STATE OF MICHIGAN
IN THE SUPREME COURT
APPEAL FROM THE MICHIGAN COURT OF APPEALS

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.	MSC No: 165961 COA No: 362272 Ingham Circuit Court No.: 2022-000058-CZ

AMICUS CURIAE BRIEF OF THE MICHIGAN ASSOCIATION FOR JUSTICE (MAJ) ‡

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‡ MAJ submits this brief at the invitation of the Court, pursuant to its order dated April 4, 2025 ("Amici who have appeared in this case are invited to file supplemental briefs amicus curiae.") At the application stage, MAJ was granted leave to file a brief as *amicus curiae* by the Court's order dated May 3, 2024.

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STATEMENT OF THE BASIS OF JURISDICTION

The Michigan Association for Justice (MAJ) adopts the Statement of Jurisdiction submitted by the Michigan Attorney General in her Merits Brief dated May 30, 2025.

STATEMENT OF QUESTIONS PRESENTED

1. The Attorney General, seeking to uphold her duty to protect consumers across the state, filed a circuit court petition seeking authority to investigate Eli Lilly, identifying a statutory exemption within the MCPA as potentially relevant to this investigation, and establishing a controversy as to the applicability of the exemption. Does this pleading adequately confer jurisdiction on the circuit court to adjudicate the applicability of the exemption, with or without an MCPA violation being alleged?

Appellant's answer:	Yes.
Appellees' answer:	No.
Trial court's answer:	Did not answer.
Court of Appeals' answer:	Did not answer.
Amicus Michigan Association for Justice answer:	Yes.

2. The Attorney General recognizes that two wrongly decided decisions construe a statutory exemption within the MCPA in a manner that may preclude her from exercising authority expressly granted to her by the MCPA. This Court has the ability to overturn these two decisions, restoring the authority granted to the Attorney General by the MCPA, and all parties agree that this poses a live, actual controversy. Was the Attorney General required to plead an MCPA claim, based on authority that has been revoked from her by these two wrongly decided decisions, as a prerequisite to a court adjudicating the controversy of these decisions revoking her authority to bring such claims?

Appellant's answer:	No.
Appellees' answer:	Yes.
Trial court's answer:	Did not answer.
Court of Appeals' answer:	Did not answer.
Amicus Michigan Association for Justice answer:	Yes.

3. The lower courts' application of *Smith v Globe Life Ins Co*, 460 Mich 446; 597 NW2d 28 (1999), and *Liss v Lewiston-Richards, Inc*, 478 Mich 203; 732 NW2d 514 (2007), effectively rewrote the MCPA's plain language, as illustrated here by the fact that they have enabled Eli Lilly to prevent an MCPA investigation merely because the FDA has approved the safety and efficacy of Eli Lilly's insulin as a prescription drug, contrary to the MCPA's plain language. Were *Smith* and *Liss* wrongly decided?

Appellant's answer:	Yes.
Appellees' answer:	No.
Trial court's answer:	Did not answer.
Court of Appeals' answer:	Did not answer.
Amicus Michigan Association for Justice answer:	Yes.

4. Despite the importance of *stare decisis*, wrongly decided opinions should be overturned when doing so has practical workability, and reliance upon the precedent does not dictate a different course. *Smith* and *Liss* unjustifiably deprived consumers of protection from unfair trade practices in a wide range of industries, and broke consumers' prior reliance on

the MCPA as a remedy for unfair, deceptive, and unconscionable conduct across all industries engaged in trade and commerce. Should *Smith* and *Liss* be overturned?

Appellant's answer:	Yes.
Appellees' answer:	No.
Trial court's answer:	Did not answer.
Court of Appeals' answer:	Did not answer.
Amicus Michigan Association for Justice answer:	Yes.

STATEMENT OF FACTS

The Michigan Association for Justice (MAJ) adopts the Statement of Facts and Proceedings submitted by the Michigan Attorney General in her Merits Brief dated May 30, 2025.

STATUTES INVOLVED

In addition to the statutes referenced in the Michigan Attorney General's Brief, the Michigan Association for Justice respectfully submits that the following statutes are also relevant to the present controversy. MCL 445.774(4)-(5) contains nearly identical language under the Michigan Antitrust Reform Act, which should be read *in pari materia* with the analogous provisions of the Michigan Consumer Protection Act. 15 USC § 45(a)(1) is also relevant because the conduct at issue is already unlawful under this section of the FTC Act and thus, reliance interests premised upon *Smith* and *Liss* are limited.

