# *Notes*

# The Cost of Survival for Insulin-Dependent Diabetics

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*Insulin, an injectable drug discovered about 100 years ago that now costs less than $5 to manufacture, is currently sold between $300 and $500 in the United States. The continuously growing price forces many insulin-dependent diabetics to forego their lifesaving medication, which can result in death. Although insulin manufacturers are a significant cause of insulin unaffordability in this country, pharmacy benefit managers (PBMs), such as CVS Caremark, OptumRx, and Express Scripts, are essential in the insulin market and pressure insulin manufacturers to provide higher rebates, leading to higher prices for consumers.*

*Some states have addressed this issue by passing legislation capping the price that insured, and in some instances uninsured, individuals pay for insulin. However, these laws generally do not provide assistance for the underinsured, or those with self-funded plans governed by federal law. State laws capping the price of insulin are a viable short-term solution, but they do not tackle the root cause of price manipulation in the pharmaceutical industry. There must be a comprehensive plan to address PBMs and their influence on the pharmaceutical market. Federal legislation capping the price of insulin for all insulin-dependent diabetics will increase transparency, create universal price limits on insulin, and prevent unnecessary deaths.*

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## INTRODUCTION

"How many more?"[1] Many insulin-dependent diabetics and their families ask this question every time the media announces that yet another individual with type 1 diabetes has died because they could not afford the price of insulin. Individuals like Meaghan Carter and Alec Smith die from rationing insulin due to a lack of insurance coverage, high deductibles, and expensive copays.[2] Every year, type 1 diabetics suffer from diabetic ketoacidosis (DKA) due to insufficient levels of insulin, which can lead to death.[3] In 2018, the CDC estimated that 34.2 million people had diabetes in the United States.[4] Of those, over 1.5 million individuals were diagnosed with type 1 diabetes.[5] Unlike type 2 diabetes, which can initially be treated with oral medication, type 1 diabetes can only be treated with insulin injections.[6] Without proper access to insulin, diabetics have increased risks for complications, such as DKA and peripheral neuropathy.[7] However, the growing price of this lifesaving medication decreases an insulin-dependent diabetic's opportunity to maintain their personal health.

An estimated 100 million individuals around the world require insulin injections to survive.[8] A study in 2018 showed that both the manufacturing and list price of insulin is much higher in the United States than in other high-income countries.[9] The manufacturing price, also known as net price, is the amount a manufacturer expects to receive from health plans, pharmacies, and pharmacy benefit managers (PBMs), while the list price reflects the amount that the patient pays.[10] For example, in 2018, the manufacturing price of one vial of fast-acting insulin in the United States was $99.94, while the prices for the same insulin in Canada and the United Kingdom were $12.99 and $8.09,

1. *"How Many More?" Family Mourns the Loss of Meaghan Carter*, RIGHT CARE ALL., https://rightcarealliance.org/article/how-many-more-family-mourns-the-loss-meaghan-carter/ (last visited Dec. 5, 2022) [hereinafter *"How Many More?"*].

2. *Id.*; Tiffany Stanley, *Life, Death and Insulin*, WASH. POST (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/.

3. *See* Stanley, *supra* note 2.

4. CTR. FOR DISEASE CONTROL & PREVENTION, NATIONAL DIABETES STATISTICS REPORT 2020, at 2 (2020), https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.

5. *Id.* at 5.

6. *Medication & Treatments*, AM. DIABETES ASS'N, https://www.diabetes.org/healthy-living/medication-treatments (last visited Dec. 5, 2022).

7. *Diabetes Complications*, AM. DIABETES ASS'N, https://www.diabetes.org/diabetes/complications [https://web.archive.org/web/20211010080854/https://www.diabetes.org/diabetes/complications].

8. *See* Dzintars Gotham, Melissa J. Barber & Andrew Hill, *Production Costs and Potential Prices for Biosimilars of Human Insulin and Insulin Analogues*, BMJ GLOB. HEALTH, Sept. 25, 2018, at 1, 1 https://gh.bmj.com/content/bmjgh/3/5/e000850.full.pdf.

9. ANDREW W. MULCAHY, DANIEL SCHWAM & NATE EDENFIELD, COMPARING INSULIN PRICES IN THE U.S. TO OTHER COUNTRIES 10 (2020), https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//196281/Comparing-Insulin-Prices.pdf.

10. *See* Inmaculada Hernandez, Alvaro San-Juan-Rodriguez, Chester B. Good & Walid F. Gellad, *Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007-2018*, 323 JAMA 854, 854 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7054846/.

respectively.[11] Meanwhile, the list price of one vial of fast-acting insulin in the United States was between $300 and $500.[12] Another study in 2018 revealed that the cost of producing one vial of insulin in the United States was between $2.32 and $3.76.[13] These studies show that the cost of producing insulin is significantly less than the price insulin-dependent diabetics pay.

The price of insulin is not only determined by production costs and demand, but is also significantly affected by the rebate, which is the percentage that the manufacturer pays the PBM.[14] Although pharmaceutical companies are responsible for setting the manufacturing price for insulin in the United States, PBMs have an influential role in determining the list price and contribute to the continuously growing price of insulin.[15] While patients are shown the list price when paying for medication, insurers often pay a negotiated rate for the prescription based on their agreements with PBMs.[16] The list price is affected by rebates and negotiated discounts between insulin manufacturers and PBMs.[17] PBMs are responsible for placing drugs into specific tiers within a formulary for over 266 million patients nationwide.[18] The largest PBMs include Express Scripts, CVS Caremark, and OptumRx, which establish formularies that affect over 70% of all prescription claims in the United States.[19]

A formulary is the list of covered prescription drugs and specific brands within a health plan.[20] PBMs receive payments in the form of rebates from manufacturers for their products to be included in the formulary.[21] Because PBMs require higher rebates to ensure manufacturer exclusivity within a health plan's coverage, manufacturers increase the price of insulin for patients to retain their profits. Between 2009 and 2015, the list price of Eli Lilly's insulin increased by 138%.[22] An investigation conducted by the U.S. Senate's Financial

11. *Id.*

12. *See* Benita Lee, *How Much Does Insulin Cost? Here's How 28 Brands and Generics Compare*, GOODRX HEALTH (Jan. 26, 2022), https://www.goodrx.com/healthcare-access/research/how-much-does-insulin-cost-compare-brands; STAFF OF S. COMM. ON FIN., 117TH CONG., REPORT ON INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG 44 (Comm. Print 2021).

13. *See* Gotham et al., *supra* note 8, at 2.

14. *See generally* DAVID H. KRELING, COST CONTROL FOR PRESCRIPTION DRUG PROGRAMS: PHARMACY BENEFIT MANAGER (PBM) EFFORTS, EFFECTS, AND IMPLICATIONS (2020), https://aspe.hhs.gov/cost-control-prescription-drug-programs-pharmacy-benefit-manager-pbm-efforts-effects-implications.

15. William T. Cefalu, Daniel E. Dawes, Gina Gavlak, Dana Goldman, William H. Herman, Karen Van Nuys, Alvin C. Powers, Simeon I. Taylor & Alan L. Yatvin, *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, 41 DIABETES CARE 1299, 1301 (2018).

16. *See* KRELING, *supra* note 14.

17. *Id.*

18. Cefalu et al., *supra* note 15, at 1303.

19. *Id.*

20. *Pharmacy Benefit Managers and Their Role in Drug Spending*, THE COMMONWEALTH FUND (Apr. 22, 2019), https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending [hereinafter *Pharmacy Benefit Managers*].

21. Class Action Complaint and Demand for Jury Trial at 6–7, Boss v. CVS Health Corp., No. 17-01823 (D.N.J. Mar. 17, 2017).

22. Cefalu et al., *supra* note 15, at 1302.

Committee found that Novo Nordisk and Sanofi, two of the largest insulin manufacturers, mirrored each other's price increases, and at times would match the price increase "within days or even hours."[23]

A hypothetical example helps demonstrate why manufacturers increase the list price. If the list price of insulin is $200 and the requested rebate is 40%, then the PBM will make $80, while the manufacturer will make $120. If the PBM demands a higher rebate of 60%, but the list price remains the same, the manufacturer will only make $80, while the PBM will get $120. If the manufacturer decides to increase the list price to $250 with a 60% rebate for the PBM, the manufacturer will get $150, while the PBM will receive $100. By increasing the list price, the manufacturer ensures that it will not reduce its profits while paying a higher percentage to PBMs to ensure a favorable placement in the formulary. Without transparency regarding pricing mechanisms, PBMs are able to influence the list price set by manufacturers, which detrimentally affects patients without insurance or high deductible plans.

