

PAY OR DIE: EVALUATING THE UNITED STATES INSULIN PRICING CRISIS AND REALISTIC SOLUTIONS TO END IT

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Insulin does not belong to me, it belongs to the world.¹
- Frederick Banting

I. INTRODUCTION

Healthcare is an issue at the forefront of American politics and the law. This field includes drug development and pricing, and more specifically the cost and production of insulin. As of 2018, there were 34.2 million Americans living with diabetes and 1.5 million people diagnosed each year.² All people with type 1 diabetes require insulin to live, and many with type 2 diabetes do as well.³ The price of insulin has tripled in the past ten years, with as many as one in four patients who need it reporting they skip doses because they cannot afford it.⁴ Insulin is not costly to produce; it only costs about three dollars to manufacture one vial, yet patients are forced to pay hundreds for it.⁵ Thus, there exists a significant disparity between the rising prices of insulin and the much lower cost to produce it.⁶ The situation has progressed to a level where

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1. *Sir Frederick Banting, MD*, CAN. MED. HALL OF FAME, <https://www.cdnmedhall.org/inductees/frederickbanting> (last visited Mar. 27, 2021).

2. *Statistics About Diabetes*, AM. DIABETES ASS'N, <https://www.diabetes.org/resources/statistics/statistics-about-diabetes> (last visited Mar. 27, 2021).

3. Alaa Elassar, *After Years of Skyrocketing Costs, Lawmakers Across the US Push for Caps on Life-saving Insulin Payments*, CNN, <https://www.cnn.com/2020/02/08/us/states-passing-bills-insulin-insurance-copay-trnd/index.html> (last updated Feb. 8, 2020, 2:08 AM EST).

4. *Id.*

5. *Id.*; Katie Thomas, *Express Scripts Offers Diabetes Patients a \$25 Cap for Monthly Insulin*, N.Y. TIMES, Apr. 3, 2019, <https://www.nytimes.com/2019/04/03/health/drug-prices-insulin-express-scripts.html>.

6. Elassar, *supra* note 3.

even people with health insurance are struggling to afford their medication, facing high deductibles before coverage kicks in as well as out-of-pocket copayments (copays) once it does.⁷

Consider Alec Smith, who died at age twenty-six because he could not afford his insulin.⁸ When Smith turned twenty-six, he could no longer be included on his parents' insurance plan and could not afford to pay for his own insurance coverage.⁹ Without health insurance coverage, Smith's insulin cost him \$1,300 per month—a cost he could not afford to pay.¹⁰ Smith did not tell his parents about these high costs and his struggles to afford his medication.¹¹ After rationing the medication he had, he fell into a diabetic coma and died alone in his apartment.¹²

The situation surrounding insulin costs is a classic example of pharmaceutical price gouging,¹³ which is similar to other drugs recently in the spotlight for exorbitant pricing like Daraprim,¹⁴ EpiPen,¹⁵ and Sovaldi.¹⁶ Still, Congress has not seriously considered any solutions.¹⁷

7. Ritu Prasad, *The Human Cost of Insulin in America*, BBC NEWS (Mar. 14, 2019), <https://www.bbc.com/news/world-us-canada-47491964>. Health insurance is a service that covers a person's medical expenses. Colin Lalley, *Health Insurance Basics: The 101 Guide to Health Insurance*, POLICYGENIUS, <https://www.policygenius.com/health-insurance/learn/health-insurance-basics-and-guide/#key-features-that-decide-how-much-you-pay> (last updated Oct. 29, 2020). There are various types of health insurance plans, offering different levels of coverage at different costs. *Id.* These plans all have varying levels of out-of-pocket costs, made up of premiums, deductibles, copays, and coinsurance. *Id.* A premium is the amount a customer has to pay each month to actually have an insurance plan, and this is paid regardless of if any benefits are used. *Id.* A deductible is how much a customer needs "to pay for health care services out-of-pocket before [their] health insurance kicks in"—so services before this deductible is reached are not covered under insurance. *Id.* Next, copays are a fixed amount that a customer must pay for a specific service or medication, after a customer meets his or her deductible. *Id.* Finally, coinsurance is another amount a customer must pay when receiving health services after meeting the deductible, which is usually a set percentage of the cost of the services. *Id.* Patients continue paying copays and coinsurance until they reach his or her out-of-pocket maximum, which for 2020 can be no more than "\$8,200 for individual plans and \$16,400 for family plans." *Id.*

8. *Woman Says Her Son Couldn't Afford His Insulin - Now He's Dead*, CBS NEWS (Jan. 4, 2019, 7:37 AM), <https://www.cbsnews.com/news/mother-fights-for-lower-insulin-prices-after-sons-tragic-death/>.

9. *Id.*; Prasad, *supra* note 7.

10. *Woman Says Her Son Couldn't Afford His Insulin - Now He's Dead*, *supra* note 8.

11. *Id.*

12. *Id.*

13. Sydney Lupkin, *A Decade Marked by Outrage over Drug Prices*, NPR (Dec. 31, 2019, 1:16 PM EST), <https://www.npr.org/sections/health-shots/2019/12/31/792617538/a-decade-marked-by-outrage-over-drug-prices>.

14. *See, e.g., id.* When a new company bought the rights to the drug Daraprim, a medication to treat the parasitic infection toxoplasmosis, the list price was raised "more than 5,000% overnight." *Id.*

15. *See, e.g., id.* In 2016, the cost of an EpiPen auto-injector, an essential medication to anaphylactic reactions, reached \$300, after "more than a dozen price hikes in just six years." *Id.* This medication is often the difference between life or death during an allergic reaction. *Id.*

16. *Id.*

17. *Id.*

Some states, such as Colorado, have taken the insulin pricing crisis into their own hands and have passed copay cap legislation to keep costs down for insured people with diabetes.¹⁸ However, states with laws in place like these are few and far between, and the legislation currently being passed and considered only caps costs for those who have health insurance.¹⁹

There is not yet a clear solution to the high costs of insulin for people with diabetes. However, there are some unexplored routes in the realm of legislation and public policy, litigation, and patient affordability initiatives that should be seriously considered and may be viable in helping to solve this problem. These options can be combined together to devise a better and more effective solution to the insulin pricing crisis. With people dying because they cannot afford their insulin doses, a solution cannot come fast enough.²⁰

This Article argues that price gouging of insulin is a national crisis. Current legislation and regulations are not adequate to address the unaffordability of insulin, causing many people to struggle to refill their prescriptions and to ration life-saving medication.²¹ To address this issue, this Article proposes a multifaceted approach urging both Congress and individual states to implement different regulations regarding pharmaceutical development, and introduce additional health insurance regulations. Further, this Article will address possible changes that physicians and pharmacists can make that will mitigate the impact of this crisis.

This Article proceeds in five parts. Part II discusses the historical background of the insulin pricing crisis, explaining why insulin is an essential medication and how the life-saving drug was discovered. This Part also shows how the state of insulin pricing has gotten to this point,

18. *Id.* (explaining that Colorado's copay cap law will limit insulin copays to \$100 per month, regardless of the amount of insulin prescribed).

19. *Id.*; see also Aila Slisco, *Illinois Becomes Second State to Cap Monthly Insulin Prices, and More States Are Considering It*, NEWSWEEK (Jan. 24, 2020, 10:00 PM EST), <https://www.newsweek.com/illinois-becomes-second-state-cap-monthly-insulin-prices-more-states-are-considering-it-1483987> (explaining Illinois' new insulin cap law and discussing other states that currently have similar legislation in the works). For a discussion of individual states' copay cap legislation, see *infra* pt. III.A.

20. Ben Popken, *With Rise in Patients Dying from Rationing Insulin, U.N. Tries a New Solution*, NBC NEWS (Nov. 15, 2019, 3:48 PM EST), <https://www.nbcnews.com/business/business-news/rise-patients-dying-rationing-insulin-u-n-tries-new-solution-n1083816>.

21. *Id.* ("Some patients can be caught in a deadly 'Catch-22' situation: Their deductible is too high to cover their insulin costs, but because they have insurance, they don't qualify for free or reduced cost programs. Patients may then turn to potentially fatal rationing, online fundraising, and trading supplies online with strangers in black market 'pay it forward' Facebook groups or through Twitter.")

laying out the details and extent of the pricing crisis. Part III presents the current actions and initiatives established to address the insulin pricing crisis, focusing on litigation, policy, and patient-targeted savings programs. Part IV analyzes the initiatives set forth in Part III, looking at both positive and ineffective attributes of those actions. Part V proposes an ideal solution to the insulin pricing crisis, incorporating the effective aspects explored above while minimizing the ineffective.

II. HISTORICAL BACKGROUND AND PERSPECTIVE

Diabetes is a condition that occurs when a person's blood glucose, or blood sugar, levels are too high, which is caused by a lack of or resistance to insulin.²² There are two main types of chronic diabetes: type 1 and type 2.²³ Type 1 diabetes is an autoimmune condition in which the body "attacks and destroys the cells in [the] pancreas that make insulin."²⁴ Without making insulin, the body is unable to use sugar in the blood as energy, causing high blood sugar, a dangerous and fatal condition if not treated fast enough.²⁵ There is no known way to prevent²⁶ or cure type 1 diabetes.²⁷ People with the condition must take insulin injections to manage it.²⁸ "Insulin can't be taken as a pill because the acid in [the] stomach would destroy it before it could get into [the] bloodstream."²⁹ Almost 1.6 million Americans have type 1 diabetes.³⁰

On the other hand, type 2 diabetes occurs when the body does not make enough or is resistant to insulin.³¹ This insulin malfunction results in high blood sugar, and it may lead to complications if untreated.³² Unlike type 1 diabetes, type 2 diabetes is linked to lifestyle factors such as being overweight and inactive, in conjunction with

22. *What is Diabetes?*, NAT'L INST. OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES, <https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes> (last visited Mar. 27, 2021).

23. *Id.*

24. *Id.*

25. *What is Type 1 Diabetes?*, CENTERS FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/diabetes/basics/what-is-type-1-diabetes.html> (last visited Mar. 27, 2021). For an explanation of the complications of high blood sugar, see *infra* pt. II.D.

26. *What is Type 1 Diabetes?*, *supra* note 25.

27. *Id.*

28. *Id.*

29. *Id.*

30. *Statistics About Diabetes*, *supra* note 2.

31. *What is Diabetes?*, *supra* note 22.

32. *Type 2 Diabetes*, CENTERS FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/diabetes/basics/type2.html> (last visited Mar. 27, 2021) [hereinafter T2D CDC].

genetic and environmental factors.³³ Type 2 diabetes may be treated with healthy eating and exercise, as well as oral diabetes medications.³⁴ Additionally, some patients with this condition also require insulin injections as part of their management regimens.³⁵ Approximately 32.6 million Americans have type 2 diabetes.³⁶

A. The History of Insulin

Diabetes has been around long before anyone knew what it was; “[t]he earliest description of diabetes appeared in a collection of medical texts in Egypt written around 552 BC.”³⁷ Before insulin was discovered, individuals with diabetes did not live long past diagnosis, and the only treatment for the condition was strict dieting with very low carbohydrate consumption.³⁸ These diets could be as restrictive as 450 calories per day,³⁹ and “sometimes even caused patients to die of starvation.”⁴⁰ Many of those diagnosed with this condition were children, and they rarely had the chance to make it to adulthood, until insulin was developed.⁴¹

In the early 1920s, Frederick Banting, John Macleod, and Charles Best discovered and developed insulin at the University of Toronto.⁴² The three researchers sold their insulin patents for one dollar each with the intent to promote access to the life-saving, revolutionary medication.⁴³ After this sale, the pharmaceutical companies Eli Lilly and

33. *Type 2 Diabetes*, MAYO CLINIC, <https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/symptoms-causes/syc-20351193> (last visited Mar. 27, 2021) [hereinafter T2D Mayo Clinic].

34. T2D CDC, *supra* note 32.

35. *Insulin Routines*, AM. DIABETES ASS’N, <https://www.diabetes.org/healthy-living/medication-treatments/insulin-other-injectables/insulin-routines> (last visited Mar. 27, 2021).