MCL 445.774(4)

> This act shall not apply to a transaction or conduct specifically authorized under the laws of this state or the United States, or specifically authorized under laws, rules, regulations, or orders administered, promulgated, or issued by a regulatory agency, board, or officer acting under statutory authority of this state or the United States.

MCL 445.774(5)

> A transaction or conduct made unlawful by this act shall not be construed to violate this act where it is the subject of a legislatively mandated pervasive regulatory scheme, including but not limited to, the insurance code of 1956, being sections 500.100 to 500.8302 of the Michigan Compiled Laws, which confers exclusive jurisdiction on a regulatory board or officer to authorize, prohibit or regulate the transaction or conduct.

15 USC § 45(a)(1)

> Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.

INTEREST OF AMICUS CURIAE

The Michigan Association for Justice (MAJ) is a 501(c)(6) non-profit organization of Michigan lawyers engaged primarily in litigation and trial work. MAJ members frequently represent consumers who have been damaged as a result of "unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce" as that phrase is defined by the Michigan Consumer Protection Act (MCPA), MCL 445.903(1). The Michigan Legislature exempted alleged "unfair, unconscionable, or deceptive methods, acts, or practices" if they were the subject of "a transaction or conduct specifically authorized under laws[.]" MCL 445.904(1)(a). The Court correctly evaluated the application of this exemption in *Diamond Mortgage*, 414 Mich 603; 327 NW2d 805 (1982). However, MAJ respectfully submits that the Court has subsequently deviated from this standard by applying the exemption more broadly to the approval of "general" transactions, even though the word "general" is not contained in the statute. MAJ further submits that the overly broad application of the exemption is harmful to the integrity of consumer markets in Michigan and deprives consumers of remedies intended by the Legislature and as provided in the text of the MCPA. MAJ recognizes an obligation to assist this Honorable Court on important issues of law that would substantially affect the orderly administration of justice in the state of Michigan. The question presented in this case is one of major significance to Michigan's consumer protection law.

INTRODUCTION

For years, insulin prices in the United States have been the highest in the world and have grown at a pace significantly above inflation. Lawsuits challenging the artificial inflation of insulin prices have been waged against manufacturers and pharmacy benefits managers, the so-called middlemen of the pharmaceutical distribution system, alleging that the pricing practices and associated conduct are "unlawful, fraudulent and unfair" practices under state consumer protections acts. *See, e.g.*, Complaint*, People of the State of California v Eli Lilly et. al.*, No. 2:23-cv-01929 (Cal Super Ct, Los Angeles County, filed Mar. 15, 2023). Ex. 1. The Federal Trade Commission has similarly challenged these pricing practices as unfair and anticompetitive practices in violation of §5 of the FTC Act, 15 USC § 45. Ex. 2.

Similar to her colleagues in other state attorneys general offices and at the Federal Trade Commission, the Michigan Attorney General attempted to exercise her investigative subpoena authority conferred under the Michigan Consumer Protection Act (MCPA) to investigate insulin manufacturer Eli Lilly and Company ("Lilly") for its pricing conduct.

Lilly has thwarted the investigation.

It argues that its pricing conduct is exempt from § 4(1)(a)[2] of the MCPA, which states:

> (1) This act does not apply to…
>
> (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.

The regulatory authorizations Lilly has received from the FDA have nothing to do with insulin *pricing*. Instead, they only address certain safety-related ***conduct*** associated with its insulin products. That conduct, how Lilly labels its drugs, limitations on the types of diseases its products

[2] MCL 445.904(1)(a).

may treat, the manufacturing protocols it must follow to ensure drug safety, etc. are not at issue in the Attorney General's investigation. And so an argument that this safety-related **conduct** is "specifically authorized" and exempt from the MCPA does Lilly no good, since drug safety is irrelevant to the Attorney General's investigation.

Since the conduct prong of § 4(1)(a) is unavailing for Lilly, it instead argues that the U.S. Food and Drug Administration (FDA) has specifically authorized a **transaction** in insulin. (Lilly Br. 35) And since transactional immunity is broader than conduct immunity, Lilly argues, then ***anything*** related to its insulin sales—even conduct that the FDA has no statutory authority to regulate—is exempt from the MCPA.

