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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,

Plaintiff-Appellant,

v

ELI LILLY AND COMPANY,

Defendant-Appellee.
_____/

Supreme Court No. 165961

Court of Appeals No. 362272

Ingham Circuit Court No. 2022-000058-CZ

AMICUS CURIAE BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

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STATEMENT OF INTEREST

Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the country's leading innovative biopharmaceutical research companies. PhRMA's members develop innovative medicines that transform lives and create a healthier world. PhRMA advocates in support of public policies to ensure patients can access and afford medicines that prevent, treat and cure disease. PhRMA member companies have invested more than $850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States. PhRMA members produce medicines that are distributed to pharmacies and hospitals throughout the United States. State laws restricting their capacity to introduce lower-priced generic drugs harm PhRMA's members and the patients they serve. PhRMA members also rely on the stability of federal supremacy over interstate and foreign commerce when investing in the search for new treatments and cures.

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INTRODUCTION

This appeal concerns whether the Michigan Consumer Protection Act ("MCPA") applies to the pricing of insulin medications in transactions that are specifically authorized by law. The Attorney General asks this Court to overrule *Smith v. Globe Life Insurance Co.*, 460 Mich. 446 (1999), and *Liss v. Lewiston-Richards, Inc.*, 478 Mich. 203 (2007), two precedents interpreting the MCPA. This Court should reject that invitation and either dismiss the appeal or affirm the decision below because *Smith* and *Liss* properly interpret the statute, *stare decisis* requires adherence to that precedent, and the Michigan Legislature has declined to revise the MCPA.

But the Attorney General's proposed investigation has an antecedent flaw: it does not even plead a violation of the MCPA and asserts theories that present enormous constitutional and practical problems. This Court clearly instructed the parties to address the adequacy of the Attorney General's pleading but, tellingly, the Attorney General ignored that instruction. That is because the petition's far-reaching MCPA theories are entirely unmoored from the statutory text and cannot withstand scrutiny.

Invoking the MCPA, the Attorney General attacks Eli Lilly and Company's ("Lilly") pricing decisions on two axes: (1) the creation of a lower-priced, generic option for patients, and (2) prices charged in Canada. If accepted, the Attorney

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General's interpretation of the MCPA would greatly disincentivize companies from seeking approval for lower-priced generics that ultimately benefit patients in Michigan. The Attorney General also overlooks the plain text of the relevant MCPA provision limiting its application to purchases by consumers, and she fails to allege that Lilly makes any sales to consumers in the state. Under her theory, manufacturers would be liable instead for downstream sales at prices set by other entities. Further, the Attorney General's demand for international pricing parity violates the Dormant Commerce Clause, and her reading of the statute would burden Michigan courts with setting prices for everyday goods. Because the Attorney General's pricing theories are incorrect and unworkable, there is no need to consider her request to overturn long-established precedent.

But it gets worse. The Attorney General's other theory of liability attempts to penalize Lilly for "false or misleading" statements she admits to be true. She does not dispute that Lilly introduced Lispro to provide a lower list price option for patients and to fill gaps in the healthcare system. She nonetheless faults Lilly for failing to disclose any additional motivations it may have had for introducing a lower-priced drug. It would be bizarre and unreasonably burdensome to interpret the MCPA to require businesses to issue exhaustive lists of alternative motivations every time they introduce a product to market or announce price reductions. This effort also likely violates the First Amendment: it is a content-based restriction on speech

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that is not necessary to prevent consumer confusion or to ensure the accurate provision of information to consumers. Instead the rule would unconstitutionally require pharmaceutical companies to serve as mouthpieces for the Attorney General's policy goals relating to pharmaceutical pricing.

For these reasons, this Court should either dismiss the appeal or affirm.

ARGUMENT

I. The Petition Does Not Adequately Plead a Violation of the MCPA's Excessive Pricing Provision

The Attorney General asserts that Lilly is liable under the MCPA for "[c]harging the consumer a price that is grossly in excess of the price at which similar property or services are sold." AG App'x at 24 (quoting MCL 445.903(1)(z)).[1] She bases this claim on two theories. She first alleges that *pharmacies*—and not Lilly—charge consumers different prices in Michigan compared to Canada. *See* AG App'x at 25. Next, she contends that Lilly is liable under the MCPA for introducing a generic insulin that is cheaper than its branded product. *See* AG App'x at 28. Neither of these theories states an MCPA claim. First, the MCPA's text does not support liability based on other market participants' sales to consumers. Second, the Attorney General may not regulate prices beyond Michigan's borders, whether it be

[1] The Attorney General's petition does not adequately plead a violation of the MCPA. To the extent that the appropriate standard is "probable cause," *see* Appellee Br. at 21-24, the Attorney General fails to meet that showing for the same reasons articulated in this brief.