36. *Statistics About Diabetes*, *supra* note 2.

37. Celeste C. Quianzon & Issam Cheikh, *History of Insulin*, 2 J. COMMUNITY HOSP. INTERNAL MED. PERSPS., July 16, 2012, at 1, 1, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3714061/pdf/JCHIMP-2-18701.pdf>.

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

39. *Id.*

40. *Id.*

41. See Quianzon & Cheikh, *supra* note 37, at 1.

42. *Id.*

43. Caitlyn McClure, *Insulin’s Inventor Sold the Patent for \$1. Then Drug Companies Got Hold of It*, OTHER98, <https://other98.com/insulins-inventor-sold-patent-1-drug-companies-got-hold/> (last visited Mar. 27, 2021). The current actions of insulin manufacturers go starkly against those of the drug’s inventor:

It made sense at the time; Banting and his team were worried that if they didn’t patent the drug at all, drug companies would rush to patent an inferior, possibly dangerous version and try to turn huge profits on it. The thinking seems to have been that if drug companies

Novo Nordisk began manufacturing insulin on a large scale.⁴⁴ These same companies continued to develop the drug over time; they originally harvested and purified insulin from animals like cattle and pigs before developing synthetic insulin that more closely mirrors the insulin that a healthy body produces.⁴⁵

B. How Insulin is Used to Treat Diabetes

Insulin can be administered in a variety of ways, with each patient having a unique injection schedule and dosing amount.⁴⁶ For type 1 diabetes, insulin can either be delivered via an insulin pump or through multiple daily injections (MDI).⁴⁷ For MDI, a person with type 1 diabetes injects multiple types of insulin throughout the day.⁴⁸ These insulins include a long-acting insulin injected once or twice per day and a short-acting insulin injected before meals.⁴⁹ The long-acting insulin “is designed to release slowly and evenly in the bloodstream for about 24 hours after it is injected” and “acts like the background insulin in a person without diabetes.”⁵⁰ On the other hand, the short-acting insulin “acts like the insulin released around mealtimes in a person without diabetes.”⁵¹ The dosage of this insulin is adjusted according to what food and the amount of carbohydrates consumed.⁵² Insulin for MDI comes in either vials, which are injected via syringe, or pens, which use disposable needle attachments.⁵³

didn't have to pay royalties, they would keep prices low. The thinking was wrong. Less than thirty years later, drug manufacturer Eli Lilly and Company and two other companies were indicted for an insulin price-fixing scheme.

Id.

44. *The History of a Wonderful Thing We Call Insulin*, *supra* note 38.

45. *Id.*

46. See Gary Scheiner, *Selecting an Insulin Program for Type 1 Diabetes*, DIABETES SELF-MANAGEMENT, <https://www.diabetesselfmanagement.com/managing-diabetes/treatment-approaches/selecting-an-insulin-program-for-type-1-diabetes/> (last updated Apr. 10, 2014).

47. *Type 1 Diabetes*, MAYO CLINIC, <https://www.mayoclinic.org/diseases-conditions/type-1-diabetes/diagnosis-treatment/drc-20353017> (last visited Mar. 27, 2021).

48. *Multiple Daily Injections Insulin Therapy*, MEDTRONIC, <https://www.medtronic.com/ca-en/diabetes/home/what-is-diabetes/insulin-therapy/mdi.html> (last visited Mar. 27, 2021).

49. *Id.*

50. *Id.*

51. *Id.*

52. *Id.*

53. *Type 1 Diabetes*, *supra* note 47.

Insulin pump therapy utilizes an insulin pump, which contains insulin and connects to a catheter that is inserted into the body.⁵⁴ The pump delivers short-acting insulin only and is programmed to deliver set doses throughout the day that takes the place of the long-acting insulin in MDI.⁵⁵ Additionally, at mealtimes, a person will give a “bolus” via the pump, where the dosage is determined using the number of carbohydrates consumed—similar to MDI.⁵⁶ Insulin needs for people with type 1 diabetes vary depending on food intake, exercise levels, stress, illness, time and location of injection, and blood sugar levels must constantly be measured to stay in a healthy range.⁵⁷

For type 2 diabetes, insulin is not always required for treatment but is sometimes considered to when other treatments have been unable to maintain glucose control.⁵⁸ Insulin regimens for people with type 2 diabetes are more flexible than for those with type 1 diabetes, and insulin needs vary extremely from person to person.⁵⁹ For some, one daily dose of is sufficient, while others require multiple.⁶⁰ For those with type 2 diabetes requiring a higher insulin dosage, insulin pump therapy may be used.⁶¹

C. Today's Insulin Market

Today, as more people are diagnosed with diabetes and require insulin, the affordability of this medication is becoming ever-more important.⁶² The primary form of insulin used by people with diabetes today is known as analog insulin, which mimics the body's metabolism and is the closest to the insulin the pancreas actually makes.⁶³ This is opposed to human insulin, which, while still available today, was developed in the 1980s and comes along with dangerous peaks in effectiveness and requires much closer monitoring to prevent blood

54. *Id.*

55. *Id.*

56. *Id.*

57. *See Insulin Routines, supra* note 35.

58. *Diabetes Treatment: Using Insulin to Manage Blood Sugar*, MAYO CLINIC (July 24, 2019), <https://www.mayoclinic.org/diseases-conditions/diabetes/in-depth/diabetes-treatment/art-20044084>.

59. *See Insulin Routines, supra* note 35.

60. *Id.*

61. Michael Dansinger, *Type 2 Diabetes and the Insulin Pump*, WEBMD, <https://www.webmd.com/diabetes/insulin-pump-type-2-diabetes> (last updated May 26, 2019).

62. By 2030, there is predicted to be a 20% increase in the demand for insulin worldwide. Elassar, *supra* note 3.

63. Dana Howe, *The Patient's Bottom Line: Human Insulin Is Not the Answer*, BEYOND TYPE 1, <https://beyondtype1.org/the-patients-bottom-line-human-insulin-is-not-the-answer/> (last updated Jan. 26, 2021).

glucose spikes and falls.⁶⁴ Although human insulin is much cheaper than analog insulin, it is not as safe and effective for people with type 1 diabetes, given the availability of the much superior analog options.⁶⁵

Eli Lilly, Novo Nordisk, and Sanofi manufacture over 90% of the world's insulin and generally raise their prices at the same time.⁶⁶ Additionally, there is no generic type of insulin because insulin is a therapeutic biologic product and not a chemically synthesized molecule.⁶⁷ Thus, no incentive exists for companies to develop cheaper generic or biosimilar⁶⁸ insulins; it costs almost as much as just developing a new drug altogether.⁶⁹ Additionally, the companies that

64. *Id.*

65. Human insulin is available from Walmart without a prescription for around \$25 per vial. Julia Belluz, *Walmart's \$25 Insulin Can't Fix the Diabetes Drug Price Crisis*, VOX, <https://www.vox.com/science-and-health/2019/4/10/18302238/insulin-walmart-relion> (last updated Apr. 11, 2019, 5:20 PM EDT). This insulin has been touted as a solution to the insulin pricing crisis, going viral on the internet after being featured on a TV news story. *Id.* However, this assertion is not true, and human insulin can be dangerous, even deadly, when administration is not properly supervised by a physician. *Id.*

66. *8 Reasons Why Insulin is So Outrageously Expensive*, T1INTERNATIONAL (Jan. 20, 2019, 6:08 PM), <https://www.t1international.com/blog/2019/01/20/why-insulin-so-expensive/>; Popken, *supra* note 20.

67. *8 Reasons Why Insulin is So Outrageously Expensive*, *supra* note 66. The U.S. Food & Drug Administration describes a biologic as:

Biological products, like other drugs, are used for the treatment, prevention or cure of disease in humans. In contrast to chemically synthesized small molecular weight drugs, which have a well-defined structure and can be thoroughly characterized, biological products are generally derived from living material-- human, animal, or microorganism-- are complex in structure, and thus are usually not fully characterized.

Frequently Asked Questions About Therapeutic Biological Products, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/frequently-asked-questions-about-therapeutic-biological-products> (last updated July 7, 2015).

68. "A biosimilar is a biologic product that is developed to be highly similar to a biologic already approved by the U.S. Food and Drug Administration (FDA), known as the reference product." *Biosimilars Facts*, BIOLOGICS & BIOSIMILARS COLLECTIVE INTELLIGENCE CONSORTIUM, <https://www.bbcic.org/resources/biosimilars-facts> (last visited Mar. 27, 2021). Additionally, "[a] biosimilar is a biologic product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product." *Biosimilar and Interchangeable Products*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products#:~:text=A%20biosimilar%20is%20a%20biological,existing%20FDA%2Dapproved%20reference%20product> (last updated Oct. 23, 2017). While generic drugs contain the same active ingredients as the original product, biosimilars are rather "highly similar" with "minor differences in clinically inactive components." *Id.*

69. *8 Reasons Why Insulin is So Outrageously Expensive*, *supra* note 66. Eli Lilly has recently introduced a generic version of its Humalog insulin, called Lispro, with a 50% lower price tag. Alex Keown, *Analysis Shows Eli Lilly's Lily's Half-Price Humalog Generic Is Not Readily Available Across the U.S.*, BIOSPACE (Aug. 29, 2019), <https://www.biospace.com/article/analysis-shows-eli-lilly-s-half-price-humalog-generic-is-not-readily-available-across-the-u-s-/>. However, this puts the list price of this drug still at \$137.35 per vial, which is still a significant hurdle, given most diabetics need several vials per month. *Id.* Additionally, reports have shown that this new option is not widely available across the United States, and many insurance companies do not even cover it, significantly reducing the potential impacts of the new medication. *Id.*

make insulin engage in “patent evergreening,” where they continually apply for patents for their drugs while making insignificant changes to the medication.⁷⁰

D. What Does the Insulin Pricing Crisis Look Like?

All of the above discussed circumstances have blended together to create the insulin pricing crisis the United States is facing today. “One of every four patients with type 1 diabetes has had to ration their insulin due to cost.”⁷¹ Additionally, since the 1990s insulin prices have increased by over 1,200%.⁷² Additionally, insulin spending by individuals with type 1 diabetes has almost doubled from \$2,900 in 2012, to \$5,700 in 2016.⁷³ A variety of factors have influenced this significant increase, including the domination of the insulin market by only three manufacturers, a lack of generic insulin options, and patent evergreening, which is detailed in the preceding section.⁷⁴ In addition, alleged price fixing, pay-for-delay schemes, and politics also play roles in the price increases.⁷⁵

These high costs are making individuals sacrifice almost everything to pay for insulin. Laura Marston, a woman with type 1 diabetes, had “already sold all of her possessions twice” to afford her insulin prescription.⁷⁶ After losing her job, Marston was left without an income

70. Sanofi has filed seventy-four applications for patents on its insulin Lantus, potentially protecting the drug and quashing competition for upwards of thirty-seven years. *8 Reasons Why Insulin is So Outrageously Expensive*, *supra* note 66. Pharmaceutical companies engage in this process of patent evergreening “to preserve and extend its ability to keep competition at bay while hiking prices.” Tahir Amin, *Patent Abuse Is Driving Up Drug Prices. Just Look at Lantus*, STAT (Dec. 7, 2018), <https://www.statnews.com/2018/12/07/patent-abuse-rising-drug-prices-lantus/>. This process strays away from what was the original intention of the patent system, innovation and rather rewards companies for minimal changes to their drug formulas. *Id.*

71. *The Insulin Price Crisis*, T1INTERNATIONAL, <https://www.t1international.com/usainsulin4allaction/> (last visited Mar. 27, 2021).

72. *Id.*

73. *Id.*

74. *8 Reasons Why Insulin is So Outrageously Expensive*, *supra* note 66; *see also supra* pt. II.C.

