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## When Market Forces Fail: The Case for Federal Regulation of Insulin Prices

Erin M. Barker  
*Campbell University School of Law*

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# When Market Forces Fail: The Case for Federal Regulation of Insulin Prices

## ABSTRACT

*Rising insulin prices entail rising economic and social costs that are shouldered by all Americans. While three insulin manufacturers cling to their control of the insulin market, consumers are unable to exercise meaningful choices between competitors to drive prices down. When market forces fail, the solution is federal regulation of the insulin market. The failure of typical forces like competition in this market necessitates federal regulation to curb the monopolistic powers of insulin manufacturers. This Comment explores the history and importance of insulin and the current ramifications of exorbitant insulin prices. This Comment then examines different categories of economic regulation and scrutinizes legislation that state governments have begun enacting to regulate insulin prices. Ultimately, this Comment argues that the federal government should implement a combination of price cap regulation and nationalization of insulin formula patents to increase competition and decrease insulin prices, thereby reducing the economic and social burdens borne by Americans.*

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## INTRODUCTION

Today, a single vial of insulin can cost more than \$250 in the United States, and most patients use between two and four vials each month.<sup>1</sup> Consequently, if a diabetic patient is without insurance, or if insurance does not cover a specific brand of insulin, that person could pay upwards of \$500 to \$1,000 per month out-of-pocket for an essential medication.<sup>2</sup> These costs are astronomical and unacceptable—the federal government must step in to regulate pricing.

On January 11, 1922, fourteen-year-old Leonard Thompson faced the end stages of a terminal illness: diabetes mellitus, otherwise known as type 1 diabetes.<sup>3</sup> Thompson weighed only sixty-five pounds after living with diabetes for three years.<sup>4</sup> His attempt to control his diabetes with a

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1. Bram Sable-Smith, *Insulin’s High Cost Leads To Lethal Rationing*, NPR (Sept. 1, 2018), <https://perma.cc/8PQV-6XAB>.

2. *See id.*

3. Howard Markel, *How a Boy Became the First to Beat Back Diabetes*, PBS NEWS HOUR (Jan. 11, 2013), <https://perma.cc/LQ92-RZN5>.

4. *Id.*

starvation diet failed to keep him from slipping in and out of a diabetic coma.<sup>5</sup> Desperate for any chance to save his son, Thompson's father agreed to let the hospital inject the boy with a recently-discovered drug—insulin.<sup>6</sup> Thompson would be the first human subject to receive the injection,<sup>7</sup> and the results were nothing short of miraculous.<sup>8</sup> His blood sugar lowered to a normal level, and the glucose and ketones<sup>9</sup> present in his urine also lowered to a tolerable level.<sup>10</sup>

Four men discovered this “wonder drug”<sup>11</sup>: Frederick Banting, Charles Best, James Collip, and John Macleod.<sup>12</sup> Following Banting's and Best's initial publication of their results,<sup>13</sup> the discovery of insulin and its successful application to human subjects landed on the covers of newspapers worldwide.<sup>14</sup> Insulin provided life-saving treatment for people who previously faced a death sentence; the drug brought diabetic patients out of comas, allowing them to end their starvation diets and eat carbohydrates.<sup>15</sup> For their discovery, Banting and Macleod won the 1923 Nobel Prize in Physiology or Medicine and split their winnings with Best and Collip.<sup>16</sup>

5. *Id.*

6. *Id.*

7. *Id.*

8. *Id.*

9. Ketones are chemicals that a person's body produces when it processes fat as energy, typically due to a lack of insulin, which would normally convert glucose into energy. See Kyla Schmiege, *Ketones—The 6 Must-Knows*, BEYOND TYPE 1, <https://perma.cc/2TJV-CKTR>. A build-up of ketones in the bloodstream can lead to diabetic ketoacidosis, a serious condition that can result in coma or death if left untreated. *Id.*

10. Ignazio Vecchio, Cristina Tornali, Nicola Luigi Bragazzi, Mariano Martini, *The Discovery of Insulin: An Important Milestone in the History of Medicine*, FRONTIERS IN ENDOCRINOLOGY, Oct. 2018, at 4, <https://perma.cc/XU7H-K9JS>.

11. Markel, *supra* note 3.

12. See *id.*; see also Frederick Banting, Charles Best, James Collip, and John Macleod, SCI. HIST. INST., <https://perma.cc/286C-MESE> [hereinafter *Frederick Banting*]. Banting was a surgeon from Ontario, Best was an eager medical student at the University of Toronto, Collip was a biochemist who made the breakthrough in purifying the insulin, and Macleod was a University of Toronto physiologist who provided the lab space and dogs on which the group initially tested the insulin. *Id.*

13. Banting and Best published their findings in the *Journal of Laboratory and Clinical Medicine* in February 1922. Markel, *supra* note 3.

14. *Id.*

15. See *id.*

16. *Id.*; see also *Frederick Banting*, *supra* note 12.

Banting, Best, and Collip acquired an American patent on insulin and its method of creation on January 23, 1923.<sup>17</sup> When applying for their patent, the trio maintained that “their goal was not profit, but ensuring the speedy and safe availability of their discovery to the public.”<sup>18</sup> They then sold their patent rights to the Board of Governors of the University of Toronto for \$1.00 each.<sup>19</sup> In a letter to the University’s president, the trio wrote, “The patent would not be used for any other purpose than to prevent the taking out of a patent by other persons. When the details of the method of preparation are published anyone would be free to prepare the extract, but *no one could secure a profitable monopoly.*”<sup>20</sup> Banting, Best, and Collip stated a clear goal: their lifesaving invention was to remain available to all. That goal has failed.

This Comment analyzes how federal regulation of insulin prices will correct failed market forces, leading to a stabilized market for the indispensable medication. Part I of this Comment will provide a brief overview of the current state of the insulin market in the United States. Part II of this Comment will explain economics-based justifications for adopting federal legislation to regulate the insulin market. It will also provide an overview of the types of regulatory schemes that the government could utilize in this market. Part III of this Comment will describe and critique legislation that two states—Nevada and Colorado—have already acted to regulate the cost of insulin and will then examine currently proposed federal legislation that aims to lower insulin prices. Lastly, Part IV of this Comment offers a solution: the addition of language to the proposed federal legislation, incentivizing competition and positively affecting market prices through the nationalization of patents.

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17. Louis Rosenfeld, *Insulin: Discovery and Controversy*, 48 CLINICAL CHEMISTRY 2270, 2280 (2002), <https://perma.cc/GVR2-5E8Y>.

18. Jeremy A. Greene & Kevin R. Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 NEW ENG. J. MED. 1171, (Mar. 19, 2015), <https://perma.cc/L76A-E9VQ>.

19. Rosenfeld, *supra* note 17.

20. MICHAEL BLISS, THE DISCOVERY OF INSULIN 133 (The Univ. of Chi. 25th anniversary ed. 2007) (emphasis added) (footnote omitted).