Lilly's argument begs two questions: where is the "specific authorization" of "a transaction" upon which Lilly relies for its exemption? And where is "a transaction" that Lilly submitted to the FDA for approval? The answer to both questions is simple. **The FDA never "authorized" a transaction because Lilly never submitted "a transaction" to the FDA for them to review.**

Under this unambiguous reading of the text of the "specific authorization" exemption contained in the Michigan Consumer Protection Act, this should have ended the inquiry and Lilly should have complied with the Attorney General's subpoena.

Game over.

Unfortunately, that is not what happened. Although the text of the statute passed by the Legislature was unambiguous, this Court has created ambiguity where none existed. In two decisions reviewing whether "a transaction" has been "specifically authorized", this Court has created confusion as to whether "a transaction" has to be reviewed or approved in order to invoke the exemption in § 4(1)(a). First, in *Smith v Globe Life,* 460 Mich 446, 465; 597 NW2d 28 (1999),

the Court stated that the relevant inquiry is not whether "a transaction" has been "specifically authorized," but instead "whether the ***general*** transaction is specifically authorized by law…"(emphasis added). Second, in *Liss v Lewiston-Richards, Inc.* 478 Mich 203, 215; 732 NW2d 514 (2007) the Court held that certain activities that are performed by residential home builders "are permitted by the M[ichigan O[ccupational] C[ode][.]" The Court concluded that "applying the *Smith* test, defendants' 'general transaction,' building a residential home, is 'specifically authorized' under the MOC and the relevant regulations."

Neither *Smith* nor *Liss* involved "a transaction" that was submitted to a regulator for review and authorization. Rather, both cases hinged upon the use of an amorphous "general transaction" that was purportedly approved—or in the *Liss* decision, simply ***permitted***.

Based upon the simple text of the MCPA, a necessary threshold for invocation of the "specifically authorized transaction" exemption was that a transaction needed to be submitted to the regulator and authorized. *Smith* and *Liss* have severed the regulatory authorization of "a transaction" under § 4(1)(a) and, instead, shifted the inquiry to an unmoored "general transaction." In both the *Smith* and *Liss* decisions, there is no indication that the ***actual*** transaction between the plaintiffs and the defendants in those cases had been submitted to the regulator and authorized ahead of time. Arguably, some amorphous "general transaction" had been reviewed and authorized but it is not clear as to whether even this level of authorization had issued in a regulatory decision. The use of the term "general transaction" creates ambiguity as to what type of conduct is embodied in such a transaction, since not all "general transactions" of a given type involve the same conduct, translating to ambiguity as to what type of conduct the regulator "authorized" in such a transaction.

Lilly capitalizes on this ambiguity in characterizing its insulin pricing conduct (the subject matter of the Attorney General's investigation) as exempt from the MCPA as part of a specifically

authorized transaction. Take Lilly's popular insulin drug Humalog, for example. Prior to marketing Humalog, Lilly was required to submit a New Drug Application with the FDA. 21 USC § 355; accord 42 USC § 262(a). The application, like any New Drug Application submitted to the FDA, is required to contain "full reports of investigations which have been made to show whether or not the drug is safe for use and whether the drug is effective in use." *Merck KGaA v Integra Lifesciences I, Ltd,* 545 US 193, 196; 125 S Ct 2372; 162 L Ed 2d 160(2005). On June 14, 1996, the FDA approved Lilly's Humalog New Drug Application as "safe and effective for use as recommended[.]" Ex. 3.

Notably, this approval letter does **not** contain a specific authorization of "a transaction." Far from it. Transaction, transact, sell, sale, distribute, purchase, buy, commerce, commercial—none of these words appear even a single time in the FDA's approval letter. Ex. 3 The FDA approval does not identify the terms of the transaction, who the purchaser was, the price charged, or any of the other material terms of "a transaction", because none of those terms were presented to the FDA. Simply put, **Lilly did not submit a transaction for the FDA to authorize.** Yet, Lilly contends that letters like this one create "[a] transaction . . . specifically authorized" by the FDA, in satisfaction of § 4(1)(a).

