

NOTE
A MODEST PROPOSAL:
LEVERAGING PRIVATE
ENFORCEMENT MECHANISMS AND
THE BAYH-DOLE ACT TO REDUCE
DRUG PRICES IN THE U.S.
HEALTHCARE INDUSTRY

BRITTANY N. DAY*

INTRODUCTION

In 2017, Alec Smith, a Type 1 diabetic, aged out of his mother's health insurance plan when he turned twenty-six.¹ He was dead a month later, likely because he was attempting to ration his insulin until he could afford to buy more at his next payday.² Alec had a job as a restaurant manager, but even with his salary of \$35,000, he still could not afford his insulin, which would have cost him \$1,300 per month.³ Unfortunately, his salary was too high to qualify for Medicaid assistance or other similar subsidies, but too low to be able to afford health insurance without a prohibitively high deductible.⁴ Not all stories involving high insulin prices involve deadly consequences, but the impacts can be severe. Laura Marston, a thirty-six-year-old woman with Type 1 diabetes, lost her job at a law firm.⁵ Without health

Copyright © 2022 Brittany N. Day

* J.D., Duke University School of Law, 2022; A.B., Duke University, 2019. I am grateful to my professor, Arti Rai, for her guidance on this piece. I would also like to thank the *Duke Journal of Constitutional Law and Public Policy* editorial staff for their diligence and hard work. This Note is dedicated to my parents, Anne and Paul Day.

1. Bram Sable-Smith, *Insulin's High Cost Leads to Lethal Rationing*, NPR (Sept. 1, 2018, 8:35 AM), <https://www.npr.org/sections/health-shots/2018/09/01/641615877/insulins-high-cost-leads-to-lethal-rationing>.

2. *Id.*

3. *Id.*

4. *Id.*

5. Ritu Prasad, *The Human Cost of Insulin in America*, BBC NEWS (Mar. 14, 2019),

insurance, she was spending \$2,880 per month on insulin.⁶ In order to move to Washington, D.C. to find a new job to afford her insulin, she had to sell most of her possessions and give up her dog.⁷

These stories are not uncommon for diabetics in the United States who need to buy insulin monthly to survive. Insulin controls blood sugar levels, and an insulin imbalance can have deadly consequences. The discoverers of insulin recognized the importance of the hormone and its life-saving potential, selling the patent for one dollar in 1923 so everyone could benefit from it.⁸ But their vision for the drug has not materialized; instead, insulin costs an average of \$300 per vial.⁹

The federal government has recognized that changes in market prices for drugs can have dire consequences. Insulin is not the only drug with prohibitive prices in recent years.¹⁰ Unlike other patented products, when drug prices skyrocket—due to the monopoly power of patents or otherwise—people may die. While advocating for various solutions, both the Biden and Trump administrations have recognized the importance of halting the rise of prescription drug prices.¹¹ Most of the solutions advanced are focused on government-side initiatives, such as allowing Medicare to directly negotiate with pharmaceutical companies.¹² Yet, the march-in rights built into the Bayh-Dole Act¹³ create an opportunity to set up a mechanism that would invite private actors to sue pharmaceutical companies for unconscionable drug pricing.¹⁴

<https://www.bbc.com/news/world-us-canada-47491964>.

6. *Id.*

7. *Id.*

8. *Id.*

9. *Id.*

10. See generally U.S. GOV'T ACCOUNTABILITY OFF., GAO-21-281, PRESCRIPTION DRUGS: U.S. PRICES FOR SELECTED BRAND DRUGS WERE HIGHER ON AVERAGE THAN PRICES IN AUSTRALIA, CANADA, AND FRANCE (2021).

11. See *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, U.S. DEP'T OF HEALTH AND HUM. SERVS., 3 (May 2018), <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf> (“One of my greatest priorities is to reduce the price of prescription drugs.”) [hereinafter *Trump Administration Blueprint*]; *Healthcare*, BIDEN HARRIS DEMOCRATS, <https://joebiden.com/healthcare/> (last visited May 7, 2021) (listing multiple reforms to reduce the power of drug companies to abusively price drugs) [hereinafter *Biden Harris Reforms*].

12. See *Trump Administration Blueprint*, *supra* note 11, at 10 (proposing Medicare reform to give plan sponsors the ability to negotiate with manufacturers); *Biden Harris Reforms*, *supra* note 11 (proposing ending regulations that permit drug corporations to avoid negotiating with government healthcare plans).

13. Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200–211).

14. 35 U.S.C. § 203 (2018) (giving the government the ability to require the licensee who

The United States has a penchant for private litigation.¹⁵ Unlike Europe, which largely regulates ex ante through centralized bureaucracies, the United States tends to rely on ex post law enforcement through private litigation.¹⁶ Although private enforcement can be ad hoc and uneven, it provides an avenue for redress when regulation has failed and gives the party with the informational advantage control over litigation.¹⁷ The United States has tried to create a robust system of ex ante regulation in the form of the Food and Drug Administration, but there are several regimes of private enforcement that work to capture inefficiencies in the health industry.

As described in detail in this Note, Congress has invited private parties into the courts to regulate various aspects of the healthcare industry through Paragraph IV litigation from the Hatch-Waxman Act, qui tam litigation aimed at Medicare and Medicaid fraud, and antitrust litigation. Taken together, these private enforcement mechanisms work to moderate drug prices, reduce fraud in healthcare billing, and ensure a healthy, competitive pharmaceutical market. Although each of these mechanisms has weaknesses, they operate to regulate a field where blanket regulation from a federal agency may not be workable or efficient. In doing so, the interests of private parties are brought closer to that of the government, effectively harnessing “selfish” private actors for the public good.

A similar mechanism of private enforcement should be implemented to control the prohibitive drug pricing in the United States. The Bayh-Dole Act includes a provision that reserves march-in rights to federal agencies if the companies that obtain patents funded by federal research do not meet certain criteria.¹⁸ Although these march-in rights have never been exercised,¹⁹ they provide an already existing statutory mechanism to control runaway drug prices. One of the weaknesses of the current march-in rights is uncertainty over the

acquired title under the Act to grant a license to a “responsible applicant,” and if refused, to grant the license itself based upon a specified set of criteria).

15. See 3 William Blackstone, Commentaries *161 (noting that the “common informer” advances the public interest).

16. Maria Glover, *The Structural Role of Private Enforcement Mechanisms in Public Law*, 53 WM. & MARY L. REV. 1137, 1140 (2012).

17. *Id.* at 1155–56.

18. 35 U.S.C. § 203.

19. JOHN R. THOMAS, CONG. RSCH. SERV., R44597, MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT 8 (2016).

criteria for exercising them.²⁰ Congress should amend the Bayh-Dole Act to clarify the criteria for the march-in rights by listing factors to define when drug prices are unreasonable or unconscionable. Congress should additionally let qui tam relators bring suits to obtain licenses to manufacture and sell drugs at a lower price should a court find the newly set-out criteria have been violated.

By allowing a private party to initiate and carry out the litigation, the private interests of the qui tam relator can be brought into alignment with the public good. When a manufacturer has a monopoly on a brand name drug, other companies have an interest in breaking that monopoly and obtaining some of the market by offering the drug at a lower price. Offering the lower-priced alternative also serves the public good. Furthermore, downstream effects triggered by the initiation of the march-in rights litigation would cause companies to consider the factors laid out in the legislation when setting drug prices in the future. Eventually, drug prices could drop to more reasonable levels to avoid unnecessary and potentially costly litigation.