## I. THE STATE OF THE INSULIN MARKET IN THE UNITED STATES TODAY

A. *Economic Impact of Rising Insulin Prices*

From 2002 to 2013, the cost of insulin nearly tripled.<sup>21</sup> Then, from 2012 to 2016, the cost of insulin rose dramatically again, nearly doubling.<sup>22</sup> In the first month of 2019 alone, insulin manufacturers Sanofi and Novo Nordisk raised some of their insulin product prices as much as 4.9% and 5.2%, respectively.<sup>23</sup>

As of 2017, diabetes treatment and complications cost the United States (“U.S.”) more than \$327 billion per year, making it the most expensive chronic illness in the country.<sup>24</sup> This cost is a combination of \$237 billion in direct medical costs, including \$15 billion for insulin, and \$90 billion in indirect costs.<sup>25</sup> The American Diabetes Association reports:

While much of the cost of diabetes appears to fall on insurers (especially Medicare) and employers (in the form of reduced productivity at work, missed work days, and higher employer expenditures for health care), in reality such costs are passed along to all of society in the form of higher insurance premiums and taxes, reduced earnings, and reduced standard of living.<sup>26</sup>

Government insurance, including Medicare, Medicaid, and insurance through the military, provide for a majority (67.3%) of the cost of diabetes care in this country.<sup>27</sup> Private insurance pays for 30.7%, and the uninsured

21. Ken Alltucker, *Struggling to Stay Alive: Rising Insulin Prices Cause Diabetics to Go to Extremes*, USA TODAY (Mar. 27, 2019), <https://perma.cc/ZHZ3-N6YA>.

22. *Id.*; see also Robin Respaut & Chad Terhune, *U.S. Insulin Costs Per Patient Nearly Doubled from 2012 to 2016: Study*, THOMSON REUTERS (Jan. 22, 2019), <https://perma.cc/2JY7-KU3R>.

23. Respaut & Terhune, *supra* note 22.

24. Press Release, Working Group, American Diabetes Association® Releases White Paper by Insulin Access and Affordability Working Group at Hearing of Senate Special Committee on Aging (May 8, 2018), <https://perma.cc/3SXZ-AF62> (footnote omitted).

25. Am. Diabetes Ass’n, *Economic Costs of Diabetes in the U.S. in 2017*, 41 DIABETES CARE 917, 924 (2018). The American Diabetes Association reports:

Indirect costs include increased absenteeism (\$3.3 billion) and reduced productivity while at work (\$26.9 billion) for the employed population, reduced productivity for those not in the labor force (\$2.3 billion), inability to work because of disease-related disability (\$37.5 billion), and lost productivity due to 277,000 premature deaths attributed to diabetes (\$19.9 billion).

*Id.* at 917.

26. *Id.* at 927.

27. *The Cost of Diabetes*, AM. DIABETES ASS’N, <https://perma.cc/9PL6-S2UK>.

pay for 2% of the cost of diabetes care.<sup>28</sup> Uninsured diabetics visit the doctor 60% less and receive 52% fewer prescriptions than insured diabetics, yet uninsured diabetics account for 168% more emergency department visits than insured diabetics.<sup>29</sup> Accordingly, because of both the direct and indirect costs of diabetes care, it is not just diabetics who are paying—all of society shoulders the financial burden of the increasing cost of diabetes.<sup>30</sup>

### *B. Social Impact of Rising Insulin Prices*

Rising insulin prices induce “negative health and financial burdens on the population.”<sup>31</sup>

Of the 30 million diabetic Americans, approximately 7.4 million require daily doses of insulin to survive.<sup>32</sup> Rising insulin prices have forced some to cut back on or skip doses of insulin.<sup>33</sup> Others elect to forgo other necessities such as food or rent in order to afford insulin.<sup>34</sup> A 2018 study found that almost 26% of diabetics in the U.S. had rationed their insulin the previous year.<sup>35</sup> Recently, poignant stories have emerged detailing the tragic societal consequences of these negative health and financial burdens, including deaths due to an inability to afford insulin.<sup>36</sup>

One such story is that of Alec Smith, a twenty-six-year-old who died less than a month after his mother’s health insurance plan removed him as a beneficiary.<sup>37</sup> Smith, who worked a full-time job and earned more than minimum wage, could afford neither new insurance nor the monthly \$1,000

28. *Id.*

29. *Id.* (“This estimate highlights the substantial burden that diabetes imposes on society.”).

30. *Id.*

31. See NEV. DIV. OF PUB. & BEHAVIORAL HEALTH, NEV. DEP’T OF HEALTH & HUMAN SERVS., DRUG TRANSPARENCY REPORT 2019 ESSENTIAL DIABETES DRUGS 19 (May 31, 2019), <https://perma.cc/77ZG-TCZV>.

32. Press Release, Am. Diabetes Ass’n, American Diabetes Association® Applauds Colorado Governor and State Legislature for Passing HB 1216: Reduce Insulin Prices Bill (May 22, 2019), <https://perma.cc/KCL7-UK5J>. These numbers account for adults with diagnosed diabetes, including both type 1 and type 2 diabetes—it does not include children or adults diagnosed with gestational diabetes. Am. Diabetes Ass’n, *supra* note 25, at 2.

33. Press Release, Am. Diabetes Ass’n, *supra* note 32.

34. See *id.*

35. T1International Releases Report on Rationing and Cost Survey Data, T1INTERNATIONAL (June 18, 2019), <https://perma.cc/72W6-7JT8>. Rationing insulin is a dangerous practice that can be fatal if the person is not taking enough insulin to adequately regulate his or her blood sugar. See *id.*

36. See, e.g., Ritu Prasad, *The Human Cost of Insulin in America*, BBC NEWS (Mar. 14, 2019), <https://perma.cc/CZ63-RYTS>.

37. *Id.*

out-of-pocket cost of his insulin.<sup>38</sup> Another story is that of Meaghan Carter, a forty-seven-year-old woman who died alone on her sofa on Christmas night because she could not afford insulin.<sup>39</sup> Carter, a nurse, was between jobs.<sup>40</sup> She planned to start a new nursing position with health insurance benefits only a week after her death.<sup>41</sup> Carter's family found empty vials of insulin among Carter's nursing supplies in her home.<sup>42</sup> According to Carter's sister-in-law Mindi Patterson, "[s]he had gauze, bandages and all her nursing supplies"—"plenty to take care of others but not enough to take care of herself."<sup>43</sup> The stories of Alec Smith and Meaghan Carter demonstrate that there is more than just money at stake here—people's lives are on the line because of insulin prices in the U.S.

Almost a hundred years after the discovery of insulin, diabetics should not be forced to ration an essential drug or face death due to excessive costs. Banting, Best, and Collip's goal was to make insulin affordable for all,<sup>44</sup> but that is not the case today. The current price of insulin in the U.S. is unacceptable and must be addressed.