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prices in Canada or the list price Lilly charges wholesalers in other states. Third, the Attorney General's attack on the introduction of a generic drug is incompatible with the MCPA's purpose, and it will ultimately harm consumers by disincentivizing companies from seeking approval for lower-priced options.

A. The Attorney General Does Not Point to Any Transaction Between Lilly and a Consumer

The MCPA prohibits businesses from charging a Michigan "consumer" a price that grossly exceeds the price at which similar property is sold. MCL 445.903(1)(z). But this provision cannot apply here because Lilly does not charge consumers anything. As the Attorney General recognizes, Lilly's list price is just a starting point. Drugs are distributed through a supply chain involving many downstream actors negotiating over prices and discounts well before consumers purchase their prescriptions from a pharmacy. Absent facts indicating that Lilly charges an excessive price to "the consumer," the Attorney General fails to plead a violation of the MCPA.

A basic understanding of the pharmaceutical supply chain demonstrates that Lilly, like other manufacturers, does not "[c]harg[e] the consumer" any "price." MCL 445.903(1)(z). Brand-name drugs typically travel through a supply chain that includes manufacturers, wholesalers, and retail and hospital pharmacies before

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reaching the patient.[2] At the first step in this chain, wholesalers purchase from manufacturers at a price based on the drug's national list price, commonly known as the wholesale acquisition cost or WAC.[3] The WAC does not vary based on the end-purchaser's circumstances, even though patients may ultimately have different out-of-pocket cost responsibility at the pharmacy based on their insurance coverage or applicable discounts.

The wholesaler then sets its own price, distributes the drug through its national supply chain, and sells it to a pharmacy or other end purchaser.[4] The pharmacy next sells the drug to the patient. Here again, the price the patient pays does not align with the manufacturer's list price or the wholesaler's price. Insured patients, for instance, pay a copay and/or a deductible to the pharmacy.[5] The co-pay amount and deductible amounts are set by the patient's insurance company, independent of the drug manufacturer. Pharmacies might also independently negotiate a lower price with the manufacturer, meaning that the wholesaler—who initially purchased the drug from

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[2] *See* Andrew W. Mulcahy & Vishnupriya Kareddy, *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships* 4, RAND Corp. (2021), https://aspe.hhs.gov/sites/default/files/documents/0a464f25f0f2e987170f0a1d7ec21448/RRA328-1-Rxsupplychain.pdf.

[3] *Id.*

[4] *Id.* at 11.

[5] *See* PhRMA, *Follow the Dollar: How the Pharmaceutical Distribution and Payment System Shapes the Prices of Brand Medicines* 8-9 (Feb. 10, 2025), https://phrma.org/resources/follow-the-dollar-report-2025.

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the manufacturer—is entitled to a reimbursement called a "chargeback" that effectively adjusts the wholesaler's acquisition price to account for the difference in the price that the wholesaler was able to charge on its sale of the drug to the pharmacy.[6] Some federal government programs also require wholesalers to sell drugs to a pharmacy at a lower price, which similarly results in a chargeback.

Complicating the supply chain further, insurance companies are typically members of a pharmacy benefit manager (PBM) network. The PBMs negotiate agreements with drug companies under which the manufacturer pays rebates in exchange for coverage of its drugs on the PBM's formulary, which is a list of drugs preferred for coverage. The insurers who are clients of the PBM typically follow the PBM formulary.

The Attorney General's petition recognizes all of this. The petition takes aim at Humalog's WAC. *See, e.g.*, AG App'x at 11-13, 27-28. But it does not assert that the WAC is a "price" paid by any "consumer." To the contrary, it explicitly recognizes that a host of market actors and actions are involved in setting drug prices ultimately paid by consumers. The petition alleges, for example, that "drug manufacturers and PBMs set the price at which the drug manufacturer will offer the drug to pharmacies." AG App'x at 14. But it does not allege that drug manufacturers "set the price" that patients pay to the pharmacy, and it does not allege that patients

[6] Mulcahy & Kareddy, *supra* note 2, at 23.

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pay manufacturers. To the contrary, the petition alleges that "pharmacies" set prices for patients, AG App'x at 14-15, and that "consumers pay a pharmacy," not Lilly. AG App'x at 17. Moreover, the petition alleges that rebates off the list price are passed from manufacturers to PBMs to health plans. *Id.* Because health plans set patient reimbursement rates, this process further divorces the list price from the amount actually charged to a patient. In short, the pharmacy charges the patient based on a mixture of insurance copays, wholesaler discounts, rebates, and copay assistance.