Part I of this Note explores recent drug price increases and offers some of the reasons behind them. Part II will provide a history of private enforcement in the United States, as well as a closer look at the three private enforcement mechanisms that create a system of ex post regulation for the healthcare industry. Part III will summarize the history and congressional intent behind the Bayh-Dole Act. Part IV will lay out the proposed private enforcement mechanisms in relation to the Bayh-Dole Act march-in rights, taking into account the failures and weaknesses of the current private enforcement mechanisms.

I. AN OVERVIEW OF U.S. HEALTHCARE PRICING

The United States healthcare system is one of the most expensive in the world. In 2009, the U.S. spent a total of \$2.47 trillion on health expenditures.²¹ Prescription drugs specifically are the fastest growing portion of national health expenditures, increasing “from 5.8 percent in 1993 to 10.7 percent in 2003.”²² The increasing prices of brand name

20. See NAT'L INST. OF STANDARDS AND TECH., U.S. DEP'T OF COM., SPECIAL PUB. NO. 1234, RETURN ON INVESTMENT INITIATIVE TO ADVANCE THE PRESIDENT'S MANAGEMENT AGENDA: FINAL GREEN PAPER 32 (2019), <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf> (finding stakeholder uncertainty as to the scope of march-in rights leads to market uncertainty).

21. D. Christopher Ohly & Sailesh K. Patel, *The Hatch-Waxman Act: Prescriptions for Innovative and Inexpensive Medicines*, 19 U. BALT. INTELL. PROP. L.J. 107, 121 (2011).

22. *Id.*

drugs, more so than generics, drain the bank accounts of everyday Americans, as generic drugs cost on average about half that of brand name drugs.²³ While brand name drug prices increased by 28.9 percent in a five-year period, generic drug prices only increased, on average, by 9.4 percent during that time.²⁴

Brand name drugs have rapidly increased in price, and inflation cannot fully explain the pace. A report found that the list prices of 600 brand name drugs rose by a median of 21.4 percent between January 2018 and June 2020.²⁵ Another study found that from 2005 to 2017, the 318 most widely used drug products in the AARP combined market basket increased in price by 203.4 percent.²⁶ Although inflation may be the cause for some of the price increases, many drug price increases outpaced inflation from 2006 to 2017.²⁷ Between July 2018 and July 2019, 50 percent of drugs covered by Medicare Part D had price increases that outpaced inflation.²⁸ Furthermore, for the drugs accounting for the most Part D spending in 2019, twenty-two of the twenty-five drugs had prices that increased faster than inflation, between a 3 percent and 19.7 percent increase compared with an inflation rate of 1.8 percent.²⁹

Chairman Elijah Cummings of the House Oversight Committee launched an investigation into the high costs of prescription medication, which resulted in a series of reports in late 2020 focusing on a few drugs with astronomical prices.³⁰ The reports collectively paint

23. *Id.* at 122.

24. *Id.*

25. STAFF OF H. COMM. ON OVERSIGHT AND REFORM, 116TH CONG., DRUG PRICING INVESTIGATION: CELGENE AND BRISTOL MYERS SQUIBB—REVLIMID 38 (2020), <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Celgene%20BMS%20Staff%20Report%2009-30-2020.pdf> (citing STATE OF CALIFORNIA, OFFICE OF STATEWIDE HEALTH PLANNING AND DEVELOPMENT, *Prescription Drug Wholesale Acquisition Cost (WAC) Increases* (Aug. 17, 2020), oshpd.ca.gov/visualizations/prescriptiondrug-wholesale-acquisition-cost-increases/).

26. Stephen W. Schondelmeyer & Leigh Purvis, *Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans: 2017 Year-End Update*, AARP PUB. POL'Y INST., 7 (Sept. 2019), <https://www.aarp.org/content/dam/aarp/ppi/2019/09/trends-in-retail-prices-of-prescription-drugs-widely-used-by-older-americans.doi.10.26419-2Fppi.00073.003.pdf>.

27. *Id.*

28. Juliette Cubanski & Tricia Neuman, *Price Increases Continue to Outpace Inflation for Many Medicare Part D Drugs*, KAISER FAMILY FOUNDATION (Feb. 4, 2021), <https://www.kff.org/medicare/issue-brief/price-increases-continue-to-outpace-inflation-for-many-medicare-part-d-drugs/>.

29. *Id.*

30. *Investigation of Skyrocketing Prescription Drug Prices*, HOUSE COMM. ON OVERSIGHT AND REFORM, <https://oversight.house.gov/investigations/investigation-of-skyrocketing-prescription-drug-prices> (last visited May 7, 2021), reports can be found at

a picture of aggressive revenue targets, manipulation of patents to extend exclusivity, and an overly burdened United States healthcare system that is forced to pay prices far above those in Europe. Whenever a company raises drug prices, the result is deadweight loss—people who could afford the fair market price of the drug are priced out.³¹ This deadweight loss arises because companies have monopolies over patented drugs, barring substitutes from the market.³² Yet, with drug monopolies, pricing out could mean that someone cannot afford life-saving medication.³³ Unfortunately, deadweight loss in healthcare means dead people.

The unusual demand curve for prescription drugs lets companies increase drug prices without losing customers. Unlike normal economic pricing, under which demand for a new product falls after a prolonged period of time—and the price for the product will likely drop even with a monopoly—prescription drugs have an almost unlimited demand curve.³⁴ Drug companies take advantage of this unlimited curve by implementing drug price increases that far outstrip inflation.³⁵ Furthermore, research and development (R&D) costs of the drugs cannot account for the astronomical price increases.³⁶ Instead, drug companies increase prices on a whim—as Celgene’s former Senior Vice President quipped “anytime they want[]”³⁷—and in response to aggressive revenue targets set by executives.³⁸ Doing so allows drug companies to lean on the United States healthcare system to pick up slack from the European healthcare system,³⁹ where drug prices are generally tightly controlled.⁴⁰

Patents confer a set period of market exclusivity for drugs, but

<https://oversight.house.gov/news/reports>.

31. See Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 293–98 (2016) (explaining the effects of deadweight loss in the pharmaceutical industry).

32. *Id.* at 294.

33. See *id.* at 297 (describing the loss in human welfare from high drug prices).

34. *Id.* at 295.

35. See Cubanski & Neuman, *supra* note 28 (describing price increases relative to inflation rates for Medicare Part D drugs).

36. See STAFF OF H. COMM. ON OVERSIGHT AND REFORM, 116TH CONG., DRUG PRICING INVESTIGATION CELGENE AND BRISTOL MYERS SQUIBB—REVLIMID ii (2020) (noting how cost decisions of Revlimid did not correspond with research and development on the drug).

37. *Id.* at 4.

38. *Id.* at 7.

39. See *id.* at 12 (showing the price of Revlimid remained steady in the European Union while increasing in price in the United States).