Due to the unaffordability of insulin in the United States, many patients choose to travel to Canada or Mexico to purchase insulin. The United States International Trade Commission estimated that in 2013, almost one million California residents traveled to Mexico for medical care, which includes the purchase of prescription drugs.[24] Some purchased plane tickets to border states and drove to pharmacies in Mexico because the transportation costs were still lower than the cost of insulin in their home states.[25] Utah created a "Pharmacy Tourism Program," which reimburses patients for travel costs to preapproved pharmacies in Mexico to obtain lifesaving medications that are too costly in the United States.[26] These drastic measures to obtain lifesaving medications emphasize the need to address the prohibitive prices of prescription medication in the United States.

Insulin rationing leads to insufficient insulin levels in the body that can cause DKA, where an affected individual may fall into a coma and die.[27] In 2017, 220,340 individuals were diagnosed with DKA, and 835 of these cases resulted in death.[28] On average, the direct hospital expenses and long-term costs of DKA are around $2.4 billion annually.[29]

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23. STAFF OF S. COMM. ON FIN., *supra* note 12, at 6.

24. *See* ARTHUR CHAMBERS, TRENDS IN U.S. HEALTH TRAVEL SERVICES TRADE 2 (2015), https://www.usitc.gov/publications/332/executive_briefings/chambers_health-related_travel_final.pdf.

25. Cathy Free, *This Couple Goes to Mexico To Buy Low-Cost Insulin for Strangers Who Need It*, WASH. POST (Mar. 6, 2020), https://www.washingtonpost.com/lifestyle/2020/03/06/this-couple-goes-mexico-buy-low-cost-insulin-strangers-who-need-it/.

26. *Pharmacy Tourism Program*, PEHP HEALTH & BENEFITS, https://www.pehp.org/pharmacy/tourism (last visited Dec. 5, 2022).

27. *Diabetes & DKA (Ketoacidosis)*, AM. DIABETES ASS'N, https://www.diabetes.org/diabetes/complications/dka-ketoacidosis-ketones (last visited Dec. 5, 2022).

28. Kamleshun Ramphul & Jyotsnav Joynauth, *An Update on the Incidence and Burden of Diabetic Ketoacidosis in the U.S.*, 43 DIABETES CARE e196, e197 (2020).

29. Abbas E. Kitabchi, Guillermo E. Umpierrez, John M. Miles & Joseph N. Fisher, *Hyperglycemic Crises in Adult Patients with Diabetes*, 32 DIABETES CARE 1335, 1335 (2009).

In 2017, Alec Raeshawn Smith turned twenty-six, which meant that he was no longer covered by his mother's health insurance plan and was required to obtain his own insurance policy.[30] However, his employer did not offer health insurance benefits, and his $35,000 income was above the threshold for Medicaid in Minnesota.[31] A private insurance option would cost $450 per month with a $7,000 deductible, requiring Alec to pay $7,000 out-of-pocket for his medical expenses before his policy began covering his costs.[32] Due to these high costs, Alec chose to forego insurance.[33] While he was on his mother's health insurance plan, his out-of-pocket monthly expenses for diabetic supplies were between $200 and $300.[34] However, his monthly insulin cost without insurance was now around $1,000.[35] The drastic increase in the price for his medical supplies led to his decision to ration his insulin, and within a month of losing his mother's insurance coverage, Alec died.[36]

Meaghan Carter was diagnosed with type 1 diabetes in 2000 and had sufficient control over her condition until she lost her job and insurance coverage in June 2018.[37] Meaghan was able to receive assistance from family and friends through September 2018 to help afford her $800 monthly insulin prescription.[38] In December 2018, Meaghan found a job that was set to start in early 2019 and was scheduled to receive a direct deposit on December 26th, which would cover the cost of her insulin until her new insurance became effective.[39] However, by December, Meaghan was running out of her usual insulin supply and turned to intermediate-acting insulin (human insulin), which costs $25 per vial, but is highly unpredictable and an inadequate replacement for good blood-glucose control.[40] On December 24th, Meaghan was feeling sick and throwing up.[41] On Christmas morning, Meaghan's roommate found her dead from DKA.[42] As insulin prices continue to rise, more individuals like Alec and Meaghan will attempt to ration their insulin, increasing their risk for complications and the possibility of death.

Type 1 diabetics require constant insulin injections to survive, because the disease cannot be prevented or cured, only managed.[43] Insulin was first developed in 1922, and the first manufacturers in the market currently hold the

30. *See* Stanley, *supra* note 2.
31. *Id.*
32. *Id.*
33. *Id.*
34. *Id.*
35. *Id.*
36. *Id.*
37. Mindi Patterson, *Losing Meaghan to the Perfect Storm*, T1 INT'L (Feb. 8, 2019, 2:48 PM), https://www.t1international.com/blog/2019/02/08/losing-meaghan-perfect-storm/.
38. *See "How Many More?"*, *supra* note 1.
39. Patterson, *supra* note 37.
40. *Id.*; Lee, *supra* note 12.
41. Patterson, *supra* note 37.
42. *Id.*
43. Stanley, *supra* note 2.

patents for modern insulin through slight modifications, limiting the number of competitors due to its classification as a biologic.[44] Even after almost a century since insulin was first introduced to type 1 diabetic patients, its price continues to incrementally increase due to market manipulation by insulin manufacturers and PBMs.

This Note explains how PBMs play a significant role in the increasing price of insulin and argues that state regulations are the most viable short-term solution, while federal legislation is required for a long-term solution. Part I analyzes the history of insulin and its price growth over multiple decades. Part II discusses the increasing role of PBMs' pricing schemes and the allegations of price manipulation that have been brought to light in several ongoing lawsuits. Part III analyzes the proposal to nationalize the patent for insulin and Colorado's legislation addressing the inaccessibility of insulin due to its high costs for patients. Part IV suggests that while state legislation capping insulin copays can benefit patients and put pressure on PBMs within the states, federal legislation will provide more effective price protections for insulin-dependent diabetics.

## I. DIABETES AND THE HISTORY OF INSULIN

Over thirty-seven million Americans, or over 11% of the population, have diabetes.[45] Diabetes can be divided into multiple categories, but the two most common are type 1 and type 2 diabetes. Type 2 diabetes affects over thirty million people and is commonly classified as insulin resistance.[46] While individuals with this condition continue to produce insulin naturally, their body does not recognize the total amount of insulin produced by the pancreas.[47] In earlier stages of this condition, many individuals can control their glucose levels with oral medication, proper diet, and exercise.[48] However, if these measures are no longer sufficient, the individual will require insulin injections to manage the disease.[49]

Type 1 diabetes is an autoimmune disease that occurs when the immune system attacks the cells in the pancreas that create insulin, called beta cells.[50] Some individuals have a gene that makes them more prone to type 1 diabetes,

44. Erin M. Barker, *When Market Forces Fail: The Case for Federal Regulation of Insulin Prices*, 42 CAMPBELL L. REV. 311, 318 (2020); Louis Rosenfeld, *Insulin: Discovery and Controversy*, 48 CLINICAL CHEMISTRY 2270, 2270, 2278 (2002).

45. *Statistics About Diabetes*, AM. DIABETES ASS'N, https://www.diabetes.org/resources/statistics/statistics-about-diabetes (last visited Dec. 5, 2022).

46. *The Difference Between Type 1 and Type 2*, JOSLIN DIABETES, https://www.joslin.org/patient-care/diabetes-education/diabetes-learning-center/difference-between-type-1-and-type-2 (last visited Dec. 5, 2022).

47. *Id.*

48. *Id.*

49. *Id.*

50. *Id.*

but this is not determinative of whether they will develop the disease.[51] Often, the development of type 1 diabetes can be triggered by environmental factors, such as a flu, and can manifest within a few weeks or months.[52] Individuals diagnosed with type 1 diabetes require insulin injections right away, because their bodies are unable to produce any insulin.[53] At this time, insulin cannot be administered in pill form, because stomach acid would break down the medication before it could be absorbed.[54] Roughly 1.6 million individuals live with this disease in the United States, and about 64,000 people are diagnosed with type 1 diabetes every year.[55] Type 1 diabetes is also known as juvenile diabetes because it tends to manifest at a young age, although it can develop at any age.[56] At this moment, no preventative measures exist that can reduce the risk or slow the progression of type 1 diabetes.[57]

Type 1 diabetics must constantly track their blood sugar to avoid hyperglycemia and hypoglycemia.[58] Hyperglycemia, also known as high blood glucose, can lead to long-term health complications and may result in death if untreated.[59] Meanwhile, hypoglycemia, or low blood glucose, can cause tremors, confusion, and even death.[60]

Providing affordable access to insulin for diabetics can reduce the risk of complications and will support the goals of the scientists who discovered the drug. There are multiple medical resources that are available to insulin-dependent diabetics to control their condition, but affordability remains a barrier for many.