The Attorney General's petition accordingly does not complain of any relationship Lilly has with consumers and thus does not plead a violation of the MCPA's provision about consumer pricing. The factual predicate on which the claim is based powerfully reinforces the point. Her evidence about the specific price that Michigan consumers pay is based on a telephone survey collecting prices charged at several pharmacies throughout the state. *See id.* at 25-27.

In short, the Attorney General does not and cannot allege that Lilly violated the MCPA based on prices that *other* businesses operating in Michigan charge consumers after independent negotiation with a host of independent market participants. The MCPA cannot be fairly read to blame a manufacturer for the decisions of downstream market participants. Both of her theories under MCL 445.903(1)(z) fail on this basis alone.

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B. The Attorney General's Theories Would Fail Even if Lilly Charged Consumers a Price

Even if a manufacturer that sells products to wholesalers could be liable under a statute that only governs prices charged to consumers (it cannot), the Attorney General's two theories for establishing that Lilly's prices are grossly excessive are not cognizable under federal or Michigan law.

1. The MCPA Cannot Control Prices Beyond Michigan's Borders

The Attorney General's first theory is that Lilly's list price for Humalog is "grossly in excess" of prices charged for similar drugs in Canada. *See* AG App'x at 25-27. According to the Attorney General, "Michiganders are charged grossly excessive prices for [Lilly's] insulin medications as compared to the prices at which those same medications are sold at pharmacies in Canada." AG App'x at 26. But accepting this theory would violate the dormant Commerce Clause twice over. First, it would unlawfully require Lilly to tie its pricing in Michigan to pricing in another country. Second, it would unlawfully require Lilly to change the wholesale prices it charges to wholesalers *outside* of Michigan, who then distribute medicines across the country.

Regulation of Prices Charged at Foreign Pharmacies. The Commerce Clause empowers Congress "[t]o regulate Commerce with foreign Nations, and among the several States." U.S. Const., art. I, § 8, cl. 3. This clause has "long been

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understood . . . to provide 'protection from state legislation inimical to the national commerce [even] where Congress has not acted.'" *Barclays Bank PLC v. Franchise Tax Bd. of Cal.*, 512 U.S. 298, 310 (1994) (quoting *S. Pac. Co. v. Ariz. ex rel. Sullivan*, 325 U.S. 761, 769 (1945)). Under the "[D]ormant Commerce Clause," *Wardair Can., Inc. v. Fla. Dep't of Revenue*, 477 U.S. 1, 7 (1986), states lack "the power unjustifiably to discriminate against or burden the interstate flow of articles of commerce." *Or. Waste Sys., Inc. v. Dep't of Env't Quality of State of Or.*, 511 U.S. 93, 98 (1994). This "constitutional principle . . . ensur[es] that the conduct of individual states does not work to the detriment of the Nation as a whole, and thus ultimately to all of the States." *Wardair*, 477 U.S. at 8.[7]

Statutes that require businesses to tie in-state prices to out-of-state prices and in effect require preferred pricing for in-state consumers are textbook violations of the dormant Commerce Clause. The United States Supreme Court has twice so held, and it has recently reaffirmed this line of precedent.

In *Brown-Forman Distillers Corp.*, a New York law required liquor distillers to sell their products to wholesalers at "no higher than the lowest price at which such

[7] The United States Supreme Court has analyzed the out-of-state domestic and foreign effects of a state's regulation under similar standards. *See, e.g. Wardair*, 477 U.S. at 7-8 (summarizing a single legal standard applicable to "the so-called dormant Commerce Clause, both interstate and foreign"); *see also Antilles Cement Corp. v. Acevedo Vila*, 408 F.3d 41, 46 (1st Cir. 2005) (explaining that analysis under the foreign and dormant Commerce Clauses is "essentially the same" (citing *Barclays Bank*, 512 U.S. at 310 & n.9).

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item of liquor [would] be sold by such [distiller] to any wholesaler anywhere in any other state." *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 576 (1986). The Court concluded that this provision "f[ell] within that category of direct regulations of interstate commerce that the Commerce Clause wholly forbids" because the law "effectively regulates the price at which liquor is sold in other States." *Id.* at 579. "[T]he critical consideration is the overall effect of the statute on both local and interstate activity." *Id.* The law's effect left a distiller no longer "free to change its prices elsewhere in the United States" after posting its prices in New York. *Id.* at 582. It did not matter that the law facially regulated conduct in New York, given that its "practical effect" was "to control liquor prices in other States." *Id.* at 583. The New York law was thus unconstitutional because it "'project[ed] its legislation' into other States, and directly regulated commerce therein." *Id.* at 584.