40. See generally Christine Leopold et al., *Differences in External Price Referencing in Europe – A Descriptive Overview*, 104 HEALTH POL’Y 50 (2012).

companies exploit gray areas in the law to both extend that exclusivity farther than they may otherwise receive and ensure their higher-priced brand name drug is still prescribed even when lacking market exclusivity. Drug companies tend to layer patents on top of their prescription drugs in order to extend market exclusivity, a process known colloquially as “evergreening.”⁴¹ The danger of this practice is that drug companies may extend their market exclusivity for a drug far beyond the twenty-year period usually attached to a patent, giving them the opportunity to raise their drug prices uninhibited for longer.⁴² Drug companies also attempt to stop generic companies from entering the market at the end of the exclusivity period by using the restrictions surrounding the Risk Evaluation and Mitigation Strategies to prevent generics from getting samples of brand name drugs to reverse engineer.⁴³

Even once drug companies have lost their market exclusivities, they engage in practices to keep prices high—such as lobbying doctors to prescribe brand name drugs and contracting with health plans and pharmacy benefit managers.⁴⁴ These companies also often market a new drug dosage combined with increasing the price of the old dosage to force patients back onto the patent-protected drug.⁴⁵ In acknowledgement of the high drug prices, pharmaceutical companies also pay into funds that provide co-pay assistance to patients, leveraging brand name loyalty to ensure patients will ask to be prescribed their favorite brands even with the prohibitive costs.⁴⁶

The government is not blind to these issues, and rules and legislation have been proposed to address the issue.⁴⁷ The Trump

41. C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 327–328 (Mar. 2012).

42. *See id.* at 328 (describing how companies use the patent system to prevent generic drugs from entering the market).

43. NAT’L ACADS. OF SCIS. ENG’G MED., *MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE*, 40 (Norman R. Augustine et al., eds., 2018).

44. STAFF OF H. COMM. ON OVERSIGHT AND REFORM, 116TH CONG., *DRUG PRICING INVESTIGATION NOVARTIS—GLEEVEC ii* (2020).

45. STAFF OF H. COMM. ON OVERSIGHT AND REFORM, 116TH CONG., *DRUG PRICING INVESTIGATION TEVA—COPAXONE iv* (2020).

46. *Id.* at ii–iii.

47. Unfortunately, the transition to the Biden administration seems to have slowed, and maybe even reversed, the initiatives supported by Trump. *See* Merle DeLancey, Jr., *Biden Administration Already Impacting Drug Prices*, JDSUPRA (Feb. 17, 2021), <https://www.jdsupra.com/legalnews/biden-administration-already-impacting-2691434/> (outlining the Biden administration’s response to Trump’s executive orders and regulations related to drug pricing).

administration pushed several rules designed to lower Medicare spending on prescriptions drugs.⁴⁸ One interim rule issued in November 2020 implemented the Most Favored Nation (MFN) model for Medicare Part B spending, which sets Medicare reimbursement at the lowest price paid by member countries of the Organisation for Economic Co-operation and Development (OECD).⁴⁹ Another rule would have eliminated rebates between drug manufacturers and pharmacy benefit managers (PBMs) and allowed drug companies to give discounts to patients directly.⁵⁰ Finally, the Trump administration issued a rule that created ways to import drugs from other countries.⁵¹ The innovation did not stop with the Trump administration.

The Biden administration recently supported a proposal to cap drug price increases at the rate of inflation.⁵² Any price increase that outstrips inflation would require the drug manufacturer to pay a rebate to the federal government.⁵³ The bill also would set up Medicare drug price negotiation, wherein the federal government could leverage its purchasing power to negotiate lower prices for Medicare Part D.⁵⁴ The CBO estimates that this proposal could save around \$450 billion over a period of 9 years.⁵⁵ The proposal was included in H.R.3, which was passed by the House of Representatives and the Senate Finance Committee in the 116th Congress.⁵⁶ In the Republican-controlled Senate, however, the bill was not brought up for a floor vote.⁵⁷ In the 117th Congress, H.R.3 was again re-introduced, although it has not yet been brought to the Floor for a vote.⁵⁸

48. *Id.* (discussing Trump administration executive orders that aspired to effect drug prices).

49. Kenneth Yood, et al., *Executive Order on Promoting Competition in the American Economy: The Biden Administration Considers Drug Pricing Strategies While Keeping the “Most Favored Nations” Drug Reimbursement Program on the Sidelines*, THE NATIONAL LAW REVIEW (Aug. 20, 2021), <https://www.natlawreview.com/article/executive-order-promoting-competition-american-economy-biden-administration>.

50. DeLancey, Jr., *supra* note 47. Again, the rule was delayed due to a lawsuit and the fate of the rule is in the Biden administration’s hands.

51. *Id.*

52. Cubanski & Neuman, *supra* note 28.

53. *Id.*

54. See Juliette Cubanski et al., *What’s the Latest on Medicare Drug Price Negotiations?*, KAISER FAMILY FOUNDATION (Jul. 23, 2021), <https://www.kff.org/medicare/issue-brief/whats-the-latest-on-medicare-drug-price-negotiations/> (discussing H.R. 3 and Medicare negotiation under the Biden administration).

55. *Id.*

56. Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 116th Cong. (2019).

57. Cubanski & Neuman, *supra* note 28.

58. *H.R.3 - 117th Congress (2021-2022): Elijah E. Cummings Lower Drug Costs Now Act*, CONGRESS.GOV, <https://www.congress.gov/bill/117th-congress/house-bill/3> (last visited Nov. 11, 2021).

This solution only touches a small portion of insured Americans, namely those covered under Medicare. In 2019, 18.1 percent of the U.S. population was covered under Medicare.⁵⁹ On the other hand, 68.5 percent of the U.S. population was covered by plans in the private health insurance market.⁶⁰ An additional 19.8 percent of individuals were covered under Medicaid.⁶¹ Those on private health insurance and the uninsured also need a solution addressing drug prices.

II. A HISTORY OF U.S. PRIVATE ENFORCEMENT

The United States has a rich history of encouraging private litigation to support its *ex ante* regulation from Congress and agencies.⁶² During the New Deal era, Congress attempted to set up a “bureaucracy-centered enforcement regime” that gave agencies the primary investigatory power to find and prevent wrongdoing.⁶³ The system, however, still left a lot of responsibility for *ex post* regulation to the common law tort regime.⁶⁴ During the twentieth century, Congress intentionally gave more power to the private enforcement system by implementing mechanisms such as private rights of action in statutes.⁶⁵ Many reasons have been put forth to explain this development, including both a pervasive doubt in the government’s ability to properly regulate, and cynical accusations of a lazy government—seeking credit for policies but shirking from the responsibility of monitoring the price and complexities of implementing said regulations.⁶⁶

Delegating the regulatory power to the courts also provides a stable system of interpretation and ensures staying power once those interpretations have been set. Courts and judges are “subject to strong institutional norms that render judicial interpretation more stable and consistent over time than interpretation by successive political

59. RYAN J. ROSSO, CONG. RSCH. SERV., IF10830, US HEALTH CARE COVERAGE AND SPENDING 1 (2021).

60. *Id.*

61. *Id.* It is important to note there may be possible dual enrollment overlap between Medicare and Medicaid.

62. See Glover, *supra* note 16, at 1147 (“[T]he primacy of *ex post* private enforcement . . . is in large part an outgrowth of America’s inherited regulatory design, which relied largely on private suits brought pursuant to common law doctrines, as opposed to *ex ante* public regulation of wrongdoing by governmental bodies.”).