75. *8 Reasons Why Insulin is So Outrageously Expensive*, *supra* note 66. Pay-for-delay agreements involve an agreement between a potential generic, or biosimilar, manufacturer and the pharmaceutical company where the generic manufacturer “agrees to refrain from marketing its product for a specific period of time” in exchange for “payment from the patent-holder.” *Id.* Insulin manufacturers spend millions of dollars each year on lobbying politicians. *Id.* Additionally, President Trump’s 2017 Secretary of Health and Human Services appointee, Alex Azar, a former executive of Eli Lilly, raised the price of its insulins significantly during his tenure from 2007 to 2017. James Elliot, *Alex Azar, Trump’s HHS Pick, Has Already Been a Disaster for People with Diabetes*, NATION (Nov. 21, 2017), <https://www.thenation.com/article/archive/alex-azar-trumps-hhs-pick-has-already-been-a-disaster-for-people-with-diabetes/>.

76. Prasad, *supra* note 7.

or health insurance, and she was forced to sell or give up everything she owned, including her car and her dog, to pay for the insulin that keeps her alive.⁷⁷

Marston is not alone, and although many will do whatever they can to afford their insulin, oftentimes there is not enough a person can do to afford the high costs of insulin, causing them to resort to rationing.⁷⁸ While rationing is not always a bad thing, it has devastating consequences when it comes to insulin.⁷⁹ When the body does not have enough insulin, blood sugar levels increase, and the body can no longer process sugar for energy.⁸⁰ When this happens, the body must find another source of energy, and it begins to break down fat which releases ketones into the bloodstream.⁸¹ Ketone buildup in the bloodstream makes the blood more acidic, and this buildup over time causes the condition of Diabetic Ketoacidosis (DKA).⁸² DKA is extremely dangerous and causes “severe dehydration and lead[ing] to kidney damage, brain swelling and brain damage, stroke, heart rhythm problems, fluid build-up in [the] lungs and respiratory failure.”⁸³ DKA begins anywhere from twelve to twenty-four hours after a person’s last insulin dose wears off, and treatment requires hospitalization.⁸⁴ For someone living alone and rationing insulin, DKA is extremely dangerous; someone can lose consciousness, fall into a coma, and die soon after if no one is there to provide medical treatment.⁸⁵ This is what happened to Alec Smith, the individual referenced at the beginning of this Article.⁸⁶

Even when rationing does not lead to DKA, it still has the potential for extreme consequences. Yale Diabetes Center researchers found that patients who had reported insulin rationing due to cost “were 3 times more likely to have poor glycemic control than those who did not.”⁸⁷ This poor glycemic control will cause complications over time, which include

77. *Id.*

78. See Sarah Gantz, *Quarter of U.S. Patients with Type 1 Diabetes Ration Insulin, Study Finds*, PHILA. INQUIRER, <https://www.inquirer.com/health/consumer/insulin-ration-diabetes-drug-costs-20190625.html> (last updated June 25, 2019).

79. Sari Harrar, *Insulin Rationing: What It Is and Why It’s So Dangerous*, ONTRACK DIABETES, <https://www.ontrackdiabetes.com/live-well/diabetes-management/insulin-rationing-what-it-why-its-so-dangerous> (last updated Jan. 17, 2019).

80. *Id.*

81. *Id.*

82. *Id.*

83. *Id.*

84. *Id.*

85. *Id.*

86. See *supra* pt. I.

87. Mary Caffrey, *Gathering Evidence on Insulin Rationing: Answers and Future Questions*, AM. J. MANAGED CARE (Sept. 26, 2019), <https://www.ajmc.com/view/gathering-evidence-on-insulin-rationing-answers-and-future-questions>.

blindness, kidney failure, or even death.⁸⁸ Deaths from insulin rationing are much less common than the other complications, however those complications also have far-reaching impacts on the healthcare system.⁸⁹

Marston and Smith are not the only ones who have been impacted by the insulin pricing crisis.⁹⁰ With insulin costing around \$300 for a single vial, and people with diabetes typically needing anywhere between two and six or more vials per month, the reaches of high insulin costs spread across the entire nation.⁹¹ The crisis has inspired the #insulin4all Movement, which is run by the organization T1International.⁹² This is a grassroots movement utilizing social media and local connections with chapters run by volunteers from different states and even spreading around the globe.⁹³ Prominent diabetes organizations have also joined the movement for affordable insulin; the American Diabetes Association and Juvenile Diabetes Research Foundation have committed to advocating for lower insulin prices.⁹⁴

III. CURRENT ACTIONS AND INITIATIVES

Currently, there are several different initiatives to address the high cost of insulin in the United States. They fall into three different categories: legislative and public policy actions, litigation, and patient savings programs. This Part will explore each of these categories and explain how they operate.

88. *Id.*

89. *Id.* The article explains:

Deaths from insulin rationing are the outer edge of a continuum that includes patients who are risking blindness, amputations, and hospital stays. For these patients, rationing could erode their health, and the costs will fall to Medicare or possibly Medicaid. Thus far, no one has tallied what avoidable costs the health system will absorb because too many patients with T1D or T2D cannot afford to use insulin in the amounts prescribed.

Id.

90. Gantz, *supra* note 78.

91. David M. Tridgell, *Insulin Is Too Expensive for Many of My Patients. It Doesn't Have to Be.*, WASH. POST, June 22, 2017, https://www.washingtonpost.com/outlook/insulin-is-too-expensive-for-many-of-my-patients-it-doesnt-have-to-be/2017/06/22/c5091c42-56cf-11e7-a204-ad706461fa4f_story.html.

92. Audrey Farley, *#insulin4all: A Global Healthcare Movement*, INSULIN NATION (Jan. 30, 2018), <https://insulinnation.com/living/315746/>.

93. *Id.*

94. Tridgell, *supra* note 91; *JDRF 2020 Advocacy Agenda*, JUVENILE DIABETES RES. FOUND., <https://www.jdrf.org/impact/advocacy/agenda/> (last visited Mar. 27, 2021).

A. Legislation and Public Policy

Some states have tried to make insulin more affordable for their citizens.⁹⁵ Colorado was the first state to pass a law placing a \$100 per month cap on insulin copays regardless of the dosage prescribed.⁹⁶ It also enlisted the state attorney general to investigate rising insulin prices in the state and then make recommendations to the legislature.⁹⁷ Following Colorado, Illinois signed a similar copay cap bill into law in January of 2020.⁹⁸ In early 2020 several more states signed insulin copay caps into law: Maine,⁹⁹ New Mexico,¹⁰⁰ New York,¹⁰¹ Utah,¹⁰² Washington,¹⁰³ West Virginia,¹⁰⁴ and Virginia.¹⁰⁵

Other states currently have insulin copay caps in the works as well. For example, a \$100 copay cap bill was introduced in the Florida Senate and passed unanimously through the Banking and Insurance Appropriations Subcommittee.¹⁰⁶ However, it was not placed on the

95. Slisco, *supra* note 19.

96. Christina Zdanowicz, *Colorado Is the First State to Cap Skyrocketing Insulin Co-pays*, CNN, <https://www.cnn.com/2019/05/23/health/colorado-insulin-price-cap-trnd/index.html> (last updated May 23, 2019, 5:17 PM EDT). The Colorado statute reads:

A carrier that provides coverage for prescription insulin drugs pursuant to the terms of a health coverage plan the carrier offers shall cap the total amount that a covered person is required to pay for a covered prescription insulin drug at an amount not to exceed one hundred dollars per thirty-day supply of insulin, regardless of the amount or type of insulin needed to fill the covered person's prescription.

COLO. REV. STAT. § 10-16-151(2) (2020).

97. COLO. REV. STAT. § 24-31-110; Zdanowicz, *supra* note 96.

98. Slisco, *supra* note 19.

99. H.R. 1493, 129th Leg., 2d Reg. Sess. (Me. 2020) (capping out-of-pocket insulin expenses at "\$100 per 30-day supply").

100. H.R. 292, 54th Leg., 2d Sess. § 1 (N.M. 2020) (capping insulin copays at \$50 per 30-day supply, "regardless of the amount, number of prescription drugs or types of insulin prescribed to meet the covered person's insulin health needs").

101. S. 7506B, 2019-2020 Leg. Sess. pt. DDD (N.Y. 2020) (capping insulin copays at \$100 per thirty-day supply, "regardless of the amount or type of insulin needed to fill such covered person's prescription").

102. H.R. 207, 2020 Gen. Sess. (Utah 2020) (capping insulin copays at \$30 per thirty-day prescription).

103. S. 6087, 66th Leg., 2020 Reg. Sess. § 2(1) (Wash. 2020) (capping copays for a thirty-day supply of insulin at \$100).

104. H.R. 4543, 2020 Reg. Sess. §33-53-1(e) (W. Va. 2020) (capping insulin copays at \$100 per thirty-day supply, "regardless of the quantity or type of prescription insulin used to fill the covered person's prescription needs").

105. H.R. 66, 2020 Sess. (Va. 2020) (capping insulin copays at "\$30 per 30-day supply of the prescription insulin drug, regardless of the amount or type of insulin needed to fill the covered person's prescription").

106. S. 116, 2020 Reg. Sess. (Fla. 2020); Samantha J. Gross, *Insulin Prices are Skyrocketing. Why Won't the Florida House Act?*, TAMPA BAY TIMES, Jan. 24, 2020, <https://www.tampabay.com/florida-politics/buzz/2020/01/24/insulin-prices-are-skyrocketing-why-wont-the-florida-house-act/>.

agenda of the next committee needed for passage after the committee chair refused to hear the bill.¹⁰⁷ Many more states are considering copay cap legislation including California,¹⁰⁸ Kansas,¹⁰⁹ Pennsylvania,¹¹⁰ and Tennessee.¹¹¹

In addition to copay cap laws, there are other forms of legislation being put in place to tackle the insulin affordability crisis. In April of 2020, Minnesota passed the Alec Smith Insulin Affordability Act.¹¹² This law allows Minnesota residents who meet certain income qualifications to receive a thirty-day supply of insulin for \$35 in case of emergency when they only have less than a seven-day supply of insulin left.¹¹³ Florida,¹¹⁴ Vermont,¹¹⁵ and Colorado¹¹⁶ have each passed laws allowing residents to import drugs, like insulin, from Canada. However, these laws must be approved by the Secretary of Health and Human Services before implementation.¹¹⁷

There are several pieces of federal legislation pending, and executive actions have been taken on the subject of affordable insulin,

107. Gross, *supra* note 106.

108. Assemb. 2203, 2019–2020 Reg. Sess. (Cal. 2020) (capping insulin copays at \$50 per thirty-day supply, “regardless of the amount or type of insulin needed to fill the covered person’s prescription or prescriptions”).

109. H.R. 2557, 2020 Reg. Sess. § 1(a) (Kan. 2020) (capping insulin copays at \$100 per thirty-day supply “regardless of the quantity or type of prescription insulin drug required to fill the covered person’s prescription or if the covered person takes multiple prescription insulin drugs per month”).

110. H.R. 1873, 2019 Reg. Sess. (Pa. 2019) (capping insulin copays at \$100 per thirty-day supply, “regardless of the amount or type of insulin needed to fill the covered individual’s prescription”).

111. H.R. 1832, 111th Gen. Assemb. (Tenn. 2020); S. 1718, 111th Gen. Assemb. (Tenn. 2020) (capping copays for a thirty-day supply of insulin at \$100).

112. MINN. STAT. § 151.74 (2020); *Alec Smith Insulin Affordability Act Goes into Effect This Week*, CBS MINN. (June 30, 2020), <https://minnesota.cbslocal.com/2020/06/30/alec-smith-insulin-affordability-act-goes-into-effect-this-week/>.

113. *Id.* On the eve of when this law was to take effect, the pharmaceutical industry trade group, PhRMA, filed a lawsuit seeking a permanent injunction to prevent the law from taking effect, claiming it to be unconstitutional. Nathaniel Weixel, *Minnesota Lawmakers Blast Pharmaceutical Industry Lawsuit over Insulin Affordability Law*, HILL (July 2, 2020), <https://thehill.com/policy/healthcare/505635-minnesota-lawmakers-blast-pharmaceutical-industry-lawsuit-over-insulin>. PhRMA wrote in its complaint, “[a] state cannot simply commandeer private property to achieve its public policy goals” and explained that the lawsuit is targeting the way the new law seeks to provide insulin to Minnesotans, which, as written, directly dictates what insulin manufacturers must do. *Id.* For a telling of Alec Smith’s story, see *supra* pt. I.