The Supreme Court considered a similar state law in *Healy v. Beer Institute, Inc.*, 491 U.S. 324 (1989). There, Connecticut required brewers and out-of-state beer importers to sell in the state at prices "no higher than the lowest prices they would charge for each beer product in" bordering states. *Healy*, 491 U.S. at 327, 329. The Court reasoned that the Connecticut law "ha[d] the practical effect of controlling Massachusetts prices." *Id.* at 338. "[A] brewer [could] undertake competitive pricing based on the market realities of either Massachusetts or Connecticut, but not both,

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because the Connecticut statute ties pricing to the regulatory schemes of the border states." *Id.* "[T]he Connecticut statute ha[d] the extraterritorial effect, condemned in *Brown-Forman*, of preventing brewers from undertaking competitive pricing in Massachusetts based on prevailing market conditions." *Id.* Indeed, if "every other State in the Nation" enacted such a law, it could lead to "price gridlock." *Id.* at 339-40. "This kind of potential regional and even national regulation of the pricing mechanism for goods is reserved by the Commerce Clause to the Federal Government and may not be accomplished piecemeal through the extraterritorial reach of individual state statutes." *Id.* at 340.

The United States Supreme Court has repeatedly reaffirmed the rule that states cannot regulate extraterritorially by requiring companies to tie in-state prices to out-of-state prices. In *PhRMA v. Walsh*, the Court considered whether the Commerce Clause prohibited Maine from requiring Medicaid participants to seek administrative approval before being dispensed a medication from a drug manufacturer that had not entered into a Medicaid rebate agreement with Maine's Medicaid program. 538 U.S. 644, 650-60 (2003). The Court reaffirmed *Healy*'s validity, but found no Commerce Clause violation because Maine's regulation did not involve tying to or regulating the price of any out-of-state transaction. *See id.* at 669. The Court revisited the issue recently in *National Pork Producers Council v. Ross*, 598 U.S. 356, 374 (2023). There, the Court rejected a challenge to California animal welfare laws but again

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reaffirmed *Brown-Forman* and *Healy*, explaining that California's law passed muster because it was not a "'price control or price affirmation statute[]' that tie[s] 'the price of . . . in-state products to out-of-state prices.'" 598 U.S. at 374 (quoting *Walsh*, 538 U.S. at 669).

The Attorney General's interpretation of the MCPA runs headlong into these precedents. On the Attorney General's theory, a price is "excessive" if it too significantly exceeds prices paid out-of-state. *See* AG App'x at 25-27 (faulting Lilly—or, more accurately, third-party pharmacies—for selling at a lower price out-of-state). Under that theory, the MCPA would directly tie the legality of pricing in Michigan to pricing in other states (or countries), and would require matching those prices in Michigan. If a company did not match prices, its price would be illegally excessive.

Just like the state laws in *Brown-Forman* and *Healy*, this construction of the MCPA purports to regulate in-state sales to Michigan consumers, but has the prohibited "practical effect of controlling [Canada] prices." *Healy*, 491 U.S. at 338. A business would be unable to lower its price outside of Michigan without incurring potential MCPA liability based on an unpredictable finding that the Michigan price is "excessive." Such a construction of the MCPA would raise even greater concerns under the Commerce Clause than the statutes in *Healy* and *Brown-Forman*. Because the "grossly in excess" and "similar" language is so indeterminate, manufacturers

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may need to prophylactically ensure that a drug sold in Michigan is priced no higher than any drug that is similar in any way sold anywhere in the world. A manufacturer under the Attorney General's rule would no longer be "free to change its prices elsewhere in the United States"—or the rest of the world, for that matter. *Brown-Forman*, 476 U.S. at 582. The Attorney General seeks to "'project[] [Michigan] legislation' into other States, and directly regulate[] commerce therein." *Id.* at 584. The Commerce Clause reserves this form of regulation to Congress rather than piecemeal actions by the states. *See Healy*, 491 U.S. at 340.

The fact that the Attorney General ties Michigan prices to those in a foreign country as opposed to another state only makes matters worse. As an initial matter, the Attorney General's theory necessarily applies to other states too; if a price can be grossly excessive based on Canadian pricing, it could surely be grossly excessive based on Indiana pricing. In any event, "a State's power is further constrained" where foreign commerce is at issue. *Barclays Bank*, 512 U.S. at 311. The "Foreign Commerce Clause" reflects a "policy of uniformity . . . which presumptively prevails when the Federal Government has remained silent." *Wardair*, 477 U.S. at 8. "In international relations and with respect to foreign intercourse and trade the people of the United States act through a single government with unified and adequate national power." *Barclays Bank*, 512 U.S. at 311 (quoting *Japan Line, Ltd. v. Los Angeles Cnty.*, 441 U.S. 434, 448 (1979)).