63. *Id.* (quoting Sean Farhang, *The Political Development of Job Discrimination Litigation, 1963-1976*, 23 *STUD. AM. POL. DEV.* 23, 24 (2009)).

64. *Id.* at 1147–48.

65. *Id.* at 1148.

66. *Id.* at 1151–52.

administrations.”⁶⁷ By explicitly giving courts the authority to interpret and implement legislation, Congress ensures the regulation will not be swayed or distorted by the next presidential administration. The private enforcement model also provides several advantages over public enforcement, such as ensuring an informational advantage to the party enforcing the right and preventing a geographically distant agency regulating from afar.⁶⁸

The healthcare field is unique in this broader system of private enforcement because Congress has explicitly provided a strict form of *ex ante* agency regulation through the Federal Food, Drug, and Cosmetic Act, which authorizes the FDA to regulate drugs.⁶⁹ The FDA, however, makes clear that the goal of the *ex ante* regulation is to reduce physical harm to patients by ensuring the safety of the drugs on the marketplace in the United States.⁷⁰ The private enforcement mechanisms that surround the healthcare system serve to pick up the slack in economic regulation, including a system to promote generic entry to reduce drug prices and *qui tam* relators to reduce healthcare fraud for the U.S. government.

A. *The Hatch-Waxman Act and Generic Drug Entry*

The Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, regulates generic drug entry into the marketplace by providing an easier avenue for FDA approval and a private enforcement mechanism to challenge patents held by brand name companies.⁷¹ The purpose of the Act is to “make available more low-cost generic drugs by establishing a generic drug approval process for pioneer drugs.”⁷² Before the Hatch-Waxman Act, generic

67. Jonathan T. Molot, *Reexamining Marbury in the Administrative State: A Structural and Institutional Defense of Judicial Power over Statutory Interpretation*, 96 NW. U. L. REV. 1239, 1247 (2002).

68. See Glover, *supra* note 16, at 1155–1158 (describing several areas of private enforcement where agencies are not the ideal party to enforce a right).

69. 21 U.S.C. §§ 301–399i (2018).

70. See *What We Do*, FDA, <https://www.fda.gov/about-fda/what-we-do#:~:text=Freedom%20of%20Information-.FDA%20Mission,and%20products%20that%20emit%20radiation> (last visited May 7, 2021) (“The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices”).

71. See Hatch-Waxman Act, Pub. L. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2018)) (discussing the approval process for new drugs and providing for a thirty month stay if an action challenging the patent is brought within forty-five days).

72. H.R. Rep. No. 98-857(I), at 14 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647.

drug companies were required to perform independent clinical drug trials to earn FDA approval.⁷³ Even though it was undeniably for “society’s benefit to introduce generic versions of . . . drugs . . . as quickly as possible,” there was no easy pathway for generic companies to get approval.⁷⁴

Under the Hatch-Waxman Act, generic drug manufacturers can file an Abbreviated New Drug Application (ANDA), which relies on the clinical trials conducted and data collected by a brand name drug manufacturer to get FDA approval.⁷⁵ A key requirement is that the generic drug manufacturer proves the generic has the same active ingredient as, and is the “bioequivalence” of, the proposed product to a branded drug.⁷⁶ The new entry mechanisms for generic manufacturers were balanced with greater protection for brand name drug manufacturers in several ways, such as a patent term extension of up to five years,⁷⁷ up to five years of data exclusivity,⁷⁸ and a thirty-month stay as a result of Paragraph IV litigation.⁷⁹

The Hatch-Waxman Act also invites litigation through a mechanism in Paragraph IV. Known as “Paragraph IV Certification,” a generic firm seeking market entry must confirm there are no patent rights preventing market entry.⁸⁰ In doing so, the generic company certifies that any existing patents are “invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.”⁸¹ Once generic companies have made this certification, brand name drug companies will often sue the filer for patent infringement.⁸² The first ANDA filer also receives a 180-day

73. Alfred Engelberg, *Unaffordable Prescription Drugs: The Real Legacy of the Hatch-Waxman Act*, STAT (Dec. 16, 2020) <https://www.statnews.com/2020/12/16/unaffordable-prescription-drugs-real-legacy-hatch-waxman-act/#:~:text=Before%20Hatch%2DWaxman,branded%20medicines%20enjoyed%20perpetual%20monopolies>.

74. Ohly & Patel, *supra* note 21, at 111 (quoting Hasneen Karbalai, *The Hatch-Waxman (Im)Balancing Act*, DIGITAL ACCESS TO SCHOLARSHIP AT HARVARD, <https://dash.harvard.edu/handle/1/10015297> (last accessed October 8, 2021)).

75. 21 U.S.C. § 355(j)(1)-(2) (2018).

76. *Id.* § 355(j)(2)(A)(iv) (2018).

77. 35 U.S.C. § 156(c), (g)(6) (2018).

78. 21 U.S.C. § 355 (c)(3)(E)(ii) (2018).

79. *Id.* § 355 (c)(3)(C) (2018).

80. *Id.* § 355 (j)(2)(A)(vii)(IV) (2018).

81. *Id.*

82. *See, e.g., AstraZeneca Pharms. LP v. Mayne Pharma (USA) Inc.*, 2005 U.S. Dist. LEXIS 26196, No. 02 Civ. 7936 (WHP), at *28 (S.D.N.Y. Nov. 2, 2005), *aff'd in part, rev'd in part sub nom. Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370 (Fed. Cir. 2006) (discussing how the patent holder pharmaceutical company brought suit for patent infringement

exclusivity against other generic drug manufacturers,⁸³ which encourages and invites this system of private litigation.

Studies have shown that Paragraph IV litigation has proven successful in increasing generic drug market entry and decreasing health spending.⁸⁴ Prior to the Act, because of the lengthy and expensive process to get generic drug approval, only 35 percent of drugs with an expired patent had a generic equivalent.⁸⁵ In 2020, with the easier approval process and automatic substitution at the pharmacy for generics, generic drugs were 90 percent of all dispensed prescriptions while only accounting for 20 percent of drug spending.⁸⁶ Furthermore, generics have generated \$313 billion of drug savings.⁸⁷ For consumers, the average copay for a generic drug was \$6.97, and for the brand name drug it was \$56.32.⁸⁸

Private litigation in this sphere has created two related issues that have captured the attention of critics: evergreening and prospecting. The issues are two sides of the same coin—evergreening is a practice that extends market exclusivity, and prospecting is a practice that shortens market exclusivity. Evergreening is the tendency of drug manufacturers to pile weak patents on top of their active ingredient patent in a bid to increase market exclusivity.⁸⁹ On the other side, there is the risk of prospecting, where generic brands over-challenge drug patents, artificially shortening the life of the patent.⁹⁰ While either side of the coin likes to point fingers at the other, criticizing this push and pull as a fundamental error in the system, the actions taken by both sides to have better market positions is the type of behavior inducement intended by Paragraph IV litigation. The public good is served by incentivizing companies to challenge drugs, and although that may lead to blockbuster drugs fielding more patent challenges,

after the generic company filed an ANDA).

83. 21 U.S.C. § 355(j)(5)(B)(iv) (2018).

84. See Ohly & Patel, *supra* note 21, at 117 (stating an FTC study found 73% of generic drug manufacturers won patent litigation between 1992 and June 2002).

