

STATE OF MICHIGAN JUDICIAL DISTRICT JUDICIAL CIRCUIT COUNTY PROBATE	SUMMONS	CASE NO. 22- 50 -CZ
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Court address 313 W. Kalamazoo St., Lansing, MI 48933	JUDGE WANDA M. STOKES	Court telephone no. (517) 483-6500
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Plaintiff's name(s), address(es), and telephone no(s).
 DANA NESSEL, Attorney General of the State of Michigan
 ex rel The People of the State of Michigan

Defendant's name(s), address(es), and telephone no(s).
 ELI LILLY AND COMPANY
 c/o National Registered Agents, Inc.
 40600 Ann Arbor Rd., E., Ste. 201
 Plymouth, MI 48170

v

Plaintiff's attorney, bar no., address, and telephone no.
 Darrin F. Fowler (P53464)
 Michigan Department of Attorney General
 Corporate Oversight Division
 P.O. Box 30736
 Lansing, MI 48909 | (517) 335-7632

Instructions: Check the items below that apply to you and provide any required information. Submit this form to the court clerk along with your complaint and, if necessary, a case inventory addendum (form MC 21). The summons section will be completed by the court clerk.

Domestic Relations Case

- There are no pending or resolved cases within the jurisdiction of the family division of the circuit court involving the family or family members of the person(s) who are the subject of the complaint.
- There is one or more pending or resolved cases within the jurisdiction of the family division of the circuit court involving the family or family members of the person(s) who are the subject of the complaint. I have separately filed a completed confidential case inventory (form MC 21) listing those cases.
- It is unknown if there are pending or resolved cases within the jurisdiction of the family division of the circuit court involving the family or family members of the person(s) who are the subject of the complaint.

Civil Case

- This is a business case in which all or part of the action includes a business or commercial dispute under MCL 600.8035.
- MDHHS and a contracted health plan may have a right to recover expenses in this case. I certify that notice and a copy of the complaint will be provided to MDHHS and (if applicable) the contracted health plan in accordance with MCL 400.106(4).
- There is no other pending or resolved civil action arising out of the same transaction or occurrence as alleged in the complaint.
- A civil action between these parties or other parties arising out of the transaction or occurrence alleged in the complaint has

been previously filed in this court, _____ Court, where

it was given case number 22-9-P2 and assigned to Judge Draganchuk.

The action remains is no longer pending.

Summons section completed by court clerk.

SUMMONS

NOTICE TO THE DEFENDANT: In the name of the people of the State of Michigan you are notified:

1. You are being sued.
2. **YOU HAVE 21 DAYS** after receiving this summons and a copy of the complaint to **file a written answer with the court** and serve a copy on the other party **or take other lawful action with the court** (28 days if you were served by mail or you were served outside this state).
3. If you do not answer or take other action within the time allowed, judgment may be entered against you for the relief demanded in the complaint.
4. If you require special accommodations to use the court because of a disability or if you require a foreign language interpreter to help you fully participate in court proceedings, please contact the court immediately to make arrangements.

Issue date JAN 25 2022	Expiration date* APR 26 2022	Court clerk MAKAILA BOLLEY
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*This summons is invalid unless served on or before its expiration date. This document must be sealed by the seal of the court.

PROOF OF SERVICE

SUMMONS
Case No. 22-58 -CZ

TO PROCESS SERVER: You are to serve the summons and complaint not later than 91 days from the date of filing or the date of expiration on the order for second summons. You must make and file your return with the court clerk. If you are unable to complete service you must return this original and all copies to the court clerk.

JUDGE WANDA M. STOKES

CERTIFICATE / AFFIDAVIT OF SERVICE / NONSERVICE

<input type="checkbox"/> OFFICER CERTIFICATE I certify that I am a sheriff, deputy sheriff, bailiff, appointed court officer, or attorney for a party (MCR 2.104[A][2]), and that: (notarization not required)	OR	<input type="checkbox"/> AFFIDAVIT OF PROCESS SERVER Being first duly sworn, I state that I am a legally competent adult, and I am not a party or an officer of a corporate party (MCR 2.103[A]), and that: (notarization required)
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- I served personally a copy of the summons and complaint,
- I served by registered or certified mail (copy of return receipt attached) a copy of the summons and complaint,

together with _____
List all documents served with the summons and complaint

_____ on the defendant(s):

Defendant's name	Complete address(es) of service	Day, date, time

- I have personally attempted to serve the summons and complaint, together with any attachments, on the following defendant(s) and have been unable to complete service.

Defendant's name	Complete address(es) of service	Day, date, time

I declare under the penalties of perjury that this proof of service has been examined by me and that its contents are true to the best of my information, knowledge, and belief.

