STATE OF MICHIGAN
IN THE 30TH JUDICIAL CIRCUIT COURT FOR INGHAM COUNTY

DANA NESSEL, ATTORNEY GENERAL OF THE STATE OF MICHIGAN, *ex rel* The People of the State of Michigan,

Petitioner,

v

ELI LILLY AND COMPANY,

Respondent.

No. 22- 9 -P2

HON. JOYCE DRAGANCHUK

ATTORNEY GENERAL'S PETITION FOR CIVIL INVESTIGATIVE SUBPOENAS

Darrin F. Fowler (P53464)
Michael S. Hill (P73084)
Assistant Attorneys General
Michigan Dep't of Attorney General
Corporate Oversight Division
P.O. Box 30736
Lansing, MI 48909
(517) 335-7632
FowlerD1@michigan.gov
HillM19@michigan.gov

ATTORNEY GENERAL'S PETITION FOR CIVIL INVESTIGATIVE SUBPOENAS

I. Introduction

During the past twenty-two months, our country has shown the great progress that can be made when serious focus is brought to addressing a health crisis. With a speed unprecedented in human history, the United States went from confronting its first diagnosed case of a disease resulting in a deadly pandemic, to reaching a point where multiple vaccines are freely available to the adults and eligible children who desire to avail themselves of such protection.

The urgent strides forward made through the cooperative efforts of the government and pharmaceutical manufacturers in confronting COVID-19 stand in sharp contrast to the stumbling retreat in the efforts to help the millions of Americans who rely upon analog insulin to manage their diabetes. While our national focus has understandably been shifted, the plight of Americans who struggle to pay for diabetes medication has worsened.

The Centers for Disease Control (CDC) estimates that there are 34.2 million Americans with diabetes.[1] In Michigan, the American Diabetes Association estimates that 865,000 people, or 11.2% of the adult population, have diabetes.[2]

Of the approximately 34.2 million Americans with diabetes, around 7.4 million depend on insulin.[3] For these Americans, including the Michiganders among them, the importance of this medication cannot be overstated. Indeed, when left untreated, diabetes causes serious complications—including heart disease, stroke, amputation, end-stage kidney disease, blindness, and even death.[4]

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[1] Centers for Disease Control and Prevention, U.S. Dep't of Health and Human Services, *National Diabetes Statistics Report*, 2020, <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf> (accessed Jan 21, 2022), p 2.

[2] American Diabetes Association, *The Burden of Diabetes in Michigan*, February 2020, <http://main.diabetes.org/dorg/docs/state-fact-sheets/ADV_2020_State_Fact_sheets_MI.pdf> (accessed Jan 20, 2022).

[3] *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, June 2018, <https://care.diabetesjournals.org/content/41/6/1299> (accessed Jan 20, 2022).

[4] See note 2, *supra*.

But as a result of high analog insulin prices, which range from $75 to $2,000 monthly depending on individual insulin requirements and insurance coverage, many people take less than prescribed, severely restrict their diet, buy a less-effective alternative, or try to spread out the medicine over time.[5] These practices have caused serious disability and even death in some patients.[6]

Such consequences are largely avoidable. The prices of analog insulin products are artificially high. This is not a supposition or a mere allegation. It is a reality that analog insulin manufacturers like Eli Lilly and Company (Eli Lilly) vaguely blame on "the system." And such assertions of helplessness are offered with no hint of the irony that it is a system that Eli Lilly and other drug manufacturers negotiate to maintain.

What is happening is unfair and unconscionable. But thankfully, there is a public act existing to protect Michiganders from unfair and unconscionable business practices like Eli Lilly's: the Michigan Consumer Protection Act (MCPA).

Through this petition, the Attorney General seeks authorization from this Court to commence an investigation under the MCPA into Eli Lilly's practices in pricing analog insulin.

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[5] Samantha Willner, Robin Whittemore, & Danya Keene, *"Life or Death": Experiences of insulin insecurity among adults with type 1 diabetes in the United States*, SSM – Population Health vol 11 (Aug 11, 2020) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7352063/> (accessed Jan 20, 2022).

[6] *Id.* See also Bram Sable-Smith, *Insulin's High Cost Leads to Lethal Rationing*, NPR (Sep 1, 2018) < https://www.npr.org/sections/health-shots/2018/09/01/641615877/insulins-high-cost-leads-to-lethal-rationing > (accessed Jan 20, 2022).

Unfortunately for Michigan consumers, two past decisions of the Michigan Supreme Court have operated to put artificial constraints on the protections fashioned by the Legislature in the MCPA. See *Smith v Globe Life Ins Co*, 460 Mich 446 (1999). See also *Liss v Lewiston-Richards, Inc*, 478 Mich 203 (2007). Since they were decided, these opinions have served to end many consumer cases, and have prevented countless others from ever beginning. Both were wrongly decided.

As the Attorney General seeks to commence this significant investigation, the potential that Eli Lilly may attempt to assert that the *Smith* and *Liss* opinions preclude any subsequent MCPA lawsuit warrants consideration. For this reason, the Attorney General is waiving the usual practice of seeking the investigative subpoenas in the *ex parte* fashion anticipated by the MCPA. This Petition is being supplied to Eli Lilly upon its filing. And the Attorney General is concurrently filing a Complaint for Declaratory Judgment so that her authority to proceed with this investigation can be confirmed.

II. Parties, Legal Authority, and Venue

1. The Michigan Department of Attorney General (Attorney General) is authorized to file an *ex parte* petition with the Circuit Court requesting issuance of investigative subpoenas pursuant to Section 7 of the MCPA, which provides in pertinent part:

> Upon the ex parte application of the attorney general to the circuit court in the county where the defendant is established or conducts business or, if the defendant is not established in this state, in Ingham county, the circuit court, if it finds probable cause to believe a person has engaged, is engaging, or is about to engage in a method, act, or

> practice which is unlawful under this act, may, after ex parte hearing, issue a subpoena compelling a person to appear before the attorney general and answer under oath questions relating to an alleged violation of this act. . . . The subpoena may compel a person to produce the books, records, papers, documents, or things relating to a violation of this act. . . . [MCL 445.907(1).]

2. Eli Lilly—a corporation headquartered in Indianapolis, Indiana—is one of three pharmaceutical companies making up nearly the entire U.S. insulin market.[7] Because Eli Lily is established in Indiana, this Court is an appropriate venue for this Petition under MCL 445.907(1). In its corporate-record filings with the Michigan Department of Licensing and Regulatory Affairs, Eli Lilly lists an address in Plymouth, Michigan as its Registered agent's address. (**Exhibit A**.)

III. Background

3. Diabetes is a disease that affects how the body processes glucose (sugar).[8] Glucose—which is a vital source of energy for the body—is processed by the hormone insulin, which is secreted by the pancreas.[9] Diabetes occurs when the pancreas produces little or no insulin (Type 1) or when the body does not effectively use insulin (Type 2), resulting in blood sugar levels that are too high.[10]

4. Prior to 1921, diabetes was extremely difficult to manage, with the most effective treatment being putting patients on strict diets that limited

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[7] See note 3, *supra*. The other two pharmaceutical companies with a significant market share are Novo Nordisk and Sanofi. *Id.*

[8] Mayo Clinic, *Diabetes* < https://www.mayoclinic.org/diseases-conditions/diabetes/symptoms-causes/syc-20371444> (accessed Jan 20, 2022).

[9] *Id.*

[10] *Id.*

carbohydrate intake.[11] These restrictive diets resulted in compromised immune systems, stunted growth, and even death by starvation.[12]

5. In 1921, however, following years of research on the pancreas, its components, its secretions, and the impact of those secretions on processes within the body, two individuals—Toronto surgeon Frederick Banting and his assistant Charles Best—discovered how to remove insulin from a dog's pancreas.[13] With this extracted substance, which looked like "thick brown muck," Banting and Best were able to keep a severely diabetic dog alive for 70 days.[14] Banting and Best did not stop there. With the help of two other individuals, J.B. Collip and John Macleod, Banting and Best developed a more refined and pure form of insulin extracted from the pancreases of cattle.[15]

6. In January 1922, the first human received an injection of this new form of insulin—a 14-year-old boy dying of diabetes in a Toronto hospital.[16] The

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[11] American Diabetes Association, *The History of a Wonderful Thing We Call Insulin* <https://www.diabetes.org/blog/history-wonderful-thing-we-call-insulin> (accessed Jan 20, 2022).

[12] Charles E. Grassley & Ron Wyden, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*, United States Senate Finance Committee Staff Report (January 2021), p. 12, available at <https://www.finance.senate.gov/download/grassley-wyden-insulin-report> (accessed Jan 20, 2022).

[13] See note 11, *supra*.

[14] *Id.*

[15] *Id.*

[16] *Id.*

injection caused the boy's blood glucose to drop to a near-normal level within 24 hours.[17]

7. In 1923, Banting, Best, and Collip received a United States Patent for the insulin extract and the process of preparing it.[18] Recognizing the importance of the availability and accessibility of insulin, they sold their patent to the University of Toronto for just $1 with the understanding that affordable insulin would become widely available.[19]

8. In an effort to begin large-scale manufacturing of insulin, the Governors of the University of Toronto entered into an agreement with Eli Lilly for the exclusive production of insulin.[20] After this exclusive agreement ended in 1923, other pharmaceutical companies were invited to apply for licenses to manufacture insulin.[21] Soon after, affordable insulin became widely available.[22]

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[17] *Id.*

[18] United States Patent no. 1,469.994 < https://insulin.library.utoronto.ca/islandora/object/insulin%3AQ10017> (accessed Nov 29, 2021).

[19] Judith A. Johnson, *Insulin Products and the Cost of Diabetes Treatment*, Congressional Research Service (Nov 19, 2018), available at <https://fas.org/sgp/crs/misc/IF11026.pdf> (accessed Jan 20, 2022). See also Irl B. Hirsch, *Insulin in America: A Right or a Privilege*, Diabetes Spectrum, American Diabetes Association (Aug 19, 2016), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5001219/> (accessed Jan 21, 2022).

[20] *Discovery of Insulin at University of Toronto*, University of Toronto Libraries < https://heritage.utoronto.ca/exhibits/insulin> (accessed, Jan 21, 2022).

[21] *Id.*

[22] See Hirsch, note 19, *supra*.

9. While this animal-derived insulin was a major breakthrough in diabetes treatment, it caused allergic reactions in many individuals.[23] As time went on, advancements were made in diabetes and insulin research, resulting in the development of a genetically engineered, synthetic "human" insulin, derived from E. coli bacteria.[24] This product, which Eli Lilly made commercially available under the brand name Humulin in 1982, largely replaced the use of animal-derived insulins for the treatment of diabetes.[25] However, Humulin was still not perfect.

10. "The ideal treatment regimen for diabetics would closely mimic the way insulin secretion occurs in the body. This would involve a consistent insulin level between meals combined with a mealtime level of insulin that has a rapid onset and duration of action to match the glucose peak that occurs after a meal."[26] Neither animal-derived insulin nor Humulin had these characteristics.

11. Thus, research has continued, resulting in the development of "insulin analogs"—including Eli Lilly's brands Basaglar (long-acting) and Humalog (rapid-acting).[27] These insulin analogs "more closely replicate normal insulin patterns in the body and[, because of their convenience,] resulted in a greater number of patients using these new products."[28] Indeed, "[i]n 2000, of privately insured adults

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[23] See note 11, *supra*.

[24] *Id.*

[25] See note 19, *supra*.

[26] *Id.*

[27] *Id.*

[28] *Id.*

with type 2 diabetes using insulin, 19% were using analog insulins; by 2010, 96% were using these products."[29]

12. Unfortunately for the patients who rely on this medication to manage their diabetes, over the past two decades, the prices of analog insulin products in the United States have skyrocketed. For example:

a. The average price of insulin tripled from 2002 to 2013 and, from 2014 to 2019 climbed 47%.[30]

b. The average annual insulin price for Americans with type 1 diabetes assuming an average use of 60 units of insulin per day, increased from $2,864 in 2012 to $5,705 in 2016.[31]

c. The per-unit price of insulin averaged between $2.36 and $4.43 for Medicaid recipients in the 1990s; those prices tripled by 2014.[32]

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[29] *Id.*

[30] See Benita Lee, MPH, *How Much Does Insulin Cost? Here's How 27 Brands Compare*, GoodRx (Nov 6, 2020) <https://www.goodrx.com/blog/how-much-does-insulin-cost-compare-brands/> (accessed Jan 21, 2022); R. Scott Rappold, *Families Cross Borders in Search for Affordable Insulin*, WebMD Health News (July 18, 2019) <https://www.webmd.com/diabetes/news/20190718/spiking-insulin-costs-put-patients-in-brutal-bind> (accessed Jan 21, 2022).

[31] See Robin Respaut, *U.S. insulin costs per patient nearly doubled from 2012 to 2016: study*, Reuters (Jan 22, 2019) <https://www.reuters.com/article/us-usa-healthcare-diabetes-cost/u-s-insulin-costs-per-patient-nearly-doubled-from-2012-to-2016-study-idUSKCN1PG136> (accessed Jan 21, 2022).

[32] Jing Luo, MD, Jerry Avorn, MD, & Aaron S. Kesselheim, MD, JD, MPH, *Trends in Medicaid Reimbursements for Insulin From 1991 Through 2014*, JAMA Internal Medicine (Oct 2015) <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2429536> (accessed Jan 21, 2022).

d. The per-vial list price of one version of insulin increased from $17 in 1997 to $138 in 2016, while another increased from $21 to $255 around the same time period.[33]

e. Between 2010 and 2015, the monthly wholesale price of the most popular insulin, Humulin (produced by Eli Lilly), increased from $258 to nearly $1,100 for the average patient.[34] A single vial of Humulin increased from $92.70 in 2009 to $274.70 in March 2019.[35]

f. The average annual per-patient cost to treat type 1 diabetes increased from $12,467 in 2012 to $18,494 in 2016.

g. A retail insulin pen that costs $140 in the U.S. costs less than $15 in Canada and Germany.[36]

h. Insulin prices are more than eight times higher in the United States than in 32 high-income comparison nations combined. [37] Compared with other countries, the average manufacturer price per standard unit across all

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[33]See **Exhibit B**. Johnson, *For Insulin Users, Price of Wellness Can be High*, The Washington Post (November 1, 2016.) p 1.

[34] See **Exhibit C**. Rosenthal, *When High Prices Mean Needless Death*, JAMA Internal Medicine (Jan 2019), p 114.

[35] See **Exhibit D**. Loftus, *As Political Scrutiny Mounts, Eli Lilly Divulges New Insulin Pricing Data*, Wall Street Journal (May 24, 2019).

[36] See Ex C *supra*.

[37] Andrew W. Mulcahy, Daniel Schwam, & Nathaniel Edenfield, *Comparing Insulin Prices in the United States to Other Countries Results from a Price Index Analysis*, RAND Corporation (Nov 2020) available at < https://www.rand.org/content/dam/rand/pubs/research_reports/RRA700/RRA788-1/RAND_RRA788-1.pdf> (accessed Jan 21, 2022).