## II. THE FEDERAL GOVERNMENT SHOULD REGULATE THE INSULIN MARKET BECAUSE OF THE FAILURE OF TYPICAL MARKET FORCES

### *A. Economics-Based Justifications*

Effective federal regulation will alleviate at least two causes of high insulin prices: patents preventing competition from manufacturers of "generic" insulins, and the failure of normal market forces due to the lack of competition.<sup>45</sup> U.S. patent law provides patent-holders with twenty years of patent exclusivity for the development of new drugs.<sup>46</sup> Exclusivity

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38. *Id.*

39. Alltucker, *supra* note 21.

40. *Id.*

41. *Id.*

42. *Id.*

43. *Id.* (internal quotation marks omitted).

44. See BLISS, *supra* note 20.

45. See Callum Borchers, *Why Insulin Defies the Normal Rules Of Economics And Keeps Getting More Expensive*, WBUR: THE PRICE OF HEALTH (June 25, 2019), <https://perma.cc/DX2N-EEP2>.

46. 35 U.S.C. § 154(a)(2) (2018).

permits patent-holders to set prices and control the market for at least twenty years.<sup>47</sup>

Currently, there are three primary pharmaceutical companies manufacturing insulin in the U.S. market: Eli Lilly, Novo Nordisk, and Sanofi.<sup>48</sup> These three pharmaceutical companies “minimize competition by patenting incremental changes” to their insulin formulas, making it extremely difficult for other manufacturers to develop affordable, effective generics known as biosimilars.<sup>49</sup> For example, even though Sanofi’s primary patents for the insulin Lantus expired in 2015, Sanofi has filed around seventy patents for incremental changes since 2000.<sup>50</sup> These secondary patents will allow Sanofi to receive patent protection over the formula for Lantus through at least March 2028.<sup>51</sup>

Thus, the three pharmaceutical companies that manufacture insulin have developed what is essentially a monopoly over the insulin market through this patent-based barrier to potential competitors.<sup>52</sup> Because it is so difficult for other manufacturers to create biosimilar insulins due to patents, there is currently very little room for competition from other drug manufacturers.<sup>53</sup> In fact, Eli Lilly and Sanofi produce the only two biosimilar insulins currently on the market, meaning these manufacturers can maintain the monopoly.<sup>54</sup>

In a typical market, product price usually falls as time goes on.<sup>55</sup> Common causes of a decrease in market value include competitors entering the market and introducing similar, cheaper alternatives, or a current manufacturer making an advancement that lowers the value of older

47. Tahir Amin, *Patent Abuse is Driving up Drug Prices. Just look at Lantus*, STAT (Dec. 7, 2018), <https://perma.cc/W3Y5-J8S5>.

48. Daniel Kowalski, *Why We Don’t Have Generic Insulin*, FOUND. FOR ECON. EDUC. (Mar. 16, 2019), <https://perma.cc/DG7G-Y9G5> (“[Research and development has] kept the patents for insulin in the hands of three big companies—Sanofi, Novo Nordisk, and Eli Lilly—because the original 1922 insulin patent included patent rights on any manufacturing improvements.”); *see also* Borchers, *supra* note 45.

49. Borchers, *supra* note 45; *see also* Amin, *supra* note 47.

50. *See* Amin, *supra* note 47.

51. SANOFI, ANNUAL REPORT FORM 20-F 2018, at 62 (Dec. 31, 2018), <https://perma.cc/2WVR-F927>.

52. *See* Irena Asmundson, *Supply and Demand: Why Markets Tick*, INT’L MONETARY FUND, <https://perma.cc/8GCR-P4N5>.

53. *See* Kowalski, *supra* note 48. Eli Lilly now produces the biosimilar Basaglar, which is comparable to Lantus and has a 15% lower list price. *Id.* Sanofi produces the biosimilar Admelog, which is comparable to Humalog and also has a 15% lower list price. *Id.*

54. *See id.*

55. Borchers, *supra* note 45.

versions of a product.<sup>56</sup> Consumers can choose to either purchase a cheaper alternative or upgrade to the newer, more advanced product—either choice would lower demand for the original product, thus lowering the market value of the older version.<sup>57</sup>

Insulin is not a typical consumer product.<sup>58</sup> Not only do patents prevent competitors from entering the market, but type 1 diabetics cannot exert pressure on the pharmaceutical companies to lower prices by simply choosing to not purchase insulin.<sup>59</sup> Instead, “[t]ype 1 diabetics without adequate insurance coverage are vulnerable to price increases because they can’t live without the drug . . . . ‘People have to buy insulin no matter what the cost is . . . [giving] a lot of strength to the people selling insulin.’”<sup>60</sup>

When the marketplace is unable to self-regulate a monopoly through competition, the traditional solution is the passage of regulation rather than leaving the monopoly free within “the unregulated marketplace or to the antitrust laws for correction.”<sup>61</sup> When determining the most appropriate type of regulation, there are several options available, the most viable of which are discussed below.<sup>62</sup>

### *B. Regulations Available to Increase Competition*

This Section describes five regulatory approaches that the government could potentially utilize in lowering insulin prices: disclosure regulation, cost-of-service ratemaking, historically based price regulation, price cap regulation, and nationalization.

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56. *Id.*

57. *See id.* (“The price of a product usually falls over time. That’s often because competitors offer alternatives, or new advances make past breakthroughs less valuable.”); *see also* M.E. Cravens, *Who Sets the Price?*, FOUND. FOR ECON. EDUC. (July 1, 1958), <https://perma.cc/43JS-6H3Q> (“The customer is free to select what he, or she, considers the best buy from the many choices available.”).

58. *See* Borchers, *supra* note 45.

59. *Id.*

60. Alltucker, *supra* note 21 (statement of Simeon Taylor). Simeon Taylor is a Professor of Medicine and diabetes research at the University of Maryland School of Medicine, as well as a former employee of both Eli Lilly and the National Institutes of Health Inter-Institute Training Program in Endocrinology. *See generally*, Simeon I. Taylor, MD, PhD, UNIV. MD. SCH. MED., <https://perma.cc/Z4Z3-L5VK>.

61. STEPHEN BREYER, REGULATION AND ITS REFORM 191 (1982).

62. *See infra* Part II.B.1–5.

