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The Pricelessness of Life vs. Profiting from Illness: A Call for Change to the Pricing Model for Lifesaving Drugs in the United States

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The Pricelessness of Life vs. Profiting from Illness: A Call for Change to the Pricing Model for Lifesaving Drugs in the United States

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"Prescription drug corporations are profiteering off of the pocketbooks of sick individuals—it's wrong. It's time to stand up to this abuse of power . . . ."

– President Joe Biden[1]

ABSTRACT

Pharmaceutical drug prices in the United States are at the highest costs yet seen, and it looks like these prices are still continuing to climb. While people in the United States are struggling to pay for necessary medications, the prices of those same medications are drastically lower in other countries.

This Article directly analyzes the issue of pharmaceutical pricing in the United States through two specific lifesaving drugs, insulin and epinephrine. Both drugs are prescriptions required to keep some people alive, and both are related to manufacturing companies with questionable, overwhelming control of the markets. While there has been recent movement in both the federal and state governments to address the issue of price, affordability continues to be in question. However, other countries manage to keep the costs of pharmaceutical drugs far below the prices of those in the United States. The United Kingdom, Canada, and Germany each has a different strategy that involves government intervention to keep prices down, using models that focus, respectively, on product price control, reference pricing, and profit control. By implementing aspects of each of these other countries' pricing models, particularly a system for reference pricing and a pharmaceutical review board, the United States can hope to make it affordable to live.

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* Duquesne University Thomas R. Kline School of Law, J.D. 2023; Case Western Reserve University, B.A. Anthropology, B.A. International Studies, 2020. Thank you to Professor Jan M. Levine for your invaluable guidance on this article and for introducing me to the world of legal writing, and thanks to the staff of the Duquesne Law Review, Volume 61, for helping throughout the editing process. Most importantly, thank you to my parents and sisters. I cannot imagine surviving law school and my T1D diagnosis without your immense love and unwavering support.

1. Joe Biden (@JoeBiden), TWITTER (Nov. 26, 2019, 6:34 PM), https://twitter.com/joebiden/status/1199471394612023303.

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I. INTRODUCTION

When he could no longer be covered by his mother's insurance at 26 years old, restaurant manager Alec Raeshawn Smith faced more than a financial problem.[2] Living with type 1 diabetes, Alec was well aware of his daily need for insulin.[3] However, he could not afford the monthly $1,300 cost of supplies without insurance or the deductible for a health insurance plan.[4] Instead, he tried to ration his insulin until he could make it to his next payday.[5] He died from diabetic ketoacidosis[6] three days before he would have gotten his pay.[7]

Another person was surprised by the need for her medication. Eating the same coconut cashew snack she had had for years

2. 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.

3. *Id.*

4. *Id.*

5. *Id.*

6. When people with type 1 diabetes skip injections or take less insulin than they need, it "can lead to diabetic ketoacidosis, which occurs when your blood sugar gets so high that your blood becomes acidic, your cells dehydrate, and your body stops functioning." *The Deadly Consequences of Insulin Rationing*, PASADENA HEALTH CTR. (Nov. 16, 2018), https://www.pasadenahealthcenter.com/blog/community-healthcare/deadly-consequences-insulin-rationing/.

7. *Id.*

without issue, Denise Ure was not expecting to taste peanuts.[8] Knowing that consuming the food she was allergic to could cause serious symptoms, Denise tried to spit out the food and watch herself for signs of anaphylaxis.[9] But instead of immediately using her EpiPen to quell any reaction, she drove herself to the hospital in hopes that her symptoms would not get severe enough to "justify" the use of her expensive medication.[10] On her blog, Denise explained the dilemma, claiming that, "[t]here is psychological resistance to using an EpiPen. You don't want to waste a very expensive auto-injector on a false alarm."[11]

Denise was lucky that she safely made it to the hospital,[12] but that is not always the case.[13] Many patients in the United States who rely on some type of prescription medication to live are struggling to afford it.[14] Instead, people are gambling with their lives because they have to choose whether to pay the outrageous prices for their medication or pay for food for their family.[15] For people struggling with conditions like type 1 diabetes or severe allergies, foregoing medication is not an option.

Although health insurance plans may cover some of the costs, copays continue to be substantial,[16] and some people, like Alec Smith, will not always be able to be insured. The full retail price of a drug can be even costlier than a home mortgage,[17] and prescription drug

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8. Elizabeth Pratt, *Rising Cost of EpiPens Forcing Some Allergy Sufferers to Switch to Syringes*, HEALTHLINE, https://www.healthline.com/health-news/cost-of-epipens-forcing-allergy-sufferers-to-syringes#EpiPens-vs.-syringes (last visited Nov. 18, 2022).

9. *Id.*

10. *Id.*

11. *Id.*

12. *Id.*

13. Severe allergic reactions require immediate medical attention because symptoms, which can include swelling in the throat and difficulty breathing, typically occur within minutes of exposure to an allergen and worsen quickly. *See Anaphylaxis*, BETTER HEALTH CHANNEL, https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/anaphylaxis (last visited Nov. 18, 2022).

14. *See* Steven Reinberg, *18 Million Americans Can't Pay for Needed Meds*, U.S. NEWS & WORLD REP. (Sept. 22, 2021, 11:52 AM), https://www.usnews.com/news/health-news/articles/2021-09-22/18-million-americans-cant-pay-for-needed-meds.

15. *See* Irl B. Hirsch, *Insulin in America: A Right or a Privilege?*, 29 AM. DIABETES ASS'N 130, 131 (2016).

16. For one type of insulin, Lantus SoloStar, the full retail price is approximately $457 for one vial. *Lantus SoloStar Prices, Coupons and Patient Assistance Programs*, DRUGS.COM, https://www.drugs.com/price-guide/lantus-solostar (last visited Nov. 18, 2022). Insurance coverage differs depending on the brand of medication, the insurance carrier, and the insurance plan. A copay for the same amount of Lantus SoloStar can range from $4 to over $400. *Lantus Medicare Coverage and Co-Pay Details*, GOODRX, https://www.goodrx.com/lantus/medicare-coverage?dosage=3ml-of-100-units-ml&form=solostar-pen&label_override=Lantus&quantity=5&sort_type=popularity (last visited Nov. 18, 2022).

17. Hirsch, *supra* note 15.

prices continue to increase.[18] A person who cannot afford insurance often will not be able to afford the out-of-pocket costs of medication.[19] Rationing medication is not a realistic option for those living with type 1 diabetes,[20] and expired epinephrine is not effective in stopping an allergic reaction.[21]

This Article directly analyzes the issue of pharmaceutical pricing in the United States through two specific lifesaving drugs: insulin, a widely-used drug in the United States predicted to increase in use;[22] and epinephrine, a medication associated with one of the highest drug price hikes in the United States.[23] Section II provides background on the history of these drugs and their current status in the United States. Section III introduces pharmaceutical pricing models used by other countries. Section IV argues that Germany's reference pricing model for drug pricing should be implemented in the United States in order to address this drug pricing crisis.

