news/press-releases/2021/03/31/treasurer-folwell-condemns-hospitals'-"pattern-deceit"-price#:~:text=(Raleigh%2C%20N.C.)%20–%20State,prices%20starting%20in%20January%202021 [hereinafter *Pattern of Deceit*].

[3] *See* Deanna Cuadra, *"Perverse Incentives": Why the Healthcare Market is Motivated to Provide High-Cost, Ineffective Care*, EMP. BENEFIT NEWS (Jan. 12, 2022), https://www.benefitnews.com/advisers/news/affordable-care-act-and-the-mlr-rule-impact-on-us-healthcare.

[4] *See Pattern of Deceit*, *supra* note 2.

the rising trend of suits against hospitals in the United States as a result of increased scrutiny of the healthcare market. Part IV investigates the existing efforts to support price transparency in the state of North Carolina and the challenges to total compliance with the Rule. Part V proposes solutions to undermining the current course of total monopolization of the healthcare sector. This Comment will ultimately argue that the Federal Rule, despite higher penalties, is illustrative of the legislature's ineffectuality against ever-growing hospitals because of the increasing monopoly that hospitals created. Finally, Part VI analyzes existing efforts and suggests solutions to encourage price transparency compliance.

I. A "Confiscatory System": History of U.S. Healthcare and Hospital Monopolization

American hospitals in the late nineteenth century were vastly different than hospitals today. Pre-industrial hospitals operated as places for the "hopelessly sick and poor" to find comfort before death.[5] However, the development of ether, antiseptic, and X-Rays transformed American hospitals from death sentences to second chances at life.[6]

In 2020, the U.S. health expenditure reached an all-time high of 19.7% of

[5] *See* MARK A. HALL ET AL., MEDICAL LIABILITY AND TREATMENT RELATIONSHIPS (4th ed. 2018).
[6] *See* Connie Y. Chang et al., *Ether in the Developing World: Rethinking an Abandoned Agent*, 15 BMC ANESTHESIOLOGY 149 (Oct. 16, 2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4608178/; *see also* HALL, *supra* note 5.

gross domestic product ("GDP"),[7] the highest by far among similarly positioned nations.[8] By 2028, U.S. healthcare expenditures are expected to top $6 trillion—approximately one-fifth of the U.S. GDP.[9] Although U.S. healthcare prices are higher than any other developed nation,[10] and rising,[11] the quantity and quality of care in the U.S is comparatively worse.[12] In a study of the fifty states and the District of Columbia, North Carolina ranked thirty-ninth best state for healthcare and the fifth most costly.[13]

The American monopolistic hospital system, intertwined and empowered by hospitals' relationship with insurance companies, continuously drives healthcare prices higher.[14] One economist compared the merging and

[7] *See NHE Fact Sheet,* CMS.GOV (Dec. 15, 2021, 4:06 PM), https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.
[8] *See* Jenny Yang, *U.S. Health Expenditure as Percent of GDP 1960-2020,* STATISTA (Jan. 4, 2022), https://www.statista.com/statistics/184968/us-health-expenditure-as-percent-of-gdp-since-1960/.
[9] *See id.*
[10] *See* Melanie Evans, *What Does Knee Surgery Cost? Few Know, and that's a Problem*, WALL ST. J. (Aug. 21, 2018, 11:29 AM), https://www.wsj.com/articles/what-does-knee-surgery-cost-few-know-and-that's-a-problem-1534865358?mod=article_inline.
[11] *See* Jeanne Whalen, *Health-Care Costs Rose for Americans with Employer-Sponsored Insurance*, WALL ST. J. (Jan. 23, 2018, 6:28 PM), https://www.wsj.com/articles/health-care-costs-rose-for-americans-with-employer-sponsored-insurance-1516750102?mod=article_inline; *see also* Ryan Knutson & Theo Francis, *Basic Costs Squeeze Families*, WALL ST. J. (Dec. 1, 2014, 7:29 PM), https://www.wsj.com/articles/americans-reallocate-their-dollars-1417476499?mod=article_inline.
[12] *See* Joseph Walker, *Why Americans Spend So Much on Health Care – In 12 Charts*, WALL ST. J. (July 31, 2018, 10:27 AM), https://www.wsj.com/articles/why-americans-spend-so-much-on-health-carein-12-charts-1533047243?mod=article_inline.
[13] *See* Adam McCann, *Best & Worst States for Health Care*, WALLETHUB (Aug. 2, 2021), https://wallethub.com/edu/states-with-best-health-care/23457.
[14] *See* Zack Cooper & Martin Gaynor, *Addressing Hospital Concentration and Rising Consolidation in the United States,* 1% STEPS 1, 5 https://onepercentsteps.com/wp-content/uploads/brief-hc-210208-1700.pdf.

monopolizing hospital system to "Dracula . . . suck[ing] some of the vibrancy out of a lot of towns across the country."[15]

The crisscrossed diagram that represents supply and demand is the cornerstone of basic economics.[16] Competition keeps prices fair and drives efficiency and quality.[17] However, waves of hospital mergers and small-town-physician-buyouts swept across the U.S., resulting in "substantially increased market concentration."[18] Now, more than 80% of hospital markets are considered highly concentrated[19] under the Department of Justice ("DOJ") and the Federal Trade Commission ("FTC") horizontal merger guidelines.[20]

The DOJ determines concentration based on the Herfindahl-Hirschman Index ("HHI"),[21] which is calculated by squaring the market share of each entity competing in the market and adding each of those numbers together.[22] The DOJ defines a highly concentrated market as a market with an HHI score of more than

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[15] Greg Rosalsky, *The Untamed Rise of Hospital Monopolies,* NPR (July 20, 2021, 9:40 AM), https://www.npr.org/sections/money/2021/07/20/1017631111/the-untamed-rise-of-hospital-monopolies.
[16] *See e.g.*, Tejvan Pettinger, *Diagrams for Supply and Demand*, ECONOMICSHELP (Sept. 3, 2019), https://www.economicshelp.org/blog/1811/markets/diagrams-for-supply-and-demand/.
[17] *See* Cooper & Gaynor, *supra* note 14, at 5.
[18] *Id.*
[19] *See id.*
[20] *See id.*; *see also* U.S. Department of Justice & FTC, *Horizontal Merger Guidelines* § 5.3 (2010).
[21] *See Hospital Concentration Index*, HEALTH CARE COST INST., https://healthcostinstitute.org/hcci-originals/hmi-interactive#HMI-Concentration-Index (last visited Feb. 27, 2022) (using detailed graphs and data to provide a nationwide analysis of healthcare market concentration and HHI scores).
[22] *See Herfindahl-Hirschman Index*, U.S. DEPT. OF JUSTICE (July 31, 2018), https://www.justice.gov/atr/herfindahl-hirschman-index.

2,500 points.[23] For reference, four hospitals each holding a 25% share of the market would equate to an HHI score of 2,500.[24] Conversely, one hospital holding a complete monopoly (100% share of the market) would have an HHI score of 10,000—the maximum.[25] Since 1998, there have been 1,519 hospital mergers—680 between 2010 and 2018.[26] This epidemic of consolidation led to substantial price increases without clear evidence of improvements in quality or efficiency.[27]

Consolidation leads to price escalation in part because hospital mergers increase the bargaining powers of the hospitals with insurers seeking to strengthen provider networks across regions, thereby attracting cross-regional employers and employees.[28] Additionally, hospital systems holding a monopoly "can influence the dynamics of negotiations with insurers" by "shifting volume to higher cost facilities."[29] This shift may limit patients to in-network, higher-costing hospitals, despite alternative, lower-costing hospitals nearby.[30]

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[23] *See* U.S. Department of Justice & FTC, *supra* note 19.
[24] *See* Eric Barette et al., *Understanding Health Spending: Lessons from the Healthy Marketplace Index*, HEALTHAFFAIRS (Dec. 7, 2017), https://www.healthaffairs.org/do/10.1377/forefront.20171205.343488/full/.
[25] *See id.*
[26] *See* Martin Gaynor, *Examining the Impact of Health Care Consolidation: Statement Before the Committee on Energy and Commerce Oversight and Investigations Subcommitee* (Feb. 14, 2018), https://docs.house.gov/meetings/IF/IF02/20180214/106855/HHRG-115-IF02-Wstate-GaynorM-20180214.pdf.
[27] *See id.*; *see also* Karyn Schwartz et al., *What We Know About Provider Consolidation*, KFF (Sept. 2, 2020), https://www.kff.org/health-costs/issue-brief/what-we-know-about-provider-consolidation/.
[28] *See* Schwartz, *supra* note 27.
[29] *Id.*; *see also* discussion *infra* Part IV(A)(ii).
[30] *See* Schwartz, *supra* note 27.