> insulin categories was $98.70 in the United States, compared with $6.94 in Australia, $12.00 in Canada, $7.52 in the United Kingdom, and $8.81 across all non-US OECD (Organisation for Economic Co-operation and Development) countries combined. Average prices in the United States and most comparison countries were higher for analog insulins than for human insulins. [38]

13. In July 2019, Senator Bernie Sanders drew attention to this pricing disparity by taking Michigan residents across the border into Canada to purchase insulin. Those Michigan residents were able to purchase a $229 trial supply of insulin in Canada that would have cost around $2,400 out-of-pocket in the U.S.[39] Similarly, other recent travelers reportedly purchased $1,265 of insulin supplies in Canada, that would have cost $12,400 in the U.S.[40]

14. In early 2019, the Finance Committee of the United States Senate began looking at what was happening with insulin drug prices.[41] This bi-partisan congressional inquiry included a hearing at which representatives of Eli Lilly and the other two major manufacturers of insulin medications testified.[42] Also

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[38] *Id.*

[39] Jonathan Oosting, *Sanders in Canada: U.S. drug prices 'an embarrassment'*, The Detroit News (July 28, 2019) <https://www.detroitnews.com/story/news/politics/2019/07/28/sanders-canada-u-s-drug-prices-an-embarrassment/1851978001/> (accessed Jan 21, 2022).

[40] See Rappold, note 30, *supra*.

[41] See Grassley & Wyden, note 12, *supra*.

[42] *Id.* at p 4, n 3.

testifying were representatives of the three largest pharmacy benefit managers (PBMs): CVS Caremark, OptumRx, and Express Scripts.[43]

15. PBMs—often referred to as the "middlemen" of the pharmaceutical industry—have gotten significant attention in the media and from Congress in recent years. PBMs administer prescription drug benefits on behalf of health insurance providers and government agencies offering health benefits.[44] They create prescription drug "formularies," which list the drugs offered through the health plans broken down by "tier."[45] The higher the tier number, the less preferred the drug and the higher the out-of-pocket cost to patients.[46]

16. Drug manufacturers like Eli Lilly negotiate with PBMs to secure access and favorable placement on these formularies.[47] During this negotiation process, drug manufacturers and PBMs set the price at which the drug manufacturer will offer the drug to pharmacies, i.e., the drug's list price.[48] The list price becomes the price upon which pharmacies base the charges to an uninsured consumer. Insured consumers also pay a price based on the list price (and based on

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[43] *Id.*

[44] *Id.* at p 29.

[45] *Id.* See also Ana Gascon Ivey, *A Guide to Medication Formularies Understanding your prescription medication coverage*, GoodRx Health (May 19, 2020) available at <https://www.goodrx.com/insurance/medication-formulary> (accessed Jan 21, 2022).

[46] See Ivey, note 45 *supra*.

[47] See Grassley & Wyden, note 12, p 29.

[48] See Elizabeth Seeley & Aaron S. Kesselheim, *Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead*, The Commonwealth Fund Issue Brief (March 2019) <https://www.commonwealthfund.org/sites/default/files/2019-03/Seeley_pharmacy_benefit_managers_ib_v2.pdf> (accessed Jan 21, 2022).

the "tier" placement) if necessary to meet insurance deductibles or to the extent required under Medicare. Naturally, the pharmacy will include a mark-up on the list price as compensation for its role in the transaction.

17. To address the high prices that pharmaceutical manufactures set for their drugs, PBMs seek rebates for the medications listed on the drug formularies.[49] Drug manufacturers pay these rebates to the PBMs at the point of sale, and the PBMs often pass the rebates on to health plans.[50] Drug manufacturers like Eli Lilly have artificially increased the list prices of medications in order to offer these rebates to PBMs. In other words, the out-of-pocket costs that Michigan consumers must pay for life-saving analog insulin is made higher by the rebates drug manufacturers give to PBMs. The drug manufacturers do this to increase their market share—the bigger the rebates they can offer to PBMs, the more medication they can sell by gaining access to formularies and, consequently, health plans that provide coverage for their medications. In certain circumstances, this is done in a way attempting to exclude placement, or secure unfavorable placement, of medications offered by competitors on the PBMs' formulary. Indeed, Eli Lilly and its competitors sell insulin analogs that are essentially interchangeable—so Eli Lilly has an incentive to offer larger rebates to PBMs in order to gain access to health plans that will provide coverage for its drugs and not to the comparable medications offered by competitors.

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[49] *Id.* at p 2.

[50] *Id.* at p 3.

18. Following its investigation, the Senate Finance Committee concluded that this competition and artificial price inflation was occurring amongst drug manufacturers and PBMs:

> First and foremost, pharmaceutical manufacturers have complete control over setting the list price (the Wholesale Acquisition Cost (WAC)) for their products. This investigation found that manufacturers aggressively raised the WAC of their insulin products absent significant advances in the efficacy of the drugs. These price increases appear to have been driven, in part, by tactics PBMs employed in the early 2010s. At that time, PBMs began to more aggressively pit manufacturers against each other by implementing formulary exclusions in the insulin therapeutic class, which effectively stopped manufacturers from reaching large blocks of patients. While insulin manufacturers had been increasing prices for their products prior to formulary exclusions being employed, this tactic appears to have been more effective in boosting the size of rebates than suppressing the upward march of WAC prices.
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> The Finance Committee found that drug manufacturers increased insulins' WAC in part to give them room to offer larger rebates to PBMs and health insurers, all in the hopes that their product would receive preferred formulary placement. This pricing strategy translated into higher sales volumes and revenue for manufacturers.[51]

19. What is occurring can also be illustrated by looking at the pricing history of Eli Lilly's popular insulin analog medication Humalog. Eli Lilly first introduced this medication in 1996 at a list price of $21 per vial. [52] According to the website www.lillypricinginfo.com, the price of Humalog is now $274.70 per vial, an

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[51] See Grassley & Wyden, note 12, p 5.

[52] See **Exhibit E**. Russel, *Lilly Insulin Prices Come Under Microscope*, Indianapolis Business Journal (Aug 25, 2017).

increase of over 1200% since 1996.[53] And at an April 2019 hearing in front of the House Energy and Commerce Oversight and Investigations Subcommittee, Eli Lilly's representative, Mike Mason, testified that approximately 75% of that price was attributable to the rebates being given to PBMs.[54] In other words, when uninsured and underinsured consumers pay a pharmacy cost based on list price, they are primarily financing the rebates Eli Lilly offers to PBMs to increase its share of the insulin market, rather than paying for costs associated with Eli Lilly's actual production and distribution of Humalog.

20. The high cost of insulin medications is having a devastating impact on Michigan consumers—an impact that endocrinologist Dr. Timothy Bodnar has acutely observed in his endocrinology practice. (**Exhibit F**, Bodnar Aff, ¶ 1.) Until just a few weeks ago, Dr. Bodnar worked at Ann Arbor Endocrinology & Diabetes Associates PC, which is a large private endocrinology practice affiliated with St. Joseph Mercy Ann Arbor Hospital. (*Id.* ¶ 3.) He is also a Key Clinical Faculty Member in the Internal Medicine Residency at St. Joseph Mercy, where he teaches and trains resident physicians in, among other things, diabetes care. (*Id.*)

21. In his endocrinology practice, approximately 30 to 40% of Dr. Bodnar's patients have diabetes. (*Id.* ¶ 4.) Approximately one-third of those (around 250

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[53] *How much should I expect to pay for Humalog U-100?* Lilly USA, LLC <https://www.lillypricinginfo.com/humalog> (accessed Jan 20, 2022).

[54] See **Exhibit J**, thumb drive, .mp4 file labeled "54". Full video available at <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-priced-out-of-a-lifesaving-drug-getting-answers-on-the-rising> (accessed Jan 21, 2022).

patients) have type 1 diabetes, all of whom must take insulin lifelong. (*Id.*) The other two-thirds (around 500 patients) have type 2 or other forms of diabetes, and approximately 50% of those patients take insulin in some form. (*Id.*) Overall, Dr. Bodnar estimates that at least two-thirds of his diabetes patients take insulin. (*Id.*) His practice, which includes five other endocrinologists, serves at least five times that number of patients, if not more. (*Id.*)

22. Since joining this practice in 2014, Dr. Bodnar has observed:

> [D]ozens of patients (both young and old) with type 1 diabetes admitted into the Intensive Care Unit (ICU) at St. Joseph Mercy with diabetic ketoacidosis—a condition that may cause diabetic coma or even death—because they could not afford, or were rationing, their insulin. And, unfortunately, for many of these patients, it is not their first trip to the ICU under the same circumstances. This situation is fraught with irony: A patient may easily incur a $15,000 to $25,000 hospital bill to treat diabetic ketoacidosis because he could not afford the insulin that would have kept him healthy and out of the hospital in the first place. [(*Id.* ¶ 9.)]

23. Eli Lilly is aware that the high list price of its insulin medications like Humalog is problematic, and, in some instances, cost-prohibitive, for uninsured and underinsured consumers. For this reason, it has implemented and actively markets initiatives aimed at offsetting the impact of the rebates it negotiates with the PBMs. This was made clear at yet another Congressional inquiry into insulin pricing in early 2019—this time by the House Energy and Commerce Oversight and Investigations Subcommittee. Eli Lilly's representative testified at that

congressional hearing that the company was launching an initiative aimed at limiting co-pays to $95.[55]

24. But Eli Lilly is also aware that such initiatives have not provided help for all consumers. During the congressional testimony, Eli Lilly's representative boasted that 95% of its customers pay less than $95 for its insulin medications.[56] But the reverse implication of this statement is that 5% of its customers at that time were paying a price inflated by the list price that exceeded $95. In 2019, the Associated Press estimated that about 700,000 people used Humalog.[57] This means that approximately 35,000 people were paying out-of-pocket costs over $95 per month for Humalog at the time of the testimony.

25. And, in any event, even with the attempt at such initiatives, Dr. Bodnar has not seen results on the ground that the initiatives actually help Michigan consumers. (Ex F, Bodnar Affidavit, ¶¶ 10, 12.)

26. In fact, the plight for diabetic Michiganders has only worsened since the COVID-19 pandemic began. (*Id.* ¶ 6.) In the early stages of this health crises, scientists observed that diabetic patients are at a greater risk of serious illness or death than other COVID-19 sufferers.[58]

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[55] See Ex J, thumb drive,.mp4 files labeled "55" and "56".

[56] *Id.*

[57] See Linda A. Johnson, *Lilly selling half-price version of popular Humalog insulin*, Associated Press (May 22, 2019) <https://apnews.com/article/f311f61e42684838bb5fd52a4b486215> (accessed Jan 21, 2022).

[58] See Elizabeth Cooney, *Why people with diabetes are being hit so hard by Covid-19*, STAT (Oct 1, 2020) <https://www.statnews.com/2020/10/01/why-people-with-

27. Even apart from the effect that contracting COVID-19 has on diabetic patients, the COVID-19 pandemic has also negatively impacted other aspects of the physical health of many diabetic Michiganders, as well as their economic health. As Dr. Bodnar observes:

> [A]t least once a day, I discuss the high cost of analog insulin with a patient, as well as what other, less costly diabetes-management options are available. These conversations have become more prevalent since the COVID-19 pandemic began—not only have many of my patients lost some or all of their income, but, in general, the stress and isolation of the pandemic has led to my diabetes patients gaining weight, which typically correlates with larger dose requirements of insulin. One of the options I discuss with my patients is a switch from analog insulin to older "human" insulin. Though, in rare circumstances, the use of human insulin is preferred, in the vast majority of cases, analog insulin is superior—and, in certain cases, immensely superior—to human insulin. Thus, patients who decide to switch to human insulin as a cost-savings measure are typically at a medical disadvantage. [(Ex F, Bodnar Affidavit, ¶ 6.)]

28. The switch to human insulin that Dr. Bodnar describes is a trend that started well before the pandemic began, and it is one very much fueled by the rapidly increasing costs of the superior medications. During the April 2019 testimony before the House Subcommittee, the representative from Novo Nordisk testified that his company had partnered with CVS Health and Express Scripts to sell expand its human insulin offering and that 775,000 people were taking advantage of this opportunity.[59] Human insulin, while inferior, is significantly

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diabetes-are-being-hit-so-hard-by-covid-19/> (accessed Jan 21, 2022); Terhune, Nelson, & Respaut, *Why COVID-19 is killing U.S. diabetes patients at alarming rates*, Reuters (July 24, 2020) <https://www.reuters.com/article/us-health-coronavirus-diabetes-insight/why-covid-19-is-killing-u-s-diabetes-patients-at-alarming-rates-idUSKCN24P1B4> (accessed Jan 21, 2022).

[59] See Ex J, thumb drive, .mp4 file labeled "59".

more affordable.[60] Indeed, in 2020, Eli Lilly's form of human insulin, Humulin, cost $148 per vial.[61] And Novo Nordisk's was available for about $25 per vial.[62]

29. To be sure, it is good that some alternative to the astronomically priced insulin analogs exists. But the notion that at least three-quarters of a million Americans were opting for what is generally an inferior treatment for a condition as serious as diabetes, even before the pandemic, speaks volumes about the scope of the pricing crisis that has arisen.

30. Switching to human insulin is not the only way consumers are trying to cope with the rising costs of the more effective medications. (Ex F, Bodnar Aff, ¶ 7.) Others are continuing to use analog insulin drugs like Humalog, but are rationing them—i.e., taking less than they need to make the drug last. (*Id.*) This problem was acknowledged by the Senate Finance Committee in its report.[63] And Dr. Bodnar sees it happening here and now with his patients:

> [A]pproximately 10% of my patients have admitted to the intentional rationing of their insulin stores; in other words, taking less insulin than their body requires to stretch their prescription and avoid purchasing more for as long as possible. The 10% is likely a conservative estimate, as many patients are reluctant to admit to intentional rationing. Although I do not formally document this, based on conversations with my patients, I believe there has been an increase in intentional rationing of insulin since the COVID-19 pandemic started. [(*Id.* at ¶ 7.)]

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[60] See Willner, Whittemore, & Keene, note 5, *supra.*

[61] See Lisa L. Gill, *How to Pay Less for Insulin*, Consumer Reports (Feb 24, 2020) <https://www.consumerreports.org/drug-prices/how-to-pay-less-for-insulin/> (accessed Jan 21, 2022). See also Willner, Whittemore, & Keene, note 5, *supra.*

[62] *Id.*

[63] See Grassley & Wyden, note 12, pp 14 & 15.

31. Also worthy of attention is that studies are now underway exploring the concern that COVID-19 is actually causing diabetes for some previously healthy people.[64] So, in addition to its devastating impact on those already diagnosed with diabetes, COVID-19 is itself increasing the population of consumers facing the physical and financial impact of diabetes.

32. The pandemic has put up yet another barrier to a method by which some diabetic Michiganders attempt to cope with rising insulin costs in the United States: purchasing their insulin across the border in Canada. As Dr. Bodnar explains:

> Pre-pandemic, other patients indicated that they traveled to Canada, where prices are significantly lower, to purchase their insulin. While I do not recommend that my patients travel to Canada to purchase insulin as a cost-savings measure, I am aware that other practitioners in the field regularly do so. [(Ex F, Bodnar Aff, ¶ 8.)]

33. The border between the United States and Canada was closed for crossings by most Americans as a means of controlling the spread of COVID-19. The concept of relaxing these restrictions has been the subject of recent news stories.[65] And the practice of consumers crossing the border to purchase

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[64] See Rubino & Amiel, *et al*, *New-Onset Diabetes in Covid-19*, New England Journal of Medicine (August 20, 2020) <https://www.nejm.org/doi/10.1056/NEJMc2018688> (accessed Jan 21, 2022).

