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STATE OF MICHIGAN
IN THE SUPREME COURT

DANA NESSEL, ATTORNEY GENERAL OF THE STATE OF MICHIGAN, *ex rel* The People of the State of Michigan,	Supreme Court No. 165961
Plaintiff-Appellant,	Court of Appeals No. 362272
v	Ingham Circuit Court No. 2022-000058-CZ
ELI LILLY AND COMPANY,	
Defendant-Appellee.	

PLAINTIFF-APPELLANT'S APPENDIX

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TABLE OF CONTENTS

Description	Page No.
Petition for Civil Investigative Subpoenas	3-35
Complaint for Declaratory Judgment	36-44
Order Authorizing Issuance of Civil Investigative Subpoenas	45-46
Plaintiff's Motion for Summary Disposition	47-73
BIO to AG's Cross-Motion for Summary Disposition	74-94
Reply in Support of Motion for Summary Disposition	95-112
Order on Cross Motions for Summary Disposition	113-117
Transcript of Motion for Summary Disposition Hearing	118-143
Attorney General v Eli Lilly and Co, unpublished per curiam opinion of the Court of Appeals, issued June 22, 2023 (Docket No. 362272)	144-146
Woodger v Taylor Chevrolet, Inc, unpublished opinion of the United States District Court for the Eastern District of Michigan, issued August 25, 2015 (Case No. 14-cv-11810), pp 6-7	147-153
Respondent Eli Lilly and Company's Motion to Stay	154-166
Stipulation Regarding the Issuance of Subpoenas to Eli Lilly Regarding Insulin Pricing	167-170
Respondent Eli Lilly and Company's Motion to Stay	171-195
April 19, 2022 Stipulation to Hold Subpoenas in Abeyance	196-199

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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

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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.

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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*.

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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).

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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

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> 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.*

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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.*

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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*.

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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.*

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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).

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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).

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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.

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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).

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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.

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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).

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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).

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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

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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-

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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".

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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.

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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).

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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.

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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.*

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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:

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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:

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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).

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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*.

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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".

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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.

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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".

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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).

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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.*

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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).

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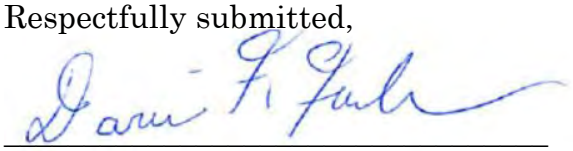
will issue subpoenas for records from Eli Lilly to shed light on its business practices, including reasons for the disparity in pricing for its products in Michigan versus Ontario, Canada; reasons for the disparity in pricing between Humalog and Lispro in Michigan; and an examination of the reasons underlying 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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Dated: January 25, 2022

Rec'd - 30th CIRCUIT COURT
JAN 25 2022
BY: _____ Deputy Clerk

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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

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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.

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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.

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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.

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[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).

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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.

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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

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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

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[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.*

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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

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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.

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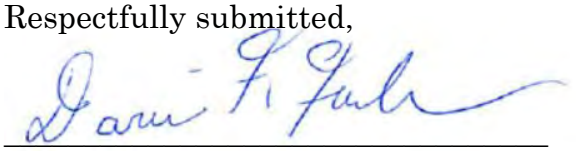
CONCLUSION AND RELIEF REQUESTED

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

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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 -CP P2

HON. JOYCE DRAGANCHUK

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DEPT OF ATTORNEY GENERAL
JAN 28 2022
CORPORATE OVERSIGHT DIVISION

ORDER AUTHORIZING ISSUANCE OF CIVIL INVESTIGATIVE SUBPOENAS

At a session of said Court, held on January 26, 2022, in the City of Lansing, Michigan.
Present: HON. Joyce Draganchuk
James S. Jamo, fac

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.*

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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.

James L. James P36650
for Hon. Joyce Draganchuk
Circuit Court Judge P-39417

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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. 2022-000058-CZ

HON. WANDA M. STOKES

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ATTORNEY GENERAL'S CONSOLIDATED CROSS-MOTION FOR SUMMARY DISPOSITION AND BRIEF IN SUPPORT (AND IN RESPONSE TO DEFENDANT'S SUMMARY DISPOSITION MOTION)

Plaintiff, Attorney General Dana Nessel, *ex rel* The People of the State of Michigan, through her attorneys Assistant Attorneys General Darrin F. Fowler, Michael S. Hill, and Carl Hammaker, for the reasons stated in the below brief in support, respectfully moves this Court for summary disposition pursuant to MCR 2.116(I)(1) and 2.116(C)((9). Defendant, Eli Lilly and Company (Lilly) has brought a summary disposition motion pursuant to MCR 2.116(C)(8) that makes clear it has no valid defense against the Attorney General's claim for declaratory

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judgment; thus judgment in the Attorney General's favor under MCR 2.116(I)(2) is also appropriate. Accordingly, the Attorney General respectfully asks that this Court enter a declaratory judgment that MCL 445.904(1)(a) does not prohibit the Attorney General's authority under MCL 445.907 to investigate Eli Lilly's pricing of its insulin medications.

INTRODUCTION

The question underlying this lawsuit is whether the Michigan Consumer Protection Act (MCPA) should still fulfill the promise inherent in its name, protecting Michigan's citizens against unfair, deceptive, and/or unconscionable conduct. Its plain language compels the conclusion it can. And for more than two decades after its 1977 enactment, that's exactly what it did. But in 1999, the Michigan Supreme Court ignored the MCPA's plain language and issued the first of two decisions transforming a law with a punch into a mere punchline. The decisions perpetrating this cruel hoax are *Smith v Globe Life Ins Co*, 460 Mich 446 (1999) and *Liss v Lewiston-Richards, Inc*, 478 Mich 203 (2007).

Now, the Attorney General seeks to commence an investigation into the pricing of a prescription medication used to treat a disease affecting nearly a million Michiganders. Lilly tells this Court that the *Smith* and *Liss* decisions bar this investigation. Strikingly, Lilly's argument is based on the text of these opinions and not that of the MCPA itself. Lilly had to take this approach because the MCPA's text simply does not lend itself to the conclusions the *Smith* and *Liss* Courts ascribe to it.

The consequential nature of the question at hand cannot be understated. If Lilly's position is correct, then the MCPA can never be used to protect consumers from deceptive or unconscionable misconduct by the manufacturer or seller of any prescription medication. Never. No matter how egregious the deceit, nor exploitive the price. Nor can the MCPA be used to

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guard against unfair practices by regulated persons and companies involved in providing a wide range of other goods and services Michiganders purchase regularly. And this is true even if the controlling regulations do not speak to the misconduct or are devoid of any remedy for consumers. The *Smith* and *Liss* decisions have unjustifiably transformed a narrowly stated exception within the MCPA into a broad shield potentially available whenever a State or Federal regulatory scheme relating to the underlying transaction can be identified—regardless of whether that regulatory scheme does anything to protect consumers from deceptions, gouging, unfairness, or other improprieties.

Fortunately, our judicial system embraces the view that errors can be corrected. An improper construction does not change the plain meaning of statutes, and the concept of stare decisis does not demand autonomic allegiance to recognizable mistakes.

STATEMENT OF FACTS

A. Procedural Background

This declaratory judgment action has been brought to confirm the Attorney General's authority to conduct an investigation into Lilly's sale of insulin medications under the MCPA. (Comp ¶¶ 24, 28.) On the same day this suit was filed, the Attorney General filed a Petition for Civil Investigative Subpoenas (Petition) with this Court. The Petition was given case number 22-09-PZ and assigned to the Honorable Joyce Draganchuk. That Petition is included as Attachment A to the Complaint and is a public court filing of which this Court may take judicial notice. MRE 201(b). For this Court's convenience, a complete copy of the Petition that includes the exhibits filed with it is being included as an exhibit accompanying this motion.

As acknowledged in the Petition's introduction the *Smith*, *supra*, and *Liss*, *supra*, decisions present an apparent barrier to the proposed investigation. (Appx Item 1, Petition.) The

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lawsuit is therefore aimed at clearing this barrier, with the understanding that will require action by the Michigan Supreme Court. (Comp ¶ 24.) In the meantime, Lilly has brought a motion for summary disposition for dismissal of the Complaint based on the effect of the *Smith* and *Liss* decisions.

B. Diabetes, insulin, and the pricing problem.

The proposed investigation relates to an insulin pricing problem that has gotten widespread attention in recent years and which affects many consumers. According to the Centers for Disease Control, over 34 million Americans have diabetes and face its devastating consequences.[1] In Michigan, approximately 912,794 people have diabetes and over 2,701,000 are confronting prediabetes.[2]

Diabetes is a disease that affects how the body processes glucose (sugar).[3] Glucose—which is a vital source of energy for the body—is processed by the hormone insulin, which is secreted by the pancreas.[4] 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.[5] Insulin, as a treatment for diabetes, was discovered in 1921 when Toronto Surgeon

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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 April 29, 2022), p 2.

[2] American Diabetes Association, The Burden of Diabetes in Michigan, Oct 2021, <https://diabetes.org/sites/default/files/2021-11/ADV_2021_State_Fact_sheets_Michigan_rev.pdf> (accessed April 29, 2022). The complaint cited the 2020 statistics.

[3] Mayo Clinic, *Diabetes* < https://www.mayoclinic.org/diseases-conditions/diabetes/symptoms-causes/syc-20371444> (accessed April 29, 2022).

[4] *Id.*

[5] *Id.*

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Frederick Banting and his assistant, Charles Best, discovered how to remove insulin from a dog's pancreas.[6] Banting and Best patented their process to extract insulin and prepared it for human injection in 1923, later selling it to the University of Toronto for just $1 with the understanding that affordable insulin would become widely available.[7] The Governors of the University of Toronto entered into an agreement with Lilly for the exclusive production of insulin.[8] The exclusivity ended in 1923 and other pharmaceutical companies were invited to apply for licenses to manufacture insulin.[9]

Lilly is now one of three pharmaceutical companies making up nearly the entire U.S. insulin market.[10] The insulin medications it manufactures include Basaglar, Humalog, and its authorized generic Lispro; which are insulin "analogs" that more closely replicate normal insulin patterns in the body and, due to their convenience, resulted in a great number of patients using these analogs.[11] Indeed, in many cases, analog insulin is a superior treatment to human insulins. (Appx Item 2, Dr. Bodnar Affidavit.)

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[6] American Diabetes Association, *The History of a Wonderful Thing We Call Insulin* <https://www.diabetes.org/blog/history-wonderful-thing-we-call-insulin> (accessed April 26, 2022).

[7] 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 Apr 26, 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 Apr 26, 2022).

[8] *Discovery of Insulin at University of Toronto*, University of Toronto Libraries < https://heritage.utoronto.ca/exhibits/insulin> (accessed, Apr 26, 2022).

[9] *Id.*

[10] *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, June 2018, <https://care.diabetesjournals.org/content/41/6/1299> (accessed April 26, 2022).

[11] See note 7, *supra*.

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Unfortunately, cost is a significant barrier for patients to access these critical medications and, over the past two decades, the prices for analog insulin products in the United States have skyrocketed. According to a study from the RAND Corporation, Insulin prices are more than eight times higher in the United States than in 32 high-income comparison nations combined.[12] The average manufacturer price per standard unit across all 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.[13]

The skyrocketing prices have garnered the attention of Federal lawmakers. In 2019, following its investigation of over 100,000 documents provided by the three major insulin manufacturers, the United States Senate Finance Committee issued a written report detailing the insulin pricing problem and factors contributing to it. While noting the role pharmacy benefit managers (PBMs) have played, the Committee concluded "pharmaceutical manufacturers have complete control over setting the list price (the Wholesale Acquisition cost)(WAC)) for their products."[14]

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[12] 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 April 26, 2022).

[13] *Id*.

[14] 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 April 26, 2022), p 5.

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Thus, the prices Lilly charges for Humalog, Lispro, and Basaglar are determined by Lilly. So, too, are the representations Lilly makes about the reasons for the pricing and discounts it offers in connection with the sale of these medications. (Comp ¶ 16.)

C. Lilly's Insulin prices affect Michigan consumers

Tens of thousands of Michigan consumers use the Lilly medications that are the subject of the proposed investigation. (Comp ¶ 10.) As of the Petition filing date, the list prices for these medications in the United States were as follows:

a. Humalog U100 (5-pack of KwikPens): $530.40_;[15]

b. Humalog U100 (10 mL vial): $274.70_;[16]

c. Humalog Mix 50/50 KwikPens: $568.00_;[17]

d. Insulin Lispro (5-pack of KwikPens): $159.12_;[18]

e. Insulin Lispro (10 mL vial): $82.41_;[19]

f. Basaglar (5-pack of KwikPens): $326.36_.[20]

In August 2019, the Attorney General conducted a telephone survey comparing the price of Eli Lilly products Humalog and Basaglar offered at pharmacies, located within just a few

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[15] *How much should I expect to pay for HumalogU-100?* Eli Lilly USA, LLC <https://www.lillypricinginfo.com/humalog> (accessed April 26, 2022).

[16] *Id.*

[17] *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 April 26, 2022).

[18] *How much should I expect to pay for a Lilly Non-Branded Insulin*? Lilly USA, LLC, <https://www.lillypricinginfo.com/insulin-lispro> (accessed April 26, 2022).

[19] *Id.*

[20] *How much should I expect to pay for Basaglar*?, Lilly USA, LLC, <https://www.lillypricinginfo.com/basaglar> (accessed April 26, 2022).

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miles of each other, at four different border crossing points between Michigan and the Canadian province of Ontario. (Appx Item 3, Lutz Affidavit.) The price differentials were significant. For example, Humalog was 855% more expensive to buy in Michigan 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. The informal survey of Canadian pharmacies showed the following prices:

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.*) The Attorney General repeated the survey in February 2021, and found Michiganders continued to be charged grossly excessive prices compared to Canadian consumers.

The cost differentials have a significant impact on the health of Michigan consumers. As the Senate Finance Committee observed in its report, some consumers ration their insulin medications because they cannot afford them.[21] A Michigan doctor supplying an affidavit in support of the Petition has observed his patients engaged in such rationing based on cost concerns. (Appx Item 2, ¶ 7.) And these high prices have caused some Michiganders to go

[21] See note 14, pp 14 and 15.

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across the border to Canada so they can purchase the same medications at far less cost. (Id. at ¶ 8.)

D. The proposed investigation

Through the Petition, the Attorney General asserts there is probable cause to believe Lilly has engaged—and continues to engage—in unfair trade practices related to its sales in Michigan of the insulin medications Humalog, Lispro, and Basaglar. (Comp ¶¶ 13-14.) Specifically, regarding 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. (Comp ¶ 14.) See MCL 445.903(1)(i). This latter assertion is supported by the information contained in paragraphs 43-50 of the Petition, and includes an observation in a bi-partisan report by United States Senators Elizabeth Warren and Blumenthal that (referring to Lilly's Lispro) " [i]ts 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."[22]

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[22] 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 April 26, 2022).

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STANDARD OF REVIEW

Lilly moved for summary disposition pursuant to MCR 2.116(C)(8). Motions brought pursuant to MCR 2.116(C)(8) "test the legal sufficiency of the complaint." *Maiden v Rozwood*, 461 Mich 109, 119 (1999). In its review under MCR 2.116(C)(8), the court should consider only the pleadings. See MCR 2.116(G)(5).[23] While the court generally accepts as true the factual allegations of the complaint, it is not required to give credence to conclusory allegations. *Rozwood,* 461 Mich at 119–120. Because a motion under MCR 2.116(C)(8) is based on the pleadings, discovery is not a consideration when a court determines whether to grant the motion. *Id*.

The Attorney General brings her cross motion for summary disposition under MCR 2.116(I)(1) and 2.116(C)(9). The former authorizes prompt resolution of cases when a question of law is controlling, and the latter tests the sufficiency of a defendant's pleadings. *Village of Dimondale v Grable*, 240 Mich. App. 553, 564; 618 N.W.2d 23 (2000). Summary disposition under MCR 2.116(C)(9) is proper if the defenses are so clearly untenable as a matter of law that no factual development could possibly deny a plaintiff's right to recovery. *Id.*

This Court has authority to enter a declaratory judgment under MCR 2.605(A) which provides "in a case of actual controversy within its jurisdiction, a Michigan court of record 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." "[W]henever a litigant meets the

[23] This Court can take judicial notice of publicly available materials cited in the Attorney General's Complaint regarding the increasing costs of, and decreasing accessibility to, insulin medications. See MRE 201(b). See also e.g. *Grisham v Romero*, 2021-NMSC-009, ¶ 34, 483 P3d 545, 559 (NM 2021) where the court took judicial notice of the health risks, transmission, and the government's response thereto.

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requirements of MCR 2.605, it is sufficient to establish standing to seek a declaratory judgment." *Lansing Sch Educ Assoc v Lansing Bd of Educ*, 487 Mich 349, 372 (2010).

ARGUMENT

A. The Attorney General's investigation of Lilly is appropriate under the MCPA's plain language.

In this lawsuit seeking to confirm her authority to use the MCPA to pursue pharmaceutical manufacturers that charge grossly excessive prices, the Attorney General contends *Smith* and *Liss* are wrongly decided. That Lilly has based its summary disposition motion on those decisions is neither surprising nor improper. But neither is its analysis availing on the ultimate question the Attorney General has openly vowed to pursue.

Lilly is correct that this Court is bound by *Smith* and *Liss*. (Def Mot p 7-8.) While this means the outcome at this stage of these proceedings is a foregone conclusion (absent intervening action by the Legislature or Michigan Supreme Court), there is nothing compelling this Court's silence in the face of a manifest injustice flowing from an erroneous legal analysis. To illustrate how *Smith* and *Liss* work such an injustice in the present context, the Attorney General here elaborates how the plain language of the MCPA should be applied to this controversy through a lens not made opaque by the varnish of the *Smith* and *Liss* analysis.

The Attorney General thus begins by doing what the *Smith* and *Liss* Courts failed to do: by acknowledging the applicable rules of statutory interpretation and applying them to the facts presented in the controversy at bar.

The primary goal of statutory interpretation is to give effect to the intent of the Legislature. *Briggs Tax Serv, LLC v Detroit Pub Sch*, 485 Mich 69, 76 (2010). The most reliable evidence of legislative intent is the plain language of the statute. *S. Dearborn Envtl Improvement Ass'n, Inc. v Dept of Envtl Quality*, 502 Mich. 349, 360-361 (2018). If the

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language of the statute is clear and unambiguous, it is presumed that the Legislature intended the meaning plainly expressed in the statute. *Gardner v Dep't of Treasury*, 498 Mich 1, 6 (2015). The court's interpretation of a statute must give effect to every word, phrase, and clause. *South Dearborn*, 502 Mich at 361. Further, an interpretation that would render any part of the statute surplusage or nugatory must be avoided. *Id*.

The Michigan Supreme Court recognizes that statutory language should be given a reasonable construction considering "its placement and purpose in the statutory scheme." *People* v *Morey*, 461 Mich 325, 330 (1999) citing *Bailey v United States*, 516 US 137, 145 (1995). And when interpreting remedial statutes courts should "liberally construe[ ]" them "to suppress the evil and advance the remedy." *Eide v Kelsey-Hayes Co*, 431 Mich 26, 35 (1988). The MCPA was enacted to prohibit unfair or deceptive practices in trade or commerce, and to "provide an enlarged remedy for consumers who are mulcted by deceptive business practices [. . .]" *Dix v American Bankers Life Assur Co of Florida*, 429 Mich 410, 417 (1987). It should be liberally construed to achieve that purpose. *Id.* at 418. It is axiomatic that fulfillment of this directive requires any exceptions to the MCPA's application to be narrowly construed.

The Act makes unlawful any "unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce." MCL 445.903(1). The term "trade or commerce" as used in the Act is broadly defined in section 2 as encompassing "the conduct of a business providing goods, property, or service primarily for personal, family, or household purposes. . ." MCL 445.902(1)(g). That Lilly is engaging in trade or commerce when it distributes the insulin medications implicated in this investigation is beyond dispute—for Michiganders, there is no purpose more personal than obtaining that which is needed to preserve one's survival and good health. Keeping in mind the interpretative obligation to apply the MCPA broadly to maximize

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the protection of consumers, a preliminary conclusion that the provision of pharmaceuticals falls within the sweep of MCPA section 2 is appropriate.

The question then becomes whether Lilly may be using "unfair, unconscionable, or deceptive methods, acts, or practices" while engaging in its business of selling insulin medications. MCL 445.903(1). Through the Petition, the Attorney General has presented probable cause to believe that it is. Further investigation into these practices in the manner anticipated by MCPA section 7 is thus appropriate unless Lilly's protestation about the applicability of the exception in MCPA section 4 is correct. In this regard, it is significant that Eli Lilly frames its argument not on the text of the MCPA, but upon the decisions in *Smith*, *Liss*, and their progeny. Resort to the latter was necessary because no help can be found in the former.

Lilly's essential premise is that the Michigan Board of Pharmacy licensure, and general FDA regulation of its manufacturing and sale of insulin medications, operate to invoke the exception under MCPA subsection 4(1)(a). Despite the requirement to read statutes as a whole and give meaning to all words and phrases, Lilly does not analyze the role of subsection 4(2) on its premise. Had it done so, the incorrectness of its position would have become apparent. But it did not need to do so because it could point to the *Smith* and *Liss* decisions—which also fail to account for the impact of subsection 4(2) on their holdings. Lilly's premise should thus be tested against MCL 445.904(1) and (2), read as a contiguous whole, which provide:

> (1) This act does not apply to either of the following:
>
> > (a) 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.
> >
> > (b) An act done by the publisher, owner, agent, or employee of a newspaper, periodical, directory, radio or television station, or other communications medium in the publication or dissemination of an advertisement unless the publisher, owner, agent, or employee knows or, under the circumstances, reasonably should know of the false, misleading,

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> or deceptive character of the advertisement or has a direct financial interest in the sale or distribution of the advertised goods, property, or service.
>
> (2) Except for the purposes of an action filed by a person under section 11, this act does not apply to or create a cause of action for an unfair, unconscionable, or deceptive method, act, or practice that is made unlawful by any of the following:
>
> (a) The banking code of 1999, 1999 PA 276, MCL 487.11101 to 487.15105.
>
> (b) 1939 PA 3, MCL 460.1 to 460.11.
>
> (c) The motor carrier act, 1933 PA 254, MCL 475.1 to 479.43.
>
> (d) The savings bank act, 1996 PA 354, MCL 487.3101 to 487.3804.
>
> (e) The credit union act, 2003 PA 215, MCL 490.101 to 490.601

Subsection 4(1) indicates that conduct or transactions specifically authorized by State or Federal laws are excepted from the MCPA's coverage. Subsection 4(2) excepts from the MCPA's scope conduct that is made unlawful in a short list of enumerated enactments relating to some regulated entities, including banks and credit unions. But by preserving private enforcement actions under MCPA section 11 within MCPA subsection 4(2), the Legislature makes clear its intention to allow actions against such regulated entities by persons other than the Attorney General (whose enforcement authority is found in MCPA sections 5 and 10). Thus, Lilly's assertion that the fact a business is generally regulated by some State or Federal agency means it is exempt from the MCPA under subsection 4(1) is unsustainable when subsection 4(2) is considered. Subsection 4(2) makes clear that the existence of other regulatory schemes is not the same as saying "conduct or transactions specifically authorized" by laws administered by State or Federal agencies. Were it otherwise, subsection 4(2) would (at best) be surplusage, and would be (at worst) in apparent conflict with subsection 4(1) to the extent it purports to allow actions under MCPA section 11 against entities already excepted under subsection 4(1) because they engage in

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general conduct or transactions that are regulated by other agencies. So, finding a harmonious construction to these subsections that gives meaning to the terms of both compels a construction different than that Eli Lilly advances here. In other words, Lilly's argument relies on the *Smith* and *Liss* Courts' pronouncements about the meaning of MCPA subsection 4(1) because an examination of MCPA section 4 as a whole reveals the incorrectness of the premise it advances.

The reverse implication of the plain text of subsection 4(2) is that the Attorney General may bring actions against entities regulated under other statutes except as enumerated in that subsection, subject to the limitation in subsection 4(1).

The role of subsection 4(1) then can be understood with reference to *American Home Products Corp v Johnson & Johnson*, 672 F Supp 135 (SD NY 1987). That case involved protracted litigation between what the district judge referred to as two titans in the pharmaceutical world—the manufacturer of Anacin (American Home Products) and the makers of Tylenol (Johnson & Johnson and McNeil Labs). *Id*. at 136. The latter had brought a counter-complaint against the former alleging that the Anacin labels prior to 1986 were deficient because the dangers of Reye Syndrome were not adequately addressed, and that the label from 1986 forward was improper since it included the FDA-approved warning, but also described the medication as safe. *Id*. The Court rejected these claims, observing that American Home Products had complied with the FDA labeling requirements—a process that included FDA review of the labeling: "when the FDA inspected the Anacin package which carried the mandatory 1986 warning, as well as the phrase "Safe, Fast Pain Relief," the FDA report stated that AHP was in full compliance." *Id*. at 141. Thus, in asking the Court to apply New York's law against deceptive practices against American Home Products, McNeil was doing so despite the FDA's specific approval of the challenged label.

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The Court observed that the Federal Trade Commission had already made clear that the FTC Act would not be applied against the conduct authorized by the FDA as it recognized the FDA "has primary jurisdiction over all matters related to the labeling of OTC drugs." *Id*. at 144 citing 36 Fed Reg 18,539 (1971). The Court then went on to elaborate how consumer protection laws throughout the country (including Michigan's) contain similar exceptions:

> The Uniform Deceptive Trade Practices Act, which has been adopted by thirteen states, contains a comparable provision in section 4(a):
>
> > This Act does not apply to (1) conduct in compliance with the orders or rules of, or a statute administered by, a federal, state, or local governmental agency.
>
> At least six other states which have adopted neither of the two uniform codes have enacted consumer protection statutes containing exemptions similar to those provided in the model code.
>
> The rationale underlying the exemptive provisions of all of these statutes is the need for uniformity in the regulation of advertising and labeling and a deference to the expertise of the responsible regulatory agency. [*American Home Products*, 672 F Supp at 144].

Thus, the *American Home Products* court recognized that a pharmaceutical company whose conduct is specifically authorized by the FDA, should not proceed at the peril of liability under State consumer protection and deceptive practices laws. Were the Attorney General here advancing allegations about Lilly's labelling of Basaglar, Humalog, or Lispro, then considerations of the role of MCPA subsection 4(1) would be appropriate. But that is not the case presented here.