Compounding the problem of price escalation and increasing monopolies is the healthcare sector's substantial lobbying efforts in the political sphere. In 2020, the healthcare sector spent over $623 million on lobbying efforts.[31] The American Hospital Association ("AHA") had the second-highest lobbying expenditure—spending over $12,121,176 in just the first six months of 2021.[32]

II. The Federal Price Transparency Bill

Few people, even healthcare professionals, know the "true cost" of healthcare.[33] In America, "[w]e don't have a system that thinks about value" of the healthcare we receive.[34] Without price transparency, the average consumer does not know what their medical procedures will cost.[35] As hospitals monopolize, prices increase and consumers lose—a "confiscatory health system" as it has not-so-affectionately been called.[36] In response to the glaring problem that is the healthcare market system, the non-partisan price transparency bill emerged.

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[31] *See* Marcus Robertson, *Top 20 Healthcare Lobbyists by 2021 Spending Through June,* BECKERS HOSP. REV. (Aug. 25, 2021), https://www.beckershospitalreview.com/finance/top-20-healthcare-lobbyists-by-2021-spending-through-june.html.
[32] *See id.*
[33] *See* Walker, *supra* note 12.
[34] *See* Steve Riley, *Dale Folwell Battled the Health Care 'Cartel'*, THE ASSEMBLY (Feb. 3, 2022), https://www.theassemblync.com/long-form/dale-folwell-battles-the-health-care-cartel/ (statement by Duke law professor, Barak Richman).
[35] *See* Walker, *supra* note 12.
[36] *See* Riley, *supra* note 34.

A. History of the Price Transparency Bill

Price transparency is one way to combat the increasing cost of healthcare.[37] In addition to "lower and more uniform prices," price transparency may increase access to healthcare as patients can compare prices among hospital systems and make educated decisions when choosing providers and services.[38]

Congress passed the Affordable Care Act ("ACA") in 2010,"[39] Among other things, the ACA requires that U.S. hospitals publish "a list of the hospital's standard charges for items and services provided by the hospital."[40] By 2018, the Centers for Medicare and Medicaid Services ("CMS"), a subset of U.S. Health and Human Services ("HHS"), informed hospitals that it would begin required that hospitals post chargemaster rates[41] online in a "machine-readable format."[42] In the summer of 2019, then-President Donald Trump ordered HHS to enforce transparency requirements, emphasizing the need for charge information to include "information based on negotiated rates and for common

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[37] *See* Allie Reed, *Medicare Holds Off on Hospital Price Disclosure Fines for Now*, BLOOMBERG LAW (Aug. 16, 2021, 5:35 AM), https://news.bloomberglaw.com/health-law-and-business/medicare-holds-off-on-hospital-price-disclosure-fines-for-now.
[38] *See id.*
[39] Kayla Leland Pragid & Shanice Cameron, *Price Transparency in Hospitals – Is Hospital Pricing Data a Protected Trade Secret?*, JD SUPRA (Sept. 13, 2021), https://www.jdsupra.com/legalnews/price-transparency-in-hospitals-is-2390227/.
[40] 42 U.S.C. § 300gg-18(e) (2018).
[41] *See* Pragid & Cameron, *supra* note 39 (explaining that chargemaster rates are "standard rates without any discounts applied").
[42] *See id.* (explaining that machine-readable format means a digital representation of a file that can be imported into a computer system).

shoppable . . . services . . . [so] as to inform patients about *actual* prices."[43] On January 1, 2021, CMS's Hospital Price Transparency Rule ("the Rule") took effect.[44]

The Rule mandates the publication of five "standard charges."[45] The first required standard charge is the "gross charge," or the non-discounted price reflected on the hospital's chargemaster.[46] The second is the "payer-specific negotiated charge," which must be "clearly associated with the name of the third party payer and plan."[47] The third and fourth required standard charges are the "de-identified minimum negotiated charge" and the "de-identified maximum negotiated charge."[48] The fifth required standard charge is the "discounted cash price," which reflects the price that an individual would pay if using cash or a cash equivalent at a hospital.[49]

The Rule requires price information to be available (1) "as a comprehensive machine-readable file with all terms and services AND [(2)] as a

[43] *See id.* (internal citations and quotations omitted) (emphasis added).
[44] *See* 45 C.F.R. § 180.10 *et seq.* (2021).
[45] *See* Hayley White, *Hospital Price Transparency and Litigation Update*, NORTON ROSE FULBRIGHT: HEALTH LAW CHECK-UP 1, 14 (2020), https://www.nortonrosefulbright.com/-/media/files/nrf/nrfweb/knowledge-pdfs/health-law-check-up---q4-2020.pdf?revision=af2d1129-6359-423b-8515-6d97686f1b0c&revision=af2d1129-6359-423b-8515-6d97686f1b0c.
[46] *See* 45 C.F.R. § 180.50(b)(2) (2018); *see also* White, *supra* note 45.
[47] *See* 45 C.F.R. § 180.50(b)(3) (2018); *see also* White, *supra* note 45.
[48] 45 C.F.R. § 180.50(b)(4)–(5)(2018); *see also* White, *supra* note 45 ("de-identified minimum and maximum charges are the lowest and highest charges that a hospital has negotiated with all third-party payers for an item or service").
[49] *See* 45 C.F.R. § 180.50(b)(6) (2018); *see also* White, *supra* note 45.

display of shoppable services in a consumer-friendly format."[50] Hospital locations that operate under a shared hospital license and have different sets of standard charges must separately publicize their standard charges applicable to each location.[51]

The initial proposed Rule included a civil monetary penalty of $300 maximum per non-compliant day, totaling up to $109,500 per year. [52] This penalty remained effective until January 2022.[53] In July 2021, President Joe Biden advocated for price transparency by ordering the HHS "to support existing hospital price transparency rules and to finish implementing bipartisan federal legislation to address surprise hospital billing."[54] Seven months after the Rule went into effect, the price transparency bill was amended to increase the penalty and implement a sliding scale to calculate penalty charges.[55] However, the maximum penalty is capped at $5,550 per day, even if a facility has over 550 beds.[56] This amounts to a $2,007,500 maximum penalty per year.

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[50] Terri L. Postma, *Compliance with Hospital Price Transparency Final 8 Steps to a Machine-Readable File*, CMS.GOV (Aug. 2021), https://www.cms.gov/files/document/august-11-2021-hospital-price-transparency-odf-slide-presentation.pdf (emphasis in original).
[51] *See* 45 C.F.R. § 180.50(a)(2) (2019).
[52] 45 C.F.R. § 180.90 (c)(2)(i) (2019).
[53] 45 C.F.R. § 180.90 (c)(2)(i)-(ii)(A)-(C).
[54] Pragid & Cameron, *supra* note 39; *see also* 45 C.F.R. § 180.10 (2019) ("Hospital price transparency helps Americans know the cost of a hospital item or service before receiving it. Starting January 1, 2021, each hospital operating in the United States will be required to provide clear, accessible pricing information online . . . .").
[55] *See* 45 C.F.R. § 180.90(c)(1)-(2)(i) (2019).
[56] *See* 45 C.F.R. § 180.90(c)(2)(ii)(C) (2019).

If hospitals complied with the Rule and implemented measures to achieve true price transparency, traditional economic analysis suggests that prices will decrease as competition and choice increase.[57] Yet many hospitals initially avoided compliance,[58] likely in an attempt to maintain the scheme that supports higher profits, inflates their systems' ratings, and insulates their control of the market.