[65] See July 19, 2021 News Release, *Government of Canada announces easing of border measures for fully vaccinated travelers*, Public Health Agency of Canada (July 19, 2021) <https://www.canada.ca/en/public-health/news/2021/07/government-of-canada-announces-easing-of-border-measures-for-fully-vaccinated-travellers.html> (accessed Jan 21, 2022); Deepa Shivaram, *Americans Will Soon Be Able To Go To Their 2nd Most Popular Travel Destination*, NPR (July 20, 2021) <https://www.npr.org/2021/07/20/1018309257/canada-border-americans-travel-vaccinated-covid> (accessed Jan 21, 2022).

medications and bring them back into the United States is itself illegal. See 21 USC § 381(d)(1). But the rising costs of Humalog and other insulin medications have forced many Michiganders into an unfair dilemma: pay the artificially inflated prices for insulin in the U.S., or travel to Canada to illegally purchase the medication at a lower, reasonable price.

IV. Michigan Consumer Protection Act Implications

34. During the April 2019 congressional hearing, the representative from Eli Lilly was asked about the financial incentives driving the rising analog insulin prices. He responded by blaming "the system."[66] Indeed, this response was echoed by the other two manufacturers as well.[67] When pressed, the PBMs and drug manufacturers ultimately pointed fingers at each other when allocating responsibility for the price increases.[68]

35. Here, the primary conclusion of the Senate Finance Committee report bears repetition: "[P]harmaceutical manufacturers have complete control over setting the list price . . . for their products."[69] In other words, when Eli Lilly negotiates rebates with PBMs in order to achieve formulary placements, it is voluntarily participating in "the system." And it does so because it profits handsomely from that system. As the Senate Finance Committee found, "[T]he

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[66] See Ex J, thumb drive, .mp4 file labeled "66 and 67 combined".

[67] *Id.*

[68] *Id.*

[69] See Grassley & Wyden, note 12, p 5.

amount of revenue pharmaceutical manufacturers are retaining from insulin has risen [. . .] even as the net price- the revenue after rebates and discounts–has declined in recent years, although it appears to remain significantly higher than in the first decade of the 21st Century." [70] In fact, Eli Lilly reported to the Senate Finance Committee a steady increase in Humalog revenue from $1.5 billion in 2007 to $3 billion in 2018. [71]

36. It is both necessary and appropriate for Eli Lilly to profit from its sale of analog insulin medications. But it must do so within the confines of all applicable laws. The Attorney General has probable cause to believe Eli Lilly is not meeting this obligation to Michigan consumers.

37. Michigan's Consumer Protection Act has a uniquely strong protection against unfair prices. The MCPA defines unfair trade practice to include "[c]harging the consumer a price that is grossly in excess of the price at which similar property or services are sold." MCL 445.903(1)(z). Unlike comparable provisions contained in the consumer protection laws of other States, application of this restriction is not limited to situations in which there has been a declaration of emergency or a shortage of supply.

38. The Attorney General's probable cause to believe that Eli Lilly is charging Michigan consumers prices for insulin products that are grossly in excess

[70] *Id.* at p 7.

[71] *Id.*

of the prices at which the same or similar insulin products are sold to others arises from two, distinct sources.

39. *First*, for the insulin medications sold within the United States, Eli Lilly has established list prices that grossly exceed the price at which the same medications are sold in other countries, including Canada. As referenced in paragraph 13 above, Senator Bernie Sanders called specific attention to the international disparity in the pricing of insulin medications in 2019. To better understand and quantify this phenomenon, the Attorney General conducted a telephone survey in August 2019 comparing the price of Eli Lilly products Humalog and Basaglar offered at pharmacies, located within just a few miles of each other, at four different border crossing points between Michigan and the Canadian province of Ontario. (**Exhibit G**, Lutz Aff, ¶ 7.) The price differentials were startling. For example, Humalog was 855% more expensive to buy in the United States than across the border. (*Id.*) Similarly, Basaglar, a long-acting insulin often used in conjunction with Humalog, was 471% more expensive to purchase in the American pharmacies than their Canadian counterparts. (*Id.*) A complete summary of the results of this survey are shown here:

Insulin Cost Comparison

Pharmacy Information & Locatin					Cost:					
Pharmacy Name	Phone	City/State	Nation	Near Bridge	Humalog U100 (5-pack of KwikPens)	Humalog U100 (10 mL vial)	Humalog Mix 50 KwikPens	Insulin Lispro (5-pack of KwikPens)	Insulin Lispro (10 mL vial)	Basaglar (5-pack of KwikPens)
Famacity Pharmacy *	313-789-8934	Detroit, MI	US	Ambassador Bridge	$600.00	$300.00	Humulin Mix 70/30 $240.00	Does Not Carry	Does Not Carry	$365.00
Sandwich I.D.A. Pharmacy	519-254-8247	Windsor, ON	Canada	Ambassador Bridge	CAD 91.20	Does Not Carry	CAD 90.23	Does Not Carry	Does Not Carry	CAD 103.05
Rite Aid	313-567-3523	Port Huron, MI	US	Bluewater Bridge	$594.00 or $124.94/ea	$307.69	Does Not Carry	$294.34	$168.29	$366.34
The Medicine Shoppe Sarnia	519-256-1600	Sarnia, ON	Canada	Bluewater Bridge	CAD 90.00	CAD 49.99	CAD 90.00	Does Not Carry	Does Not Carry	CAD 100.00
CVS Pharmacy	810-987-3663	Detroit, MI	US	Detroit Windsor Tunnel	$626.99	$323.99	Does Not Carry	Does Not Carry	Does Not Carry	$388.99
Downtown Windsor Pharmacy *	519-337-1119	Windsor, ON	Canada	Detroit Windsor Tunnel	CAD 100.00	CAD 50.00	CAD 100.00	Does Not Carry	Does Not Carry	CAD 120.00
Sault Community Pharmacy **	906-632-2122	Sault Ste. Marie, MI	US	Sault Ste Marie Int'l Bridge	$560.00	$295.00	Does Not Carry	$250.00	$150.00	$350.00
Merret's Pharmacy *	705-945-8465	Sault Ste. Marie, ON	Canada	Sault Ste Marie Int'l Bridge	CAD 90.00	CAD 50.00	CAD 90.00	Does Not Carry	Does Not Carry	CAD 95.00
	* Pharmacist stated these were only approximate pricing									
	** Pharmacy Tech stated prices were approximate and included a "club member discount"									

(*Id.*)

40. Earlier this year, in February 2021, the Attorney General repeated the same telephonic survey to see whether the situation has improved for diabetic Michiganders. (*Id.* ¶ 8.) The results show that Eli Lilly continues to propagate a system under which Michiganders are charged grossly excessive prices for its insulin medications as compared to the prices at which those same medications are sold at pharmacies in Canada that are mere miles away:

Insulin Cost Comparison

Pharmacy Information & Location					Cost:					
Pharmacy Name	Phone	City/State	Nation	Near Bridge	Humalog U100 (5-pack of KwikPens)	Humalog U100 (10 mL vial)	Humalog Mix 50 KwikPens	Insulin Lispro (5-pack of KwikPens)	Insulin Lispro (10 mL vial)	Basaglar (5-pack of KwikPens)
Famacity Pharmacy *	313-789-8934	Detroit, MI	US	Ambassador Bridge	$550.00	$400.00	Humulin Mix 70/30 $300.00	$300.00	$350.00	$400.00
Sandwich I.D.A. Pharmacy *	519-254-8247	Windsor, ON	Canada	Ambassador Bridge	CAD 93.00	Does Not Carry	Could Not Find	Does Not Carry	Does Not Carry	CAD 107.00
Rite Aid	810-987-3663	Pine Grove Ave Port Huron, MI	US	Bluewater Bridge	$700.00 or $146.99/ea	$329.64	Humulin Mix 75/25 $700.00	No Price for 5-pack *about* $63.65/ea	$164.82	$430.99 or $89.99/ea
The Medicine Shoppe Sarnia	519-337-1119	Sarnia, ON	Canada	Bluewater Bridge	CAD 90.00	CAD 49.99	CAD 85.00	Does Not Carry	Does Not Carry	CAD 100.00
CVS Pharmacy	313-567-3523	Renaissance Center Dr. Detroit, MI	US	Detroit Windsor Tunnel	$632.99	$323.99	Does Not Carry	$315.99	$162.99	$388.99
Downtown Windsor Pharmacy	519-256-1600	Windsor, ON	Canada	Detroit Windsor Tunnel	CAD 84.71	CAD 49.36	CAD 84.34	Does Not Carry	Does Not Carry	CAD 96.76
Sault Community Pharmacy **	906-632-2122	Sault Ste. Marie, MI	US	Sault Ste Marie Int'l Bridge	$535.00	$290.00	Does Not Carry	$370.00	$130.00	$345.00 - $350.00
Merret's Pharmacy *	705-945-8465	Sault Ste. Marie, ON	Canada	Sault Ste Marie Int'l Bridge	CAD 90.00	CAD 60.00	Does Not Carry	Does Not Carry	Does Not Carry	CAD 95.00
	* Pharmacist stated these were only approximate pricing									
	** Pharmacy Tech stated prices were approximate and included a "my prescriptions saving club discount"									

(*Id.*)

41. As of the date of this Petition, the list prices for these medications in the United States are as follows:

a. Humalog U100 (5-pack of KwikPens): $530.40_;[72]

b. Humalog U100 (10 mL vial): $274.70_;[73]

c. Humalog Mix 50/50 KwikPens: $563.00_;[74]

d. Insulin Lispro (5-pack of KwikPens): $159.12_;[75]

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[72] *How much should I expect to pay for HumalogU-100?* Eli Lilly USA, LLC <https://www.lillypricinginfo.com/humalog> (accessed Jan 20, 2022).

[73] *Id.*

[74] *Humalog Mix 50/50 KwikPen Prices, Coupons and Patient Assistance Programs*, Drugs.com <https://www.drugs.com/price-guide/humalog-mix-50-50-kwikpen#:~:text=The%20cost%20for%20Humalog%20Mix,not%20valid%20with%20insurance%20plans> (accessed Jan 20, 2022).

[75] *How much should I expect to pay for a Lilly Non-Branded Insulin*? Lilly USA, LLC, <https://www.lillypricinginfo.com/insulin-lispro> (accessed Jan 20, 2022).

e. Insulin Lispro (10 mL vial): $82.41_;[76]

f. Basaglar (5-pack of KwikPens): $326.36_.[77]

42. *Second*, probable cause arises when evaluating Eli Lilly's marketing and sale of a drug called Lispro, an authorized generic for Humalog. Eli Lilly announced the launch of Lispro in March 2019—at the same time it was responding to requests from the Senate Finance Committee and preparing for testimony by its representative the following month.[78] According to Eli Lilly's press release, Lispro is the "same molecule" as Humalog, yet Eli Lilly said it would be sold at half the price of Humalog.[79] Sales of Lispro then began in May 2019.[80] From this point forward, each Michigan consumer who paid a price for Humalog at or above its list price was paying a price grossly in excess of the price at which Eli Lilly was selling the chemically identical drug Lispro.

43. In announcing Lispro, Eli Lilly expressly said it was to help make insulin medications more affordable.[81] The Attorney General does not dispute some truth may underlie this statement, but there is probable cause to believe it is

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[76] *Id.*

[77] *How much should I expect to pay for Basaglar*?, Lilly USA, LLC, <https://www.lillypricinginfo.com/basaglar> (accessed Jan 20, 2022).

[78] See March 4, 2019 Press Release, *Lilly to Introduce Lower-Priced Insulin*, Eli Lilly and Company <https://investor.lilly.com/node/40881/pdf> (accessed Jan 20, 2022).

[79] *Id.*

[80] See May 22, 2019 Press Release, *Lilly's Lower Priced Insulin Now Available*, Eli Lilly and Company <https://investor.lilly.com/node/41336/pdf> (accessed Jan 20, 2022).

[81] See note 78, *supra*.

misleading because it leaves unspoken Eli Lilly's motivation to keep intact a system from which it is deriving significant profit at the expense of consumers.

44. The timing of Eli Lilly's announcement also contributes to this determination of probable cause. Although Humalog has been sold since 1996, this announcement was made during a time of intense congressional scrutiny of insulin manufacturers and PBMs and significant media attention being given to the insulin-pricing crisis.

45. Next, the availability of Lispro and its overall impact on the insulin market should be considered. In the context of the congressional inquiries being made during 2019, Eli Lilly made representations suggesting Lispro would be a game-changer for insulin pricing. The March press release stated, "[i]ntroducing an alternative insulin option allows [Eli] Lilly to provide a lower-priced insulin more quickly while providing payers time to renegotiate downstream contracts and adjust to new system economics."[82] And the Eli Lilly representative testifying at the April 2019 House Subcommittee hearing went so far as to say that the company was dropping the list price on Humalog by 50%.[83] But no such reduction in the list price of Humalog has emerged since that testimony was given.

46. In December 2019, Senators Elizabeth Warren and Richard Blumenthal issued a report—titled "Inaccessible Insulin: The Broken Promise of Eli Lilly's Authorized Generic"—raising concerns both about the availability of Lispro,

[82] See note 78, *supra*.

[83] See Ex J, thumb drive, .mp4 file labeled "83".

and Eli Lilly's motivations behind the launch of this authorized generic.[84] In that report, the Senators explained that staff from their offices had conducted a telephone survey of nearly 400 chain and independent pharmacies across the country, and found that Lispro was generally not available from more than 80% of them.[85] Senators Warren and Blumenthal also observed that drug manufacturers sometimes use authorized generics to discourage true generics from other manufacturers from reaching the marketplace.[86] Finally, the Senators concluded:

> Ultimately, Eli Lilly has failed to take consequential steps—such as simply lowering the list price of Humalog—to provide lower-cost access to this important diabetes drug. Eli Lilly appears to have also failed to take basic steps, such as educating patients and pharmacists about the authorized generic or working with supply chain partners to properly stock pharmacies, in order to make the lower cost version more accessible. Its authorized generic, rather than expanding access to low-cost insulin, appears instead to be a public relations move intended to ease scrutiny on the rising price of insulin.[87]

47. By late 2019, only 50,000 to 67,000 of the millions of Americans using this form of insulin were turning to Lispro.[88] And a GoodRx article in April 2020 explained that this is due, in part, to the fact that it is not available through many

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[84] See U.S. Senator Elizabeth Warren & U.S. Senator Richard Blumenthal, *Inaccessible Insulin: The Broken Promise of Eli Lilly's Authorized Generic* (Dec 2019) <https://www.fdanews.com/ext/resources/files/2019/12-16-19-InaccessibleInsulinreport.pdf?1576536304> (accessed Jan 21, 2022).

[85] *Id.* at p 1.

[86] *Id.* at p 3.

[87] *Id.* at p 6.

[88] See **Exhibit H**. Rowland, *Senators Accuse Insulin Manufacturer of 'Broken Promise'*, The Washington Post (Dec 31, 2019), p 2.

insurance plans.[89] And its availability through insurance coverage is ultimately the product of negotiations between Eli Lilly and the PBMs.[90] For his part, Dr. Bodnar has not seen the introduction of Lispro as providing meaningful help to his patients, and it has not impacted market costs. (Ex F, Bodnar Aff, ¶ 11.) Dr. Bodnar now only prescribes Lispro when the patient's insurance plan explicitly states that it covers Lispro. (*Id.*)

48. Notably, Lispro and Humalog do not compete with each other in a free market. The extent to which these medications are available to Michigan consumers under health plans is determined, in part, by the extent to which Eli Lilly negotiates such offerings with the PBMs. Given the finding in the Senate Finance Committee report that the emphasis for Eli Lilly in negotiating with PBMs is in offering large rebates—as opposed to lowering list prices—the Attorney General seeks, through the proposed investigation, to gain an understanding of the extent to which Eli Lilly has sought to negotiate the inclusion of Lispro within PBM formularies. One of the largest PBMs, Express Scripts, expressly stated that Lispro would not be covered by its plans.[91] Yet, Express Scripts's representative at the Congressional Hearing pointed to the sale of Lispro as an important development in addressing the insulin pricing problem.[92]

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[89] See Amanda Brooks, *Generic Insulins Are on the Market—So Why Aren't People Using Them*, GoodRx (April 3, 2020) <https://www.goodrx.com/blog/generic-insulins-see-low-fills-insulin-lispro-insulin-aspart/> (accessed Jan 21 ,2022).