### 1. Disclosure Regulation

Disclosure regulations require sellers or manufacturers to provide certain information to consumers.<sup>63</sup> For example, the Food and Drug Administration requires drug manufacturers to disclose information about side effects and active ingredients in prescription drug advertisements.<sup>64</sup> Another example is Nevada's recently-implemented drug transparency law, which is a type of disclosure regulation.<sup>65</sup> The economic aim of disclosure regulation is to provide consumers with the ability to make informed choices and facilitate comparison between products by providing enough information for consumers to make a meaningful choice.<sup>66</sup> However, disclosure of information is effective only when consumers understand the information, are free to make purchasing choices on the basis of that information, and when the information disclosed is "materially relevant to the choice."<sup>67</sup> The insulin market, however, lacks competition due to patent protection and the necessity of insulin for diabetics, which prevents consumers from having any meaningful choice.<sup>68</sup> Thus, disclosure in a monopoly-controlled market would be an ineffective regulation because it would have "little practical effect on choice."<sup>69</sup>

### 2. Cost-of-Service Ratemaking

Another option to regulate a monopoly, which would likely be more effective than disclosure, is cost-of-service ratemaking.<sup>70</sup> This type of regulation lowers prices by equating them with production costs and eliminating some of the profit that manufacturers earn from holding a monopoly.<sup>71</sup> Ideally, a cost-of-service ratemaking regulatory system would keep prices near the cost of production, offer incentives to the manufacturers for production efficiency, and provide the consumers with "some guarantee of fair dealing."<sup>72</sup>

Downsides of cost-of-service ratemaking regulation include an incentive to *under-invest* in increasing production efficiency or increasing technological innovations in order to maximize profits under the regulatory

63. See BREYER, *supra* note 61, at 161.

64. 21 C.F.R. § 202.1 (2019).

65. See NEV. REV. STAT. §§ 439B.635, .645, .650 (2019); *infra* Part III.A.

66. See BREYER, *supra* note 61, at 162.

67. *Id.* at 164.

68. Borchers, *supra* note 45.

69. BREYER, *supra* note 61, at 164.

70. *Id.* at 191.

71. *Id.*

72. BREYER, *supra* note 61, at 285.

scheme.<sup>73</sup> Indeed, until the issues of patent protections and lack of competition in the insulin market are addressed, cost-of-service ratemaking regulation would do little to incentivize insulin manufacturers to invest in efficiency or technology.<sup>74</sup> Until competitors are able to enter the market, manufacturers can remain unconcerned with losing customers to more efficient or more technologically-advanced competitors.<sup>75</sup>

### 3. *Historically Based Price Regulation*

A practical alternative to cost-of-service ratemaking regulation is historically based price regulation.<sup>76</sup> This type of regulation sets current industry prices by allowing each firm to charge a previous price for a product that the government deems acceptable.<sup>77</sup> Administratively, it is an attractive type of regulation because “(1) historical prices are usually ascertainable, (2) producers can determine cost increases fairly readily, (3) the same rule can apply to all indust[ries], and (4) the rules are understandable and to some extent self-enforceable.”<sup>78</sup>

So far, governments have infrequently and temporarily implemented historically based price regulation systems.<sup>79</sup> Indeed, the longer a government utilizes this type of regulation, the less advantageous it becomes.<sup>80</sup> Downsides to historically based price regulation are

73. See Jorry M. Mwenechanya, *Approaches to Economic Regulation*, NAT’L ASS’N REG. UTIL. COMMISSIONERS (April 2011), <https://perma.cc/87N4-SC73>.

74. See generally Borchers, *supra* note 45 (“[P]atent laws allow the few dominant insulin makers to minimize competition by patenting incremental changes to their products, which makes it hard for cheaper generics to enter the market.”); Kowalski, *supra* note 48 (“Innovation costs a lot of money on the research and development end because it is expensive to develop and test new drugs.”).

75. See Borchers, *supra* note 45; Kowalski, *supra* note 48 (“Manufacturing insulin is different from other drug manufacturing because you are biologically replicating a human hormone rather than creating a chemical medicine that interacts with the body. The costs of purchasing the equipment necessary to enter this market are prohibitively expensive.”).

76. BREYER, *supra* note 61, at 60.

77. *Id.*

78. *Id.* at 62. Historical prices may be unascertainable when products are custom-made for purchasers, such as purchasers of steel who require individual specifications, or sellers that have contracts with purchasers for future delivery that provide for price increases. *Id.* at 60–61.

79. *Id.* at 61. For example, historically based price regulations have previously been used in wartime, such as the General Maximum Price Regulation during World War II or the General Ceiling Price Regulation during the Korean War. *Id.* at 60. In these cases, regulators had to make exceptions to fit circumstances such as seasonal products or sales. *Id.*

80. See *id.* at 62. In prior instances of historically based price regulations, producers learned to fit their products into exemptions, and shortages of products increased when

unavoidable and tend to worsen over time.<sup>81</sup> The same problems that appear in cost-of-service ratemaking will plague a historically based price system, including a lack of incentive for investment in efficiency or technological advancement.<sup>82</sup>

#### 4. Price Cap Regulation

Another alternative regulatory system is price cap regulation.<sup>83</sup> Price cap regulation most commonly appears in the telecommunications and utilities industries.<sup>84</sup> Colorado recently adopted this type of regulatory scheme through its “Reduce Insulin Prices” law that caps out-of-pocket insulin costs for patients at \$100 per month.<sup>85</sup>

Typically, price cap regulation is a temporary measure that aims to subject manufacturers to market pressures by promoting competition, thereby incentivizing producers to increase efficiency, reduce costs, and invest in technological innovations.<sup>86</sup> Like with disclosure regulation, price cap regulation can only increase competition if there are competitors in the market, and competitors are lacking in the insulin market due to patent protections.<sup>87</sup>

#### 5. Nationalization

An additional option, and likely the most controversial type of insulin-price regulation, is nationalization.<sup>88</sup> Nationalization occurs when the

producers switched to exempted products. For example, producers would sell apple jelly with sugar but would not sell sugar alone to avoid price freezes. *Id.* at 61.

81. *Id.* at 62–63.

82. *See id.* at 64–70. In addition, historically based price regulation can foster shortages because producers “hesitate to make new investment, discontinue unprofitable product lines, or even go out of business.” *Id.* at 66.

83. *See generally* Mark A. Jamison, *Regulation: Price Cap and Revenue Cap*, in 3 *ENCYCLOPEDIA ENERGY ENGINEERING AND TECHNOLOGY* 1245 (Barney L. Capehart ed., 2007).

84. *See generally* Ian Alexander & Timothy Irwin, Note, *Price Caps, Rate-of-Return Regulation, and the Cost of Capital*, *PUBLIC POLICY FOR THE PRIVATE SECTOR*, Sept. 1996.

85. *Colorado H.B. 19-1216: Bill Summary*, COLO. GEN. ASSEMBLY, <https://perma.cc/TJF3-V9Z4>.

86. *See* Mwenechanya, *supra* note 73. When a manufacturer is subject to a cap on the price it can charge consumers for its goods or services, the manufacturer has an incentive to increase productivity and efficiency to maximize profits. *See* FED. COMM’NS COMM’N, REPORT NO. CC 97-22, COMMISSION REFORMS ITS PRICE CAP PLAN (1997).

87. *See id.*; *see also* Borchers, *supra* note 45.