B. Willful Noncompliance with the Rule

The Rule became effective in January 2021, but hospitals across the nation did not immediately comply.[59] Six months after the Rule's effective date, approximately 5.6% of hospitals in the U.S. were in compliance with the rule.[60] The remaining 94.4% were unambiguously non-compliant—missing required variables and failing to comply with variable requirements in their price data files.[61] Despite the widespread disregard of the Rule, and CMS's knowledge of

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[57] *See* Price Transparency Requirements, 84 Fed, Reg. 65524-01, 65544 (Nov. 27, 2019) (to be codified at 45 C.F.R. subchapter E).
[58] *See Semi-Annual Hospital Price Transparency Compliance Report*, PATIENT RIGHTS ADVOCATE.ORG 1, 2 (July 2021), https://static1.squarespace.com/static/60065b8fc8cd610112ab89a7/t/60f1c225e1a54c0e42272fbf/1626456614723/PatientRightsAdvocate.org+Semi-Annual+Hospital+Compliance+Report.pdf (providing a study of 500 randomly selected hospitals across the United States) [hereinafter *Compliance Report*].
[59] *See* Morgan A. Henderson & Morgane C. Mouslim, *Low Compliance from Big Hospitals on CMS's Hospital Price Transparency Rule*, HEALTHAFFAIRS (Mar. 16, 2021), https://www.healthaffairs.org/do/10.1377/forefront.20210311.899634/full/.
[60] *See Compliance Report*, *supra* note 58; *see also* Jill McKeon, *94% of Hospitals Noncompliant with Hospital Price Transparency Rule*, REV CYCLE INTEL. (July 21, 2021), https://revcycleintelligence.com/news/94-of-hospitals-noncompliant-with-hospital-price-transparency-rule.
[61] *See Compliance Report*, *supra* note 58; *see also* McKeon, *supra* note 60; *see also* Henderson & Mouslim, *supra* note 59.

willful noncompliance,[62] CMS had not issued a fine to any non-compliant hospital by late February 2022.[63]

In August 2021, CMS said it would temporarily halt enforcement of price transparency noncompliance penalties to provide hospitals the time to adjust to the new rule.[64] CMS also announced that it would not enforce the requirement that hospitals make public the "machine-readable files for in-network rates and out-of-network allowed amount and billed charges" until July 2022.[65] Yet in December 2021, CMS issued at least 335 warning notices to non-compliant hospitals.[66]

While CMS played wait-and-see, changes to the healthcare market stalled until hospitals decided to comply. Despite the increased penalty going into effect in January 2022, a February 2022 report by a Patient Rights Advocate group

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[62] *See* Sarah Kliff & Josh Katz, *Hospitals and Insurers Didn't Want You to See These Prices. Here's Why.*, N.Y. TIMES (Aug. 22, 2021), https://www.nytimes.com/interactive/2021/08/22/upshot/hospital-prices.html ("As of July [2021], the Centers for Medicare and Medicaid Services had sent nearly 170 warning letters to noncompliant hospitals").

[63] *See* Reed, *supra* note 37; Dave Muoio, *CMS Issued Over 300 Warnings, but No Fines, to Hospitals Falling Short on Price Transparency Last Year*, FIERCE HEALTHCARE (Jan. 7, 2022, 5:32 PM), https://www.fiercehealthcare.com/hospitals/cms-has-issued-over-300-warnings-but-no-fines-to-hospitals-falling-short-price.

[64] *See* Jill McKeon, *CMS Holds Off on Hospital Price Transparency Noncompliance Penalties*, REV CYCLE INTEL. (Aug. 17, 2021), https://revcycleintelligence.com/news/cms-holds-off-on-hospital-price-transparency-noncompliance-penalties?__cf_chl_managed_tk__=pmd_TItakZOA9xVcNbKnVbaVoQLSRqjqDKp2nXenfXXTOTI-1631283902-0-gqNtZGzNA9CjcnBszQcR.

[65] *See* Thomas Sullivan, *CMS Delays Enforcement of Certain "Transparency in Coverage" Final Rule Requirements*, POL'Y & MED. (Dec. 5, 2021), https://www.policymed.com/2021/12/cms-delays-enforcement-of-certain-transparency-in-coverage-final-rule-requirements.html.

[66] *See* Muoio, *supra* note 63.

found only meager compliance improvements.[67] Essentially, hospitals continued to flout the Rule. [68] Of the 1,000 hospitals reviewed in the February study, only 14.3% complied with the Rule.[69] Notably, 0.5% of hospitals, "owned by the three largest systems in the country—HCA Healthcare, CommonSpirit Health, and Ascension," were in compliance.[70] HCA Healthcare is the largest for-profit hospital system in America, amassing over $58.8 billion in revenue in 2021.[71] Out of the 188 HCA hospitals in the sample, none were in compliance with the rule.[72] In response to the widespread and unambiguous non-compliance, PatientRightsAdvocate.org stated that,

> "[t]he lack of compliance by hospitals is about more than simply the failure to follow the legal requirements. It is also about the failure of hospitals to provide critically needed information to consumers so they can make better health decisions. Empowered with comparative price and quality information in advance of care, consumers, including employers and unions, can improve health outcomes while lowering costs by taking advantage of the benefits of competitive market efficiencies. Moreover, known prices help prevent billing errors, overcharges, and fraud."[73]

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[67] *See The Second Semi-Annual Hospital Price Transparency Compliance Report*, PATIENTRIGHTSADVOCATE.ORG (Feb. 7, 2022), 1, 1 https://www.patientrightsadvocate.org/semi-annual-compliance-report-2022.
[68] *See id.*
[69] *See id.*
[70] *Id.* ("In 2021, these three large noncompliant hospital systems' combined total revenue approached $120 billion. The cost of compliance calculated in the rule is only $12,000 per hospital.").
[71] *See id.* at 4-5.
[72] *See id.* at 4.
[73] *Id.* at 4–5.

America's "largest hospital systems are effectively ignoring the law, with no consequences."[74]

C. Hospitals Would Rather be Non-Compliant

Hospitals and insurance companies alike have good reason to conceal prices—they are charging drastically different amounts for the same services.[75] Data suggests that major health insurers are negotiating "surprisingly unfavorable rates" with patients, thereby creating situations where some rates are higher with insurance than without insurance.[76] Without knowledge of what health care services cost, hospitals may tout "steep discounts" while patients are entirely unaware that they are being charged significantly more than what public programs pay.[77] Yet, contrary to basic economic principles, the American Hospital Association claimed the "rate sheets are not helpful to anyone."[78]

The lack of compliance with the Rule in its first year of applicability was hardly surprising considering the menial $109,500 per-year fine.[79] The recent increase in the price of non-compliance is still insufficient as some hospital

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[74] *Id.* at 4.
[75] *See* Sarah Kliff & Josh Katz, *Hospitals and Insurers Didn't Want You to See These Prices. Here's Why.*, N.Y. TIMES (Aug. 22, 2021), https://www.nytimes.com/interactive/2021/08/22/upshot/hospital-prices.html.
[76] *See id.*; *see also* Steve Riley, *Dale Folwell Battled the Health Care 'Cartel'*, THE ASSEMBLY (Feb. 3, 2022), https://www.theassemblync.com/long-form/dale-folwell-battles-the-health-care-cartel/.
[77] *See* Kliff & Katz, *supra* note 75.
[78] *See id.*
[79] *See id.*

systems gross over $5 billion in revenue per year.[80] For example, UNC Hospitals reported a record total profit of $516 million in fiscal year 2021.[81] The same organization also received nearly $15 million in COVID-19 aid and relief from the North Carolina Legislature—the same legislature tasked with enforcing the Price Transparency Rule—during the same fiscal period.[82] In 2020, Duke University Health System paid seven individuals more than $1 million each,[83] including its CEO who received $2.7 million[84]—approximately $600,000 more than the now-enforceable (but not enforced) maximum penalty for noncompliance with the Rule.[85]

III. Bucking the Rule: Early Litigation Surrounding Price Transparency

In addition to the initial unambiguous non-compliance with the price transparency rule, numerous healthcare organizations launched offensive attacks via litigation in attempts to challenge the Rule. However, most of these attempts failed and the Rule remains in effect, despite the initial lack of enforcement.

A. *American Hospital Association v. Azar*

In December 2019, numerous health organizations, including the AHA, challenged the Rule in the D.C. Circuit by suing the Secretary of HHS, Alex M.