B. Lilly's pricing practices were not specifically authorized under laws administered by any State or Federal agency

In this case, the Attorney General's ability to use investigatory tools and enforce the MCPA against potential violators is at stake because of the potential applicability of the MCPA section 4 exception, that is phrased narrowly by the Legislature, but given broad application by

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the Michigan Supreme Court. Before they can be sold in interstate commerce, insulin medications, like Humalog, Basaglar, and Lispro must be approved by the FDA. See 21 USC 355. Although the FDA has authority to approve or prohibit the sale of any medication in interstate commerce, it has no such authority with respect to the medication's pricing. Nowhere in the Food, Drug, and Cosmetic Act, and its associated regulations, does the FDA have authority to regulate the price a manufacturer charges for a medication. In fact, the FDA expressly disclaims any such authority on its website, where it states it "has no legal authority to investigate or control the prices set by manufacturers, distributors, and retailers."[24]

Lilly's contention that the rebate provisions in federal law, 42 USC § 1396r-8(a)(1) and § 1395w-3a(c)(3), constitute regulation of drug prices is misleading due to the omission of context. (Def Mot, p 11.) Lilly cites statutes that relate to the government acting in the role of an insurer through its Medicare and Medicaid programs, not to the regulation of drug pricing generally. These rebates only apply to drugs purchased by the Medicaid and Medicare programs, not to the broader market. And rather than being regulations that authorize prices, they are instead provisions speaking to rebates Lilly must make for the Medicare and Medicaid programs on whatever list price it has elected to charge upon the broader market. Thus Lilly's assertion helps illustrate the adverse consequences apparently endorsed by *Smith*: a general regulation potentially affecting the pricing of Lilly's insulin medications to persons served through the Medicare and Medicaid programs is being used to assert the MCPA is entirely inapplicable to the potentially unfair pricing and misrepresentations affecting all Michigan consumers (including

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[24] 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).

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those not served by either program). Lilly is thus asserting the *Smith* shield even though the rebate provisions it points to do not specifically authorize the prices they charge for anyone.

Further, drug pricing is not regulated under Michigan law. Eli Lilly holds manufacturer and wholesale distributor licenses under the Public Health Code, MCL 333.17701 *et seq.* The code establishes the Michigan Board of Pharmacy, which has the authority to regulate, control, and inspect standard pharmacy practice and drugs and devices manufactured, distributed, prescribed, dispensed, administered, or issued in this state. MCL 333.17722. The authority, however, does not extend to the pricing of drugs such as insulin.

Because Michigan and Federal law do not regulate drug pricing, MCPA section 4 should not apply to Lilly because the price it charges for its analog insulin medications is not "specifically authorized" by law. See MCL 445.904(1)(a).

C. This plain language construction of the MCPA subsection 4(1) exception was adopted by the Michigan Supreme Court long before *Smith* and *Liss*.

This is consistent with how the Michigan Supreme Court originally interpreted the MCPA subsection 4(1) exception in *Attorney General v Diamond Mortgage Co*, 414 Mich 603 (1982). In *Diamond Mortgage*, the Attorney General brought an MCPA action against a mortgage company and its officers alleging defendants misrepresented the loan interest rate and fee structures advertised and then offered to homeowners. 414 Mich at 607. The circuit court applied subsection 4(1) and dismissed the action on the grounds that the officers, as licensed real estate brokers, are "under the auspices of the Michigan Department of Licensing and Regulation, as authorized by the Michigan real estate brokers licensing act." *Id.* at 616. On appeal, the defendants argued for a broad application of the exception stating that the circuit court's ruling was correct because its real estate brokers license authorized it to negotiate the "mortgage of real estate" under MCL 451.202. The Attorney General, however, argued for a narrow application of

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the exception and that holding a license to engage in an activity is not a basis for concluding deceptive conduct is "specifically authorized". *Id*. The Court found Attorney General Frank Kelly's statement so compelling that he was quoted in the opinion for the following:

> If every person or business which engages in an activity authorized by some statute or regulation were exempt from the Michigan Consumer Protection Act, pursuant to § 4(1), *then the Michigan Consumer Protection Act, would be a cruel hoax on the many legislators * * * and others who sought to give Michigan consumers protection in the marketplace*. A consumer could sue an unlicensed optician for deception, but not a licensed optometrist. A consumer could sue a grocery store, but not a licensed car dealer or auto repair facility. A licensed hearing-aid dealer would be exempt from suit, but not the corner baker. [*Id.*] [Emphasis added.]

The Michigan Supreme Court ultimately agreed with the Attorney General and reversed the circuit court specifically holding "[w]hile defendants are correct in stating that no statute or regulatory agency specifically authorizes misrepresentations or false promises, the exemption will nevertheless apply where a party seeks to attach such labels 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". *Id*. For this case, we need only decide that a real estate broker's license is not specific authority for all the conduct and transactions of the licensee's business. *Id*. In other words, the holding of a specific license overseen by a regulatory authority, does not automatically exempt all of the licensee's business conduct and transactions from the MCPA. The Court's narrow application comports with subsection 4(1)(a)'s plain language and also comports with the Court's prior precedent that the remedial provisions of the MCPA be "construed liberally to broaden the consumers' remedy." *Dix v Am Bankers Life Assur Co of Florida*, 429 Mich 410, 417 (1987).

Under the *Diamond Mortgage* Court's interpretation of MCPA subsection 4(1), Lilly would not be exempt from potential MCPA liability regarding its pricing of Basaglar, Humalog, and Lispro. The FDA's approval of these medications means they meet the regulatory criteria

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and standards to be sold and safely prescribed to patients by providers, but it does not specifically authorize the price Lilly charges for these medications or any representations made regarding the pricing of authorized generic medications. Similarly, the Michigan Board of Pharmacy's licensure of Lilly is aimed at assuring safe practices, but not at affecting the prices. This is because the Michigan Board of Pharmacy and FDA do not regulate and cannot, "specifically authorize" Eli Lilly's mechanisms, methods, or formulas for determining its list prices for its insulin medications. As alleged in the Complaint, it was Lilly that set these prices.

D. *Smith* and *Liss* enter the scene and depart from the MCPA's plain language.

Seventeen years after Diamond Mortgage, the Michigan Supreme Court clouded its clear narrow application of the MCPA subsection 4(1) exception. In *Smith,* the Michigan Supreme Court held the section 4 exception barred MCPA claims against a life insurance company accused of misrepresenting benefits, terms, and conditions of its life insurance policy. 460 Mich at 468. Similar to *Diamond Mortgage*, the defendant argued the exemption applied because the immediate transaction, the sale of life insurance, was "specifically authorized" when the State Commissioner of Insurance implicitly approved defendants' application and certificate of insurance forms. *Smith*, 461 Mich at 462. The Court specifically stated in applying the subsection 4(a) exception to Globe Life Insurance Co.:

> [W]e conclude the relevant inquiry is not whether the specific misconduct alleged by the plaintiffs is "specifically authorized." Rather it is whether the general transaction is specifically authorized by law, regardless of whether the specific misconduct alleged is prohibited.
>
> Therefore, we conclude that § 4(1)(a) generally exempts the sale of credit life insurance from the provisions of the MCPA [. . .]. [*Id.* at 465.]

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Inexplicably, the Court broadened the exception's application in sharp contrast to the *Diamond Mortgage* Court's narrow application. The *Smith* Court, however, did not explicitly overrule *Diamond Mortgage*, but purported to distinguish it. As the Court stated:

> *Diamond* is distinguishable from the case at bar. The activities of the defendant in *Diamond* which the plaintiffs there were complaining of were not subject to any regulation under the real estate broker's license of the defendant and thus such conduct was not reviewable by the applicable licensing or regulatory authority. [*Id.* at 464-65.]

The Court's rationale for broadening the exemption's scope from *Diamond Mortgage* is that "[t]he insurance industry is under the authority of the State Commissioner of Insurance and subject to the extensive statutory and regulatory scheme all administered 'by a regulatory board or officer acting under statutory authority of this state.'" While the Court stated the *Diamond Mortgage* defendants' alleged conduct of misrepresenting the interest rate and fee structures of its mortgages was not subject to a specific regulation under defendants' real estate broker's license, the Court also did not identify any specific statute or regulation that addressed the *Smith* defendant's alleged improper conduct of misrepresenting the benefits, coverages, and exceptions in its life insurance policies.

Of course, the Court did not need to identify a specific regulation addressing such conduct because it held that if the general transaction is specifically authorized by law, then the legality of the specific conduct complained of is irrelevant. The confusion, however, is that the *Smith* Court's broadening of the exception would also cover the *Diamond Mortgage* defendants' alleged conduct since it argued that the general transaction of negotiating mortgages was specifically authorized by its real estate broker's license.[25]

[25] The *Diamond Mortgage* defendants cited MCL 451.202 as authorizing the negotiation of mortgages under its Real Estate License. That statute was subsequently repealed and replaced by the Michigan Occupational Code, 1980 PA 299. MCL 339.2501(u), however, defines a "Real

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The confusion surrounding MCPA subsection 4(1)'s applicability after *Smith* could have been partially reconciled by limiting the *Smith* Court's holding to MCPA claims against licensed insurance companies. However, in *Liss*, the Court again extended its broad application of the exception—this time to a residential builder licensed under the Michigan Occupational Code. 478 Mich at 206. In *Liss*, the plaintiff homeowners brought MCPA claims against the defendant builder alleging the construction of a residential home was not completed on time and not in a workmanlike manner. The Court again applied its *Smith* test and held the subsection 4(1) exemption applied to the builder because "[r]esidential home builders are licensed under the [Michigan Occupational Code] and are regulated by the Residential Builders' and Maintenance and Alteration Contractors' Board, which oversees licensing and handles complaints filed against residential builders." *Id.* at 213. In other words, since the defendant held a license and was subject to the Michigan Occupational Code and its associated regulations, the general transaction of constructing a residential home was "specifically authorized" by law, notwithstanding the legality of the defendant's alleged conduct.

In her dissent, Justice Kelly recognized the conflict between *Smith* and *Diamond Mortgage* regarding the application of MCPA subsection 4(1), arguing that *Smith* should be limited to the insurance industry, but also noting that subsection 4(1) as interpreted by *Smith* did not apply to defendant because the law did not specifically authorize residential home builders to engage in residential home building. *Id.* at 218-19. Justice Kelly succinctly summarized the conflict between the court's *Smith* and *Diamond Mortgage* decisions:

Estate Broker" as "an individual or business entity that, with intent to collect or receive a fee, compensation, or valuable consideration [. . .] that negotiates the mortgage of real estate [. . .]."

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> It is apparent to me that the decisions in *Diamond Mortgage* and *Smith* cannot be squared. *Diamond Mortgage* asked whether the transaction or conduct alleged to be in violation of the MCPA is "specifically authorized" by another statute, and it created a narrow exception. *Diamond Mortgage*, 414 Mich. at 617. *Smith* asked whether the general transactions of the industry are "specifically authorized," and it created a broad exemption exempting the entire insurance industry. *Smith*, 460 Mich. at 465. Because the two interpretations are inconsistent, this Court should determine which was intended by the Legislature. [*Liss*, 478 Mich at 220.]

Although fifteen years have now passed since *Liss,* the Michigan Supreme Court has still not reconciled these holdings. In this case, the conflict between *Smith*, *Liss*, and *Diamond Mortgage* is readily apparent, and ripe for further review as the applicability of the MCPA has dire consequences for Michigan diabetics. While the general transaction of selling insulin medications is generally authorized by Federal law when the FDA approves a medication under its authority under the Food, Drug, and Cosmetics Act; no state or Federal law "specifically authorizes" or regulates a drug manufacturer such as Eli Lilly regarding the pricing of any FDA approved medications. Under the Court's *Diamond Mortgage* interpretation, MCPA subsection 4(1) would not apply to Lilly's pricing of Basaglar, Humalog, and Lispro because the conduct associated with pricing these medications is not "specifically authorized" under Federal or Michigan law. A result that makes sense under the statute's plain language. On the other hand, under the *Smith* and *Liss* Court's broad application, subsection 4(1) applies to the pricing of insulin medications because the general transaction of selling insulin medications is "specifically authorized" by 21 USC 355, once Eli Lilly obtains FDA approval for each medication.

The Attorney General's proposed investigation of Lilly under the MCPA seeks additional information on how it set the pricing of its analog insulin medications. If the investigation uncovers evidence that Eli Lilly charged Michigan consumers grossly excessive prices for its analog insulin medications or made misrepresentations with respect to its pricing and marketing of Lispro; the MCPA is the only remedial tool available to consumers since pricing is not

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regulated by the FDA, or by the Michigan Board of Pharmacy under the Public Health Code. In this case, the stakes regarding the Attorney General's ability to use the MCPA's remedial tools for Michigan consumers have never been higher. As Dr. Bodnar noted:

> 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 these circumstances. This situation is fraught with irony. A patient may easily incur at $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. [Ex D, ¶ 9.]

While this court is bound to apply the *Smith* and *Liss* Court's broad interpretation of MCPA subsection 4(1), in doing so it can note the ways that the Michigan Supreme Court can ultimately bring clarity to the controversy regarding its application under *Smith*, *Liss,* and *Diamond Mortgage* and end the "cruel hoax" to Michigan's consumers the Attorney General warned of 40 years ago. The Attorney General submits that both *Smith* and *Liss* were wrongly decided and intends to seek further relief from the Michigan Supreme Court.

E. *Smith* and *Liss* foreclose all relief to consumers from unfair, deceptive, or unconscionable conduct when a regulatory scheme does not contain a consumer-protection enforcement mechanism.

Smith and *Liss* rendered the MCPA unavailable to most consumers affected by unfair, deceptive, or unconscionable conduct. Slamming the door on what was a very powerful remedial law has not gone unrecognized. As the National Consumer Law Center stated in its 2018 overview of state unfair and deceptive practices laws:

> In a few states, courts have interpreted a statutory exemption for "regulated industries" so broadly that the UDAP statute covers almost nothing. For example, Michigan had a relatively strong UDAP statute until it was gutted by a court decision that construed an exception for "a transaction or conduct specifically

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> authorized under" laws administered by a state or regulatory board to exclude entire industries whenever they are subject to any regulation or licensing.[26]

This transformation from punch to punchline has wide-ranging consequences beyond shielding the manufacturers and sellers of prescription medications from the MCPA's reach. *Smith* and *Liss* present a substantial problem in a myriad of contexts where an entity is subject to a regulatory scheme that does not contain a consumer-protection enforcement component. Because there is an applicable regulatory scheme, these entities are likely engaging in "general transactions" that are "specifically authorized," and therefore, under *Smith* and *Liss*, the entities would be exempt from the MCPA. And because the regulatory scheme contains no consumer-protection component, consumers that are harmed by "specific misconduct" that occurs during the "specifically authorized general transactions" are unable to seek redress.

An example of this circumstance exists in the context of the Michigan Public Service Commission (MPSC). The MPSC is charged with regulating telecommunication providers. MCL 484.2201. But under the Michigan Telecommunications Act, MCL 484.2101 *et seq*, the MPSC does not have regulatory authority over pricing and terms. Where a telecommunication provider makes a deceptive offer to a consumer, and the consumer does not receive what is offered or is charged a higher price than what was offered, the MPSC does not have authority to prevent or punish this type of behavior. And because telecommunication providers operate within the MPSC's regulatory scheme, under *Smith* and *Liss*, they are engaged in "general transactions" that are "specifically authorized," and are therefore exempt from the MCPA. As

[26] National Consumer Law Center, *Consumer Protection in the States, A 50-State Evaluation of Unfair and Deceptive Practices Laws*, Oct 2018, p 17, available at https://www.nclc.org/images/pdf/udap/udap-report.pdf (accessed Apr 29. 2022).

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such, consumers who are harmed when telecommunication providers make deceptive offers are left without sufficient legal recourse.

Smith and *Liss* also present a barrier to a consumer's ability to obtain relief in situations where an agency charged with enforcing the regulatory scheme is unwilling or unable to do so, and the regulatory scheme does not otherwise provide for a private cause of action or Attorney General enforcement. Like the circumstance described above, where a regulated entity is engaging in "general transactions" that are "specifically authorized" under the regulatory scheme, meaning it therefore would be exempted from the MCPA under *Smith* and *Liss*, the consumer is deprived of a remedy when the regulatory scheme is not enforced.

For instance, pet shops in Michigan are subject to Michigan Department of Agriculture and Rural Development (MDARD) regulation and licensing. MCL 287.333. Since 2009, however, MDARD has suspended the licensing of pet shops, (Appx Item 4, MDARD Regulation Overview, p 1), and the regulatory scheme does not provide a private cause of action. Still, because the regulatory scheme exists, a pet shop could claim that it is engaged in "general transactions" that are "specifically authorized" under the MDARD regulatory and licensing scheme, and therefore exempt from the MCPA. Consequently, the pet shop evades liability under both the regulatory scheme (through lack of enforcement) and under the MCPA (under *Smith* and *Liss*), and consumers are left helpless.

CONCLUSION

For the reasons stated above, Eli Lilly's motion for summary disposition should be denied, and judgment entered for the Attorney General under MCR 2.116(I)(2). And the Attorney General respectfully requests this Court grant her Motion for Summary Disposition, enter a judgment declaring that MCL 445.904(1)(a) does not prohibit the Attorney General's

authority under MCL 445.907 to investigate Eli Lilly's pricing of its insulin medications, and grant any other relief the Court deems appropriate under the circumstances.

Respectfully submitted,



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STATE OF MICHIGAN
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.

Case No. 2022-000058-CZ
Hon. WANDA M. STOKES

DEFENDANT ELI LILLY AND COMPANY'S OPPOSITION TO ATTORNEY GENERAL'S CONSOLIDATED CROSS-MOTION FOR SUMMARY DISPOSITION

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TABLE OF CONTENTS

I. INTRODUCTION 1

II. ARGUMENT 3

A. The Parties Agree that Lilly Is Entitled to Summary Disposition 3

B. An Advisory Opinion Criticizing *Smith* and *Liss* Would Be Inappropriate and Erroneous 4

1. The Attorney General Misunderstands Precedent 5

2. The Attorney General's Alternative View Conflicts with the MCPA's Plain Text, Context, and History 8

3. The Attorney General Continues to Rely on Inaccurate Factual Allegations 12

III. CONCLUSION 15

RECEIVED by MSC 5/30/2025 4:48:54 PM

TABLE OF AUTHORITIES

Page(s)

Cases

Att'y Gen. v. Diamond Mortg. Co.,
414 Mich. 603; 327 N.W.2d 805 (1982).....2

State ex rel. Gurganus v. CVS Caremark Corp.,
496 Mich. 45; 852 N.W.2d 103 (2014).....1, 4

Liss v. Lewiston-Richards, Inc.,
478 Mich. 203; 732 N.W.2d 514 (2007)..... *passim*

Loughrin v. U.S.,
573 U.S. 351 (2014).....9

Manhattan Props. v. Irving Trust Co.,
291 U.S. 320 (1934).....11

Monat v. State Farm Ins. Co.,
469 Mich. 679; 677 N.W.2d 843 (2004).....1, 4

NLRB v. Bell Aerospace Co. Div. of Textron, Inc.,
416 U.S. 267 (1974).....11

Smith v. Globe Life Ins. Co.,
460 Mich. 446; 597 N.W.2d 28 (1999)..... *passim*

State Treasurer v. Sprague,
284 Mich. App. 235; 772 N.W.2d 452 (2009).....1, 4

Statutes

42 U.S.C. §1395w-3a(c)(3).....14

42 U.S.C. §1396r-8(a)(1).....14

MCL 445.904..... *passim*

Pub. Act No. 10, H.B. 4204 (1993) 11

Pub. Act No. 432, H.B. No. 5332 (2000).....10, 11

Pub. Act No. 216, S.B. No. 493 (2003) 11

Pub. Act No. 251, H.B. No. 5558 (2014).....11, 12

RECEIVED by MSC 5/30/2025 4:48:54 PM

Other Authorities

Dep't of Att'y Gen., Press Release, *AG Nessel Launches Investigation into Excessive Insulin Prices, Intends to Challenge MSC Decisions Impacting Consumer Protection* (Jan. 26, 2022), https://bit.ly/3vcGEhx 12

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House Fiscal Agency, *A Summary of House Bill 5558 as Enacted* (July 2, 2014).....10

Lilly Insulin Value Program, https://www.insulinaffordability.com/.....13

News Release, *New $35 Co-Pay Now Available Through Lilly Insulin Value Program in Response to COVID-19 Crisis in U.S.* (Apr. 7, 2020), https://bit.ly/3wzer4Z.....13

RECEIVED by MSC 5/30/2025 4:48:54 PM

I. INTRODUCTION

There is no dispute that Lilly is entitled to summary disposition and to a declaration that the Attorney General's proposed investigation is ultra vires under settled law. Indeed, the parties agree that "this Court is bound by *Smith* and *Liss*";[1] that the MCPA does not apply "to the pricing of insulin medications"; and that the outcome of the pending motions is "a foregone conclusion." A.G. Br. at 11, 23. Even so, the Attorney General uses her brief to preview theories she eventually hopes to present to the Supreme Court—although the Legislature is the only correct venue for those arguments because the long-settled, binding precedent that resolves this case simply reflects the plain text of the MCPA. The Attorney General also requests an advisory opinion from this Court that would charge the Supreme Court (and, by extension, the Legislature) with committing what she calls a "manifest injustice" and perpetrating a "cruel hoax [on] Michigan's consumers." *Id.* at 11, 24 (quotations omitted).

That request is untenable. There are many familiar reasons why courts should not issue advisory opinions challenging established doctrine, including the Supreme Court's sole prerogative to overrule its own precedents, *State Treasurer v. Sprague*, 284 Mich. App. 235, 242; 772 N.W.2d 452 (2009), the wastefulness of rehashing matters that have been frequently decided, *Monat v. State Farm Ins. Co.*, 469 Mich. 679, 693; 677 N.W.2d 843 (2004), and the impropriety of opining on issues not necessary to decide a case, *State ex rel. Gurganus v. CVS Caremark Corp.*, 496 Mich. 45, 67; 852 N.W.2d 103 (2014). But that is not all. An advisory opinion in ***this*** litigation would be especially inapt because the Attorney General's request is premised on three independently dispositive errors.

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[1] *Smith v. Globe Life Ins. Co.*, 460 Mich. 446; 597 N.W.2d 28 (1999); *Liss v. Lewiston-Richards, Inc.*, 478 Mich. 203; 732 N.W.2d 514 (2007).

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First, the Attorney General inaccurately characterizes *Smith* and *Liss*, the very decisions with which she disagrees. Rather than squarely addressing those cases on their merits, the Attorney General suggests that the Supreme Court ignored the rules of statutory interpretation, overlooked nearby statutory provisions, departed from its earlier decision in *Diamond Mortgage*,[2] and rendered the MCPA a nullity for all regulated entities. But any fair reading of *Smith* and *Liss* dispenses with those claims, and therefore eliminates any reason for second-guessing the Supreme Court.

Second, the Attorney General's alternative interpretation of the MCPA violates bedrock rules of statutory construction by ignoring key textual provisions and substantial evidence that the Legislature agrees with the current state of the law. As to text, the Attorney General reads out crucial statutory language. According to the Attorney General, the exemption for an authorized "transaction or conduct" should apply ***just*** to authorized conduct, but that interpretation ignores half of what the Legislature said when it immunized "transaction[s]" as well. MCL 445.904(1)(a). The Attorney General never addresses that textual point. Instead, the Attorney General reasons that the existence of a ***different*** set of MCPA exemptions for certain types of unlawful activities somehow creates the "reverse implication" that she "may bring actions against entities regulated under other statutes." A.G. Br. at 13-15 (citing MCL 445.904(2)). But that mode of analysis only confirms that the Attorney General's view is irreconcilable with the Legislature's. Crucially, the Supreme Court itself once employed the same reasoning—using the other statutory exemptions to cut back on the broad exemption for "transaction[s]" in subsection 4(1), the provision at issue here—only for the Legislature to step in and abrogate that approach. And as the Legislature

[2] *Att'y Gen. v. Diamond Mortg. Co.*, 414 Mich. 603; 327 N.W.2d 805 (1982).

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repeatedly amended those ***other*** exemptions, it preserved the exact language of the transactional exemption that the Supreme Court had already interpreted in *Smith* and *Liss*.

Third, the Attorney General again unfairly characterizes Lilly's business practices. Her brief relies on irrelevant and outdated information. It also does not engage with the extensive public evidence—all of which Lilly has repeatedly raised—that Lilly's insulins are available and affordable to Michiganders regardless of insurance coverage, status, or design. Indeed, the Attorney General does not and cannot dispute that Lilly's insulins are available for $35 per month—regardless of the numbers of vials or pens—or that the average monthly out-of-pocket cost for Lilly's insulins is just $21.80.

At bottom, the advisory opinion the Attorney General seeks would require this Court to disregard the Supreme Court's reasoned analysis, dispense with the statutory text, and reject the Legislature's assurances that the current interpretation of the MCPA is correct. There is no reason to do any of that—and certainly not when settled law requires a straightforward judgment in Lilly's favor.

II. ARGUMENT

A. The Parties Agree that Lilly Is Entitled to Summary Disposition

The Attorney General's brief confirms that Lilly is entitled to summary disposition on the complaint's single count. The parties agree that Lilly's sales of insulin are exempt from the MCPA under *Smith* and *Liss*'s definitive holding "that the relevant inquiry 'is whether the general transaction is specifically authorized by law, regardless of whether the specific misconduct alleged is prohibited.'" *Liss*, 478 Mich. at 206 (quoting *Smith*, 460 Mich. at 465); *see* A.G. Br. at 11, 23. The parties also agree that only the Supreme Court can overrule those precedents. *See* A.G. Br. at 11.

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In light of this consensus, the path forward here is clear: Summary disposition in favor of Lilly and a declaration that the Attorney General's investigation is ultra vires.

B. An Advisory Opinion Criticizing *Smith* and *Liss* Would Be Inappropriate and Erroneous

Despite recognizing that inevitable result, the Attorney General asks the Court to look two steps ahead and issue an advisory opinion urging the Supreme Court to change the law. Under even the best of circumstances, such an opinion would be improper for any number of reasons: It would violate "the fundamental principle that only the Supreme Court has the authority to overrule one of its prior decisions"—let alone ***several*** prior decisions—a rule that applies even if a "lower court[] … believe[s] that [precedent] was wrongly decided or has become obsolete." *Sprague*, 284 Mich. App. at 242 (brackets and quotations omitted). It would transgress the settled understanding that the judiciary's "scarce resources" should not be used to revisit the "same issue" that has been "repeatedly adjudicat[ed]" over many decades. *Monat*, 469 Mich. at 693. And it would require the Court to needlessly "opine on matters unnecessary to the resolution of this case." *Gurganus*, 496 N.W.2d at 67 & n.48 (explaining that the Supreme Court has "question[ed] why, in a prior case, the Court had addressed arguments after analyzing a dispositive [threshold] issue").