88. BREYER, *supra* note 61, at 191.

government takes over ownership and control of a private industry.<sup>89</sup> For example, in the U.S., the federal government has nationalized private industries in the form of “bailouts,” such as the bailout of AIG in 2008 and General Motors Company in 2009.<sup>90</sup>

However, nationalization is generally unpopular in the U.S. due to concerns that the resulting firm would be overly susceptible to political pressures and partisan interests.<sup>91</sup> Notwithstanding these concerns, nationalization has been an accepted practice in the U.S. in the face of industries that “cause widespread suffering and populist anger.”<sup>92</sup> Once more people realize the economic and social impact of today’s high insulin prices,<sup>93</sup> the insulin market may be an ideal candidate for nationalization to allow competitors to access the insulin formula patents and decrease insulin prices.<sup>94</sup>

In reality, an optimal regulatory solution for a complex industry such as the insulin market, which has many moving parts,<sup>95</sup> may require a

89. Justin Pritchard, *What Does It Mean to Nationalize Banks and Industries?*, BALANCE (June 15, 2019), <https://perma.cc/6TBH-ADMN>.

90. Will Kenton, *Nationalization*, INVESTOPEDIA, <https://perma.cc/XVQ8-TZRU>.

91. BREYER, *supra* note 61, at 191. People often associate nationalization with the implementation of communist or socialist government systems, such as those in Russia in 1918, Iran in 1951, and Cuba in 1960. Mary Shepard Spaeth, *Nationalization*, ENCYCLOPAEDIA BRITANNICA, <https://perma.cc/5CGB-Y85K>. Additionally, people who view a free enterprise system as an economic ideal can find nationalization troubling, especially if the government makes profit by taking over a private business. See Thomas J. Donahue, *Can the Government Nationalize a Business?*, U.S. CHAMBER COM. (Feb. 26, 2018), <https://perma.cc/2R43-JK4H>.

92. Pritchard, *supra* note 89.

93. See *supra* Part I.

94. BREYER, *supra* note 61, at 181–83. The government has previously found success in nationalizing industries during wartime, such as nationalizing railroads and coal mines during World War II. See *A History of Corporate Nationalization*, CBS NEWS (June 2, 2009), <https://perma.cc/R7WA-M7QA>. More recently, during the mortgage crisis that began in 2007, the U.S. government nationalized the nation’s largest banks that were deemed “too big to fail” because they created excessive risk for both the U.S. and global marketplace. Pritchard, *supra* note 89. Arguably, the healthcare industry is ripe for nationalization because of a growing awareness amongst the population of “abuse, a lack of transparency, and great suffering.” *Id.*

95. Diana DeGette & Tom Reed, *Insulin: A Lifesaving Drug Too Often Out of Reach*, CONG. DIABETES CAUCUS 7–11, <https://perma.cc/YZ4K-N3E8>. The insulin supply chain essentially involves two pathways, each of which implicates multiple entities. *Id.* at 7. The first pathway is from the insulin manufacturer to the pharmacy, and the second pathway is from the pharmacy to the patient/consumer. *Id.* In the first pathway, manufacturers set a list price for insulin, which forms the starting point for negotiations between the manufacturer, wholesalers, and pharmacy benefit managers. *Id.* Manufacturers give rebates, or discounts, to wholesalers that offer competitive shipping contracts. *Id.* Wholesalers then sell the

combination of types of regulation.<sup>96</sup> For example, a combination of historically based price regulation and nationalization of insulin-formula patents would likely promote competition and address the failure of market forces in the insulin market.<sup>97</sup>

### III. DESCRIPTION AND CRITIQUE OF CURRENTLY ENACTED STATE LEGISLATION AND CURRENTLY PROPOSED FEDERAL LEGISLATION AIMED AT REDUCING INSULIN PRICES

States have begun responding to the high insulin costs affecting many patients by proposing and enacting legislation.<sup>98</sup> This Section analyzes the approaches taken by Nevada and Colorado, which were the first states to enact insulin price regulation. In addition, several pieces of legislation aimed at regulating the insulin market are awaiting action in Congress.<sup>99</sup>

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insulin to pharmacies for a profit. *Id.* In the second pathway, insured patients purchase insulin from a pharmacy and typically pay for out-of-pocket expenses such as a co-payment or a co-insurance payment. *Id.* at 8. The pharmacy then collects the remainder of the list-price from the patient's pharmacy benefit manager, which likely negotiated rebates with manufacturers in exchange for preferential placement of specific insulins on the insurer's list of formulary drugs. *Id.* at 8–9. Uninsured patients, on the other hand, pay the full list-price for the insulin. *Id.* at 9.

96. *See, e.g.,* Wendell Pritchett, *Types of Regulation*, REG. REV. (Apr. 5, 2016), <https://perma.cc/F4KN-6RK7> (explaining effective regulation of a complex industry, such as higher education, may require a “mixture of approaches”).

97. *See infra* Part IV.

98. States that have proposed insulin price legislation include Florida, Massachusetts, Michigan, New Jersey, New York, Ohio, Pennsylvania, Virginia, and Wisconsin. *See* Christopher Brown, *Capping Patients' Insulin Costs on Agenda in Several States*, BLOOMBERG L. (Dec. 20, 2019), <https://perma.cc/5UZM-YSH8>; Jackson Danbeck, *Virginia's House Passes Bill to Limit Insulin Copay to \$30 for Month Supply*, NBC15 (Feb. 4, 2020), <https://perma.cc/6YSS-KDF5>. States that have passed insulin price legislation include Colorado, Nevada, and Illinois. *See* NEV. REV. STAT. § 439B.635 (2019); *HB19-1216 Bill Summary*, *supra* note 85; Jackson Danbeck, *Illinois Governor Signs Law Capping Insulin Costs at \$100 Per Month*, NBC15 (Jan. 28, 2020), <https://perma.cc/5C2Q-WYVV>.

99. Besides the Insulin Price Reduction Act, currently proposed legislation aimed at reducing insulin prices includes the Affordable Drug Manufacturing Act, which Senator Elizabeth Warren introduced on December 18, 2018. Affordable Drug Manufacturing Act of 2018, S.3775, 115th Cong. (2018). This bill proposes the establishment of an Office of Drug Manufacturing within the Department of Health and Human Services to manufacture affordable prescription drugs, including insulin. *Id.* Currently proposed legislation also includes the Affordable Insulin Act, which Representative Peter Welch introduced on February 28, 2019. Affordable Insulin Act of 2019, H.R.1478, 116th Cong. (2019). This bill proposes an amendment to the Federal Food, Drug, and Cosmetic Act to allow wholesale distributors, pharmacies, and individuals to import affordable, safe insulin from select countries. *Id.*

This Section will also examine one piece of proposed legislation—the Insulin Price Reduction Act<sup>100</sup>—and analyze the type of regulation it advances and the likely efficacy of that type of regulation in the insulin market.