### A. TYPES OF INSULIN AND WAYS TO ADMINISTER THE MEDICATION

There are multiple types of insulin, such as analog insulin—commonly sold as rapid-acting, long-acting, and intermediate-acting—which is human insulin.[61] The most common types of insulin used are rapid-acting, such as Humalog and NovoLog, and long-acting, such as Lantus and Levemir.[62] Rapid-acting insulin

51. *What Is Type 1 Diabetes?*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/diabetes/basics/what-is-type-1-diabetes.html (last visited Dec. 5, 2022).

52. *Id.*

53. *Id.*

54. Lutz Heinemann & Yves Jacques, *Oral Insulin and Buccal Insulin: A Critical Reappraisal*, 3 J. DIABETES SCI. & TECH. 568, 571 (2009).

55. Mary A.M. Rogers, Catherine Kim, Tanima Banerjee & Joyce M. Lee, *Fluctuations in the Incidence of Type 1 Diabetes in the United States from 2001 to 2015: A Longitudinal Study*, 15 BMC MED. 1, 5 (2017); *Type 1 Diabetes Facts*, JDRF, https://www.jdrf.org/t1d-resources/about/facts/ (last visited Dec. 5, 2022).

56. *What Is Type 1 Diabetes?*, *supra* note 51.

57. *Id.*

58. *Id.*

59. *Manage Blood Sugar*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/diabetes/managing/manage-blood-sugar.html (last visited Dec. 5, 2022).

60. *Low Blood Sugar (Hypoglycemia)*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/diabetes/basics/low-blood-sugar.html (last visited Dec. 5, 2022).

61. *Insulin Basics*, AM. DIABETES ASS'N, https://diabetes.org/healthy-living/medication-treatments/insulin-other-injectables/insulin-basics (last visited Dec. 5, 2022).

62. *Id.*

is typically injected fifteen minutes before diabetics eat or drink anything with carbohydrates.[63] Long-acting insulin is used by type 1 diabetics once or twice a day, depending on the body's needs, and usually stays in the body for twenty-four hours.[64] The least commonly used insulin is intermediate-acting insulin, also known as NPH.[65] This type of insulin typically costs $25 per vial, but it is made from human insulin.[66] Human insulin takes between one and three hours to begin working and remains active for ten to sixteen hours, making it difficult to predict and therefore rarely used.[67] Type 1 diabetics who cannot afford their usual rapid-acting insulin tend to turn to this affordable option, which does not provide a long-term solution and can result in fatal DKA.[68]

In addition to the multiple types of insulin, individuals may choose to purchase vials or insulin pens, depending on their treatment. Individuals who use insulin pens require both long-acting and rapid-acting insulin and must attach single-use pen needles to the insulin pen when self-administering the medication.[69] Individuals who use vials may purchase syringes to inject the insulin directly, or can administer the medication with an insulin pump.[70] By using an insulin pump, the individual only requires rapid-acting insulin, because the pump delivers micro doses every few minutes to keep blood sugar at a stable level without the need for long-acting insulin.[71] Although the individual may save money by eliminating the need for long-acting insulin, the cost of a pump is around $4500 and requires additional monthly supplies that cost over $1500 per year.[72] Only three insulin pump brands are currently available for purchase in the United States, and each pump limits patients to specific insulin brands,

63. *See id.*; *About Humalog®*, ELI LILLY, https://www.humalog.com/fast-acting-mealtime-insulin (last visited Dec. 5, 2022).

64. *Insulin Basics*, *supra* note 61; *Diabetes and Insulin*, BETTER HEALTH CHANNEL, https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/diabetes-and-insulin#types-of-insulin (Oct. 17, 2021).

65. Jewels Doskicz & Sophie Vergnaud, *The 6 Types of Insulin: A Guide to Regular, Short, and Long-Acting Insulins*, GOODRX HEALTH, https://www.goodrx.com/classes/insulins/insulin-types-how-to-use (Mar. 30, 2022); Mike Watts, *Intermediate Acting Insulin*, DIABETES.CO.UK (Jan. 15, 2019), https://www.diabetes.co.uk/insulin/intermediate-acting-insulin.html.

66. Watts, *supra* note 65; *see* Lee, *supra* note 12.

67. *Basal Insulins (Intermediate and Long-Acting)*, THE JOHNS HOPKINS PATIENT GUIDE TO DIABETES, https://hopkinsdiabetesinfo.org/medications-for-diabetes-intermediate-and-long-acting-insulins/ (last visited Dec. 5, 2022).

68. *See* Audrey Farley, *Drug Prices Are Killing Diabetics. 'Walmart Insulin' Isn't the Solution*, WASH. POST (Feb. 19, 2019), https://www.washingtonpost.com/outlook/2019/02/19/drug-prices-are-killing-diabetics-walmart-insulin-isnt-solution/.

69. *Insulin Pens*, AM. DIABETES ASS'N, https://www.diabetes.org/healthy-living/devices-technology/insulin-pens (last visited Dec. 5, 2022).

70. *Insulin & Other Injectibles: Insulin Routines*, AM. DIABETES ASS'N, https://diabetes.org/healthy-living/medication-treatments/insulin-other-injectables/insulin-routines (last visited Dec. 5, 2022).

71. *Insulin Pumps: Relief and Choice*, AM. DIABETES ASS'N, https://www.diabetes.org/healthy-living/medication-treatments/insulin-other-injectables/insulin-pumps-relief-and-choice (last visited Dec. 5, 2022).

72. Ronald T. Ackermann, Amisha Wallia, Raymond Kang, Andrew Cooper, Theodore A. Prospect, Lewis G. Sandy & Deneen Vojta, *Comparative Effectiveness and Costs of Insulin Pump Therapy for Diabetes*, 23 AM. J. MANAGED CARE 353, 353–54 (2017).

further reducing the options.[73] The lack of competition and high prices for analog insulin requires patients to attempt unviable solutions, which only adds to their day-to-day stress, making this disease even more difficult to manage.

### B. HISTORY OF INSULIN

Insulin was discovered over a century ago, and while the medication has evolved to become more effective, the price has exponentially increased, making it difficult to afford and frustrating the mission of its creators. On January 23, 1922, a fourteen-year-old diabetic boy was the first to receive an effective insulin injection.[74] On January 25, 1922, Frederick Banting, Charles Best, and James Collip, the co-creators of insulin, signed a memorandum agreeing not to exploit their creation.[75] When the scientists decided to create insulin on a larger scale for further testing and distribution, they ran into complications, forcing them to accept an offer to collaborate with an American pharmaceutical company, Eli Lilly.[76] In 1923, Banting, Best, and Collip obtained an American patent for insulin and the University of Toronto's manufacturing method.[77] Shortly after, they agreed to sell the patent to the Board of Governors at the University of Toronto for $1.[78]

That same year, representatives from the University of Copenhagen received authorization from the University of Toronto to take a bottle of insulin to reproduce in Europe.[79] The representatives transported the insulin to a European nonprofit company, Nordisk Insulin Laboratory.[80] It was later renamed Novo Nordisk Foundation and remains a nonprofit organization with control over the Danish pharmaceutical company Novo Nordisk.[81]

At first, the price of insulin was not a significant cause for concern for type 1 diabetics in the United States. In 1982, human insulin was introduced and marketed at $14 per vial.[82] Then in 1996, Eli Lilly introduced analog insulin, which works faster and reduces the risk of allergies in patients.[83] Eli Lilly set the price of analog insulin at $24 per vial.[84] By 2005, the price had gone up to $60

73. *T:slim X2 Insulin Pump*, TANDEM DIABETES CARE, https://www.tandemdiabetes.com/products/t-slim-x2-insulin-pump (last visited Dec. 5, 2022) (discussing important safety information cautioning that this product can only be used with U-100 insulin, such as Novolog and Humalog).

74. Rosenfeld, *supra* note 44, at 2278.

75. *Id.*

76. *Id.* at 2279.

77. *Id.* at 2280.

78. *Id.*

79. Celeste C. Quianzon & Issam Cheikh, *History of Insulin*, 2 J. CMTY. HOSP. INTERNAL MED. PERSPS. 1, 1 (2012).

80. *Id.*

81. *The History of Novo Nordisk Foundation*, NOVO NORDISK FOUND., https://novonordiskfonden.dk/en/about-the-foundation/history/ (last visited Dec. 5, 2022).

82. Irl B. Hirsch, *Insulin in America: A Right or a Privilege?*, 29 DIABETES SPECTRUM 130, 130 (2016).

83. *See id.*

84. *Id.*

per vial, and in 2012, the price was around $138 per vial.[85] Today, the price of Humalog, produced by Eli Lilly, costs around $333.96 per vial, and Novolog, produced by Novo Nordisk, is priced around $351.10 per vial.[86] Most diabetics require two to three vials of insulin per month, sometimes even more.[87] The growing price of a medication that was sold to the University of Toronto for a single dollar creates an unforgivable situation for insulin-dependent diabetics who cannot afford their lifesaving medication.