[90] See, e.g., Grassley & Wyden, note 12, p 29.

[91] See Brooks, note 89, *supra.*

[92] See Ex J, thumb drive,.mp4 file labeled "92".

49. The MCPA also defines unfair trade practices to include "[m]aking false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions." MCL 445.903(1)(i). There is probable cause to believe Eli Lilly has made misleading representations of fact regarding the reasons for the price reductions achieved through Lispro, as explained above. Further, the arbitrary nature of the Lispro pricing beginning with its 2019 launch should be considered. As noted in paragraph 19, *infra*, Eli Lilly acknowledged that 75% of Humalog's price was attributable to the rebates negotiated by PBMs; yet, Eli Lilly chose to price Lispro at an cost that was 25% higher than what its own representative said should be the true cost for the same molecule.

50. The announced reason for the discounted Lispro product could have been better achieved through a significantly different price. Notably, on September 28, 2021, Eli Lilly announced it was dropping the Lispro price an additional 40%, a cost closer to, but still above, the benchmark suggested by Mr. Mason's testimony. [93] Considered in this light, the pricing of Lispro from the time of its initial launch in 2019 was both grossly in excess of the price at which the same molecule was available in Canada, and the suggested basis for the discounted retail price was wholly inconsistent with the price itself.

[93] See September 28, 2021 News Release, *Lilly again reduces list price of Insulin Lispro Injection as latest change to affordability options*, Eli Lilly and Company, available at < https://investor.lilly.com/news-releases/news-release-details/lilly-again-reduces-list-price-insulin-lispro-injection-latest> (accessed Jan 20, 2022).

51. Finally, as a general matter, insulin manufactures are subject to the requirements of the MCPA. The MCPA exempts any "transaction or conduct specifically authorized under laws administered by a regulatory board or officer acting under statutory authority of this state or the United States." MCL 445.904(1)(a). Eli Lilly's conduct in grossly inflating the price of its insulin products does not fall within any transaction specifically authorized by a governing body and is thus subject to the MCPA.[94]

52. The Food and Drug Administration (FDA) has authority to regulate only some of the transactions that touch and concern food and drug commerce in the United States. For instance, it has authority to monitor drug research, inspect manufacturing facilities, and evaluate prescription drug advertising. 21 USC § 301 *et seq*. Notably, the FDA cannot regulate the vast segment of the drug industry involving drug pricing. On its website, the FDA expressly states that it "has no legal authority to investigate or control the prices set by manufacturers, distributors and retailers."[95] It further tells consumers to "consider contacting the Federal Trade Commission[,]" which "enforces a variety of federal antitrust and consumer protection laws."[96] However, like the FDA, the FTC also has no authority

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[94] To the extent *Smith v Globe Life Ins Co*, 460 Mich 446 (1999), may suggest otherwise, the Attorney General asserts that case was wrongly decided.

[95] See "What can the FDA do about the cost of drugs?", *Frequently Asked Questions about CDER*, U.S. Food and Drug Administration (current as of Oct 28, 2019) <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/frequently-asked-questions-about-cder#16> (accessed Jan 20, 2022).

[96] *Id.*

to regulate prescription drug prices.[97] Acknowledging its lack of authority in this area, the FDA has made other attempts to influence the cost of insulin, such as encouraging a market in biosimilars. Considered a generic version of biopharmaceutical drugs, there is hope that biosimilars will reduce monopoly power and costs in the future.[98] Finally, the Michigan Board of Pharmacy also regulates certain aspects of the industry, but again, not the price of drugs.[99] As such, there is no governing body that regulates prescription drug pricing—the very conduct the Attorney General seeks to investigate here.

53. In sum, there is probable cause to believe that Eli Lilly violated, and continues to engage in violations, of the MCPA. As such, an investigation into the business practices of Eli Lilly is appropriate.

V. Conclusion and Relief Sought

The Attorney General respectfully requests that this Court authorize an investigation under the MCPA. Through this investigation, the Attorney General

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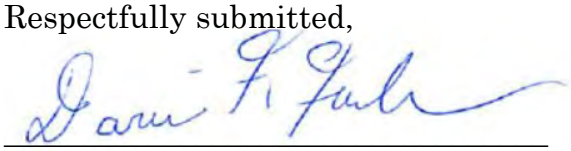
[97] Alan Friedman, *From the antitrust mailbag: What can the FTC do about prescription drug price spikes?* Federal Trade Commission, Bureau of Competition (May 18, 2015) available at <https://www.ftc.gov/news-events/blogs/competition-matters/2015/05/antitrust-mailbag-what-can-ftc-do-about-prescription> (accessed Jan 21, 2022).

[98] Epstein, MS; Ehrenpreis, ED; Kulkarni, PM, *Biosimilars: the need, the challenge, the future: the FDA perspective*. The American Journal of Gastroenterology (December 2014) available at <http://www.epsteinassociatesllc.com/wpress/wp-content/uploads/2015/06/Biosimilars-The-Need-The-Challenge-The-Future-The-FDA-Perspective_-Epstein-et-al.pdf.> (accessed Jan 21, 2022).

[99] Michigan Board of Pharmacy, LARA. < https://www.michigan.gov/lara/0,4601,7-154-89334_72600_72603_27529_27548_91200-59186--,00.html> (Jan 20, 2022).

will issue subpoenas for records from Eli Lilly to shed light on its business practices, including reasons for the disparity in pricing for its products in Michigan versus Ontario, Canada; reasons for the disparity in pricing between Humalog and Lispro in Michigan; and an examination of the reasons underlying the cost savings being promoted in relation to the sale of Lispro. The Attorney General will seek information elaborating how Eli Lilly has transacted business within Michigan on these topics. The Attorney General will also seek the investigative testimony of Eli Lilly agents on these topics. And documents and testimony from Express Scripts, one of the three major PBM's, will be sought so the Attorney General can understand the communications between that entity and Eli Lilly giving rise to the announcement related to Lispro described in paragraph 48 of this Petition. A proposed order authorizing the issuance of subpoenas for this investigation is attached. (**Exhibit I**.)

Respectfully submitted,



Darrin F. Fowler (P53464)
Michael S. Hill (P73084)
Assistant Attorneys General
Michigan Dep't of Attorney General
Corporate Oversight Division
P.O. Box 30736
Lansing, MI 48909
(517) 335-7632
FowlerD1@michigan.gov
HillM19@michigan.gov

Dated: January 25, 2022

Dana Nessel, Attorney General of the State of Michigan, ex rel The People of the State of Michigan v Eli Lilly and Company

INDEX OF EXHIBITS

Encryption Code: MiAg525!

EXHIBIT A

Eli Lilly and Company corporate filing with Michigan Department of Licensing and Regulatory Affairs

LARA Corporations Online Filing System
Department of Licensing and Regulatory Affairs

ID Number: 800995310 Request certificate Return to Results New search

Summary for: ELI LILLY AND COMPANY

The name of the FOREIGN PROFIT CORPORATION: ELI LILLY AND COMPANY

Entity type: FOREIGN PROFIT CORPORATION

Identification Number: 800995310 **Old ID Number:** 615925

Date of Qualification in Michigan: 11/10/1966

Incorporated under the laws of: the state of Indiana

Purpose:

Term: Perpetual

Most Recent Annual Report: 2020 **Most Recent Annual Report with Officers & Directors:** 2020

The name and address of the Resident Agent:

Resident Agent Name: NATIONAL REGISTERED AGENTS, INC.

Street Address: 40600 ANN ARBOR RD E STE 201

Apt/Suite/Other:

City: PLYMOUTH State: MI Zip Code: 48170

Registered Office Mailing address:

P.O. Box or Street Address:

Apt/Suite/Other:

City: State: Zip Code:

The Officers and Directors of the Corporation:

Title	Name	Address
PRESIDENT	DAVID A RICKS	LILLY CORPORATE CENTER INDIANAPOLIS, IN 46285 USA
TREASURER	PHILIP L. JOHNSON	LILLY CORPORATE CENTER INDIANAPOLIS, IN 46285 USA
SECRETARY	BRONWEN L. MANTLO	LILLY CORPORATE CENTER INDIANAPOLIS, IN 46285 USA
DIRECTOR	RALPH ALVAREZ	LILLY CORPORATE CENTER INDIANAPOLIS, IN 46285 USA

Total Authorized Shares	Shares Attributable to Michigan	Most Recent Apportionment %	Year Ending
3,200,000,000	73,561,600	0.1449%	2018

View filings for this business entity:

ALL FILINGS
ANNUAL REPORT/ANNUAL STATEMENTS
CERTIFICATE OF CORRECTION
CERTIFICATE OF CHANGE OF REGISTERED OFFICE AND/OR RESIDENT AGENT
RESIGNATION OF RESIDENT AGENT
CERTIFICATE OF ASSUMED NAME

View filings

Comments or notes associated with this business entity:

EXHIBIT B

Johnson, Carolyn Y., For Insulin Users, Price of Wellness Can be High, The Washington Post (November 1, 2016)

Record: 1

Title: For insulin users, price of wellness can be high

Authors: Carolyn Y. Johnson

Source: Washington Post, The. 11/01/2016.

Document Type: Article

Abstract: Researchers considered drug a 'gift to humanity.' Industry saw otherwise. [ABSTRACT FROM PUBLISHER]

Accession Number: wapo.78bf4024-8587-11e6-a3ef-f35afb41797f

Database: Newspaper Source Plus

Researchers considered

drug a 'gift to humanity.' Industry saw otherwise.

At first, the researchers who discovered insulin agonized about whether to patent the drug at all. It was 1921, and the team of biochemists and physicians based in Toronto was troubled by the idea of profiting from a medicine that had such widespread human value, one that could transform diabetes from a death sentence into a manageable disease.

Ultimately, they decided to file for a patent - and promptly sold it to the University of Toronto for $3, or $1 for each person listed. It was the best way, they believed, to ensure that no company would have a monopoly and patients would have affordable access to a safe, effective drug.

"Above all, these were discoverers who were trying to do a great humanitarian thing," said historian Michael Bliss, "and they hoped their discovery was a kind of gift to humanity."

But the drug also has become a gift to the pharmaceutical industry. A version ofinsulin that carried a list price of $17 a vial in 1997 is priced at $138 today. Another that launched two decades ago with a sticker price of $21 a vial has been increased to $255.

Seventy-five years after the original insulin patent expired - a point at which drug prices usually decline - three companies have made incremental improvements to insulin that generate new patents and profits, creating a family of modern insulins worth billions of dollars.

The history of insulin captures one of the mystifying complexities of the pharmaceutical market - how long-standing drugs become more expensive with time and competition fails to hold down prices. Companies point to improvements in their drugs, but medical experts say some of those changes are simply a strategy to keep prices high with new patent protections. They question how much the molecular tweaks to insulin really improve patients' health.

Some of the improvements have been substantial, replacing insulin derived from animals with a genetically engineered human version with fewer side effects. But the latest generation of "ultra-long acting" insulins, in particular, has generated a debate about whether the newest versions are really worth the cost.

"I don't think it takes a cynic such as myself to see most of these drugs are being developed to preserve patent protection," said David Nathan, a Harvard Medical School professor. "The truth is they are marginally different, and the clinical benefits of them over the older drugs have been zero."

The nation faces a diabetes epidemic: About 6 million American adults depend on the drug. As is true with many medicines, most patients don't pay the full list price. The rising cost of insulin is often masked by health insurance.

But people with gaps in insurance, skimpy health coverage, or who break or lose a vial have learned the hard way how much the price has risen.

Among them is Laura Marston, 34, of the District, who has been on insulin for more than half of her life. When she was diagnosed with Type 1 diabetes as a teenager, meaning her body can't make insulin, she took Humulin, a drug invented the year she was born. With insurance, her insulin cost $10 for a month's supply.

Shortly after, Marston's doctor switched her to a brand-new insulin called Humalog, which took effect faster. The drug was just as affordable with insurance.

Then, in 2012, Marston abruptly lost her job and health insurance. She found herself suddenly on the hook for the full price of Humalog, which was listed at $140 a vial - and she needed three vials each month. She managed to obtain a very pricey insurance plan, but the insulin still cost her about $200 a month.

An older insulin could have been cheaper, but she didn't know it was an option. She had years of experience and comfort managing her disease on her current regimen. But she's been closely tracking the price of new and old insulins ever since.

"Nor will I, ever again, go on a new insulin. I've learned my lesson," Marston said.

Drug companies commonly say that their rising prices reflect, in part, the costs of future innovation - the research and development to create new and better drugs. That makes Marston feel trapped: Companies say they charge high prices for old drugs so they can launch newer and better ones - and charge more for them, too.

"If the justifications pharma is giving are true, then it never ends for us," Marston said.Evolution of insulin

Irl Hirsch remembers when insulin cost 75 cents a vial. The 58-year-old doctor has used insulin for more than half a century and knows firsthand that pricing and access weren't an issue for much of that time.

Drugstore ads from the 1960s published in The Washington Post advertised insulin for as little as 84 cents a vial - less than a bottle of Breck shampoo, three bags of Halloween candy bars or a can of Suave hair spray. The most expensive version listed in the ad was less than $2 a vial.

For years, the price was affordable as far as he knows, Hirsch says - as it should be.

"This is not a concierge medication," he said.

As a diabetes specialist at the University of Washington School of Medicine in Seattle and as a patient, Hirsch has witnessed insulin's evolution: a scientific quest driven by an effort to make insulin molecules that more closely mimic the way the hormone works in the body. The first insulin he took was crude by today's standards, extracted from the macerated pancreas of farm animals. Some patients had allergic reactions, such as skin rashes.

The modern age of insulin innovation kicked off with Eli Lilly's introduction of Humulin, in 1982. Using genetic engineering, biologists figured out a way to modify bacteria into tiny, specialized factories that could create

insulin that matches the kind the human body produces. Allergic reactions became rare as more people used the newer version.

Humulin could be created in vats instead of harvested from cows or pigs, and it relieved doctors' worries that the looming diabetes epidemic would cause a shortage.

"These were an incredibly efficient way of making insulin. We'd never run out; it would keep the prices under control," Nathan said. "How that has changed."

The Danish company Novo Nordisk began making its own bioengineered human insulin in 1991. Rather than lower the price, however, competition had an unusual effect: The list prices began to rise.

As concerns about drug prices have simmered among the public and politicians, the long history of insulin shows the ripple effect of the industry-wide practice of raising list prices of existing drugs: All boats rise with the tide. Price increases on old drugs recalibrate how much it costs to treat the disease, paving the way for new drugs to be launched at ever higher prices.

According to a Washington Post analysis of Truven Health Analytics data, over the past two decades, Eli Lilly and Novo Nordisk raised prices on their human insulins 450 percent above inflation, closely in sync.

That's not what Eli Lilly anticipated, at least not publicly. When Humulin was introduced in 1982, company spokesman Ronald Culp told the New York Times, "The long-term desire is that the cost will come down, but at this point we cannot speculate on just how far."