This case, moreover, is a particularly poor candidate for an advisory opinion. Each justification the Attorney General offers for the highly unusual step of challenging the Supreme Court is not only flawed on its own terms, but in fact proves why this Court should stick with existing precedent. First, the Attorney General misunderstands that very precedent, and thus aims her arguments at strawman versions of *Smith* and *Liss*. Second, the Attorney General's alternative interpretation of the MCPA requires her to overlook the operative text and on-point statutory history. And third, the Attorney General continues to rely on unfair and inaccurate claims about

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Lilly's business practices. Any one of those flaws is reason enough to decline the Attorney General's invitation to do more than what the law allows.

1. The Attorney General Misunderstands Precedent

The Attorney General's fundamental premise for an advisory opinion is that *Smith* and *Liss* are indefensible "hoax[es]." A.G. Br. at 2. In her view, the Supreme Court erred at every turn in holding that subsection 4(1) of the MCPA—which exempts a "transaction or conduct specifically authorized under [federal or state] law[]"—looks to "whether the general transaction is specifically authorized by law, regardless of whether the specific misconduct alleged is prohibited." *Liss*, 478 Mich. at 205-06. The Supreme Court reached that conclusion, so the story goes, only by bypassing the rules of statutory interpretation, eliding other relevant textual provisions, discarding precedent, and rendering the MCPA meaningless for most businesses. Those characterizations, however, have no basis in what *Smith* and *Liss* actually said or did.

First, the Attorney General lacks any support for her recurring claim that "the *Smith* and *Liss* Courts failed to … acknowledg[e] the applicable rules of statutory interpretation and apply[] them to the facts presented." A.G. Br. at 11; *accord id.* at 2. In reality, *Liss* stressed at the outset the need "to give effect to the Legislature's intent by ***looking at the statutory text, giving meaning to every word, phrase, and clause in the statute and considering both their plain meaning and their context***." 478 Mich. at 207 (emphasis added). It then did just that, even employing dictionaries to define key statutory terms. *E.g.*, *id.* at 212-13 & nn.34 & 35. *Smith*, for its part, examined "[t]he language of [MCL 445.904]" and painstakingly juxtaposed two textual provisions—subsections 4(1) and 4(2)—in reaching its bottom-line holding that a private suit against an insurance company could proceed. 460 Mich. at 462, 465-67. That sort of deliberate analysis is incompatible with the accusation that the Supreme Court disregarded the text, context, and structure of the MCPA.

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Second, the Attorney General's assertion that *Smith* and *Liss* "fail[ed] to account for the impact of subsection 4(2) on their holdings" again cannot be reconciled with what precedent actually says. A.G. Br. at 13. *Smith* considered subsection 4(2)[3] at length, and indeed found this provision necessary to its decision that a private plaintiff's suit against the defendant insurer was proper: "***Giving effect to both §4(1) and §4(2)***, we conclude that private actions are permitted against an insurer pursuant to §11 of the MCPA." 460 Mich. at 467 (emphasis added). This express reasoning—to say nothing *Smith*'s ultimate conclusion—belies the Attorney General's claim that the Supreme Court has somehow overlooked subsection 4(2).

Third, and equally unfounded, is the suggestion that the Supreme Court failed to "reconcile[] the[] holdings" of *Smith* and *Liss* with its earlier decision in *Diamond Mortgage*. A.G. Br. at 23. The Supreme Court has repeatedly explained that these decisions are in accord, and indeed that "*Diamond Mortgage* ***control[led] the resolution*** of" the later cases. *Smith*, 460 Mich. at 463 (emphasis added); *accord Liss*, 478 Mich. at 209-10. For example, *Smith* quoted *Diamond Mortgage* at length, found that the earlier decision "instruct[ed] that the focus is on whether the transaction at issue, not the alleged misconduct, is specifically authorized," and noted that the challenged behavior in *Diamond Mortgage* was "not subject to ***any*** regulation under the [defendant's] license." *Smith*, 460 Mich. at 464 (emphasis added and quotation omitted). *Liss* took a similar approach. It stressed *Diamond Mortgage*'s "critical explanation" that the proper focus was the general transaction, rejected the dissent's effort to draw "a distinction between the tests articulated in *Diamond Mortgage* and *Smith*," and explained that the defendants in *Diamond Mortgage* fell on the wrong side of the MCPA because they were "engaged in activity, mortgage

[3] Subsection 4(2) includes an additional set of exemptions that immunize certain unlawful activities from public-enforcement actions under the MCPA. *See* MCL 445.904(2).

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writing, that their real estate broker license simply did not permit them to do" and possessed "***no*** statutory authorization" for such transactions. *Liss*, 478 Mich. at 211-12, 215 & nn.17 & 23 (emphasis added). What explains the different outcomes in the cases is not a different approach to the statute, but simply different facts. There is no conflict among these decisions—let alone an unresolved one.

Finally, the Attorney General suggests at times that *Smith* and *Liss* are so broad as to immunize "a business" or "entit[y]" simply because that business or entity "is generally regulated by some State or Federal agency." A.G. Br. at 14-15; *see also id.* at 2-3 ("Nor can the MCPA be used to guard against unfair practices by regulated persons and companies …."); *id.* at 24-25 ("*Smith* and *Liss* present a substantial problem in a myriad of contexts where an entity is subject to a regulatory scheme that does not contain a consumer-protection enforcement component"). That sweeping characterization is incorrect. As *Liss* explained, merely being subject to some sort of regulatory scheme does not immunize a business or entity from MCPA liability: the statutory inquiry "do[es] not focus on the actor" itself, but rather asks whether the "transaction or conduct" in question is authorized by law. *Liss*, 478 Mich. at 212 n.34 (quotation omitted). Contrary to the Attorney General's concern that *Smith* and *Liss* somehow rendered the MCPA meaningless for most companies, both decisions just applied the same test found in MCL 445.904(1)(a)'s plain language: whether the "transaction or conduct" is permitted by law.

* * *

The Attorney General offers no basis to depart from the Supreme Court's decisions, much less to criticize how the Supreme Court arrived at those decisions. By their plain terms, *Smith* and *Liss* carefully examined the statutory text, including the neighboring provisions in subsection 4(2) that are critical to the Attorney General's current theories. Both decisions were careful to square

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their reasoning with existing precedent. And the Supreme Court has made clear that the MCPA is not a dead letter. Nothing about what *Smith* and *Liss* actually say can justify an advisory opinion questioning the Supreme Court's judgment.

2. The Attorney General's Alternative View Conflicts with the MCPA's Plain Text, Context, and History

An advisory opinion proposing a novel interpretation of the MCPA would be improper for a second dispositive reason: the Supreme Court's current approach is the only one consistent with the statutory text and the Legislature's frequent revisions of the MCPA. The parties agree that statutory interpretation requires a court to respect the "plain language of the statute" and "the intent of the Legislature." A.G. Br. at 11. Yet the Attorney General's current view of the MCPA overlooks both.

As to text, the Attorney General barely mentions the language of the ***actual*** exemption at issue here—subsection 4(1)—which applies to a "transaction or conduct specifically authorized under [federal or state] law[]." MCL 445.904(1)(a). The Attorney General's interpretation seems to be that subsection 4(1) should apply only if federal or state law permits the specific "conduct" alleged, regardless of any authorization for the broader "transaction" in which that conduct occurs. *See* A.G. Br. at 16-17, 23, 25. Under this approach, for example, it would be irrelevant that Lilly's medications "must be approved by the FDA" before Lilly can enter into commercial transactions "s[elling] any medication in interstate commerce," because the specific conduct of "pricing and marketing" the medications sold in those authorized transactions is allegedly not controlled by any specific law. *Id.* at 17-18, 23.

That interpretation is not reconcilable with the MCPA's plain text. Subsection 4(1) applies to "[a] ***transaction*** or conduct specifically authorized under [federal or state] law[]." (Emphasis added). As the Attorney General concedes, statutory interpretation must "give effect to ***every***

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word, phrase, and clause." A.G. Br. at 12 (emphasis added and citation omitted). That principle compels the conclusion here that legal authorization for the "transaction" in which the alleged wrongdoing occurs is sufficient to invoke subsection 4(1)—the exact view the Supreme Court took in *Liss* and *Smith*. After all, the Legislature chose to protect "transaction[s] ***or*** conduct," MCL 445.904(1)(a) (emphasis added), inserting the term "or" in the middle of those words to express that they should "be given separate meanings" and should not be collapsed into "an identical element." *Loughrin v. U.S.*, 573 U.S. 351, 357 (2014). Any effort to restrict subsection 4(1) to specific conduct (pricing and marketing of medications) and not the transactions in which that conduct occurs (sales of medications) is incompatible with the text the Legislature enacted and that the Supreme Court correctly interpreted in *Liss* and *Smith*.

Because the Attorney General cannot overcome the actual language of the relevant statutory provision, she rests her argument on a different provision altogether: subsection 4(2) and its exemptions for conduct forbidden by certain state laws. In the Attorney General's view, the fact that subsection 4(2) prevents her from using the MCPA to police "conduct that is made unlawful" by other statutes somehow creates the "reverse implication" that she "may bring actions against entities regulated under other statutes except as enumerated in that subsection, subject to the limitation in subsection 4(1)." A.G. Br. at 14-15. This convoluted reasoning fails for multiple reasons, not least of which is that the Attorney General admits that her enforcement powers remain "subject to the limitation ***in subsection 4(1)***," *id.* at 15 (emphasis added)—a provision that ***expressly*** exempts "transaction[s]" in addition to "conduct." MCL 445.904(1)(a).

Nor is there anything superfluous or inconsistent about the current interpretation of these two subsections, as the Attorney General claims. *See* A.G. Br. at 14. By their express terms, each performs a different, important function: Subsection 4(1) exempts transactions that are

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"authorized" by law, whereas subsection 4(2) insulates certain activities that are ***"unlawful"*** under various statutes. MCL 445.904(1)-(2) (emphases added). Nothing about the Legislature's decision to shield particular ***unlawful activities*** under subsection 4(2) implies that this Court should disregard the Legislature's independent command that ***authorized*** (*i.e.*, lawful) ***transactions*** should enjoy protection under subsection 4(1) as well. Just the opposite; it makes perfect sense that the exemption for legal transactions would be substantially broader than the one for illegal activities (and have independent force to boot). Thus, it is actually the interpretation advanced by the Attorney General that would "render … part of the statute surplusage or nugatory" by hollowing out subsection 4(1)'s express textual exemption for authorized transactions. A.G. Br. at 12.

In fact, should there be any doubt, the Legislature has already rejected the Attorney General's approach of using subsection 4(2) to undercut subsection 4(1). When the Supreme Court decided *Smith* in 1999, it reasoned that although subsection 4(1) exempted "general transaction[s]" authorized by law "regardless of whether the specific misconduct alleged is prohibited," the fact that subsection 4(2) allowed certain private suits over behavior made illegal by the insurance laws meant that a private plaintiff's suit against an insurer could nonetheless proceed. 460 Mich. at 465-67. The Legislature made clear that it agreed with the Supreme Court's interpretation of subsection 4(1)—but ***not*** its limiting construction of subsection 4(2). "In response to the *Smith* decision," the Legislature updated MCL 445.904 to include the ***exact same*** language for subsection 4(1) while simultaneously revising ***other*** parts of the statute to clarify that "the MCPA does not apply to or create a cause of action for an unfair, unconscionable, or deceptive method, act, or practice made unlawful by Chapter 20 of the Insurance Code." House Fiscal Agency, *A Summary of House Bill 5558 as Enacted* at 2 (July 2, 2014); *also compare* Pub. Act No. 432, H.B. No. 5332

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(2000), *with* Pub. Act. No. 10, H.B. 4204 (1993). And when decisions of the Supreme Court and Court of Appeals frustrated this change by refusing to give it retroactive effect, the Legislature again intervened to make "clear that consumers may not bring an action" based on "conduct [that] happened before, on, or after [when the amendment] became law." House Fiscal Agency, *supra*, at 3; *see also* Pub. Act No. 251, H.B. No. 5558, Enacting §2 (2014). It did so over objections—much like those of the Attorney General here—that this move left consumers without "effective avenues for remedies." House Fiscal Agency, *supra*, at 4. And in doing so, it again reinstated the familiar language of subsection 4(1)'s exemption for authorized transactions or conduct, which by that point had been definitely construed by *Liss* in addition to *Smith*. *See* Pub. Act No. 251, H.B. No. 5558 (2014).

This history dispels any contention that the Legislature has quietly acquiesced to an erroneous judicial interpretation of the MCPA. In reality, the Legislature has independently and actively confirmed how the law should operate. Since *Smith* and *Liss*, the Legislature repeatedly modified MCL 445.904 to correct ***other*** disagreements with the Judiciary, but otherwise "re-enacted the statute without pertinent change" to subsection 4(1)'s exemption for authorized transactions. *NLRB v. Bell Aerospace Co. Div. of Textron, Inc.*, 416 U.S. 267, 275, 288 (1974); *accord Manhattan Props. v. Irving Trust Co.*, 291 U.S. 320, 336 (1934) ("From 1898 to 1932 the Bankruptcy Act was amended seven times without alteration of the section. This is persuasive that the construction adopted by the courts has been acceptable to the legislative arm of the government.").[4] It did so notwithstanding the objections of the *Smith* and *Liss* dissenters. And it

[4] *Compare* MCL 445.904(1)(a) (1976) (original language), *with* Pub. Act No. 10, H.B. No. 4204 (1993) (same language for subsection 4(1)(a)), Pub. Act No. 432, H.B. No. 5332 (2000) (same language for subsection 4(1)(a)), Pub. Act No. 216, S.B. No. 493 (2003) (same language for

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did so in the face of the same law review and bar journal articles criticizing the supposed "destruction the *Smith* and *Liss* decisions brought to the MCPA." A.G. Mot. to Expedite Br. at 10-11 & nn.9-12 (collecting sources dating to 2003). In light of this history, to say nothing of the clear text and on-point precedent it has yielded, the only faithful interpretation of subsection 4(1) is the one that the Supreme Court has repeatedly articulated—the same one that the Legislature has consistently confirmed.

3. The Attorney General Continues to Rely on Inaccurate Factual Allegations

Because this is a motion for summary disposition, the Court cannot resolve the parties' conflicting versions of the facts. That said, Lilly has little choice but to respond to the Attorney General's ongoing, unfair, and demonstrably inaccurate allegations about its business practices—for example, the false claim that "[t]he average out-of-pocket cost of a single vial of insulin is nearing $100."[5] At least for Lilly's insulins, third-party prescription data confirms the cost is actually between $7 and $10, a reality Lilly has shared over and over but the Attorney General ignores.

Lilly has also explained that its comprehensive suite of insulin affordability solutions ensures that anyone is eligible to purchase their monthly prescription of Lilly insulin for $35 or less, whether they are uninsured, use commercial insurance, or are enrolled in Medicaid or a

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subsection 4(1)(a)), *and* Pub. Act No. 251, H.B. No. 5558 (2014) (same language for subsection 4(1)(a)).

[5] Dep't of Att'y Gen., Press Release, *AG Nessel Launches Investigation into Excessive Insulin Prices, Intends to Challenge MSC Decisions Impacting Consumer Protection* (Jan. 26, 2022), https://bit.ly/3vcGEhx; *see also* A.G. Br. at 6-9; A.G. Mot. to Expedite Br. at 4-10.

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participating Medicare Part D plan.[6] The Lilly Insulin Value Program covers individuals who lack insurance or who use private commercial insurance, and Lilly's partnership with the Centers for Medicare and Medicaid Services means that the Senior Savings Model program does the same for individuals enrolled in participating Medicare Part D plans. The Lilly Diabetes Solution Center fields thousands of calls each month to help people living with diabetes navigate the complexities of the healthcare system, connect them to various solutions based on their individual circumstances, and even provide immediate emergency supplies of insulin. And Insulin Lispro (a non-branded version of Humalog, Lilly's most-prescribed insulin, which is exactly the same molecule) currently has a list price that is effectively the same as Humalog's list price ***in 2008***. The bottom line is that the average monthly out-of-pocket cost for a prescription of Lilly insulin, regardless of the number of vials or pens, is just $21.80—a 44 percent ***decrease*** since 2017. Indeed, contrary to the Attorney General's suggestion that insulin prices are on a perpetually upward trend, Lilly has not raised the list price of ***any*** insulin (the only price manufacturers set) over the past five years. *See* A.G. Br. at 6.

The Attorney General cannot contest any of this, and instead relies on other allegations that are neither illuminating nor accurate. She invokes, for example, the list price of insulin—a federally defined term that looks to prices that "***wholesalers or direct purchasers***" pay when they

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[6] *See, e.g.*, Lilly Insulin Value Program, https://www.insulinaffordability.com/; News Release, *New $35 Co-Pay Now Available Through Lilly Insulin Value Program in Response to COVID-19 Crisis in U.S.* (Apr. 7, 2020), https://bit.ly/3wzer4Z; diaTribe Learn, *Lilly Announces $35 Monthly Cap on Insulin in Response to COVID-19* (Apr. 14, 2020), https://bit.ly/3LgNUOd.

The only exceptions are individuals enrolled in federal government insurance programs other than Medicaid and Medicare Part D, whom federal law restricts from accessing Lilly's solutions.

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make direct purchases from drug manufacturers, 42 U.S.C. §1395w-3a(c)(3) (emphasis added)[7]—while overlooking that ***patients*** pay far less for Lilly's insulins. *See, e.g.*, A.G. Br. at 6-7. After all, patient-level purchases occur at the opposite end of a complex drug-distribution system populated by intermediary wholesalers, pharmacy benefit managers, health plans, and pharmacies, which is why Lilly has adopted patient-level solutions aimed at ensuring that no patient falls through the cracks of that system. The Attorney General makes a similar mistake by stressing the prices that independent pharmacies set—again, regardless of whether patients actually pay those prices and notwithstanding that Lilly's programs mean that patients need not ever pay more than $35 per month for insulin regardless of insurance coverage or the number of pens or vials prescribed. *See id.* at 8. No better is the year-old declaration from a single doctor who speaks in sweeping terms about insulin prices and makes erroneous claims such as that patient-assistance programs are a minefield of "income cutoff[s]" and "spending" requirements. A.G. Br. App'x 2 ¶ 12. That is simply untrue for Lilly's programs. The Insulin Value Program, for example, just requires patients (including the uninsured) to check two boxes confirming that the patient (1) is "a resident of the United States or Puerto Rico who is 18 years of age or older" and (2) is "not enrolled

[7] Although unable to move the needle in a case controlled by precedent, the Attorney General is also incorrect to suggest that 42 U.S.C. §§1395w-3a(c)(3) and 1396r-8(a)(1) are irrelevant. *See* A.G. Br. at 17-18. The former speaks directly to "rebates" and is therefore by its plain terms pertinent to the allegations here that rebates improperly distort drug pricing. *E.g.*, Compl. Exh. A ¶ 17 ("Drug manufacturers like Eli Lilly have artificially increased the list prices of medications ***in order to offer these rebates***" (emphasis added)); *id.* ¶¶ 48-49 (discussing allegedly "fair" prices against the backdrop of "rebates"). And the latter expressly requires rebates in certain circumstances. To be sure, both provisions come from the Medicare and Medicaid statutes, but that hardly lessens their salience here. Section 1395w-3a(c)(3), for example, recognizes that rebates will be paid in ***private*** transactions between manufacturers, wholesalers, and direct purchasers. And given that the Attorney General suggested at the motion-to-expedite hearing that she is concerned about insulin pricing for patients enrolled in government-sponsored programs, she cannot disclaim the relevance of section 1396r-8(a)(1), which requires "rebate agreement[s]" for certain government programs.

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in a governmental program," after which the patient can instantly download a copay card with no application, income cutoff, or waiting period. *See* insulinaffordability.com (capitalization omitted). And the Attorney General confusingly faults Lilly for introducing Lispro at a ***lower*** list price, *see* A.G. Br. at 9—a criticism that is both at odds with the overarching theory that list prices are too high and that unfairly minimizes all of Lispro's tangible benefits: reducing list prices to 2008-levels, providing an alternative insulin without disrupting the ability of patients to access branded insulins through their insurance plans (or for $35 through the Insulin Value Program), and offering immediate relief to patients in government-funded plans who, at the time of Lispro's introduction, could not take advantage of other cost-savings programs because of government restrictions.

To be clear, Lilly is entitled to summary disposition as a matter of law for all the reasons detailed above, and not because it is correct on the facts. But the Attorney General has continued to suggest that Lilly's alleged business practices should tip the scales in favor of an advisory opinion. The realities of the case, however, cannot support that unusual and inappropriate request.

III. CONCLUSION

This litigation presents no good reason to second-guess the Supreme Court, much less contravene the Legislature's understanding and intent for the MCPA. The Court should simply grant summary disposition in favor of Lilly and declare that the Attorney General's investigation is ultra vires under settled law.

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Dated: June 17, 2022

Respectfully submitted,

HONIGMAN LLP

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PROOF OF SERVICE

I hereby certify that on June 17, 2022, I caused a copy of the foregoing document to be served via email and first-class mail upon all attorneys of record. I declare under penalty of perjury that the foregoing statements are true to the best of my information, knowledge, and belief.

/s/ Matthew Schneider

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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. 2022-000058-CZ

HON. WANDA M. STOKES

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ATTORNEY GENERAL'S REPLY IN SUPPORT OF CONSOLIDATED CROSS-MOTION FOR SUMMARY DISPOSITION AND BRIEF IN SUPPORT

I. Lilly's concerns about an advisory opinion are unfounded.

It is unsurprising Eli Lilly & Company (Lilly) does not want revisited the decisions in *Smith v Globe Life Ins Co*, 460 Mich 446 (1999), and *Liss v Lewiston-Richards, Inc*, 478 Mich 203 (2007). These decisions render the Michigan Consumer Protection Act (MCPA) inapplicable to the sale of prescription medications, including Lilly's insulins. The Michigan Supreme Court can revisit such decisions, *Robinson v Detroit*, 462 Mich 439, 463 (2000), and one Supreme Court Justice has expressed an interest in doing so on this issue. *Cyr v Ford Motor Co*, 507 Mich 1029 (2021) (Welch, J., concurring with denial of leave) ("I write separately because I am persuaded, with the input of the amici curiae in this case, that this Court should

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examine whether our previous decisions in *Smith v Globe Life Ins Co*, 460 Mich 446 (1999) and *Liss v Lewiston-Richards, Inc*, 478 Mich. 203 (2007), properly interpreted the safe-harbor provision in the Michigan Consumer Protection Act, MCL 445.901 *et seq*. I look forward to the opportunity to review this issue in a future matter.")

Lilly incorrectly says that the Attorney General is asking this Court to "needlessly 'opine on matters unnecessary to the resolution of this case.'" (Lilly BIO to AG's Cross MSD at 4 (quoting *State ex rel Gurganus v CVS Caremark Corp*, 496 Mich, 45, 67, 67 n 48 (2014)). The sole issue presented by the Attorney General is the question about her authority to proceed with the investigation in light of the *Smith* and *Liss* decisions. Lilly acknowledges this and the Attorney General's intention to appeal. (Lilly BIO to AG's Cross Motion at 1.) The Attorney General is simply asking this Court to inform the appellate process by offering insights on that sole and controlling issue. This Court is obligated to make a decision and both parties acknowledge that decision is dictated by *Smith* and *Liss*. But Lilly points to no precedent telling this Court what it can or cannot say in making that decision.

II. On the facts, Lilly doth protest too much.

If a consumer searches online asking "how much does Humalog cost" the first result is https://www.lillypricinginfo.com/humalog. In large font in the middle of the screen it states: "How much should I expect to pay for Humalog U-100®?"

The site provides the following answer:

> Prescription drug prices can be confusing. Two people may pay different prices for the same drug, depending on their insurance situation.
>
> The list price of a 5-pack of 3 mL Humalog U-100 KwikPens (15 mL or 1,500 units) is $530.40 and the list price of a Humalog U-100 10 mL (1,000 units) vial is $274.70, but the amount you pay will largely depend on your insurance plan.
>
> Insulin needs vary significantly from person to person, some take only 5 units per meal while others take over 100 units per meal. Given this variability, providing a relevant average cost for a month's supply of Humalog U-100 is difficult.

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> The information below will give you a good idea of what to expect based on your insurance situation and support that may be available to you.

There are drop downs for several different insurance situations. The fourth and final situation is "I don't have insurance or Humalog is not covered by my insurance plan." Lilly's response states: "If you do not have prescription medication insurance coverage, or if your insurance does not cover Humalog, you can expect to pay close to the list price shown above, plus any additional pharmacy charges depending on where you purchase your medicine."[1]

Looking backward, there is a six-year statute of limitations on MCPA actions. MCL 445.910(5). So, Lilly's $35 pricing program introduced in response to COVID does not cover that period. And as relates to the Attorney General's ongoing concerns, the program simply benefits only those who know about it, and don't bump against any of its limitations.[2]

III. Lilly's statutory analysis makes sense only in light of *Smith* and *Liss*, and not the MCPA's plain text.

The fundamental problem is that the *Smith* and *Liss* Courts violated the principles of statutory construction by re-writing the text of MCL 445.904(1) to accomplish something

---

[1] This internet search result is in open view of this Court and so judicial notice may be taken of this material. MRE 201. In reviewing these pages, this Court can observe the Lilly savings program is also mentioned, though not as overtly as the information quoted here. Anticipating Lilly may wish to improve its marketing to more clearly tout the benefits of its $35 program to the public as it does so in the appellate courts, the Affidavit of Kassie Lutz is included as **Attachment A** to preserve the information currently in the view of this Court.

[2] It seems not everyone is in the know, as Lilly admits it, Lilly "fields thousands of calls each month to help people living with diabetes navigate the complexities of the healthcare system, connect them to various solutions based on their individual circumstances, and even provide immediate emergency supplies of insulin." (Lilly BIO to AG's Cross Motion at 13.) Lilly acknowledges the program does not cover certain Medicare beneficiaries. (Lilly BIO to AG's Cross Motion at 17.) Further, the $35 program is advertised with this caveat: "Offer subject to a monthly cap of wholesale acquisition cost plus usual and customary pharmacy charges and a separate annual cap of $7,500." This is enough to pay full freight for a 5 pack of pens per month with some wiggle room. This may not be enough insulin for some people. As Lilly notes in the website material quoted above, how much insulin any given consumer may use varies widely.