114. FLA. STAT. § 381.02035 (2020) (“The Agency for Health Care Administration shall establish the Canadian Prescription Drug Importation Program for the importation of safe and effective prescription drugs from Canada which have the highest potential for cost savings to the state.”).

115. VT. STAT. ANN. tit. 18, §§ 4651–56 (2020).

116. COLO. REV. STAT. §§ 25.5-2.5-201–207 (2020).

117. Thomas Sullivan, *Implementation of Florida Drug Importation Law Faces Uphill Battle*, POL’Y & MEDICINE, <https://www.policymed.com/2019/08/implementation-of-florida-drug-importation-law-faces-uphill-battle.html> (last updated Aug. 14, 2019).

but they have not yet materialized.¹¹⁸ For example, the Insulin Price Reduction Act aims to reduce insulin list prices to the 2006 level.¹¹⁹ Additionally, the Safe Step Act seeks to eliminate “step therapy” in health plans, which occurs when diabetic patients must try a certain type of insulin and fail on it before insurance will pay for a type of insulin that is effective for a patient.¹²⁰ Lastly, the Chronic Condition Copay Elimination Act aims to eliminate copays for certain items used to treat chronic conditions.¹²¹

In addition to federal legislation, there have also been several recent attempts by the executive branch to lower the costs of insulin.¹²² On May 26, 2020, President Trump announced plans for enhanced Medicare Part D prescription drug coverage, which will limit monthly copays for insulin for Medicare beneficiaries to \$35 per month starting in 2021.¹²³ This initiative, while extremely beneficial to people with diabetes who qualify for Medicare, does not impact a majority of insulin-dependent diabetics.¹²⁴

Following the Medicare Part D order, on July 24, 2020, President Trump signed four executive orders aimed at lowering prescription drug prices.¹²⁵ These orders contain “variations of drug pricing proposals” that the Trump administration introduced last year.¹²⁶ Of the four orders, one of them specifically targeted insulin, requiring insulin to be included in an existing federal program that mandates pharmaceutical companies “to provide steep discounts to thousands of hospitals and community health centers that serve large numbers of low-income patients,” known as the 340B program.¹²⁷ However, these executive

118. *Bills Addressing Drug and Insulin Affordability Endorsed by American Diabetes Association*, AM. DIABETES ASS'N. (Jan. 15, 2020), <https://www.diabetes.org/newsroom/press-releases/2020/drug-insulin-affordability>.

119. H.R. 4906, 116th Cong. (2019); S. 2199, 116th Cong. (2019).

120. H.R. 2279, 116th Cong. (2019); S. 2546, 116th Cong. (2019).

121. H.R. 4457, 116th Cong. (2019).

122. Yasmeen Abutaleb & Josh Dawsey, *Trump Signs Executive Orders Aimed at Lowering Drug Prices in Largely Symbolic Move*, WASH. POST, July 24, 2020, <https://www.washingtonpost.com/politics/2020/07/24/trump-expected-sign-drug-pricing-executive-orders-friday-angering-pharma/>; *President Trump Announces Lower Out of Pocket Insulin Costs for Medicare's Seniors*, CENTERS FOR MEDICARE & MEDICAID SERVICES (May 26, 2020), <https://www.cms.gov/newsroom/press-releases/president-trump-announces-lower-out-pocket-insulin-costs-medicare-seniors>.

123. *President Trump Announces Lower Out of Pocket Insulin Costs for Medicare's Seniors*, *supra* note 122.

124. *Id.*; see also Ryan Kobe, *Letter: Trump's Order Won't Help Most Diabetics*, SALT LAKE TRIBUNE (Oct. 7, 2020, 8:00 AM) <https://www.sltrib.com/opinion/letters/2020/10/07/letter-trumps-order-wont/> (pointing out that “only a percentage” of insulin-dependent diabetes are Medicare beneficiaries who stand to be impacted by the executive order).

125. Abutaleb & Dawsey, *supra* note 122.

126. *Id.*

127. *Id.*

orders are expected to have little effect as “power to implement drug pricing policy through executive order is limited,” and the pharmaceutical industry will likely challenge the orders in court.¹²⁸

B. Litigation

There is currently a large class-action suit specifically addressing the behavior of the three dominant insulin manufacturers.¹²⁹ In 2017, twelve people with diabetes filed a class-action lawsuit against Novo Nordisk, Eli Lilly, and Sanofi (Novo Nordisk lawsuit) alleging the defendants worked in tandem to raise the list price of their insulins to gain favor with Pharmacy Benefit Managers (PBMs), who also profit from the scheme.¹³⁰ More specifically, the Plaintiffs accused the drug manufacturers of violating the Racketeer Influenced and Corrupt

128. *Id.*

129. Craig Idlebrook, *Class-Action Lawsuit Against Insulin Companies Clears Legal Hurdle*, T1D EXCHANGE (Apr. 24, 2019), <https://web.archive.org/web/20200215154053/https://myglu.org/articles/class-action-lawsuit-against-insulin-companies-clears-legal-hurdle>.

130. Complaint and Demand for Jury Trial ¶¶ 4–5, *Chaires et al v. Novo Nordisk Inc. et al.*, (D.N.J. Feb. 2, 2017) (No. 3:17-CV-00699-BRM-LHG) [hereinafter Complaint]. The complaint describes the alleged scheme:

11. Drug manufacturers, including Defendants, can manipulate this dynamic to the detriment of patient consumers. Where two or more drug manufacturers make largely interchangeable products, those companies would, in an ideal world, continuously drop their real prices to undercut the prices offered by their competitors. But the practice of publicly-publishing one price, while secretly offering another, has enabled drug manufacturers competing within the same therapeutic class to secure PBM business without significantly reducing their real prices. The drug companies know that the PBMs stand to profit from large spreads between real and benchmark prices. Inflated benchmark price increases do not cost the PBMs so long as real prices remain constant (after all, they pay the real price, not the benchmark price). Taking advantage of these realities, drug manufacturers competing with the same therapeutic class have begun to offer the PBMs higher *benchmark prices* instead of lower *real prices*. In other words, instead of marketing lower *real prices* to PBMs, they market the spread *between* prices. The drug manufacturer with the largest spread between benchmark and real price is more likely to secure a PBM’s preferred formulary position, and, as a result, the business of that PBM’s clients.

...

14. All three Defendants have exponentially raised the benchmark prices of their medicines while maintaining constant (and even slightly lowering) their real prices. This behavior has enabled them to market larger spreads to the big PBMs in exchange for formulary status. Insidiously, an arms race in the escalation of reported benchmark prices—and consequently spreads—has ensued between Defendants: each Defendant raises its benchmark price just a bit more than its competitors, encouraging the large PBMs to keep its drug on formulary. And Defendants have done so in perfect lock step. . . .

Id. ¶¶ 11, 14.

Organizations (RICO) Act,¹³¹ as well as violating consumer protection laws in several states.¹³²

In February of 2019, the district court granted a motion to dismiss for the RICO claim while also denying the motion to dismiss for the consumer protection claim, which established viability for the suit.¹³³ Following the issuance of this opinion, the plaintiffs filed a second amended complaint, and the defendants filed a partial motion to dismiss.¹³⁴ In February of 2020, the district court again dismissed the plaintiffs' RICO claims for injunctive relief, following persuasive authority giving that "a private party may not seek equitable relief under RICO."¹³⁵ The district court upheld the plaintiffs' claims relating to new insulins that have recently come to market, such as Fiasp and Basaglar.¹³⁶ It found that the Second Amended Complaint included a sufficiently "detailed depiction of the alleged fraudulent scheme as it relates to the other insulin products," and it was permissible for Plaintiffs to "allege Defendants have included the New Insulins in the same scheme."¹³⁷ Finally, the district court dismissed several state law consumer protection claims while upholding several of them fully or in

131. 18 U.S.C. §§ 1962, 1964 (2018) (criminalizing and providing a civil cause of action for racketeering activity associated with an enterprise). The complaint alleged that all three major insulin manufacturers violated RICO and described the violating actions by the manufacturers. *See* Complaint, *supra* note 130, ¶¶ 167–292.

132. Complaint, *supra* note 130, ¶¶ 304–674 (alleging consumer protection violations under the laws of all 50 states and the District of Columbia).

133. *In re Insulin Pricing Litigation*, No. 3:17-CV-00699-BRM-LHG, 2019 WL 643709 (D.N.J. Feb. 15, 2019).

134. *In re Insulin Pricing Litigation*, No. 3:17-CV-00699-BRM-LHG, 2020 WL 831552 (D.N.J. Feb. 20, 2020).

135. *Id.* at *3.

136. *Id.* at *4.

137. *Id.*

part.¹³⁸ The suit remains viable and is still in the discovery process as of October 2020.¹³⁹

C. Patient Savings Programs

Although insulin affordability still remains a huge issue in the United States,¹⁴⁰ the three large insulin producers, Sanofi, Novo Nordisk, and Eli Lilly, have each developed programs to try to help their customers afford their insulin products.¹⁴¹

In June of 2019, Sanofi updated its “Valyou Savings Program,” which offers its insulins for the price of \$99 for a month supply.¹⁴² However, the only individuals eligible for this program are those without health insurance and who also do not qualify for other patient assistance programs.¹⁴³ Before this time, the program existed under the same name

138. *Id.* at *10. The conclusion of the opinion reads with regard to the state law claims:

Defendants’ Partial Motion to Dismiss state consumer protection law causes of action is **GRANTED** with respect to Arizona (Count Six), Georgia (Count Fifteen), Mississippi (Count Twenty-Eight), Washington (Count Forty-Seven), and West Virginia (Count Forty-Eight) and **DENIED** with respect to Colorado (Count Ten) and Utah (Count Forty-Five); Defendants’ Partial Motion to Dismiss is **GRANTED** to the extent Plaintiffs seek disgorgement and restitution with respect to California (Count Nine); Defendants’ Partial Motion to Dismiss is **GRANTED** to the extent Plaintiffs seek injunctive relief with respect to Louisiana (County Twenty-One); and Defendants’ Partial Motion to Dismiss is **GRANTED** to the extent Plaintiff’s seek an award of monetary damages with respect to Minnesota (Count Twenty-Seven).

Id.

139. See Order Granting the Admission *Pro Hac Vice* of Ian C.J. Hogg, Catherine E. Kennedy, and Benjamin Wasserman, Chaires et al v. Novo Nordisk Inc. et al., <https://www.docketbird.com/court-documents/Chaires-et-al-v-Novo-Nordisk-Inc-et-al/ORDER-granting-leave-to-appear-pro-hac-vice-as-to-Ian-C-J-Hogg-Catherine-E-Kennedy-and-Benjamin-Wasserman-Signed-by-Magistrate-Judge-Lois-H-Goodman-on-9-3-2020/njd-3:2017-cv-00699-00368> (D.N.J. Sept. 3, 2020) (No. 3:17-CV-00699).

140. See *supra* pt. II.D.

141. In this Part, I will be discussing the programs and initiatives insulin manufacturers have implemented before the COVID-19 pandemic. In the midst of COVID-19, both Eli Lilly and Novo Nordisk have taken steps beyond their original affordability programs to help those struggling during this time. Linda A. Johnson, *Lost Insurance & Need Insulin? Makers Offer It Free or Cheap*, ABC NEWS (Apr. 14, 2020, 2:37 PM), <https://abcnews.go.com/Health/wireStory/lost-insurance-insulin-makers-offer-free-cheap-70146666>. Lilly is offering a month supply of its insulins for \$35 in its Insulin Value Program. *Id.* The program applies to those with and without health insurance. *Id.* Novo Nordisk is offering free insulin to those who can show they have lost their job and health insurance due to COVID-19. *Id.* For most, this program is limited to three months of support. *Id.* Lilly has not yet set an end date for its program, and Novo Nordisk says this program will end at the end of 2020. *Id.*

142. *Sanofi Provides Unprecedented Access to Its Insulins for One Set Monthly Price*, SANOFI (Apr. 10, 2019), <http://www.news.sanofi.us/2019-04-10-Sanofi-provides-unprecedented-access-to-its-insulins-for-one-set-monthly-price>.