Service fee	Miles traveled	Fee	
\$		\$	
Incorrect address fee	Miles traveled	Fee	TOTAL FEE
\$		\$	\$

Signature

Name (type or print)

Title

Subscribed and sworn to before me on _____, _____ County, Michigan.
Date

My commission expires: _____ Date Signature: _____
Deputy court clerk/Notary public

Notary public, State of Michigan, County of _____

ACKNOWLEDGMENT OF SERVICE

I acknowledge that I have received service of the summons and complaint, together with _____
Attachments

_____ on _____
Day, date, time

_____ on behalf of _____
Signature

JAN 25 2022

BY: _____
Deputy Clerk

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,

Plaintiff,

v

ELI LILLY AND COMPANY,

Defendant.

No. 22- 58 -CZ

HON. JUDGE WANDA M. STOKES

COMPLAINT FOR
DECLARATORY JUDGMENT

Darrin F. Fowler (P53464)
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COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff, Dana Nessel, Attorney General of The State of Michigan, *ex rel* the
People of the State of Michigan, through Assistant Attorneys General Darrin F.
Fowler and Michael S. Hill, states the following for her Complaint for Declaratory
Judgment:

A. Parties, Jurisdiction, and Venue

1. Plaintiff Dana Nessel is the Attorney General of the State of Michigan.

This suit is brought by the Attorney General in her official capacity.

2. Defendant Eli Lilly and Company (Eli Lilly) is a corporation organized and existing under the laws of the State of Indiana and has a principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

3. Eli Lilly sells insulin and other diabetic medications, transacts business in the State of Michigan, and has a Michigan registered agent: National Registered Agents, Inc., 40600 Ann Arbor Rd, Suite 201, Plymouth, MI 48170.

4. Through this lawsuit, the Attorney General seeks a declaratory judgment pursuant to MCR 2.605. This Court has jurisdiction to provide such relief.

5. The circumstances giving rise to this Complaint have arisen in Ingham County, making this Court an appropriate venue for this Complaint.

6. Venue is also appropriate in Ingham County Michigan under MCL 14.102 which permits any action brought by the Attorney General in the name of the People of the State of Michigan, to be brought “in the circuit court in and for the county of Ingham.”

B. Background

7. The Centers for Disease Control (CDC) estimates that there are 34.2 million Americans with diabetes.¹ In Michigan, the American Diabetes Association

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.

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.

8. 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.⁴ These practices have caused serious disability and even death in some patients.⁵

9. Eli Lilly is one of the three primary manufacturers of insulin medications in the United States. Among the brands of analog insulin medications it manufactures are Basaglar (long-lasting) and Humalog (rapid-acting). Beginning in 2019, Eli Lilly also began distributing some of its Humalog products under the name Lispro. Lispro is an authorized generic for Humalog.

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 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).

⁵ *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).

10. Upon information and belief, at least tens of thousands of Michigan consumers use Eli Lilly medications distributed under the Basaglar, Humalog and Lispro labels.

11. The Attorney General is authorized to bring actions against persons who are engaging in unfair trade practices under the Michigan Consumer Protection Act, MCL 445.901 et seq. In furtherance of this responsibility, the Attorney General may conduct investigations under section 7 of the MCPA. Such investigations are commenced by making application to a circuit court. The circuit court may authorize such an investigation “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.” MCL 445.907.

12. Contemporaneous with the filing of this Complaint, the Attorney General is filing with this Court an application for authority to commence an investigation in the manner anticipated by MCL 445.907, except that the Attorney General is waiving the opportunity for an *ex parte* hearing on such application. This application, which is entitled “Attorney General’s Petition for Civil Investigative Subpoenas,” (Petition) is attached as **Exhibit A** to this Complaint. ⁶

13. As detailed in the Petition, under the plain language of the MCPA, an investigation of Eli Lilly is warranted because there is probable cause to believe it

⁶ The attachment to this Complaint will not include the attachments to the Petition. This Court may take judicial notice of them as they are included in the corresponding court file.

has engaged—and continues to engage—in unfair trade practices related to its sales in Michigan of the insulin medications Humalog, Lispro, and Basaglar.

14. Specifically, with regard to all three medications, the Attorney General presents probable cause to believe Eli Lilly has charged prices grossly in excess of the price at which similar medications have been, and are being, sold. See MCL 445.903(1)(z). And, with respect to Lispro, the Attorney General presents probable cause to believe Eli Lilly’s representations about the reasons for offering this medication at a discounted price are misleading. See MCL 445.903(1)(i).

15. Within the MCPA, there are two express exceptions to its application. One of these says the MCPA does not apply to “A 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).

16. The prices Eli Lilly charges for Humalog, Lispro, and Basaglar are determined by Eli Lilly. So, too, are the representations Eli Lilly makes about the reasons for the pricing and discounts it offers in connection with the sale of these medications. The prices Eli Lilly charges for these medications, and the representations it makes about such charges, are not specifically authorized under laws administered by a regulatory board or officer acting under statutory authority of this state or the United States.

17. Through the Federal agency known as the Food and Drug Administration (FDA), the United States has sought to ensure the safety of medications sold in this country. Eli Lilly’s manufacturing and distribution of

Humalog, Lispro, and Basaglar has thus been done following the approvals anticipated by 21 USC 355.