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[80] *See id.*
[81] *See* Riley, *supra* note 76.
[82] Riley, *supra* note 76.
[83] *Id.*
[84] *See* Riley, *supra* note 76.
[85] *See* 45 C.F.R. § 180.90 (2019). The maximum daily penalty for hospitals with more than 550 beds is $5,500, or $2,007,500 annually if a hospital is noncompliant for a full year.

Azar II.[86] The claimants argued that the Rule's specific provision that defines "standard charges" as including prices that hospitals charge insurers "violate[s] the statute, the Administrative Procedure Act, and the First Amendment."[87] The push for the public release of negotiated rates was the impetus for the lawsuit, as healthcare administrators' and insurers' collusive and arguably arbitrary pricing mechanisms would be called into question.[88] The D.C. Circuit's analysis of the Rule and its practical implications on hospital administrators, healthcare professionals, and insurers illustrates the current posture of the Rule and is likely the first of many cases to come. As discussed below, the D.C. Circuit addressed and dismissed common concerns surrounding the implementation of the Rule.

Hospital charges "look nothing like hotel room rates or car prices."[89] While 10% of patients "self-pay" out of pocket for healthcare, 90% rely on insurers, including federal and state government insurance programs like Medicare and Medicaid.[90] Medicare and Medicaid rates, set by the states and by CMS, are already publicly available.[91] Comparatively, negotiated rates between private insurers and hospitals are much more elusive and complex.[92] An earlier version of the Rule did not establish a clear requirement for the disclosure of

[86] *See* Am. Hosp. Ass'n v. Azar, 983 F.3d 528 (D.C. Cir. 2020).
[87] *Id.* at 531.
[88] *See generally id.*
[89] *Id.* at 530.
[90] *See id.* at 531
[91] *See id.*
[92] *See* Am. Hosp. Ass'n v. Azar, 938 F.3d 528, 531 (D.C. Cir. 2020).

negotiated rates, and the system continued to function in an "upward spending trajectory"[93] until the Secretary recognized the need for published negotiated rates in order to achieve lower healthcare prices.

The AHA argued that it would take far too long for hospitals to create and maintain a system that the Rule requires.[94] Though the Secretary initially estimated it would take each hospital approximately twelve hours to create a system that comports with the Rule; however, after a significant comment period, the Secretary liberally increased the estimation to 150 hours in the initial year, plus forty-six per year for maintenance and upkeep.[95] The court noted that while this is not a trivial amount of time for hospitals to invest in the system, the Secretary adjusted the original estimate tenfold and pushed the effective date after receiving nearly 4,000 comments on the proposed rule.[96] The Secretary's use of the notice-and-comment period illustrates an appropriate method to establish fair and attainable requirements for the healthcare system.[97] Despite pushback from hospital systems, the task may not be as insurmountable as they seem to suggest. The Rule does not require an exhaustive list of "all possible permutations of costs

[93] *See id.* at 532.
[94] *See id.* at 533.
[95] *See id.*
[96] *See id.* at 532.
[97] *See id.* at 533.

based on hypothetical additional care,"[98] but rather the base rate of the negotiated price between the hospital and the third-party payer.[99]

The AHA further argued that the Rule would misinform patients and facilitate anticompetitive effects.[100] However, the court rejected that assertion, admonishing the hospital systems for raising arguments that run contrary to traditional economics.[101] Indeed, it is well settled among economists that markets function at their most efficient when consumer prices reflect the actual costs of creating and delivering products.[102] Furthermore, "traditional economic analysis suggests that if consumers were to have better pricing information for healthcare services, providers would face pressure to lower prices and provide better quality care."[103] The Rule's purpose is to shift the burden patients currently face in a non-transarent system to hospitals and "fill the information gap in easily accessible pricing information for consumers."[104] The court acknowledged that the original rule, which required the disclosure of the price applicable to only publically insured patients, is misleading without the new requirement of the disclosure of privately negotiated rates.[105]

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[98] *See* Am. Hosp. Ass'n v. Azar, 983 F.3d 528, 536 (D.C. Cir. 2020).
[99] *See id.* at 537.
[100] *See id.* at 538.
[101] *See id.* at 539.
[102] Price Transparency Requirements, 84 Fed. Reg. 65524, 65547 (Nov. 27, 2019) (to be codified at 45 C.F.R. subchapter E).
[103] *Id.* at 65526.
[104] Am. Hosp. Ass'n v. Azar, 983 F.3d 528, 539-40 (D.C. Cir. 2020) (internal quotation marks omitted).
[105] *See id.* at 541.

Finally, the court dismissed the AHA's constitutionality claim without much commentary. The Court opined that the Rule does not require expressive content, nor does it require a hospital "to endorse a particular viewpoint []or prevent[] them from adding their own message on the same website . . . or file."[106] The Rule was upheld and became effective on January 1, 2021.[107] The court's upholding of the Rule in *American Hospital Association v. Azar* clearly underscores the importance of price transparency.

The motives and reasoning behind the Rule and the importance of price transparency are realized by the judicial system, and the complaints and excuses of the healthcare administrative system have been hushed—at least for now. Yet, the legislature's inability to regulate hospital systems exposes a terrible flaw in our system: If hospitals willingly disobey the law as written in the statute and as reaffirmed by the courts, what chance do we stand to regulate them and maintain the integrity of the American legal system against the American hospital system? Are we at the mercy of the monopoly?

B. *People of the State of California ex rel. Xavier Becerra v. Sutter Health*

In 2018, a study conducted by the University of California-Berkeley found evidence of significantly higher healthcare prices in the highly concentrated

[106] *Id.*
[107] *See* 45 C.F.R. § 180.10 *et seq.* (2021).

Northern California hospitals.[108] Following this study, the California Attorney General filed suit against Sutter Health claiming that the hospital system required anti-competitive clauses in its contracts, artificially exaggerating its market share and ultimately increasing healthcare costs for consumers.[109] The complaint alleged that the "expenditures of funds correspond with anticompetitive monopolist behavior in which excessive surpluses can go to protect or enhance market power, to wasteful innovation, or to further inequality."[110]

Sutter Health is similar in size to Atrium, with twenty-four acute care centers, thirty-six ambulatory surgery centers, and sixteen cardiac and cancer centers.[111] Sutter Health is an economic force, collecting nearly $13,220,000,000 in gross operating revenue in 2020 alone.[112] On the eve of the trial, Sutter Health elected to settle.[113] The terms of the settlement included a payment of $575

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[108] *See* Marc B. Collier & Vic Domen, *Potential Contracting Issues of "All-or-nothing" Clauses: New HHS Secretary, Policy Priorities*, NORTON ROSE FULBRIGHT (Mar. 18, 2021), https://www.nortonrosefulbright.com/en/knowledge/publications/8fd44164/potential-contracting-issues-of-all-or-nothing-clauses (comparing Northern California to the lesser concentrated Southern California); *see also Consolidation in California's Health Care Market 2010-2016: Impact on Prices and ACA Premiums*, THE NICHOLAS C. PETRIS CTR. (Mar. 26, 2018), http://petris.org/wp-content/uploads/2018/03/CA-Consolidation-Full-Report_03.26.18.pdf.

[109] *See* Collier & Domen, *supra* note 108.

[110] Complaint at 6, California ex rel. Becerra v. Sutter Health, No. CGC-18-565398 (Cal. Mar. 29, 2018).

[111] *See* Press Release, Rob Bonta, Attorney General, California Department of Justice, Attorney General Becerra Files Opposition to Sutter Health's Delay of Landmark Settlement of Anticompetitive Practices (June 25, 2020), https://oag.ca.gov/news/press-releases/attorney-general-becerra-files-opposition-sutter-health's-delay-landmark.

[112] *See Sutter Health Financial Performance*, SUTTER HEALTH, https://www.sutterhealth.org/about/financials (last visited Feb. 24, 2022).

[113] Collier & Domen, *supra* note 108.

million and numerous methods of injunctive relief.[114] Methods of injunctive relief included limiting out-of-network charges, increasing transparency by providing access to pricing information, halting low-cost plan denials, stopping all-or-nothing contract deals, ceasing bundling of services and products, cooperating with a compliance monitor, and setting definitions on clinical integration and patient access considerations.[115] The settlement was approved in August 2021.[116]

After the AHA's failed attempt to block the transparency rule and the landmark Sutter Health settlement, the healthcare industry should anticipate both a tougher crack-down on monopolistic and anti-competitive systems and an insistent attitude toward price transparency. As the *AHA v. Azar* ruling and the recent Sutter Health settlement suggest, litigation is an effective way to enforce compliance with the Rule, regardless of CMS's authority to enforce price transparency.