II. LIFESAVING DRUGS AND THE UNITED STATES

The pharmaceutical industry is almost unfettered in the United States when it comes to pricing,[24] with companies continuing to

18. *See* Alex Keown, *Drug Price Increases for 460 Drugs in 2022*, BIOSPACE (Jan. 4, 2022), https://www.biospace.com/article/a-new-year-means-price-increases-for-many-prescription-drugs/.

19. Alec Smith, for example, was deterred from getting insurance when he realized he would have to pay $7,600 before insurance would kick in; but then he could not afford the $1,300 costs of his medical supplies per month. Sable-Smith, *supra* note 2.

20. *See supra* note 6 and accompanying text.

21. Although expired epinephrine may be somewhat effective and better than no epinephrine at all, the drug "deteriorates over time and relying on an outdated one . . . can leave [a person with severe allergies] with an auto-injector that's less effective, or not effective at all, when [he or she] most need[s] it." Ginger Skinner, *What You Need to Know About Expired EpiPens*, CONSUMER REPS. (Aug. 26, 2016), https://www.consumerreports.org/drugs/expired-epipens-what-you-need-to-know/.

22. *See generally* Tara O'Neill Hayes & Margaret Barnhorst, *Understanding the Insulin Market*, AM. ACTION F. (Mar. 30, 2020), https://www.americanactionforum.org/research/understanding-the-insulin-market/ ("Soon, nearly 10 million Americans will need to take insulin every day to live.").

23. Epinephrine is available through Viatris, formerly named Mylan, a corporation which raised the price over 400% since acquiring the drug's delivery device. Emily Willingham, *Why Did Mylan Hike EpiPen Prices 400%? Because They Could*, FORBES (Aug. 21, 2016, 9:00 AM), https://www.forbes.com/sites/emilywillingham/2016/08/21/why-did-mylan-hike-epipen-prices-400-because-they-could/?sh=7339d742280c.

24. Unlike other countries, "the U.S. lets manufacturers of drugs and biologics set whatever price they choose." Paul B. Ginsburg & Steven M. Lieberman, *Government Regulated or Negotiated Drug Prices: Key Design Considerations*, BROOKINGS INST. (Aug. 30, 2021), https://www.brookings.edu/essay/government-regulated-or-negotiated-drug-prices-key-design-considerations/.

raise prices on older drugs.[25] Because of the sheer number of pharmaceutical lobbyists in D.C.,[26] the lack of restrictions on corporate "donations" to politicians,[27] and the nature of our capitalist society,[28] public outcry for federal price negotiation has been successfully squelched up to this point, keeping drug prices far higher in the United States than comparable countries.[29] According to a 2019 study by the U.S. House Committee on Ways and Means, the international average cost of a pharmaceutical, excluding United States prices, is $124.45.[30] In comparison, the average cost in the United States is $466.15, and the most expensive drug in the United States is a staggering $12,000 more than its counterpart in Germany, the country with the next highest-priced drug.[31] This staggering price gap cannot be explained by gross domestic product levels alone.[32] Despite promises for change, President Biden has yet to make headway in closing the gap.[33] The United States "continue[s] to be an outlier among wealthy, Western nations with such a scant

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25. *See generally* PHARMA BRO (Amazon Prime Video 2021) (documenting the story of Martin Shrekli, a convicted felon, who raised the price of a dated, lifesaving, antiparasitic medication by 5500% overnight).

26. In 2021, there were approximately 1,780 pharmaceutical lobbyists, spending over $350 million lobbying for pharmaceuticals and health products. *Industry Profile: Pharmaceuticals/Health Products*, OPEN SECRETS, https://www.opensecrets.org/federal-lobbying/industries/summary?cycle=2021&id=H04 (last visited Nov. 18, 2022).

27. Politicians continue to accept campaign donations from "drugmakers" including insulin-manufacturers Sanofi, Eli Lilly, and Novo Nordisk. *See* Victoria Knight et al., *Pharma Campaign Cash Delivered to Key Lawmakers with Surgical Precision*, KHN (Oct. 25, 2021), https://khn.org/news/article/pharma-campaign-cash-delivered-to-key-lawmakers-with-surgical-precision/.

28. *See generally* Mark S. Levy, Comment, *Big Pharma Monopoly: Why Consumers Keep Landing on "Park Place" and How the Game is Rigged*, 66 AM. U. L. REV. 247 (2016).

29. *See* Dan Diamond & Amy Goldstein, *A Bitter Pill: Biden Suffers Familiar Defeat on Prescription Drug Prices*, WASH. POST (Oct. 29, 2021, 12:43 PM), https://www.washingtonpost.com/health/2021/10/29/biden-medicare-drug-negotiation/.

30. COMM. ON WAYS AND MEANS, A PAINFUL PILL TO SWALLOW: U.S. VS. INTERNATIONAL PRESCRIPTION DRUG PRICES 15 (2019) [hereinafter A PAINFUL PILL TO SWALLOW].

31. *Id.*

32. *See id.* at 16 (noting that: "If per capita GDP is positively associated with drug prices in a given country, we would expect the 11 non-U.S. countries in our analysis to have drug prices at about 80 percent of those in the U.S. . . . this was not the case: [f]or the drugs included in this analysis, the combined average drug prices were 26.8 percent . . . of average U.S. drug prices.").

33. A 2,000-page omnibus piece of potential legislation called the Build Back Better Act is currently making its way through Congress in an attempt to solve multiple issues in the United States, including drug pricing. If adopted, the act "would empower Medicare to negotiate prices for a relatively small number of the priciest prescription drugs, require rebates when drug prices rise faster than inflation and cap out-of-pocket costs for many Americans purchasing insulin." *See* Jeff Overley & Adam Lidgett, *Buckle Up: Wild Ride Awaits Health, Life Sci Policy in 2022*, LAW360 (Jan. 3, 2022, 12:03 PM), https://plus.lexis.com/newsstand#/article/1449226. Though the act has made its way to the Senate, it is not expected to pass in its current iteration due to its bipartisan nature. *Id.* If it did, the act will only affect the pricing problems concerning a few drugs, such as insulin. *Id.*

government role in determining the prices consumers pay for the medicines they need."[34]

Even for those citizens covered by health insurance plans in the United States, many patients cannot afford the medications they require,[35] instead having to choose between their own health and lives and providing food for their families.[36] Two of these lifesaving drugs, in particular, show the extent of this issue: insulin, a medication with pricing issues affecting a growing number of people,[37] and epinephrine, a medication that has had one of the highest price hikes permitted in the United States.[38]

A. Insulin

Insulin is a biologic drug required by people with type 1 diabetes[39] because their pancreas makes little to no natural insulin and cannot break down sugar by itself, letting more sugar than necessary into the blood stream and making the blood too acidic.[40] The patient either injects the medicine prior to each meal and before nighttime, or he or she receives a constant distribution of insulin to the blood stream through a pump.[41] Type 1 diabetes is a genetic autoimmune disorder that currently cannot be prevented; without treatment, the resulting high blood sugar and diabetic ketoacidosis will lead to a coma and eventual death.[42]

For many decades there were no effective treatments for diabetes.[43] Patients tried to stick to simple diets with very low amounts

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34. Diamond & Goldstein, *supra* note 29.