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Under the Attorney General's theory, the MCPA directly regulates prices businesses may charge in other countries: once a company has set a price in Michigan, it must match that price in Canada (or France) or else risk liability in Michigan. This is so even if market conditions and regulations differ, if intellectual property protections vary, and even if the comparator country has a completely different health care system. The Commerce Clause prohibits this outcome, which would prevent the United States from "speaking with one voice" on foreign commerce. *Japan Line*, 441 U.S. at 452.

Regulation of Out-of-State Sales to Wholesalers. The Attorney General's theory would violate the Commerce Clause even if it did not rely on price-tying. In the particular context of drug pricing, any attempt to hold an out-of-state manufacturer liable for the prices charged to in-state consumers necessarily regulates extraterritorially. The Attorney General acknowledges that Lilly does not charge consumers in Michigan directly, *see supra*, and so if the MCPA imposes liability on *manufacturers*, it necessarily does so by controlling the prices that they charge to out-of-state companies. Indeed, the avowed goal of the petition is to expand the MCPA's scope to require out-of-state companies to change the list prices they charge to out-of-state wholesalers who ultimately sell products to pharmacies in Michigan. *See* AG App'x at 12, 14-19, 23, 25-27 (faulting Lilly's list price). The Attorney General argues, in essence, that Lilly has influence over prices that pharmacies

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charge consumers, via setting the WAC. But even if that were right, then on the Attorney General's own theory, Lilly quite literally cannot change the price charged to consumers in Michigan other than by changing the price it charges to out-of-state wholesalers.

Lilly is an Indiana company, *see* AG App'x at 7, and the three largest national wholesalers, which control approximately 95 percent of the market, are headquartered in Ohio, Pennsylvania, and Texas.[8] These wholesalers purchase drugs in bulk quantities from manufacturers like Lilly at WAC for distribution throughout the country,[9] and most of these transactions occur outside Michigan. "The Commerce Clause . . . precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State." *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982); *see also Healy*, 491 U.S. at 336 (emphasizing that laws directly controlling out-of-state commerce are "invalid regardless of whether the statute's extraterritorial reach was intended by the legislature").

The MCPA cannot, consistent with the Commerce Clause, empower the Attorney General to demand that an out-of-state pharmaceutical manufacturer

[8] *See Follow the Dollar*, *supra* note 5 at 5 (listing McKesson, Cencora, and Cardinal as major wholesalers).

[9] *See id.*

change the price it charges to out-of-state wholesalers. The Supreme Court said as much in *Walsh*, observing that Maine's law was constitutional because it "does not insist that manufacturers sell their drugs to a wholesaler for a certain price." *Walsh*, 538 U.S. at 669; *see Ass'n for Accessible Medicines v. Frosh*, 887 F.3d 664, 666 (4th Cir. 2018) (holding that Maryland price-control law violated the Commerce Clause because it reached upstream sales to wholesalers outside of Maryland).

All of this reflects that the MCPA is best read to mean "grossly in excess" of prices charged in *Michigan*, not anywhere. The Attorney General's contrary interpretation would task Michigan district courts with the policy-laden and subjective evaluation of what prices in other states and other countries might be "grossly in excess" of prices charged by a Michigan business. Michigan judges—whose dockets are already overburdened—would become price control ratemaking bodies for businesses throughout the state, monitoring prices for any major disparities and creating judge-made price lists applicable in Michigan and beyond.

In sum, this Court should not entertain the Attorney General's efforts to compare pharmacies' prices across international boundaries and to pressure Lilly to alter the nationwide WAC for Humalog, because those theories violate the Commerce Clause.

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2. Penalizing Introduction of Generic Drugs Will Harm Michigan Consumers

The Attorney General's second theory of excessive pricing fares no better. In one breath, the Attorney General argues that Lilly violated the MCPA because its list price for insulin is too high. *See* AG App'x at 25. In the next, she asserts that Lilly violated the MCPA because it introduced a lower-priced generic. *See* AG App'x at 28. Those positions are irreconcilable and antithetical to the purpose of the MCPA: reducing harm to consumers. *See* Mich. House Leg. Analysis Section, Sen. B. 1, 1975-SB-1 (Dec. 7, 1976).[10] The Attorney General's proposed course of action would disincentivize pharmaceutical companies from making available lower-priced generic options that ultimately reduce costs and improve access to medicines.