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different than the Legislative purpose. That this is exactly what happened is clear from a side-by-side reading of the statute's actual text and the construction the *Smith* and *Liss* Courts gave to it:

The statute states:	But under *Smith* and *Liss:*
"This act does not apply to either of the following: 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).]	"[T]he relevant inquiry 'is whether the general transaction is specifically authorized by law, regardless of whether the specific misconduct alleged is prohibited.'" *Liss*, 478 Mich. at 206 (quoting *Smith*, 460 Mich. at 465).

The *Smith* and *Liss* Courts thus added the word "general" to modify the kind of "transaction" the statute refers to. This judicial draftsmanship has a profoundly transformative effect on construction.

Consider first the statute's plain language without the "general" modifier. To determine whether a "transaction" was "specifically authorized" by State or Federal law, one ought to take a narrow approach to identifying the transaction by ensuring that it is specifically, rather than generally, authorized. So, when Lilly sells a Humalog pack to a Michigan pharmacy at its list price of $530.40 that will then be absorbed by the consumer purchasing it, the appropriate analysis is that Lilly was generally authorized to manufacture and sell Humalog, but nothing in the State or Federal regulatory schemes specifically authorized the price attached to that transaction. And where a consumer does not enter into the transaction because of the high price, focus would turn to whether Lilly's pricing conduct is specifically authorized—which it is not. Similarly, with respect to the representations Lilly makes regarding the reasons for its pricing of Lispro at discounted prices, the appropriate conclusion would be that Lilly is generally

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authorized to sell Lispro, but no State or Federal regulation specifically authorizes the statements it makes about that products pricing.

By turning the exemption's "transaction" into a "general transaction," the *Smith* and *Liss* Courts flipped its narrow scope into a broad impact. And although the *Smith* and *Liss* Courts gave lip service to the term "specifically authorized" in their re-framing to a "general transaction," the practical effect of the test they announced was to render the word "specifically" surplusage. A determination that the general transaction is authorized by law thus became sufficient to defeat an MCPA claim by construing transactions so broadly that other conduct, such as price-setting or pre-transaction representations and post-transaction mischief became encompassed by the concept, rather than allowing the lower courts to undertake the legislatively-intended test of determining whether particular transactions or conduct were specifically authorized by some other statute or regulatory scheme.

Although the *Smith* Court had included the word "specifically" in its framing of the relevant test, the practical effect of the reformulated construction it announced can be observed in that word's disappearance later in the *Liss* decision. Lilly describes the *Liss* decision in its brief: "the statutory inquiry 'do[es] not focus on the actor' itself, but rather asks whether the 'transaction or conduct' in question is authorized by law." (Lilly BIO to AG's Cross Motion at 7 (quoting *Liss*, 478 Mich at 212 n 34 (quotation omitted)). Thus, Lilly's statutory analysis purports to "compel[] the conclusion here that legal authorization for the 'transaction' in which the alleged wrongdoing occurs is sufficient to invoke subsection 4(1)." *Id*. at 9.[3]

[3] By focusing on the general transaction rather than that which is specifically authorized by law, Lilly is able to assert that its other conduct does not even need to be considered. The broad concept of the "general transaction" from *Smith* and *Liss* carries with it far more danger of subsuming the "conduct" inquiry under MCPA section 4(1) than would exist if courts were to apply the proper narrow test to consider whether a transaction was specifically authorized, and

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The beneficial impact from Lilly's perspective then is that it can charge whatever it wants for Humalog, even if that price is grossly excessive within the meaning of the MCPA, because the *Smith* and *Liss* Courts have said that all it need do is show it is generally authorized to manufacture and sell Humalog. And, similarly, Lilly can take the position it is free under the MCPA to make any misrepresentations it wants about the reasons for the Lispro discount price since it is authorized to make and sell that drug.

This approach is simply wrong.[4] And it is time for the MCPA to be restored to its original dignity.

Respectfully submitted,

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HammakerC@michigan.gov

Dated: July 1, 2022

then—if it were not—moving on to determine whether the alleged misconduct was nevertheless specifically authorized by law.

[4] And it should be compared to the approach taken by the Tennessee Supreme Court construing highly similar text in its consumer protection law. *Skinner v Steele*, 730 SW2d 335, 338 (Tenn 1987).

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ATTACHMENT A

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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 June of 2022, I was asked to search for Humalog pricing information published on the internet by Eli Lilly.

4. On June 29, 2022, I used the Google search engine and performed a search for "how much does Humalog cost." (Attachment 1.)

5. The first search result was for a webpage titled "Humalog® (insulin lispro injection) - Lilly Pricing Info" at the web address https://www.lillypricinginfo.com/humalog.

6. Following this link led to an Eli Lilly web page with the heading, "How much should I expect to pay for Humalog U-100®?" (Attachment 2.)

7. Under this heading, the website stated "Prescription drug prices can be confusing. Two people may pay different prices for the same drug, depending on their insurance situation." (Attachment 2.)

8. It goes on to state, "The list price of a 5-pack of 3 mL Humalog U-100 KwikPens (15 mL or 1,500 units) is $530.40 and the list price of a Humalog U-100 10 mL (1,000 units) vial is $274.70, but the amount you pay will largely depend on your insurance plan." (Attachment 2.)

9. The website has four drop-down options describing different insurance situations including one for private insurance, one for Medicare Part D, one for Medicaid, and one for those without insurance or whose insurance does not cover Humalog.

10. The first three drop down tabs for private insurance, Medicare Part D, and Medicaid provide the range that most individuals in those categories pay under their insurance and what percentage of total

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sales fall within that range. The private insurance tab and the Medicare D tab also list the average amount paid for Humalog for patients whose cost falls outside of the standard range.

11. The tab for the uninsured or for those whose insurance does not cover Humalog instructs, "If you do not have prescription medication insurance coverage, or if your insurance does not cover Humalog, you can expect to pay close to the list price shown above, plus any additional pharmacy charges depending on where you purchase your medicine." (Attachment 2.)

12. I captured the attached screenshots of the website and search results using the Snagit screen capture application.

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 SAYTH NOT.

Kassandra Lutz

Kassandra Lutz

Subscribed and sworn to before me
This 30th day of June 2022.

Judie K. Bridleman, Notary Public
Eaton County, Michigan
Commission Expires: 11-30-2025
Acting in Ingham County, MI

Attachment 1

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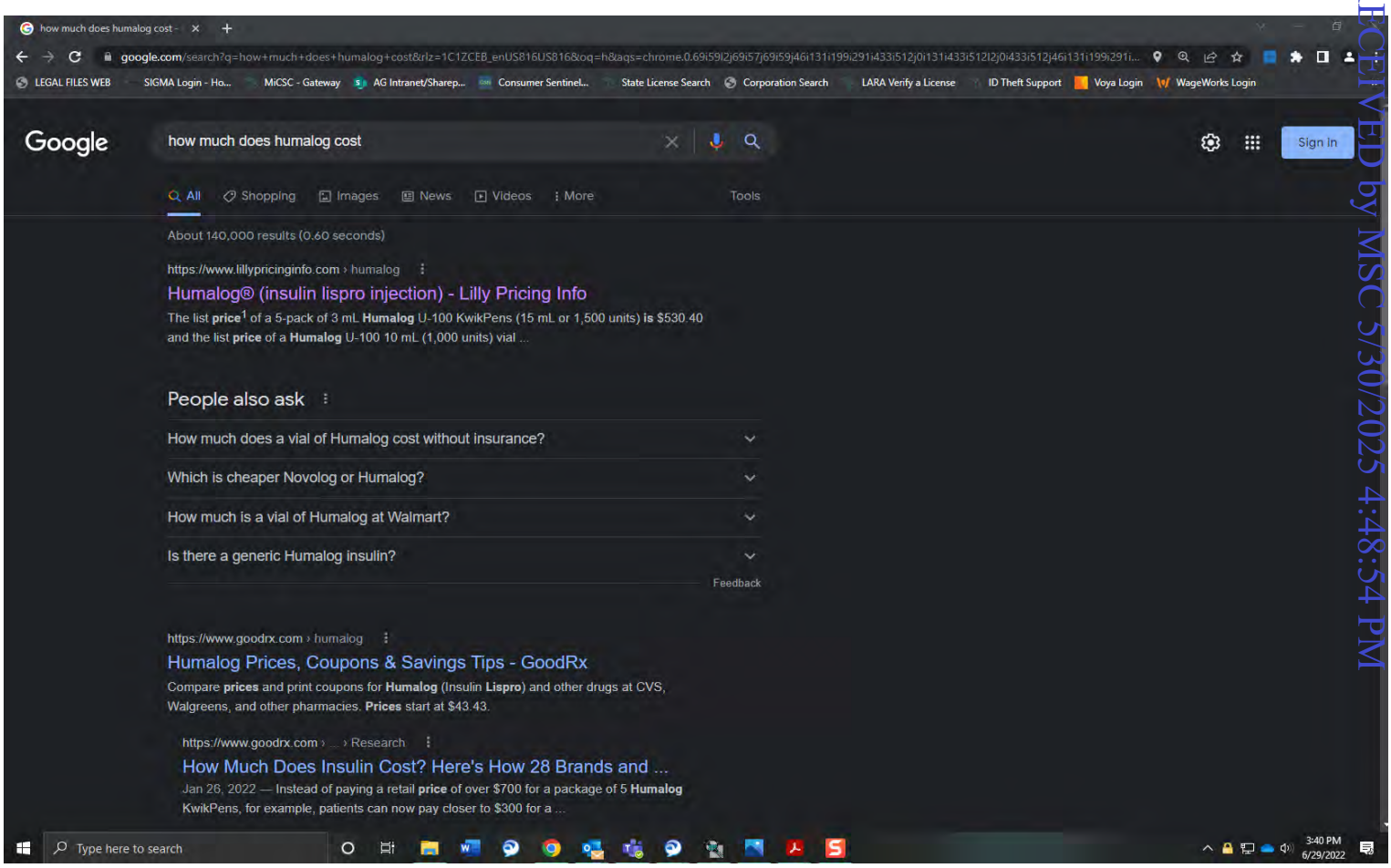

Attachment 2

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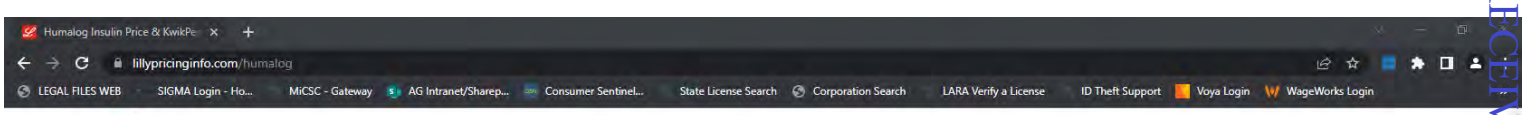


Lilly

Home Select a medicine

Through **Lilly's Insulin Value Program**, anyone with Employer/Private Insurance or no insurance can fill their monthly prescription for Lilly insulins for $35. Call the Lilly Diabetes Solution Center at (833) 808-1234 for more information.

How much should I expect to pay for Humalog U-100®?

Prescription drug prices can be confusing. Two people may pay different prices for the same drug, depending on their insurance situation.

- The list price[1] of a 5-pack of 3 mL Humalog U-100 KwikPens (15 mL or 1,500 units) is $530.40 and the list price of a Humalog U-100 10 mL (1,000 units) vial is $274.70, but the amount you pay will largely depend on your insurance plan.

Insulin needs vary significantly from person to person, some take only 5 units per meal while others take over 100 units per meal. Given this variability, providing a relevant average cost for a month's supply of Humalog U-100 is difficult.

The information below will give you a good idea of what to expect based on your insurance situation and support that may be available to you.

For the most accurate information, talk to your insurance provider who knows the details of your plan.

Humalog® insulin lispro injection
100 units/mL

Go to Humalog.com

Which Option Below Best Describes Your Insurance Situation?

1. I Have Insurance Through an Employer or Private Individual Policy

About 97% (vial) or 96% (5-pack KwikPens) of Humalog prescriptions cost between $0 and $95 per month, and the remaining cost an average of $345 (vial) or $323 (5-pack KwikPens) per month.[2]

What you pay for Humalog will depend on your insurance plan. Each plan has different preferred drug lists and out-of-pocket amounts, and most include an annual deductible. If you haven't met your deductible, you'll see higher prices until the deductible is met, then your out-of-pocket cost will likely drop.

For personalized assistance on the most affordable options for you, please call the Lilly Diabetes Solution Center at (833) 808-1234.



Get your savings card.

Lilly Diabetes Solution Center

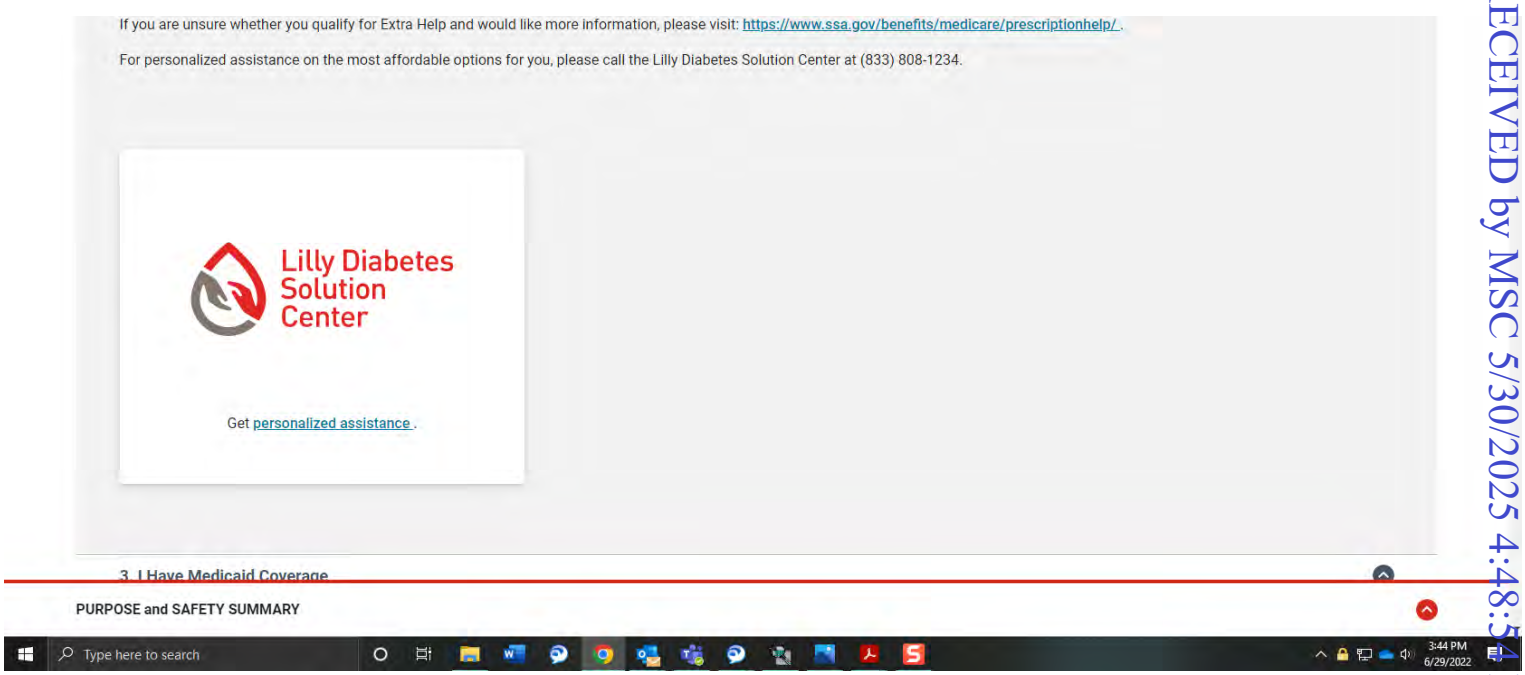
Get personalized assistance.

2. I Have Medicare Part D Coverage

For most patients with Medicare Part D coverage, out-of-pocket costs can vary throughout the year depending on which phase of the Part D benefit you are currently in. Overall, about 81% (vial) or 82% (5-pack KwikPens) of Humalog prescriptions cost between $0 and $95 per month, and the remaining prescriptions cost an average of $189 (vial) or $177 (5-pack KwikPens) per month.[2]

Through the Part D Senior Savings Model, you may be able to get Medicare drug coverage that offers broad access to many types of insulin for no more than $35 for a 30-day supply. You can get this savings on insulin if you join a Medicare drug plan or Medicare Advantage Plan with drug coverage that participates in the insulin savings model. This model lets you choose among drug plans that offer insulin at a predictable and affordable cost.[6]

Looking for a Medicare Part D plan that covers your Lilly insulin? We can help: https://www.insulinaffordability.com/plan-finder
Some Medicare patients qualify for extra financial support through the Extra Help[3] program. If you are eligible for Extra Help, you can expect to pay $4 to $9 for each prescription.[4]



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3. I Have Medicaid Coverage

For most people on Medicaid, prescription drugs like Humalog range from $4 to $9 per month.[5] Some states allow even lower copays, or eliminate the copay requirement altogether.

To find out if you qualify for Medicaid, or for more information about copayments in your state, please visit: https://www.medicaid.gov/state-overviews/index.html .

For personalized assistance on the most affordable options for you, please call the Lilly Diabetes Solution Center at (833) 808-1234.

Lilly Diabetes Solution Center

Get personalized assistance .

4. I Don't Have Insurance or Humalog Is Not Covered by My Insurance Plan

If you do not have prescription medication insurance coverage, or if your insurance does not cover Humalog, you can expect to pay close to the list price shown above, plus any additional pharmacy charges depending on where you purchase your medicine.

If you are interested in obtaining insurance, there are resources available to help you:

- To find out if you qualify for Medicaid and for information about copayments in your state, please visit: https://www.medicaid.gov/state-overviews/index.html .
- To learn more about private individual policies via the Insurance Marketplace, please visit: https://mat.org/Health-Insurance-Resources .

See below for information regarding additional support services that may be available to you.

For personalized assistance on the most affordable options for you, please call the Lilly Diabetes Solution Center at (833) 808-1234.



Get your savings card .

Lilly Diabetes Solution Center

Get personalized assistance .

PURPOSE and SAFETY SUMMARY

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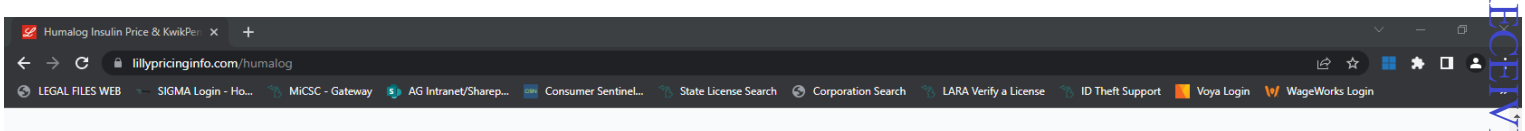

Lilly Diabetes Solution Center

Want More Information?

For personalized assistance on the most affordable options for you, please call the Lilly Diabetes Solution Center at (833) 808-1234. Although we won't replace the advice of your healthcare provider, we'll do our best to find affordable options for you.

Lilly Cares® Foundation

Need Another Option?

Lilly donates medicines to the Lilly Cares® Foundation, a separate nonprofit organization that helps qualified people in need receive Lilly medicines at no cost. Learn more at www.lillycares.com or by calling Lilly Cares at 1-800-545-6962.

[1] List price, also referred to as wholesale acquisition cost or WAC, is the price at which Lilly sells its products to wholesalers and may not represent actual transactional prices patients pay at the pharmacy. WAC from AnalySource accessed on January 1, 2022. Reprinted with permission by First Databank, Inc. All rights reserved. 2022. https://www.fdbhealth.com/policies/drug-pricing-policy.

[2] Source: IQVIA™: OPC Provider for the period of 12 months reflecting estimates of real-world activity for the period September 2019 - August 2020. Data access as of September 28, 2020. All rights reserved.

[3] Social Security Administration (SSA). Extra Help with Medicare Prescription Drug Plan Costs. https://www.ssa.gov/benefits/medicare/prescriptionhelp/. Accessed on January 16, 2020.

[4] Centers for Medicare & Medicaid Services (CMS). Announcement of Calendar Year (CY) 2021 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. https://www.cms.gov/files/document/2021-announcement.pdf. Accessed on May 29, 2020.

[5] Centers for Medicare & Medicaid Services (CMS). Cost Sharing Out of Pocket Costs. Maximum Allowable Copayments for Eligible Populations by Family Income. **All out-of-pocket charges are based on the specific state's defined payment amount for that service. Certain groups, including children, terminally ill individuals, and individuals residing in an institution are exempt from cost sharing. Refer to your state agency for details about Medicaid out-of-pocket costs. https://www.medicaid.gov/medicaid/cost-sharing/cost-sharing-out-pocket-costs/index.html. Accessed on January 16, 2020.

[6] Insulin savings through the Part D Senior Savings Model. Insulin Coverage (medicare.gov) Accessed on <<Month, date, year>>.

PURPOSE and SAFETY SUMMARY

Important Facts About Humalog® (HU-ma-log) and Insulin Lispro Injection

- Humalog is also known as insulin lispro injection.
- Humalog and Insulin Lispro Injection are fast-acting insulins. They are used to control high blood sugar in adults and children with diabetes. They are available only with a prescription.
- Humalog comes in two strengths: U-100 (100 units per milliliter) and U-200 (200 units per milliliter). The Humalog U-200 prefilled pen contains **2 times as much insulin** per 1 milliliter as standard (U-100) insulin. The dose window on the pen shows your insulin dose.
- It is not known if Humalog or Insulin Lispro Injection are safe and effective for children with type 2 diabetes or for children younger than 3 years of age with type 1 diabetes. There were no studies done with these insulins in these groups of children. If your doctor decides to give your child one of these insulins, he or she may give you special instructions.

Important Facts about Humalog® Mix50/50™, Humalog® Mix75/25™, and Insulin Lispro Protamine and Insulin Lispro Injectable Suspension Mix75/25

- Humalog Mix50/50 and Humalog Mix75/25 are known as insulin lispro protamine and insulin lispro injectable suspension.
- Humalog Mix50/50, Humalog Mix75/25, and Insulin Lispro Protamine and Insulin Lispro Injectable Suspension Mix75/25 are mixed U-100 insulins. This means they contain a mix of fast-acting and intermediate-acting insulins. They are used to control high blood sugar in people with diabetes. They are available only with a prescription.
- It is not known if Humalog Mix50/50, Humalog Mix75/25, or Insulin Lispro Protamine and Insulin Lispro Injectable Suspension Mix75/25 are safe and effective for children younger than 18 years of age. There were no studies done with these insulins in children younger than 18. If your doctor decides to give your child one of these insulins, he or she may give you special instructions.

All Humalog and Insulin Lispro Injection products contain insulin lispro. Humalog Mix50/50, Humalog Mix75/25, and Insulin Lispro Protamine and Insulin Lispro Injectable Suspension Mix75/25 contain insulin lispro protamine mixed with insulin lispro.

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WARNINGS

Do not take Humalog, Insulin Lispro Injection, Humalog Mix50/50, Humalog Mix75/25, or Insulin Lispro Protamine and Insulin Lispro Injectable Suspension Mix75/25 if you have:

- symptoms of low blood sugar (hypoglycemia)
- an allergy to insulin lispro products or any of their ingredients.

Do not reuse needles or share your insulin injection supplies with other people. This includes your:

- prefilled pen for use by a single patient
- cartridges
- reusable pen that works with Lilly 3mL cartridges
- needles
- syringes

You or the other person can get a serious infection. This can happen even if you change the needle.

Do not change the type of insulin you take or your dose, unless your doctor tells you to. This could cause low or high blood sugar, which could be serious.

Do not use a syringe to remove Humalog from your prefilled pen. This can cause you to take too much insulin. Taking too much insulin can lead to severe low blood sugar. This may result in seizures or death.

Humalog, Insulin Lispro Injection, Humalog Mix50/50, Humalog Mix75/25, and Insulin Lispro Protamine and Insulin Lispro Injectable Suspension Mix75/25 may cause serious side effects. Some of these can lead to death. The possible serious side effects are:

- **Low blood sugar.** This can cause:
  - dizziness or light-headedness
  - sweating
  - confusion
  - headache
  - blurred vision
  - slurred speech
  - shakiness
  - fast heartbeat
  - anxiety
  - irritability
  - mood change
  - hunger

  If you are at risk of having severely low blood sugar, your doctor may prescribe a glucagon emergency kit. These are used when your blood sugar becomes too low and you are unable to take sugar by mouth. Glucagon helps your body release sugar into your bloodstream.
- **Severe allergic reaction.**
  Get emergency help right away if you have:
  - a rash over your whole body
  - trouble breathing
  - a fast heartbeat
  - sweating
  - a faint feeling
  - shortness of breath
  - extreme drowsiness
  - dizziness
  - confusion
  - swelling of your face, tongue, or throat
- **Low potassium in your blood.** This can lead to severe breathing problems, irregular heartbeat, and death.
- **Heart failure.**Taking diabetes pills called thiazolidinediones (thIE-uh-zOH-li-dEEn-dIE-OHns), or "TZDs," with insulin lispro products may cause heart failure in some people. This includes people who do not have any heart problems. If you have heart failure, it may get worse if you take TZDs with these insulin lispro products. Tell your doctor if you have any new symptoms of heart failure, or if they get worse. Some symptoms of heart failure include: shortness of breath, swelling of ankles and feet, and sudden weight gain. Your doctor may need to change or stop treatment with TZDs and your insulin lispro product.
- **High blood sugar and ketoacidosis.** You can have these serious problems when your insulin pump or infusion set stops working. They can also happen if your insulin is no longer effective. For these reasons, always keep extra insulin injection supplies with you.

COMMON SIDE EFFECTS

The most common side effects of Humalog, Insulin Lispro Injection, Humalog Mix50/50, Humalog Mix75/25, and Insulin Lispro Protamine and Insulin Lispro Injectable Suspension Mix75/25 are:

- low blood sugar
- allergic reactions
- reactions where you have injected insulin
- changes in fat tissue where you have injected insulin
- swelling of your hands or feet
- weight gain
- itching
- rash

These are not all of the possible side effects. Tell your doctor if you have any side effects. You can report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch .

BEFORE USING

Talk with your doctor about low blood sugar and how to manage it. Also tell your doctor:

- about all of the medicines you take, including over-the-counter medicines, vitamins, and herbal supplements.
- about any other prescription medicines you take, especially ones called TZDs.
- about all of your medical conditions, including if you have heart failure or other heart, liver, or kidney problems.
- if you are pregnant, breastfeeding, or plan to become pregnant or breastfeed.