35. Copays range widely. *See supra* note 16 and accompanying text. Even then, not all insurances and plans cover the exact types of medications that people need or that is effective, including common emergency medications like the EpiPen. *See* Patti Neighmond, *When Insurance Won't Cover Drugs, Americans Make 'Tough Choices' About Their Health*, NPR (Jan. 27, 2020, 5:05 AM), https://www.npr.org/sections/health-shots/2020/01/27/799019013/when-insurance-wont-cover-drugs-americans-make-tough-choices-about-their-health.

36. Hirsch, *supra* note 15.

37. *See supra* note 22 and accompanying text.

38. *See supra* note 23 and accompanying text.

39. Insulin is also required in treatment for other types of diabetes, such as more severe cases of Type 2 Diabetes. Approximately 26.9 million people in the United States are diagnosed with diabetes, while millions of others are potentially undiagnosed. Around 11% of these people began using insulin in their care within a year of diagnosis, and the numbers are increasing. *See* CTRS. FOR DISEASE CONTROL & PREVENTION, NATIONAL DIABETES STATISTIC REPORT 4 (2020), https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.

40. *What is Diabetes?*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/diabetes/basics/diabetes.html (last visited Nov. 18, 2022).

41. *See* Daphne E. Smith-Marsh, *Insulin Delivery*, ENDOCRINEWEB (May 16, 2019), https://www.endocrineweb.com/guides/insulin/insulin-delivery.

42. *What is Diabetes?*, *supra* note 40.

43. *See generally* MICHAEL BLISS, THE DISCOVERY OF INSULIN (1982).

of carbohydrates and sugars, rarely living to adulthood if diagnosed as a child.[44] Frederick Banting and Charles Best first discovered the only extant treatment when they isolated insulin from the pancreas of an animal in 1921.[45] Banting and Best sold the insulin patent two years later to the University of Toronto for $1 to each inventor, intending that the drug be distributed as widely and quickly as possible, and insisting on affordability and accessibility for every diabetic.[46] Yet one hundred years later, diabetics are still struggling without the lifesaving medication that they need, unsuccessfully rationing medication because of the drug's current unaffordability.[47] Between the cost of care and the exorbitant price of the drug, diabetics must pay up to thousands of dollars a month to manage their health.[48]

There have been substantial changes to diabetic care since the discovery of the insulin drug, but insulin continues to be necessary for those living with type 1 diabetes. Banting and Best's first iteration was animal insulin;[49] however, human insulin[50] was later introduced in 1982 and analog insulin[51] was developed in 1996.[52] Though animal and human insulin may still be used in some cases, these iterations are suboptimal because the drugs are less predictable and do not work the same way as natural insulin does in the body.[53] Analog insulins can keep the body regulated over a longer period of time and are less likely to cause dangerous spikes and falls in glucose levels in human blood.[54] Each iteration, with notably nominal changes from the last variety, came with a request for a new patent, along with the increased reliability.[55]

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44. *The History of a Wonderful Thing We Call Insulin*, AM. DIABETES ASS'N (July 1, 2019), https://diabetes.org/blog/history-wonderful-thing-we-call-insulin.

45. *Id.*

46. Amy Moran-Thomas, *One Hundred Years of Insulin for Some*, 385 NEW ENG. J. MED. 293, 293 (2021).

47. *Id.* at 294.

48. *See, e.g.*, Sable-Smith, *supra* note 2.

49. Animal insulin is taken from the pancreases of cows and pigs. Daniel Yetman, *What to Know About Human Insulin and How It Works*, HEALTHLINE (Oct. 27, 2021), https://www.healthline.com/health/diabetes/human-insulin.

50. Human insulin, first introduced in the 1980s, is synthetically created in a lab "by growing insulin proteins inside *E. coli* bacteria." *Id.*

51. Insulin analogs "are made in the same way as human insulin but are genetically altered to change the way they act in your body," and are quicker to lower blood sugar. *Id.*

52. Hirsch, *supra* note 15, at 130.

53. Unlike human and animal insulins, analogs tend to clump less under the skin and "are absorbed more predictably." Yetman, *supra* note 49.

54. Jessica Zelitt, *Pay or Die: Evaluating the United States Insulin Pricing Crisis and Realistic Solutions to End It*, 50 STETSON L. REV. 453, 459 (2021).

55. *See* S. Vincent Rajkumar, MD, *The High Cost of Insulin in the United States: An Urgent Call to Action*, MAYO CLIN. PROC., Jan. 2020, at 23.

Currently, three companies—Sanofi, Eli Lilly, and Novo Nordisk—practically dominate the market for insulin, manufacturing approximately 90% of the global market of the drug.[56] These companies maintain their monopolies through "filing and securing multiple patents on the same drug" to extend patent protection, and they have virtually no competition.[57] The way these companies tend to hike their prices for insulin at the same time[58] alone shows the cooperation agreement created amongst themselves to ensure keeping the market's profits to themselves.[59] Other companies may not have room to get involved and create cheaper alternatives because of the actions of these insulin manufacturers.[60]

Consequently, prices have climbed exponentially in the last 15 years, even adjusting for inflation.[61] While in the early 2000s a vial of analog insulin would cost around $60 out-of-pocket, the cost of the same amount of the drug climbed 116% by 2012.[62] As of 2019,

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56. Zelitt, *supra* note 54, at 460.

57. Rajkumar, *supra* note 55. *See also infra* notes 93-97 and accompanying text (explaining how filing patents in this manner is legal).

58. A government study shows that these insulin manufacturers engaged in these agreed-on price hikes with each other, a process known as "shadow pricing":

> Internal documents show that the three largest insulin manufacturers raised their prices in lockstep in order to maintain "pricing parity," and that senior executives encouraged this practice. Eli Lilly and Novo Nordisk have raised prices in lockstep on their rapid-acting insulin products, Humalog and NovoLog, while Sanofi and Novo Nordisk have raised prices in lockstep on their long-acting insulin products, Lantus and Levemir. In a discussion among Novo Nordisk employees about an Eli Lilly price increase for a different diabetes product on December 24, 2015, a Novo Nordisk pricing analyst remarked, "[M]aybe Sanofi will wait until tomorrow morning to announce their price increase . . . that's all I want for Christmas."

U.S. HOUSE OF REPRESENTATIVES' COMM. ON OVERSIGHT AND REFORM, DRUG PRICING INVESTIGATION xii (2021) [hereinafter DRUG PRICING INVESTIGATION].