Since then, other insulins have come on the market in faster-acting or longer-lasting formulations. Experts have been divided about how beneficial those advancements are and whether they are necessary for many patients. Meanwhile, the new drugs' prices have risen rapidly. Humalog, for instance, has soared from $21 a vial to more than $250 in the past 20 years.

"Yes, in a dramatic fashion, the newer insulins may not have been as large ... as those previous leaps," said Todd Hobbs, chief medical officer of Novo Nordisk in North America. "I think it's tough to compare the price increases over the decades, but if you look at the advancements from where we were 25 years ago, it's been considerable."

Critics don't argue that the new drugs are ineffective or that there aren't subsets of patients who do better or prefer the newer drugs. Instead, the debate centers on whether the benefit is worth the increased cost.

Pharmacy benefit managers - the middlemen hired by insurers to negotiate prices with drugmakers - have been among the loudest voices in that debate.

"In some ways you might want to put the [word] 'improvements' or 'improved' in quotes," said Glen Stettin, a senior vice president at Express Scripts Holding, the largest pharmacy benefit manager. "For some people, some elements of convenience or how the insulin works for them may be different. But for most people, most of the time the improvements are not really improvements at all."List-price inflation

Drug companies have long argued that list prices are fiction. Health insurers hire pharmacy benefit managers to bargain for secret rebates and discounts off the list price. Insurance, and in some cases financial-assistance programs, then helps patients with the rest of the tab.

All three drug companies that dominate the insulin market said that list-price inflation is deceiving for these reasons. But increasingly, as drug prices have risen and insurance companies have changed how benefits are structured, they do matter. There's growing evidence that patients are shouldering more of the cost of their drugs.

Still, drug companies do not always realize the profit from the rising list price of insulin, said Enrique Conterno, a senior vice president at Eli Lilly. As the price increases, he said, drugmakers often give deeper rebates to pharmacy benefit managers. Those that don't might receive less-favorable coverage from insurers, he said.

That's led to a situation in which the list price for Humalog has increased about 150 percent since 2009 - but the net price of the drug after rebates has been flat, Conterno said.

That's not to say drug companies aren't benefiting from list-price increases over the long term, or even in a given year. Last year, Lilly reported that the revenue from Humalog grew 9 percent in the United States, driven mostly by price increases. But last week, Lilly reported that revenue from U.S. sales of Humalog in the past quarter declined compared with a year ago, even though the company sold more of the drug, because of deeper rebates and discounts.

Ken Inchausti, a spokesman for Novo Nordisk, said in an email that price increases of its insulins "were offset by those rebates and other fees charged by wholesalers and others in the supply chain."

Sanofi said that the net price for its best-selling drug, the insulin Lantus, has fallen over the past five years. Express Scripts said that the net price for that drug declined nearly 14 percent in 2015.

There have been few efforts to create a cheaper insulin. Walmart, for instance, sells a version of human insulin under the name ReliOn for $25 a vial. Eli Lilly is expected to release the first copycat insulin analog, a chemically altered form of insulin, at the end of this year.

But insulin is a large, complex molecule that can't be easily made into a pill like a traditional generic. It requires an expensive process using living cells and a bioreactor.

Jeremy Greene, a physician and historian of medicine at Johns Hopkins University School of Medicine, said that when he began practicing medicine in Baltimore, he was surprised to find patients coming in with poorly controlled blood sugar. They weren't taking their insulin, they said, because it was too expensive.

"It shocked me ... that it could be true that this drug that had been around for 95 years was not available generically," Greene said.

That leaves diabetes patients subject to the decisions drugmakers and insurers make behind closed doors.

Patricia Bailey, 66, of Springville, Tenn., said her insurer once switched her to another brand of insulin without explanation or warning. Although the new drug works the same, she said, it's disquieting to feel at the whim of a process she can't control, and in the past she's had allergic reactions to certain insulins. Her costs have only gone up, and now she pays about $400 out of pocket for a three-month supply.

Bailey is frugal with her insulin now. When she gets a "low reservoir" warning from her pump, she'll leave it until the tubing is completely empty of insulin. If she runs out at night, she'll leave it for a few hours, even though it means her blood sugar goes up.

She doesn't consider it rationing, just stretching her insulin as far as it can possibly go - and she doesn't tell her doctor.

That leaves a mixed legacy for one of the most important advances in modern medicine: Patients who were once called "living skeletons" on starvation diets can now live normal lives, thanks to drugs that are being constantly tweaked. But they feel like they're being held captive to an ever-rising price tag on their lives.

"It's the idea that I have no alternative, I have no choice, I have to pay whatever is asked of me," Bailey said. "And it's just continually, continually going up."

carolyn.johnson@washpost.com

Source: Washington Post, The, 11/01/2016
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EXHIBIT C

Elizabeth Rosenthal, *When High Prices Mean Needless Death*, JAMA Internal Medicine (Jan 2019)

methodology.[5] Combining hospital and police data may allow for a more complete picture of violence.

Limitations of the study include that findings are generated from a single city. Furthermore, this study focused on violence occurring in public places only and does not provide information on reporting by injury severity. Third, this study does not include comparison with minor criminal charges such as "simple assault"; although not readily used as a criminal charge for violent injuries necessitating ED treatment in this study's jurisdictions, use of criminal charges can vary across police jurisdictions. Last, beyond the potential of misreporting by patients, only approximately 40% of violent incidents contained enough information to be mapped. Nonetheless, we hypothesize that patients declining to provide detailed information to nurses have specific reasons for nondisclosure[6] and would therefore also be unlikely to provide such information to police. This suggests that the number of incidents unreported to police may be even higher than we detected.

In summary, these findings emphasize the potential of ED and police data to provide a complementary and comprehensive understanding of violent injury resulting in significant morbidity. This study provides new support for the United States on the value of cross-sectoral partnerships, the importance of ED-collected violence data, and the potential of such efforts to improve violence prevention.

Daniel T. Wu, MD
Jasmine C. Moore, MPH
Daniel A. Bowen, MPH
Laura M. Mercer Kollar, PhD
Elizabeth W. Mays, MPH
Thomas R. Simon, PhD
Steven A. Sumner, MD, MSc

Author Affiliations: Grady Health System, Atlanta, Georgia (Wu, Moore, Mays); Emory University School of Medicine, Atlanta, Georgia (Wu); Oak Ridge Institute for Science and Education, Oak Ridge, Tennessee (Bowen); Division of Violence Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, Atlanta, Georgia (Bowen, Mercer Kollar, Simon, Sumner).

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Corresponding Author: Steven A. Sumner, MD, MSc, Division of Violence Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Hwy NE, Mail Stop F-63, Atlanta, GA 30341 (hvo5@cdc.gov).

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Study concept and design: Wu, Bowen, Mercer Kollar, Mays, Simon, Sumner.
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Drafting of the manuscript: Bowen, Mercer Kollar, Sumner.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Bowen, Mercer Kollar, Sumner.
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Cost-Related Insulin Underuse Among Patients With Diabetes

Insulin is lifesaving for people with diabetes and is included on the Model List of Essential Medicines formulated by the World Health Organization.[1] This means it should be available at all times at a price the individual and the community can afford.[1] However, over the past decade, insulin prices have tripled in the United States, while out-of-pocket costs per prescription doubled.[2,3] High costs of medications can contribute to nonadherence,[4] but the prevalence of cost-related insulin underuse is unknown.

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Methods | We administered a survey to patients with type 1 or type 2 diabetes for whom insulin was prescribed within the past 6 months and who had an outpatient visit at the Yale Diabetes Center (YDC) between June and August of 2017. The YDC serves a diverse patient population from New Haven, Connecticut and surrounding counties. The survey questions were based on previously validated surveys[5,6] and review of prior literature and refined based on cognitive interviews. The Yale University Human Investigations Committee approved the study. Written informed consent was obtained from participants.

The primary outcome was cost-related underuse in the past 12 months, defined by a positive response to any 1 of 6 questions: did you...(1) use less insulin than prescribed, (2) try to stretch out your insulin, (3) take smaller doses of insulin than prescribed, (4) stop using insulin, (5) not fill an

Table. Characteristics of Survey Participants

Characteristic	Participants, No.	With Cost-Related Insulin Underuse, No. (%)	Odds Ratio (95% CI)
All Participants	199	51 (25.5)	
Age, y			
18-44	63	20 (31.7)	1 [Reference]
44-64	84	20 (23.8)	1.14 (0.40-3.35)
≥64	52	11 (21.2)	0.90 (0.25-3.28)
Sex			
Female	101	28 (27.7)	1 [Reference]
Male	98	23 (23.5)	1.14 (0.49-2.66)
Race/ethnicity			
White	121	26 (21.5)	1 [Reference]
Latino/Hispanic/Latin American	14	4 (28.6)	1.00 (0.17-4.86)
Black/African American	49	16 (32.7)	1.71 (0.58-5.05)
Other/did not report	15	4 (33.3)	1.66 (0.38-6.83)
Diabetes			
Type 1	83	22 (26.5)	1 [Reference]
Type 2	115	29 (25.2)	0.91 (0.33-2.55)
Did not report	1		
Type of insulin used			
Analog	181	44 (24.3)	1 [Reference]
Human	12	4 (33.3)	3.17 (0.68-13.36)
Both	6	3 (50.0)	2.79 (0.30-37.85)
Prescription drug coverage			
Medicare Part D	40	7 (17.5)	1 [Reference]
Employer-sponsored	66	21 (31.8)	1.03 (0.29-3.95)
Medicaid with/without Medicare	85	19 (22.4)	3.05 (0.80-13.01)
None/other/unknown	8	4 (50)	2.19 (0.24-19.37)
Annual Income, $			
100 000 and greater	24	1 (4.2)	1 [Reference]
50 000-99 999	26	10 (38.5)	12.51 (1.83-255.85)
25 000-49 999	37	14 (37.8)	11.50 (1.62-239.06)
10 000-24 999	53	13 (24.5)	9.79 (1.15-220.25)
<10 000	36	7 (19.4)	6.42 (0.65-154.07)
Did not report[a]	23		
Difficulty buying diabetes medical equipment			
No	144	21 (14.6)	1 [Reference]
Yes	55	30 (56)	5.89 (2.52-14.50)

[a] Missing Income values were excluded from multivariable analysis.

insulin prescription, or (6) not start insulin…because of cost? We examined the association between sociodemographic, economic, and clinical factors and cost-related underuse using multivariable logistic regression.

We then examined the association between cost-related underuse and poor glycemic control (HbA1c ≥9% obtained at time of visit or within 3 months) adjusting for sex, body mass index (BMI, calculated as weight in kilograms divided by height in meters squared), diabetes duration, and income using a separate multivariable logistic regression model. We performed all analyses using R statistical software (version 3.1.1, R Foundation).

Results | Of 354 eligible patients (184 [52.0%] women, 191 [54.0%] white, 123 [34.8%] type 1 diabetes), 199 (56.2%) completed the survey (101 [50.8%] women, 121 [60.8%] white, 83 [41.7%] type 1 diabetes). Of these patients, 51 (25.5%) reported cost-related insulin underuse. The type of prescription drug coverage was not significantly associated with cost-related underuse (**Table**). Patients with cost-related underuse were more likely to report lower incomes; 31 [60.8%] of these patients discussed the cost of insulin with their clinician and 15 [29.4%] changed insulin type owing to cost. Patients who reported cost-related underuse (vs those who did not) were more likely to have poor glycemic control in the multivariable analysis (22 [43.1%] vs 41 [28.1%]; odds ratio = 2.96; 95% CI, 1.14-8.16; P = .03). Of the 199 patients, 2 had missing HbA1c levels.

Discussion | One in 4 patients at an urban diabetes center reported cost-related insulin underuse and this was associated with poor glycemic control. These results highlight an urgent need to address affordability of insulin.

More than one-third of patients who experienced cost-related underuse did not discuss this with their clinician. These findings are consistent with a previous study, which found that 37% of patients did not speak to clinicians about cost issues.[4] Patients with lower incomes were more likely to report cost-related underuse; nearly two-thirds of these patients also experienced difficulty affording diabetes equipment, indicating broader cost barriers to diabetes management.

This study has limitations. This single-center study may be limited in its broader generalizability. Given its cross-sectional design, a causal relationship between cost-related underuse and poor glycemic control cannot be established.

Insulin is a life-saving, essential medicine, and most patients cannot act as price-sensitive buyers. Regulators and the medical community need to intervene to ensure that insulin is affordable to patients who need it. At minimum, individual clinicians should screen all patients for cost issues to help them address these challenges.

Darby Herkert, BS
Pavithra Vijayakumar, BA
Jing Luo, MD, MPH
Jeremy I. Schwartz, MD
Tracy L. Rabin, MD, SM
Eunice DeFilippo, MD
Kasia J. Lipska, MD, MHS

Author Affiliations: Yale College, New Haven, Connecticut (Herkert); Yale School of Medicine, New Haven, Connecticut (Vijayakumar, DeFilippo); Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts (Luo); Department of Internal Medicine, Yale School of Medicine, New Haven, Connecticut (Schwartz, Rabin, Lipska).

Corresponding Author: Kasia J. Lipska, MD, MHS, Section of Endocrinology, Department of Internal Medicine, Yale School of Medicine, PO Box 208020, 333 Cedar St, New Haven, CT 06520 (kasia.lipska@yale.edu).

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Critical revision of the manuscript for important intellectual content: All authors.
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Invited Commentary

When High Prices Mean Needless Death

I have spent the last 5 years of my life as a journalist writing about the irrational costs and prices across the US health care system. But if there is 1 fact that should cause national embarrassment it is the high price tag we affix to living with type 1 diabetes.

The medicinal and technological advances of the last century have turned type 1 diabetes from a rapidly fatal disease into a treatable illness. But doing so takes discipline and care—as well as increasingly expensive technology and medicine—that is far more expensive in the United States than elsewhere.

Related article page 112

That is because people with type 1 diabetes are both beneficiaries and pawns in the business ventures of drug makers, device manufacturers, and insurers, and sometimes these companies seem willing to sacrifice a pawn or 2 for profits. Today people with type 1 diabetes are again at an increased risk of becoming ill and even dying prematurely because of the price.

Between 2007 and 2017, the average wholesale price of 4 of the most popular insulins has more than tripled in price.[1] Between 2010 and 2015, the monthly wholesale price of Humulin, the most popular insulin, rose to nearly $1100, up from $258 for the average patient.

In this issue of *JAMA Internal Medicine*, Herkert et al[2] report the results of a survey on insulin underuse that was associated with costs that was administered at the Yale Diabetes Center. Of 199 patients who completed the survey (57% response rate), 51 (25.5%) reported cost-related underuse and were 3 times more likely to have poor glycemic control.

As a journalist, I hear wrenching patient stories, such as that of a restaurant manager who died shortly after turning age 26 years and going off his mother's insurance. The price tag to treat his diabetes was $1300 a month, which was mostly for insulin. He died of diabetic ketoacidosis 3 days before his payday. An empty insulin pen was found in his apartment.[3]

A student at DePauw University with type 1 diabetes was losing weight, fatigued, and doing poorly in school. It was only after a coach, alarmed, notified his parents that they discovered he had been skimping on his insulin to save money.[1]

Such tragedies and tragedies in the making are explained by Herkert et al[2]; to save money, 25% of people are using less insulin than prescribed. What is more alarming is that a third of those did not tell their physician (or, presumably, their parents) that they were taking the risk.