143. *Id.*

but only offered one vial for the \$99 price tag.¹⁴⁴ The Valyou program allows a customer to pay one price for a month supply of all insulins made by Sanofi, up to ten vials or packs of pens total, and the customer's prescriptions must be filled at the same time.¹⁴⁵

Novo Nordisk offers several programs to assist with insulin affordability.¹⁴⁶ The Patient Assistance Program offers free insulin to those without public or private insurance with a total household income at or below 400% of the federal poverty line.¹⁴⁷ Novo Nordisk also offers savings cards for customers with health insurance, which allows customers to pay as little as \$25 for a month supply of insulin.¹⁴⁸ However, this program limits the total savings a customer can see to between \$100 and \$150 per month supply depending on the type of insulin.¹⁴⁹ For example, if a customer's monthly insulin cost was \$700, and a savings card had a \$100 savings cap, the customer would be required to pay \$600 for the monthly supply.¹⁵⁰ Finally, Novo Nordisk also offers a "My\$99Insulin" program, allowing customers to receive a thirty-day supply of Novo Nordisk insulin products for \$99, up to three vials or two packs of pens.¹⁵¹

Eli Lilly offers a savings card program very similar to Novo Nordisk.¹⁵² The program covers three of Lilly's popular insulins and involves similar savings caps as Novo Nordisk.¹⁵³ This program is unavailable to those enrolled in any government-funded health program, such as Medicaid or Medicare, and a customer must have some form of commercial health insurance to qualify.¹⁵⁴ On its insulin affordability website, Lilly also touts its biosimilar version of Humalog

144. *Id.*

145. *Insulin Valyou Savings Program*, SANOFI, <https://www.admelog.com/insulins-valyou-savings-program> (last visited Mar. 27, 2021).

146. Novo Nordisk, *Savings and Support Options to Help You Afford Your Diabetes Medicine*, NOVO CARE, <https://www.novocare.com/diabetes-overview.html> (last visited Mar. 27, 2021).

147. Novo Nordisk, *Patient Assistance Program*, NOVO CARE, <https://www.novocare.com/novolog/let-us-help/pap.html> (last visited Mar. 27, 2021).

148. Novo Nordisk, *Diabetes Savings Card Program*, NOVO CARE, <https://www.novocare.com/content/novocare/en/diabetes-overview/savings-offers.html> (last visited Mar. 27, 2021).

149. For example, Novo Nordisk's Savings Card offer details the insulin Levemir states: "[p]ay as little as ('PALA') \$45 per 30-day, \$90 per 60-day, or \$135 per 90-day supply . . . subject to a maximum savings of \$100 per 30-day ('Savings Benefit'), \$200 per 60-day, or \$300 per 90-day supply." *Id.* (emphasis added).

150. *Id.*

151. *My\$99Insulin*, NOVO NORDISKNOVO CARE, <https://www.novocare.com/insulin/my99insulin.html> (last visited Mar. 27, 2021).

152. *Savings Cards for Lilly Diabetes Medicines*, LILLY, <https://www.insulinaffordability.com/savings-cards> (last visited Mar. 27, 2021).

153. *Id.*

154. *Id.*

insulin discussed above, Lispro,¹⁵⁵ as well as discount programs available at pharmacies.¹⁵⁶

In addition to programs developed by the insulin manufacturers themselves, there are also many third-party savings and coupon programs that can help patients afford their insulin. One of these programs runs through the company FamilyWize, which offers a prescription drug discount card program.¹⁵⁷ This program is available to everyone and to participate, a patient signs up through the FamilyWize website.¹⁵⁸ Overall, this program aims to save patients money on prescriptions not covered by insurance, in cases where a patient has “exceeded [their] plan’s maximum limits,” or when the cost of the medication with the discount card is lower than the amount paid with an insurance copay.¹⁵⁹ According to the FamilyWize website, this program works by negotiating lower drug prices at pharmacies and then passing 100% of these savings on to patients.¹⁶⁰ Using the FamilyWize pricing tool, one vial of the insulin Lantus will cost about \$221.45 using the discount card, compared to the \$283.56 list price.¹⁶¹

Another third-party savings program is GoodRx, which offers a very similar discount card program to FamilyWize.¹⁶² GoodRx, in addition to offering a discount card that can be used repeatedly for various prescriptions, offers a prescription drug coupon program.¹⁶³ The coupon program pulls coupon offers from various pharmacies and collects them in its database.¹⁶⁴ A patient then uses this database to find savings for the particular medication needed and must show the coupon at the pharmacy to receive savings.¹⁶⁵ Using a GoodRx coupon, one vial of Lantus will cost \$203.24, compared to the \$283.56 list price.¹⁶⁶ There are a multitude of other drug-savings programs available to patients

155. See *supra* note 69 and accompanying text.

156. *Our Goal: Helping People with Diabetes get the Medicine They Need*, LILLY, <https://www.insulinaffordability.com> (last visited Mar. 27, 2021).

157. *Save on Your Prescriptions with Our Free Prescription Discount Card*, FAMILYWIZE, <https://www.familywize.org/free-prescription-discount-card> (last visited Mar. 27, 2021).

158. *Id.*

159. *Id.*

160. *Id.*

161. *Id.*; *How Much Should I Expect to Pay for Lantus?*, SANOFI (2019), <https://www.lantus.com/-/-/-/media/EMS/Conditions/Diabetes/Brands/Lantus2/Consumer/Lantus-Pricing.pdf>.

162. *Get a GoodRx Prescription Discount Card for Free*, GOODRX, <https://www.goodrx.com/discount-card> (last visited Mar. 27, 2021).

163. *Id.*

164. *Id.*

165. *Id.*

166. *Lantus*, GOODRX, <https://www.goodrx.com/lantus> (last visited Mar. 27, 2021); *How Much Should I Expect to Pay for Lantus?*, *supra* note 161, at 1.

including NeedyMeds,¹⁶⁷ WellCard Savings,¹⁶⁸ and Reduced Rx,¹⁶⁹ which all offer various levels of savings.

IV. ANALYSIS

This Part of the Article will evaluate the pros and cons of the solutions presented above: legislation and public policy, litigation, and patient savings programs. Ultimately, a practical solution for the insulin pricing crisis will take into account the positive attributes and minimize the ineffective attributes of these current initiatives.

A. Legislation

Legislation is a very important and valuable tool in dealing with the insulin pricing crisis. One clear strength of legislation is that it is definite and applies to everyone in the relevant jurisdiction.¹⁷⁰ In the context of insulin affordability, this means that all residents of a state will automatically be affected by these initiatives without having to take individual action. Furthermore, individuals do not have to expend any funds for legislative solutions to be passed—as opposed to litigation where parties to a suit must expend significant amounts of money to see any result.

Not only is there little cost to develop legislation, copay cap legislation in particular would only modestly financially impact those with health insurance.¹⁷¹ A study by Milliman determined that a zero-dollar insulin copay cap would only raise insurance premiums by an average of \$5.12 per year.¹⁷² This is only a 0.12% increase in premiums.¹⁷³ In Colorado, where an insulin copay cap has already taken effect, minimal insurance premium increases were seen.¹⁷⁴ Most

167. *NeedyMeds Drug Discount Card*, NEEDYMEDS, <https://www.needymeds.org/drug-discount-card> (last visited Mar. 27, 2021).

168. *Pharmacy*, WELLCARD SAVINGS, <https://www.wellcardsavings.com/public/pharmacy.aspx> (last visited Mar. 27, 2021).

169. *About Reduced Rx*, REDUCED RXCVS CAREMARK, <http://www.reducedrx.com> (last visited Mar. 27, 2021).

170. *See generally Legislation*, CORNELL L. SCH. LEGAL INFO. INST., <https://www.law.cornell.edu/wex/legislation> (last visited Mar. 27, 2021).

171. Matt Berman, Scott Lain & Luke Metz, *Mitigating Out-of-Pocket Costs for Insulin Users*, MILLIMAN 13–15 (May 30, 2019), <https://milliman-cdn.azureedge.net/-/media/milliman/importedfiles/ektron/mitigating-costs-insulin-users.ashx>.

172. *Id.* at 15.

173. *Id.*

174. John Ingold, *Critics Worried Colorado's New Law Capping Insulin Costs Would Raise Insurance Rates. It Hasn't*, COLORADO SUN (Sept. 11, 2019, 5:00 AM MDT), <https://coloradosun.com/2019/09/11/colorado-insulin-price-insurance/>.

insurance companies, when releasing their premiums for the year after the copay cap was passed, “didn’t mention the insulin caps at all as being a factor in their calculations. When they did, they used words like ‘negligible’ and ‘de minimus.’”¹⁷⁵

In addition to economic considerations, legislative initiatives, like insulin copay caps, serve as a great way to bring attention to the issue of insulin affordability and are a great starting point for states that want to do something to fix this issue.¹⁷⁶ As discussed previously, copay cap legislation is growing increasingly common around the United States, with nine states having passed some type of copay cap law and many others currently considering it.¹⁷⁷

While legislative initiatives do offer many benefits, there are also a multitude of downsides to these types of fixes. Pragmatically, legislation is often hard to pass, with one committee having the ability to completely stop a bill’s chances for passage.¹⁷⁸ Additionally, healthcare is a politicized issue, and party positions may prevent this type of legislation from passing even if a majority of the legislature believes it should pass.¹⁷⁹ Also on the pragmatic side, the insulin-related legislation seen so far has only been at the state level, resulting in drastic differences around the country.

Going beyond practical considerations, insulin pricing legislation and copay caps in particular also have many substantive downsides. First, the copay caps being passed across the country do not apply to those without health insurance.¹⁸⁰ Among those who do have health insurance, many still do not qualify for insulin copay cap reductions under these laws.¹⁸¹ Colorado’s legislation only applies to commercial insurance plans that are regulated by the Colorado Division of

175. *Id.*

176. See *Insulin Co-Payment Cap Bills*, DIABETES DAILY (Mar. 9, 2020), <https://www.diabetesdaily.com/blog/insulin-co-payment-cap-bills-639890/>.

177. See *supra* pt. III.A.

178. See Gross, *supra* note 106 (discussing how a Florida committee chair prevented the insulin copay cap bill from moving forward in the legislative process).

179. For a discussion of the politicization of healthcare in the United States, see Paul Firstenberg, *Politicization of Health Care Has Harmed Americans*, IDAHO MOUNTAIN EXPRESS (June 21, 2017), https://www.mtexpress.com/opinion/guest_opinions/politicization-of-health-care-has-harmed-americans/article_6b0f75b8-55e6-11e7-bead-2bb4d3a4bfe0.html.

180. Justin Mendoza & Frederick Isasi, *Insulin and Other Prescription Drug Copay Caps: Helpful Solution or Playing Right into the Hands of the Pharmaceutical Industry?*, FAMILIES USA (Apr. 2020), https://familiesusa.org/wp-content/uploads/2020/04/RX_Insulin-Copay_Analysis_4-2-20.pdf.

181. See, e.g., Meg Wingerter, *Colorado’s Trailblazing Insulin Price Cap Isn’t Helping Everyone, as Some Discover They Aren’t Covered*, DENVER POST (Feb. 17, 2020), <https://www.denverpost.com/2020/02/17/colorado-insulin-price-cap-loopholes/>.

Insurance.¹⁸² This exempts Medicare, Medicaid, out-of-state plans, and self-funded plans¹⁸³ from the cap, although Medicare will now be capping insulin costs for itself.¹⁸⁴ And it is not only Colorado's insulin cap law that has these exceptions; there are currently federal regulations in place that preempt state laws from applying to these types of plans.¹⁸⁵

For those who do end up qualifying under the copay cap legislation, cost savings may not be as significant as expected, especially for patients who already meet their maximum out-of-pocket spending.¹⁸⁶ The Milliman study, in analyzing insulin copay cap initiatives, found that patients would see, on average, insulin savings of \$1,162 per year, while only seeing an overall average health savings of \$481.¹⁸⁷ This means that for many people, even though insulin will cost less, overall savings will be minimized because of other health costs.¹⁸⁸ In fact, these statistics take into account in the 25% of patients who will not see any total savings from even a \$0 insulin copay cap.¹⁸⁹ Furthermore, even though the added costs of insurance premiums are low, these costs still exist and will be passed on to other insurance enrollees without diabetes.¹⁹⁰

Along with the direct consequences of copay cap legislation, there are also many unintended and collateral effects that these laws may bring. For example, mandated copay caps for insulin may incentivize insurance companies to deny those with diabetes health coverage, as the cost of insulin will be something insurance companies must offset, lowering profit margins for diabetic patients.¹⁹¹ There is also valid

182. *Id.*

183. A self-funded insurance plan is when the employer takes on the costs of benefit claims. *Id.* These plans may utilize an insurance company to manage the payments, but the employer itself is the party that actually pays the claims. *A Self-funded Plan Can be Part of Your Strategy to Lower Health Care Costs*, AETNA, <https://www.aetna.com/employers-organizations/self-insurance-plans.html> (last visited Mar. 27, 2021).