59. Zelitt, *supra* note 54, at 460.

60. *See generally* Ryan Knox, *Insulin Insulated: Barriers to Competition and Affordability in the United States Insulin Market*, J. L. BIOSCI. 1, 17 (2020). Civica Rx, a not-for-profit generic drug company and consortium of numerous hospital systems and philanthropic groups, is attempting the feat of entering the market and selling insulin vials for no more than $30, but the company is awaiting approval from the Food and Drug Administration, construction of its own pharmaceutical plant, and more funding. *See* Christopher Rowland, *A Group of Hospitals Has a Plan to Get Around Congress's Refusal to Lower the Cost of Insulin*, WASH. POST (Mar. 3, 2022, 7:00 AM), https://www.washingtonpost.com/business/2022/03/03/cheaper-insulin-plan/; *see also* Carolyn Y. Johnson, *Hospitals Are Fed Up With Drug Companies, So They're Starting Their Own*, WASH. POST (Sept. 6, 2018, 12:01 AM), https://www.washingtonpost.com/national/health-science/hospitals-are-fed-up-with-drug-companies-so-theyre-starting-their-own/2018/09/05/61c27ec4-b111-11e8-9a6a-565d92a3585d_story.html.

61. For example, according to the U.S. Bureau of Labor Statistics' CPI Inflation Calculator, Humalog, which cost $21 in 1999 would only cost $32.85 in December 2019 if inflation was the only consideration. U.S. BUREAU OF LAB. & STAT., https://www.bls.gov/data/inflation_calculator.htm (last visited Nov. 18, 2022).

62. Hirsch, *supra* note 15, at 130.

one fast-acting brand, Humalog, cost $332 per vial when it previously cost $21 in 1999.[63] While some of the increase may be accounted for by slight changes in manufacturing[64] and by inflation over the years, this is not reflected to the same degree in other countries where these same pharmaceutical drugs are sold.[65] For example, in the United States, Lantus SoloStar insulin costs 170% more than it does in other countries, on average.[66] Depending on how many vials or pens of insulin are needed, a diabetic may have to pay thousands of dollars a month to obtain the drug.[67]

B. Epinephrine

Epinephrine is another lifesaving drug with a pricing structure that causes serious problems for those who may need it. Epinephrine, or adrenaline, is the main treatment used for anaphylaxis, a severe allergic reaction—and another issue for which there is not a cure.[68] Allergic reactions can be the result of a multitude of occurrences, including anything from accidently eating peanuts to getting stung by a bee to coming in contact with grass, but when these reactions do occur, immediate action is needed.[69] Approximately 32 million Americans have food allergies alone.[70] A person who experiences a severe allergic reaction has mere minutes to inject epinephrine into their outer thigh to stop the reaction, keep airways from further swelling so the patient is able to breathe, and provide time to get to a hospital if needed.[71] Without the medication, these reactions may be life-threatening.[72]

The Food and Drug Administration ("FDA") initially approved the drug in 1987.[73] Now, the primary form of the drug available outside of a hospital setting, commonly referred to as the EpiPen,

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63. Rajkumar, *supra* note 55, at 22.

64. Typically, in business, slight changes are made in the manufacturing process of products to create more efficient products with cheaper costs and quicker methods of manufacturing. *Change Management in Manufacturing*, FORCAM, https://forcam.com/en/change-management-in-manufacturing/ (last updated Apr. 19, 2021).

65. *See generally* A PAINFUL PILL TO SWALLOW, *supra* note 30, at 4.

66. *Id.* at 20.

67. Moran-Thomas, *supra* note 46.

68. Ismael Carrillo-Martin et al., *Self-injectable Epinephrine: Doctors' Attitude and Patients' Adherence in Real-life*, 20 WOLTERS KLUWER HEALTH 474, 474 (2020).

69. *See id.*

70. *Facts and Statistics: The Food Allergy Epidemic*, FARE, https://www.foodalergy.org/resources/facts-and-statistics (last visited Nov. 18, 2022).

71. Carrillo-Martin et al., *supra* note 68.

72. *Id.*

73. Rose Rimler, *The Long, Strange History of the EpiPen*, HEALTHLINE, https://www.healthline.com/health-news/strange-history-of-epipen (last updated April 9, 2020).

is manufactured by the drug company Viatris (formerly Mylan), and it is administered through a self-injectable device.[74]

Viatris—who only bought the rights to the drug from another company in 2007 to sell it as a package deal with the delivery system Viatris manufactured—has been increasing the price of epinephrine for years.[75] At that time, two EpiPens cost less than $100, and the drug manufacturer, King Pharmaceuticals, provided epinephrine exclusively for Viatris.[76] When Pfizer took over the drug manufacturing process from King Pharmaceuticals in 2010, the former president and CEO, Heather Bresch, made a deal with Pfizer to create a monopoly by agreeing that Pfizer would disinvest in Viatris's main competitor to eliminate the competition.[77] Soon after, and with few obstacles, Viatris began hiking the price of the EpiPen by more than $600 in five years.[78]

Viatris also began selling EpiPens in pairs, forcing patients to buy two at any time of purchase regardless of need.[79] The drug expires after one year, so it technically needs to be replaced annually even if it is not used.[80] It is also recommended that people with allergies carry more than one EpiPen at a time because one dose may not be enough to counter severe reactions, and people, especially children, may need to keep multiple EpiPens on hand at different locations, such as their homes and schools.[81] However, many EpiPen users are instead incentivized to keep their expired pens rather than pay exorbitant prices which they cannot afford. Now,

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74. *Id.*

75. Ryan Grim, *Heather Bresch, Joe Manchin's Daughter, Played Direct Part in EpiPen Price Inflation Scandal*, INTERCEPT (Sept. 7, 2021, 12:48 PM), https://theintercept.com/2021/09/07/joe-manchin-epipen-price-heather-bresch/.

76. *Id.*

77. *See id.* The generic branch of Pfizer, Upjohn, later joined with Mylan in 2021 to form the company Viatris. Kevin Dunleavy, *Viatris Inks $264M Deal to Resolve Long-Running EpiPen Pay-for-Delay Case*, FIERCE PHARMA (Feb. 28, 2022, 10:05 AM), https://www.fiercepharma.com/pharma/viatris-agrees-settle-264-million-without-admitting-liability-epipen-pay-delay-scheme-teva.

78. Grim, *supra* note 75. After this price hike, the company CEO blamed the concerns over the changes on "a lack of transparency in the pharmaceutical pricing system" and claimed that the profits were going toward investments "'to create access and awareness and improve the product.'" Ed Silverman, *Mylan CEO Accepts Full Responsibility for Price Hikes, But Offers Little Explanation*, PHARMALOT (Dec. 1, 2016), https://www.statnews.com/pharmalot/2016/12/01/mylan-ceo-responsibility-epipen-price/.