The production of generic drugs is critical to medication affordability and accessibility, and the Attorney General's petition threatens this key mechanism. As the National Academies of Science, Engineering, and Medicine have observed, "[t]he entry of generic drugs into the market provides competing products that are generally sold at much lower prices than the original branded product."[11] One trade

[10] https://lmdigital.contentdm.oclc.org/digital/collection/p16110coll6/id/109350/rec/1.

[11] Making Medicines Affordable: A National Imperative 74 (Norman R. Augustine, Guru Madhavan, and Sharyl J. Nass, Eds., 2018), https://pubmed.ncbi.nlm.nih.gov/29620830/.

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organization estimates that generic and biosimilar drugs collectively account for 90 percent of prescriptions filled in the United States.[12]

In the Attorney General's view, production of a lower-priced generic medication would force a brand-name manufacturer either to stop selling its branded medication or to decrease the branded medication's price to match the generic. Given this forced choice, manufacturers would naturally think twice before creating generic versions of drugs to complement their branded products, inevitably resulting in fewer lower cost options on the market. Given the size of the generic market, punishing manufacturers for creating a generic drug would have an outsized impact on the affordability of medications. The Attorney General's construction of the MCPA would ultimately work to the detriment of patients in Michigan and throughout the country.

Nor is the Attorney General's theory neatly confined to branded and generic products offered by the same manufacturer. Instead, the MCPA could apply whenever a drug comes off patent and a generic becomes available, requiring a manufacturer of a branded drug to drop its list price immediately as a matter of Michigan law as opposed to in response to market forces. *See Biotechnology Indus.*

[12] Assoc. for Accessible Med., U.S. Generic & Biosimilar Medicines Savings Report 7 (Sept. 2024), https://accessiblemeds.org/wp-content/uploads/2025/01/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf.

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Org. v. Dist. Columbia, 496 F.3d 1362, 1373 (Fed. Cir. 2007) (explaining that Congress intended "new participation" in the "market" to drive prices for off-patent drugs). This is far from the mechanism Congress has envisioned for this competitive process. *See id.* at 1371-74 (discussing the structure and function of federal laws governing pharmaceutical patents).

II. The Attorney General Does Not Adequately Plead that Lilly Made False or Misleading Statements Regarding the Reasons for a Price Reduction

The Court should also reject the Attorney General's second theory of liability, which would enormously and improperly expand the MCPA's false statement provision and violate core First Amendment principles.

The Attorney General agrees that Lilly's announcement of Lispro as a lower-priced insulin was literally true. AG App'x at 28. The Attorney General nonetheless claims that Lilly's press release was somehow "misleading" under MCL 445.903(i) because the manufacturer "leaves unspoken" an additional motivation "to keep intact a system from which it is deriving significant profit at the expense of consumers." AG App'x at 28-29. Interpreting the MCPA to penalize a company's public statements unless it simultaneously releases an exhaustive list of alternative motives would be wholly unworkable. This form of attack would once again harm consumers by discouraging manufacturers from creating and advertising cheaper versions of their products, including generic drugs. It would also penalize a broad range of

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uncontroversial sales practices. In addition to these practical hurdles, the Attorney General's construction of the statute likely violates the First Amendment.

Absurdity. This Court interprets statutes to avoid "absurd results." *Jennings v. Southwood*, 446 Mich. 125, 133 (1994). This includes outcomes that are "'unthinkable' or 'bizarre,'" *Mich. Educ. Ass'n v. Sec'y of State,* 489 Mich. 194, 224 (2011) (quoting *Green v. Bock Laundry Machine Co.*, 490 U.S. 504, 527 (1989) (Scalia, J., concurring)), as well as results that are "quite impossible that [the Legislature] could have intended." *Id.* (quoiting *Pub. Citizen v. United States Dep't of Just.*, 491 US 440, 471 (1989) (Kennedy, J., concurring)). It would be quite strange to interpret MCL 445.903(i) to reach the conduct the Attorney General cites in her petition.

The Attorney General asserts that Lilly's March 4, 2019, press release announcing the introduction of Lispro creates probable cause to investigate the company for "[m]aking false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions." MCL 445.903(i). That press release announced that Lilly would "introduce a lower-priced version of Humalog," "providing people with diabetes an insulin option that will have a list price 50

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percent lower than the current Humalog list price."[13] Lilly expressed that it was "eager to bring forward a low-priced rapid-acting insulin" called Lispro that is "the same molecule as Humalog."[14] Lispro would be distributed as an authorized generic drug with a "list price" of "$137.35," and "a five-pack of KwikPens [would] be $265.20."[15] In addition, Lilly explained that "[i]ntroducing an alternative insulin option allows [it] to provide a lower-priced insulin more quickly while providing payers time to renegotiate downstream contracts and adjust to new system economics."[16]