## II. HIDDEN PRICING SCHEMES THAT AFFECT INSULIN PRICES

Although the cost to produce insulin in the United States is under $10, the price of insulin continues to grow as each company incrementally increases its list price to match the high prices set by competitors.[88] The lack of transparency allows the parties in the insulin supply chain to manipulate the prices for a higher profit.[89] PBMs are responsible for negotiating the lowest possible price for pharmacies, health plans, and consumers. However, the price of insulin continues to grow and costs consumers more without providing a clear explanation for the increase.[90] PBMs operate in secrecy with insulin manufacturers, while individuals around the country struggle to afford their lifesaving medication.[91] As the middlemen, PBMs are able to affect the price of insulin at every step of the chain, which further allows them to manipulate the market in their favor.[92] This has led to multiple class-action lawsuits, local government suits, and government investigations into their insulin pricing schemes.[93]

### A. HOW PHARMACY BENEFIT MANAGERS AND INSULIN MANUFACTURERS OPERATE

PBMs portray themselves as a crucial component of the drug market by acting as the middlemen responsible for negotiating discounts for all parties involved in the transaction.[94] PBMs work with drug manufacturers, health plans, pharmacies, and consumers. Although PBMs do not interact directly with

85. *Id.*

86. Lee, *supra* note 12.

87. 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.

88. *See* Gotham et al., *supra* note 8, at 2.

89. STAFF OF S. COMM. ON FIN., *supra* note 12, at 76.

90. Cefalu et al., *supra* note 15, at 1301.

91. *See* STAFF OF S. COMM. ON FIN., *supra* note 12, at 32–33.

92. *Pharmacy Benefit Managers*, *supra* note 20.

93. *See* Harris Cnty. v. Eli Lilly & Co., No. H-19-4994, 2020 WL 5803483, at *3 (S.D. Tex. Sept. 29, 2020); Complaint and Demand for Jury Trial at 4, Chaires v. Novo Nordisk Inc., No. 17-cv-00699 (D.N.J. Feb. 2, 2017); Class Action Complaint and Demand for Jury Trial at 12, Boss v. CVS Health Corp., No. 17-cv-01823 (D.N.J. Mar. 17, 2017); *see also* STAFF OF S. COMM. ON FIN., *supra* note 12, at 27.

94. *Pharmacy Benefit Managers*, *supra* note 20.

consumers, many large PBMs, including Express Scripts, CVS, and OptumRx, operate mail-order pharmacies that allow them to provide prescription medications directly to patients.[95] PBMs' interactions with almost all parties in the insulin supply chain allow them to lead negotiations and provide minimal disclosures to each party involved.[96] This secrecy allows PBMs to manipulate the insulin market and increase their profits[97] while insulin prices substantially grow, negatively affecting uninsured and underinsured consumers.

The insulin supply chain revolves around PBMs, because they act as the center point between manufacturers, pharmacies, and insurers.[98] PBMs are responsible for establishing the formulary and determining which brands will be "preferred" and therefore covered by the individual's health plan, resulting in a larger market share for the manufacturer.[99] Excluded brands are not covered by insurance plans and thus require patients to pay the full costs out of their own pockets, unless the insurer grants an exception.[100] It is crucial for a manufacturer to have its insulin included in the formulary, because it is otherwise unlikely to be purchased by patients. The use of formularies allows PBMs to exert control over manufacturers and push patients toward specific medications.[101]

The structure of the formulary gives manufacturers an incentive to pay PBMs a larger rebate to ensure their inclusion in the formulary.[102] Sanofi's CEO, Olivier Brandicourt, discussed the importance of remaining in good relations with the PBMs after its insulin, Lantus, was excluded from the formulary by CVS Health.[103] In order to avoid incurring losses, manufacturers raise the price of insulin to then pay a higher rebate to the PBMs.[104] In 2019, Sanofi offered OptumRx a 79.5% rebate for a preferred commercial formulary placement, a significant increase from its 42% rebate in 2015.[105] Congressional investigations have begun to slowly uncover the exorbitant rebates that PBMs demand from manufacturers, which directly affect the price that patients have to pay for insulin.[106]

The comparison between the rebates from Sanofi to OptumRx in 2015 and 2019 demonstrates the effect of rapidly increasing rebates on insulin prices. In

95. *Harris Cnty.*, 2020 WL 5803483, at *5.

96. *See* STAFF OF S. COMM. ON FIN., *supra* note 12, at 33.

97. *Id.* at 43.

98. *Pharmacy Benefit Managers*, *supra* note 20.

99. Samuel F. Ernst, *The Pharmaceutical Industry's Corrupt Price Discrimination System: A Single Solution?*, 51 U. PAC. L. REV. 475, 483 (2020).

100. *See* STAFF OF S. COMM. ON FIN., *supra* note 12, at 66.

101. Class Action Complaint and Demand for Jury Trial at 5–6, Boss v. CVS Health Corp., No. 17-cv-01823 (D.N.J. Mar. 17, 2017).

102. *Id.* at 6–7.

103. *See* Sanofi's CEO, Olivier Brandicourt, CEO, Sanofi, Remarks at the Bank of America Merrill Lynch Global Healthcare Conference (Sept. 16, 2016).

104. *Id.*

105. *See* STAFF OF S. COMM. ON FIN., *supra* note 12, at 60.

106. Class Action Complaint and Demand for Jury Trial at 9, Boss v. CVS Health Corp., No. 17-cv-01823 (D.N.J. Mar. 17, 2017).

2015, one vial of Lantus, Sanofi's insulin, had a list price of $248.50.[107] In order for OptumRx to include Lantus in its formulary, Sanofi paid a rebate of 42%.[108] For every vial that Sanofi sold through OptumRx, the PBM took $119.28, and Sanofi received $129.22. In 2019, Sanofi offered OptumRx a rebate of 79.5% and increased the price of Lantus to $339.92.[109] Now, OptumRx receives $270.24 for each vial, while Sanofi only nets $69.68 of profit. Thus, although Sanofi increased the price of insulin, its profit did not increase, but rather decreased under OptumRx's formulary because of the high rebate.[110]

Once PBMs negotiate the rebate and formulary placements with insulin manufacturers, they provide the formulary to health plans for an administrative fee.[111] The formulary also includes "preferred" pharmacies.[112] This provides pharmacies with an incentive to pay the PBMs to be included in the health plan. Additionally, some plans provide a discount for patients who opt to use the PBMs' mail-order pharmacies and order a three-month supply rather than visit their local pharmacy every month.[113] PBMs are also responsible for negotiating the price that the pharmacy will pay the insulin manufacturer or the wholesaler for the insulin that it then sells to patients.[114] The common factor among all of these interactions is that the PBMs are supposed to divide the rebate that they receive from the insulin manufacturer and distribute portions to the health plan and pharmacy.[115] However, some health plans are reporting that PBMs are not properly distributing the rebate.[116] Instead, PBMs are billing the health plans a higher price for medications than what they are actually paying pharmacies for the drugs, resulting in an even higher profit for PBMs.[117] The growing price of insulin and the secret rebate mechanisms are sparking inquiries by health plans and government agencies.[118]

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107. OptumRx 2015 MMA Part D Bid Proposal, in Documents Produced by Sanofi, to Sens. Charles Grassley & Ron Wyden, Senate Comm. on Fin. (Nov. 1, 2013), https://www.finance.senate.gov/imo/media/doc/Sanofi_Redacted.pdf.

108. *See* STAFF OF S. COMM. ON FIN., *supra* note 12, at 60.

109. BU Pricing Review Board Bid Proposal, in Documents Produced by Sanofi, to Sens. Charles Grassley & Ron Wyden, Senate Comm. on Fin. 4 (Nov. 30, 2017), https://www.finance.senate.gov/imo/media/doc/Sanofi_Redacted.pdf.; Lee, *supra* note 12.

110. BU Pricing Review Board Bid Proposal, *supra* note 109, at 270.

111. Cefalu et al., *supra* note 15, at 1303.

112. *See Pharmacy Benefits*, BLUESHIELD OF CAL., https://myoptions.blueshieldca.com/cseba/cseba/_/pharmacy_benefits (last visited Dec. 5, 2022).

113. *PBM Basics*, PHARMACISTS SOC'Y OF THE STATE OF N.Y., INC., https://www.pssny.org/page/PBMBasics (last visited Dec. 5, 2022).

114. Cefalu et al., *supra* note 15, at 1303.

115. *See id.*

116. *See Pharmacy Benefit Managers*, *supra* note 20.

117. *Id.*

118. *See* Harris Cnty. v. Eli Lilly & Co., No. H-19-4994, 2020 WL 5803483, at *2 (S.D. Tex. Sept. 29, 2020).