184. *See supra* pt. III.A.

185. Mendoza & Isasi, *supra* note 180, at 3.

186. Berman et al., *supra* note 171, at 13–15.

187. *Id.* at 4. The reason for this lower overall health savings is due to the way health insurance coverage operates. *Id.* "If insulin has \$0 member cost sharing, subsequent claims can shift into the deductible where member cost sharing is typically higher, partially offsetting the out-of-pocket savings on insulin." *Id.*

188. *Id.*

189. *Id.* at 14.

190. *Id.* at 15.

191. The Affordable Care Act currently prohibits insurance companies from denying coverage due to pre-existing conditions. Ashley Turner, *Here's Who Will Lose Their Insurance if Obamacare is Overturned*, CNBC, <https://www.cnbc.com/2019/05/03/heres-who-will-lose-their-insurance-if-obamacare-is-overturned.html> (last updated May 4, 2019). However, the Trump Administration has considered repealing the Act. *Id.* If this were to occur, copay caps on insulin may be a compelling reason for insurance companies to deny people with diabetes health insurance, which would be even more detrimental than high insulin prices themselves. *Id.*

concern about the effectiveness of copay caps and similar legislation in actually solving the insulin affordability issue.¹⁹² Copay caps do little to change the list price of insulin itself and also hide its increasing costs from consumers, shielding them from experiencing the increases “firsthand at the point of sale.”¹⁹³ Since copay caps have been passed, many pharmaceutical company lobbyists are now arguing that enough has already been done and that there is no longer a need to address insulin pricing any further.¹⁹⁴ Overall, “legislators aiming to help solve insulin access in their states inadvertently could be playing right into the hands of the pharmaceutical lobby if they don’t also connect copay caps to meaningful reforms to stop pricing abuses.”¹⁹⁵

Furthermore, there may be constitutional challenges when it comes to insulin pricing legislation. Minnesota’s emergency insulin access law is currently being challenged by the Pharmaceutical Research and Manufacturers of America (PhRMA).¹⁹⁶ As described previously, this law would allow those with “urgent need” to receive a “30-day supply of insulin . . . for no more than \$35” and would also allow certain eligible Minnesota residents to obtain “a year supply of insulin for no more than \$50 per 90-day refill.”¹⁹⁷ However, the Minnesota law, as enacted, requires insulin manufacturers to provide the insulin dispensed via the program to pharmacies free of charge because the price paid goes not to the insulin manufacturer but rather to the pharmacy to reimburse costs for processing and dispensing the insulin.¹⁹⁸ This specific provision is what PhRMA is challenging in its lawsuit, claiming it “violates the Takings Clause of the Fifth and Fourteenth Amendments.”¹⁹⁹ The violation, PhRMA alleges, is because the law forces the insulin manufacturers to give their products to residents of the state for free, without compensation being given to the manufactures from the state in return.²⁰⁰

In its complaint, PhRMA referenced the insulin affordability programs already enacted by insulin manufacturers and also invoked a slippery slope argument stating that if this law is deemed constitutional,

192. Mendoza & Isasi, *supra* note 180, at 3.

193. *Id.* at 2.

194. *Id.* at 3.

195. *Id.* at 2.

196. Weixel, *supra* note 113.

197. *Id.*

198. See MINN. STAT. § 151.74 3(d)–(e), 6(c)–(e) (2020).

199. *Statement on Litigation Challenging the Constitutionality of Minnesota’s HF 3100*, PhRMA (June 30, 2020), <https://www.phrma.org/Press-Release/Statement-on-Litigation-Challenging-Constitutionality-of-Minnesotas-HF-3100>.

200. *Id.*

it will pave the way for similar laws relating to other prescription medications as well.²⁰¹ Regardless of the outcome of this lawsuit, the fact that insulin affordability laws may be subject to constitutional challenges is a significant downside to this type of solution.

B. Litigation

Litigative solutions have fewer positive attributes than other solutions, but there are still several benefits to these methods. First, litigation is a way to target the at-fault parties in the insulin pricing crisis. For example, the Novo Nordisk lawsuit specifically names the insulin manufacturers as defendants.²⁰² Litigation is a great way to make sure the parties, such as the insulin manufacturers who have played a role in perpetuating the insulin pricing crisis, are held legally responsible for their actions.

Furthermore, litigation offers recourse for patients after they have already been harmed. When a verdict is reached and damages are awarded, patients are able to recoup the losses they have sustained because of high insulin prices. By comparison, legislation and savings cards do not apply retroactively. Finally, litigation is often times high-profile and publicized, especially lawsuits with large corporations named as parties. Litigation has the potential to raise more awareness

201. Complaint ¶¶ 4, 7, *Pharm. Research & Mfr. of Am. v. Williams*, <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/2020-06-30--Complaint--ECF-1.pdf> (D. Minn. June 30, 2020) (No. 0:20-cv:01497). The complaint reads:

Indeed, before Minnesota enacted its confiscatory law, three of PhRMA's members that collectively manufacture most of the insulin sold in the United States were already committing significant resources to provide insulin to those in need, so that individuals living with diabetes are not forced to ration or forgo life-saving insulin because they cannot afford it. All three manufacturers have affordability programs that provide discounts and co-payment assistance to significantly reduce patients' out-of-pocket costs, and the manufacturers also provide free insulin (directly or through charitable organizations) to a great number of patients. The manufacturers and charitable organizations operate these programs in all 50 states.

...

7. The Act's implications are staggering. If Minnesota can appropriate privately manufactured insulin for distribution to its residents without paying any compensation—let alone just compensation—to the manufacturers, states can compel manufacturers to dispense other medications for free as well. And, if a state's compulsory appropriation of medicine is permissible, there is no reason a state cannot commandeer other products for its residents as the state sees fit to advance its public policy goals.

Id.

202. *See supra* pt. III.B.

to the insulin pricing crisis, garnering more public support for initiatives to combat it. The high-profile nature of litigation is also beneficial because successful suits may prompt more, inspiring others to bring their own actions based on the legitimate claims of the previous suits.²⁰³

Litigative solutions have a significant number of downsides. First, litigation is costly and less efficient than other solutions.²⁰⁴ Litigation is extremely slow-moving and comes with significant costs like attorney's fees, investigative procedures, and court fees.²⁰⁵ For example, the Novo Nordisk lawsuit was filed in February 2017 and is still in the discovery process as of October 2020.²⁰⁶ In a situation like insulin pricing where lives may be at stake, this is a significant drawback. Furthermore, the high costs and large amount of time associated with litigation makes this solution inaccessible to many of the people affected by the insulin pricing crisis the most. These individuals are already struggling to pay for their insulin, so they realistically do not have the time or resources to devote to suing such large entities.

Getting past the logistical issues, questions of standing may preclude many from litigating this issue.²⁰⁷ Because of constitutional standing principles, only those who have been harmed by a party may enter into a lawsuit against that party.²⁰⁸ Thus, litigative solutions do not provide a means for non-diabetic individuals to take action on behalf of their loved ones and place the burden of action on those with diabetes who have faced the effects of the insulin pricing crisis firsthand.

Finally, even if a party does have appropriate standing to bring a claim, there is currently no consensus on what cause of action might be viable in producing judgments against large players in the insulin pricing crisis.²⁰⁹ Other than the Novo Nordisk lawsuit, there are few others that have specifically targeted players in the insulin pricing crisis for perpetuating high insulin prices.²¹⁰ In reality, determining what specific

203. See William Ohlemeyer, *Dealing with High-Profile Trials in the Press*, ABA (June 9, 2020), <https://www.americanbar.org/groups/litigation/committees/trial-evidence/articles/2020/high-profile-trials-press/>.

204. *Litigation Can Be Inefficient and Expensive. Why Litigate?*, PWC, <https://www.pwc.com/gx/en/services/advisory/forensics/dispute-services/litigation.html> (last visited Mar. 27, 2021).

205. See *id.*

206. Docket, *Chaires et al v. Novo Nordisk Inc. et al.* (D.N.J. Oct. 11, 2020) (No. 3:17-CV-00699).

207. See *generally Standing*, CORNELL L. SCH. LEGAL INFO. INST., <https://www.law.cornell.edu/wex/standing> (last visited Mar. 27, 2021).

208. *Id.*

209. This point is clear given the fact that a significant number of claims were dismissed in the Novo Nordisk lawsuit; there is no generally accepted cause of action that applies in this type of suit. In re Insulin Pricing Litigation, No. 3:17-CV-00699-BRM-LHG, 2020 WL 831552, at *10 (D.N.J. Feb. 20, 2020).

210. See Idlebrook, *supra* note 129.

claims to bring against a party, such as an insulin manufacturer, is difficult. Prior to the Novo Nordisk lawsuit being filed, the Type 1 Diabetes Defense Foundation filed a suit against CVS Health, a PBM, in 2017 but voluntarily dismissed the suit in 2019 due to interference from the Novo Nordisk suit itself.²¹¹ The district court dismissed the Novo Nordisk lawsuit RICO claim because the insulin manufacturers are not “the final seller of the product to the consumer in a system that includes pharmacies, insurers, and PBMs.”²¹² Overall, the fact that there has yet to be a solid cause of action established for insulin pricing lawsuits is a significant downside of litigative solutions.

C. Patient Savings Programs

Patient savings programs have several positive attributes that make them a potential solution to the insulin pricing crisis. First, these programs are a relatively easy way to lower out-of-pocket costs.²¹³ Savings programs help make it possible for patients to afford their insulin when they have no other means of doing so. Also, savings cards and coupons provide immediate accessibility, which is vital to patients in need of a life-sustaining medication like insulin. Consequently, savings card programs have the potential to help someone faced with the decision of whether to put food on the table or pay for insulin.²¹⁴

Furthermore, participation in these types of programs is often not tied to income.²¹⁵ Additionally, although some of the programs do require information about a patient’s health insurance, there are also

211. *Id.* The dismissal reads:

This Notice is entered by the Foundation Plaintiffs as it has become impossible for us to prosecute our claims in *Boss v. CVS Health* (Civil Action No. 17-01823), *Bewley v. CVS Health* (Civil Action No. 17-12031), and *Prescott v. CVS Health* (Civil Action No. 17-13066), for three main reasons: . . . (2) Keller Rohrback’s participation in the Joint PBM-Payer Enterprise in the Joint PBM-Payer Enterprise—i.e. its execution of the Tolling and Standstill Agreement in *In re Insulin Pricing Litigation*, which specifically references *Boss v. CVS Health* (Article 9) and which extends co-lead counsel’s control over all current named plaintiffs and part of the putative classes in the *Bewley* and *Prescott* cases (Article 2). . . .

Notice of Voluntary Dismissal Without Prejudice Pursuant to F.R.C.P. 41(a)(1)(A)(i) and Proposed Order 1–4, *Boss v. CVS*, <https://www.scribd.com/document/396811280/Boss-v-CVS-Health-Notice-of-Voluntary-Dismissal> (D.N.J. Jan. 13, 2019) (No. 3:17-cv-01823-BRM-LHG).

212. Idlebrook, *supra* note 129.

213. Associated Press, *The Pros and Cons of Drug Coupon Cards*, STAT (Sept. 14, 2016), <https://www.statnews.com/2016/09/14/pros-cons-drug-coupon-cards/> [hereinafter *The Pros and Cons of Drug Coupon Cards*].