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HOW TO TAKE

Read the **Instructions for Use** that come with your **Humalog, Insulin Lispro Injection, Humalog Mix50/50, Humalog Mix75/25, or Insulin Lispro Protamine and Insulin Lispro Injectable Suspension Mix75/25**. Be sure to take your insulin lispro product and **check your blood sugar levels** exactly as your doctor tells you to. Your doctor may tell you to change your dose because of illness, increased stress, or changes in your weight, diet, or physical activity level. He or she may also tell you to change the amount or time of your dose because of other medicines or different types of insulin you take.

Before injecting your insulin lispro product

You can inject your insulin dose yourself, or you can have a trained caregiver inject it for you. Make sure you or your caregiver:

- Check the insulin label before each injection. This will help you make sure that you are taking the correct insulin.
- Use a new needle for each injection. You can get a serious infection or the wrong dose of insulin if you re-use needles.
- Change (rotate) where you inject your insulin with each dose. This can reduce your chance of getting pits, lumps, or thickened skin where you inject your insulin. **Do not** inject your insulin into the exact same spot or where the skin has pits or lumps. **Avoid** injecting into thickened, tender, bruised, scaly, hard, scarred, or damaged skin.

When you are ready to inject

- If you are taking Humalog or Insulin Lispro Injection, inject it under your skin within 15 minutes before or right after you eat a meal.
- If you are taking Humalog Mix50/50, Humalog Mix75/25, or Insulin Lispro Protamine and Insulin Lispro Injectable Suspension Mix75/25, inject it under your skin within 15 minutes before you eat a meal.

Staying safe while taking your insulin lispro product

To stay safe while taking your insulin, be sure to **never** inject Humalog U-200, Humalog Mix50/50, Humalog Mix75/25, or Insulin Lispro Protamine and Insulin Lispro Injectable Suspension Mix75/25 in your vein, muscle, or with an insulin pump. Also be sure **not to**:

- mix Humalog U-200, Humalog Mix50/50, Humalog Mix75/25, or Insulin Lispro Protamine and Insulin Lispro Injectable Suspension Mix75/25 with other insulins or liquids.
- drive or use heavy machinery until you know how your insulin lispro product affects you.
- drink alcohol or use other medicines that contain alcohol when taking your insulin lispro product.

LEARN MORE

For more information, call 1-800-545-5979 or go to www.humalog.com or www.lillyinsulinlispro.com .

This summary provides basic information about Humalog, Insulin Lispro Injection, Humalog Mix50/50, Humalog Mix75/25, and Insulin Lispro Protamine and Insulin Lispro Injectable Suspension Mix75/25. It does not include all information known about these medicines. Read the information that comes with your prescription each time your prescription is filled. This information does not take the place of talking with your doctor. Be sure to talk to your doctor or other health care provider about your insulin lispro product and how to take it. Your doctor is the best person to help you decide if these medicines are right for you.

Humalog®, Humalog® Mix50/50™, and Humalog® Mix75/25™ are trademarks and registered trademarks owned or licensed by Eli Lilly and Company, its subsidiaries, or affiliates.

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Call (800) 545-5979

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Instructions for Use - Vial

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STATE OF MICHIGAN
IN THE 30TH JUDICIAL CIRCUIT 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.

ORDER ON CROSS MOTIONS FOR SUMMARY DISPOSITION

CASE NO. 22-58-CZ

HON. WANDA M. STOKES

At a session of said Court
held in the city of Mason, County of Ingham,
this 20 day of July, 2022.

PRESENT: HON. WANDA M. STOKES

This matter comes before the Court on cross motions for summary disposition. Defendant, Eli Lilly and Company (Eli Lilly), brings its motion pursuant to MCR 2.116 (C)(8) alleging that Plaintiff's Complaint fails to state a cause of action for which relief can be granted. Plaintiff, Dana Nessel, Attorney General of the State of Michigan, seeks dismissal pursuant to MCR 2.116 (C)(9) and (I)(2). After reviewing the briefs, and hearing arguments, the Court Grants Defendant's motion and dismisses Plaintiff's Complaint for the reasons stated more fully below. As the Court has reached this conclusion on the dispositive threshold issue, it does not need to address the merits of Plaintiff's motion for summary disposition as it is moot.

BACKGROUND

In February 2022 Plaintiff filed a Complaint for Declaratory Judgment seeking a ruling from the Court that the Attorney General (AG) has the authority to investigate Defendant for potential violations of the Michigan Consumer Protection Act (MCPA). Defendant Eli Lilly

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produces insulin. While the AG does not dispute that Eli Lilly is in full compliance with the MCPA, she questions whether its pricing practices merit investigation which is specifically prohibited under the current interpretation of the act articulated by the Michigan Supreme Court in *Smith v. Globe Life Ins. Co.*, 460 Mich. 446; 597 N.W.2d 28 (1999); *Liss v. Lewiston-Richards, Inc.*, 478 Mich. 203; 732 N.W.2d 514 (2007). These decisions make clear that the MCPA does not apply "to the pricing of insulin medications." The parties agree that Eli Lilly's sales of insulin are exempt from the MCPA under *Smith* and *Liss's* definitive holding "that the relevant inquiry 'is whether the general transaction is specifically authorized by law, regardless of whether the specific misconduct alleged is prohibited.'" *Liss,* 478 Mich. at 206 (quoting *Smith,* 460 Mich. at 465); *also see* A.G. Br. at 11, 23. The parties also agree that only the Supreme Court can overrule those precedents.

STANDARD OF REVIEW

A motion filed under MCR 2.116(C)(8) "tests the legal sufficiency of the claim on the pleadings alone," taking as true "all well-pled facts and reasonable inferences drawn therefrom," so as "to determine whether the plaintiff has stated a claim on which relief may be granted." *Spiek v DOT*, 456 Mich 331, 337; 572 NW2d 201, 204 (1998); *Markis v Grosse Pointe Park*, 180 Mich App 545, 551; 448 NW2d 352, 355 (1989). "The motion must be granted if no factual development could justify the plaintiffs' claim for relief." *Spiek*, 456 Mich at 337. In the alternative, the motion should be denied unless the claims are "so clearly unenforceable that no factual development could possibly justify recovery." *El-Khalil v Oakwood Healthcare, Inc*, 504 Mich 152; 934 NW2d 665 (2019); *Varela v Spanski*, 329 Mich App 58, 68; 941 NW2d 60, 66 (2019).

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ANALYSIS

In reviewing the facts alleged in the AG's complaint and the current legal interpretations, this Court must conclude that the claims asserted by the AG are so clearly unenforceable that no factual development could possibly justify recovery. Under the MCPA, "[u]nfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce are unlawful ...." However, the Legislature included an exemption in MCPA § 4(1)(a) that 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." The party claiming the exemption bears the burden of proving its applicability. *Liss*, *supra*. As noted earlier, in *Smith*, *supra* at 465, the Michigan Supreme Court states that the test or inquiry is "whether the general transaction is specifically authorized by law, regardless of whether the specific misconduct alleged is prohibited."

"An elemental tenet of our jurisprudence, stare decisis, provides that a decision of the majority of justices of [the Supreme] Court is binding upon lower courts." *People v. Mitchell*, 428 Mich. 364, 369, 408 N.W.2d 798 (1987). The doctrine of vertical stare decisis, as defined by *Black's Law Dictionary* (10th ed.), p 1626, is "[t]he doctrine that a court must strictly follow the decisions handed down by higher courts within the same jurisdiction." *In re AGD*, 327 Mich App 332, 339 (2019). Thus, when our Supreme Court interpreted the language of the MCPA in *Smith* and *Liss*, the holdings in those decisions are binding and must be followed as this Court does now.

CONCLUSION

Defendant's motion for summary disposition asks this Court to determine whether the allegations in the Complaint assert a valid cause of action for which relief can be granted. In as much as there is a statute that precludes the remedy that Plaintiff seeks, and our Supreme Court

has addressed this issue on multiple occasions, the path forward is clear and dismissal is appropriate. Dismissal of the Complaint forecloses further discussion of the arguments raised by Plaintiff in her cross-motion for summary disposition, which are rendered moot.

SO ORDERED.

In accordance with MCR 2.602(A)(3), this Order resolves the last pending claim and closes the case.

JUL 20 2022
Date

Hon. Wanda M. Stokes
Circuit Court Judge

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PROOF OF SERVICE

I hereby certify that I mailed a copy of the above ORDER to each attorney of record, or upon the parties, by placing the true copy in a sealed envelope, addressed to each, with full postage prepaid and placing said envelope in the United States mail at Mason, Michigan, or by electronic email communication pursuant to MCR 2.107(C)(4) on July 20, 2022.

Christina Beahan
Judicial Assistant to Hon. Wanda M. Stokes

RECEIVED by MSC 5/30/2025 4:48:54 PM

STATE OF MICHIGAN

IN THE CIRCUIT COURT FOR THE COUNTY OF INGHAM

DANA NESSEL,

Plaintiff,

-v- Case No. 22-58-CZ

ELI LILLY AND COMPANY, Hon. Wanda M. Stokes

Defendant.

_____

MOTION FOR SUMMARY DISPOSITION

BEFORE THE HONORABLE WANDA M. STOKES

INGHAM COUNTY CIRCUIT COURT

MASON, MICHIGAN - THURSDAY, JULY 7, 2022

APPEARANCES:

For the Plaintiff: DARRIN FOWLER
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Lansing, Michigan 48933

For the Defendant: TAJ CLAYTON
Kirkland & Ellis, LLP
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Chicago, IL 60654

For the Defendant: MATTHEW SCHNEIDER
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Detroit, Michigan 48226

Reported By: Leslie Fox, CSR-3850
Ingham County Circuit Court

RECEIVED by MSC 5/30/2025 4:48:54 PM

INDEX

WITNESSES:	PAGE:
None.	

EXHIBITS:	MARKED:	ADMITTED:
None Marked.		

RECEIVED by MSC 5/30/2025 4:48:54 PM

Mason, Michigan

Thursday, July 7, 2022

10:42 a.m.

LAW CLERK: All rise.

THE COURT: You may be seated. Good to see all of you. Wow. Darrin, did you call on this?

MR. FOWLER: This is my first time in a courtroom since the pandemic started. I'm thrilled to be here.

THE COURT: Oh, good. Yeah. We enjoy it, has a certain flavor to the advocacy.

MR. Fowler: Absolutely.

THE COURT: You all worked hard on this one. For the record, this is Case Number 22-58-CZ, Dana Nessel, Attorney General, State of Michigan, ex rel, the People of the State of Michigan versus Eli Lilly and Company. I have Counsel present today for cross motions for summary disposition, and I will ask the attorneys to make their appearances beginning with the Plaintiffs.

MR. FOWLER: Thank you, Judge. Assistant Attorney General Darrin Fowler.

MR. HILL: Good morning, Your Honor. Assistant Attorney General Michael Hill.

MR. HAMMAKER: Your Honor, Assistant Attorney General Carl Hammaker.

THE COURT: You have your client here?

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MR. FOWLER: Judge, the Attorney General is the client entity. The Attorney General herself is not here present, but my paralegal Sara Felts is in the courtroom as well as law student Tom Valano.

THE COURT: Good morning. I can say that.

MR. CLAYTON: Good morning, Your Honor. Taj Clayton on behalf of Eli.

MR. SCHNEIDER: May it please the Court, Matthew Schneider on behalf of Eli Lilly.

MR. COOPER: Good morning, Your Honor. Octale Cooper (sic), and I'm observing this morning.

THE COURT: Good morning. I like to know who's here. Okay. As I mentioned earlier, we are here on cross-motion for summary disposition. I'm going to begin with the Defendant's motion for summary disposition and who's going to argue?

MR. CLAYTON: I will, Your Honor. Do you want me to argue from the podium?

THE COURT: Right front and center. Mr. Brooks (sic).

MR. CLAYTON: Good morning, Your Honor. Thank you. So we're here today not because there's a disagreement about whether the MCPA applies to Eli Lilly's sale of its medicines, it does not. Both parties are clear about that in our briefing. So that's not a dispute.

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We're here today because the Attorney General has a disagreement with the Michigan Supreme Court. And in their briefing the Attorney General makes it clear that the outcome at the Trial Court level is a forgone conclusion. They fully intend to take this up with the Supreme Court and air out their arguments there. So the good news is that the resolution of these cross-motions for summary disposition is not in dispute. Both parties agree that binding legal precedent that is well settled and is long standing compels summary disposition in favor of Eli Lilly because it qualifies under the MCPA exemption. And that's an agreement because it's clear from the statute itself, it's clear from Supreme Court precedent, it's clear from legislative action since the Supreme Court precedent has come down and it's clear from the briefing of the parties. So there is a few, a few...

THE COURT: I don't know if it's necessarily clear since the Attorney General doesn't agree with it.

MR. CLAYTON: So that's what I want to focus on.

THE COURT: Alright.

MR. CLAYTON: There are three pretty clear admissions in the briefing to this Court that the Attorney General made that I'd like to highlight. So in their original motion for summary disposition on page 11, the Attorney General wrote that the outcome of this stage of

these proceedings is a forgoing conclusion. It goes on to write that Lilly is correct, that this Court, the Trial Court is bound by Smith and Liss. Smith and Liss of the Supreme Court decision is correctly on point. And then in its reply brief that was filed last week, there's a very clear admission that binding Supreme Court precedent, quote, renders the Michigan Consumer Protection Act inapplicable to the sale of prescription medicines including Lilly's insulin.

So we both have admissions clear that the resolution for the trial stage is not in dispute, and that's based on rock solid longstanding precedent. So the statutory exemption at issue has been on the books since 1976. We briefed about this, but it says that MCPA does not apply to a transaction of conduct specifically authorized under laws administered by a regulatory board or officer acting under statutory authority of this State or the United States. And in the Liss and Smith decisions I just referred to made it clear that the MCPA exemption that I just read applies if the transaction is specifically authorized by law regardless of whether specific misconduct alleged is prohibited.

And so here the issue is, whether the transaction is Eli Lilly's sale of insulin medications. The specific conduct that's alleged in its pricing for those medications

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and representations about those medications.

THE COURT: So it's advertising as well.

MR. CLAYTON: I believe so. I believe that's what the AG wants to look into.

THE COURT: So those, the web sites that they had me look at.

MR. CLAYTON: So under Liss it makes it very clear that when there's applicable law that authorizes licensure to engage in certain types of transactions, that's enough to qualify for the exemption, and that's exactly what we have here. No entity can sell pharmaceuticals without being properly licensed and authorized by the FDA and the Michigan Board of Pharmacy. Those are authorizations that Eli Lilly has, and so we clearly qualify for the MCPA exemption under Liss, under Smith, and under the statute itself.

THE COURT: But are you then saying that the Attorney General still cannot, this exemption is absolute? I mean, the Attorney General as the entity who's trying to make sure that the rights of individuals are being protected, they don't have, the Attorney General doesn't have a right to look at this because Liss and the Supreme Court has said, it's exempt, so do what you want to do, Eli Lilly?

MR. CLAYTON: I think that's right. They can't

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look at it under the MCPA because it's a very clear exemption, and I think they've admitted that in their briefing.

THE COURT: So what are we talking about here then in terms of having an investigation? You're saying that this, the Attorney General just cut off?

MR. CLAYTON: I'm saying that the Attorney General cannot investigate the sale of Eli Lilly's insulin medications under the MCPA. If there are other avenues or other avenues, that's not what's at issue here. The issue here is that there is a very clear exemption that they cannot investigate under that statute exemption.

THE COURT: I'll see what they have to say about that.

MR. CLAYTON: Okay. And so I think from what I've read in the briefing, I think the resolution on these cross-motions for summary disposition are clear. I think binding legal precedent, but there is statutory or there's common law dictates that it has to favor Eli Lilly. But then the Attorney General would like this Court to go above and beyond, take the highly unusual step of issuing an advisory opinion for ultimate fight there and special review with the Michigan Supreme Court.

And I think that issue is problematic for a couple of reasons. First, the Attorney General uses pretty

RECEIVED by MSC 5/30/2025 4:48:54 PM

surprising and over the top rhetoric against the Michigan Supreme Court and the Court here. In their briefing they said that the Supreme Court decisions have perpetrated a, quote, full hoax. They've written that the Michigan Supreme Court precedent has turned MCPA into a, quote, punch line, that the decisions create manifest injustice flowing from the legal analysis, and that the Smith and Liss decisions are, quote, unjustifiable.

And so it's our position that we don't think that the Court should align with the Attorney General in this type of inflammatory disparage and criticism of the Michigan Supreme Court. We think that the resolution of this particular issue at the Trial Court level should focus on the sole issues you need to resolve this issue. And that's whether or not the MCPA exemption applies. The Supreme Court in Michigan has made it clear that the Court should only decide issues necessary to resolve the cases before them without going into extraneous issues. And they've also made it clear that the Supreme Court there, that the Courts should not spend time adjudicating issues over and over and over again, taking time away from other litigants who looking to see their day in Court and for this issue, the Statute on the books since 1976, Smith was handed down in 1999, this issue has been litigated, and it's well settled law.

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THE COURT: Well, it's been litigated, and so doesn't that beg the question, can it be litigated again?

MR. CLAYTON: I think that's a question for the Michigan Supreme Court because I think that's...

THE COURT: How do we get there?

MR. CLAYTON: Sorry?

THE COURT: How do we get there?

MR. CLAYTON: I think, I think the plan by the Attorney General is based on what they briefed is that they will bring this Court before you. They said it's a forgone conclusion, the Court is bound by the Supreme Court decisions so then you'll have to appeal, and then it's a question of whether or not the Supreme Court will take it up.

THE COURT: Isn't that the way it happens, though?

MR. CLAYTON: It is.

THE COURT: So, I mean, I understand your comments about some of the rhetoric. But when we - when we look at what's being attempted here, is that it's an issue that the Attorney General, at least, believes merits review.

MR. CLAYTON: Yeah. I think the Attorney General, sorry.

THE COURT: And, no. And I don't think you would disagree that even the legislature has looked at the statute and has made revisions, and so maybe this is

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another opportunity to do that.

MR. CLAYTON: That's a great point, Your Honor. So on that particular point, if I may, the legislature has been very attuned to the Supreme Court decisions, and since the issuance of Smith and Liss, it's amended the statute multiple times in direct response to the decisions that have come down that's disagreed with, and so it made subsection 42 not applicable to certain insurance misconduct. They made another provision retroactive. It has never touched subsection 41 which is the exemption at issue here. It's kept it intact verbatim which is really good evidence that the Supreme Court jurisprudence and the legislature, 100 percent aligned and consistent with each other, which means that is settled law not only in common law, in case law, but it's also settled law by the legislature. They felt no need to amend subsection 41 at all. And so this is issue where the law is what it is and the AG is really, the only option is to get the Michigan Supreme Court to overturn its previous rulings.

And so for that reason, it's Eli Lilly's position that a ruling is compelled by binding, well settled, well settled, long-standing legal authority in Eli Lilly's favor.

THE COURT: Mr. CLAYTON, I don't have any other questions.

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MR. CLAYTON: Thank you, Your Honor.

THE COURT: Mr. Fowler.

MR. FOWLER: Good morning, Judge.

THE COURT: Good morning.

MR. FOWLER: Eli Lilly's Counsel in answer to a question emphasized that the law as passed by the Michigan Legislation, the Michigan Consumer Protection Act want designed clearly both by its name and its contact to protect consumers from unlawful business activities such as grossly excessive pricing and misrepresentations and the advertising of products is a law that it can in no way be used to protect Michigan consumers against Eli Lilly's business practices. That no matter how much Eli Lilly chooses to charge for it's lifesaving insulin medications, there is nothing that can be done with that law to even investigate, much less vindicate consumer rights. That no matter how misleading Eli Lilly's misrepresentations about the reasons for its pricing on a product like they are, there is absolutely nothing that the State of Michigan can do about it if it's under the Consumer Protection Act because of these Smith and Liss decisions. That absurd statement, that outcome ultimately can be made in this courtroom because of the Smith and Liss decisions. Opposing Counsel pointed out the Michigan Legislature, on behalf of the Michigan Consumer Protection Act 1976. It

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was not until 1999 that the Smith decision came along. That's 23 years later. We're also 23 years since 1999. The Michigan Consumer Protection Act existed as long without these restraints as it has operated since they have been put in place. This is not longstanding precedent. It's been around a little over two decades and changed, and these are at their core decisions that were very poorly reasoned. The cruel hoax language that Counsel criticised of the Attorney General for using during Eli Lilly's presentations, it's actually language that the Michigan Supreme Court found so compelling in describing the kind of construction in section 4 of the Consumer Protection Act that Eli Lilly is here defending today, that it was the Michigan Supreme Court that adopted the Attorney General's description as that construction as a cruel hoax, and that was done by the Michigan Supreme Court in its 1982 decision in the Diamond Mortgage matter.

What happened after Diamond Mortgage for 17 years after Diamond Mortgage, the Michigan Consumer Protection Act proceeded unimpeded by the kind of constraints that came into effect after the Smith and Liss. And what ultimately happened if the rest of what Eli Lilly will perceive as more rhetoric, really is a constructionist's problem and analogous to the game of telephone that we all played in elementary school. A teacher whispers into a

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student's ear a message, that student whispers into another student's ear the message and on down the line until the last one reveals what the original statement got morphed into when the teacher reveals the original statement.

We have tried to demonstrate the beginning and the end in our response brief here, Judge, pointing side by side of the actual statutory language of the section 4, sub 1 exemption, what it actually says, a transaction or conduct specifically authorized by the State or Federal agency. Counsel quoted it more directly than I can standing, but against what Smith and Liss morphed it into a general transaction specifically authorized. What happened over the years is the Diamond Mortgage Court began by looking at the statutory language, issued an appropriate determination that it was a very narrow exception to an act that broadly works to protect consumers, and it's important to emphasize that. The Michigan Supreme Court did in 1987 in its decision in Dixon versus Bankers Trust. There the Michigan Supreme Court pulled all folks in Michigan, construed the Michigan Consumer Protection Act, keep in mind to give a literal construction to protect, to achieve its purpose protecting consumers.

THE COURT: Mr. Fowler, I understand that, but in this, in my environment, I'm compelled to follow what the Supreme Court has said, and it is not ambiguous, and it has

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survived, you know, subsequent decisions. And so for me to now at this point I understand, you know, the Attorney General wants another bite of the apple, but it's not this Court's job to influence or to try in any way change the legislation. It's to follow it, try to make sure we follow it, and the Supreme Court has given us guidance, and that's what I'm compelled to do.

MR. FOWLER: This Court's obligation is actually are two-fold. One to follow the legislation but ultimately follow precedent. The Michigan Supreme Court has put this Court in an unfortunate situation by leaving it on the table in contradiction there. And legislation to compel one outcome yet the Smith and Liss decisions required another. And because the Michigan Supreme Court has told this Court it has to follow its decision even if they're wrong, Eli Lilly is right here acknowledged in our brief, as counsel quoted quite appropriately, this Court's outcome, it is determined, the Attorney General will lose because of these poorly decided Smith and Liss decision. The Court's question to Eli Lilly is also insightful. But the only way the Attorney General to raise through the Michigan Supreme Court's attention, the problems which earlier decisions is to start here in the Circuit Court. So that is what the Attorney General has done well, I think appropriately acknowledging that this Court is bound by

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these precedents. The Attorney General is going to be heard, we know that. But when we start on that premise, I think that the courts in general, the judicial system benefits when decisions are examined and considered. This Court may have to rule against the Attorney General, but Eli Lilly has pointed to no Court decision that says, this Court cannot identify or point up to the Supreme Court for its attention concerns it may have about the analysis coming down from Smith and Liss. And since the Attorney General's position is and our brief demonstrates the Smith and Liss analyses are hard departure from the actual text of the MCPA. We think that the overall process that the Supreme Court goes through would benefit from having that point emphasized by this Court here. This Court sees it obviously.

In that vein, I want to point out in terms of the telephone analogy, how the Smith Court proceeded. In its analysis, the Smith Court did not examine subsection 1 and clearly look at those words and their implications due to context in the case report. Instead, it analyzed the Diamond Mortgage Court because a block quote from that case and then draws a conclusion that it's not even called naturally from the text it had just quoted from Diamond Mortgage. The Smith Court says something, I'm paraphrasing here, in short, the focus, in short, Diamond Mortgage from

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stop spending focuses on the transaction and not the misconduct at issue. That conclusion pulls neither from the Diamond Mortgage text that was quoted and more from the plain language in subsection 41. 41 plainly says, that the exception applies to transaction or conduct specifically authorized. So Smith started reading out the conduct concept by looking at Diamond Mortgage rather than sub 1. The Smith Court goes on to add this qualifier to the word transaction, the word general. That is not in the statute. So then a few years later when the Supreme Court again revisits the MCPA in the context of Liss, it starts literally right from the opening sentence by grabbing ahold of not the statutory language that's at issue, but now the Smith's articulation of that exception that is based on the Diamond Mortgage articulation of that exception.

So Liss takes us even further astute of the statutory language by now reframing the test to be one essentially on whether a general transaction is authorized by law. And in so doing, although the initial part of the holding it uses the specifically authorized language, it later reads specifically even out of it which is the natural effect of adding the word general, and that was so apparent in terms of the effect that Eli Lilly in its response brief of our summary disposition motion, even wrote it the same way. All Eli Lilly needs to show is that

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its sale of these insulin medications is authorized by law. The concept is specifically having disappeared as a practical effect adding the general qualifier to the word transaction.

To clarify a little bit of what the Attorney General is seeking to investigate based on the Court's question to opposing counsel, there are two aspects. The pricing aspect that I believe is clear in terms of the grossly excessive price on the insulin products, but in terms of a misrepresentation at issue in the investigation, that is emphasized at paragraphs 43 through 50 of the ex parte petition, or excuse me, of the petition that sought to initiate this investigation. Specifically, we are talking about the statements that Eli Lilly was making in launching and advertising the authorized generic Lispro. Eli Lilly has made statements suggesting that this lower priced analog insulin is being made available to try to help consumers struggling with the high cost of insulin. We present proofs through the petitions to demonstrate that there were also, at least there's probable cause to believe, there's also other motivations giving rise to the pricing of Lispro such as maintaining the overall structure of grossly excessive pricing on Humalog.