In presenting this argument, Lilly confuses specific authorization of a transaction with a general regulatory approval necessary to engage in a transaction. And it uses the "general transaction" language from *Smith* and *Liss* as grist to obscure the fact that no transaction was submitted to, or authorized by, the FDA. Lilly notes that "[f]ederal authorization, which is required to sell a particular product that the defendant could not sell at all but for that very authorization for that very product, constitutes the specific authorization required under the MCPA." Lilly Br. at 35. But this "but-for" test is obviously not the defining characteristic of a transaction that is specifically

authorized. If Lilly's "but-for" test were adopted, any of dozens of regulatory requirements that Lilly must satisfy could be pointed to as government "authorization" of a transaction. Lilly can't sell its insulin products but for being a registered corporation; but for having a registered EIN number; but for ensuring that its production facilities successfully complete a pre-license inspection; but for being registered to transact business in the State of Michigan. The list could go on and on. Satisfying each of these regulatory requirements are but-for conditions of Lilly being permitted to sell its insulin products, but this but-for status does not mean that satisfaction of each of these requirements creates "a transaction" that has been "specifically authorized."

Each of these—like the FDA approval letter—are preconditions that Lilly must meet in order to sell insulin. They may even authorize Lilly to engage in specific conduct. And Lilly might claim an exemption limited to the conduct that has been specifically authorized. But they do not create, as required under the plain words of § 4(1)(a) of the MCPA, "a transaction" that has been "specifically authorized." In short, Lilly has engrafted the confusion caused by the "general transaction" language in *Smith* and *Liss* to immunize any egregious pricing conduct that it wishes to engage in.

The FDA, which possesses no statutory authority to review Lilly's pricing conduct even if it wanted to, has not "specifically authorized" a single transaction for insulin. Rather, it has issued a regulatory decision that Lilly's insulin products are "safe and effective" for certain limited uses, with certain labeling restrictions and under certain manufacturing protocols designed to assure drug safety. Under Lilly's gambit, pretending that an FDA safety determination constitutes authorization of a transaction, transmogrifies a narrow regulatory approval of certain limited safety-related conduct into blanket transactional immunization of conduct that the FDA has no authority to review, much less "authorize."

For these reasons, the decision of the lower courts should be reversed and Lilly should be required to comply with the Attorney General's investigative subpoena.

ARGUMENT

In its April 4, 2025, Order granting the Attorney General's application for leave to appeal, this Court identified four questions for review. As to the first two questions, the Michigan Association for Justice agrees with the argument presented in pp. 12-27 of the Attorney General's Merits Brief in support of the position that the Attorney General adequately pled a claim that Lilly violated the MCPA, even though it was not necessary for her to do so in order for a court to determine whether MCL 445.904(1)(a) applies.

The Michigan Association for Justice (MAJ) turns its focus to the third and fourth questions:

- whether *Smith* and *Liss* correctly interpreted MCL 445.904(1)(a);
- if they were incorrectly decided, whether they should nonetheless be retained under principles of *stare decisis, Robinson v Detroit,* 462 Mich 439, 463-468; 613 NW2d 307 (2000).

Respectfully, MAJ submits that the *Smith* and *Liss* decisions are contrary to the plain meaning of the Legislature's language in MCL 445.904(1)(a), were wrongly decided, and must be overturned.

I. A PLAIN READING OF THE STATUTE LEAVES NO ROOM FOR CONFUSION: A TRANSACTION IS ONLY EXEMPT FROM THE MCPA WHERE THE TRANSACTION WAS SPECIFICALLY AUTHORIZED.

"Where the language of the statute is clear and unambiguous, the Court must follow it." *Robinson*, 462 Mich at 459. There is no ambiguity in MCL 445.904(1)(a). It exempts "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" from the MCPA. In this case, the exemption as to "a transaction" is what is disputed.[3]

Parsing the language of this exemption, as it relates to transactions, three elements are necessary under the statute in order to invoke the exemption:

1. There must be "**a transaction"**;
2. The transaction must have been "**specifically authorized"**;
3. That specific authorization must have been made by a federal/state regulatory board or officer "**acting under statutory authority of this state or the United States**."

This is clear from a plain reading of the statutory language. Each of these requirements, as Michigan's caselaw has evolved from the decision in *Attorney Gen v Diamond Mortg Co,* 414 Mich 603; 327 NW2d 805 (1982) through the decisions in *Smith* and *Liss*, have generated confusion in the caselaw that is addressed below.