79. *Id.*

80. Daniel More, MD, *Be Prepared for an Allergy with the Right Number of EpiPens*, VERYWELL HEALTH, https://www.verywellhealth.com/how-many-epipens-do-you-need-82914?print (last updated Mar. 29, 2021).

81. *Id.*

a two-pack of EpiPens costs upwards of $650.[82] Although people with allergies typically do their best to avoid these life-threatening reactions, there is always a chance that a person could accidently come in contact with whatever they are allergic to, like by ordering food at a restaurant and not being aware it was cooked in the same pan previously used for peanuts. Still, it may be difficult to justify spending that type of money when a person may not use the drug before it expires, even if his or her life depends on it.[83]

As for generic versions of epinephrine, there are not many to date that would alleviate the pricing problem.[84] Viatris released its own generic version, but it was still triple the price that the EpiPen had been only a few years before.[85] The FDA did not approve a generic brand from a competitor company until 2018.[86] However, this brand still costed more than Viatris's authorized generic pen.[87] Now, more generics are starting to enter the market, enabling some cash customers to pay $110 for two pens.[88] Still, without assistance from outside companies, such as additional insurances and prescription savings cards, affording the drug is a difficulty.[89]

C. General Pharmaceutical Pricing Problems in the United States

Not much has been done to change the current pricing system in the United States as most federal legislation introduced on the matter have been thus far rejected.[90] Pharmaceutical companies have

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82. Tori Marsh, MPH, *Generic EpiPen is Still Expensive – Here's How You Can Save*, GOODRX (Oct. 30, 2019, 2:13 PM), https://www.goodrx.com/blog/generic-epipen-is-still-expensive-heres-how-you-can-save/.

83. *See* Frank David, *Calculating the Value of an EpiPen*, FORBES (Aug. 29, 2016, 6:00 AM), https://www.forbes.com/sites/frankdavid/2016/08/29/epipen/?sh=219239714f30.

84. Peter Atwater, *The Wild EpiPen Price Hike Points to a Looming Pharmaceutical Crisis*, TIME MAG., Sept. 2016, at 32.

85. *Id.*

86. Maggie Fox, *FDA Approves First Generic Competitor to EpiPen*, NBC NEWS (Aug. 16, 2018, 1:14 PM) https://www.nbcnews.com/health/health-news/fda-approves-first-generic-competitor-epipens-n896171.

87. *Id.*

88. *See A More Affordable EpiPen Alternative*, CVS PHARMACY, https://www.cvs.com/content/epipen-alternative (last visited Nov. 18, 2022).

89. *See* Neighmond, *supra* note 35.

90. *See, e.g.*, Ginsburg & Lieberman, *supra* note 24 (discussing the Elijah E. Cummings Lower Drug Costs Now Act, 116 H.R. 3, which would have "sharply expanded the boundaries of drug pricing reform discussions by authorizing the Secretary of Health and Human Services (HHS) to set drug prices for both government and commercial payers through a combination of formulas and negotiation and imposed prohibitive tax penalties on pharmaceutical manufacturers that did not accept the government price"); Halper & Romm, *Republicans Block Cap on Insulin Costs for Millions of Patients*, WASH. POST (Aug. 7, 2022, 10:57 AM) https://www.washingtonpost.com/nation/2022/08/07/insulin-cap-budget-congress/

been able to raise prices, partly under their own intended strategies of "[protecting] free-market competition-based pricing for Medicare and commercial insurance."[91] The U.S. House of Representatives' Committee on Oversight and Reform recognized drug pricing as a major issue after an intensive three-year study, describing the existing pricing strategies as "unsustainable, unjustified, and unfair to patients and taxpayers."[92] According to this study, there are three main problems with pricing; pharmaceutical companies have: (1) "manipulated the patent system"; (2) actively worked to stop competition, such as by blocking other similar drugs from the market; and (3) "raised prices with abandon . . . to meet ever-increasing revenue targets" that are not balanced by competition.[93]

A continuous renewal of patents is one of the drivers of the pricing crisis.[94] Known as patent evergreening, renewal of patents on the same drug for the smallest changes ensures that the drug is kept under patent protection for a longer period of time.[95] One company has filed over seventy patents on the long-acting insulin, Lantus SoloStar, to "technically provide more than 30 additional years of monopoly protection."[96] Patent evergreening continues to defeat competition in an already controlled field.[97]

Lately, there has been movement in the United States to address the insulin pricing crisis through encouraging biosimilars.[98] Biosimilars are drugs that are biologically similar to the current drugs so that they produce the same reaction in the body, yet they are cheaper to produce.[99] The FDA recently announced permission for interchangeable biosimilars, which promises safe and effective medications at lower costs, including Semglee for glycemic control.[100] However, forming biosimilars is a difficult process, and patent protections continue to block them from being on the market.[101]

(discussing how lawmakers stripped an insulin price cap from the Inflation Reduction Act before passing it).

91. DRUG PRICING INVESTIGATION, *supra* note 58, at viii.

92. *Id.* at iii.

93. *Id.* at i–ii.

94. *See id.* at i.

95. Rajkumar, *supra* note 55.

96. *Id.*

97. *See id.*

98. *See* Dave Simpson, *'Momentous Day' as FDA Oks 1st Interchangeable Biosimilar*, LAW 360 (July 28, 2021, 8:58 PM), https://plus.lexis.com/newsstand#/article/1407739; *see also* Rowland, *supra* note 60 (noting that the required "'biosimilar' regulatory framework from the [FDA] was not fully established until 2020").

99. *Biosimilar and Interchangeable Products*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products#biosimilar (last visited Nov. 18, 2022).

100. Simpson, *supra* note 98.

101. *See id.*

The three insulin companies have also been engaging in "shadow pricing," raising prices at the same time as each other to fix the competition problem.[102]

Patent evergreening and difficulties with biosimilars have created obstacles by not allowing incentives for price decreases. Competition typically prevents price gouging, but companies like Viatris and Eli Lilly are acting as monopolies, controlling the drug markets and increasing prices without much consequence.[103] People are willing to pay almost anything to be able to live, and drug companies use lobbying to ensure their ability to take advantage of that pricelessness.[104] These companies are intentionally targeting deficiencies in our system, such as those keeping the federal insurance Medicare Part D from negotiating prices.[105] As "[a]n internal Novo Nordisk slide deck from October 2013 emphasized, 'Part D is the most profitable market for the Novo Nordisk insulin portfolio,' and . . . insulin volume for the Part D market was growing three times faster than for the commercial market."[106] This shows that companies conduct business mainly for profit. For a change in position, the federal government must intervene so that any overcharge in the cost of individual medical care is not merely spread among its citizens.

D. State-Level and Federal-Level Responses

While the federal government has rejected most drug negotiation schemes,[107] there are other structures in the United States aiming to control pharmaceutical prices. Some states, including Colorado, have started to move in the right direction by implementing price

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102. DRUG PRICING INVESTIGATION, *supra* note 58, at v.