85. Garth Boehm et al., *Development of the Generic Drug Industry in the US After the Hatch-Waxman Act of 1984*, 3 ACTA PHARMACEUTICA SINICA B 297, 298 (2013).

86. 2020 *Generic Drug & Biosimilars Access & Savings in the U.S. Report*, ASSOCIATION FOR ACCESSIBLE MEDICINES 1, 16 (2020), <https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf>.

87. *Id.* at 4.

88. *Id.* at 17.

89. Hemphill & Sampat, *supra* note 41, at 330.

90. See *id.* at 333 (describing a study which found that the market life for drugs making more than \$500 million is 12.7 years, whereas those drugs which make less than \$50 million have a market life of 15.1 years).

those challenges serve to limit the negative effects of evergreening. The system preserves only the strongest patents, which are meant to protect valuable drugs, while the weaker fall in favor of generics. This process will ultimately lower drug prices.

Another currently unraveling issue is the potential antitrust liability created by pay-for-delay settlements.⁹¹ Drug manufacturers are using the creative solution of paying a settlement to generic manufacturers so that they stay out of the market for a period of time.⁹² Because monopoly pricing always exceeds duopoly pricing, and the first-filer for ANDA applications has the exclusive right to generic challenges,⁹³ the drug manufacturer has an incentive to keep the first-filer out of the field for a price. Pay-for-delay settlements are an example of unintended consequences of private enforcement, where settlements may lead to longer market exclusivities than without private enforcement.⁹⁴

B. Qui Tam Litigation and Healthcare Industry Fraud

The Civil False Claims Act (FCA) implements a system of qui tam litigation to combat fraud in payment to the government.⁹⁵ The Act allows qui tam plaintiffs,⁹⁶ known as relators, to bring a civil action for any violation of the FCA and receive up to twenty-five percent of the judgment or settlement.⁹⁷ Under the FCA, relators bring civil actions in the name of the government.⁹⁸ The statute was drafted to place the government in control of the prosecutions with the assistance of private parties.⁹⁹ When an action is filed by a relator, the action remains under seal for sixty days while the government decides whether or not to

91. See generally Raymond J. Prince, *Pay-For-Delay: How Brand-Name and Generic Pharmaceutical Drug Companies Collude and Cost Consumers Billions*, 68 S.C. L. REV. 689 (2017) (providing an overview of pay-for-delay settlements in the pharmaceutical industry).

92. *Id.* at 693.

93. 21 U.S.C. § 355(j)(5)(B)(iv) (2018).

94. See generally Prince, *supra* note 91 (providing an overview of pay-for-delay settlements in the pharmaceutical industry).

95. Christina Orsini Broderick, *Qui Tam Provisions and the Public Interest: An Empirical Analysis*, 107 COLUM. L. REV. 949, 952 (2007).

96. Qui tam comes from the Latin term “qui tam pro domino rege quam se ipso in hac parte sequitur,” meaning “who as well for the king as for himself sues in this matter.” *Qui tam action*, BLACK’S LAW DICTIONARY 1282 (8th ed. 2004).

97. 31 U.S.C. § 3730(b) (2018).

98. *Id.* § 3730(b)(1) (2018).

99. Dayna Bowen Matthew, *The Moral Hazard Problem with Privatization of Public Enforcement: The Case of Pharmaceutical Fraud*, 40 U. MICH. J.L. REFORM 281, 285–86 (2007).

intervene.¹⁰⁰ After the sixty days, the relator may proceed with the suit, either with the government as prosecutor or with the government actively monitoring the case.¹⁰¹

FCA claims have been on the rise recently, both generally and as to healthcare fraud. Congress amended the FCA in 1986 to incentivize relators to bring claims by making it easier for a relator to recover in an action and making it safer to be a whistleblower as a relator.¹⁰² Furthermore, the Deficit Reductions Act of 2005 specifically requires any entity making payments under State Medicaid plans to provide its employees with information about the FCA.¹⁰³ The number of qui tam suits has risen dramatically since the amendment, from 32 suits in 1987, to 533 in 1997,¹⁰⁴ to 672 in 2020.¹⁰⁵

The majority of recent FCA litigation has targeted the pharmaceutical industry.¹⁰⁶ In 2020, of the \$2.2 billion recovered through the FCA, \$1.8 billion involved healthcare industry fraud.¹⁰⁷ Overall, \$1.6 billion was recovered specifically through qui tam suits.¹⁰⁸ In the healthcare industry, FCA claims help to prevent money from fraudulently flowing to private pharmaceutical companies.¹⁰⁹ These claims also effectively lower pharmaceutical drug prices by stopping companies from illegally subsidizing co-pays to support their high drug prices.¹¹⁰ Furthermore, kickback schemes and fraudulent payments can

100. *Id.* at 286.

101. *Id.* at 286–87.

102. See Broderick, *supra* note 95, at 954 (stating that the amendment allowed private parties the right to continue as a party even after government intervention, increased the relator's recovery, and protected relators from retaliatory actions).

103. Deficit Reduction Act of 2005, Pub. L. No. 109-171, 120 Stat. 4 (2006) (codified at 42 U.S.C. § 1396a(68)(A) (2018)). The Act also put into place incentives for states to pass false claims acts similar to the FCA by allowing states 10 percent of any recovery under those laws. 42 U.S.C. § 1396h(a). Currently, 21 states have approved laws under this statute. See *State False Claims Act Reviews*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF THE INSPECTOR GENERAL, <https://oig.hhs.gov/fraud/state-false-claims-act-reviews/> (last visited May 7, 2021) (listing approved state laws).

104. Broderick, *supra* note 95, at 955.

105. Press Release, U.S. Department of Justice Office of Public Affairs, Justice Department Recovers Over \$2.2 Billion from False Claims Act Cases in Fiscal Year 2020 (Jan. 14, 2021), <https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020>.

106. See *id.* (stating that \$1.8 billion of the \$2.2 billion recovered in Fiscal Year 2020 under the FCA involved the healthcare industry).

107. *Id.*

108. *Id.*

109. See *id.* (describing a settlement with Novartis for \$591 million to resolve claims relating to kickbacks to induce prescriptions for Novartis drugs).

110. *Id.* (detailing two settlements with Novartis and Gilead which paid over \$148 million to resolve claims that they paid co-pays for the companies' own drugs through supposedly

lead to potentially poorer health outcomes by interfering with the independent decision-making of healthcare professionals.¹¹¹ Overall, qui tam litigation in the pharmaceutical industry serves to regulate ex post by uncovering behavior that, without private relators, might never come to light.

Qui tam litigation is especially important when it regulates industries with asymmetric information between the regulator and the regulated party, such as in Medicare payment fraud.¹¹² The aim of the enforcement mechanism is to find the party with the most accurate information at the lowest possible cost to the public, and hopefully deter fraudulent behavior by increasing the likelihood of punishment.¹¹³ In order to operate efficiently and with the lowest cost to the public, the system should be designed to bring forward only the highest quality suits. Yet, in practice that has not happened.¹¹⁴

When the government participates in a qui tam action, the parties will likely receive a larger recovery than without government intervention, leading to potential over-utilization of the qui tam system.¹¹⁵ Despite the high number of frivolous qui tam lawsuits, the government still recovers a significant amount of money, meaning the qui tam provision still holds value as a way to find fraudulent activity.¹¹⁶ The number of government-initiated actions, however, has decreased at the same rate qui tam suits have increased—suggesting a loss to the public in the cost of having to investigate qui tam suits as private parties when the government may have the capability of investigating these actions on its own.¹¹⁷

Qui tam litigation also creates the issue of moral hazard by allowing the government to benefit from private enforcement while letting private relators shoulder the risk. The availability of private enforcers

independent foundations).