IV. Existing Efforts in North Carolina and Challenges to Healthcare Market Fairness

North Carolina[117] is a popular forum of choice for attacks on anti-

[114] *See id.*
[115] *See id.* (explaining that integration is not arbitrary but rather is leading to more efficient and less costly, higher quality care).
[116] *See* Robert King, *Federal Judge Grants Final Approval of $575M Settlement Against Sutter Health*, FIERCE HEALTHCARE: HOSPS. (Aug. 20, 2021, 1:06 PM), https://www.fiercehealthcare.com/hospitals/federal-judge-grants-final-approval-575m-settlement-against-sutter-health.
[117] This Comment focuses on North Carolina as an example. However, North Carolina's problems are widespread and affect both state and federal health care systems.

competitive practices within the healthcare market.[118] The DOJ settlement with Atrium Health in 2018 prohibits Atrium from using anti-steering and anti-tiering clauses in contracts between its providers in the Charlotte metropolitan area and commercial health insurers.[119] Additionally, the North Carolina Court of Appeals recognized, in at least two cases, that non-compete agreements in contracts are detrimental to public health.[120] The court accordingly set precedent to find such clauses unenforceable.[121]

Furthermore, North Carolina Attorney General Josh Stein is a vocal critic of consolidation and has advocated for increased scrutiny of mergers by the Attorney General's office.[122] Although North Carolina failed to implement All Player Claims Databases ("APCDs"),[123] the state enacted some legislation[124] on surprise billing protections, merger reviews, and anti-competitive contract

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[118] *See North Carolina*, THE SOURCE ON HEALTHCARE & COMPETITION, https://sourceonhealthcare.org/states/north-carolina/ (last visited Feb. 24, 2022) [hereinafter THE SOURCE] (explaining how North Carolina has historically opposed MFN clauses and has been the site of several cases challenging provider non-compete agreements, that the NC attorney general has actively enforced oversight of healthcare mergers, and that the state is a "national leader" in value-based payment reforms).
[119] *See id.*; *see also Atrium Health Agrees to Settle Antitrust Lawsuit and Eliminate Anticompetitive Setting Restrictions*, U.S. DEPT. OF JUST. (Nov. 15, 2018), https://www.justice.gov/opa/pr/atrium-health-agrees-settle-antitrust-lawsuit-and-eliminate-anticompetitive-steering.
[120] *See* THE SOURCE, *supra* note 118 (citing *Aesthetic Facial & Ocular Plastic Surgery Ctr., P.A. v. Zaldivar*, 826 S.E.2d 723 (N.C. Ct. App. Mar. 19, 2019) and *Calhoun v. WHA Med. Clinic, PLLC*, 644 S.E.2d 5 (N.C. Mar. 8, 2007)).
[121] *See id.*
[122] *See id.*
[123] *See* discussion *infra* Part V(B).
[124] *See infra* Table 1.

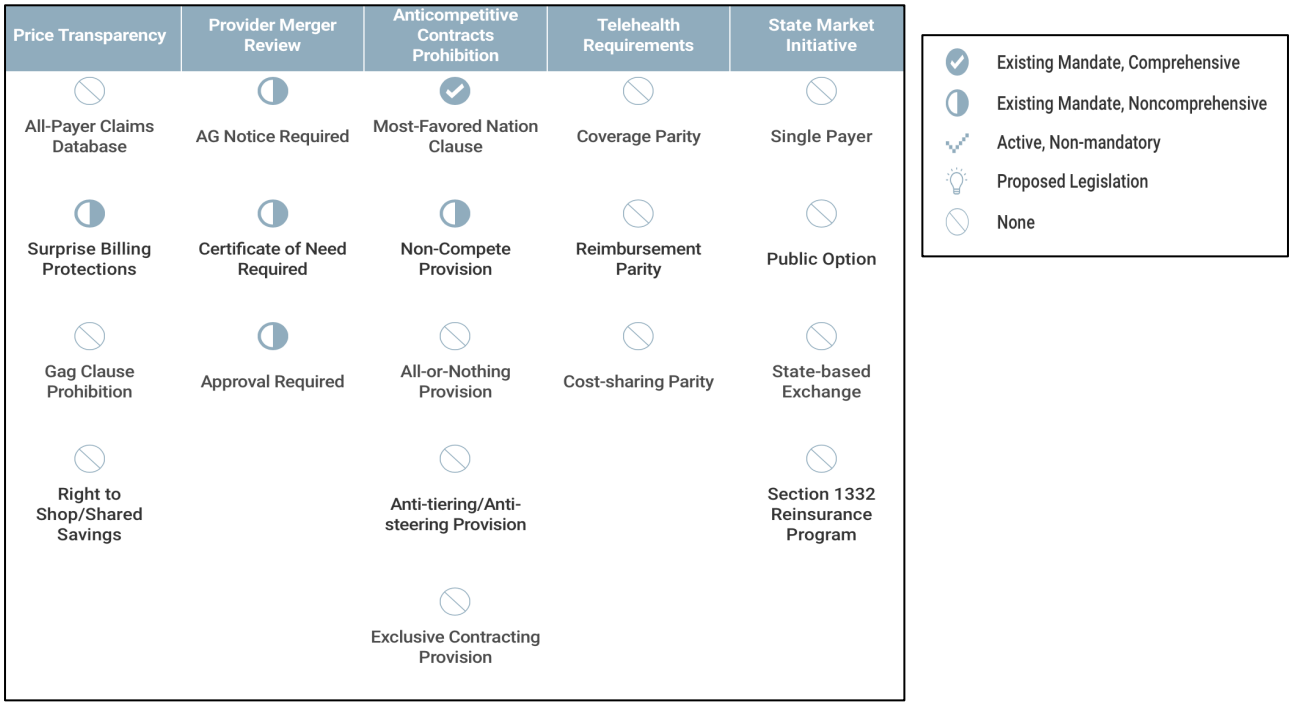
prohibitions.[125] Despite North Carolina's experience with healthcare market reform, there is still substantial progress to be made.

Table 1: Existing Legislation on Healthcare Market Regulation in North Carolina[126]

Price Transparency	Provider Merger Review	Anticompetitive Contracts Prohibition
Surprise Billing Protections N.C. Gen. Stat. § 58-3-190 N.C. Gen. Stat. § 58-3-250	**AG Notice Required, Nonprofit Only** N.C. Gen. Stat. § 55A-11-02 N.C. Gen. Stat. § 131E-184 **Certificate of Need Required, Nonprofit Only** N.C. Gen. Stat. § 131E-184 **Approval Required, Nonprofit Only** N.C. Gen. Stat. § 55A-11-02 N.C. Gen. Stat. § 131E-184	**Most-Favored Nation Clause** N.C. Gen. Stat. § 58-50-295 **Non-Compete Provision** N.C. Gen. Stat. § 75-1

[125] *See* THE SOURCE, *supra* note 118.
[126] *See id.*

Table 2: Existing Price Transparency and Healthcare Market Regulation in North Carolina[127]



A. *Davis v. HCA Healthcare* and the Potential Challenges to Obtaining the Rule's Objective

A North Carolina plaintiff alleged that Mission Hospital and HCA Healthcare used their monopoly power to charge supracompetitive prices.[128] The complaint alleged that anti-competitive tactics such as "tying arrangements[,] all-or-nothing arrangements, gag clauses,. . . non-participating provider rate clauses[,] and anti-tiering or anti-steering arrangements" are "designed to

[127] *See id.*
[128] *See* Katherine L. Gudiksen, et al., *Mitigating the Price Impacts of Health Care Provider Consolidation*, MILBANK MEM'L FUND 1, 6 (Sept. 23, 2021), https://www.milbank.org/wp-content/uploads/2021/09/Mitigating-the-Price-Impacts-of-Health-Care-Provider-Consolidation_2.pdf.

suppress competition and transparency in the market for the sale of acute hospital services and increase the prices [hospitals] can charge [a] commercial health plan."[129] The complaint is a harbinger of the potential legal clashes with the Rule. Even if hospitals comply with the Rule in its entirety, there remain significant hurdles to achieving a fair and accurately priced healthcare market. Below are potential challenges to the Rule's goals.