### *A. Enacted State Legislation Aimed at Lowering Insulin Prices*

In 2017, Nevada adopted Senate Bill 539, otherwise known as the Insulin Price Transparency Act.<sup>101</sup> More recently, in 2019, Colorado adopted House Bill 19-1216, which has been referred to as an insulin price cap.<sup>102</sup> The contents, current effects, and potential shortcomings of both laws are discussed below.<sup>103</sup>

#### *1. Nevada's Response to Rising Insulin Prices*

On June 15, 2017, Nevada implemented a disclosure system of regulation by enacting a price transparency law.<sup>104</sup> The purpose of this law is “to provide transparency to consumers regarding significant diabetes drug price increases, the justifications for those price increases, and attempt to modify the method by which we spend money on prescription drugs.”<sup>105</sup> Lawmakers hope that the transparency resulting from the law will allow both legislatures and patients to push for drug pricing reform in the insulin market, but the law itself does not affect prices.<sup>106</sup>

Nevada’s price transparency law includes provisions requiring manufacturers of essential diabetes drugs to report data to the state regarding production costs, profit, and marketing costs of the drugs, as well as what rebates the manufacturers provide to pharmacy benefit managers.<sup>107</sup>

100. Insulin Price Reduction Act, S. 2199, 116th Cong. (2019).

101. Lydia Ramsey, *Nevada Just Passed One of the Strictest Drug Pricing Transparency Laws in the Country*, BUS. INSIDER (June 15, 2017), <https://perma.cc/TNL7-LDRM>.

102. Allison Bailey & Erin Gilmer, *Colorado's Insulin Price Cap: A Foundation to Build Upon*, TIINTERNATIONAL (July 9, 2019), <https://perma.cc/Z8LH-TLBH>.

103. See *infra* Part III.A.1–2.

104. *SB539 Overview*, NEV. ELECTRONIC LEGIS. INFO. SYS., <https://perma.cc/3DW7-6JXD>.

105. *Drug Transparency Nevada*, NEV. DEP'T HEALTH & HUM. SERVICES (Sept. 2018), <https://perma.cc/BK7F-SVJ7>.

106. See Megan Messerly, *First Diabetes Drug Transparency Report Reveals Profits, Costs Associated with Treating the Disease*, NEV. INDEP. (Mar. 13, 2019), <https://thenevadaindependent.com/article/first-diabetes-drug-transparency-report-reveals-profits-costs-associated-with-treating-the-disease>.

107. NEV. REV. STAT. § 439B.635 (2019); Ramsey, *supra* note 101. A pharmacy benefit manager is “an entity that contracts with or is employed by a third party and manages the pharmacy benefits plan or prescription drug coverage provided by a third party.” NEV. DEP'T

The law also requires pharmacy benefit managers to disclose information about the rebates they negotiate with manufacturers, along with the rebates that the pharmacy benefit managers retain for themselves.<sup>108</sup>

Once the manufacturers and pharmacy benefit manufacturers have submitted their reports to the Nevada Department of Health and Human Services (“the Department”), the law requires the Department to “analyze the information . . . and compile a report on the price of the [essential diabetes drugs], the reasons for any increases in those prices and the effect of those prices on overall spending on prescription drugs in this State.”<sup>109</sup> The Department’s 2019 Drug Transparency Report found that there was a significant price increase, during the previous year or two, of 22.4% of essential diabetes drugs.<sup>110</sup> Of those essential diabetes drugs, insulin had the second-highest significant price increase.<sup>111</sup> The average one-year increase in price for essential diabetes drugs was 6.4%, while the average two-year increase in price was 21.7%.<sup>112</sup>

According to the Department’s report, the one-year increase far exceeded the annual 2017 or 2018 Consumer Price Index, Medical Care Component, “which were 2.5% and 2.0% respectively.”<sup>113</sup> The Report concluded that “[p]rice increase percentages greater than these published [Consumer Price Index] values during each one-year period cannot be justified alone as maintaining pace with general medical inflation.”<sup>114</sup> The Report also found that “[t]he most frequent justifications for price increases in order of prevalence were research and development investments (26%), the drug has more competitive value (12%), changes in marketplace dynamics (11%), rebates provided to [pharmacy benefit managers], insurers, and others (11%), and investment in manufacturing (8%).”<sup>115</sup>

As of October 2, 2019, Nevada imposed \$17.4 million in fines on twenty-one companies for failure to comply or late compliance with the

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OF HEALTH & HUMAN SERV., SB539 DRUG TRANSPARENCY FREQUENTLY ASKED QUESTIONS, at 9 (FAQs) (Aug. 10, 2018).

108. NEV. REV. STAT. § 439B.645; Ramsey, *supra* note 101.

109. NEV. REV. STAT. § 439B.650.

110. SCOTT JONES ET AL., NEV. DEP’T OF HEALTH & HUMAN SERVS., DRUG TRANSPARENCY REPORT: 2019 ESSENTIAL DIABETES DRUGS 4 (2019), <https://perma.cc/N4PZ-8PHT>.

111. *Id.*

112. *Id.*

113. *Id.*

114. *Id.*

115. *Id.* at 10.

reporting requirements under the law.<sup>116</sup> The Department informed the companies of the requirement to either pay the fines in full within thirty days or request an informal dispute resolution meeting within ten days.<sup>117</sup> Failure to respond would result in a case referral to the attorney general's office to collect the fines through a court order.<sup>118</sup>

Transparency regulations, like Nevada's, are meant to inform patients and consumers about insulin prices, but the laws on their own "are unlikely to substantially reduce insulin prices in the [United States]."<sup>119</sup> Instead, these laws are designed to enable future reforms using the data.<sup>120</sup> It is admirable that states like Nevada are seeking to increase insulin price transparency; however, while it may eventually lead to pricing reforms in the future,<sup>121</sup> it is not enough. Lowering insulin costs for patients who are struggling to survive will require more aggressive legislation aimed at decreasing out-of-pocket costs of insulin.

## 2. Colorado's Response to Rising Insulin Prices

Unlike Nevada, Colorado enacted a law aimed at capping insulin prices.<sup>122</sup> House Bill 19-1216 became effective on January 1, 2020.<sup>123</sup> The Act caps out-of-pocket insulin costs at \$100 for a one-month prescription supply.<sup>124</sup> In addition, "[t]he bill requires the department of law to investigate the pricing of prescription insulin drugs and submit a report of its findings to the governor, the commissioner of insurance, and the judiciary committees of the senate and house of representatives."<sup>125</sup>

Colorado's approach raises the concern that it will result in increased insurance premiums because insurance companies will have to absorb the

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116. Megan Messerly, *Nevada Levies \$17 Million in Fines on Drug Companies for Noncompliance with Diabetes Drug Transparency Law*, NEV. INDEP. (Oct. 2, 2019), <https://perma.cc/AT3C-7USP>.

117. *Id.*

118. *Id.*

119. Jing Luo et. al., *Strategies to Improve the Affordability of Insulin in the USA*, 5 LANCET DIABETES & ENDOCRINOLOGY 159 (Mar. 1, 2017), <https://perma.cc/HQG8-XXZ3?type=image>.

120. *Id.*

121. See NEV. REV. STAT. § 439B.650 (2019); S.F. 366, 91st Leg., Reg. Sess. (Minn. 2019).

122. *Colorado H.B. 19-1216 Bill Summary*, *supra* note 85.