The Attorney General asserts that this press release was in some way false or misleading because she suspects that Lilly had other, unstated motivations and that Lilly wanted to keep selling its higher-priced branded drug. If this Court were to adopt that theory, then any business providing consumer goods in Michigan would be required to issue an exhaustive list of disclaimers and alternative motivations whenever it lowers prices. Failure to do so would invite consumers to flood trial courts with lawsuits speculating about businesses' subjective mental states when

[13] Press Release, Eli Lilly, Lilly to Introduce Lower-Priced Insulin (Mar 4, 2019), https://investor.lilly.com/node/40881/pdf.

[14] *Id.*

[15] *Id.*

[16] *Id.*

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deciding to decrease a price. And because no such list could detail every conceivable motivation for action, businesses would have almost no defense to these claims. It is hard to see how a manufacturer could ever offer a lower-priced generic version alongside a higher-priced branded version under the Attorney General's theory if the fact of continued sale of the branded version imposes such a burdensome disclosure standard on manufacturers.

This dynamic would unquestionably work to the detriment of Michigan consumers by inhibiting businesses from making "price reductions," lest their "reasons for" doing so be challenged in court.[17] Retail stores, for instance, would be unable to offer loss-leaders to attract customers without the risk that a plaintiff would claim the store hoped to entice them to make unplanned purchases. So too could car dealers and grocery stores be liable for reducing prices to clear inventory unless they disclose that motivation to consumers.

Just like the Attorney General's first two theories, her advertising claim would also penalize drug manufacturers for providing lower cost alternatives that make drugs more accessible to uninsured and underinsured patients. This construction of the MCPA would undermine the statute's core purpose of protecting consumers by artificially propping up drug prices. Even if a manufacturer could introduce a lower-

[17] A plaintiff need not even seek damages under the MCPA, but may instead obtain declaratory relief that a business's practices violate the act. *See* MCL 445.911(1) (providing a cause of action "[w]hether or not a person seeks damages").

priced drug, the Attorney General's interpretation of MCL 445.903(i) would prevent the company from telling anyone about it, muting its beneficial effect within the state. This Court should not endorse an interpretation of the MCPA that would harm Michigan patients.

Constitutionality. The Attorney General's claims also raise serious constitutional concerns. This Court recognizes that "[i]n the area of commercial speech, the most commonly recognized First Amendment interest is preserving the free flow of information." *Matter of Jaques*, 407 Mich. 26, 42 (1979); *see also City of Rochester Hills v. Schultz*, 459 Mich. 486, 489 (1999) (observing that "commercial . . . speech is protected by the First Amendment from 'unwarranted governmental regulation.'" (quoting *Cent. Hudson Gas & Elec. Corp. v. Pub Serv. Comm'n of New York*, 447 US 557, 561 (1980)). Companies have the right to express their opinions and communicate information about their products, and they cannot be put to the choice of either not speaking or completely exposing all of their subjective motivations to the world. The First Amendment covers statements like Lilly's, and the Attorney General's proposed application of the MCPA to those expressions would be unconstitutional.

"Truthful advertising related to lawful activities is entitled to the protections of the First Amendment." *In re RMJ*, 455 U.S. 191, 203 (1982). Although the First Amendment grants the government some leeway to prohibit false or misleading

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commercial speech, the Attorney General's expansive reading of the term "misleading" is not consistent with the First Amendment. The Attorney General concedes that the press release is truthful, AG App'x at 28, and the petition points to no information that might be considered untruthful—Lilly's representation of Lispro and its advertised prices were accurate. Assuming for the sake of argument that Lilly did not disclose every impetus behind its price decrease, its activities would still enjoy First Amendment protection. "Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all." *Cent. Hudson*, 447 U.S. at 562; *see also Bates v. State Bar of Arizona*, 433 U.S. 350, 374 (1977) ("[I]t seems peculiar to deny the consumer, on the ground that the information is incomplete, at least some of the relevant information needed to reach an informed decision."). The Supreme Court has thus rejected the rationale the Attorney General advances in her petition, as statements are not inherently misleading just because they leave some information unsaid.

Consumers purchasing Lispro got exactly what Lilly said they would: an effective medicine comprising the same molecule as Humalog for half the price. Lilly did not, for instance, suggest to consumers that its product had certain characteristics when it did not. *Cf. Zauderer v. Off. of Disciplinary Couns. of Supreme Ct. of Ohio*, 471 U.S. 626, 652 (1985) (finding lawyer's advertisement

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misleading because it implied services "would come entirely free of charge" despite potential for taxed costs). Nor did its statement upset the "fair bargaining process" and "the public's interest in receiving accurate commercial information." *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 496, 501 (1996).