i. Non-Disclosure Agreements

Non-disclosure agreements ("NDAs"), often in contracts between private insurers and health care providers, require negotiated rates to remain confidential and deny rate disclosures to third parties, including the government.[130] The concern surrounding non-disclosure agreements appeared in the notice-and-comment phase of the Rule.[131] The commenters responded that obscuring negotiated price information perserves the dominant systems' power to hike prices and maintain their molopoly as insurers aare unable to avoid paying inflated rates to other providers and noted that traditionally there are exceptions to

[129] *See* Complaint at 35, *Davis v. HCA Healthcare, Inc.*, No. 21-CV-03276 (N.C. Super. Ct., 2021); *see also Davis v. HCA Healthcare, Inc.*, 2022 NCBC 52, 2022 WL 4354142 (N.C. Sept. 19, 2022) (granting in part and denying in part the defendant's motion to dismiss).
[130] *See An Analysis of Popular Legal Arguments Against Price Transparency*, CATALYZE: 2015 REP. CARD ON STATE PRICE TRANSPARENCY L. 1, 1 (2015), https://www.catalyze.org/wp-content/uploads/woocommerce_uploads/2017/04/Legal-Brief-on-Price-Transparency.pdf [hereinafter *Popular Legal Arguments Against Price Transparency*] (explaining that non-disclosure agreements are also known as "gag clauses").
[131] *See Price Transparency Requirements*, 84 Fed, Reg. 65,524-01, 65,544 (Nov. 27, 2019) (to be codified at 45 C.F.R. subchapter E).

contract provisions that prohibit publication of its terms, where disclosure is required by Federal law.[132]

Congress enacted the Consolidated Appropriations Act in 2021 to "prohibit[], subject to privacy rules and other limitations, health insurance plans from entering into agreements with health care providers that restrict the plans from accessing and sharing cost or quality information or anonymous claims information."[133] However, the U.S. Departments of Health and Human Services, Labor, and Treasury will not issue regulations to implement the Consolidated Appropriations Act because the law is supposedly "self-implementing."[134] Given that the bill recently became effective on January 1, 2022,[135] it is currently unclear whether this issue will be adjudicated.

ii. Anti-Tiering and Anti-Steering Clauses

Anti-tiering and anti-steering clauses between providers and insurers, also known as "anti-incentive clauses," are the second challenge that the Rule should address.[136] Anti-tiering clauses require that the insurer place the provider in a

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[132] *Id.*
[133] Consolidated Appropriations Act, 2021, Pub. L. No. 116-60, 134 Stat. 1182.
[134] *See* Katie Keith, *New Guidance on Transparency Requirements, Advances Explanations of Benefits, and More*, HEALTHAFFAIRS (Aug. 25, 2021), https://www.healthaffairs.org/do/10.1377/forefront.20210825.604994/full/.
[135] *See* Jennifer Austin, *2022 Employer Health Plan Requirements from the Consolidated Appropriations Act*, THE ALLIANCE (Nov. 2, 2021), https://the-alliance.org/2022-employer-health-plan-requirements-from-the-consolidated-appropriations-act/ (last updated Feb. 11, 2022).
[136] *See* Amy Y. Gu, *[Case Brief] Atrium Health Settlement Encourages Enforcement of Anti-tiering/ Anti-steering Clauses in Healthcare Contracts*, THE SOURCE ON HEALTHCARE PRICE & COMPETITION: THE SOURCE BLOG (Nov. 16, 2020), https://sourceonhealthcare.org/case-brief-

favorable tier in a tiered insurance plan.[137] Anti-steering clauses require that insurers agree not to "steer" patients to other healthcare systems.[138] These clauses hinder patients' ability to properly compare and "choose providers based on cost and quality" because they conceal material information.[139]

iii. Most-Favored-Nation Clauses

A most-favored-nation ("MFN") clause promises an insurer that the healthcare provider will not give a more favorable price for the same service to the insurer's competitors.[140] MFN clauses generally arise when an insurer seeks to secure a "dominant provider organization" and pays them an above-market price in exchange for an exclusive relationship.[141] As discussed, healthcare systems are becoming more consolidated, likely increasing the bargaining power of dominant providers and prices.[142] With MFN clauses in effect, insurers have no incentive to negotiate lower prices.[143] These clauses interfere with traditional economic theory; even if prices are disclosed, MFNs will continue to drive prices

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atrium-health-settlement-encourages-enforcement-of-anti-tiering-anti-steering-clauses-in-healthcare-contracts/.

[137] *See Anti-Tiering or Anti-Steering Definition*, L. INSIDER, https://www.lawinsider.com/dictionary/anti-tiering-or-anti-steering (last visited Feb. 10, 2022); *see also* Gudiksen, *supra* note 128, at 3, 5 (Sept. 23, 2021), https://www.milbank.org/wp-content/uploads/2021/09/Mitigating-the-Price-Impacts-of-Health-Care-Provider-Consolidation_2.pdf.

[138] *See Anti-Tiering or Anti-Steering Definition*, *supra* note 137.

[139] *See Popular Legal Arguments Against Price Transparency supra* note 130, at 2.

[140] *See* Gudiksen, *supra* note 128.

[141] *See Popular Legal Arguments Against Price Transparency*, *supra* note 130, at 2.

[142] *See* Gudiksen, *supra* note 128, at 6.

[143] *See id.* at 5.

higher without the traditional offset of demand.[144]

iv. All-or-Nothing Clauses

"All-or-nothing" clauses force insurers to contract with every hospital in a hospital system, irrespective of price or quality.[145] Thus, large hospital systems such as Atrium—which has forty hospitals and over 1,400 care locations[146]—have extreme bargaining power and leverage to force contracts. Further, it follows that business-motivated and anti-patient policies persist more easily in mammoth healthcare systems. One of the few potential upsides of the extensive intertwining of enormous healthcare systems and insurance companies is healthcare systems' ability to implement widespread change by merely setting a company policy.

B. Implications of *HCA Healthcare v. Davis*

Failure to abide by the Rule coupled with manipulating the system to charge supracompetitive prices may constitute unfair or deceptive trade practices under N.C. Gen. Stat. § 75-1.1(a).[147] This provision states that "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are declared unlawful."[148] Furthermore, N.C. Gen. Stat. § 75-2.1 states that "[i]t is unlawful for any person to monopolize, or attempt

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[144] *See, e.g.*, *Popular Legal Arguments Against Price Transparency*, *supra* note 130, at 2.
[145] *See* Collier & Domen, *supra* note 108.
[146] *See About Atrium Health*, ATRIUM HEALTH, https://atriumhealth.org/about-us (last visited Feb. 10, 2022).
[147] *See, e.g.*, Complaint at 35, *Davis v. HCA Healthcare, Inc.*, No. 21-CV-03276 (N.C. 2021).
[148] N.C. Gen. Stat. § 75-1.1(a) (1977).

to monopolize, or combine or conspire with any other person or persons to monopolize, any part of trade or commerce in the State of North Carolina."[149]

The HCA Healthcare system arguably violated both N.C. Gen. Stat. § 75-1.1(a) and N.C. Gen. Stat. § 75-2.1 by implementing the price-hiking strategies and through its initial "unambiguous[] noncompliance" with the Rule.[150] If courts were to view the system's manipulative price hiking and efforts to keep prices concealed as "unfair or deceptive acts or practices,"[151] hospitals would likely be responsible for the Rule's civil penalty *and* for damages incurred through litigation by patients, likely via class actions.[152]

V. Existing Efforts to Achieve Healthcare Market Fairness in Addition to Price Transparency

A. Investigating Mergers and Post-Merger Conduct

In July 2021, President Biden condemned the upward trend of hospital consolidation and stated that its consequences include inadequate options for "convenient and affordable healthcare" in communities, especially rural communities.[153] In an Executive Order, the President emphasized the harm that

[149] N.C. Gen. Stat. § 75-2.1 (1977).
[150] *See, e.g.*, Jill McKeon, *94% of Hospitals Noncompliant with Hospital Price Transparency Rule*, REV CYCLE INTEL. (July 21, 2021), https://revcycleintelligence.com/news/94-of-hospitals-noncompliant-with-hospital-price-transparency-rule; Henderson & Mouslin, *supra* note 59.
[151] *See* N.C. Gen. Stat. § 75-1.1(a) (21977).
[152] *See, e.g.*, Complaint, *Davis v. HCA Healthcare, Inc.*, No. 21-CV-03276 (N.C. Super. Ct. 2021).
[153] *See* FACT SHEET: Executive Order Promoting Competition in the American Economy, THE WHITE HOUSE (July 9, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/.

hospital mergers have on patients and communities and encouraged the Justice Department and the Federal Trade Commission to review and revise merger guidelines.[154] The Order specifically requested a focus on "healthcare markets" as a "key market" in desperate need of monitoring, analysis, and reform.[155] Notably, merger guidelines are highly persuasive and often relied upon by courts, but they are not ultimately binding; the legality of a merger is determined solely by the court system.[156] This reliance on the merger guidelines emphasizes the importance of reform.