123. *Id.*

124. *Id.*

125. *Id.*

costs of the insulin list price beyond the \$100 price cap.<sup>126</sup> However, insurance companies' justifications for the 2020 insurance rates either did not mention the insulin price cap as a factor in their calculations or referred to the influence of the insulin price cap as "negligible" and "*de minimus* [sic]."<sup>127</sup> Indeed, so far, insurance rates for Colorado residents have not increased as a result of the law.<sup>128</sup>

Another concern about Colorado's price cap regulation is that it does not cap the price of insulin for all diabetics; rather, it caps the price only for individuals with private health insurance.<sup>129</sup> This means that individuals without insurance, or individuals covered by government programs like Medicare or employer self-funded "ERISA plans," will not benefit from the price cap.<sup>130</sup>

Additionally, Colorado legislators are already planning to respond to a "loophole" in the law.<sup>131</sup> While the law is meant to cap total out-of-pocket monthly expenses on insulin at \$100, the law currently limits what patients pay to \$100 *per prescription*, so patients could still pay \$200 or \$300 per month if they require two or three types of insulin.<sup>132</sup>

### *B. Proposed Federal Legislation Aimed at Lowering Insulin Prices*

On July 22, 2019, Senator Jeanne Shaheen introduced the Insulin Price Reduction Act, which is co-sponsored by Senators Collins, Carper, and Cramer.<sup>133</sup> Senators Shaheen and Carper are Democrats, and Senators Collins and Cramer are Republicans, making this a bipartisan bill.<sup>134</sup>

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126. John Ingold, *Critics Worried Colorado's New Law Capping Insulin Costs Would Raise Insurance Rates. It Hasn't*, COLO. SUN (Sept. 11, 2019), <https://perma.cc/4VYN-MY7G>.

127. *Id.*

128. See Meg Wingerter, *Lawmaker Looks to Close "Loophole" in Colorado's First-In-The-Nation Insulin Price Cap*, DENVER POST (Jan. 10, 2020), <https://perma.cc/HP2D-NX4C> ("So far, insurance plans in Colorado haven't substantially increased rates in response to the insulin price cap . . .").

129. *Id.*

130. *See id.*

131. *Id.*

132. *Id.*

133. Insulin Price Reduction Act, S. 2199, 116th Cong. (2019); Todd Boudreaux, *Senate Bill Aims to Cut Price of Insulin by 75%*, BEYOND TYPE 1 (July 22, 2019), <https://perma.cc/U3BJ-VEGR>.

134. Boudreaux, *supra* note 133.

### 1. Overview of the Insulin Price Reduction Act

The Insulin Price Reduction Act, a form of historically based price regulation, targets rebates from insulin manufacturers to pharmacy benefit managers and insurers<sup>135</sup> by restricting the use of rebates<sup>136</sup> for insulin if the manufacturer voluntarily reduces the list price to no higher than its 2006 list price.<sup>137</sup> In addition, the Insulin Price Reduction Act would bar the pharmacy benefit manager or insurer from excluding such an insulin from formulary lists or otherwise adding barriers to patients' access to that insulin.<sup>138</sup> To continue to qualify for the restrictions, the manufacturer could not increase the list price of that insulin by more than the medical inflation increase<sup>139</sup> for that year.<sup>140</sup> If the law passes, patients could expect a 75% price decrease from the otherwise expected prices of popular insulin brands for 2020.<sup>141</sup>

### 2. Potential Downsides of the Insulin Price Reduction Act

The Insulin Price Reduction Act has not yet been passed in the Senate, let alone passed in the House and sent to the President for signing.<sup>142</sup> However, it is possible to speculate on the types of issues that could arise from historically based price regulation.<sup>143</sup>

Because the Insulin Price Reduction Act was recently introduced, it still has to make it through committees, Senate debates,<sup>144</sup> and other obstacles. One such obstacle could be competing legislative measures, such

135. The rebate restrictions applied to both private insurers and Medicare Part D. *Id.*

136. See Degette & Reed, *supra* note 95.

137. Craig Idlebrook, *The Senate's Insulin Price Reduction Act: What You Need to Know*, T1D EXCHANGE GLU (July 24, 2019), <https://perma.cc/7RRS-QTFJ>. Limiting the cost to no more than the price for the same product in 2006 appears to be a type of historically price-based regulation. See *id.*

138. *Id.*

139. Medical inflation "refers to medical trends and developments, and the increase in cost to support them. This often includes the cost of advances in treatments and procedures, and the increased availability and usage of them around the world." *The Mystery Behind Medical Inflation*, AXA (Aug. 27, 2018), <https://perma.cc/JAL5-Y5JR>. The Consumer Price Index measures and reports this rate of inflation annually. *Measuring Price Change in the CPI: Medical Care*, U.S. BUREAU LAB. STATS. (Apr. 24, 2019), <https://perma.cc/9NMW-NCUV>.

140. Idlebrook, *supra* note 137.

141. Boudreaux, *supra* note 133.

142. See Insulin Price Reduction Act, S. 2199, 116th Cong. (2019).

143. See BREYER, *supra* note 61, at 60–70.

144. See *How Laws Are Made and How to Research Them*, USA Gov, <https://perma.cc/R8P5-DKA3> (last updated Aug. 27, 2019).

as other drug pricing laws that have recently been introduced.<sup>145</sup> Another obstacle may be partisan measures as the 2020 election approaches and politicians need to garner support from their electorates, even though the Insulin Price Reduction Act is a bipartisan bill.<sup>146</sup>

If the Insulin Price Reduction Act is signed into law, the law will face the shortcomings attendant to historically based price regulation systems.<sup>147</sup> For example, the Act may end up only a temporary solution as drug manufacturers find loopholes, stop investing in efficiency or technological advancements, and decrease production of popular insulin brands.<sup>148</sup>

Additionally, historically based price regulation systems are typically utilized in industries with “large numbers of firms with disparate costs.”<sup>149</sup> In the insulin manufacturing market, there are only three major firms—Eli Lilly, Novo Nordisk, and Sanofi<sup>150</sup>—and their costs are not disparate.<sup>151</sup> Without competitors in the market, these three manufacturers have little financial incentive to keep costs down once the historically based price regulation is lifted or once the manufacturers find loopholes or exemptions in the system.<sup>152</sup> Accordingly, because the Insulin Price Reduction Act fails to address insulin manufacturers’ monopolistic power, the law is missing a crucial element to allow natural market forces to function—competition.

#### IV. PROPOSED SOLUTION

While the Insulin Price Reduction Act seeks to address the current high prices of insulin as a historically based price regulation, it is likely a temporary solution.<sup>153</sup> Until competitors can enter the market and exert downward pressure on the three large insulin manufacturers to reduce

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145. See Idlebrook, *supra* note 137. One such competing bill seeks to cap drug prices for Medicare recipients, which has gained more publicity and has been featured in more news stories than the Insulin Price Reduction Act. *Id.*

146. *Id.*

147. See BREYER, *supra* note 61, at 60–70.

148. See *id.*

149. *Id.* at 60.