As drug costs have generally increased in the United States, we know that many patients are skimping on medicines, taking less than prescribed, and cutting pills in half to make every fill last longer. This is terrible, but for many diseases, it is not catastrophic. If you use less of your asthma inhaler you will be somewhat short of breath. If you skimp a bit on sleeping medicines or even blood pressure pills, you will have a chance to self-correct. But skimping on insulin can be rapidly deadly in people whose bodies make none of their own and can result in a life-threatening metabolic disturbance.

It can also hasten disability (eg, blindness and kidney failure) and early death. Thanks to tight glucose control and more precise insulin dosing, researchers estimated in 2012 that children with diabetes born between 1965 and 1980 were living 15 years longer than those born between 1950 and 1965.[4]

Will that 15-year gain now be erased because of the price? It is important to consider that this is typically a disease that starts in childhood, meaning that people with diabetes must traverse their 20s with the illness, a decade during which their earnings are low and Americans are likely to be uninsured or underinsured.

Frederick Banting and colleagues, who discovered and isolated insulin in the early 1920s, licensed the patent for $1, so the blame is not with them.[5] Who then is to blame for the price inflation?

The for-profit drug and device makers who sell insulins and insulin delivery devices have not followed the example of Banting et al. The have increased the price of their products year after year because, simply, they can. They have spent millions filing lawsuits that successfully keep competitors off of the US mar-

ket. A biosimilar of Sanofi's popular insulin Lantus was approved for use in the European Union in 2014 but was initially delayed for 2 more years by a lawsuit in the United States.[6] Now that the biosimilar product, Basaglar, has finally hit the market, its price is only minimally lower than the original brand.[7] The same insulin pen that retails for $140 in the United States costs less than $15 in Germany and Canada.[8]

The US insurance system—private and public—does not cut people with chronic disease a break but instead tends to penalize them. People with type 1 diabetes are people who drew a short straw in the disease lottery. Most other developed countries have concluded that their citizens should therefore not be subject to copays or high deductibles. "If you have a chronic disease, you shouldn't be burdened by the cost," York F. Zöllner, a professor of health economics at Hamburg University of Applied Sciences, told me in an interview for the *New York Times* before explaining the German approach, in which out-of-pocket contributions for insulin are less than $100 per year.[9] Until very recently, the disease foundations (JDRF and the American Diabetes Association among them), as well as many diabetes patient groups, did not protest much as the prices rose, in part likely because so many receive funding from pharmaceutical companies.

Extreme prices can lead to extreme solutions. A 29-year-old student in Missouri with diabetes whom I interviewed for my book[10] told me that she would only consider doctoral programs outside of the United States. "My one goal in life has been to move to Europe so I don't have to pay these staggering prices just to survive," she said.

But others—that 25%—will quietly skimp on their insulin, taking less than they need but more, perhaps, than they can really afford. Some of them will die.

Elisabeth Rosenthal, MD

Author Affiliation: Kaiser Health News.

Corresponding Author: Elisabeth Rosenthal, MD, Kaiser Health News, 1330 G St NW, Washington, DC 20009 (e.rosenthal429@gmail.com).

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Association Between Cannabis Use and Risk for Diabetic Ketoacidosis in Adults With Type 1 Diabetes

Cannabis use is increasing with the shifts in legality and public perceptions in the United States.[1] Studies have reported improvement in insulin sensitivity and pancreatic beta cell function with cannabis use,[2,3] generating widespread media attention suggesting cannabis as a potential therapeutic agent for treatment of type 2 diabetes. By contrast, we published a case series[4] reporting recurrent diabetic ketoacidosis (DKA) with cannabis use in patients with type 1 diabetes (T1D). Because little is known about cannabis use and its contribution to DKA in T1D, we investigated the characteristics of cannabis use among adults with T1D and the association of cannabis use with DKA.

Methods | Between June 2017 and January 2018, adults aged 18 years or older with T1D attending the Barbara Davis Center for Diabetes, the largest T1D treatment center in Colorado, where cannabis is legal for medical and recreational use, were invited to complete an in-person questionnaire on their cannabis use. Patients with diabetes other than T1D, pregnancy, and repeat follow-up visits within the study duration were excluded. A questionnaire was used to collect demographic characteristics, diabetes history and complications, severe hypoglycemia requiring assistance, and cannabis use information. Point-of-care hemoglobin A_{1c} level (HbA_{1c}; DCA Vantage Analyzer) was measured during the clinic visit. Scores on the Cannabis Use Disorder Identification Test-Revised[5] were used to define hazardous cannabis use (score ≥8 and <12) and possible cannabis use disorder (score ≥12). The Colorado Multiple Institutional Review Board (Aurora, Colorado) approved this study, and all participants provided written informed consent.

The primary outcome was DKA hospitalization during the preceding 12 months. All self-reported DKA hospitalizations were confirmed by medical record review. Comparison of categorical variables was conducted with 2-tailed χ^2 tests, and 2-sample *t* tests were used to test normally distributed continuous variables. A logistic regression model was built to calculate the odds of DKA hospitalization by cannabis use. Clinical evidence-based risk factors for DKA, such as age, sex, diabetes duration, income, educational level, HbA_{1c} level, and insurance (derived from income), were modeled, and a stepwise selection method was used to confirm the final model. Model fit was assessed by Akaike information criterion. Sensitivity analyses were performed using propensity score matching of cannabis users and nonusers, adjusting for age, sex, ethnicity, tobacco and alcohol use, educational level, income,

EXHIBIT D

Loftus, *As Political Scrutiny Mounts, Eli Lilly Divulges New Insulin Pricing Data*, Wall Street Journal (May 24, 2019)

https://www.wsj.com/articles/as-political-scrutiny-mounts-eli-lilly-divulges-new-insulin-pricing-data-11553436000

BUSINESS

As Political Scrutiny Mounts, Eli Lilly Divulges New Insulin Pricing Data

Lilly says the price it was paid for popular insulin Humalog fell 8.1% from 2014 to 2018 due to increasing rebates it gave to companies in the drug-supply chain

Lilly hasn't raised the U.S. list price for Humalog since May 2017.

PHOTO: DANIEL ACKER/BLOOMBERG NEWS

By *Peter Loftus*

March 24, 2019 10:00 am ET

Eli Lilly LLY **-2.66%** ▼ & Co., facing mounting scrutiny in the U.S. Congress over big increases in the list price of a widely used insulin, says the price it was paid dropped by 8.1% during the previous five years after accounting for rebates and discounts.

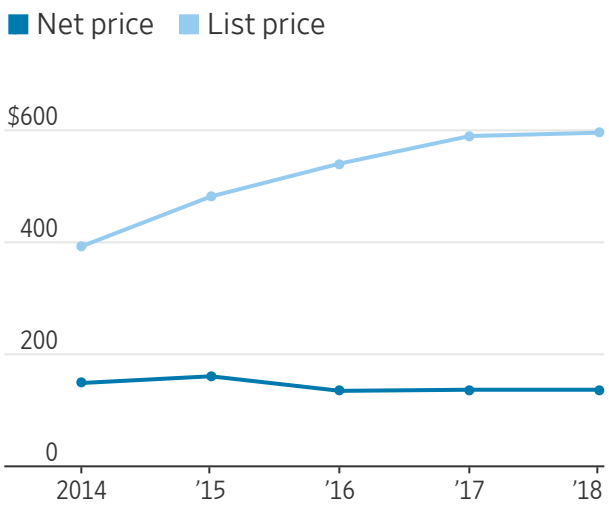
Lilly says the net price for its Humalog insulin—the price after discounts and rebates—fell to an average of $135 a patient a month in 2018, from $147 in 2014. During the same period, the product's average list price rose 51.9% to $594 per patient monthly.

Humalog is among the most widely used insulins in the U.S., where an estimated 30 million Americans have diabetes.

Price Spread

Eli Lilly says rebates it provides to industry middlemen have cut the net price for its Humalog insulin despite list price increases.

Average U.S. Humalog price



Note: Prices are yearly averages for Humalog U100, the most widely used Lilly insulin.
Source: the company

Lilly said the monthly per-patient prices were based on average use of Humalog if taken as prescribed. This amounts to about two vials or more than six pen injectors, though actual utilization may vary by patient.

The rising cost of diabetes treatments has figured prominently in broader scrutiny of drug prices, and diabetes drugmakers like Lilly are facing criticism from patients, doctors and lawmakers.

The rising list prices have especially hit patients without insurance and those with prescription plans that carry high out-of-pocket costs. Due to the costs, some patients have rationed doses, switched to low-cost versions sold at Walmart stores, or turned to unapproved versions.

This year, House and Senate committees sent letters to diabetes drugmakers Lilly, Sanofi SA and Novo Nordisk A/S, seeking information on the rising cost of their insulins and details about rebates paid to drug-supply chain companies. The drugmakers say they are cooperating.

And Sen. Ron Wyden (D., Ore.) criticized Sanofi for raising the price of its insulin during a February hearing on drug prices where Sanofi CEO Olivier Brandicourt and six other

pharmaceutical executives testified.

In response to the pressure over insulin pricing, Indianapolis-based Lilly has begun taking steps, including announcing earlier this month it would start selling a generic version of Humalog at half the list price of the brand-name drug.

Lilly had reported average list and net price changes for its entire drug portfolio since 2017, but hadn't previously released the figures by product. The company included the new price details in an annual report that it is mailing to shareholders and will post online.

The company says it increased the rebates and discounts paid to middlemen in the drug supply chain as Humalog's list price rose.

A Lilly spokesman said the Humalog pricing information "will provide greater transparency into the significant rebates and discounts we provide to payers and other supply chain entities for this important medicine."

Lilly and other drugmakers say pharmacy-benefit managers and other middlemen aren't passing along savings to consumers. But PBMs say their negotiations for rebates help reduce overall drug costs.

U.S. list prices for some brands of insulin have roughly tripled in the past decade. The list price for one vial of Humalog has risen to $274.70 from $92.70 in 2009, while prices for Novo Nordisk's Novolog and Sanofi's Lantus rose by similar magnitudes, according to the IBM Micromedex Red Book database.

Lilly hasn't raised the U.S. list price for Humalog since May 2017. U.S. sales of the drug rose 4% to $1.79 billion in 2018, which Lilly said was primarily driven by demand.

Write to Peter Loftus at peter.loftus@wsj.com

Appeared in the March 25, 2019, print edition as '.'

EXHIBIT E

Russel, *Lilly Insulin Prices Come Under Microscope*, Indianapolis Business Journal (Aug 25, 2017)

Lilly insulin prices come under microscope

August 25, 2017 | John Russell

KEYWORDS DIABETES / DRUG DISCOVERY / ELI LILLY AND CO. / HEALTH CARE & INSURANCE / HEALTH CARE COSTS / PHARMACEUTICAL / R&D

Over the past 20 years, while the price of a gallon of milk climbed 23 percent and the sticker on a Dodge Caravan minivan rose 21 percent, the list price of the insulin Humalog, made by Eli Lilly and Co., shot up 1,157 percent.

Other Lilly insulins saw hefty price increases, too, including Humulin, on the market since 1982. It has seen price increases totaling nearly 800 percent over the last two decades.

The soaring prices at Indianapolis-based Lilly—and two other insulin makers, whose prices are climbing at similar rates—are sending sticker shock through the diabetes community. In recent months, patients have filed lawsuits and called for congressional investigations, and now they're planning a

demonstration next month in front of Lilly's headquarters on South Delaware Street.

The actions are casting a bright glare on Lilly's oldest and perhaps most famous franchise. The company was the first to mass produce insulin in the 1920s, a move that allowed it to attract scientists and make other breakthroughs in fields from cancer to depression.

It's a critical time for Lilly, as it tries to increase its dominance in the $10 billion diabetes-drug market against chief rivals Sanofi of France and Novo Nordisk of Denmark.

Lilly CEO David Ricks continues to point to diabetes as a key area for investment and growth, but the company's ability to keep patients and physicians satisfied could depend on how well it addresses their concerns over prices.

Already, some physicians say high insulin prices across the industry are causing financially strapped patients to ration or discontinue their medicines, which could lead to serious medical problems.

"It's an everyday thing," said Dr. Michael Hancock, an endocrinologist with Franciscan Health. "It comes up in at least 15 to 20 percent of office visits, patients saying they can't afford insulin."

Sometimes, he said, patients don't bother telling him until much later, when their blood-sugar levels get out of control.

Hancock

If left untreated, diabetes can lead to heart disease, kidney disease, foot ulcers and eye damage. About 30.3 million Americans, or 9.4

percent of the population, have diabetes, up from 29.1 million in 2014.

Lilly launched Humalog in 1996 with a list price of $21 a vial—about a month's supply for many patients. Over the next two decades, the company increased the list price more than 30 times, including an 8 percent price bump this spring. The vial now has a list price of $274.70.

Those figures were compiled by Truven Health Analytics, a market research firm. The firm said it did not know whether the price of insulin was rising faster than for other classes of drugs.

Lilly acknowledged the price of Humalog and other insulins has increased sharply, but said few people pay the sticker price. Instead, the company said, they pay lower amounts as a result of rebates and discounts arranged with pharmacy-benefit managers—companies that negotiate drug prices for insurers.

"So you really have to look at the net prices that insurance companies pay," said Mike Mason, vice president of Lilly's U.S. diabetes business. "Net prices have gone down since 2009."

Lilly's U.S. revenue for Humalog fell 5 percent last year, to $1.68 billion, driven by "lower realized prices," according to the company's annual report.

Mason

However, Lilly declined to disclose net prices for its insulins, calling it proprietary information in a highly competitive industry.

"Our lawyers don't allow us to talk about net prices or rebates," Mason said. He pointed out that Lilly has patient-assistance programs that reduce the cost or in some cases make it free.

Patient pushback

Last year, Lilly counted on diabetes drugs for nearly 25 percent of its $21.2 billion in revenue. The company declined to say how profitable insulin drugs are compared with other classes of medicine.

But experts say drugmakers have become increasingly aggressive about using insulin to boost the bottom line. The average price more than tripled—from $231 to $736 a year for a typical patient—from 2002 to 2013, according to a study in the Journal of the American Medical Association.

During the same period, general inflation went up 32 percent, according to the U.S. Bureau of Labor Statistics.

Michael Schwarb, 57, who lives in Fountain Square, said he spends about $300 a month to treat his Type 1 diabetes, a condition in which the body does not produce its own insulin.

He's been on insulins since 1974, and these days he takes five daily shots of Lilly's fast-acting Humalog and one shot of intermediate-acting Levemir, made by Novo Nordisk.

IBJ.COM EXTRA

See how Lilly's insulin prices have skyrocketed.

His monthly tab actually is low by diabetic standards because Schwab watches his diet and exercises for hours each week as an endurance cyclist.

Even so, it's putting him in a pinch. He said he dropped his high-deductible insurance plan because it wouldn't pay for his insulins until he paid $6,000 a year out of pocket. So now he goes without insurance in order to afford the medicines.

He works as a customer service representative for a graphics company, and to make ends meet, he sometimes uses expired

insulin or has friends donate their insulin to him.

“I don’t really see a reason for the price increases,” Schwab said. “A lot of these insulins have been on the market for years. It seems kind of criminal for them to charge that much to keep me alive.”

Legal challenge

The trend toward high-deductible insurance plans means more patients are feeling the bite of drug costs, including insulins.

Earlier this year, a group of patients filed a lawsuit in federal court in Massachusetts, accusing the three major insulin makers of violating federal racketeering laws by systemically increasing the prices.