The web sites that we presented to this Court in our most recent response filing were presented for a very

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different purpose. It was to illustrate that the savings program that Eli Lilly has been pointing to throughout its briefing to this Court is having some great benefit that is somehow mute the Consumer Protection Act concerns is really not as solid, doesn't supply the kind of protections that Eli Lilly has been saying it does. In fact, some of the representations Eli Lilly has made are contradicted by statements on the website. For example, attached are two affidavits highlights pricing for consumers who are insured. Eli Lilly has assured this Court everybody under the savings program can pay $35. That website as it still exists this morning, I stand here and argue, the explanation on Lilly's consumer pricing website is that 97 percent of people using its Humalog vial medication or 96 percent of those who use the quick pens are going to pay a price between zero and $95 per month, and those outside, that is the other three or four percent are going to pay an average cost of $345 per month for the vial or $323 for the quick pens. Obviously, when you talk about those averages, $345 a month, $323 a month, there is always people on both sides of the average. We don't from Eli Lilly's website how much above $335 some consumers are having to pay that Humalog medication. What we do know based on the math of Eli Lilly's website, this is hurting 10,000 Michigan consumers who are using Humalog within the State of

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Michigan, at least 3 or 400 who are paying prices of above $95, in that range, that average range of 323 to $345. They also note Eli Lilly caps its savings program at $7,500. You can do the math on some of the Lilly's website and find out its Humalog vials contain 1,000 units Humalog. That's right in the quoted text we provided within our response brief. Right in that website articulation Eli Lilly acknowledges there are some consumers who need as much as a 100 units of insulin per meal. Now, as are admittedly their consumers, they do exist, and everyone should be protected when you're talking about isolating medication. Consumers who needs 100 units of lifesaving medication per meal needs 300 units a day. Three meals a day times 30 days a month is 9,000 units of medication. That's nine vials of medication that Lilly tells us right on that same website costs $372.70 a vial. Buying nine vials a month for 12 months is 108 vials, a hundred vials of lifesaving medication a month times $274.70 a vial, you get your price of $29,667.60, something that is needed to protect the person from a stroke, protect them from blindness, kidney disease, losing their life. A cap of $7,500 in that context comes directly from Lilly's website shows that $7,500 cap is far exceeding that savings program is not going to help them. The savings program does not provide adequate protection for all Michigan consumers. It

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can't protect people who don't know about it.

THE COURT: And, Mr. Fowler, I know this is going more to the merits, but I do recall seeing on that website that it made clear that this program doesn't apply to everybody, may not apply to everyone, so what's wrong with that? I mean it just doesn't.

MR. FOWLER: It helps, it helps many people, certainly, but it doesn't protect everyone which leaves us looking, where can Michigan consumers find protection? Lilly can take away this program tomorrow. It could arrange the price to whatever it wants to with the savings program. Where can Michigan consumers find protection? They can't find it in the Federal Law, the State Law that regulates Lilly as a manufacturer or seller of this medication. Lilly is not here saying that the only law that anyone has identified that could help consumers be protected against grossly excessive pricing from the misrepresentations in the sale of those products, that doesn't apply because of Smith and Liss. And, Judge, that is why the Attorney General is here pointing out this problem, and we very much appreciate your time in reviewing the briefs and hearing the arguments in a case that, unfortunately, the outcome of which is determined in this Court but ultimately one for which we will see addressed at the time Michigan Supreme Court.

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THE COURT: Okay. Thank you, Mr. Fowler.

I'll have final rebuttal from you, Mr. CLAYTON.

MR. CLAYTON: Thank you, Your Honor. Just a few quick points on the facts. So the Attorney General sent briefing in its reply that quoted from Eli Lilly's website. What it did not quote verbatim at the top of the website, it actually had the details and for the $35 per month program that any consumer whether they're insured or not can take advantage of. So that is prominently spelled out on the website.

Number two, an independent objective third party did an analysis and found out that the average Michigan consumer pays $21.80 cents per month for the Eli Lilly insulin medicines. And Eli Lilly has not raised its prices on its medicine since 2017. So those are the facts. But those facts are not dispositive of the motion for summary disposition here today.

Opposing Counsel just talked about his interpretation of the Smith and Liss decisions and alleged that they focus on the transaction piece of the statutory motion. That argument is not dispositive of the issue here, because even under the language of the statute alone, it says transaction or conduct, if it's specifically authorized by law, and here there is no question by either side that the transaction, Eli Lilly's sale of

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pharmaceuticals is specifically authorized under the law and Eli Lilly got authorization from the FDA and the Michigan Board of Pharmacy. And so at the end of the day, it's Eli Lilly's position that the resolution of these motions are not in dispute at the trial court level. And it's our position that the Court should not issue an advisory opinion, and if it does, it should support the long-standing binding precedent that it's bound by.

Thank you, Your Honor.

THE COURT: Thank you, Mr. Brooks.

MR. CLAYTON: No, Clayton.

THE COURT: I'm sorry. Have I been calling you the wrong name?

MR. CLAYTON: Yes.

THE COURT: I absolutely apologize.

MR. CLAYTON: No problem.

THE COURT: I'm better with faces. In this case the Court has gone to great lengths to make sure I try to read everything that's been provided, and while I'm still, I have to admit, I'm still on the fence about advisory orders. I have some concern about those, especially when you're looking at a situation where the law appears to be very clear. And here at the Trial Court level, we have to be very careful that we are addressing the issues that are before us and that we are staying in our lane, if you will,

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with respect to trying to provide an adequate interpretation of what the legislature intended and we base that principally on what has been said before by higher courts and then we in areas that are gray, and I have to admit, I've seen a number of gray issues since being on this bench that surprise me. But where there is a gray area, we do our level best to try to articulate what the statutory language means and how it is to be interpreted within the framework of the laws that we, of the precedent that we have or no precedent within the body of statutory interpretation and the laws that the case law that we do have that exists.

That having been said, I am going to issue a written ruling. I think that's important for this case because I do believe that whoever, I guess it's a matter of perception, but whoever wins or loses will be taking this further. And it's important, what I've learned, it's important that our Court of Appeals who would be the next level that they have an opinion that expresses this Court's position and what this Court believes its role is with respect to this matter, that they have a clear outline of what that is. And so I will issue a written order. I will do that within 10 days. I realize that this is, we moved the dates up because we want to move this case along, and so I'm not going to hold it any longer than I need to. And

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so we will commit to getting an order, a written order out to the parties within 10 days. It will be e-mailed to you even though we are not an electronic filing Court, we will, we will based the Court Rule that allows for electronic communication, we will send you an e-mail version that has been filed and then you can proceed to your next action.

Are there any questions or comments before we adjourn?

MR. CLAYTON: No, Your Honor, thanks.

MR. FOWLER: Judge, we fully thank you for your thoughtful attention to the briefing and arguments.

THE COURT: You're welcome, Mr. Fowler. If nothing more, we're adjourned. Enjoy the rest of your day.

LAW CLERK: All rise.

(At 11:23 a.m., proceedings concluded.)

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STATE OF MICHIGAN)

COUNTY OF CLINTON)

I, Leslie Fox, Certified Shorthand Reporter and Notary Public in and for the County of Clinton, Acting in the County of Ingham, State of Michigan, do hereby certify that the foregoing was taken before me at the time and place hereinbefore set forth.

I FURTHER CERTIFY THAT said witnesses were duly sworn in said cause; that the testimony then given was reported by me stenographically; subsequently with computer-aided transcription, produced under my direction and supervision; and that the foregoing is a true and correct transcript of my original shorthand notes.

IN WITNESS WHEREOF, I have hereunto set my hand and seal this 2nd day of September, 2022.

Leslie Fox

_____

Leslie Fox, CSR-3850

If this opinion indicates that it is "FOR PUBLICATION," it is subject to revision until final publication in the Michigan Appeals Reports.

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STATE OF MICHIGAN

COURT OF APPEALS

ATTORNEY GENERAL,

Plaintiff-Appellant,

v

ELI LILLY AND COMPANY,

Defendant-Appellee.

UNPUBLISHED
June 22, 2023

No. 362272
Ingham Circuit Court
LC No. 22-000058-CZ

Before: RIORDAN, P.J., and BORRELLO and BOONSTRA, JJ.

PER CURIAM.

In this case involving the Michigan Consumer Protection Act (MCPA), MCL 445.901 *et seq*., plaintiff, the Attorney General of Michigan, appeals as of right an order granting summary disposition under MCR 2.116(C)(8) to defendant Eli Lilly and Company. We affirm.

On January 25, 2022, plaintiff filed a petition for civil investigative subpoenas, seeking to "commence an investigation under the MCPA into [defendant's] practices in pricing analog insulin." The MCPA makes unlawful any "[u]nfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce[.]" MCL 445.903(1). Plaintiff also filed a complaint for a declaratory judgment, seeking a declaration that the MCPA "applies to the conduct she seeks to explore in the Petition."

The dispute over whether the MCPA applies involves two Supreme Court opinions, *Smith v Globe Life Ins Co*, 460 Mich 446; 597 NW2d 28 (1999), superseded in part by statute as stated in *Dell v Citizens Ins Co of America*, 312 Mich App 734; 880 NW2d 280 (2015), and *Liss v Lewiston-Richards, Inc*, 478 Mich 203; 732 NW2d 514 (2007). Those opinions interpreted MCL 445.904(1)(a), a provision of the MCPA that exempts from the act "[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." Simply put, the Court in *Smith* and *Liss* concluded that if a general category of conduct or a general transaction is specifically authorized by law, the § 4(1)(a) exemption applies, even if the granular transaction or conduct might otherwise be improper. See *Smith*, 460 Mich at 465 (explaining that the proper inquiry "is whether

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the general transaction is specifically authorized by law, regardless of whether the specific misconduct alleged is prohibited"); *Liss*, 478 Mich at 212 (quoting same).

The trial court concluded that, on the basis of *Smith* and *Liss*, plaintiff's complaint for declaratory relief was not viable as a matter of law because the actions plaintiff sought to investigate were specifically authorized by law. In other words, defendant was authorized by law to manufacture and sell insulin. Thus, the trial court granted defendant's motion for summary disposition and dismissed the case.

Plaintiff filed a claim of appeal in this Court, as well as a bypass application for leave to appeal in our Supreme Court. Our Supreme Court denied the bypass application but directed this Court to "expedite its consideration of this case." *Attorney Gen v Eli Lilly & Co*, ___ Mich ___; 982 NW2d 395 (2022).

This Court reviews de novo a trial court's grant of summary disposition under MCR 2.116(C)(8). *Dalley v Dykema Gossett*, 287 Mich App 296, 304; 788 NW2d 679 (2010). "Questions of statutory interpretation, construction, and application are reviewed de novo." *Johnson v Johnson*, 329 Mich App 110, 118; 940 NW2d 807 (2019).

In the present case, it is not in dispute that defendant manufactures and sells drugs, including insulin, pursuant to licenses issued under Part 177 of the Public Health Code, MCL 333.17701 *et seq*. Clearly, then, under *Smith* and *Liss*, the § 4(1)(a) exemption applies. The trial court correctly reached that conclusion in its order dismissing the case. Indeed, plaintiff concedes in her brief on appeal that "affirmance is currently required in light of *Smith* and *Liss*."

However, plaintiff asserts that, in light of our Supreme Court's denial of her bypass application, our Supreme Court implicitly indicated to this Court that it should consider her arguments that *Smith* and *Liss* were wrongly decided. Plaintiff argues that this Court should issue an opinion urging our Supreme Court to overturn the pertinent holdings in *Smith* and *Liss*. We decline the invitation to do so.

Our Supreme Court is responsible for overturning its own precedent and can do so if it chooses. "It is the duty of the Supreme Court to overrule or modify [its] caselaw . . . , and the Court of Appeals and the lower courts are bound by the precedent established by the Supreme Court until it takes such action." *People v Metamora Water Serv, Inc*, 276 Mich App 376, 387-388; 741 NW2d 61 (2007). We note that our Supreme Court, in other cases, has expressly directed this Court to address one or more specific issues. See, e.g., *People v Samuels*, 507 Mich 928 (2021); *Schutt v Suburban Mobility Auth for Regional Trans*, 507 Mich 897 (2021); *Woodring v Phoenix Ins Co*, 501 Mich 883 (2017). It did not do so here. Thus, the denial of plaintiff's bypass application may signal nothing more than the fact that our Supreme Court concluded that none of the discretionary grounds for granting such an application were satisfied. See MCR 7.305(B)(4).

Affirmed.

/s/ Michael J. Riordan
/s/ Stephen L. Borrello
/s/ Mark T. Boonstra

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Woodger v. Taylor Chevrolet, Inc.

United States District Court for the Eastern District of Michigan, Southern Division

August 25, 2015, Decided; August 25, 2015, Filed

Civil Action No. 14-cv-11810

Reporter
2015 U.S. Dist. LEXIS 112589 *; 2015 WL 5026176

DAVIDA WOODGER, Plaintiff, v. TAYLOR CHEVROLET, INC., Defendants.

Prior History: *Woodger v. Taylor Chevrolet, Inc., 2015 U.S. Dist. LEXIS 182914 (E.D. Mich., Feb. 12, 2015)*

Core Terms

mileage, odometer, intent to defraud, summary judgment, Inconsistency, disclosure statement, discrepancy, parties, genuine issue of material fact, sales agent, disclosure, regulation, transferor, reckless, warning, summary judgment motion, motor vehicle, denies, suggests, argues

Counsel: **[*1]** For Davida Woodger, Plaintiff: Jonathan R. Marko, The Rasor Law Firm, PLLC, Royal Oak, MI; Sarah Marie Thomas, James B. Rasor, Rasor Law Firm, Royal Oak, MI.

For Taylor Chevrolet, Incorporated, Defendant: Michael J. Weikert, Kemp Klein Law Firm, Troy, MI.

Judges: HON. MARK A. GOLDSMITH, United States District Judge.

Opinion by: MARK A. GOLDSMITH

Opinion

OPINION AND ORDER (i) DENYING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT (Dkt. 19) AND (ii) DISMISSING PLAINTIFF'S CLAIM UNDER THE MICHIGAN CONSUMER PROTECTION ACT (COUNT III) WITHOUT PREJUDICE

I. INTRODUCTION

This is a case regarding an inaccurate odometer disclosure statement, with claims brought pursuant to the Motor Vehicle Information and Cost Savings Act, *49 U.S.C. § 32701, et seq.* ("Federal Odometer Act") (Count I), as well as Michigan's odometer disclosure statute, *Mich. Comp. Laws § 257.233a* (Count II), and the Michigan Consumer Protection Act ("MCPA"), *Mich. Comp. Laws § 445.901, et seq.* (Count III). The parties agree that Defendant Taylor Chevrolet, Inc. ("Taylor") sold Plaintiff Davida Woodger a used vehicle, and that Taylor provided an inaccurate odometer disclosure statement during the sale; the statement reflected approximately 10,000 less miles than were actually attributable to the vehicle. However, the parties disagree whether **[*2]** Taylor can be held liable for this error.

The discovery period has ended. Taylor filed a motion for summary judgment (Dkt. 19), Woodger filed a response (Dkt. 28), and Taylor filed a reply (Dkt. 31). The Court heard oral argument on May 21, 2015, and took the matter under advisement. Pursuant to a subsequent Order, the parties then submitted supplemental briefing (Dkts. 37, 38). Because the Court concludes that a genuine issue of material fact exists regarding the "intent to defraud" requirement for Woodger's odometer act claims, the Court denies Taylor's motion for summary judgment. However, because Woodger's claim under the MCPA raises a novel and complex issue of Michigan law, the Court dismisses this claim without prejudice, pursuant to *28 U.S.C. § 1367(c)*.

II. BACKGROUND

The facts of this case are largely undisputed, although the inferences to be drawn therefrom are contested. On October 11, 2013, Taylor acquired a 2011 Nissan Murano from a customer as part of a trade. Def. Br. at 1; Pl. Resp. at 4. The vehicle had 56,160 miles on it, which was reflected on an odometer disclosure statement. Def. Br. at 1; Pl. Resp. at 4; see also 10/11/2013 Odometer Disclosure Statement (Dkt. 19-2).

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At the time of the **[*3]** trade, the vehicle's information — including the mileage — was entered into Taylor's data management system. Def. Br. at 1; Pl. Resp. at 4. It is the job of the title clerk — in this case, Erica Anderson — to take the mileage off the vehicle and put it into the data management system. Def. Br. at 1; Pl. Resp. at 4.

Taylor subsequently submitted an application for title and registration for the vehicle to the State of Michigan. See Application (Dkt. 19-6). On the application, Taylor listed the odometer mileage as "46,160" — 10,000 miles less than when the vehicle was obtained by Taylor. Id. The box in which this mileage was listed warns, "The odometer mileage reading must match the mileage reading disclosed to the purchaser on the title and/or mileage statement." Id. The State of Michigan subsequently issued a certificate of title reflecting a mileage of 46,260. See Certificate of Title (Dkt. 19-7).

Woodger purchased the vehicle from Taylor on November 8, 2013. Id. The odometer disclosure statement that Woodger was provided reflected an odometer mileage of 46,260. See 11/8/2013 Odometer Disclosure Statement (Dkt. 19-8). This same mileage was placed on the assignment of the title. See **[*4]** Certificate of Title (Dkt. 19-7). Both parties agree that this mileage was incorrect, and that the correct mileage was approximately 56,160 miles. See Def. Br. at 1-2; Pl. Resp. at 4-6; Def. Reply at 1-2.

At some point during the sale negotiations with Woodger, Taylor's sales agent obtained a copy of a CARFAX report, which discloses reported information about a car's history. Pl. Resp. at 6-7; Def. Reply at 2; see also T. Schiftar Dep. at 10:10-15 (Dkt. 28-6). The agent showed the report to Woodger, who signed a document acknowledging having been offered the opportunity to see and review the report. Pl. Resp. at 6-7; Def. Reply at 2; see also D. Woodger Dep. at 31:10-33:6 (Dkt. 28-2). Woodger claims that the report the sales agent obtained revealed the mileage discrepancy, but that she was not permitted to review the report in detail or keep it after the sale. Pl. Resp. at 7; see also D. Woodger Dep. at 31:10-33:6.

Woodger brought the vehicle back to Taylor a few days later for the replacement of tires. Def. Br. at 2; Pl. Resp. at 5. At that time, the mileage discrepancy came to the parties' attention. Def. Br. at 2; Pl. Resp. at 5. The parties were unable to resolve the matter informally, **[*5]** Def. Br. at 2; Pl. Resp. at 5, and this lawsuit followed.

III. SUMMARY JUDGMENT STANDARD

A court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *Fed. R. Civ. P. 56(a)*. When a defendant seeks summary judgment, the defendant "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett, 477 U.S. 317, 323, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986)* (quotation marks omitted). "[T]he plaintiff must present affirmative evidence in order to defeat a properly supported motion for summary judgment." *Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 257, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986)*. A mere scintilla of evidence is insufficient; rather, "there must be evidence on which the jury could reasonably find for the [nonmovant]." *Id. at 252*.

When evaluating the evidence on a motion for summary judgment,

> credibility judgments and weighing of the evidence are prohibited. Rather, the evidence should be viewed in the light most favorable to the non-moving party. Thus, the facts and any inferences that can **[*6]** be drawn from those facts must be viewed in the light most favorable to the non-moving party.

Biegas v. Quickway Carriers, Inc., 573 F.3d 365, 373 (6th Cir. 2009) (brackets and citations omitted).

IV. ANALYSIS

Taylor raises two arguments in support of its motion for summary judgment. First, Taylor argues that both the federal and state odometer statutes require "intent to defraud" to hold a seller liable, and there is no evidence of such an intent with respect to the odometer statement here. Instead, Taylor suggests that this simply was a clerical error when the mileage was entered into the data management system. See Def. Br. at 4-7. Second, Taylor argues that its sale of the vehicle is exempt from the MCPA, because the sale is "specifically authorized under laws administered by a regulatory board or officer acting under statutory authority of this state" — in this case, the Michigan Motor Vehicle Code, the Secretary

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of State, and the Bureau of Regulatory Services. Id. at 8-10.

The Court first addresses Taylor's argument regarding an "intent to defraud." The Court concludes that a genuine issue of material fact exists regarding this element, and thus denies Taylor summary judgment on the odometer act claims. However, although the Court denies summary judgment on **[*7]** Counts I and II, the Court dismisses Woodger's MCPA claim (Count III) as raising a novel and complex issue of Michigan law, pursuant to *28 U.S.C. § 1367(c)(1)*.

A. Whether Woodger Has Sufficiently Shown Intent to Defraud

Woodger raises claims under both the federal and Michigan odometer statutes. Congress enacted the Federal Odometer Act, *49 U.S.C. § 32701, et seq.*, because consumers "rely heavily on the odometer reading as an index of the condition and value of a vehicle," and "are entitled to rely on the odometer reading as an accurate indication of the mileage of the vehicle." Id. *§ 32701(a)*. That statute provides, in relevant part, as follows:

> (a)(1) Under regulations prescribed by the Secretary of Transportation that include the way in which information is disclosed and retained under this section, a person transferring ownership of a motor vehicle shall give the transferee the following written disclosure:
> (A) Disclosure of the cumulative mileage registered on the odometer.
> (B) Disclosure that the actual mileage is unknown, if the transferor knows that the odometer reading is different from the number of miles the vehicle has actually traveled.
>
> (2) A person transferring ownership of a motor vehicle may not violate a regulation prescribed **[*8]** under this section or give a false statement to the transferee in making the disclosure required by such a regulation.

Id. *§ 32705(a)*. The National Highway Traffic Safety Administration has, in turn, promulgated regulations requiring the disclosure of odometer mileage and its accuracy. See *49 C.F.R. §§ 580.1*, *580.2*, *580.5(a)*, *(c)*, *(e)*.

The statute also permits enforcement by private parties through civil litigation, and sets forth the permissible relief: "A person that violates this chapter or a regulation prescribed or order issued under this chapter, with intent to defraud, is liable for 3 times the actual damages or $10,000, whichever is greater." *49 U.S.C. § 32710(a)*. The statute further allows for recovery of costs and reasonable attorney fees. Id. *§ 32710(b)*.

Michigan similarly regulates the provision of odometer mileage information upon selling a vehicle. *Michigan Compiled Laws § 257.233a* provides, in relevant part, as follows:

> (1) When the owner of a registered motor vehicle transfers his or her title or interest in that vehicle, the transferor shall present to the transferee before delivery of the vehicle, written disclosure of odometer mileage by means of the certificate of title or a written statement signed by the transferor including the transferor's printed name, containing all of **[*9]** the following:
> (a) The odometer reading at the time of transfer not to include the tenths of a mile or kilometer.
> * * *
> (g) One of the following:
> (i) A statement by the transferor certifying that to the best of his or her knowledge the odometer reading reflects the actual mileage of the vehicle.
> (ii) If the transferor knows that the odometer reading reflects the amount of mileage in excess of the designed mechanical odometer limit, a statement to that effect.
> (iii) If the transfer [sic] knows that the odometer reading differs from the mileage and the difference is greater than that caused by odometer calibration error, a statement that the odometer reading does not reflect the actual mileage and should not be relied upon. This notice shall include a warning notice to alert the transferee that a discrepancy exists between the odometer and the actual mileage.

Mich. Comp. Laws § 257.233a(1). Like its federal counterpart, the state statute also sets forth the penalties for non-compliance: "A person who, with intent to defraud, violates any requirement under subsection (1) . . . is liable in an amount equal to 3 times the amount of actual damages sustained or $1,500.00 whichever is greater, and in the case of a successful recovery of damages, **[*10]** the costs of the action together with reasonable attorney's fees." Id. *§ 257.233a(15)*.

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Both the federal and state statutes require an "intent to defraud." See *49 U.S.C. § 32710(a)*; *Mich. Comp. Laws § 257.233a(15)*. Taylor argues that "there is absolutely no evidence of any intent to defraud on behalf of the Defendant and the facts clearly show a mistake on behalf of the dealership." Def. Br. at 5. Taylor suggests that, "it appears that the title clerk for the dealership made a mistake and accidentally entered the mileage for the Vehicle into the data management system as 46,160 instead of 56,160." Id. Taylor also asserts that "[i]t is not plausible that a class 'A' auto dealer in the state of Michigan would put its dealer license at risk to attempt to defraud the Plaintiff with respect to a 10,000 mileage discrepancy when the difference in value is negligible and only in the range of $575.00 to $776.00." Id. at 6-7.

Woodger responds that a question of fact exists as to Taylor's intent to defraud. Pl. Resp. at 9-16. Woodger first argues that, pursuant to *Michigan Compiled Laws § 257.233a(14)*, Taylor's provision of a false odometer disclosure statement is prima facie evidence of a fraudulent act. Id. at 10. Woodger also argues that the "intent to defraud" requirement can be satisfied based on Taylor's failure **[*11]** to take steps to verify the accuracy of the disclosure statement. Id. at 11. In support of this argument, Woodger asserts that: (i) the CARFAX report at the time of the sale reflected a mileage discrepancy, but Taylor failed to investigate this issue; and (ii) Taylor's sales agent rushed Woodger through the sales transaction and did not print the CARFAX report or permit Woodger to examine it in detail, instead having her sign a waiver — as part of numerous other documents during the process — acknowledging that she had seen the report. Id. at 13-15.

A threshold issue exists regarding the proper interpretation of the phrase "intent to defraud" in the odometer statutes. Woodger suggests that the term goes beyond willful conduct, also encompassing a reckless standard, i.e., where the seller closes its eyes to a glaring deficiency. Indeed, Woodger claims that the "dealership's assertion that a clerical error occurred on the paperwork is not a legal excuse," because "the standard of review . . . is whether the transferor may have had reason to know of the mileage discrepancy." Pl. Resp. at 14 (emphasis removed).

The Sixth Circuit might well disagree with Woodger's interpretation for purposes of the federal statute. **[*12]** In *Paul's Auto World v. Boyd, 881 F.2d 1077 (Table), 1989 U.S. App. LEXIS 11648, *4, 1989 WL 88484, at *2 (6th Cir. 1989)*, the Sixth Circuit set forth the requirements for establishing liability under the predecessor to the current federal statute. The court concluded that the phrase "intent to defraud" requires a showing of a "'willful' act done with specific intent to deceive a purchaser of the mileage on a car." Id. This suggests that recklessness is not sufficient. See also *Moss v. Farr Motor Co., Inc., 82 F.3d 418 (Table)* [published in full-text format at *1996 U.S. App. LEXIS 12165*], 1996 WL 166734, *2 (6th Cir. Apr. 9, 1996) (uncertainty as to the accuracy of the odometer is insufficient; liability requires that the defendant knew the mileage on the odometer was false).