214. For an example of the impossible decisions that come with high insulin pricing, see *supra* pt. II.D.

215. *The Pros and Cons of Drug Coupon Cards*, *supra* note 213.

many that do not, which provides a wide range of accessible options for those struggling to afford their medication.²¹⁶ The Patient Advocate Foundation describes savings card and coupon programs as “beneficial because they’re pretty seamless,” allowing many to participate regardless of income.²¹⁷ This lack of income barriers is important because the cost of insulin is so high, and individuals from a wide range of income brackets often struggle to afford their medication.²¹⁸

Patient assistance programs also provide benefits beyond those associated with costs. These programs often allow physicians to “prescribe newer and potentially more-effective products without their patients incurring financial barriers.”²¹⁹ This is important because newer medications could increase glycemic control in patients, which can hinder or prevent diabetes-related complications.²²⁰ Along similar lines, patient assistance programs are also an alternative to step therapy,²²¹ as patients can utilize coupons to get started on a type of insulin not originally covered by insurance and then “demonstrate condition stabilization, making it difficult for utilization management programs, such as step therapy or prior authorization, to play a role.”²²²

While patient savings programs are an immediate way to reduce the costs of insulin for diabetic patients, they are not perfect. Logistically, these programs are patient-driven and must be sought out by diabetic patients individually.²²³ If a patient does not know about these programs and subsequently does not apply for them, he or she cannot benefit. Furthermore, there are many different types of patient assistance programs, and a patient must navigate these options themselves.²²⁴ Once a patient does identify a program they would like to participate in, some of these programs require either proof of insurance or proof of income, as well as require a patient to “adhere to the program’s specific

216. *Id.*; Sharon Orrange, *How to Save on Insulin With or Without Insurance Coverage*, GOODRX (Aug. 21, 2018, 2:20 PM PT), <https://www.goodrx.com/blog/insulin-savings-tips-copay-cards-patient-assistance-insurance-coverage/>.

217. *The Pros and Cons of Drug Coupon Cards*, *supra* note 213.

218. Darby Herkert et al., *Cost-Related Insulin Underuse Among Patients with Diabetes*, 179 JAMA INTERN. MED. 112, 113 (2018), <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2717499>.

219. Mari Edlin, *Pharma Coupons: Pros and Cons*, MANAGED HEALTHCARE EXECUTIVE (May 4, 2016), <https://www.managedhealthcareexecutive.com/mhe-articles/pharma-coupons-pros-and-cons>.

220. *See supra* pt. II.D.

221. For a brief explanation of Step Therapy, see *supra* pt. III.A.

222. Edlin, *supra* note 219.

223. See Alyssa Kanagaki Greenleaf, *10 (Safe) Ways to Reduce Patients’ Insulin Costs*, CLINICIAN REVIEWS, Sept. 2019, at 1e, <https://cdn.mdedge.com/files/s3fs-public/CR02909001.PDF>.

224. *See id.*

criteria.”²²⁵ Additionally, savings and copay cards or coupons have an expiration date, and many programs require patients to renew each year to keep receiving benefits.²²⁶ Finally, the savings seen from these programs are oftentimes minimal, especially compared to the amounts that copay caps and other legislation aim to have insulin cost.²²⁷

Another downfall to these programs is that patients on federally funded health programs, like Medicaid and Medicare, do not qualify.²²⁸ This is because these programs “are considered to be remuneration to consumers to induce purchases, which implies violation of an anti-kickback statute.”²²⁹ Patients on Medicaid and Medicare are often those who are the most vulnerable, so the fact that they cannot utilize these savings programs is especially devastating.²³⁰

There is a particular set of drawbacks associated with programs run by individual insulin manufacturers. First, patients often use insulin from multiple manufacturers and have to apply for the programs for each supplier individually.²³¹ This also reduces savings because patients would have to pay several amounts for each type of insulin. The fact that programs are established by the insulin manufacturers themselves is also problematic because it places control in the hands of the companies being benefited or harmed from the programs. Insulin manufacturers are in the position to alter or discontinue the programs at any time. This has the potential to create fear and anxiety among patients; patients describe “insulin as being like oxygen: Scavenging for it invokes a primal fear, like the gasp you make just before you run out of air.”²³²

Overall, these programs are not seen as a sustainable solution for promoting affordable insulin prices.²³³ A study of potential solutions to the insulin pricing crisis concluded that patient assistance programs are

225. *Id.*

226. *Id.*

227. *See supra* pt. III.C.

228. *The Pros and Cons of Drug Coupon Cards, supra* note 213.

229. Edlin, *supra* note 219. The anti-kickback law applies “because using the coupon would be steering Medicare’s business toward a particular entity.” Michelle Andrews, *Medicare Beneficiaries Feel the Pinch When They Can’t Use Drug Coupons*, KAISER HEALTH NEWS (May 8, 2018), <https://khn.org/news/medicare-beneficiaries-feel-the-pinch-when-they-cant-use-drug-coupons/>.

230. *See CMS Fast Facts*, CENTERS FOR MEDICARE & MEDICAID SERVICES, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Fast-Facts> (last updated Dec. 16, 2020) (under “downloads,” select “CMS Fast Facts (ZIP)”).

231. *See supra* pt. III.C.

232. Tiffany Stanley, *Life, Death and Insulin*, WASH. POST MAGAZINE (Jan. 7, 2019), <https://www.washingtonpost.com/news/magazine/wp/2019/01/07/feature/insulin-is-a-lifesaving-drug-but-it-has-become-intolerably-expensive-and-the-consequences-can-be-tragic/>.

233. William T. Cefalu et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, 41 DIABETES CARE 1299, 1308 (2018), <https://care.diabetesjournals.org/content/early/2018/05/03/dci18-0019>.

“not deemed to be a long-term or comprehensive answer to the rising cost of insulin for the vast majority of people with diabetes.”²³⁴ Part of the reason why this is the case is that these programs place the emphasis on the wrong place, as experts believe that “emphasis should be placed on affordable medications rather than affording expensive medications.”²³⁵ Dr. Aaron Kesselheim, a professor at Harvard Medical School, explains further: “[c]oupons are not a public health solution, they are a minor fix for a small number of people.”²³⁶

V. IDEAL INSULIN PRICING SOLUTION

In analyzing both the effective and ineffective aspects of current insulin pricing initiatives, it is clear that a more ideal solution is needed to minimize the downfalls already discussed and maximize the benefits. Overall, a solution should seek to impact the most people as possible while maximizing reductions in insulin costs. On the other hand, this solution also needs to be sustainable and something that can be kept up long into the future.

With these considerations in mind, it is clear that the solution to the insulin pricing crisis will need to be a multifaceted approach, with different systems working together to make insulin affordable for everyone. The facets of this approach include: consideration of the roles of state and federal governments; health insurance reform; streamlining the biosimilar process; and physician and pharmacy initiatives.

A. Federal and State Balance

The first step in establishing a solution to the insulin pricing crisis that involves any sort of legislation is evaluating the state and federal roles in the lawmaking process and determining what types of initiatives must be brought in either jurisdiction.²³⁷ Overall, a benefit of federal legislation is that it applies to everyone in the United States, but it also does not consider differences from state to state, which may make it less effective. Similarly, state legislation is specifically applicable to an individual state’s situation and has the ability to be tailored specifically to a state’s unique socioeconomic situation. However, it only applies

234. *Id.*

235. Greenleaf, *supra* note 223, at 1e.

236. *The Pros and Cons of Drug Coupon Cards*, *supra* note 213.

237. See Michelle M. Mello & Rebecca E. Woltz, *Legal Strategies for Reining in “Unconscionable” Prices for Prescription Drugs*, 114 NW. U. L. REV. 859, 957 (2020).

within a single state's jurisdiction, producing inequities around the country when it comes to insulin pricing.

Historically, consumer protection laws are established by states,²³⁸ so states should lead the effort to pass laws that will effectively manage insulin pricing and expand the avenues for recourse for individuals affected by it. Additionally, since states are the primary authority in regulating health insurance plans, legislation targeting insurance providers, such as copay caps, should be established at the state level.²³⁹ State-based solutions must also be cognizant of the Dormant Commerce Clause,²⁴⁰ steering clear of violations to avoid constitutional challenges.²⁴¹

Additionally, the federal government does have some ability to regulate insurance, given the passage of the Patient Protection and Affordable Care Act (PPACA) in 2010.²⁴² However, there are major drawbacks to this type of overarching federal legislation given that the PPACA has already seen a slew of constitutional challenges.²⁴³ The federal government is responsible for patent law and drug regulation, so any solutions relating to these topics, such as patent reform targeting evergreening or streamlining the biosimilar-approval process, should be federal in nature.²⁴⁴

B. Health Insurance Regulation

One promising method for reducing insulin costs for patients with diabetes is the introduction of health-insurance-regulation measures. Among these measures includes two vastly different solutions that have the potential to turn this pricing crisis around.

238. *Id.*

239. *Alternative Coverage Options*, NAT'L CONFERENCE OF STATE LEG. (Sept. 29, 2020), <https://www.ncsl.org/research/health/out-of-state-health-insurance-purchases.aspx>.

240. The Dormant Commerce Clause is the constitutional principle, born out of the Commerce Clause, which prohibits states from "passing legislation that discriminates against or excessively burdens interstate commerce." *Commerce Clause*, CORNELL L. SCH. LEGAL INFO. INST., https://www.law.cornell.edu/wex/commerce_clause (last visited Mar. 27, 2021). Thus, it limits the power of states to regulate commerce. *Id.*

241. Mello & Wolitz, *supra* note 237, at 957.

242. See generally *How Obamacare Has Faced Five Years of Constitutional Challenges*, CONST. DAILY (Mar. 23, 2015), <https://constitutioncenter.org/blog/how-obamacare-survived-five-years-of-constitutional-challenges>.

243. See generally *id.*

244. *Federal vs. State Law*, DIFFEN, https://www.diffen.com/difference/Federal_Law_vs_State_Law (last visited Mar. 27, 2021); see *FDA Rules and Regulations*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/regulatory-information/fda-rules-and-regulations> (last updated June 1, 2020).

1. Changing the IRS Definition of Preventive Drugs

The conservative method involves “expanding the definition of preventive drugs” under the PPACA which would make insulin available for a \$0 copay.²⁴⁵ Currently, preventive drugs are defined in the Internal Revenue Code, which specifies:

[D]rugs or medications are preventive care when taken by a person who has developed risk factors for a disease that has not yet manifested itself or not yet become clinically apparent (*i.e.*, asymptomatic), or to prevent the reoccurrence of a disease from which a person has recovered. . . . However, the preventive care safe harbor under section 223(c)(2)(C) does not include any service or benefit intended to treat an existing illness, injury, or condition, including drugs or medications used to treat an existing illness, injury or condition.²⁴⁶

While insulin is not currently included in this definition, some insurance companies are in favor of including it within the definition.²⁴⁷ In its report on drug pricing, CVS Health suggested incorporating medications for treating chronic diseases into the IRS preventive drug list, explaining: “[r]esearch we recently completed indicates that expanding preventive drug lists to the five most chronic diseases—diabetes, hypertension, hyperlipidemia, asthma/COPD, and depression—could substantially improve care and lower costs.”²⁴⁸

There is clearly justification for making this change, as making insulin affordable upfront will reduce later costs of complications due to insulin rationing and underuse. It is likely that the president can initiate this process via an executive order; however, the IRS would likely still be subject to the usual rulemaking process for implementing the change.²⁴⁹ This initiative would only impact those with health insurance coverage, as it only limits copays paid by patients.²⁵⁰ Regardless, a

245. Berman et al., *supra* note 171, at 13.

246. I.R.S. Notice 2004-50, 2004-33 I.R.B. 189, 201.

247. Berman et al., *supra* note 171, at 13.

248. *Current and New Approaches to Making Drugs More Affordable*, CVS HEALTH 8 (Aug. 2018), <https://cvshhealth.com/sites/default/files/cvs-health-current-and-new-approaches-to-making-drugs-more-affordable.pdf>.