Diabetes portfolio

Eli Lilly has been producing insulin and other diabetes treatments for nearly a century, since it became the first drugmaker to commercialize insulin (called Iletin, made from pancreas glands of livestock) in 1923. Here's a lineup of Lilly's diabetes medicines today:

	Launched	2016 revenue
Humulin	1982	$1.37 billion
Humalog	1996	$2.77 billion
Tradjenta*	2011	$436.6 million
Jardiance*	2014	did not disclose
Trulicity	2014	$925.5 million
Glyxambi*	2015	did not disclose
Synjardy*	2015	did not disclose
Basaglar	2016	not applicable

**Tradjenta, Jardiance, Glyxambi and Synjardy are trademarks of Boehringer Ingelheim International, and commercialized in the United States under license by Lilly.*

Source: Eli Lilly and Co.

The lawsuit claimed that the drugmakers have been increasing prices, nearly in lockstep, in order to expand discounts and rebates to pharmacy-benefits managers. The practical effect, according to the lawsuit, was to saddle patients with “crushing out-of-pocket expenses.”

Lilly and the other drugmakers say the suit is without merit and plan to fight it.

Physicians say patients most vulnerable to price increases are those without insurance, those with high-deductible plans, and those on Medicare, who have a coverage gap known as a “doughnut hole.”

The doughnut hole refers to the limit on what Medicare will cover for drugs. The gap begins after a patient has spent a certain amount on drugs, then has to pay out of pocket.

One option is to buy an off-brand Novo Nordisk insulin sold by Walmart for about $25 a vial, several physicians said.

“I think it’s unfortunate we’re seeing these price increases,” said Dr. Paris Roach, an endocrinologist at Indiana University Health. “It’s just crazy. … We find ourselves having to change to less expensive insulins, which we can do, but if somebody is stable on one medication, change is always disruptive.”

Another challenge is that doctors often don’t know what insurance plans patients have, said Dr. Clark Perry, an endocrinologist with Community Health Network.

“But I can tell you it’s not at all an infrequent process when a patient we’re seeing comes back and tells us they need something less expensive.”

Roach

Pursuing innovation

For Lilly, coming up with the next breakthrough in insulin is an ongoing project.

In recent years, the company has launched several new diabetes drugs, including Jardiance, heralded for its weight-loss benefits, and Trulicity, a once-a-week drug.

The company points to diabetes as one of its five core disease areas, with big promise for the future. Lilly has seven experimental diabetes drugs in its pipeline. In March, the company said it would spend $85 million to expand a

manufacturing operation at the Lilly Technology Center southwest of downtown that assembles Trulicity injection pens.

Perry

In the meantime, Lilly—and its competitors—must deal with a rising tide of anger. The American Diabetes Association is circulating a petition calling for more transparency, affordability and access to insulin.

It is also asking Congress to hold hearings with all the players in the insulin supply chain—including drugmakers, insurers, pharmacy-benefit managers and pharmacy chains—"to ensure that all people who use insulin have affordable access" to the life-saving medicine. So far, more than 225,000 people have signed the petition.

Last year, Sen. Bernie Sanders asked the Department of Justice and the Federal Trade Commission to investigate insulin makers for possible price collusion. In a letter to the agencies, he pointed to 13 instances in which the prices of Lilly, Sanofi and Novo Nordisk insulin brands rose in lockstep, a practice known as shadow pricing.

"The original insulin patent expired 75 years ago," Sanders' letter said. "Instead of falling prices, as one might expect after decades of competition, three drugmakers who make different versions of insulin have continuously raised prices on this life-saving medication."

Next month, critics will take their complaint to Lilly's doorstep. From 1 p.m. to 3 p.m. on Sept. 9, two patient groups plan to demonstrate at the company's headquarters. Their goal: to "stop price-gouging" of people with diabetes, according to a flier circulating on the internet.

The main organizer is Elizabeth Rowley, who was diagnosed with Type 1 diabetes at age 4. She grew up in Illinois but now lives in England.

In an email exchange with IBJ, she said she could not move back to the United States for fear that the cost of diabetes would bankrupt her or force her to make “incredibly dangerous choices.”

“The insulin makers like to point to the ‘complex system’ to avoid blame for the insulin pricing crisis,” she wrote. “While the system is certainly broken, at the end of the day, these companies are the ones who set the prices.”

EXHIBIT F

Affidavit of Dr. Timothy Bodnar

AFFIDAVIT OF DR. TIMOTHY W. BODNAR, M.D.

Dr. Timothy W. Bodnar, M.D., being first duly sworn, deposes and says as follows:

1. I am an endocrinologist in Ypsilanti, Michigan. As an endocrinologist, I specialize in treating disorders of the endocrine system, which is a system of glands that secrete hormones within the body. A significant disorder of the endocrine system is diabetes—a disease that occurs when a person's blood sugar is too high. A very common treatment for diabetes is long-term use of injectable insulin. I am providing this affidavit to express my concerns regarding the rising cost of analog insulin in the marketplace, and to discuss the negative ramifications of such rising costs on the health of my patients.

2. I am board certified in Internal Medicine and Endocrinology. I received my M.D. from the University of Michigan Medical School, and completed my postgraduate medical training at the University of Michigan Health System: Residency in Internal Medicine (including serving an additional year as Chief Medical Resident) and Fellowship in Metabolism, Endocrinology, and Diabetes. Throughout my education and training, I was published in several journals, including The Journal of Clinical Endocrinology & Metabolism.

3. I currently work at a large private endocrinology practice called Ann Arbor Endocrinology & Diabetes Associates PC, which is affiliated with St. Joseph Mercy Ann Arbor Hospital. I am also a Key Clinical Faculty Member in the Internal Medicine Residency at St. Joseph Mercy, where I teach and train resident physicians in, among other things, diabetes care.

4. In my endocrinology practice, approximately 30 to 40% of my patients have diabetes. Approximately one-third of those (around 250 patients) have type 1 diabetes, all of whom must take insulin lifelong. The other two-thirds (around 500 patients) have type 2 or other forms of diabetes, and approximately 50% of those patients take insulin in some form. Overall, I estimate that at least two-thirds of my diabetes patients take insulin. My practice, which includes five other endocrinologists, serves at least five times that number of patients, if not more.

5. Since joining the practice in July of 2014, I have observed the adverse, and, at times, devastating, impact that the steadily rising cost of analog insulin has had on my patients, and those of my colleagues.

6. For instance, at least once a day, I discuss the high cost of analog insulin with a patient, as well as what other, less costly diabetes-management options are available. These conversations have become more prevalent since the COVID-19 pandemic began—not only have many of my patients lost some or all of their income, but, in general, the stress and isolation of the pandemic has led to my diabetes patients gaining weight, which typically correlates with larger dose requirements of insulin. One of the options I discuss with my patients is a switch from analog insulin to older "human" insulin. Though, in rare circumstances, the use of human insulin is preferred, in the vast majority of cases, analog insulin is superior—and, in certain cases, immensely superior—to human insulin. Thus, patients who decide to switch to human insulin as a cost-savings measure are typically at a medical disadvantage.

7. In addition, approximately 10% of my patients have admitted to the intentional rationing of their insulin stores; in other words, taking less insulin than their body requires to stretch their prescription and avoid purchasing more for as long as possible. The 10% is likely a conservative estimate, as many patients are reluctant to admit to intentional rationing. Although I do not formally document this, based on conversations with my patients, I believe there has been an increase in intentional rationing of insulin since the COVID-19 pandemic started.

8. Pre-pandemic, other patients indicated that they traveled to Canada, where prices are significantly lower, to purchase their insulin. While I do not recommend that my patients travel to Canada to purchase insulin as a cost-savings measure, I am aware that other practitioners in the field regularly do so.

9. Perhaps the most tragic example, I have observed dozens of patients (both young and old) with type 1 diabetes admitted into the Intensive Care Unit (ICU) at St. Joseph Mercy with diabetic ketoacidosis—a condition that may cause diabetic coma or even death—because they could not afford, or were rationing, their insulin. And, unfortunately, for many of these patients, it is not their first trip to the ICU under the same circumstances. This situation is fraught with irony: A patient may easily incur a $15,000 to $25,000 hospital bill to treat diabetic ketoacidosis because he could not afford the insulin that would have kept him healthy and out of the hospital in the first place.

10. It appears that the insulin manufacturers have recognized these adverse effects of high insulin pricing and have publicized various steps they are

ostensibly taking to make insulin more affordable. Regardless of the manufacturer's expressed "patient-centric" motives, in reality, I have not seen insulin affordability improve for the vast majority of my patients.

11. For example, in March of 2019, Eli Lilly introduced a generic version of its analog insulin product, called Lispro, seemingly to lower out-of-pocket costs for insulin users. However, in my experience, prescribing the generic version does not automatically result in cost-savings for my patients. Now, I typically only prescribe the generic insulin Lispro if a patient's insurance specifically states that this is the "covered" option. Moreover, the release of the generic version did not result in a downward trend in the price of the name brand version, as I had hoped it would. Indeed, the lack of a price decrease is contrary to what typically occurs when a generic is introduced into the market.

12. The three major insulin manufacturers have also instituted some form of prescription drug assistance programs, touted as an opportunity for eligible patients to obtain insulin at no cost. But the eligibility requirements for such programs have become significantly stricter since their rollout. In fact, given the stringent requirements, my practice only attempts to get approval through such a program when a patient seems to have no other option. When we do, a significant percentage of our attempts are failures, as patients either earn too much for the income cutoff, or they cannot afford other requirements such as initially spending $1000 per year on insulin before receiving free insulin through the program. And even if a patient does qualify for prescription drug assistance, there are still

potential problems and wasted resources. For example, there is significant paperwork and coordination required on the part of the physician's office (oftentimes including a staff-member at the physician's office dedicated in large part to administering the program). And, prior to the COVID-19 pandemic, the insulin received through the program was required to be delivered to the physician rather than directly to the patient. If the insulin (which must be kept refrigerated) is delivered when the office is closed and/or is not properly packaged or stored, it is not usable. Moreover, insulin deliveries are not always coordinated with a patient's appointment time, requiring that the patient make multiple trips to the office—for some of my patients, a two- to three-hour round trip—to obtain their insulin through the program.

13. I have personal knowledge of the facts stated in this affidavit and I am competent to testify about them if called upon to do so.

FURTHER, AFFIANT SAYETH NOT.

Dr. Timothy W. Bodnar, M.D.

Subscribed and sworn to before me on this
the 17th day of March, 2021.

Candace Black

Candace Black, Notary Public
State of Michigan, County of Ingham
My commission expires: 12/16/2021
[Acting in the County of Ingham]
Notarized using electronic/remote notarization

CANDACE BLACK
NOTARY PUBLIC, STATE OF MI
COUNTY OF INGHAM
MY COMMISSION EXPIRES Dec 16, 2021
ACTING IN COUNTY OF Ingham

Notary Certification under Public Act 336

I remotely notarized this document under Public Act 336, and certify:

1. The signatory signed this document while I was observing the signatory through a two-way real-time audiovisual technology that allowed direct, contemporaneous interaction by sight and sound between the signatory and me.

2. The two-way real-time audiovisual technology was capable of creating an audio and visual recording of the complete notarial act and such recording was made and retained as a notarial record in accordance with sections 26b(7) to 26b(9) of the Michigan Law on Notarial Acts, MCL 55.286b(7) to 55.286b(9).

3. The individual seeking my services and any required witnesses, if not personally known to me, presented satisfactory evidence of identity (e.g., a valid state-issued photo identification) to me during the video conference; they did not merely transmit that proof prior to or after the transaction, to satisfy the requirements of the Michigan Law on Notarial Acts, MCL 55.261 et seq., and any other applicable law.

4. The signatory affirmatively represented either that the signatory was physically situated in the State of Michigan, or that the signatory was physically located outside of Michigan's geographic boundaries and that either: (a) The document is intended for filing with or relates to a matter before a court, governmental entity, public official, or other entity subject to the jurisdiction of this state; or (b) The document involves property located in the territorial jurisdiction of this state or a transaction substantially connected to this state.

5. If the signatory was physically located outside of Michigan's geographic boundaries, I do not have actual knowledge that the signatory's act of making the statement or signing the document was prohibited by the laws of the jurisdiction in which she or he was physically located.

6. The signatory, any required witnesses, and I have affixed our signatures to the document in a manner that renders any subsequent change or modification of the remote online notarial act to be tamper-evident.

7. The signatory or the signatory's designee transmitted by fax, mail, or electronic means a legible copy of the entire signed document directly to me on the same date it was signed.

8. Upon receiving a legible copy of the document with all necessary signatures, I notarized the document and transmitted it back to the signatory.

9. I have certified the official date and time of the notarization as of the date and time when I witnessed the signatory's signature via two-way real-time audiovisual technology as required under the Public Act.

My full notarial certification is below; the foregoing representations are incorporated into that certification.

Candace Black

Candace Black

Timothy W. Bodnar, MD acknowledged this document before me on March 17, 2021. At the time of the acknowledgment, this person was located in Washtenaw County, Michigan, and I was located in Ingham County, Michigan. This document was notarized under Public Act 336; my representations regarding the circumstances of this notarial act are detailed in the preceding page of this document and are incorporated by reference into this certification.

Candace Black

Candace Black, Notary Public,
State of Michigan, County of Ingham
My commission expires 12/16/2021
Notary located in Ingham County, Michigan
Person making acknowledgment located in Washtenaw County, Michigan

EXHIBIT G

Affidavit of Kassandra Lutz

AFFIDAVIT OF KASSANDRA LUTZ

Kassandra Lutz, being first duly sworn, deposes and says as follows:

1. I am a Department Technician in the Michigan Department of Attorney General's Consumer Protection Division. I have worked in this capacity for approximately four years.

2. As a Department Technician, my job duties include assisting the attorney staff in gathering information and data related to companies or industries that are the targets of civil investigations.

3. In August 2019, I was asked to assist in gathering information regarding the cost of insulin prescriptions filled at pharmacies located in the United States and Canada.

4. Specifically, I was instructed to contact various pharmacies and inquire about the price of insulin for an uninsured individual.

5. The pharmacies that I contacted were pre-selected as targets due to their proximity to the United States/Canadian border.

6. When I contacted each pharmacy, I generally adhered to the following script to obtain the necessary pricing information:

> Hello, I am calling to ask you about your insulin prices for someone without any prescription coverage. I am interested in Humalog and Basaglar. How much does 5-pack of Humalog U100 KwikPens cost? How much does a 10 mL vial of Humalog U100 cost? Do you carry the generic Humalog? How much would a 5-pack of Insulin Lispro (generic) KwikPens cost? How much would a 10 mL vial of Insulin Lispro (generic) cost? How much does a 5-pack of Basaglar Kwik Pens cost? Thank you. Goodbye.