18. There is nothing within the FDA’s authority under this statute or the related universe of Federal regulations giving the FDA any authority to regulate Eli Lilly’s pricing of Humalog, Lispro, and Basaglar. Nor do the Federal statutes and regulations administered by the FDA give it any authority to regulate the representations Eli Lilly makes about these prices and any discounts it offers on them.

19. Indeed, the FDA expressly disclaims any such authority over drug prices. 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.”⁷ It further tells consumers to “consider contacting the Federal Trade Commission[,]” which “enforces a variety of federal antitrust and consumer protection laws.”⁸

20. Thus, under the plain language of MCL 445.904, Eli Lilly cannot claim an exception to the MCPA’s application to its pricing practices as detailed in the Petition based on the FDA’s regulation of Basaglar, Humalog, and Lispro.

21. Similarly, as the State of Michigan is also concerned about the safe manufacturing and distribution of medications throughout this State, it licenses entities for such activities through the Michigan Board of Pharmacy. Eli Lilly holds

⁷ 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).

⁸ *Id.*

a manufacturer's license issued by the Michigan Board of Pharmacy, and four licenses for the wholesale distribution of its medications in Michigan. These licenses are issued under the Public Health Code, MCL 333.17701 et seq. There is nothing within the Board of Pharmacy's authority under this statute or the related universe of State administrative rules giving the Board of Pharmacy any authority to regulate Eli Lilly's pricing of Humalog, Lispro, and Basaglar. Nor do the statutes and rules administered by the Board of Pharmacy give it any authority to regulate the representations Eli Lilly makes about these prices and any discounts it offers on them.

22. Thus, under the plain language of MCL 445.904, Eli Lilly cannot claim an exception to the MCPA's application to its pricing practices as detailed in the Petition based on the Michigan Board of Pharmacy's regulation of the safe manufacture and distribution of its medications.

23. There are two Michigan Supreme Court opinions that give the exception in MCL 445.904(1)(a) a construction inconsistent with its plain language. See *Smith v Globe Life Ins Co*, 460 Mich 446 (1999) and *Liss v Lewiston-Richards, Inc*, 478 Mich 203 (2007). These cases were wrongly decided. Nevertheless, upon information and belief, Eli Lilly may attempt to rely upon them to assert the MCPA does not apply to the pricing activities described in the Petition because of the regulation done by the FDA and Michigan Board of Pharmacy.

24. Upon information and belief, an actual controversy exists between the Attorney General and Eli Lilly as to whether the MCPA applies to the conduct

described in the Petition. Rather than have this Court authorize the issuance of subpoenas *ex parte* only to have Eli Lilly then raise this issue through a motion to quash, the Attorney General seeks to resolve this controversy at the inception of this investigation. Similarly, it would be a waste of resources for the Attorney General to proceed with this investigation, only to have Eli Lilly raise the *Smith* and *Liss* opinions as a defense in a lawsuit under the MCPA, should the evidence gathered under subpoena substantiate the concerns raised in the Petition.

COUNT I- DECLARATORY JUDGMENT

25. The Attorney General incorporates by reference the other paragraphs of this complaint.

26. Under MCR 2.605 in a case of actual controversy within its jurisdiction, this Court may declare the rights and other legal relations of an interested party seeking a declaratory judgment, whether or not other relief is or could be sought or granted.

27. There is an actual controversy within this Court's jurisdiction regarding whether the MCPA exception in MCL 445.904(1)(a) applies to Eli Lilly's conduct alleged in the Petition.

28. The Attorney General seeks a declaratory judgment that the MCPA applies to the conduct she seeks to explore in the Petition, and that the exception in MCL 445.904(1)(a) does not apply in this context.

CONCLUSION AND RELIEF REQUESTED

Accordingly, the Attorney General respectfully requests that this Court issue a declaratory judgment pursuant to MCR 2.605 that the MCPA applies to the conduct described in the Petition included as **Exhibit A**, and that this investigation and any resultant lawsuit on such pricing activities on analog insulin medications are not foreclosed by the exception included in MCL 445.904(1)(a).

Respectfully submitted,



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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*

EXHIBIT A

Attorney General's Petition for Civil Investigative 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.

**ATTORNEY GENERAL'S
PETITION FOR CIVIL
INVESTIGATIVE
SUBPOENAS**

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**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

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.

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 Lilly 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

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

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

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

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

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

³³See **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

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

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.

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.

* * *

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

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

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

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

[diabetes-are-being-hit-so-hard-by-covid-19/](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); 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.)]

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

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

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): \$530.40⁷²;
- b. Humalog U100 (10 mL vial): \$274.70⁷³;
- c. Humalog Mix 50/50 KwikPens: \$563.00⁷⁴;
- d. Insulin Lispro (5-pack of KwikPens): \$159.12⁷⁵;

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

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

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

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 a 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

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

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/wp-content/uploads/2015/06/Biosimilars-The-Need-The-Challenge-The-Future-The-FDA-Perspective -Epstein-et-al.pdf](http://www.epsteinassociatesllc.com/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,



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