## B. INSULIN PRICING LITIGATION

The secrecy behind the insulin pricing mechanism has resulted in needlessly high prices and has sparked multiple class-action lawsuits. These lawsuits highlight the growing concern for insulin prices around the country and the unaffordability of this lifesaving medication. In 2017, multiple insulin-dependent diabetics filed class-action lawsuits against the major PBMs and insulin manufacturers.[119] The complaint in *Boss v. CVS Health Corp.* alleged that the continuous increase of insulin prices creates an immense financial benefit to PBMs and manufacturers but puts an unjustified financial burden on patients.[120] The plaintiffs in *Chaires v. Novo Nordisk* have alleged that manufacturers violated multiple state consumer protection laws, as well as the Federal Racketeer Influenced and Corrupt Organizations Act (RICO).[121] *Chaires* is currently pending in New Jersey against three pharmaceutical companies, Sanofi-Aventis, Novo Nordisk, and Eli Lilly.[122] Additionally, in 2019, Harris County of Texas filed a lawsuit against the three insulin manufacturers and the three largest PBMs for RICO violations, conspiracy, and fraud, which was dismissed in 2022.[123] The ongoing *Chaires* case highlights the issues with the current insulin-pricing system around the country.

### *1. Chaires v. Novo Nordisk*

The plaintiffs in *Chaires v. Novo Nordisk* have alleged that insulin manufacturers are manipulating the price of insulin in violation of RICO and multiple state consumer fraud statutes.[124] The complaint states that the insulin manufacturers consistently raise the list price of insulin to increase rebates to the PBMs to ensure their "preferred" status on the formulary, increasing the manufacturers' market spread.[125] Furthermore, insulin manufacturers allegedly raise their prices of insulin in response to each other, sometimes within hours.[126] Additionally, analog insulin, the most commonly prescribed insulin, has not substantially changed in the past ten years, yet the price has increased by about 169%.[127] In response, the manufacturers argue that they do not increase the price

119. Class Action Complaint and Demand for Jury Trial at 1, Boss v. CVS Health Corp., No. 17-cv-01823 (D.N.J. Mar. 17, 2017).

120. *Id.* at 9.

121. Complaint and Demand for Jury Trial at 9, Chaires v. Novo Nordisk Inc., No. 17-cv-00699 (D.N.J. Feb. 2, 2017).

122. *Id.* at 54.

123. *Harris Cnty.*, 2020 WL 5803483, at *1; Harris Cnty. v. Eli Lilly & Co., No. H-19-4994, 2022 WL 479943, at *1 (S.D. Tex. Feb. 16, 2022).

124. *See* Complaint and Demand for Jury Trial at 9, Chaires, v. Novo Nordisk Inc., No. 17-cv-00699 (D.N.J. Feb. 2, 2017).

125. *Id.* at 76.

126. *See* STAFF OF S. COMM. ON FIN., *supra* note 12, at 4.

127. Complaint and Demand for Jury Trial at 43, Chaires v. Novo Nordisk Inc., No. 17-cv-00699 (D.N.J. Feb. 2, 2017).

for personal gain.[128] Eli Lilly stated that the drug makers must increase the list prices to remain profitable, because "PBMs demand higher rebates in exchange for including the drug on their preferred-drug lists."[129]

The first claim in the *Chaires* complaint is that the insulin manufacturers violated RICO; the defendants moved to dismiss.[130] RICO requires that the plaintiff prove:

> (1) the existence of an enterprise affecting interstate commerce; (2) that the defendant was employed by or associated with the enterprise; (3) that the defendant participated . . . , either directly or indirectly, in the conduct or the affairs of the enterprise; and (4) that he or she participated through a pattern of racketeering.[131]

The court determined that the plaintiffs had adequately pleaded all of the above requirements, because, under a competitive market strategy, the prices would not rise in such a manner.[132] Additionally, these increases would not be possible unless the insulin manufacturers were cooperating with the PBMs and maintaining the secrecy of the pricing scheme.[133] Nevertheless, the court held that the plaintiffs were barred from pursuing their RICO claim under the indirect-purchaser rule, because the patients did not purchase insulin directly from the insulin manufacturers but from pharmacies.[134]

The plaintiffs filed a third amended class-action complaint arguing that while they did not directly purchase insulin from the pharmaceutical companies, they were directly harmed by the fraud and directly relied on the false list prices.[135] The complaint alleges that although patients cannot purchase insulin directly from the manufacturers, they are the only available defendants.[136] On December 17, 2021, the court granted in part and denied in part the manufacturers' partial motion to dismiss.[137] The court granted the motion to dismiss the federal RICO claim and several state racketeering claims, but denied the motion as to the state civil conspiracy claims.[138] The case remains active.[139]

128. *Id.*
129. *Id.* at 43–44.
130. *In re* Insulin Pricing Litig., No. 17-cv-00699, 2019 WL 643709, at *5, *7 (D.N.J. Feb. 15, 2019).
131. *Id.* at *5.
132. *Id.* at *6–7.
133. *Id.* at *6.
134. *Id.* at *13.
135. Third Amended Class Action Complaint at 145, *In re* Insulin Pricing Litig., No. 17-cv-00699 (D.N.J. Apr. 20, 2021).
136. *Id.* at 147.
137. *In re* Insulin Pricing Litig., No. 17-cv-00699, 2021 WL 5980629, at *17 (D.N.J. Dec. 17, 2021).
138. *Id.*
139. *Insulin Overpricing*, HAGENS BERMAN, https://www.hbsslaw.com/cases/insulin-overpricing (last visited Dec. 5, 2022).

*2. Harris County v. Eli Lilly & Co.*

Harris County in Texas filed a lawsuit against Eli Lilly, Sanofi-Aventis, Novo Nordisk, Express Scripts, CVS Health, and OptumRx in 2019, alleging that the insulin pricing scheme has significantly increased the list price of insulin in order to offer PBMs larger rebates.[140] The County provides health benefits for about 38,000 individuals, which include subsidizing the cost of insulin.[141] The County alleged that the PBMs violated RICO by (1) misrepresenting the price that they negotiated with manufacturers, (2) making multiple fraudulent statements, (3) and sending fraudulent written solicitation materials by mail.[142] Furthermore, it argued that while the price has significantly increased over the past fifteen years, the increase could not be attributed to inflation or other market forces.[143] These price increases significantly affected the County, because from 2013 to 2018, it spent over $27 million on insulin.[144]

When PBMs receive rebates from insulin manufacturers, it is expected of them to provide part of the rebate to pharmacies and health plans. Harris County negotiated contracts with PBMs requiring them to pay the County a portion of the rebates that they received from the manufacturer.[145] However, the County alleged that the PBMs instead "relabeled the rebates with vague terms like 'administrative fees, volume discounts, services fees, [and] price of margin guarantees' so that they could keep more of the rebate money for themselves."[146] In addition to the RICO violations, the County alleged that the PBMs violated the Texas Deceptive Trade Practices-Consumer Protection Act and conspired to commit fraud and unjust enrichment.[147]

The PBMs moved to dismiss all claims.[148] Their first argument was that they were not working with the manufacturers to artificially inflate the prices.[149] However, in 2020, the court denied the motion, stating that the County successfully alleged that insulin prices would not be so high under competition in a legitimate market.[150] The PBMs' second argument was that—as in previous lawsuits against PBMs and insulin manufacturers—the County was an indirect purchaser and was therefore barred from asserting a RICO claim.[151] However, the court noted that the PBMs make money by providing medications to patients through their mail-order pharmacies.[152] The County stated that PBMs charge

140. Harris Cnty. v. Eli Lilly & Co., No. H-19-4994, 2020 WL 5803482, at *2 (S.D. Tex. Sept. 29, 2020).
141. *Id.* at *1.
142. *Id.* at *5.
143. *Id.* at *2.
144. *Id.*
145. *Id.* at *3.
146. *Id.*
147. *Id.* at *15, *18.
148. *Id.* at *1.
149. *Id.* at *8–9.
150. *Id.* at *9.
151. *Id.* at *13.
152. *See id.*

their customers, which include County-operated health plans, higher prices for drugs, resulting in higher profits for PBM-owned mail-order pharmacies.[153] Although the County did not receive the medications directly from the PBMs, it "pa[id] the PBM Defendants *directly* for the overcharges of the diabetes medication at issues in th[e] case"; therefore, the court held that the indirect-purchaser rule did not bar the County from successfully pleading its RICO claim.[154] While the court denied the PBMs' initial motions to dismiss, in March 2022, the court entered final judgment dismissing the case as to all defendants with prejudice.[155]

Despite the fact that *Harris County* was dismissed, states have initiated new investigations and lawsuits.[156] These lawsuits against insulin manufacturers and PBMs will be protracted, but they will open further inquiry into the secrecy behind insulin pricing.