150. William T. Cefalu et. al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, 41 *DIABETES CARE* 1299, 1300 (June 2018), <https://perma.cc/7U6G-JGYN>.

151. For example, “when one insulin manufacturer increases the price for a given insulin formulation, the other insulin manufacturers often increase their prices by a similar amount shortly thereafter.” *Id.* at 1301.

152. See, e.g., Borchers, *supra* note 45.

153. See BREYER, *supra* note 61, at 61 (“[A] pure historical price freeze has never been imposed for long.”).

prices, the monopolistic power of those manufacturers will persist.<sup>154</sup> To resolve this issue, this Comment proposes that Congress pass a law that contains the provisions already written in the Insulin Price Reduction Act *plus* a provision directing the government (through a department such as the U.S. Department of Health and Human Services) to nationalize insulin formula patents and allow competitors to enter the market.

#### *A. Source of the Government's Power to Seize Control of Patents*

Congress has provided the United States government with the power of nationalization to use and manufacture patented items.<sup>155</sup> The statute, 28 U.S.C. section 1498(a), provides:

Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States . . . [the patent holder can sue the United States in the Court of Federal Claims for a remedy of] reasonable and entire compensation for such use and manufacture.<sup>156</sup>

Because section 1498(a) provides a remedy to patent-holders for the government's use or manufacture of patented items, the statute necessarily presupposes that the government can use or manufacture patented items in the first place.<sup>157</sup> Indeed, section 1498(a) has been referred to as "eminent domain for patents."<sup>158</sup> Under section 1498(a), "patent holders can demand royalties but cannot stop the government from producing the medicine or allowing [generic manufacturers] to produce or import the medicine."<sup>159</sup>

#### *B. Historical Uses of 28 U.S.C. Section 1498(a)*

The government has previously enforced section 1498(a) in at least two areas: military supplies and pharmaceuticals.<sup>160</sup> In the past, the government has mostly utilized section 1498(a) in the military context, such

154. See, e.g., *Competition Counts: How Consumers Win When Businesses Compete*, FED. TRADE COMMISSION, <https://perma.cc/83XS-DK2J>.

155. See 28 U.S.C. § 1498(a) (2018); see also Amy Kapczynski & Aaron S. Kesselheim, 'Government Patent Use': A Legal Approach To Reducing Drug Spending, 35 HEALTH AFF. 791 (2016) (discussing the potential use of section 1498(a) in the context of direct-acting antiviral drugs for the treatment of hepatitis C).

156. 28 U.S.C. § 1498(a).

157. See Scott A. Felder, *Federal Circuit Reinforces Broad Reach of 28 U.S.C. § 1498*, WILEY REIN LLP (Sept. 21, 2015), <https://perma.cc/YA7P-A5W5>.

158. Natalie Shure, *Force Drug Companies to Lower Prices*, AM. PROSPECT (Sept. 26, 2019), <https://perma.cc/6K2L-PGQR> (internal quotation marks omitted).

159. Kapczynski & Kesselheim, *supra* note 155, at 792.

160. See Shure, *supra* note 158.

as procuring night-vision goggles and lead-free bullets.<sup>161</sup> In the pharmaceutical context, the government has sought to use section 1498(a) at least once,<sup>162</sup> laying precedent that it can be used in the insulin market. For example, the threat of anthrax as a chemical weapon in 2001 prompted the government to attempt to stockpile ciprofloxacin (Cipro), an antibiotic used to treat exposure to anthrax.<sup>163</sup> The manufacturer of Cipro, Bayer, resisted producing more Cipro and refused to lower prices for the government.<sup>164</sup> In response, the health and human services secretary threatened to import generic versions of Cipro under section 1498.<sup>165</sup> Bayer relented, guaranteeing both an adequate supply of Cipro and a 50% discount in the drug's price.<sup>166</sup> Because the government has previously brandished section 1498 in the pharmaceutical context, it follows that the government could choose to use section 1498 to correct the current insulin market.

*C. Combining 28 U.S.C. Section 1498(a) With the Insulin Price Reduction Act*

If the Insulin Price Reduction Act were to include a provision directing a department, such as the U.S. Department of Health and Human Services to use insulin formula patents, many of the shortcomings of a historically based price regulation system could be curtailed.

Historically based price regulation systems must usually be temporary measures to avoid shortages.<sup>167</sup> The 2006 pricing regulation provision of the Insulin Price Production Act could similarly be a temporary measure until competitors enter the market through the use of insulin formula patents.<sup>168</sup> Once competitors have entered the market, the 2006 pricing regulation could be lifted. Normal competitive market forces could keep insulin prices reasonable without the 2006 pricing regulation, and consumers would have the power to choose an effective, affordable product from whichever competitor they prefer, as in a typical product market.<sup>169</sup>

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161. *Id.*

162. Kapczynski & Kesselheim, *supra* note 155, at 794.

163. *Id.*

164. *Id.*

165. *Id.*

166. *Id.*

167. See BREYER, *supra* note 61, at 60.

168. See generally Kowalski, *supra* note 48.

169. See, e.g., Kowalski, *supra* note 48; see also Mwenechanya, *supra* note 73; Borchers, *supra* note 45.

*D. Probable Objections to the Use of 28 U.S.C. Section 1498(a)*

As with any individual facing a governmental exercise of eminent domain over his or her property, insulin manufacturers would probably object to the government's use of their closely-guarded patents.<sup>170</sup> One likely objection would be an argument that the nationalization of insulin formula patents would interfere "with their incentives to invest in innovation."<sup>171</sup> However, this argument is likely without merit, as "such incentives would remain robust if the government royalties [paid to the drug manufacturers] were sufficient to compensate the companies for research and development costs, adjusted for risk of failure and margins of error in calculations made by a court or agency."<sup>172</sup>

## CONCLUSION

The combination of historically based price regulation and nationalization will allow typical market forces to resume in the insulin market. Congress should amend and pass the Insulin Price Reduction Act<sup>173</sup> to reflect this Comment's suggestion to include nationalization of insulin formula patents. As written, the Insulin Price Reduction Act is only a partial, temporary solution—a band-aid—for a larger problem of failed market forces. If amended and passed, the Insulin Price Reduction Act will reduce insulin prices both immediately through historically based price regulation and long-term by fostering competition—the foundation of a successful market economy.<sup>174</sup>

*Erin M. Barker\**

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170. See, e.g., Mwenechanya, *supra* note 73; see also Borchers, *supra* note 45.

171. Kapczynski & Kesselheim, *supra* note 155, at 795.

172. *Id.*

173. Insulin Price Reduction Act, S. 2199, 116th Cong. (2019).

174. See, e.g., J.H. Cullum Clark, *Why America's Free Market Economy Works Better in Some Places than Others*, GEORGE W. BUSH INST. (2019), <https://perma.cc/B3M3-PPRH>.

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