Even the authority Woodger cites in support of her reckless standard recognizes the Sixth Circuit's stricter "willful" requirement. In *Haynes v. Manning, 917 F.2d 450, 453 (10th Cir. 1990)*, the Tenth Circuit joined the majority of courts in holding that "reckless disregard is sufficient to prove intent to defraud" for the federal odometer statute. In so holding, however, the Haynes court expressly rejected the position taken by the Eastern District of Tennessee — and affirmed by the Sixth Circuit — that "'intent to defraud' means 'to act willfully and with the specific intent to deceive any purchaser or potential purchaser of a motor vehicle who inspects the odometer of a motor vehicle as an index of the condition and value of such **[*13]** vehicle." Id. (citing *Shipe v. Mason, 500 F. Supp. 243, 245 (E.D. Tenn. 1978)*, aff'd, *633 F.2d 218 (Table) (6th Cir. Sept. 29, 1980)*). At least one other district court in this circuit has similarly looked to Sixth Circuit law in concluding that a plaintiff's reliance on a gross negligence or reckless standard was not persuasive. See *Scherber v. Online Auctions, LLC, No. 13-530, 2014 U.S. Dist. LEXIS 111492, 2014 WL 3908114, at *3 (N.D. Ohio July 3, 2014)*. But see *Nabors v. Auto Sports Unlimited, Inc., 475 F. Supp. 2d 646, 652 (E.D. Mich. 2007)* (holding, without explanation, that "to show an intent to defraud under the Act, [the plaintiff] must show an intentional violation or that Auto Sports exhibited a reckless disregard for the truth as to the Jeep's mileage").[1]

Nevertheless, the Court need not resolve this issue, as Woodger has raised a genuine issue of material fact

[1] The Nabors court cited *Jones v. Hanley Dawson Cadillac Co., 848 F.2d 803 (7th Cir. 1988)* in support of its statement that a plaintiff under the federal odometer statute must show either an intentional or reckless violation; however, Jones held only that mere negligence was insufficient to establish an intent to defraud.

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even at the higher "wilfull" level. Woodger's argument focuses almost exclusively on her allegations regarding the CARFAX report. In particular, Woodger claims that the report shown to her at the time of the sale revealed a mileage discrepancy, but that Taylor's agent rushed her through the sale and did not permit her to carefully review **[*14]** the report, which would have revealed the problem. Woodger asserts that the evidence can support a finding that the sales agent "noticed the mileage inconsistency, pushed through the sale despite the inconsistency, and intentionally withheld the CARFAX report from Plaintiff, knowing that there was a [mileage inconsistency] warning." See Pl. Supp. Br. at 3 (Dkt. 38); Pl. Resp. at 13-14.

In support of her claim, Woodger has provided a CARFAX report that was generated on or around December 4, 2013 — nearly a month after the sale. See CARFAX Report (Dkt. 28-5); see also Compl. ¶ 20 (Dkt. 1). This report contains an entry dated October 12, 2013, which reveals both a mileage of 46,160 and the following statement: "MILEAGE INCONSISTENCY[.] The mileage reported here conflicts with this vehicle's odometer history. Ask a mechanic or the seller to confirm the actual mileage — this entry may just be a clerical error." CARFAX Report (Dkt. 28-5); see also id. ("Odometer Check[.] Inconsistent mileage indicated."). Woodger claims the notifications in this report suffice for purposes of showing an intent to defraud, because they suggest that Taylor's agent knew or recklessly disregarded the mileage **[*15]** issue.

Although the CARFAX report that Woodger has provided was generated a month after the sale, the Court concludes that there is a genuine issue of material fact whether the report at the time of sale, i.e., November 2013, contained the same information. After the hearing on Taylor's motion, the Court ordered the parties to submit supplemental briefing setting forth any and all evidence regarding "[w]hether the [December 2013] CARFAX report . . . contained the same information — and, in particular, the 'Mileage Inconsistency' warnings on pages 2 and 4 of 5 of the report — at the time of the November 2013 sale." 7/28/2015 Order (Dkt. 36). Although Taylor filed a supplemental brief disputing whether the November 2013 report contained the actual "Mileage Inconsistency" warnings, Taylor appears to have conceded that the November 2013 report did state that there were approximately 46,000 miles on the vehicle. See Def. Supp. Br. at 2 (Dkt. 37) ("Plaintiff's pleading supports the fact that the CARFAX presented to Plaintiff showed 46,000 miles on the Vehicle and did not show any sort of mileage inconsistency."). Woodger similarly testified in her deposition that the CARFAX report she was shown at **[*16]** the time of the sale disclosed a mileage of 46,000. See D. Woodger Dep. at 30:16-31:1 (Dkt. 28-2).

The 46,160 mileage reading appears in the October 12, 2013 line entry on the report — the same line entry containing one of the "Mileage Inconsistency" warnings. While Taylor's counsel argued at the motion hearing that this entry was not added to the report until after the sale of the vehicle to Woodger (a point he admitted was not in the record), see Rough Tr. at 15-18, this is belied by Taylor's most recent briefing, in which Taylor sets forth that Woodger's complaint supports "the fact that the CARFAX presented to Plaintiff showed 46,000 miles on the Vehicle." (Emphasis added). Therefore, given that Taylor now appears to concede that the October 12, 2013 entry showing 46,160 miles appeared on both the November 2013 and December 2013 reports, the Court concludes that, taking all inferences in Woodger's favor, the evidence supports a finding that the "Mileage Inconsistency" warning that is included in that same line entry was on both reports as well. This is a logical conclusion, given that the "Mileage Inconsistency" warning likely resulted from the discrepancy between the October 12, **[*17]** 2013 entry (46,160 miles), and the September 21, 2013 entry immediately preceding it (55,319 miles).

The Court also finds that a genuine issue of material fact exists regarding Taylor's knowledge about the mileage issue. Taylor's sales agent testified that he gave Woodger a "clean CARFAX, no accidents, no damage." T. Schiftar Dep. at 10:14-15 (Dkt. 28-6). This suggests that the sales agent at least reviewed the report prior to giving it to Woodger; otherwise, he could not have known that the CARFAX report revealed "no accidents, no damage." Id. And given that Taylor concedes that the November 2013 report revealed a mileage of 46,160, and the report showed a mileage of 55,319 directly above that, a reasonable factfinder could infer that the sales agent was aware of the mileage problem but did not correct the odometer disclosure statement, thereby potentially satisfying the "intent to defraud" requirement under either a "wilfull" or "reckless" standard.

Taylor's arguments in favor of summary judgment are not well taken. Taylor claims that this was nothing more than a clerical error committed by the title clerk. See Def. Br. 5-6. In support of this argument, Taylor highlights testimony **[*18]** that the title clerk ultimately

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was terminated due to making mistakes. Id. Taylor also claims that it is "not plausible that a class 'A' auto dealer in the state of Michigan would put its dealer license at risk to attempt to defraud the Plaintiff with respect to a 10,000 mileage discrepancy when the difference in value is negligible and only in the range of $575.00 to $776.00." Id. at 6-7.

While these arguments are appropriate for Taylor to make before the ultimate factfinder, they are premised on credibility determinations and disputed facts, which are inappropriate on summary judgment. In light of the inferences that can be drawn from the evidence discussed earlier, as well as the fact that those inferences must be viewed in the light most favorable to Woodger at this time, the Court concludes that a genuine issue of material fact exists regarding Taylor's intent to defraud. Summary judgment is, therefore, inappropriate.[2]

Accordingly, the Court denies Taylor's motion as to Counts I and II, the federal and Michigan odometer act claims, respectively.[3]

B. The MCPA Claim

Although the Court denies Taylor's motion for summary judgment on Woodger's claims under the federal and Michigan odometer acts, the Court dismisses Woodger's claim under the MCPA (Count III) without prejudice. The parties dispute whether this sales transaction, and thus Taylor, is exempt from MCPA liability in this case. Taylor cites broad language from a Michigan Supreme Court decision, as well as language from Justice Cavanagh's separate opinion in that case, in support of its position that the MCPA cannot apply. Def. Br. at 8-10 (citing *Smith v. Globe Life Ins. Co., 460 Mich. 446, 597 N.W.2d 28 (Mich. 1999)*). Woodger responds by citing an older Michigan Court of Appeals decision. See Pl. Resp. at 16-19 (citing *McRaild v. Shepard Lincoln Mercury, 141 Mich. App. 406, 367 N.W.2d 404 (Mich. Ct. App. 1985)*).

Taking Taylor's theory to its logical conclusion, any

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[2] In its supplemental brief, Taylor raises a new argument — that it cannot be liable for fraud based on the CARFAX report, because Woodger reviewed the report and, thus, "would have been on notice that representations regarding the mileage of the vehicle may have been inaccurate." **[*19]** Def. Supp. Br. at 3-4. This is an issue raised for the first time in Taylor's supplemental brief, and it goes beyond the bounds of the limited issue the Court asked the parties to address in supplemental briefing: whether the November 2013 report contained the same information as the December 2013 report. See 7/28/2015 Order. The Court, thus, refuses to consider this argument at this time. See *Trustees of the Painters, Union Deposit Fund v. G&T Comm. Coatings, Inc., No. 13-13261, 2014 U.S. Dist. LEXIS 81792, 2014 WL 2743340, at *2-3 (E.D. Mich. June 17, 2014)* (rejecting interpretation of a fringe benefit clause that was raised for the first time in a supplemental brief, because this was "far beyond the appropriate time to assert a new argument"); *United Am. Healthcare Corp. v. Backs, 997 F. Supp. 2d 741, 747 (E.D. Mich. 2014)*; see also *Howard v. Pierce, 738 F.2d 722, 723 n.2 (6th Cir. 1984)* (refusing to consider argument raised for the first time in a reply brief).

Moreover, Taylor cites *The Mable Cleary Trust v. The Edward-Marlah Muzyl Trust, 262 Mich. App. 485, 686 N.W.2d 770, 783 (Mich. Ct. App. 2004)*, in support of its claim that it cannot be liable if Woodger was "either presented with the information and chose to ignore it or had some other indication that further inquiry was needed." Def. Supp. Br. at 3. However, in *Titan Insurance Co. v. Hyten, 491 Mich. 547, 817 N.W.2d 562 (Mich. 2012)*, the Michigan Supreme Court held that to the extent Mable Cleary Trust "can be read to support the proposition that a party has an independent duty to investigate and corroborate representations, we overrule Mable Cleary Trust." *Id. at 555, n.4*.

In addition, Woodger alleges that although she **[*20]** was shown the report, she was not permitted to examine it or keep a copy of it. See D. Woodger Dep. at 31:2-4. Viewing all inferences in Woodger's favor, a reasonable factfinder could conclude that this was because the sales agent knew of the mileage issue in the report and did not want Woodger to see it, as described above. This would undermine Taylor's suggestion that Woodger was adequately presented with information that she chose to ignore.

[3] Woodger relies on *Michigan Compiled Laws § 257.233a(14)* to support her argument that a false odometer statement is prima facie evidence of a fraudulent act, but this is a red herring. Pl. Resp. at 10. That provision establishes that a false statement can constitute prima facie evidence of a fraudulent act for purposes of *section 249*, which deals with the Secretary of State's authority to deny, suspend, or revoke a dealer's license if the Secretary finds that the "[t]he applicant or licensee has been guilty of a fraudulent act in connection with selling . . . vehicles of a type required to be registered under this act." See *Mich. Comp. Laws § 257.249(d)*. *Michigan Compiled Laws § 257.233a(14)* says nothing about establishing prima facie **[*21]** evidence of fraud for purposes of *section 257.233a(15)* — the provision establishing civil liability for a violation that was committed with "intent to defraud." Nevertheless, given the actual evidence discussed above, the Court finds that summary judgment is not appropriate.

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transaction that is in any way regulated by a governmental board or officer acting under statutory authority, even minimally, would be wholly exempt from the MCPA. Such a far reaching interpretation could, potentially, eviscerate **[*22]** the protections the statute was designed to provide. This complex and novel issue requires interpreting the scope of an important state statute and a Michigan Supreme Court decision's discussion of that statute, which the Court believes would best be addressed by Michigan's courts, particularly given the parties' cursory briefing on this issue before this Court. Therefore, the Court declines to exercise supplemental jurisdiction over this claim, and dismisses it without prejudice. See *28 U.S.C. § 1367(c)(1)*.

V. CONCLUSION

For the foregoing reasons, the Court denies Defendant Taylor's motion for summary judgment (Dkt. 19) regarding Counts I and II, but dismisses Count III without prejudice.

The Court will issue an amended scheduling order setting new dates for the settlement conference, final pretrial conference, and trial, as well as due dates for the final pretrial order and non-dispositive motions. All other aspects of the Court's Case Management and Scheduling Order remain in effect (Dkt. 8).

SO ORDERED.

Dated: August 25, 2015

Detroit, Michigan

/s/ Mark A. Goldsmith

MARK A. GOLDSMITH

United States District Judge

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STATE OF MICHIGAN
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.

Case No. 2022-000009-PZ
Hon. JOYCE DRAGANCHUK

RESPONDENT ELI LILLY AND COMPANY'S MOTION TO STAY

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Appellant's Appendix
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RESPONDENT ELI LILLY AND COMPANY'S MOTION TO STAY

By this motion, Respondent Eli Lilly and Company ("Lilly") moves to stay all proceedings in this matter pending resolution of the Attorney General's simultaneously filed declaratory judgment action (No. 22-58-CZ, Ex.A), which directly and exclusively concerns the Attorney General's legal authority to proceed against Lilly under the Michigan Consumer Protection Act ("MCPA"). In support of this motion, Lilly states as follows:

1. Lilly is a pharmaceutical manufacturer licensed to sell its products, including insulin medications, in the State of Michigan.

2. On January 25, 2022, the Attorney General simultaneously filed two actions in the 30th Judicial Circuit Court related to Lilly's insulin sales: (1) this case (No. 22-9-PZ), in which the Attorney General filed a petition for authorization to issue investigative subpoenas under the MCPA; and (2) a declaratory judgment action seeking a determination that the Attorney General has authority to proceed with the investigation and with future litigation against Lilly under the MCPA, notwithstanding binding Michigan Supreme Court precedent exempting Lilly's alleged conduct from MCPA liability. *See generally Liss v. Lewiston-Richards, Inc.*, 478 Mich. 203; 732 N.W.2d 514 (2007); *Smith v. Globe Life Ins. Co.*, 460 Mich. 446; 597 N.W.2d 28 (1999); MCL 445.904(1)(a).

3. The Attorney General has repeatedly acknowledged that any MCPA action against Lilly is barred under settled precedent, but still hopes to "tee[] up the *Smith* and *Liss* issue" for appeal in light of the Attorney General's view that those cases "were wrongly decided." Dep't of Att'y Gen., Press Release, *AG Nessel Launches Investigation into Excessive Insulin Prices, Intends to Challenge MSC Decisions Impacting Consumer Protection* (Jan. 26, 2022), https://bit.ly/3vcGEhx; Decl. J. Compl. ¶¶ 23-24 (recognizing that, under *Liss* and *Smith*, "the

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MCPA does not apply to the" challenged conduct).

4. The day after this action was filed, on January 26, 2022, the Honorable Judge Jamo, acting for this Court, authorized the Attorney General to issue subpoenas pursuant to the MCPA against Lilly and Express Scripts Inc. ("ESI"—an independent pharmacy benefit manager), in connection with Lilly's sale of insulin medications. The Attorney General has not yet issued any such subpoenas, but has since served Lilly with the petition in this action and the complaint in the declaratory judgment action and has informed Lilly that she intends to serve a subpoena on Lilly soon.

5. As the Attorney General has repeatedly acknowledged, the pure legal question concerning the scope of the Attorney General's authority under the MCPA is dispositive for any subpoena, investigation, or lawsuit relating to the sale of insulin medications in Michigan because current Supreme Court precedent renders such actions ultra vires and contrary to law.

6. That critical issue is the sole question presented in the declaratory judgment action.

7. Lilly intends to file a response to the declaratory judgment action on or before March 28, 2022.

Accordingly, and as further set forth in its accompanying brief, Lilly respectfully requests that the Court stay all proceedings in this action, including issuance of any subpoenas, until the dispositive legal question of the MCPA's scope is resolved in the Attorney General's pending declaratory judgment action. Doing so will help avoid duplicative proceedings; unnecessary burdens on the parties, third parties, and Court; and the potential need to litigate other defenses and objections. *See generally* MCR 1.105 (requiring "the parties and the court" to "construe[], administer[], and employ[]" the Michigan Court Rules "to secure the just, speedy, and economical determination of every action"); *Dietz v. Bouldin*, 579 U.S. 40, 47 (2016) (courts have "inherent

power to stay proceedings pending resolution of parallel actions in other courts" (citing *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936), which found this "power inherent in every court")); *Banta v. Serban*, 370 Mich. 367, 368; 121 N.W.2d 854 (1963) ("recogniz[ing] the inherent power of a court to control the movement of cases on its docket").

Respectfully submitted,

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STATE OF MICHIGAN
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.

Case No. 2022-000009-PZ
Hon. JOYCE DRAGANCHUK

BRIEF IN SUPPORT OF RESPONDENT ELI LILLY AND COMPANY'S MOTION TO STAY

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I. INTRODUCTION

Respondent Eli Lilly and Company ("Lilly") respectfully requests a stay of proceedings in this matter pending final resolution of the Attorney General's declaratory judgment action in Case No. 22-58-CZ (Ex. A). The Attorney General herself has already made the case for a stay. As she candidly put it in her declaratory judgment complaint, "it would be a waste of resources for the Attorney General"—not to mention the Court and Lilly—"to proceed with this investigation only to have" the courts confirm that the whole endeavor is ultra vires. Decl. J. Compl. ¶ 24. And, to be clear, it is undisputed that this investigation *is* ultra vires under settled law. The Court should not permit the Attorney General to proceed with an investigation that she admits is unlawful under binding Michigan Supreme Court precedent.

The Attorney General's filings speak for themselves. The Attorney General wants to investigate Lilly for potential violations of the Michigan Consumer Protection Act ("MCPA") arising from Lilly's sale of insulin. But, as the Attorney General again recognizes, Lilly's sales of insulin are exempt from MCPA liability under the Supreme Court's binding opinions in *Smith* and *Liss*. *Id.*; *see Liss v. Lewiston-Richards, Inc.*, 478 Mich. 203; 732 N.W.2d 514 (2007); *Smith v. Globe Life Ins. Co.*, 460 Mich. 446; 597 N.W.2d 28 (1999). That "current MSC precedent" is the whole "reason" the Attorney General simultaneously filed the "Complaint for Declaratory Judgment": Her planned investigation depends on getting those decisions overturned, and the declaratory judgment posture is the mechanism to try to achieve that goal. Dep't of Att'y Gen., Press Release, *AG Nessel Launches Investigation into Excessive Insulin Prices, Intends to Challenge MSC Decisions Impacting Consumer Protection* (Jan. 26, 2022), https://bit.ly/3vcGEhx (explaining that "[a] Complaint for Declaratory Judgment teeing up the *Smith* and *Liss* issue was filed contemporaneously with the Petition" and that the Attorney General "is prepared to follow the appellate track").

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Accordingly, there is only one viable path forward to save the Court and the parties from the pointless burdens of an investigation that will inevitably fail under settled law: stay all activity here until the Attorney General receives a definitive answer to her question in the declaratory judgment action. Although the Honorable Judge Jamo, acting for this Court in the petition action, immediately responded to the petition by authorizing the Attorney General to issue subpoenas to both Lilly and third-party Express Scripts Inc. ("ESI"—an independent pharmacy benefit manager allegedly involved in insulin sales but who is not a defendant in either action),[1] any attempt by the Attorney General to actually do so and proceed with an investigation into Lilly's challenged conduct—to say nothing of bringing an enforcement suit—will be ultra vires unless and until the Supreme Court takes the dramatic and unlikely step of overruling longstanding precedent. Rather than force Lilly to participate in an investigation that contravenes settled law, that this Court lacks the authority to authorize, and that can be saved only by reversal of binding authority on appellate review, the Court should stay proceedings in this matter and allow the parties to litigate the dispositive legal question already "tee[d] up" in the "contemporaneou[s]" declaratory judgment action—just as the Attorney General intended. Dep't of Att'y Gen., Press Release, *supra*.

II. ARGUMENT

In pursuit of her misguided belief that Lilly has misrepresented the reasons for its pricing of various insulin medications in Michigan—including Lilly's reasons for ***decreasing*** prices, no less—the Attorney General simultaneously initiated two judicial proceedings on January 25, 2022. The first is the petition in this case, in which the Attorney General expressly waived her right to proceed *ex parte* and asked for authority to "issue subpoenas" to Lilly and ESI that the Attorney

[1] Lilly, of course, reserves the right to raise all objections and defenses to any subpoena the Attorney General may attempt to issue under that authorization.

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General plans to use to compel records, testimony, and other information relating to purported MCPA violations. *See* MCL 445.907; No. 22-9-PZ Petn. ("Petn.") at 4, 32-33. The second is a single-count declaratory judgment action in which the Attorney General seeks to overturn long-settled Supreme Court precedent so the Court can then declare that the MCPA applies to Lilly's alleged conduct. *See* Decl. J. Compl. ¶¶ 25-28. In that suit, the Attorney General has indicated that she plans to investigate Lilly, issue subpoenas in support of her investigation (including to Lilly and third parties, like ESI), and ultimately "bring [an] actio[n]" against Lilly. *Id.* ¶¶ 11, 28. But, as she plainly recognizes, licensed entities' regulated conduct, including the sale of pharmaceuticals by licensed manufacturers like Lilly, is exempt from MCPA liability under MCL 445.904(1)(a) according to the Supreme Court's plain-text construction of the statute in *Liss* and *Smith*. *See* Dep't of Att'y Gen., Press Release, *supra* (recognizing that those precedents provide "a broad shield for regulated entities" and "will hold significant weight in [the Attorney General's] ability to pursue action against Eli Lilly").

Those decisions, which accurately reflect the "Legislature's intent [and] the statutory text," *Liss*, 478 Mich. at 207, will indeed present at least two dispositive barriers to the Attorney General as this matter proceeds. First, they provide an obvious basis to immediately quash any subpoena that the Attorney General seeks to issue regarding Lilly's sale of pharmaceuticals. Under *Liss* and *Smith*, conduct is exempt from MCPA liability if "the ***general*** transaction" at issue (*e.g.*, the sale of pharmaceuticals) "is specifically authorized by law, regardless of whether the ***specific misconduct alleged***" (*e.g.*, overcharging or misrepresenting) "is prohibited." *Liss*, 478 Mich. at 206 (emphases added) (quoting *Smith*, 460 Mich. at 465). And a "general transaction … is 'specifically authorized'" if a licensure scheme "defines" who can engage in the activity and generally excludes "non-licensed" entities from participating. *Id.* at 213-15. There is no dispute

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here that the Michigan Board of Pharmacy and FDA authorize the sale of insulin in Michigan. Because federal and state law impose "licensure requirement[s]" on Lilly's sales, the law "'specifically authorizes' [Lilly's] engage[ment] in" those sales for the purpose of the MCPA exemption. *Id.* at 214 n.39.

The Attorney General's candid admission is thus exactly right: "[I]t would be a waste of resources" to force everyone involved to litigate "motion[s] to quash" and engage in costly and complex discovery disputes when the settled interpretation of the MCPA already provides a clear answer. Decl. J. Compl. ¶ 24. That is true even though the Attorney General thinks that binding precedent was "wrongly decided or has become obsolete"; the Attorney General (and, of course, "the Court of Appeals and all lower courts") is "bound" to follow it under "the fundamental principle that only the Supreme Court has the authority to overrule one of its prior decisions." *State Treasurer v. Sprague*, 284 Mich. App. 235, 242; 772 N.W.2d 452 (2009) (brackets and quotations omitted) (collecting cases).

Granted, all that issuance of a subpoena would ultimately produce (besides expense and prejudice for Lilly and others, and additional press releases from the Attorney General[2]) is confirmation that Lilly is indeed deeply committed to ensuring that anyone with a prescription for Lilly insulin can access it affordably—something the Attorney General presumably already knows based on widely available information.[3] But to avoid any doubt, Lilly will say it again here: Anyone is eligible to purchase their monthly prescription of Lilly insulin for ***$35 or less***—

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[2] *See* Dep't of Att'y Gen., Press Release, *supra* (inviting public commentary on the litigation and admitting that settled law is against the Attorney General).

[3] *See, e.g.*, Eli Lilly and Company, https://www.insulinaffordability.com/ (last visited Mar. 7, 2022) (providing simple instructions to patients about how to acquire their prescriptions of Lilly insulin for $35 per month).

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regardless of the number of pens or vials prescribed, and regardless whether a patient is uninsured or uses commercial insurance, Medicaid, or a participating Medicare Part D plan.[4] And the average monthly out-of-pocket cost for a prescription of Lilly insulin (regardless of the number of pens or vials used) is currently $22.59, or about $9 per vial—not "nearing $100" per vial as the Attorney General wrongly claims. *See, e.g.*, Dep't of Att'y Gen., Press Release, *supra*.

Lilly is proud of its efforts to promote affordable access to insulin. But nothing entitles the Attorney General to compel Lilly to participate (at great expense and inconvenience) in a sweeping investigation that is wholly and admittedly premised on an impermissible exercise of the limited authority the Legislature codified in the MCPA. So rather than require the parties to engage in ultimately pointless and wide-ranging subpoena disputes piecemeal, it makes far more sense—as the Attorney General has already indicated—"to resolve th[e] controversy" over that pure legal question "at the inception" by pausing this matter until the declaratory judgment action has concluded. Decl. J. Compl. ¶ 24.

Second, even if the Attorney General were somehow able to overcome a motion to quash and proceed with this investigation, the fact remains, to borrow the Attorney General's words, that Lilly ***still*** could raise the exemption for regulated conduct "as a defense in [an ensuing] lawsuit under the MCPA." *Id.* Again, there is no room for serious debate about the current state of the law. Under *Liss* and *Smith*—which remain binding until overruled by the Supreme Court—the MCPA exemption applies to the conduct the Attorney General contends is unlawful (the sale of regulated medications) because that general conduct is "authorized" by law for purposes of the MCPA. *Liss*, 478 Mich. at 213-15; *see* Decl. J. Compl. ¶ 21 ("Lilly holds a manufacturer's license

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[4] *See* Note 3, *supra*.

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issued by the Michigan Board of Pharmacy, and four licenses for the wholesale distribution of its medications"). In any event, the dispositive legal issue—whether to overrule longstanding precedent—will be fully briefed in the declaratory judgment action. There is no need to force the parties to brief the same issue in two separate proceedings, especially when the issue is settled under Supreme Court law and can be "overrule[d] or modif[ied]" by that Court alone. *Sprague*, 284 Mich. App. at 242.