111. *Id.* (describing schemes which induced the purchase of good and services).

112. Anthony Casey & Anthony Niblett, *Noise Reduction: The Screening Value of Qui Tam*, 91 WASH. U. L. REV. 1169, 1178 (2014).

113. *Id.*

114. *See id.* at 1186 (stating that “increasing the rewards for informing or decreasing the private cost of informing . . . dilutes the quality of the information brought forward”).

115. *See* Matthew, *supra* note 99, at 293 (finding that several FCA cases recently prosecuted cost taxpayers hundreds of millions of dollars, but were only questionably supported by the facts of the case).

116. *See* Broderick, *supra* note 95, at 955 (finding the government had recovered \$8.4 billion from qui tam lawsuits over a period of less than twenty years).

117. *Id.* at 979.

raises a significant risk of over-enforcement of the statute.¹¹⁸ Instead of pursuing only the best and most reliable cases of fraud, the government passively awaits case outcomes while private litigants bear the costs of litigation.¹¹⁹ This leads to an increased number of lower quality lawsuits, creating a schism between the original intent of the FCA and the operation of the statute in reality.¹²⁰ Therefore, although qui tam suits may correct information imbalances when uncovering fraudulent practices—especially in the healthcare industry—the field also suffers from over-litigation and frivolous suits.

C. Private Antitrust and Potential Pharmaceutical Litigation

Federal antitrust law prohibits anticompetitive behavior under the Sherman Act,¹²¹ inviting both private and public enforcement in court. The Sherman Act Section 1 prohibits price fixing and collective anticompetitive behavior.¹²² The Sherman Act Section 2 prohibits monopolies and conspiracies to monopolize, as well as mergers that have the risk of creating a monopoly.¹²³ Enforcement power for these sections lies with the United States government,¹²⁴ state attorneys general,¹²⁵ and private parties who have been “injured in their business” by behavior forbidden in the Sherman Act,¹²⁶ affectionately known as “private attorneys general.”¹²⁷ Relatedly, the Federal Trade Commission (FTC) can also enforce antitrust behavior under the Federal Trade Commission Act, which prohibits similar antitrust behavior as the Sherman Act.¹²⁸

The Sherman Act incentivizes private enforcement by authorizing treble damages for private lawsuits.¹²⁹ Legislative history suggests the

118. Matthew, *supra* note 99, at 282.

119. *Id.* at 297-98.

120. *Id.*

121. 15 U.S.C. § 1 (2018).

122. *See id.* (“Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal.”).

123. 15 U.S.C. § 2 (2018).

124. *Id.* § 15f.

125. *Id.* § 15c.

126. *Id.* § 15.

127. *Hawaii v. Standard Oil Co.*, 405 U.S. 251, 262 (1972).

128. *See* 15 U.S.C. § 45 (“Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful”); *see also* Neil W. Averitt, *The Meaning of “Unfair Methods of Competition” in Section 5 of the Federal Trade Commission Act*, 21 B.C. L. REV. 227 (1980).

129. *See* 15 U.S.C. § 15(a) (2018) (authorizing treble damages).

Act was meant to compensate injured victims and prevent money from flowing to firms with market power.¹³⁰ In that way, treble damages are meant as both an incentive for private parties and punitive damages for trusts as a way to deter future anticompetitive behavior.¹³¹ Whatever the motivation for treble damages, private enforcement is more successful in deterring anticompetitive behavior than the suits brought by the government.¹³²

Antitrust enforcement specifically plays a critical role in regulating pharmaceutical firms' behavior in the healthcare industry.¹³³ Two potential avenues for future litigation regulating antitrust and pharmaceutical companies are "product hopping"¹³⁴ and pay-for-delay settlements.¹³⁵ Both have potential to increase drug prices and delay generic entry and competition in the pharmaceutical industry. Therefore, these practices are a future target for increased regulation aimed at creating a more efficient healthcare industry.

Although it is unclear whether product hopping is a future avenue for antitrust litigation, one exemplar case in the field precipitated by private parties is *Mylan Pharmaceuticals Inc. v. Warner Chilcott Public Limited Co.*¹³⁶ There, Mylan Pharmaceuticals sued Warner Chilcott and Mayne Pharma under Section 2 of the Sherman Act for unlawful monopoly activity related to Warner Chilcott's actions with its drug, Doryx.¹³⁷ Warner Chilcott took a series of steps, known as "product hopping," to prevent generic drug substitution for Doryx by switching

130. Robert H. Lande, *The Rise and (Coming) Fall of Efficiency as the Ruler of Antitrust*, 33 ANTITRUST BULL. 429, 449 (1988) (noting that many statements were made by legislators which positioned the Act as a way to stop the "robbery" of overcharges by antitrust firms, stating trusts "extorted wealth" and have "stolen untold millions from the people").

131. See Robert H. Lande & Joshua P. Davis, *Benefits from Private Antitrust Enforcement: An Analysis of Forty Cases*, 42 U.S.F. L. Rev. 879, 883 (2008) (stating private enforcement treble damages serve as a deterrent, but also may reflect "unawarded prejudgment interest, . . . difficult-to-quantify unawarded damages items such as the allocative inefficiency effects of market power and the value of plaintiffs' time expended pursuing litigation").

132. See *id.* at 905 (finding the forty private antitrust cases studied deterred anticompetitive behavior more than any criminal fines or sentences imposed by the DOJ).

133. For an overview of the areas of antitrust enforcement related to pharmaceuticals, see Michael A. Carrier, *Antitrust in the Pharmaceutical Sector: An Overview of US Case Law*, ANTITRUST CASE LAWS E-BULLETIN, Oct. 8, 2018, <https://scholar.harvard.edu/files/sinha/files/ssrn-id3269506.pdf> (last visited May 7, 2021).

134. See generally Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471 (2008) (describing the practice of product hopping in the pharmaceutical industry).

135. See generally Prince, *supra* note 91 (providing an overview of pay-for-delay settlements in the pharmaceutical industry).

136. 838 F.3d 421 (3d Cir. 2016).

137. *Id.* at 426.

the drug from a capsule version to a tablet version.¹³⁸ In doing so, Warner Chilcott blocked its potential generic competitors from being able to automatically substitute their already approved capsule drugs with the new Doryx tablet formulation.¹³⁹ The FTC filed an amicus brief for the case in both the U.S. District Court for the Eastern District of Pennsylvania and the Third Circuit Court of Appeals urging the court to recognize antitrust liability for product hopping because of harm to generic competition.¹⁴⁰

The Third Circuit was unconvinced by the arguments for anticompetitive behavior, holding the generic company still had other available actions in the market they could have taken, such as developing a tablet version before Doryx took the tablet off the market.¹⁴¹ Furthermore, the court found that Warner Chilcott had reasons other than pure anticompetitive behavior for the product changes, including harmonization with European drug dosages.¹⁴² Though, here, the private enforcement failed to successfully enforce antitrust laws for product hopping, the mechanism of private enforcement can still lead to effective and targeted regulation for pharmaceutical companies.