A. "A transaction" refers to a single transaction.

The statutory exemption in § 4(1)(a) is unambiguously written with the term "a transaction." The word "a" is singular. As such, "a transaction" necessarily refers to a singular transaction, not a "type" of transactions or "general" transactions. It would have been improper for § 4(1)(a) to instead have been written with a definite article as referencing "the" transaction, since

[3] The parties do not dispute that "conduct" is exempt when a particular form of conduct is what is authorized. Eli Lilly contends that transaction is the "broader" term, subsuming conduct. Eli Lilly Br. at 36-37. This is a nonsensical position, as conduct can absolutely occur outside of a transaction. *See, e.g.,* MCL 445.903(1)(f), contemplating an individual "[d]isparaging the goods, services, business, or reputation of another by false or misleading representation of fact." Anyone engaging in conduct violative of this provision is almost certainly doing so outside of a transaction with the party they're disparaging. But notwithstanding disputes about the exclusivity of the terms "transaction" and "conduct", the issue of when "conduct" is "specifically authorized" under MCL 445.904(1)(a) is not at issue here. Lilly's pricing conduct is not authorized by the FDA.

the exemption was not intended to be limited to a transaction "identified or specified" within the language of the statute itself.[4] But if a party cannot point to "the" singular transaction at issue and its corresponding specific authorization by the time it claims § 4(1)(a) applies, the language of § 4(1)(a) is inherently not satisfied—**it requires that "a" transaction has been identified and specifically authorized.**

Edwin Bladen, former Assistant Attorney General and Division Head of the Consumer Protection and Economic Crimes Divisions of the Michigan Attorney General's office was the primary author of the MCPA in 1976. In a paper describing the drafting, negotiation and passage of the MCPA, he states:

> [T]he use of the words 'a transaction' in subsection 4(1)(a) is singular in nature. Our intent was to exempt those specific statutorily authorized transactions which the legislature had already permitted. I personally wrote those words and chose the word 'a' to emphasize the singular nature of the transaction to keep with the overall thrust of the act's view that we look to see, not whether the entity is subject to the act, but whether the method, act or practice alleged to violate the act is indeed one addressed and prohibited by the act. To the extent *Smith v. Globe Life Insurance* 460 Mich 446, 597 NW2d 28(1999) arrived at a different view, it is clearly erroneous and totally illogical given the other exemption sections and investigative coverages in the act.[5]

The plain language of the statute and the singular form "a transaction" contradicts Lilly's interpretation. At the oral argument on the application for leave to appeal, Lilly articulated its true position.[6] Justice Clement asked: How specific do you think the authorized transaction needs to

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[4] Definite Article, Merriam-Webster.com Dictionary, https://www.merriam-webster.com/dictionary/definite%20article (last visited Aug. 24, 2025).

[5] Edwin Bladen, *How and Why the Consumer Protection Act Came to Be*, CONSUMER LAW SECTION OF THE STATE BAR OF MICHIGAN, at 12 (2005), available at https://higherlogicdownload.s3.amazonaws.com/MICHBAR/3b217bd2-fb65-46ff-86c0-ea1a7b303b13/UploadedImages/pdfs/HowWhy.pdf (last accessed Aug. 20, 2025).

[6] *Attorney General v Eli Lilly and Co*, Mich Sup Ct Docket No. 165961, oral argument on application for leave to appeal, Oct. 10, 2024, available at https://www.youtube.com/watch?v=lhNKYMDNjKs ("App. Oral Arg.").

be? Lilly's attorney, John O'Quinn, responded: "our modest point . . . is that you simply need specific authorization to engage in a ***type*** of transaction." App. Oral Arg. at 35:26. This is in stark contrast to the statutory language: the exemption in § 4(1)(a) applies to "A transaction or conduct specifically authorized" by state or federal regulatory bodies. The word "type" is nowhere to be found in the statute.

Far from abdicating this position as some sort of misspeak, Lilly restates it in its brief. On one hand, it instructs that: "[t]he court can leave intact settled precedent that faithfully applies the exemption when there is specific authorization for a transaction[.]" Lilly Br. at 31 (emphasis added). On the other, it declaims that: "[s]ome laws specifically authorize certain types of transactions . . . [a]nd other laws specifically authorize certain types of conduct[.] . . . The disjunctive language of the exemption allows for its application in either circumstance." Lilly Br. at 40-41 (emphasis added). But Lilly does not—and cannot—tie these two propositions together; "types" of transactions or "types" of conduct are not exempted under the plain language of the statute.