The Federal Trade Commission ("FTC") should review and reform the horizontal and vertical merger guidelines.[157] To achieve this goal, adequate resources should be allocated to the DOJ and the FTC to enforce current guidelines and proactively develop further restrictions on monopolization.[158] In 2020, the FTC and the DOJ issued new Vertical Merger Guidelines; these guidelines were rescinded in September 2021.[159] In January 2022, the FTC and

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[154] *See id.*
[155] *See id.*
[156] *See FTC Rescinds Vertical Guidelines, Introducing Opacity into Merger Review*, PAUL WEISS (Sept. 15, 2021), https://www.paulweiss.com/practices/litigation/antitrust/publications/ftc-rescinds-vertical-guidelines-introducing-opacity-into-merger-review?id=40984.
[157] *See* Exec. Order No. 14036 (July 9, 2021).
[158] *See* Martin Gaynor, *Antitrust Applied: Hospital Consolidation Concerns and Solutions: Statement Before the Judiciary Subcommittee On Competition Policy, Antitrust, and Consumer Rights,* at 3, (May 19, 2021), https://www.judiciary.senate.gov/imo/media/doc/Gaynor_Senate_Judiciary_Hospital_Consolidation_May_19_2021.pdf
[159] *See FTC Rescinds Vertical Guidelines, Introducing Opacity into Merger Review*, PAUL WEISS (Sept. 15, 2021), https://www.paulweiss.com/practices/litigation/antitrust/publications/ftc-rescinds-vertical-guidelines-introducing-opacity-into-merger-review?id=40984.

the DOJ's Antitrust Division announced they would be seeking public input on "ways to modernize federal merger guidelines to better detect and prevent illegal, anticompetitive deals in today's modern markets."[160]

The new guidelines should reflect the skeptical views towards mergers as economic theory solidly confirms the negative effects that healthcare mergers have on both patients and the healthcare economy.[161] Guidelines to restrict the monopolization of the healthcare market are imperative to maintain competition, drive prices down to economically appropriate prices, and drive quality up to a competitive standard of care.

B. All-Payer Claims Databases

All-payer claims databases ("APCDs") are large state databases that "systematically" collect medical, pharmaceutical, and dental claims in addition to eligibility and provider files from both private and public payers.[162] Most APCDs receive data from state-mandated reporting initiatives.[163] According to the APCD Council, states with APCDs are better equipped to assess the effect of reform

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[160] Press Release, Federal Trade Commission, Federal Trade Commission and Justice Department Seek to Strengthen Enforcement Against Illegal Mergers (Jan. 18, 2022), https://www.ftc.gov/news-events/press-releases/2022/01/ftc-and-justice-department-seek-to-strengthen-enforcement-against-illegal-mergers.
[161] *See, e.g.*, THE WHITE HOUSE, *supra* note 153; *see also* PAULWEISS, *supra* note 156 (providing critical analysis of vertical mergers and their impact on competition).
[162] *See* Jo Porter et al., *The Basics of All-Payer Claims Databases*, STATE HEALTH AND VALUE STRATEGIES 1, 2 (Jan. 2014), http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2014/rwjf409988.
[162] *Id.* at 2.
[163] *See id.*

efforts and the impact on the "health of and health care provided to their citizens."[164]

APCDs are more comprehensive than the existing price transparency rule because they often include information about the service provider, prescribing physician, health plan payments, member payment responsibility, type and date of the bill paid, facility type, and patient demographics, among many other things.[165] Unlike the Rule's requirement that hospitals report price data, APCDs require insurance carriers, third-party administrators, CMS, and other payers to report data.[166] Thus, an APCD requirement would work in tandem with the current Rule to fill gaps and supplement the public's perception of prices.

An APCD requirement would also give policymakers a clearer understanding of the U.S. healthcare system's economic status to enable policymakers to implement realistic standards for healthcare pricing reform.[167] The data acquired from APCDs "can be used to evaluate the functioning of markets, identify opportunities for state-based policy interventions, identify

[164] *See id.*
[165] *See id.*
[166] *Compare id. with* 45 C.F.R. § 180.90 (2019).
[167] *See* Porter et al., *supra* note 162, at 6 (asserting that APCD can inform governors and legislatures of the distribution of spending between commercially and publically insured patients).

payment disparities that result from market power, and garner public support for policymakers seeking to intervene in state health care markets."[168]

Eighteen states have implemented legislation mandating APCD reporting.[169] North Carolina is labeled as a state with a "strong interest" in ACPD reporting on the APCD website, despite its failure to enact or propose legislation.[170] North Carolina is categorized as having a strong interest because it implemented a task force that is run by the North Carolina Institute of Medicine ("NCIOM").[171] The task force convened five times between 2016 and 2017, made a series of recommendations in a single report, and then effectively disappeared.[172] Thus, to further the goals of price transparency and efficient healthcare markets in North Carolina, legislation should be enacted to mandate APCD reporting and the NCIOM recommendations.[173]

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[168] Robert A. Berenson et al., *Addressing Health Care Market Consolidation and High Prices*, URB. INST. 11 (Jan. 2020), https://www.urban.org/sites/default/files/publication/101508/addressing_health_care_market_consolidation_and_high_prices_1.pdf.

[169] *See Interactive State Report Map*, ACPD COUNCIL, https://www.apcdcouncil.org/state/map (last visited Nov. 12, 2022) (WA, OR, UT, CO, KA, AK, MN, FL, VA, MD, DE, NY, CT, RI, MA, VT, NH, ME); *see also, e.g.*, *ACPD Legislation by State*, ACPD COUNCIL, https://www.apcdcouncil.org/apcd-legislation-state (last visited Feb 24, 2022) (non-exhaustive list of ACPD legislation examples).

[170] *Id.*

[171] *See North Carolina*, ACPD COUNCIL, https://www.apcdcouncil.org/state/north-carolina (last visited Feb. 24, 2022).

[172] *See Task Force on All-Payer Claims Database*, NCIOM, https://nciom.org/task-force-on-all-payer-claims-database/ (last visited Nov. 15, 2022) (listing five meeting dates and linking the single report on ACPD).

[173] *See Claims Data to Improve Health in North Carolina: A Report from the NCIOM Task Force on All-Payer Claims Database*, NCIOM, 29 (Apr. 2017), https://nciom.org/wp-content/uploads/2018/02/FULL-REPORT-COMPRESSED.pdf (detailing the recommendations of NCIOM, including establishing an APCD to collect all claims data).