249. Valerie C. Brannon, *Legal Sidebar: Can a President Amend Regulations by Executive Order?*, CONG. RESEARCH SERV. 3 (July 18, 2018), <https://fas.org/sgp/crs/misc/LSB10172.pdf>.

250. Berman et al., *supra* note 171, at 13.

patient with even a high deductible insurance plan would still only have a \$0 insulin copay.²⁵¹

2. Universal Health Insurance

Another method of addressing the insulin pricing crisis through healthcare reform is by establishing universal health insurance coverage in the United States. This is a more extreme measure, but this type of initiative would stop the insulin pricing crisis dead in its tracks, as well as have the potential to create other positive changes in the U.S. healthcare system.²⁵²

A complete discussion of the establishment of a universal healthcare system in the United States is beyond the scope of this Article, however, if this type of system were established, it would lower insulin costs for diabetic patients. In countries that have established this type of system, drug prices are regulated by a pricing review board.²⁵³ For example, Canada has a “Patented Medicine Prices Review Board,” which reviews the prices of patented drugs in Canada and ensures that drug prices are not excessive.²⁵⁴ This results in insulin prices being almost ten times lower in Canada than they are in the United States.²⁵⁵

Germany has a similar process where a panel sets maximum prices that insurers will pay for drugs, known as “reference pricing.”²⁵⁶ Because 90% of German residents have public health insurance plans that are heavily regulated, these insurance plans do not have many ways to compete with one another, and one way they do compete is by

251. *Id.*

252. Peter S. Arno & Philip Caper, *Medicare for All: The Social Transformation of US Health Care*, HEALTH AFF. (Mar. 25, 2020), <https://www.healthaffairs.org/doi/10.1377/hblog20200319.920962/full/>.

253. Sima Shakeri, *This is Why Insulin and Other Drugs are So Much Cheaper in Canada*, HUFFPOST, https://www.huffingtonpost.ca/entry/insulin-cheaper-canada-americans_ca_5d3e2e49e4b0a6d6374181de (last updated July 29, 2019).

254. *Id.*

255. *Id.*

256. Shefali Luthra, *Postcard from Germany: Moved for School, Stayed for Insulin*, TIME (Oct. 24, 2019, 8:00 AM EDT), <https://time.com/5706668/insulin-pricing-us-germany/>. Reference pricing is explained:

When a new drug comes to the German market, an independent panel assesses its effectiveness and whether its treatment value is commensurate with the manufacturer’s proposed price. Drugs serving a similar purpose or delivering the same benefit get grouped together. The panel sets a maximum price that insurers will pay for these medications—a practice known as “reference pricing.”

Id.

negotiating lower prescription-drug prices from drug manufacturers.²⁵⁷ Germany caps out-of-pocket health costs for all of its public plans, setting out-of-pocket limits at 1% of household income for those with a chronic health condition, like diabetes, and at 2% for those without a chronic condition.²⁵⁸ Germany has some of the lowest out-of-pocket costs for individuals with diabetes in the world.²⁵⁹

As mentioned, establishing a public health insurance system in the United States would be an extreme measure. However, the systems of countries like Germany and Canada are something the United States may model a future healthcare system on.

C. Streamlining the Biosimilar Development Process

Another aspect of the solution to the insulin pricing crisis involves streamlining the biosimilar development process to encourage more generic and biosimilar insulins. As discussed, there is a significant lack of these options when it comes to insulin, especially compared to other medications. With more biosimilar options available, there will be an increase of options in the insulin market; “[o]pen competition between branded and generic insulin, waged in terms of cost and evidence of efficacy, would undoubtedly be the most effective way of driving down the price of insulin. . . .”²⁶⁰ However, the pricing of biosimilar insulins will not be lower than the insulin prices of today, “unless there are multiple biosimilars that can be substituted for the brand-name analog insulin, rather than only one.”²⁶¹ This makes sense, as once a market for biosimilar insulins is established, regular economic forces will take over, preventing these biosimilars from being price gouged.²⁶²

In approving biosimilar drugs, the FDA ultimately looks for data showing that the biosimilar drug is interchangeable with the original reference drug.²⁶³ The process for approving these drugs is less involved than that for approving new biologic drugs, but is still thorough and very

257. *Id.*

258. *Id.*

259. *Id.*

260. Edwin A. M. Gale & John S. Yudkin, *Politics of Affordable Insulin*, 343 BRIT. MED. J. 566, 566 (2011), <https://www.bmj.com/content/343/bmj.d5675.full>.

261. Cefalu et al., *supra* note 233, at 1310.

262. Adam Hayes, *Perfect Competition*, INVESTOPEDIA, <https://www.investopedia.com/terms/p/perfectcompetition.asp> (last updated July 1, 2020).

263. *Biosimilar Development, Review, and Approval*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/biosimilars/biosimilar-development-review-and-approval> (last updated Oct. 20, 2017).

data-driven.²⁶⁴ Experts believe that this process can be streamlined even further to increase the number of biosimilars that can get to market.²⁶⁵ Currently, the approval process requires testing in animals that do not often “have comparable human-like features” that would make the data meaningful.²⁶⁶ These studies are an unnecessary use of time and money that could be better used elsewhere in developing biosimilars.²⁶⁷ There is also currently a large emphasis placed on clinical-efficacy testing for biosimilar candidates but less emphasis placed on testing that shows how a “biosimilar is going to interact with the human body.”²⁶⁸ In addition, “structural and functional differences in a biosimilar are not necessarily detrimental to the approvals process if they have no clinical relevance.”²⁶⁹ In streamlining the biosimilar approval process, the FDA may be able to specify these structural differences that do not translate to differences in clinical efficacy.²⁷⁰

Once biosimilar insulins are developed and approved, it is important for the medical community to support them.²⁷¹ Currently, doctors and patients are often weary of biosimilar drugs and worried about the interchangeability between a biosimilar drug and the original.²⁷² Thus, it is imperative that physicians be included in the discussions of the biosimilar streamlining process; “[i]f the medical community were more involved in creating biosimilar regulations and substitution programs, the effectiveness of regulatory and cost-reduction policies might improve significantly.”²⁷³

D. Physician and Pharmacy Initiatives

It is in the physician’s office and at the pharmacy where diabetic patients have the majority of their face-to-face interaction regarding their insulin. These points of contact are extremely valuable in

264. *Id.*

265. *E.g.*, Tony Hagen, *Remove Roadblocks to Streamline the Biosimilar Approval Process, Industry Veteran Says*, CENTER FOR BIOSIMILARS (Feb. 14, 2020), <https://www.centerforbiosimilars.com/view/remove-roadblocks-to-streamline-the-biosimilar-approval-process-industry-veteran-says>.

266. *Id.*

267. *Id.*

268. *Id.*

269. *Id.*

270. *Id.*

271. Toon van der Gronde, Carin A. Uyl-de Groot & Toine Pieters, *Addressing the Challenge of High-Priced Prescription Drugs in the Era of Precision Medicine: A Systematic Review of Drug Life Cycles, Therapeutic Drug Markets and Regulatory Frameworks*, PLOS ONE, Aug. 16, 2017, at 1, 15-16, <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0182613>.

272. *Id.*

273. *Id.* at 16.

addressing the insulin pricing crisis and provide a great opportunity for communication and education among patients.

1. Physicians

When it comes to physicians, studies have shown that healthcare providers are not well-informed about the costs of the medications they are prescribing.²⁷⁴ In one study, “four out of [five] physicians indicated that they were often unaware of actual drug costs, and most underestimated the cost of common brand-name medications” that the study asked about.²⁷⁵ The study also found that these physicians were not very attuned to how insurance companies pay for the medications they were prescribing and what the actual costs to patients were.²⁷⁶ Furthermore, a survey of U.S. medical school students found that 89% of those surveyed wanted more information about healthcare policy incorporated into their medical school curriculum.²⁷⁷ When armed with more knowledge regarding insulin prices, physicians may have the ability to facilitate reductions in overall costs to patients. While health outcomes are a doctor’s first priority, it is very clear that health outcomes cannot be improved if a patient cannot afford his or her prescribed insulin doses.²⁷⁸ Thus, at least for the sake of insulin, finding cost-effective insulin regimens should be a primary goal of healthcare providers in the treatment of diabetes.

There are several initiatives that can help facilitate cost considerations by physicians. First, physicians must be taught, starting in medical school and residency, about the healthcare system as a whole, specifically focusing on “the large price differences between inexpensive and expensive drugs, the economies of time and scale, local coverage or copayment strategies, and perhaps that rising drug cost[s] negatively impact funding to other areas.”²⁷⁹ With more focus on this during medical training, physicians will be more accustomed to considering pricing when prescribing insulin for their patients. In addition,

274. See, e.g., G. Michael Allan, Joel Lexchin, & Natasha Wiebe, *Physician Awareness of Drug Cost: A Systematic Review*, 4 PLOS MED. 1486, 1491 (2007), <https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0040283>; Steven Reichert, Todd Simon & Ethan A. Halm, *Physicians’ Attitudes About Prescribing and Knowledge of the Costs of Common Medications*, 160 ARCH. INTERNAL MED. 2799, 2802 (2000), <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/485464>.

275. Reichert et al., *supra* note 274, at 2802.

276. *Id.*

277. Allan et al., *supra* note 274, at 1493.

278. See *supra* pt. II.D.

279. Allan et al., *supra* note 274, at 1493.

increasing accessibility to price information has been shown to impact how doctors prescribe medications.²⁸⁰ One study found that just adding a sticker showing the price of anesthetic drugs per hour of use in operating rooms reduced their usage and, thus, their cost.²⁸¹

In the context of insulin, these strategies may be incorporated by developing cost-education programs for the physicians that prescribe insulin and taking into account costs to the patient when prescribing insulin. While these methods are definitely not foolproof and are minimized by the few insulin options available, they are a relatively simple and inexpensive way to make an impact.

2. Pharmacists

Pharmacists also have the potential to make significant impacts on the insulin pricing crisis; “[p]harmacists are perfectly positioned to navigate patients and other healthcare providers to various resources to enhance accessibility and affordability to combat the insulin price inflation.”²⁸² They should more commonly discuss the costs of various types of insulin with patients, including the pros and cons of different formulas and what impacts they might have on a patient’s health.²⁸³

Pharmacists are also in a unique position to educate patients about the available patient assistance programs discussed above.²⁸⁴ This is extremely valuable because one of the downsides of these patient assistance programs is that many patients are unaware of their existence, unsure of how to apply, or unaware of whether they qualify.²⁸⁵ Another thing pharmacists may be able to do is inform patients about alternative delivery methods for insulin, as insulin vials and pens often have much different costs for the same medication.²⁸⁶

VI. CONCLUSION

The insulin pricing crisis is a complicated issue in the United States which is aggravated by the fact that a mere three insulin manufacturers produce almost all of the insulin used by diabetic patients in the country.

280. *Id.* at 1493–94.

281. Van der Gronde et al., *supra* note 271, at 17.

282. Hyma P. Gogineni & Revant V. Gogineni, *Increasing Insulin Prices - Role of Pharmacists in Assisting Patients with Diabetes to Enhance Access*, 8 BIOMED. J. OF SCI. & TECH. RESEARCH, Aug. 23, 2018, at 1, 2, <https://biomedres.us/pdfs/BJSTR.MS.ID.001633.pdf>.

283. *Id.*

284. *Id.* at 4.

285. *See supra* pt. IV.C.

286. Gogineni & Gogineni, *supra* note 282, at 4.

Measures currently in place to address this crisis are inadequate, as one in four individuals with diabetes in the United States have reported needing to ration their insulin due to cost.²⁸⁷ A solution to the insulin pricing crisis must be multifaceted. This Article has identified the methods currently in place to address high insulin costs and has evaluated their strengths and weaknesses. Utilizing the results of this analysis, this Article proposes that a combination of state and federal measures, health insurance reform, streamlining of the biosimilar approval process, and physician and pharmacy initiatives is a solution to the insulin pricing crisis. While these new solutions will never be able to bring back Alec Smith, or the countless others who have lost their lives due to insulin rationing, they have the potential to save many more and pave the way for a future where people with diabetes do not have to choose to pay or die.

287. *Supra* pt. II.D.