In fact, the United States Supreme Court addressed precisely this issue—"prescription drug price advertising"—in its pivotal case recognizing protections for commercial speech. *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 (1976); *see also Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 368 (2002) (holding that restrictions on compound drug advertisements were unconstitutional). In *Virginia State Board*, the Court held that a State may not suppress "the dissemination of concededly truthful information about entirely lawful activity, fearful of that information's effect upon its disseminators and its recipients." 425 U.S. at 773. The Court reasoned that a speaker's "purely economic" interest "hardly disqualifies him from protection under the First Amendment." *Id.* at 762. Consumers have a strong "interest in the free flow of commercial information," including "[t]hose whom the suppression of prescription drug price information hits the hardest": "the poor, the sick, and particularly the aged." *Id.* at 763. Commercial speech through press releases and advertisements represents "dissemination of information as to who is producing and selling what product, for what reason, and at what price," and it is necessary to

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"preserve a predominantly free enterprise economy." *Id.* at 765. "[T]he best means to that end is to open the channels of communication rather than to close them." *Id.* at 770. The Supreme Court of course never conditioned a pharmacist's right to participate in the marketplace on the disclosure of each and every one of his internal motivations for doing so. No such requirement applies to Lilly, either.

The Attorney General's proposed requirement that businesses disclose each and every one of their motivations for reducing prices "is designed to impose a specific, content-based burden on protected expression" and is therefore subject to "heightened scrutiny." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 565 (2011). The state "must show at least that the statute directly advances a substantial governmental interest and that the measure is drawn to achieve that interest." *Id.* at 572. The Attorney General's interpretation of the MCPA would be a poor "'fit' between" the government's consumer-protection "ends and the means chosen to accomplish those ends." *Id.* (quoting *Bd. of Trs. of State Univ. of New York v. Fox*, 492 U.S. 469, 480 (1989)).

The Attorney General claims a government interest in mitigating unfair, unconscionable, and deceptive trade practices. *See* MCL 445.903. The Attorney General's proposed interpretation of the MCPA is not constitutionally viable unless it "directly advance[s]" this interest. *Sorrell*, 564 U.S. at 572. Yet when the government "target[s] truthful, nonmisleading commercial messages," it "rarely

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protect[s] consumers from such harms." *44 Liquormart*, 517 U.S. at 502-03. "Instead, such bans often serve only to obscure an 'underlying governmental policy' that could be implemented without regulating speech." *Id.* at 503. "Without this requirement" of proving direct connection to the government's asserted interest, the "State could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression." *Edenfield v. Fane*, 507 U.S. 761, 771 (1993).

It is difficult to imagine how broad disclosure of manufacturers' subjective motivations for making business decisions might provide consumers with any better information to choose among drugs based on their prices, efficacy, and suitability for their own health needs. In fact, the Attorney General's theory would "only hinder consumer choice" by discouraging drug manufacturers from informing consumers about their products. *44 Liquormart*, 517 U.S. at 503.

Interpreting the MCPA to require the Attorney General's proposed free-wheeling disclosures is not aimed at addressing any harms emanating from Lilly's announcement of a lower-cost alternative insulin, or prevent any deception of consumers. It would simply serve a "nonspeech-related policy" involving price regulation. *Cent. Hudson*, 447 U.S. at 566 n.9. This underlying objective is clear from the face of the petition. *See, e.g.*, AG App'x at 32 ("The announced reason for the discounted Lispro product could have been better achieved through a

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significantly different price."); *id.* at 29 (complaining of "a system" through which Lilly derives profit). Such a restriction on commercial speech "in the service of other objectives" is precisely what the Supreme Court warned of in *Sorrell* and in *Edenfield*. The Attorney General may not lawfully pursue her separate policy objectives by stifling pharmaceutical manufacturers' protected speech.

CONCLUSION

This Court should either dismiss the appeal or affirm the decision below.

Dated: August 28, 2025

Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this document complies with the formatting rules in MCR 7.305(A) and MCR 7.212(B). The document contains 6,253 words in the sections covered by MCR 7.212(C)(6)-(8), one-inch page margins, the font is Times New Roman, and the text is 14-point type and double-spaced (except block quotations and footnotes which are single-spaced).

Dated: August 28, 2025

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ATTESTATION

Pursuant to MCR 7.312(H)(2), I hereby certify that this brief is being filed on behalf of an organization that is tax exempt under 501(c)(6) of the Internal Revenue Code, 26 U.S.C. § 501.

Dated: August 28, 2025

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