Lilly thus respectfully submits that the only path consistent with this Court's authority under *Liss* and *Smith*, and the best way to "save the parties, the [C]ourt, and society ... costly time and litigation expense[s]," *Dietz v. Bouldin*, 579 U.S. 40, 47 (2016), is to follow the Attorney General's initial plan as represented to this Court: litigate the pure legal question about the scope of the MCPA's exception in the declaratory judgment posture. *See Detroit Base Coal. for Human Rights of the Handicapped v. Dep't of Soc. Servs.*, 431 Mich. 172, 191; 428 N.W.2d 335 (1988) (a "declaratory judgment [is] a broad, flexible remedy" capable of "sharpening ... the issues raised"); Petn. at 4. Because Lilly is virtually certain to prevail on that pure legal question unless and until the Supreme Court overrules its on-point precedent, there is no reason to expend judicial and party resources litigating a motion to quash and engaging in other investigation-related disputes (let alone an eventual lawsuit). *See, e.g.*, Decl. J. Compl. ¶ 23 (insisting that precedent immunizing Lilly was "wrongly decided"); Petn. at 4, 31 & n.94 (same).

III. CONCLUSION

This Court should not permit complex and wasteful litigation over subpoenas that the Attorney General may attempt to issue to Lilly (and perhaps other third parties) when a dispositive legal question that the Attorney General has already "tee[d] up" in a parallel action will provide complete resolution. Dep't of Att'y Gen., Press Release, *supra*. Lilly thus respectfully requests

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that the Court stay all proceedings in this matter, including issuance of all subpoenas, pending final resolution of the Attorney General's parallel declaratory judgment action.

Respectfully submitted,

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Attorneys for Respondent

Dated: March 8, 2022

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PROOF OF SERVICE

I hereby certify that on March 8, 2022, I caused a copy of the foregoing document to be served via email and first-class mail upon all attorneys of record. I declare under penalty of perjury that the foregoing statements are true to the best of my information, knowledge, and belief.

/s/ Matthew Schneider

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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-PZ

HON. JOYCE DRAGANCHUK

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Michael S. Hill (P73084)
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STIPULATION REGARDING THE ISSUANCE OF SUBPOENAS TO ELI LILLY REGARDING INSULIN PRICING

On January 25, 2022, the Attorney General filed a Petition in the above-captioned matter seeking authorization from this Court for the issuance of subpoenas in furtherance of an investigation of Eli Lilly and Company (Lilly) under the Michigan Consumer Protection Act (MCPA), MCL 445.901 et seq. The proposed investigation relates to Lilly's sale of insulin medications.

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On the same day, the Attorney General commenced a lawsuit against Lilly seeking a declaratory judgment that she has authority to investigate Lilly's sales of diabetes medications as potential violations of the Michigan Consumer Protection Act ("MCPA"). That action was assigned Ingham County Circuit Court docket number 22-000058-CZ and is assigned to Judge Wanda M. Stokes. For purposes of this stipulation, that lawsuit shall be referred to as the Declaratory Judgment Action.

On January 26, 2022, this Court issued an order authorizing the Attorney General's proposed investigation of Lilly. The Attorney General then communicated to counsel for Lilly an intention to issue investigative subpoenas pursuant to this authorization.

On March 8, 2022, Lilly filed a motion and supporting brief seeking to stay all proceedings in this action, including issuance of any subpoenas, until the Declaratory Judgement Action is resolved. Lilly contends that the Attorney General's investigation in the above-captioned matter is ultra vires in light of the decisions in *Smith v Globe Life Ins. Co.*, 460 Mich. 446; 597 N.W.2d 28 (1999) and *Liss v Lewiston-Richards, Inc.*, 478 Mich. 203; 732 N.W.2d 514 (2007).

In order to resolve the dispute manifest through the pending motion, the Attorney General agrees here to refrain from issuing subpoenas to Lilly at this time. Lilly and the Attorney General agree that the Attorney General shall not issue any subpoena to Lilly unless and until one of the following conditions is met:

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A. The Declaratory Judgment Action results in an order or decision permitting the Attorney General to proceed with the above-captioned investigation;

B. There is a legislative amendment to the Michigan Consumer Protection Act resolving the barrier to this investigation suggested by the *Smith*, supra, and *Liss*, supra, decisions; or

C. Upon a further event or development making issuance of such subpoena appropriate, provided counsel for Lilly is given at least ten (10) days' notice of the Attorney General's intention to issue such subpoena. If Lilly files a motion to stay or any other motion to prevent the issuance of or the obligation to respond to any subpoena from the Attorney General to Lilly under the MCPA (a "Motion") before the end of the ten (10) day period, no subpoena shall issue until the Motion is resolved provided a hearing to resolve Lilly's Motion is held within thirty (30) days after the Motion is filed. If a hearing to resolve Lilly's Motion is not held within thirty (30) days of the filing of the Motion, the Attorney General may issue the subpoena at the end of the thirty-day period, but Lilly shall have no obligation to respond to the subpoena while the Motion is pending. The limitations set forth in this subsection shall not be construed as applying should one of the events in subsections A or B occur.

Until one of these conditions is met, the Attorney General will refrain from issuing subpoenas to Lilly pursuant to this Court's order in the above-captioned

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matter or any other matters arising under the Michigan Consumer Protection Act that are related to the allegations in the Petition. Based upon this agreement, Lilly will withdraw (without prejudice) the pending Motion to Stay. Nothing in this stipulation shall be construed as impacting the Attorney General's authority to issue subpoenas to any other entity or person.

Dated: April 19, 2022

/s/ Darrin F. Fowler
Darrin F. Fowler (P53464)
Attorney for Petitioner

Dated: April 19, 2022

/s/ Matthew Schneider (w/ permission)
Matthew Schneider (P62190)
Attorney for Respondent

DEPT OF ATTORNEY GENERAL
CORPORATE OVERSIGHT DIVISION
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STATE OF MICHIGAN
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.

Case No. 2022-000009-PZ
Hon. JOYCE DRAGANCHUK

RESPONDENT ELI LILLY AND COMPANY'S MOTION TO STAY

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RESPONDENT ELI LILLY AND COMPANY'S MOTION TO STAY

By this motion, Respondent Eli Lilly and Company ("Lilly") moves to stay all proceedings in this matter pending resolution of the Attorney General's simultaneously filed declaratory judgment action (No. 22-58-CZ, Ex.A), which directly and exclusively concerns the Attorney General's legal authority to proceed against Lilly under the Michigan Consumer Protection Act ("MCPA"). In support of this motion, Lilly states as follows:

1. Lilly is a pharmaceutical manufacturer licensed to sell its products, including insulin medications, in the State of Michigan.

2. On January 25, 2022, the Attorney General simultaneously filed two actions in the 30th Judicial Circuit Court related to Lilly's insulin sales: (1) this case (No. 22-9-PZ), in which the Attorney General filed a petition for authorization to issue investigative subpoenas under the MCPA; and (2) a declaratory judgment action seeking a determination that the Attorney General has authority to proceed with the investigation and with future litigation against Lilly under the MCPA, notwithstanding binding Michigan Supreme Court precedent exempting Lilly's alleged conduct from MCPA liability. *See generally Liss v. Lewiston-Richards, Inc.*, 478 Mich. 203; 732 N.W.2d 514 (2007); *Smith v. Globe Life Ins. Co.*, 460 Mich. 446; 597 N.W.2d 28 (1999); MCL 445.904(1)(a).

3. The Attorney General has repeatedly acknowledged that any MCPA action against Lilly is barred under settled precedent, but still hopes to "tee[] up the *Smith* and *Liss* issue" for appeal in light of the Attorney General's view that those cases "were wrongly decided." Dep't of Att'y Gen., Press Release, *AG Nessel Launches Investigation into Excessive Insulin Prices, Intends to Challenge MSC Decisions Impacting Consumer Protection* (Jan. 26, 2022), https://bit.ly/3vcGEhx; Decl. J. Compl. ¶¶ 23-24 (recognizing that, under *Liss* and *Smith*, "the

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MCPA does not apply to the" challenged conduct).

4. The day after this action was filed, on January 26, 2022, the Honorable Judge Jamo, acting for this Court, authorized the Attorney General to issue subpoenas pursuant to the MCPA against Lilly and Express Scripts Inc. ("ESI"—an independent pharmacy benefit manager), in connection with Lilly's sale of insulin medications. The Attorney General has not yet issued any such subpoenas, but has since served Lilly with the petition in this action and the complaint in the declaratory judgment action and has informed Lilly that she intends to serve a subpoena on Lilly soon.

5. As the Attorney General has repeatedly acknowledged, the pure legal question concerning the scope of the Attorney General's authority under the MCPA is dispositive for any subpoena, investigation, or lawsuit relating to the sale of insulin medications in Michigan because current Supreme Court precedent renders such actions ultra vires and contrary to law.

6. That critical issue is the sole question presented in the declaratory judgment action.

7. Lilly intends to file a response to the declaratory judgment action on or before March 28, 2022.

Accordingly, and as further set forth in its accompanying brief, Lilly respectfully requests that the Court stay all proceedings in this action, including issuance of any subpoenas, until the dispositive legal question of the MCPA's scope is resolved in the Attorney General's pending declaratory judgment action. Doing so will help avoid duplicative proceedings; unnecessary burdens on the parties, third parties, and Court; and the potential need to litigate other defenses and objections. *See generally* MCR 1.105 (requiring "the parties and the court" to "construe[], administer[], and employ[]" the Michigan Court Rules "to secure the just, speedy, and economical determination of every action"); *Dietz v. Bouldin*, 579 U.S. 40, 47 (2016) (courts have "inherent

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power to stay proceedings pending resolution of parallel actions in other courts" (citing *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936), which found this "power inherent in every court")); *Banta v. Serban*, 370 Mich. 367, 368; 121 N.W.2d 854 (1963) ("recogniz[ing] the inherent power of a court to control the movement of cases on its docket").

Respectfully submitted,

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Attorneys for Respondent

Dated: March 8, 2022

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STATE OF MICHIGAN
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.

Case No. 2022-000009-PZ
Hon. JOYCE DRAGANCHUK

BRIEF IN SUPPORT OF RESPONDENT ELI LILLY AND COMPANY'S MOTION TO STAY

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I. INTRODUCTION

Respondent Eli Lilly and Company ("Lilly") respectfully requests a stay of proceedings in this matter pending final resolution of the Attorney General's declaratory judgment action in Case No. 22-58-CZ (Ex. A). The Attorney General herself has already made the case for a stay. As she candidly put it in her declaratory judgment complaint, "it would be a waste of resources for the Attorney General"—not to mention the Court and Lilly—"to proceed with this investigation only to have" the courts confirm that the whole endeavor is ultra vires. Decl. J. Compl. ¶ 24. And, to be clear, it is undisputed that this investigation *is* ultra vires under settled law. The Court should not permit the Attorney General to proceed with an investigation that she admits is unlawful under binding Michigan Supreme Court precedent.

The Attorney General's filings speak for themselves. The Attorney General wants to investigate Lilly for potential violations of the Michigan Consumer Protection Act ("MCPA") arising from Lilly's sale of insulin. But, as the Attorney General again recognizes, Lilly's sales of insulin are exempt from MCPA liability under the Supreme Court's binding opinions in *Smith* and *Liss*. *Id.*; *see Liss v. Lewiston-Richards, Inc.*, 478 Mich. 203; 732 N.W.2d 514 (2007); *Smith v. Globe Life Ins. Co.*, 460 Mich. 446; 597 N.W.2d 28 (1999). That "current MSC precedent" is the whole "reason" the Attorney General simultaneously filed the "Complaint for Declaratory Judgment": Her planned investigation depends on getting those decisions overturned, and the declaratory judgment posture is the mechanism to try to achieve that goal. Dep't of Att'y Gen., Press Release, *AG Nessel Launches Investigation into Excessive Insulin Prices, Intends to Challenge MSC Decisions Impacting Consumer Protection* (Jan. 26, 2022), https://bit.ly/3vcGEhx (explaining that "[a] Complaint for Declaratory Judgment teeing up the *Smith* and *Liss* issue was filed contemporaneously with the Petition" and that the Attorney General "is prepared to follow the appellate track").

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Accordingly, there is only one viable path forward to save the Court and the parties from the pointless burdens of an investigation that will inevitably fail under settled law: stay all activity here until the Attorney General receives a definitive answer to her question in the declaratory judgment action. Although the Honorable Judge Jamo, acting for this Court in the petition action, immediately responded to the petition by authorizing the Attorney General to issue subpoenas to both Lilly and third-party Express Scripts Inc. ("ESI"—an independent pharmacy benefit manager allegedly involved in insulin sales but who is not a defendant in either action),[1] any attempt by the Attorney General to actually do so and proceed with an investigation into Lilly's challenged conduct—to say nothing of bringing an enforcement suit—will be ultra vires unless and until the Supreme Court takes the dramatic and unlikely step of overruling longstanding precedent. Rather than force Lilly to participate in an investigation that contravenes settled law, that this Court lacks the authority to authorize, and that can be saved only by reversal of binding authority on appellate review, the Court should stay proceedings in this matter and allow the parties to litigate the dispositive legal question already "tee[d] up" in the "contemporaneou[s]" declaratory judgment action—just as the Attorney General intended. Dep't of Att'y Gen., Press Release, *supra*.

II. ARGUMENT

In pursuit of her misguided belief that Lilly has misrepresented the reasons for its pricing of various insulin medications in Michigan—including Lilly's reasons for ***decreasing*** prices, no less—the Attorney General simultaneously initiated two judicial proceedings on January 25, 2022. The first is the petition in this case, in which the Attorney General expressly waived her right to proceed *ex parte* and asked for authority to "issue subpoenas" to Lilly and ESI that the Attorney

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[1] Lilly, of course, reserves the right to raise all objections and defenses to any subpoena the Attorney General may attempt to issue under that authorization.

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General plans to use to compel records, testimony, and other information relating to purported MCPA violations. *See* MCL 445.907; No. 22-9-PZ Petn. ("Petn.") at 4, 32-33. The second is a single-count declaratory judgment action in which the Attorney General seeks to overturn long-settled Supreme Court precedent so the Court can then declare that the MCPA applies to Lilly's alleged conduct. *See* Decl. J. Compl. ¶¶ 25-28. In that suit, the Attorney General has indicated that she plans to investigate Lilly, issue subpoenas in support of her investigation (including to Lilly and third parties, like ESI), and ultimately "bring [an] actio[n]" against Lilly. *Id.* ¶¶ 11, 28. But, as she plainly recognizes, licensed entities' regulated conduct, including the sale of pharmaceuticals by licensed manufacturers like Lilly, is exempt from MCPA liability under MCL 445.904(1)(a) according to the Supreme Court's plain-text construction of the statute in *Liss* and *Smith*. *See* Dep't of Att'y Gen., Press Release, *supra* (recognizing that those precedents provide "a broad shield for regulated entities" and "will hold significant weight in [the Attorney General's] ability to pursue action against Eli Lilly").

Those decisions, which accurately reflect the "Legislature's intent [and] the statutory text," *Liss*, 478 Mich. at 207, will indeed present at least two dispositive barriers to the Attorney General as this matter proceeds. First, they provide an obvious basis to immediately quash any subpoena that the Attorney General seeks to issue regarding Lilly's sale of pharmaceuticals. Under *Liss* and *Smith*, conduct is exempt from MCPA liability if "the ***general*** transaction" at issue (*e.g.*, the sale of pharmaceuticals) "is specifically authorized by law, regardless of whether the ***specific misconduct alleged***" (*e.g.*, overcharging or misrepresenting) "is prohibited." *Liss*, 478 Mich. at 206 (emphases added) (quoting *Smith*, 460 Mich. at 465). And a "general transaction … is 'specifically authorized'" if a licensure scheme "defines" who can engage in the activity and generally excludes "non-licensed" entities from participating. *Id.* at 213-15. There is no dispute

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The Attorney General's candid admission is thus exactly right: "[I]t would be a waste of resources" to force everyone involved to litigate "motion[s] to quash" and engage in costly and complex discovery disputes when the settled interpretation of the MCPA already provides a clear answer. Decl. J. Compl. ¶ 24. That is true even though the Attorney General thinks that binding precedent was "wrongly decided or has become obsolete"; the Attorney General (and, of course, "the Court of Appeals and all lower courts") is "bound" to follow it under "the fundamental principle that only the Supreme Court has the authority to overrule one of its prior decisions." *State Treasurer v. Sprague*, 284 Mich. App. 235, 242; 772 N.W.2d 452 (2009) (brackets and quotations omitted) (collecting cases).

Granted, all that issuance of a subpoena would ultimately produce (besides expense and prejudice for Lilly and others, and additional press releases from the Attorney General[2]) is confirmation that Lilly is indeed deeply committed to ensuring that anyone with a prescription for Lilly insulin can access it affordably—something the Attorney General presumably already knows based on widely available information.[3] But to avoid any doubt, Lilly will say it again here: Anyone is eligible to purchase their monthly prescription of Lilly insulin for ***$35 or less***—

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[2] *See* Dep't of Att'y Gen., Press Release, *supra* (inviting public commentary on the litigation and admitting that settled law is against the Attorney General).

[3] *See, e.g.*, Eli Lilly and Company, https://www.insulinaffordability.com/ (last visited Mar. 7, 2022) (providing simple instructions to patients about how to acquire their prescriptions of Lilly insulin for $35 per month).

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regardless of the number of pens or vials prescribed, and regardless whether a patient is uninsured or uses commercial insurance, Medicaid, or a participating Medicare Part D plan.[4] And the average monthly out-of-pocket cost for a prescription of Lilly insulin (regardless of the number of pens or vials used) is currently $22.59, or about $9 per vial—not "nearing $100" per vial as the Attorney General wrongly claims. *See, e.g.*, Dep't of Att'y Gen., Press Release, *supra*.

Lilly is proud of its efforts to promote affordable access to insulin. But nothing entitles the Attorney General to compel Lilly to participate (at great expense and inconvenience) in a sweeping investigation that is wholly and admittedly premised on an impermissible exercise of the limited authority the Legislature codified in the MCPA. So rather than require the parties to engage in ultimately pointless and wide-ranging subpoena disputes piecemeal, it makes far more sense—as the Attorney General has already indicated—"to resolve th[e] controversy" over that pure legal question "at the inception" by pausing this matter until the declaratory judgment action has concluded. Decl. J. Compl. ¶ 24.

Second, even if the Attorney General were somehow able to overcome a motion to quash and proceed with this investigation, the fact remains, to borrow the Attorney General's words, that Lilly ***still*** could raise the exemption for regulated conduct "as a defense in [an ensuing] lawsuit under the MCPA." *Id.* Again, there is no room for serious debate about the current state of the law. Under *Liss* and *Smith*—which remain binding until overruled by the Supreme Court—the MCPA exemption applies to the conduct the Attorney General contends is unlawful (the sale of regulated medications) because that general conduct is "authorized" by law for purposes of the MCPA. *Liss*, 478 Mich. at 213-15; *see* Decl. J. Compl. ¶ 21 ("Lilly holds a manufacturer's license

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[4] *See* Note 3, *supra*.

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issued by the Michigan Board of Pharmacy, and four licenses for the wholesale distribution of its medications"). In any event, the dispositive legal issue—whether to overrule longstanding precedent—will be fully briefed in the declaratory judgment action. There is no need to force the parties to brief the same issue in two separate proceedings, especially when the issue is settled under Supreme Court law and can be "overrule[d] or modif[ied]" by that Court alone. *Sprague*, 284 Mich. App. at 242.

Lilly thus respectfully submits that the only path consistent with this Court's authority under *Liss* and *Smith*, and the best way to "save the parties, the [C]ourt, and society … costly time and litigation expense[s]," *Dietz v. Bouldin*, 579 U.S. 40, 47 (2016), is to follow the Attorney General's initial plan as represented to this Court: litigate the pure legal question about the scope of the MCPA's exception in the declaratory judgment posture. *See Detroit Base Coal. for Human Rights of the Handicapped v. Dep't of Soc. Servs.*, 431 Mich. 172, 191; 428 N.W.2d 335 (1988) (a "declaratory judgment [is] a broad, flexible remedy" capable of "sharpening … the issues raised"); Petn. at 4. Because Lilly is virtually certain to prevail on that pure legal question unless and until the Supreme Court overrules its on-point precedent, there is no reason to expend judicial and party resources litigating a motion to quash and engaging in other investigation-related disputes (let alone an eventual lawsuit). *See, e.g.*, Decl. J. Compl. ¶ 23 (insisting that precedent immunizing Lilly was "wrongly decided"); Petn. at 4, 31 & n.94 (same).

III. CONCLUSION

This Court should not permit complex and wasteful litigation over subpoenas that the Attorney General may attempt to issue to Lilly (and perhaps other third parties) when a dispositive legal question that the Attorney General has already "tee[d] up" in a parallel action will provide complete resolution. Dep't of Att'y Gen., Press Release, *supra*. Lilly thus respectfully requests

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that the Court stay all proceedings in this matter, including issuance of all subpoenas, pending final resolution of the Attorney General's parallel declaratory judgment action.

Respectfully submitted,

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Attorneys for Respondent

Dated: March 8, 2022

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PROOF OF SERVICE

I hereby certify that on March 8, 2022, I caused a copy of the foregoing document to be served via email and first-class mail upon all attorneys of record. I declare under penalty of perjury that the foregoing statements are true to the best of my information, knowledge, and belief.

/s/ Matthew Schneider

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Exhibit A

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Approved, SCAO

Original - Court
1st copy - Defendant

2nd copy - Plaintiff
3rd copy - Return

STATE OF MICHIGAN 30th JUDICIAL DISTRICT JUDICIAL CIRCUIT COUNTY PROBATE	SUMMONS	CASE NO. 22- 58 -CZ

Court address
313 W. Kalamazoo St., Lansing, MI 48933

JUDGE WANDA M. STOKES

Court telephone no.
(517) 483-6500

Plaintiff's name(s), address(es), and telephone no(s).	v	Defendant'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		ELI LILLY AND COMPANY c/o National Registered Agents, Inc. 40600 Ann Arbor Rd., E., Ste. 201 Plymouth, MI 48170
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	Expiration date*	Court clerk
JAN 25 2022	APR 26 2022	MAKALA ISOLLEY

*This summons is invalid unless served on or before its expiration date. This document must be sealed by the seal of the court.

MC 01 (9/19) **SUMMONS**

MCR 1.109(D), MCR 2.102(B), MCR 2.103, MCR 2.104, MCR 2.105

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SUMMONS
Case No. 22-58 -CZ

PROOF OF SERVICE

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

☐ **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

☐ **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)

☐ 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 _____ (Date), _____ County, Michigan.

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

Recd - 30th CIRCUIT COURT

JAN 25 2022

BY: _____ Deputy Clerk

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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

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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.

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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.

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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.

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[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).

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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.

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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

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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

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[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.*

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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

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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.

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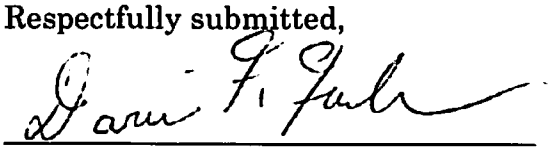
CONCLUSION AND RELIEF REQUESTED

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

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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-PZ

HON. JOYCE DRAGANCHUK

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STIPULATION REGARDING THE ISSUANCE OF SUBPOENAS TO ELI LILLY REGARDING INSULIN PRICING

On January 25, 2022, the Attorney General filed a Petition in the above-captioned matter seeking authorization from this Court for the issuance of subpoenas in furtherance of an investigation of Eli Lilly and Company (Lilly) under the Michigan Consumer Protection Act (MCPA), MCL 445.901 et seq. The proposed investigation relates to Lilly's sale of insulin medications.

APR 20 2022

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On the same day, the Attorney General commenced a lawsuit against Lilly seeking a declaratory judgment that she has authority to investigate Lilly's sales of diabetes medications as potential violations of the Michigan Consumer Protection Act ("MCPA"). That action was assigned Ingham County Circuit Court docket number 22-000058-CZ and is assigned to Judge Wanda M. Stokes. For purposes of this stipulation, that lawsuit shall be referred to as the Declaratory Judgment Action.

On January 26, 2022, this Court issued an order authorizing the Attorney General's proposed investigation of Lilly. The Attorney General then communicated to counsel for Lilly an intention to issue investigative subpoenas pursuant to this authorization.

On March 8, 2022, Lilly filed a motion and supporting brief seeking to stay all proceedings in this action, including issuance of any subpoenas, until the Declaratory Judgement Action is resolved. Lilly contends that the Attorney General's investigation in the above-captioned matter is ultra vires in light of the decisions in *Smith v Globe Life Ins. Co.*, 460 Mich. 446; 597 N.W.2d 28 (1999) and *Liss v Lewiston-Richards, Inc.*, 478 Mich. 203; 732 N.W.2d 514 (2007).

In order to resolve the dispute manifest through the pending motion, the Attorney General agrees here to refrain from issuing subpoenas to Lilly at this time. Lilly and the Attorney General agree that the Attorney General shall not issue any subpoena to Lilly unless and until one of the following conditions is met:

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A. The Declaratory Judgment Action results in an order or decision permitting the Attorney General to proceed with the above-captioned investigation;

B. There is a legislative amendment to the Michigan Consumer Protection Act resolving the barrier to this investigation suggested by the *Smith*, supra, and *Liss*, supra, decisions; or

C. Upon a further event or development making issuance of such subpoena appropriate, provided counsel for Lilly is given at least ten (10) days' notice of the Attorney General's intention to issue such subpoena. If Lilly files a motion to stay or any other motion to prevent the issuance of or the obligation to respond to any subpoena from the Attorney General to Lilly under the MCPA (a "Motion") before the end of the ten (10) day period, no subpoena shall issue until the Motion is resolved provided a hearing to resolve Lilly's Motion is held within thirty (30) days after the Motion is filed. If a hearing to resolve Lilly's Motion is not held within thirty (30) days of the filing of the Motion, the Attorney General may issue the subpoena at the end of the thirty-day period, but Lilly shall have no obligation to respond to the subpoena while the Motion is pending. The limitations set forth in this subsection shall not be construed as applying should one of the events in subsections A or B occur.

Until one of these conditions is met, the Attorney General will refrain from issuing subpoenas to Lilly pursuant to this Court's order in the above-captioned

matter or any other matters arising under the Michigan Consumer Protection Act that are related to the allegations in the Petition. Based upon this agreement, Lilly will withdraw (without prejudice) the pending Motion to Stay. Nothing in this stipulation shall be construed as impacting the Attorney General's authority to issue subpoenas to any other entity or person.

Dated: April 19, 2022

/s/ Darrin F. Fowler
Darrin F. Fowler (P53464)
Attorney for Petitioner

Dated: April 19, 2022

/s/ Matthew Schneider (w/ permission)
Matthew Schneider (P62190)
Attorney for Respondent

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