## III. PROPOSED SOLUTIONS AND CURRENT LEGISLATION

The issue of high insulin prices has been ongoing for many years. Scholars have offered multiple proposals,[157] and several states have begun to address this problem with copay caps on insulin for their constituents.[158] One solution that has been offered is to nationalize the patents for insulin production, which would allow the U.S. government to use or distribute the patented insulin formula.[159] Although nationalizing patents for insulin production would require bipartisan support, there is precedent for such an action in 2001 with ciprofloxacin.[160] Another suggestion is to increase transparency in the pharmaceutical industry.[161] This would eliminate PBMs' ability to hide their profits and continue increasing the price of insulin without repercussions or explanation. However, increasing

153. *Id.* at *14.

154. *Id.*

155. Harris Cnty. v. Eli Lilly & Co., No. H-19-4994, 2022 WL 479943, at *14–15 (S.D. Tex. Feb. 16, 2022) (dismissing all claims as to defendant OptumRx with prejudice); Harris Cnty. v. Eli Lilly & Co., No. H-19-4994, slip op. at 1 (S.D. Tex. Mar. 16, 2022) (entering final judgment dismissing the case as to all defendants with prejudice).

156. *See generally* Mississippi *ex rel.* Fitch v. Eli Lilly & Co., No. 21-cv-00674, 2022 WL 1624780 (S.D. Miss. Aug. 9, 2022); Press Release, FTC, FTC Launches Inquiry into Prescription Drug Middlemen Industry (June 7, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry; Press Release, Dana Nessel, Att'y Gen., Mich. Dep't. of Att'y Gen., Let My Department Investigate Prescription Drug Prices (Feb. 12, 2022), https://www.michigan.gov/ag/news/press-releases/2022/02/12/ag-nessel-let-my-department-investigate-prescription-drug-prices; Anna Wilde Mathews, *States Probe Business Practices of Pharmacy Benefit Managers*, WALL ST. J. (May 11, 2021, 7:00 AM), https://www.wsj.com/articles/states-probe-business-practices-of-pharmacy-benefit-managers-11620730804.

157. *See generally* Barker, *supra* note 44; Ernst, *supra* note 99; Jessica Zelitt, *Pay or Die: Evaluating the United States Insulin Pricing Crisis and Realistic Solutions To End It*, 50 STETSON L. REV. 453, 460 (2021).

158. *See* COLO. REV. STAT §§ 10-16-151, 12-280-139 (2021); DEL. CODE ANN. tit. 29, § 5212 (2020); 215 ILL. COMP. STAT. 5/356z.41 (2021); N.M. STAT. ANN. § 13-7-25 (2021); UTAH CODE ANN. § 31A-22-626 (West 2021).

159. Barker, *supra* note 44, at 332.

160. *Id.*

161. Ernst, *supra* note 99, at 486.

transparency will not necessarily force PBMs and manufacturers to release all the pertinent information. Furthermore, they may choose to release a burdensome amount of information that will be cumbersome to investigate.[162] There is another solution: states could simply cap insulin prices or copays. Colorado is the first state to pass legislation to cap the price of insulin for patients within the state. Following Colorado's example, several other states have passed legislation capping the copay for insulin to alleviate some of the financial hardships that insulin-dependent diabetics must overcome to afford their lifesaving medication.

### A. NATIONALIZE THE PATENT FOR INSULIN TO INCREASE PRODUCTION

Many high-income countries around the world have special government organizations responsible for negotiating drug prices. If the manufacturer agrees on a price, the organization recommends its inclusion. However, if no agreement is reached, the drug is excluded from the market and another brand is offered to consumers. For example, in the United Kingdom, the National Institute for Health and Clinical Excellence determines which drugs to include in its National Health Service coverage.[163] Similarly, Germany established the Institute for Quality and Efficiency in Healthcare, which affects all insurers in the county and sets the price for a drug after it has been on the market for one year.[164] Meanwhile, the U.S. government does not negotiate prices with pharmaceutical companies. This financially impacts both patients and the government, because Health and Human Services (HHS) cannot negotiate for lower prices, forcing the government and certain Medicare patients to pay the full price for medication.[165]

A proposed solution is to nationalize the insulin patents, which would allow other companies to create insulin with the same effectiveness and provide more options in the market.[166] One scholar who has written on this topic, Erin Barker, argues that this provision implies the government's right to use or manufacture patent-protected items as long as the patent holder receives compensation, similar to the concept of eminent domain.[167] Under this presumption, the patent holder can demand compensation but cannot prevent the U.S. "government from producing the medicine or [authorizing other companies] to produce or import

162. *Id.*

163. Aaron S. Kesselheim, Jerry Avorn & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States*, 316 JAMA 857, 860 (2016).

164. *Id.* at 860 tbl.3.

165. *Id.* at 862. As of August 16, 2022, HHS cannot negotiate for lower prices, but will be able to negotiate prices for eligible drugs starting in 2026. Inflation Reduction Act of 2022, ch. 169, sec. 1194, § 1320f-3, 136 Stat. 1818, 1836–49. Additionally, it is unlikely that HHS will be able to negotiate prices for analog insulin based on restrictions in the Inflation Reduction Act of 2022. *Id.* Although the laws governing Medicare are important to this topic, they are beyond the scope of this Note and will not be further elaborated.

166. Barker, *supra* note 44, at 331.

167. *Id.*

the medicine."[168] The proposal relies on 28 U.S.C. § 1498(a) to support the theory that the U.S. government has the right to nationalize the use of patented items like insulin.[169] The federal statute provides damages and compensation for the patent holder if the invention is used by the government or with the government's consent without receiving license from the patent holder.[170]

This proposal is based on precedent set by the U.S. government in 2001, when there was a looming threat of anthrax being used as a chemical weapon.[171] The government wanted to stock its supply of ciprofloxacin (Cipro), which is used to treat the effects of anthrax exposure. However, the manufacturer, Bayer, refused to produce larger quantities of the antibiotic and would not reduce the price of the medication for the government.[172] In response, the U.S. government threatened to nationalize the patent for Cipro and import generic versions under § 1498.[173] Although the government did not have to go through with its threat, the risk of losing its market share forced Bayer to agree to reduce the price and provide the government with an adequate supply of Cipro.[174]

The U.S. government may attempt a similar tactic with insulin manufacturers. If, however, the threats do not achieve effective results, the government could nationalize the patent and offer it to generic manufacturers. The FDA classifies insulin as a biologic and requires that the follow-on product be highly similar and have no "clinically meaningful differences" from the original drug.[175] This makes it difficult for generic manufacturers to enter the market, because creating a biologic is costly, costing up to as much as developing a new drug for new companies.[176] Additionally, insulin manufacturers participate in "patent evergreening" by making incremental changes to their product to continuously patent it, creating additional financial barriers for generic manufacturers.[177] Only two follow-on insulins have been released since its reclassification as a biologic—one of which was created by Eli Lilly—and have yet to influence insulin prices.[178] By nationalizing or threatening to nationalize the patents, there could be wider opportunities for generic manufacturers to develop biosimilar insulin, or the threat may force current manufacturers to decrease their prices.[179]

168. *Id.*
169. *Id.*
170. 28 U.S.C. § 1498(a).
171. Barker, *supra* note 44, at 332.
172. *Id.*
173. *Id.*
174. *Id.*
175. Ariel Dora Stern, Jacqueline L. Chen, Melissa Ouellet, Mark R. Trusheim, Zeid El-Kilani, Amber Jessup & Ernst R. Berndt, *Biosimilars and Follow-on Products in the United States: Adoption, Prices, and Users*, 40 HEALTH AFFS. 989, 990 (2021).
176. Zelitt, *supra* note 157, at 460.
177. *Id.* at 461.
178. *See Basaglar*, ELI LILLY, https://www.basaglar.com/ (last visited Dec. 5, 2022); *see also Semglee*, VIATRIS, https://www.semglee.com/ (last visited Dec. 5, 2022).
179. Barker, *supra* note 44, at 330–31.

While this proposal has potential, it does not address PBMs' influence over prescription prices. Barker's proposed solution does not discuss PBMs' influence over insulin prices.[180] Eli Lilly's Basaglar was released in 2016 as a "generic" to Sanofi's Lantus.[181] However, insulin is not considered under the same category as most generic drugs and therefore does not require physicians and pharmacies to automatically provide patients with the cheaper generic version of the drug. Additionally, PBMs still have the discretion to decide which brands will be a part of the formulary. For example, under OptumRx's 2021 formulary, Lantus, Sanofi's insulin, is included under the brand-tier.[182] Meanwhile, Eli Lilly's "generic," Basaglar, is excluded from the formulary.[183] Additionally, the newly released Semglee, the first interchangeable biosimilar insulin—meaning that pharmacies now have the right to substitute it for brand name insulin—is also excluded under OptumRx's formulary.[184] While adding more insulin manufacturers to the market may push the main manufacturers to reduce their prices, the rebate practices can continue to stifle competition through formulary exclusions.