The United States Supreme Court dealt a crippling blow to APCDs in the 2016 case *Gobeille v. Liberty Mutual Insurance Company*.[174] The 6-2 opinion authored by Justice Kennedy held that APCD reporting requirements for self-funded employee health plans are invalidated by the Employee Retirement Income Security Act ("ERISA").[175] The Court stated that because APCD requirements interfere with ERISA's aim to provide a "single uniform national scheme for the administration of ERISA plans without interference from laws of the several States even when those laws, to a large extent, impose parallel requirements."[176] However, the challenge is that ERISA reporting and recordkeeping primarily focuses on "retirement benefits plans and their solvency, not employee health plans and their claims," leaving gaps in ERISA that APCDs would fill.[177] Despite the Supreme Court's negative treatment of APCDs, the importance of supplying healthcare information to the American public should not be discounted. Perhaps ERISA would benefit from APCD elements reflected in a revised act.[178]

C. Expand FTC Authority

The FTC enforces consumer protection and antitrust laws and identifies

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[174] *See Gobeille v. Liberty Mut. Ins. Co*., 577 U.S. 312, 326 (2016).
[175] *See id.* at 317, 326-27.
[176] *See id.* at 326-27.
[177] *See* Erin C. Fuse Brown & Jamie S. King, *The Consequences of* Gobeille v. Liberty Mutual *for Health Care Cost Control*, HEALTHAFFAIRS (Mar. 10, 2016), https://www.healthaffairs.org/do/10.1377/forefront.20160310.053837/full/.
[178] *See id.*

"deceptive and unfair practices in the marketplace."[179] The agency is thus well prepared to identify and reprimand unfair and deceptive practices in the healthcare industry, especially related to pricing and price transparency.[180] However, more support and authority should be granted to the FTC in order to tackle mammoth acquisitions and bad faith noncompliance with the new regulations.[181]

The FTC is acutely aware of the significant increase in the healthcare industry's mammoth mergers and has dedicated numerous resources toward addressing them.[182] From 2016 to 2020, nearly 50% of all FTC enforcement actions were within the healthcare sector.[183] In July 2021, the FTC announced that one of its priority targets is healthcare businesses.[184] The FTC expanded its authority in this arena in two ways.[185] First, "priority targets" are subject to a

[179] *See* Adam Hayes, *Federal Trade Commission (FTC)*, INVESTOPEDIA, https://www.investopedia.com/terms/f/ftc.asp (last updated July 16, 2021).
[180] *See id.*
[181] *See* Collier & Domen, *supra* note 108; *see, e.g.*, Joe Simmons, Chairman of the FTC, *Oversight of the Enforcement of the Antitrust Laws: Hearing Before the U.S. Senate Committee on the Judiciary: Subcommittee On Antitrust, Competition Policy and Consumer Rights*, 3, 6 (Sept. 17, 2019), https://www.ftc.gov/system/files/documents/public_statements/1544480/senate_september_competition_oversight_testimony.pdf (showing that the FTC handles large mergers and non-compliance).
[182] *See id.* (stating that the FTC spent $15.84 million in fiscal year 2018 on expert fees in competition cases, compared to $4.84 million in fiscal year 2014).
[183] *See Stats & Data 2020*, FTC, https://www.ftc.gov/reports/annual-highlights-2020/stats-data-2020 (last visited Feb. 25, 2022).
[184] *See* Press Release, Federal Trade Commission, FTC Authorizes Investigations into Key Enforcement Priorities (July 1, 2021), https://www.ftc.gov/news-events/press-releases/2021/07/ftc-authorizes-investigations-key-enforcement-priorities (including pharmaceutical companies, pharmacy benefit managers, hospitals, and the like).
[185] *See id.*

"compulsory process" such as subpoenas and civil investigative demands that require any commissioner to approve and initiate an investigation rather than requiring approval from the entire commission.[186] Second, the FTC modified the existing rulemaking procedures to target "unfair methods of competition," giving the Commission control over the rulemaking process instead of an administrative law judge.[187]

These procedural shifts in the FTC's operation will likely promote efficiency and the FTC's ability to achieve its goals without procedural impediments.[188] But with the rescission of the 2020 Vertical Merger Guidelines and the call for a review of the 2010 Horizontal Merger Guidelines, the FTC needs more resources and staff to undertake this massive overhaul[189]—reform that will likely change the U.S. economy at its most fundamental level.

Furthermore, some legal scholars have argued that in addition to merger guideline reform, the FTC should also lower the reporting threshold under the Hart-Scott-Rodino (HSR) Act.[190] The HSR Act requires that entities provide the

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[186] *See id.*
[187] *See* Kenneth M. Vorrasi et al., *A Reinvigorated FTC: Key Updates on Antitrust Enforcement in the Health Care Sector*, FAEGRE DRINKER (July 13, 2021), https://www.faegredrinker.com/en/insights/publications/2021/7/a-reinvigorated-ftc-key-updates-on-antitrust-enforcement-in-the-health-care-sector.
[188] *See id.*
[189] *See id.* (asserting that the FTC could seek to lower the HSR Act's reporting thresholds to capture more transactions because filing is only required for transactions valued at $92 million or more); *see also* Press Release, Department of Justice, Office of Public Affairs, Justice Department Issues Statement on the Vertical Merger Guidelines (Sept. 15, 2021), https://www.justice.gov/opa/pr/justice-department-issues-statement-vertical-merger-guidelines.
[190] *See* Vorrasi, *supra* note 187.

FTC and the DOJ Antitrust Division with advance notice of large mergers and acquisitions.[191] The FTC and the DOJ then determine whether the transaction will adversely affect U.S. commerce under antitrust laws.[192] In addition to requiring a substantial fees and imposing a thirty-day waiting period before closing, the notice provides the FTC an opportunity to issue a Request for Additional Information and Documentary Materials, also known as a "Secondary Request."[193] This Secondary Request provides the FTC an opportunity to investigate a merger before it is finalized.[194] Ultimately, increasing the FTC's discretion and jurisdiction over mergers would allow the FTC to employ stricter scrutiny of hospital consolidation, increase competition, and decrease healthcare costs.

D. Proposals to Directly Regulate Prices in Concentrated Provider Markets

Some proposals to Congress suggest that measures of market structure, such as the Herfindahl-Hirshman Index (HHI)[195] or provider market shares,

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[191] *See* Robert M. Buchanan, Jr. & Sue Kim, *2021 Hart-Scott-Rodino Requirements*, CHOATE: INSIGHTS (Feb. 4, 2021) https://www.choate.com/insights/2021-hart-scott-rodino-requirements.html.
[192] *See The Enforcers*, FED. TRADE COMM'N, https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws/enforcers (last visited Dec. 19, 2022).
[193] *See id.*; *see also Not So Fast: New FTC Guidance Means More Hospital Mergers Will Require HSR Filings Before Closing*, CROWELL (Nov. 1, 2018), https://www.crowell.com/NewsEvents/AlertsNewsletters/all/Not-So-Fast-New-FTC-Guidance-Means-More-Hospital-Mergers-Will-Require-HSR-Filings-Before-Closing.
[194] *See id.*
[195] *See supra* text accompanying notes 20–24.

should be an indicating factor for when regulation should be imposed.[196] Some argue that hospitals in markets where HHI exceeds 4,000 should be required to either negotiate with the FTC to lower their HHI score or cap prices at a percentage of Medicare Advantage rates.[197] The Hospital Competition Act (H.R. 506) and the Fair Care Act of 2019 (H.R. 1332) would require hospitals with market shares at or exceeding 15% in markets with HHI scores above 4,000 in urban areas and 5,000 in rural areas to accept reimbursement from commercial payers at Medicare rates.[198] As hospital mergers and acquisitions become more pervasive, consolidations in markets with high HHI scores should be highly scrutinized to avoid the negative effects of monopolistic hospital systems.

VI. Conclusion

The U.S.—and its ailing healthcare system—is facing an incredible paradigm shift. However, if the system structure buckles under the pressure of hospital mega-mergers, the system will likely fall into irreparable disrepair.

The initial noncompliance with the Price Transparency Rule demonstrates the power that the healthcare sector holds in the U.S. The inability of legislation to have immediate effects despite public outcry and governmental condemnation

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[196] *See* Maximillian J. Pany et al., *Regulating Hospital Prices Based on Market Consolidation is Likely to Leave High-Price Hospitals Unaffected*, HEALTHAFFAIRS 1386, 1387 (Sept. 13, 2021), https://www.hbs.edu/ris/Publication%20Files/Pany%20Dafny%20Chernew%20-%20Regulating%20Prices_6b075d6d-7b48-4535-befe-d94a2fd39c9b.pdf.
[197] *See id.* at 1387.
[198] *See id.*

of the anti-competitive healthcare market should concern Americans.

Mass compliance with the Rule and other legal efforts will have substantial positive effects on the healthcare market, patient satisfaction, efficiency, and quality of care—*if* hospitals readily comply. For the legislature to be most effective, the system must change. As discussed, lawmakers should be flexible and willing to adjust their current methods, laws and regulations should be updated, and enforcement must increase. As our most relied-upon industries expand and consolidate, they should become more efficient and accessible—not the opposite.