III. THE BAYH-DOLE ACT

Congress passed the Bayh-Dole Act in 1980 under Pub. L. 96-517, Amendments to the Patent and Trademark Act to encourage technological innovation.¹⁴³ The Act allows a contractor to obtain a patent developed with federal government support, which was intended to incentivize private actors to commercialize federal R&D.¹⁴⁴ By providing patent protection to private parties that develop and commercialize products funded by federal money, the Bayh-Dole Act both encourages innovations and promotes the public good by

138. *Id.* at 429.

139. *Id.*

140. *See generally* Brief for Amicus Curiae Federal Trade Commission Supporting Plaintiff-Appellant, Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 421 (E.D. Pa. 2015) (No. 15-2236) (urging the court to recognize product hopping in the pharmaceutical industry as a source for antitrust liability).

141. *Mylan Pharmaceuticals, Inc.*, 838 F.3d at 438.

142. *Id.* at 439.

143. 35 U.S.C. § 200 (2018) (“It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development [and] to encourage maximum participation of small business firms in federally supported research and development efforts.”).

144. Abigail Amato Rives, *Reorienting Bayh-Dole’s March-In: Looking to Purpose and Objectives in the Public’s Interest*, 5 AM. U. INTELL. PROP. BRIEF 77, 85 (2013).

increasing access to new inventions.¹⁴⁵ In return, the government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for the government’s own benefits,¹⁴⁶ as well as “march-in rights” for federal agencies.¹⁴⁷ The march-in rights allow the government under certain circumstances to force the private parties that own the patents granted under the Act to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.”¹⁴⁸

These march-in rights have never been exercised, despite six petitions that have been submitted to the National Institutes of Health (NIH).¹⁴⁹ The differing opinions regarding the potential effect of exercising march-in rights on the patent system has proven to be an issue. Some believe march-in rights have the potential to stifle innovation by discouraging investment in government-funded R&D.¹⁵⁰ Others, however, believe the government should be able to protect taxpayers from excessive pricing on products that have been developed using public funding.¹⁵¹

The uncertainty of the statutory language and the pertinent regulations for march-in rights is another issue. The Secretary of Commerce delegated the authority to promulgate implementing regulations of the Bayh-Dole Act to the Director of National Institute of Standards and Technology (NIST), a primarily nonregulatory body.¹⁵² The regulations that control the exercise of march-in rights only require a fact-finding process and consideration of the policy and objective of the Bayh-Dole Act.¹⁵³ The policy and objective of the Act are written with broad strokes, but the most relevant section is likely the phrase “protect the public against nonuse or unreasonable use of inventions.”¹⁵⁴ Without clear regulations, however, businesses that

145. See Stephen Ezell, *The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System*, ITIF: INFORMATION TECHNOLOGY AND INNOVATION FOUNDATION (Mar. 4, 2019) <https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system> (explaining the significant role the Bayh-Dole Act plays in encouraging commercialization and utilization of inventions).

146. 35 U.S.C. § 202(c)(4) (2018).

147. *Id.* § 203(a).

148. *Id.*

149. JOHN R. THOMAS, CONG. RSCH. SERV., R44597, MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT 8 (2016).

150. *Id.* at 13.

151. *Id.*

152. Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 86 Fed. Reg. 35 (proposed Dec. 31, 2020) (to be codified at 37 C.F.R. pt. 401 and 404).

153. 37 C.F.R. § 401.6(g).

154. 35 U.S.C. § 200 (2018).

acquire patents eligible for march-in rights have expressed their worries and reticence over the potential use of march-in rights in the future.¹⁵⁵

Finally, courts have refused to read a private right of action into the Bayh-Dole Act,¹⁵⁶ precluding any possible private enforcement mechanisms for the Act. Because there is no explicit private right of action, courts turned to legislative history—determining that the Act primarily regulates the relationship between the government and researchers and not private parties.¹⁵⁷ Therefore, in the future, private parties will be unable to use the Bayh-Dole Act in other private litigation unless the statute is amended.

IV. AMENDING THE BAYH-DOLE ACT FOR PRIVATE ENFORCEMENT

Congress should amend the Act to include an invitation for private parties to enter the market and sue drug companies with unconscionable pricing, in return receiving a license to manufacture that drug at lower costs (the “Amendment”). This policy change would lead to lower drug prices and solve the issues with march-in rights inherent in the Bayh-Dole Act. By leaving the enforcement of the march-in rights to the courts, Congress can avoid the need to regulate each drug on the market and ensure stable interpretation of the Act down the line. In the future, a manufacturer that enters the market with a new brand name drug will have clear, enforceable precedent to create a price ceiling to influence their pricing decisions. Although the Act would invite increased litigation for drug manufacturers, potentially leading to over-utilization of the courts, the number of suits can be controlled through a first actor provision in the Amendment and the inherent power of the court to punish private parties who pursue frivolous suits.

First, Congress should amend the march-in rights provision of the

155. See NAT’L INST. OF STANDARDS AND TECH., U.S. DEP’T OF COM., SPECIAL PUB. NO. 1234, RETURN ON INVESTMENT INITIATIVE TO ADVANCE THE PRESIDENT’S MANAGEMENT AGENDA: FINAL GREEN PAPER 32 (2019), <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf> (finding stakeholders believe the existing regulation is unclear regarding the federal government’s march-in rights, leading to market uncertainty).

156. *Madey v. Duke Univ.*, 413 F.Supp. 2d 601, 613 (M.D.N.C. 2006) (“[T]he Bayh-Dole Act is designed to regulate the relationship between the Government and its funding recipients, but it would not be available to a private third party as the basis for a private right of action or private defense.”).

157. *Id.*

Bayh-Dole Act to include more specific definitions and situations where those rights should be exercised in private litigation, as well as restrict the use of the march-in rights only to those drug companies with unconscionable pricing. Congress should define what factors the court should consider for a reasonableness analysis when determining whether a specific drug company's prices are unconscionable. When setting out these factors, Congress should use a variety of mechanisms to center drug pricing analysis around value to human life, and especially for the march-in rights, the amount of public funding each drug received during R&D.

One potential reasonableness measure would be to use the European drug pricing control of assessing the added value of a new drug compared with what is on the market to set a maximum price for the new drug.¹⁵⁸ A way to visualize this is through the Quality Added Life Years (QALY) measure. By equating the additional QALYs each drug creates above the previously available treatment, Congress can create a guidepost for the courts to visualize how expensive a drug should be relative to its benefit to consumers. A related consideration would be the drug's importance in treatment regimes or supply chains. For example, insulin must be affordable not only because it saves lives, but because its users need multiple doses per day.

One important limiting factor to the Amendment's finding of unconscionable drug pricing would be the inclusion of a statutory factor that requires the court to weigh the amount of public funding that was received for the creation of the patent. The Bayh-Dole Act arguably over-captures those patents that are eligible for march-in rights by declaring any patent that received any amount of public funding may potentially be invaded.¹⁵⁹ The purpose behind the Amendment, however, is to recoup the investment the public has made in these drug patents through taxpayer money—*not* to unduly punish companies for competitive behavior. Therefore, the Amendment would require a court's reasonableness analysis to account for the amount of public funding received for a specific patent. A drug manufacturer that received nominal public funding during a drug's development would

158. Marc A. Rodwin, *What Can the United States Learn from Pharmaceutical Spending Controls in France?*, THE COMMONWEALTH FUND (Nov. 11, 2019), <https://www.commonwealthfund.org/publications/issue-briefs/2019/nov/what-can-united-states-learn-drug-spending-controls-france>.