### B. COLORADO'S INSULIN PRICE CAP LEGISLATION

In 2019, Colorado became the first state in the United States to pass legislation that capped copays for insulin for Colorado residents. The first version of the statute required health insurance plans to cap the copay for insulin at $100.[185] Any additional costs for the medication would be paid by the insurance provider.[186] Colorado set the cap at $100 after multiple deliberations with insurance companies to ensure that monthly premiums would not be significantly impacted.[187] Later that year, when insurers submitted their proposed monthly rates to the state for approval, they did not mention the insulin price caps as being a factor in the rates, stating that the caps were "negligible" and "de minimis," which shows that capping the price of insulin does not financially impact the general insured population.[188]

The 2019 legislation provided the initial step toward curtailing the price of insulin. However, the statute neglected to address individuals without insurance

180. *See id.*

181. *FDA Approves Basaglar® (Insulin Glargine Injection), a Long-Acting Insulin Treatment*, ELI LILLY (Dec. 16, 2015), https://investor.lilly.com/news-releases/news-release-details/fda-approves-basaglarr-insulin-glargine-injection-long-acting.

182. OPTUM RX, YOUR PRESCRIPTION DRUG LIST/FORMULARY 76 (2021), https://www.optumrx.com/content/dam/openenrollment/pdfs/ers/1.1.2021-Prescription-Drug-List.pdf.

183. *Id.*

184. *Id.* at 77.

185. COLO. REV. STAT § 10-16-151(2) (effective from Aug. 2, 2019, to Sept. 7, 2021).

186. *Id.*

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

188. *Id.*

coverage or those with high deductible plans. Additionally, the state law could not impact Medicare and self-funded health plans, which fall under the Federal Employee Retirement Income Security Act (ERISA). These individuals continue to bear the burden of high insulin costs. Furthermore, the statute capped the copays for insulin per prescription.[189] If an individual required multiple types of insulin per month, they would be able to take advantage of the cap for each prescription separately. Therefore, if an individual required both rapid-acting and long-acting insulins, their copay would be capped at $200 instead of $100, while the health plan would be responsible for the remaining amount.

In 2021, Colorado passed a new bill amending the existing insulin price cap to add new protections for uninsured individuals and those with high deductibles.[190] The first change capped the price of insulin at $100 "regardless of the amount or type of insulin needed to fill the covered person's prescription or the number of prescriptions."[191] Now, individuals with prescriptions for multiple types of insulin will not be required to pay more than $100 per month. Additionally, the new bill established a price cap on insulin for those without insurance.[192] Effective January 2022, a program must be established to allow enrolled individuals to purchase their insulin supply for no more than $50 per month.[193] Although individuals with health plans governed under ERISA are not explicitly mentioned in the statute, they may also be eligible for the price cap under this statute if they choose to purchase insulin without using their health plan.[194] This program allows pharmacies to submit an electronic claim to insulin manufacturers for reimbursement, which is calculated by taking the difference between the list price and the cost that the patient pays.[195] Any amount that remains after the patient pays their capped copay will be paid by the manufacturer.[196] This new program may potentially limit PBMs' effect on insulin prices, because the uninsured do not rely on formularies. Therefore, manufacturers do not need to pay rebates to reach these patients.

Colorado's legislation provided a push for other states to pass similar bills to limit the cost of insulin for their constituents. However, Colorado's price cap remains expensive for many consumers and has not explicitly addressed plans that fall under ERISA. These plans are governed by federal law, and state law capping insulin prices does not apply. Additionally, these price limits only apply to Colorado's constituents; those who live in other states cannot take advantage of the lower prices. While Colorado provided financial relief for many

189. *Id.*

190. H.R. 21-1307, 73rd Gen. Assemb., Reg. Sess. (Colo. 2021).

191. COLO. REV. STAT § 10-16-151(2) (effective Sept. 7, 2021).

192. *Id.* § 12-280-139(7).

193. *Id.*

194. The language in section 12-280-139(7) does not explicitly include or disqualify individuals with health plans governed by ERISA, nor does it mention ERISA plans. *See id.*

195. *Id.* § 12-280-139(8)(a).

196. *Id.* § 12-280-139(8)(c)(I).

individuals within the state, much more must be done to relieve the financial burden of insulin costs.

## IV. ADDITIONAL STATE ACTION AND FEDERAL LEGISLATION FOR AN EFFICIENT SOLUTION

Insulin prices have impacted individuals for years, and while multiple solutions have been proposed, none have offered permanent relief. Colorado's example provides a framework empowering a state to provide financial assistance to insulin-dependent diabetics without affecting insurance premiums for the state's general population. Colorado's legislation can be used as a model in other states to provide their constituents with similar relief as a statewide solution. However, to comprehensively address the issue and permanently reduce the price of insulin, the federal government must get involved. Many legal roadblocks limit a state's ability to fully cap the cost of insulin, such as patent protections, federally regulated health plans, and state borders. By enacting legislation similar to the Insulin Price Reduction Act, which was introduced in the Senate in 2019,[197] the federal government will be able to effectively regulate insulin prices and demand disclosure from insulin manufacturers and PBMs.

### A. COLORADO'S INSULIN CAP LEGISLATION AS A MODEL FOR OTHER STATES

Colorado's House Bill 21-1307 closed many loopholes that were exploited by insurers, pharmacies, and insulin manufacturers under House Bill 19-1216.[198] Following Colorado, fourteen other states and the District of Columbia have passed legislation capping the price of insulin. Some states have drafted legislation similar to Colorado's original price cap bill, capping the copay at $100 for individuals with commercial insurance.[199] New Mexico, Utah, and Texas opted to limit the copay further. New Mexico capped the copay for insulin at $25 for individuals with commercial insurance.[200] Utah capped the price of insulin at $30 for individuals with commercial insurance and the uninsured.[201] Additionally, the $30 per month will be applied regardless of whether the individual has met their deductible.[202] Texas passed legislation capping the copay for each insulin prescription at $25 per month for individuals with commercial insurance.[203] Therefore, in Texas, individuals with multiple types of insulins will end up paying more than $25 per month.

197. S. 2199, 116th Cong. (2019).

198. *See* H.R. 21-1307, 73rd Gen. Assemb., Reg. Sess. (Colo. 2021); H.R. 19-1216, 71st Gen. Assemb., Reg. Sess. (Colo. 2019).

199. DEL. CODE ANN. tit. 29, § 5212(b)(1) (2020); 215 ILL. COMP. STAT. 5/356z.41(c) (West 2021).

200. N.M. STAT. ANN. § 13-7-25 (West 2021).

201. UTAH CODE ANN. § 31A-22-626(4)(a) (West 2021).

202. *Id.* § 31A-22-626(4)(b).

203. TEX. INS. CODE ANN. art. 1358.103(b) (West 2021).

Colorado's legislation not only caps the price of insulin, but also allows the Attorney General to investigate the insulin pricing scheme.[204] In 2020, the investigation resulted in a report recommending legislation to address drug price transparency and require compliance from all actors in the supply chain, such as PBMs, manufacturers, insurance carriers, and distributors.[205] The report also recommends joining a "bulk purchasing plan" to increase the state's purchasing power and reduce the role of the PBM.[206] Colorado could choose to create its own bulk purchasing plan within the state, or it could join one of five existing multi-state bulk-buying organizations.[207] By reducing the role of the PBM, manufacturers would lose the incentive to provide PBMs with such high rebates for a "preferred" formulary status.

Many health insurance plans already provide some copay limit for certain insulin brands commonly placed into the brand or second-tier formulary. The uninsured or individuals with high-deductible plans are the most affected, because they have to pay the full list price for insulin, which continues to increase due to the higher rebates demanded by PBMs. Colorado's and Utah's laws, which cap the copay for the uninsured and individuals with high deductibles, can also reduce PBMs' dominance over formularies. Uninsured patients do not rely on formularies, because they are not included in a health plan and therefore can purchase any insulin. This will provide manufacturers an incentive to appeal to consumers directly to increase their market share and will potentially decrease their interest in paying PBMs a higher rebate. Furthermore, by minimizing PBMs' control through bulk-purchasing plans, states can reduce the costs of state-sponsored health plans and provide affordable medication for insulin-dependent diabetics.

There have been concerns that capping the price of insulin may increase insurance premiums for everyone. However, a study by Milliman has shown that a "zero-dollar insulin co-pay cap would only raise insurance premiums by an average of $5.12 per year."[208] Most states that have passed insulin price legislation have a copay cap between $25 and $100. In 2020, health plans in Colorado submitted their materials to justify their proposed monthly rates to the Colorado Division of Insurance. The health plans either did not mention the insulin price caps or stated that the caps were "negligible" and "de minimis" and did not affect the cost of premiums.[209] Health plans tend to negotiate the price that they pay for insulin, and it seems that the copay caps have not affected the cost for plans, showing that price limits on insulin can be beneficial to diabetes patients without causing additional financial expenditures for others.