103. Both companies have recently been involved in lawsuits that have yet to result in accountability over Big Pharma for the price hikes. *See* In re EpiPen Epinephrine Injection, Mktg., Sales Pracs. & Antitrust Litig., No. 2785, 2022 U.S. Dist. LEXIS 122137 (D. Kan. July 11, 2022); In re Insulin Pricing Litig., No. 3:17-CV-699-BRM-LHG, 2020 U.S. Dist. LEXIS 29345 (D.N.J. Feb. 20, 2020).

104. *See supra* note 26 and accompanying text.

105. *See* DRUG PRICING INVESTIGATION, *supra* note 58, at ix.

106. *Id.*

107. *See generally* Diamond & Goldstein, *supra* note 29. In April 2021, the Ending Pricey Insulin Act was also introduced in a federal attempt to limit insulin copays to $50 a month no matter the amount of insulin needed, but it has a low chance of moving forward. Ending Pricey Insulin Act, S. 1132, 117th Cong. §1 (2021). Two other acts, the INSULIN Act and the Affordable Insulin Now Act, have also been introduced to limit insulin prices, but they face low approval rates and, even if one did pass, it would not cover uninsured people. Rachel Tillman, *Senators Introduce Bipartisan Bill to Cap Cost of Insulin*, SPECTRUM NEWS NY1 (June 22, 2022, 1:20 PM) https://www.ny1.com/nyc/all-boroughs/news/2022/06/22/jeanne-shaheen-susan-collins-senate-insulin-monthly-price-cap.

cap statutes.[108] Colorado's statute implements price caps of $100 on monthly copays for insulin, no matter the amount of insulin needed by a diabetic per month.[109] Similar statutes have been adopted in Illinois, Maine, New Mexico, New York, Utah, Washington, and West Virginia, with others being considered throughout the United States.[110]

However, these statutes will only affect people who are covered by certain health insurance plans.[111] Insulin is only one of many lifesaving drugs that needs to have a regulated price, and those people who cannot afford health insurance will not be able to afford lifesaving drugs with or without it.[112] Although this is a start, the pricing problem is too broad, due to the issues discussed above, to be solved only by state caps for copays with certain health insurances. Companies will only begin to change if there is serious negotiation at the federal level. A general comparison of the United States pharmaceutical prices to global levels shows that drugs are far more expensive in the United States than in almost any other country.[113] The Committee on Oversight and Reform has even claimed that these pharmaceutical companies have "specifically targeted the U.S. market for higher prices, even while cutting prices in other countries, because weaknesses in our health care system have allowed them to get away with outrageous prices and anticompetitive conduct."[114]

III. GLOBAL PRICING MODELS

Developed Western countries spend much less than the United States on pharmaceuticals per capita[115] through combinations of

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108. *See* COLO. REV. STAT. § 10-16-151 (2020).

109. *Id.*

110. Karena Yan, *Eight States Pass Legislation to Place Caps on Insulin Price; Five More Await Ruling*, DIATRIBE FOUND., https://diatribe.org/foundation/about-us/dialogue/eight-states-pass-legislation-place-caps-insulin-price-five-more-await-ruling (last visited Nov. 18, 2022).

111. *Id.* (noting, in reference to COLO. REV. STAT. § 10-16-151, that "[s]ome health plans fell into an exemption in the legislation, leaving the people on those health plans ineligible for the insulin price cap when purchasing their monthly insulin").

112. *See supra* notes 16, 19 and accompanying text. Sanofi has announced a plan to lower the prices of its insulin for people without insurance. *See* Kevin Dunleavy, *With Congress Weighing Insulin Cost Cap, Sanofi Slashes Price for Uninsured in US*, Fierce Pharma (Jun. 29, 2022, 11:17 AM) https://www.fiercepharma.com/pharma/us-close-capping-insulin-costs-some-sanofi-slashes-price-uninsured-us. The author was not able to confirm whether these price changes have been implemented. However, this change could cause price increases at pharmacies for insured options.

113. *See generally* A PAINFUL PILL TO SWALLOW, *supra* note 30.

114. DRUG PRICING INVESTIGATION, *supra* note 58, at i.

115. *See generally* A PAINFUL PILL TO SWALLOW, *supra* note 30, at 4.

health insurance and governmental regulations.[116] This section analyzes three types of these pricing models based on product price control, reference pricing, and profit control. The drug pricing problem in the United States needs to be addressed by a combination of these methods. Ultimately, this combination, along with a focus on reference pricing, will be most beneficial.

A. Product Price Control

Product price control is one option for regulating pharmaceutical drug prices by focusing on the drugs themselves. Canada has used this type of regulation through its Patented Medicine Prices Review Board ("PMPRB") since 1987.[117] The purpose of this board is to "ensur[e] that the prices of patented medicines sold in Canada are not excessive,"[118] which is done through "monitor[ing] the prices charged by patentees for patented drugs on an ongoing basis."[119] The PMPRB reviews pharmaceuticals, taking into consideration affordability before approving prices of pharmaceuticals in order to ensure prices are reasonable for patients[120] based on a predetermined set of guidelines.[121] According to the PMPRB website, this process includes a scientific review of the "level of therapeutic improvement" of a new drug, a price review of involving comparable drugs and countries, and later investigations to determine whether or not certain product prices are too high.[122]

Manufacturers may not exceed set maximum price limits because the companies voluntarily agree to comply with the PMPRB's guidelines when the patent for the drug is filed.[123] If a company is found to have exceeded the permitted maximum price, the board has the ability to hold a public hearing and subsequently "issue an order to reduce the price and to offset revenues received as a result

116. While different types of health insurance around the globe will likely play a part in pricing differences, this article will mainly address governmental regulations of pharmaceutical companies. It is beyond the scope of this article to fully analyze the issue and benefits of universal health care.

117. Zelitt, *supra* note 54, at 484.

118. *About the PMPRB*, GOV'T OF CANADA, http://pmprb-cepmb.gc.ca/home (last visited Nov. 18, 2022).

119. *Regulatory Process*, GOV'T OF CANADA, https://www.canada.ca/en/ patented-medicine-prices-review/services/regulatory-process.html (last updated Sept. 7, 2021).

120. Zelitt, *supra* note 54, at 484.

121. *See* COMPENDIUM OF POLICIES, GUIDELINES AND PROCEDURES, PATENTED MEDICINE PRICES REVIEW BOARD (2017).

122. *Regulatory Process*, *supra* note 119.