159. See 35 U.S.C. § 203 (defining the rights under the Bayh-Dole Act which allows nonprofit organizations or small businesses to keep title to inventions when under a federal funding agreement).

have a stronger case to keep their drug prices high.

Notably, the Amendment would not regulate the field of all drugs, but instead only target those drugs where the public has already contributed to the drug's R&D and so should benefit from its use on the market. By tying reasonableness of pricing to the amount of federal R&D money received, it would not encourage the government to become a regulator in the free marketplace of pharmaceutical goods. Rather, the Amendment would encourage private competitors to act on behalf of the government to recoup sunk costs for research, without double paying for both research and receipt of the final product.

The Amendment to the Act would also include a *qui tam* provision similar to the FCA's to invite private parties—more specifically qualified competitor pharmaceutical companies with the manufacturing capabilities to take on the march-in license—to sue on behalf of the government. Unlike the FCA, which gives private parties a fixed amount of the recovery in a *qui tam* suit,¹⁶⁰ the litigant pharmaceutical company here would only be rewarded a license for the overpriced drug for a limited period of time,¹⁶¹ with renewal dependent on the original pharmaceutical company's revised pricing after the duopoly period. The Amendment would also include a first actor provision similar to the Hatch-Waxman Act, under which only the first qualified pharmaceutical competitor could sue within a set period, limiting the potential amount of litigation in the future.

The Amendment would also implement the solutions found to fix the moral hazard issue in *qui tam* litigation by requiring the government to approve any litigation, and further, to pre-screen relators to ensure they have the manufacturing capabilities necessary to properly compete in the field with the primary manufacturer. By requiring this approval from the government, the Amendment would ensure there will not be frivolous and time-wasting litigation. Therefore, although a company's drug pricing may be unconscionably high, the Amendment would be designed to only challenge those drugs that have a competitive manufacturer, thus decreasing the number of drugs that can be challenged at one time while limiting the number of frivolous and harassing lawsuits that could potentially be invited.

160. 31 U.S.C. § 3730(b) (2018).

161. It is beyond the scope of this Note to determine the ideal period of time for the temporary license, however, the period of time should be enough to motivate the pharmaceutical companies to litigate for the right to manufacture the drug.

By empowering qui tam relators, the Amendment would ensure the parties with the informational advantage, in this case a competitor in the direct economic market, can participate in the litigation. Courts generally do not have the institutional competence to make decisions regarding complex pricing schemes such as drug pricing, lacking the career economists who are often at the whim of Congress. Yet, through qui tam litigation which would require a competitor in the field as the relator, the Amendment ensures the parties in court will bring their best arguments relating to the factors in the Amendment. Therefore, the parties themselves will be incentivized to bring economists or health experts before the court to convince the court of the reasonableness, or unreasonableness, of the drug pricing—thus curing some of the institutional limits of the court.

Another added benefit of the Amendment is that it would serve as a potential case study to fix the uneven bargaining power in the healthcare industry. Only actors with high bargaining power in an economy can influence prices, meaning average U.S. citizens have no bargaining power to influence drug prices. Theoretically, Medicare is the health body with the most bargaining power in the United States due to the sheer volume of payments related to Medicare patients.¹⁶² Although the government may soon give Medicare the ability to negotiate directly for drug prices, the negotiation process would only protect those patients covered by Medicare.¹⁶³ By providing an avenue for private enforcement that would regulate drug prices for all buyers in the healthcare marketplace, the Amendment's litigation would artificially level the current imbalance in bargaining power in the healthcare industry, thus effectively regulating the cost of drugs broadly throughout the market.

Inviting ex post regulation of drug prices in the court means the application of the Amendment will not be subject to the whims of political parties as different actors rotate through federal agencies. By delineating specific statutory factors and inviting litigation, the Amendment would ensure stable and relatively uniform interpretation of whether a given drug price is unconscionable. Although a drug company could be open to new litigation avenues, the manufacturers

162. See *Prescription Drug Prices: Harnessing Medicare's Purchasing Power*, THE CENTER FOR AMERICAN PROGRESS (Jan. 28, 2004), <https://americanprogress.org/article/prescription-drug-prices-harnessing-medicare-purchasing-power/> (discussing Medicare's purchasing power).

163. See Cubanski et al., *supra* note 54 (discussing H.R. 3 and Medicare negotiation under the Biden administration).

could also rely on the stable interpretations. In doing so, companies could alter their competitive behavior in the marketplace, and any inefficiencies caused by the litigation could be mitigated in the future by encouraging companies to lower drug prices to avoid litigation altogether.

At some point, the cost of a competitor challenging an unconscionable drug price will be higher than any duopoly pricing they may gain through a license. Manufacturing and distribution are expensive endeavors for drug companies, and a rational company would only seek a license when the potential profits make up the loss. If a rational drug manufacturer, however, were to rely on the courts' interpretation of the Amendment and accordingly price their drug at or below the estimated unconscionable threshold, the risk of losing the lawsuit would be too high for a rival manufacturer to want to litigate. For the FCA, this would be seen as a failure of the private enforcement mechanism to adequately bring forward informed parties. But here, the decline in the number of lawsuits could be attributed to the decrease in drug prices, and the successful implementation of the Amendment.

CONCLUSION

The United States healthcare industry has sky-rocketing drug prices, and although there are many private enforcement mechanisms surrounding the industry that regulate *ex post* as to fraud, anticompetitive activity, and generic entry, no private enforcement mechanism directly encourages private parties to litigate to lower drug prices. Private enforcement mechanisms do not always function properly—with risks of over-utilization and potential illegal anticompetitive behavior as firms attempt to avoid private enforcement. Nevertheless, private enforcement mechanisms generally have been successful in both incentivizing private parties to regulate industries *ex post* as well as making regulation easier than it would be with only agency action.

Congress has already expressed intent to design mechanisms which regulate patents created with public funding by building march-in rights into the Bayh-Dole Act. Drug patents created with public funding should be subject to a higher standard of regulation than drug patents created without public funding to protect U.S. citizens from double paying for both the development of and access to the drug. Passing an Amendment to the Bayh-Dole Act that clearly defines when march-in rights would be exercised and inviting private manufacturers

to sue for the right to get a manufacturing license would create a system of ex post regulation for drug prices without stifling innovation or creating an unpredictable regulatory regime. Courts are experienced in implementing reasonableness analyses, and with specified factors from Congress, manufacturers could rely on a relatively stable form of regulation and alter their economic behavior accordingly.

Overall, this solution is a moderate proposal that would affect the behavior of a modest number of drug manufacturers. The Amendment, however, would be a step forward to encourage tighter regulation of drug prices and hopefully provide a model for other proposals down the line. Although the Amendment is specifically tied to the Bayh-Dole Act to temper the risks of over-utilization, a more expansive private enforcement mechanism that affects all drug companies could be implemented in the future. Regulating drug prices to reduce market inefficiencies in the healthcare industry will lead to more lives saved.