7. The pricing information that I obtained from the pharmacies in August 2019 is documented in the below chart:

Insulin Cost Comparison

Pharmacy Information & Locatin					Cost:					
Pharmacy Name	Phone	City/State	Nation	How to Cross	Humalog U100 (5-pack of KwikPens)	Humalog U100 (10 mL vial)	Humalog Mix 50 KwikPens	Insulin Lispro (5-pack of KwikPens)	Insulin Lispro (10 mL vial)	Basaglar (5-pack of KwikPens)
Famacity Pharmacy *	313-789-8934	Detroit, MI	US	Ambassador Bridge	$600 00	$300.00	Humulin Mix 70/30 $240 00	Does Not Carry	Does Not Carry	$305 00
Sandwich I D.A. Pharmacy	519-254-8247	Windsor, ON	Canada	Ambassador Bridge	CAD 91 20	Does Not Carry	CAD 90 23	Does Not Carry	Does Not Carry	CAD 103 05
Rite Aid	313-567-3523	Port Huron, MI	US	Bluewater Bridge	$594.00 or $124.94/ea	$307 09	Does Not Carry	$294 34	$108.29	$306 34
The Medicine Shoppe Samia	519-250-1600	Samia, ON	Canada	Bluewater Bridge	CAD 90 00	CAD 49 99	CAD 90 00	Does Not Carry	Does Not Carry	CAD 100 00
CVS Pharmacy	810-987-3603	Detroit, MI	US	Detroit Windsor Tunnel	$626 99	$323.99	Does Not Carry	Does Not Carry	Does Not Carry	$388 99
Downtown Windsor Pharmacy *	519-337-1119	Windsor ON	Canada	Detroit Windsor Tunnel	CAD 100 00	CAD 50.00	CAD 100 00	Does Not Carry	Does Not Carry	CAD 120 00
Sault Community Pharmacy * *	906-632-2122	Sault Ste. Marie, MI	US	Sault Ste Marie Int'l Bridge	$500 00	$295 00	Does Not Carry	$250 00	$150 00	$350.00
Merret's Pharmacy *	705-945-8405	Sault Ste. Marie, ON	Canada	Sault Ste Marie Int'l Bridge	CAD 90 00	CAD 50.00	CAD 90.00	Does Not Carry	Does Not Carry	CAD 95 00
	* Pharmacist stated these were only approximate pricing									
	* * Pharmacy Tech stated prices were approximate and included a "club member discount"									

8. Over a year later, in February 2021, I was asked to conduct the same survey, so I contacted the same pre-selected pharmacies and utilized the same script. The pricing information that I obtained from the pharmacies in February 2021 is outlined in the below chart:

Insulin Cost Comparison

Pharmacy Information & Location					Cost:					
Pharmacy Name	Phone	City/State	Nation	How to Cross	Humalog U100 (5-pack of KwikPens)	Humalog U100 (10 mL vial)	Humalog Mix 50 KwikPens	Insulin Lispro (5-pack of KwikPens)	Insulin Lispro (10 mL vial)	Basaglar (5-pack of KwikPens)
Famacity Pharmacy *	313-789-8934	Detroit, MI	US	Ambassador Bridge	$550.00	$400.00	Humulin Mix 70/30 $300 00	$300 00	$350.00	$400.00
Sandwich I.D.A. Pharmacy *	519-254-8247	Windsor, ON	Canada	Ambassador Bridge	CAD 93.00	Does Not Carry	Could Not Find	Does Not Carry	Does Not Carry	CAD 107 00
Rite Aid	810-987-3603	Pine Grove Ave Port Huron, MI	US	Bluewater Bridge	$700 00 or $146 99/ea	$329 64	Humulin Mix 75/25 $700 00	No Price for 5-pack about $63.65/ea	$164.82	$430.99 or $89.99/ea
The Medicine Shoppe Samia	519-337-1119	Samia ON	Canada	Bluewater Bridge	CAD 90.00	CAD 49 99	CAD 85.00	Does Not Carry	Does Not Carry	CAD 100.00
CVS Pharmacy	313-667-3523	Renaissance Center Dr. Detroit, MI	US	Detroit Windsor Tunnel	$632.99	$323.99	Does Not Carry	$315 99	$162.99	$388.99
Downtown Windsor Pharmacy	519-256-1600	Windsor ON	Canada	Detroit Windsor Tunnel	CAD 84.71	CAD 49 36	CAD 84.34	Does Not Carry	Does Not Carry	CAD 90.76
Sault Community Pharmacy * *	906-632-2122	Sault Ste. Marie, MI	US	Sault Ste Marie Int'l Bridge	$535.00	$290 00	Does Not Carry	$370 00	$130.00	$345 00 - $350.00
Merrot's Pharmacy *	705-945-8405	Sault Ste. Marie ON	Canada	Sault Ste Marie Int'l Bridge	CAD 90 00	CAD 00 30	Does Not Carry	Does Not Carry	Does Not Carry	CAD 95 00
	* Pharmacist stated these were only approximate pricing									
	* * Pharmacy Tech stated prices were approximate and included a "my prescriptions saving club discount"									

9. I have personal knowledge of the facts stated in this affidavit and I am competent to testify about them if called upon to do so.

FURTHER, AFFIANT SAYETH NOT.

Kassandra Lutz

Kassandra Lutz

Subscribed and sworn to before me on this
the 7th day of April, 2021.

Sarah J. Lutz

Notary Public, Clinton County, Michigan
My Commission Expires: 11/24/2021
[Acting in the County of Eaton]

[Tracer line]

EXHIBIT H

Rowland, *Senators Accuse Insulin Manufacturer of 'Broken Promise'*, The Washington Post (Dec 31, 2019)

Record: 1

Title: Senators accuse insulin manufacturer of 'broken promise'

Authors: Christopher Rowland

Source: Washington Post, The. 12/31/2019.

Document Type: Article

Abstract: Each year brings a fresh episode of popular and political outrage overhigh drug prices. In 2019, it was insulin's turn in the spotlight. The lifesaving drug for diabetics surged in list price more than 250-percent over a recent 10-year span " despite being a century-old invention. The three largest manufacturers, one American and two European, were accused of excessively pricing their drugs. The media featured stories of patients rationing their insulin, sometimes with fatal results. [ABSTRACT FROM PUBLISHER]

Accession Number: wapo.6c440b44-204e-11ea-86f3-3b5019d451db

Database: Newspaper Source Plus

Each year brings a fresh episode of popular and political outrage overhigh drug prices. In 2019, it was insulin's turn in the spotlight.

The lifesaving drug for diabetics surged in list price more than 250-percent over a recent 10-year span " despite being a century-old invention. The three largest manufacturers, one American and two European, were accused of excessively pricing their drugs. The media featured stories of patients rationing their insulin, sometimes with fatal results.

Eli Lilly, the U.S. manufacturer of Humalog brand insulin, sought to douse political anger with a pledge in March to distribute an 'authorized generic' that would cost 50-percent less than Humalog's $300 price per vial.

Although an authorized generic may carry a lower price tag, it doesn't pose the same level of aggressive market competition as a real generic drug. By the end of the year, Senate Democratssaid the benefit to consumers appeared minimal and accused Eli Lilly of a 'broken promise.'

Sens. Elizabeth Warren (D-Mass.) and Richard Blumenthal (D-Conn.) commissioned a spotcheckof nearly 400 pharmacies by their staffs. They found Eli Lilly's authorized generic, called Lispro, available in only 17-percent of pharmacies contacted across the country.

'Its authorized generic, rather than expanding access to low-cost insulin, appears instead to be a public relations move intended to ease scrutiny on the rising price of insulin,' the senators' survey concluded.

The scathing report was an indication that high insulin prices will remain a flash point in the debate over prescription drugs in 2020.

Anger over high insulin prices is bipartisan. Sen. Charles E. Grassley (R-Iowa), chairman of the Senate Finance Committee, opened an investigation into insulin price increases and has denounced high costs in speeches and opinion columns.

The Trump administration's approach has been mixed. The Food and Drug Administration says it is tweaking rules to encourage true generic competition,but it is unclear when those efforts will bear fruit.

Trump administration regulationsproposed last month to allow imports of certain cheaper prescriptions from Canada excluded insulin and other complex biologic drugs. Insulin in Canada costs one-tenth the list price in the United States.

The administration supported a maneuver in last month's budget deal that it said will improve the odds of generic-insulin development, but some advocates say it could have the opposite effect.

Brand-name manufacturers contend they are responding with meaningful steps to lower costs. In a TV interview, Eli Lilly's chief executive called Warren and Blumenthal's conclusions 'nonsense.' The company published full-page newspaper ads Dec.-19 intended to increase awareness about the availability of Lispro, free insulin for people struggling to pay and insurance co-payment discounts.

'We've heard too many stories about people with diabetes who struggle to afford their insulin. That needs to change,' the company's chief executive, Dave Ricks, wrote in an open letter to consumers.

The ads had a phone number for its Diabetes Solution Center, which Eli Lilly says can deliver Lispro to an individual pharmacy in one to two days.

The company said the timing of the open letter was not linked to the Senate findings about the availability of lower-cost Lispro in pharmacies. It said it is anticipating the January 2020 reset of deductibles in Medicare Part D and private insurance plans, which could expose patients to big costs at pharmacy counters until their coverage kicks in.

Lispro was used by 67,000 Americans in November, the company said, up from 50,000 in October. Even with that increase, it is a tiny sliver of the market.

About 7.4-million Americans with diabetes use some form of insulin, according to the American Diabetes Association.

Novo Nordisk, headquartered in Denmark, said in September that it will introduce its authorized generic insulin in January. Eli Lilly, Novo Nordisk and a third large insulin maker, Sanofi, based in France, each have discount programs for patients, with out-of-pocket caps of less than $100 a month and free drugs for low-income people.

But authorized generics and discount programs are just Band-Aids applied to the real problem, which is a lack of meaningful generic competition that could cut prices 30 to 40-percent, said Dana P. Goldman, director of the Leonard D. Schaeffer Center for Health Policy and Economics at the University of Southern California.

The absence of low-cost alternatives is especially upsetting to policymakers, he said, because insulin has been around since 1922. Making generic copies of insulin and winning FDA approval is more difficult because it is a biologic drug, not a pill.

'The situation with insulin, no one was paying attention, and all of a sudden we have a crisis,' Goldman said.

He did not point a finger exclusively at Eli Lilly, Novo Nordisk and Sanofi but said blame rests throughout the health-care system " including doctors, researchers and insurance companies.

Under the current system, pharmacy benefit managers, which control drug coverage, prefer brand drugs with high list prices, because they get big discounts " in the form of cash rebates " from manufacturers, Goldman added. They have no financial incentive to push an authorized generic drug into the marketplace, he said.

'We need some transparency in this marketplace, and insulin would be the best place to start,' he said. 'The blame is not just on the manufacturers.'

Goldman said that he has Type 1 diabetes and that his insurance pays for Humalog.

His co-pay is $750 for a 90-day supply, he said.

Mike Mason, Eli Lilly's senior vice president for insulin products, said in an interview that the company's automatic discount co-pay programs for people with insurance should limit those co-payments to $95 per month. (He said Goldman should call Eli Lilly's consumer hotline.)

Mason said insurance companies do not prioritize access to lower-cost Lispro because the rebates they receive from drug manufacturers such as Lilly for more expensive brand-name drugs are used to lower insurance premiums overall for all of their covered customers.

'As long as payers prioritize lower premiums, then solutions like Lispro won't be fully utilized. It's that calculus that payers are making,' he said. 'It's health-care design. Do I want a lower premium for the general population, or do I want lower co-pays for chronic diseases? There's no villains in this, but it's how the system has evolved.'

Mason's boss, Ricks, was more blunt in a CNBC interview after Warren and Blumenthal issued their pharmacy survey results about the low availability of Lispro.

'Some pharmacies have chosen not to carry it,' Ricks said. 'Why? Because this exposes the underlying economics in our system . . . which is that the middlemen, both in the supply chain as well as [pharmacy benefit managers] and insurance companies, prefer high-list-priced products with a lot of rebate. This has a lower list price and less rebate.'

The drug companies say net price payments they receive under insurance contracts have risen little, or even declined, as the list prices have shot up. The trouble for consumers with no insurance or high prescription deductibles is that they pay a percentage of list price. Sanofi, for instance, reported that net prices it has received for insulin declined 25-percent from 2012 to 2018, even as its list prices rose 126-percent.

CVS Caremark, the pharmacy benefit manager affiliated with CVS pharmacies and health insurer Aetna under the CVS Health corporate umbrella, said it favors Novo Nordisk's branded insulins, NovoLog and NovoLog Mix, over the authorized generic Lispro, because those branded products are more economical.

'They are exclusively positioned on our standard template formularies because they offer the lowest net prices for insulin products " significantly lower than Lispro,' Thomas Moriarty, chief policy and external affairs officer for CVS Health, said in a statement.

Walgreens, meanwhile, said it has 'taken steps to help ensure that Lispro is available at our pharmacies. Those locations that do not routinely stock this product can order it upon patient or prescriber request.'

Rite Aid said it was not aware of any supply issues with Lispro.

'Rite Aid pharmacists dispense medications based on prescriptions written by physicians,' the company said. The chain's pharmacists use authorized generics 'if allowed by the prescriber, insurance formulary (if applicable), and state regulations.'

The Pharmaceutical Care Management Association, the trade and lobbying association representing pharmacy benefit managers such as Express Scripts, CVS Caremark and Optum, said drug manufacturers are responsible for prices.

'Drug manufacturers alone set and raise prices completely unrelated to the rebates they negotiate with pharmacy benefit managers,' the association said.

Express Scripts, one of the largest pharmacy benefit managers, said it has a program starting in January that will set a $25-cap on monthly out-of-pocket insulin expenses for consumers covered by its plans.

christopher.rowland@washpost.com

Source: Washington Post, The, 12/31/2019
Item: wapo.6c440b44-204e-11ea-86f3-3b5019d451db

EXHIBIT I

Proposed Order Authorizing Issuance of Subpoenas

STATE OF MICHIGAN
IN THE 30TH JUDICIAL CIRCUIT COURT FOR INGHAM COUNTY

DANA NESSEL, ATTORNEY GENERAL OF THE STATE OF MICHIGAN, *ex rel* The People of the State of Michigan,

Petitioner,

v

ELI LILLY AND COMPANY,

Respondent.

No. 22- -CP

HON.

Darrin F. Fowler (P53464)
Michael S. Hill (P73084)
Assistant Attorneys General
Michigan Dep't of Attorney General
Corporate Oversight Division
P.O. Box 30736
Lansing, MI 48909
(517) 335-7632
FowlerD1@michigan.gov
HillM19@michigan.gov

ORDER AUTHORIZING ISSUANCE OF CIVIL INVESTIGATIVE SUBPOENAS

At a session of said Court, held on
_____, 2022, in the City of Lansing, Michigan.
Present: HON. _____

The Attorney General has presented this Court with a Petition for Civil Investigative Subpoenas related to an investigation of Respondent Eli Lilly and Company. Through the Petition, the Attorney General alleges that there is probable cause to believe Respondent has violated the Michigan Consumer Protection Act (the Act), MCL 445.901 *et seq*.

Having had an opportunity to review these materials, this Court finds that probable cause exists to believe Respondent has violated the Act.

THEREFORE, IT IS ORDERED that the Attorney General, acting through her assistants, is authorized to issue investigative subpoenas for both documentation and testimony, to Respondent, its parents, affiliates, and subsidiaries as may be identified during the course of this investigation

IT IS FURTHER ORDERED that the Attorney General, acting through her assistants, is authorized to issue additional subpoenas seeking testimony and documentation from persons and entities that are identified during the course of this investigation including, but not limited to Express Scripts Inc, its parents, affiliates, and subsidiaries as may be identified during the course of this investigation.

IT IS SO ORDERED.

_____

Hon. _____

Circuit Court Judge

EXHIBIT J

USB Thumb Drive containing video of Testimony before House Energy and Commerce Oversight and Investigations Subcommittee

Encryption Code: MiAg525!

Full video available at:
https://energycommerce.house.gov/committee-activity/hearings/hearing-on-priced-out-of-a-lifesaving-drug-getting-answers-on-the-rising
(accessed Jan 21, 2022)

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HON.

Darrin F. Fowler (P53464)
Michael S. Hill (P73084)
Assistant Attorneys General
Michigan Dep't of Attorney General
Corporate Oversight Division
P.O. Box 30736
Lansing, MI 48909
(517) 335-7632
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IT IS SO ORDERED.

_____

Hon. _____

Circuit Court Judge