123. *Id.*

of the excessive price," subject to judicial review in the Federal Court of Canada.[124]

B. Reference Pricing

Another method of regulation, which is used in Germany, is reference pricing.[125] Governments reference price by comparing groups of similar medications, then set limits on reimbursement for the price of each group of medications.[126] Unlike with product price control, reference pricing does not require approval by the government at the time that a product is launched.[127] However, in Germany, reference pricing is used to cover all medications.[128] The process consists of "two phases, starting with a health technology assessment conducted by Germany's Federal Joint Committee, followed by the reimbursement price negotiations between the Association of Statutory Health Insurance Funds and the respective pharmaceutical company."[129] Introduced in 1989,[130] reference pricing is used for "noninnovative drugs with therapeutically similar alternatives," such as insulin and epinephrine, forcing manufacturers of similar drugs to charge no more than its competitor and "compete for market share with lower prices."[131] Innovative drugs, on the other hand, are medications which are determined to have an "incremental benefit" over existing versions of a drug used for the same purpose.[132] These drugs are also given a standard for prices based on comparable products but are granted higher prices than those that are noninnovative.[133]

During the reference pricing process, drugs are "allocated to specific 'reference price groups'" established on the basis of having the same or similar active pharmaceutical ingredients or comparable

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124. *Id.*

125. *See* Ulrich Reese & Carolin Kemmner, *Pricing & Reimbursement Laws and Regulations 2021*, GLOB. LEGAL INSIGHTS, https://www.globallegalinsights.com/practice-areas/pricing-and-reimbursement-laws-and-regulations/germany.

126. *See* Shefali Luthra, *Postcard from Germany: Moved for School, Stayed for Insulin*, TIME MAG. (Oct. 24, 2019, 8:00 AM), https://time.com/5706668/insulin-pricing-us-germany/.

127. Reese & Kemmner, *supra* note 125.

128. Karl Lauterbach et al., *The German Model for Regulating Drug Prices*, HEALTHAFFAIRS (Dec. 29, 2016), https://www.healthaffairs.org/do/10.1377/forefront.20161229.058150/full/.

129. Reese & Kemmner, *supra* note 125.

130. *Id.*

131. James C. Robinson et al., *Drug Price Moderation in Germany: Lessons for U.S. Reform Efforts*, COMMONWEALTH FUND (Jan. 23, 2020), https://www.commonwealthfund.org/publications/issue-briefs/2020/jan/drug-price-moderation-germany-lessons-us-reform-efforts.

132. *See id.*

133. *Id.*

effects.[134] Generics and biosimilars can be in the same groups as drugs that are patented.[135] Germany's Federal Joint Committee then sets the group's price "at a level ensuring a sufficient, cost-effective, quality-assured and appropriate treatment of patients."[136] The reference price represents the amount a pharmacist can be reimbursed, leaving a patient to subsequently have to pay the difference between it and the actual price of the drug.[137] Because patients, in order to not pay a co-pay, ask for a drug from the same reference group that does follow the price standard, pharmaceutical companies typically lower their prices to fit the standard and escape being passed up in favor of the competition.[138]

C. Profit Control

The United Kingdom has historically used a more indirect method of controlling prices; this pricing model is based off of profit control.[139] Under this method, manufacturers are able to "freely set its launch price at any level, as long as company profits do not exceed a negotiated target."[140] This method relies on a mutual, voluntary agreement between the government and the pharmaceutical industry for the companies to follow these targets.[141] This target and process is centered around negotiations made by its National Health Service, the national health insurer that funds the "vast majority of medicines prescribed to patients" in the United Kingdom.[142] After the initial introduction of a new drug into the United Kingdom, manufacturers may only increase prices if the change is approved by the government.[143] By allowing negotiations to be conducted primarily by the National Health Service rather than any

134. Reese & Kemmner, *supra* note 125.
135. *Id.*
136. *Id.*
137. *Id.*
138. *See id.*
139. *See* David J. Gross et al., *International Pharmaceutical Spending Controls: France, Germany, Sweden, and the United Kingdom*, 15 HEALTH CARE FIN. REV. 127, 131 (1994).
140. *Id.*
141. DRUG PRICING, HOUSES OF PARLIAMENT: PARLIAMENTARY OFFICE OF SCI. & TECH. (Oct. 2010), https://www.parliament.uk/globalassets/documents/post/postpn_364_Drug_Pricing.pdf.
142. Grant Castle et al., *Pricing & Reimbursement Laws and Regulations 2021, United Kingdom*, GLOB. LEGAL INSIGHTS, https://www.globallegalinsights.com/practice-areas/pricing-and-reimbursement-laws-and-regulations/united-kingdom.
143. Gross et al., *supra* note 139.

health insurance companies, the administration can negotiate the most cost-effective prices.[144]

The United Kingdom also keeps a focus on what is most affected by drug pricing regulations: the lives of those who are sick. To do this, additional strategies involve reducing out-of-pocket costs for chronically ill people,[145] so that medications are "mostly free to patients at the point of need."[146] The United Kingdom's addition of such strategies shows that further considerations may need to be made when considering a plan for the United States, specifically implying that one of these methods may not be enough on its own.

IV. A COMBINATION OF REFERENCE PRICING AND PRODUCT PRICE CONTROL IS NECESSARY FOR THE MOST EFFECTIVE RESULTS

While each of these pricing models have strengths that may be potentially helpful in addressing the pharmaceutical drug problem, no single model would be effective in the United States because of existing problems within the nation's pharmaceutical industry.[147]

Studies have shown that people are dying because of an inability to afford essential lifesaving medications.[148] Meanwhile, pharmaceutical companies are acting as monopolies, blocking competition from ruining their profits, and the United States government is not effectively moving to protect the American people who need these medications to live.[149] This is not a question of profit but a question of life or death. And survival is not a partisan issue. Other countries manage to keep drug prices at substantially lower prices than those in the United States,[150] so there is hope that this change is possible.

Employing a federal system to regulate by product price control would be a step in the right direction. Canada's system, in particular, could offer a solution for patent evergreening. Because

144. *See* Marc A. Rodwin, *How the United Kingdom Controls Pharmaceutical Prices and Spending: Learning from its Experience*, 51 INT'L J. OF HEALTH SERVS. 229, 229 (2021); *see also* Castle et al., *supra* note 142.

145. *See* Zelitt, *supra* note 54.

146. Castle et al., *supra* note 142.

147. *See supra* Part I, Section C.

148. *See, e.g.*, Dan Witters, *Millions in U.S. Lost Someone Who Couldn't Afford Treatment*, GALLUP (Nov. 12, 2019), https://news.gallup.com/poll/268094/millions-lost-someone-couldn-afford-treatment.aspx (citing a study by Gallup and West Health which stated "about 34 million [American adults] report knowing of at least one friend or family member in the past five years who died after not receiving needed medical treatment because they were unable to pay for it" and further acknowledging a "rising percentage of adults who report not having had enough money in the past 12 months to 'pay for needed medicine or drugs that a doctor prescribed' to them").

149. *See* Rowland, *supra* note 60.

150. *See generally* A PAINFUL PILL TO SWALLOW, *supra* note 30, at 4.

Canada's Patent Act[151] requires patentees to file price and sales information both when the drug is patented and twice a year thereafter, the review continues on an ongoing basis.[152] As part of the review includes an analysis of the "level of therapeutic improvement" to determine a comparative price, manufacturers would likely be unable to increase prices when filing patents for nominally different drugs.[153] However, such a review board would need further instruction and power to stop companies from the repeated use of patent evergreening in order to block competition.