204. H.R. 19-1216, 71st Gen. Assemb., Reg. Sess. (Colo. 2019).

205. COLO. DEPT. OF L., PRESCRIPTION INSULIN DRUG PRICING REPORT 58 (2020), https://coag.gov/app/uploads/2020/11/Insulin-Report-102020.pdf.

206. *Id.* at 59.

207. *Id.*

208. Zelitt, *supra* note 157, at 472.

209. Ingold, *supra* note 187.

Although some states and the District of Columbia have started to follow Colorado's example and even to offer lower copay limits for their constituents, the price cap, individuals affected, and requirements vary among the states. For example, Utah's legislation applies the price cap to commercially insured and uninsured individuals, and limits the price at $30 per month for the entire monthly supply.[210] However, Texas's law does not mention deductibles and is applied per prescription, which means that an individual who uses two types of insulin each month will pay $50 instead of $25 for their monthly supply.[211] While these price limits provide some financial relief to insulin-dependent diabetics, the variation creates confusion. Additionally, the majority of states have yet to pass legislation addressing the price of insulin. Therefore, a national solution is necessary to efficiently address insulin prices across the country.

### B. FEDERAL INSULIN PRICE CAP

State legislation affecting the price of insulin only impacts the residents of that state and does not provide much support for individuals with ERISA or Medicare plans. There are few states with insulin price caps, and with fifty states, it can take a long time for the entire country to pass similar legislation. By enacting federal legislation that caps the price of insulin, the U.S. government would be able to address many of the loopholes that states and the District of Columbia have struggled to overcome. Although a federal insulin price cap bill will not resolve the underlying problems with pharmaceutical pricing, it is a politically viable solution, and health plans have shown their willingness to cooperate with price caps on insulin.

Federal legislation can provide a stronger foundation for price caps because federal laws preempt state laws, which can affect the state's ability to regulate pharmaceutical prices. In 2005, the District of Columbia passed the Prescription Drug Excessive Pricing Act, which prohibited the sale of any patented drug for an excessive price within that jurisdiction.[212] The Act defined an "excessive" price as being over 30% higher than the "comparable price in any high-income country in which the product is protected by patents."[213] The high-income countries used for comparison were the United Kingdom, Germany, Canada, and Australia.[214] In response, Pharmaceutical Research and Manufacturers of America filed a suit against the District, alleging that the Act was preempted by federal patent laws.[215] Although federal patent laws do not prohibit a state from regulating the price of patented items,[216] the court

210. UTAH CODE ANN. § 31A-22-626(4) (West 2021).

211. *See* TEX. INS. CODE ANN. art. 1358.103(b) (West 2021).

212. D.C. CODE ANN. § 28-4553 (West 2007) (preempted by Biotech. Indus. Org. v. District of Columbia, 496 F.3d 1362 (Fed. Cir. 2007)).

213. *Id.* § 28-4554(a).

214. *Id.* § 28-4552(2).

215. *Biotech. Indus. Org.*, 496 F.3d at 1366.

216. *Id.* at 1372.

concluded that assigning penalties for high prices limits the "full exercise of the exclusionary power that is derived from the patent" and creates an obstacle to the objectives of patent laws.[217]

Insulin remains a patented biologic, which can potentially cause issues for states that aim to regulate its price. Sanofi's main patent for Lantus expired in 2015; however, the company has filed around seventy additional patents since 2000 and thus will receive patent protection for Lantus until at least 2028.[218] While manufacturers continue to extend their patent protection, the possibility of increased competition remains slim and requires federal interference. Insulin has been around for almost a hundred years, and the estimated cost of production of certain types is between $2.32 and $3.76, yet companies are able to increase the price of insulin every year.[219]

Furthermore, states cannot affect Medicare plans, and state copay caps cannot reduce the government's spending on Medicare prescription drugs. Total Medicare Part D spending on insulin was $1.4 billion in 2007 and increased to $13.3 billion in 2017.[220] The cost per prescription increased from $96 in 2007 to $363 in 2017.[221] Currently, the federal government does not allow Medicare to negotiate insulin prices, and therefore insulin's costs are continuously increasing as manufacturers increase the list price to appease PBMs.[222] Only federal legislation can cap insulin copays for Medicare or ERISA plans and reduce the government's high spending on a medication that has remained unchanged for over a decade.

Federal legislation is a long-term goal and solution, because it may take time for Congress to reach a bipartisan agreement that will cap the cost of insulin for all diabetics. However, the government is moving in a direction that may cap insulin prices for many insulin-dependent diabetics. In August 2022, the President signed into law the Inflation Reduction Act of 2022, which caps the price of insulin at $35 per month or 25% of a plan's negotiated price, whichever is lower for Medicare Parts B and D, starting in 2023.[223] This Act limits the insulin copay price for Medicare patients, but does not address insulin copays for private insurance, ERISA plans, or for uninsured individuals.

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217. *Id.* at 1374.

218. Barker, *supra* note 44, at 318. The topics of biologics and patent "evergreening" are beyond the scope of this Note. *See generally* Adam P. Hustad, *Competing with Patent Thickets: Antitrust Law's Role in Promoting Biosimilars*, 102 B.U. L. REV. 675 (2022); Reed F. Beall, Jason W. Nickerson, Warren A. Kaplan & Amir Attaran, *Is Patent "Evergreening" Restricting Access to Medicine/Device Combination Products?*, PLOS ONE, Feb. 24, 2016; Susan Mayor, *Insulin Has Never Become a Cheap Generic Drug in the US Because of Companies' Small Changes to "Evergreen" the Patent*, 350 BMJ, Mar. 20, 2015.

219. *See* Gotham et al., *supra* note 8, at 2.

220. Juliette Cubanski, Tricia Neuman, Sarah True & Anthony Damico, *How Much Does Medicare Spend on Insulin?*, KAISER FAM. FOUND. (Apr. 1, 2019), https://www.kff.org/medicare/issue-brief/how-much-does-medicare-spend-on-insulin/.

221. *Id.*

222. Emily Hanson, *The Economic Burdens of Life: Trade Secrecy and the Insulin Pricing Crisis in the United States*, 27 J. INTELL. PROP. L. 251, 264–65 (2020).

223. Inflation Reduction Act of 2022, ch. 169, sec. 1194, § 1320f-3, 136 Stat. 1818, 1902–03.

By enacting federal legislation that caps the price of insulin for all diabetics, individuals in states without price caps and those with insurance plans under ERISA will be able to save money on their lifesaving medication. However, the Act does not mention any price protections for the uninsured.[224] The Act will not resolve the underlying issue of price manipulation in the pharmaceutical industry by PBMs, but it may provide assistance for some, until a more comprehensive strategy to tackle PBM influence can be established. Until federal legislation is passed to cap the cost of insulin for all insulin-dependent diabetics, nonprofit diabetic groups will continue to call on the federal government to act to eliminate the financial burden caused by the rising costs of a lifesaving drug that has been available for decades.

## CONCLUSION

The price of insulin has consistently increased over the past several years, resulting in unnecessary death and medical complications for insulin-dependent diabetics around the United States. The list price that patients pay at pharmacies is significantly affected by rebate negotiations between insulin manufacturers and PBMs. To achieve a preferred placement on a health plan's formulary, insulin manufacturers pay PBMs ever-increasing rebates to ensure their inclusion. Although investigations and reports have revealed parts of these pricing schemes, not much has been done to curb insulin prices. States like Colorado and Utah have passed insulin price cap legislation; however, these limits only affect individuals in states with insulin copay caps and are inapplicable to federally regulated health plans. While insulin price caps at the state level are a possible and beneficial short-term solution, the better solution is to enact federal legislation that will apply to all individuals, regardless of the type of health plan. Expanding the insulin price cap in the Inflation Reduction Act of 2022 to all insulin-dependent diabetics may provide the necessary financial relief to many around the country to prevent the tragic outcomes of Alec and Meaghan that continue to devastate families throughout the United States.

Insulin prices are affected by manufacturers, PBMs, distribution chains, and the lack of competition due to the strictness of the FDA's biologic requirements. Therefore, state and federal legislation is vital to protecting insulin-dependent diabetics from the effects of PBMs' and manufacturers' price manipulation. Redesigning the entire pharmaceutical industry in the United States will take not years, but decades. Alec and Meaghan are only two examples of the hundreds of type 1 diabetics who have died in this country because they could not afford their lifesaving medication. It is too late for them, but it is not too late to help others like them now.

224. *See generally id.*