While the addition of a review board to determine drug prices seeks to address the core of the issue, implementing a review board, by itself, will not solve the drug-pricing problem in the United States. Pharmaceutical companies may not be disincentivized by the board's decisions, if receptive to it at all, because there are practically no legal consequences.[154] Furthermore, it is not uncommon for companies to pay their way out of any judgments imposed by the court system.[155]

Potential standards also need to be taken into consideration. While Canada's review board uses the drug prices from other countries in its comparison to judge reasonable maximum limits for prices, companies like Sanofi, Eli Lilly, and Novo Nordisk would likely adjust prices in their own favor. These companies, in particular, dominate approximately 90% of the global insulin market.[156] Controlling the global market could mean control of the review board's ability to make these comparisons. Moreover, to base decisions off our own existing prices would be impractical.

Another concern with this approach is determining how much of the industry a review board could practically oversee. Incorporating a review board, possibly under the requirements of the FDA, would enable immediate access, but there are many drugs that would need to be reviewed. Beginning only with new drugs and grandfathering others would defeat the purpose of finding a way to make current drugs like insulin and epinephrine available to people that require them. However, the process of including all

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151. R.S.C., 1985, c. P-4.
152. *Regulatory Process*, *supra* note 119.
153. *Id.*
154. Past litigation concerning this matter, particularly when class actions arose between patients reliant on the medication and the companies alleged to have unaffordable drug prices, have typically resulted in favor of the corporations. *See, e.g.*, *In re EpiPen Epinephrine Injection, Mktg., Sales Pracs. & Antitrust Litig.*, 2022 U.S. Dist. LEXIS 122137; *In re Insulin Pricing Litig.*, 2020 U.S. Dist. LEXIS 29345.
155. *See id.*
156. *See* Zelitt, *supra* note 54, at 460.

pharmaceutical drugs sold in the United States would be extensive and cost valuable time, which many people who need these medications do not have.

Canada continues to experience problems with its pricing model as well; it even recognizes that further drug reform is needed.[157] Although plans to implement new guidelines for the PMPRB have been delayed, the reformation tactics include having the review board drop the United States' prices from the drug price comparison, because the prices are so far outside the average of those of the rest of the world, as well as having the board consider the cost-effectiveness of new drugs.[158] If such a board were to be implemented in the United States, it alone would not be as effective as quickly as it needs to be.

Profit control and the drug pricing methods are also not the most efficient choice for the United States to effectively address the pharmaceutical pricing crisis. In the United Kingdom, prices are not universally regulated; "significant price control mechanisms only really exist for branded products and not generics (whose prices are broadly controlled by market forces)."[159] Enforcing the pricing model of the United Kingdom in the United States would not improve the anti-competition issue in the pharmaceutical industry. The pricing structures in the United Kingdom are also set for significant reform, showing that they too ultimately require more regulation on drug pricing.[160]

Reference pricing, however, may better address the pharmaceutical pricing problem in the United States. Germany's system of drug pricing may have the most promising results for people who are living with type 1 diabetes or severe allergies[161] as prices of drugs, and health insurance co-pays for those drugs, are substantially lower in Germany than they are in the United States.[162] Reference pricing could be used to give competitors a chance against the monopolies of Viatris, Sanofi, Eli Lilly, and Novo Nordisk. The introduction of biosimilars, medications that are cheaper to produce but create the same biological reactions as other drugs, could potentially force price reductions by providing competition if given an

157. *See Canada to Delay Drug Price Reforms by Six Months, Cites Pandemic*, REUTERS (Dec. 23, 2021, 3:06 PM), https://www.reuters.com/business/healthcare-pharmaceuticals/canada-delay-drug-price-reforms-by-six-months-cites-pandemic-2021-12-23/.

158. *Id.*

159. Castle et al., *supra* note 142.

160. *Id.*

161. *See* Luthra, *supra* note 126.

162. *See* A PAINFUL PILL TO SWALLOW, *supra* note 30, at 4.

opportunity and space to compete, or at least present a cheaper alternative.[163] Government regulations in this manner would not only provide this space and force competition back into these pharmaceutical industries, but also incentivize these large companies to think about the consumer and their choices.

While people may voice concerns that any regulations forced on pharmaceutical companies will negatively affect drug production, research, and development,[164] strong limits on drug pricing will not disrupt the development of vital new medications, and, in any case, "[s]ky-high drug prices are not justified by the need to innovate."[165] Currently, most of the money flowing through these pharmaceutical companies goes to the pockets of their investors,[166] and any research and development is typically applied on the slight changes made to enable patent evergreening.[167] Instead, Germany's pricing model could be used to change incentives for pharmaceutical companies. Innovative drugs "that offer an incremental benefit" over existing medications could be permitted to sell at "higher [] prices proportional to their greater benefit over comparable products" in the United States and other markets.[168]

If the federal government were to implement a reference pricing system, it may become part of the duties under the Secretary of Health and Human Services, as previously suggested in proposed bills on new forms of drug pricing regulation,[169] to research, compare, and set prices. The prices then may be established through a process of notice and comment rulemaking, allowing for additional discussion and understanding between this underlying administrative agency and pharmaceutical manufacturers. This would permit the agency to balance the concerns of the industry with those of the people receiving the medications.

V. CONCLUSION

Many Americans are having difficulties paying for the lifesaving prescription drugs that they need[170] due to the exponential price

163. *See* Simpson, *supra* note 98.
164. *See* Ginsburg & Lieberman, *supra* note 24.
165. DRUG PRICING INVESTIGATION, *supra* note 58, at ii.
166. *See id.* (noting in the study that "[t]he largest drug companies spend more on payouts for investors and executives than on research and development").
167. *See id.*
168. Robinson et al., *supra* note 131.
169. *See* Ginsburg & Lieberman, *supra* note 23.
170. Reinberg, *supra* note 14.

increases over the last few years that are not seen to the same extent in other countries.[171]

The United States cannot continue on its current path—letting pharmaceutical companies continue to raise prices on sick people just to reap more profits. The House of Representatives Committee on Oversight and Reform agreed, calling for reform and price caps.[172]

A combination of the drug pricing models from Canada, Germany, and the United Kingdom is necessary for the United States to finally and fully address the pharmaceutical pricing crisis. By implementing reference pricing and a pharmaceutical review board, pharmaceutical companies will have more incentives to decrease prices, permit biosimilars into the market, and stop patent evergreening.

Rather than profiting from sick individuals who do not have a choice on whether or not they need to buy medication, companies can adhere to regulations set by the federal government, but legislation needs to be accepted by both parties as soon as possible. As it was for Alec Smith and Denise Ure, time is of the essence.

171. *See generally* A PAINFUL PILL TO SWALLOW, *supra* note 30.
172. *See generally* DRUG PRICING INVESTIGATION, *supra* note 58.