A "type" is "a particular kind, class, or group[.]"[7] A kind, class, or group is inherently not limited to a single member of said kind, class, or group.

The Court understood this in *Diamond Mortgage*, 414 Mich at 617. "While the [real estate broker's] license generally authorizes Diamond to engage in the activities of a real estate broker, it does not specifically authorize the conduct that [the Attorney General] alleges is violative of the Michigan Consumer Protection Act, nor transactions that result from that conduct." In other words, the unanimous *Diamond* court understood that a license that "generally authorizes" activities that

[7] *Type*, Merriam-Webster.com Dictionary, https://www.merriam-webster.com/dictionary/type (last visited Aug. 24, 2025).

will naturally result in transactions does not "specifically authorize" all of the transactions that follow from the license. This makes sense: at the time the license was granted, no other transaction existed, and more specifically, the transaction at issue in the case did not yet exist to receive specific authorization. The same is true as it pertains to Lilly's FDA approvals, which in the case of Humalog, occurred over 20 years before Lilly engaged in the pricing conduct that the Attorney General has sought to investigate.

B. The Legislature's use of the past verb tense in "specifically authorized" requires that the transaction for which an exemption is claimed has already been authorized.

A second source of confusion associated with the term "specifically authorized" is that Michigan courts have cited regulatory authority that may be exercised in the future as a basis for exempting a transaction or conduct. This temporal confusion impermissibly broadens the scope of the statutory exemption.

As set forth in the statute, the Legislature's use of the term "specifically authorized" employed the past tense past participle form of the verb "authorize".[8] The Legislature is presumed to be aware of the rules of grammar. *People v Beardsley,* 263 Mich App 408, 412-13 (2004). Thus, in selecting the term specifically "authorized" and employing a past tense past participle, the Legislature created an exemption for transactions or conduct that ***had already been*** specifically authorized under laws that have already been enacted or regulatory actions that have already been taken.[9]

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[8] **"Word forms: authorizes** 3rd person singular present tense, **authorizing** present participle, **authorized** past tense past participle" *See* https://www.collinsdictionary.com/us/dictionary/english/authorize.

[9] "A past participle is a 'nonfinite verb form ending usu. in ---*ed'* which 'may also function adjectivally.' Garner, *Garner's Modern American Usage* (3rd ed) (New York: Oxford University Press, 2009, p.909. As a past participle, it has a perfective aspect, which is a 'verb aspect that expresses action as complete.' *Id.* at 920. Additionally, the past-perfect tense denotes 'an act, state,

Courts applying the "specifically authorized" language have sometimes failed to recognize the verb tense selected by the Legislature. In *Kekel v Allstate Insurance Company,* 144 Mich App 379 (1985); 375 NW2d 455, *rev'd on other grounds* in *Smith,* at 466, for example, the Michigan Court of Appeals used the following language to describe its application of the "specifically authorized" exemption in MCL §445.904(1)(a):

> We first look to the exemption language of § 4(1)(a) to determine if plaintiffs' complaint speaks to a transaction or conduct ***which would be*** the subject of regulatory control "under laws administered by a regulatory board or officer acting under statutory authority of this state or the United States".

(emphasis added). In describing the application of the "specifically authorized" test, the *Kekel* Court impermissibly changed the verb tense selected by the Legislature and, in doing so, broadened the scope of the exemption to actions a regulator may take in the future, not actions a regulator has taken in the past. The *Kekel* court further elaborated "the conduct complained of by the plaintiffs in this case is subject to the regulation and scrutiny of the applicable licensing or regulatory authority." Id. at 384. But application of the specific authorization exemption, as stated by the Legislature, is not based upon whether the transaction or conduct "***would be*** the subject of regulatory control" or whether it "is subject to the regulation and scrutiny" of a regulator. Rather, the Legislature created a narrower exemption that requires the entity asserting the exemption to demonstrate that the conduct or transaction ***has already been*** the subject of specific authorization.

The proper inquiry is not **what can a regulator do**, but instead, **what has the regulator done.** As one court correctly noted, § 4(1)(a) itself "expressly delineates the breadth of its exemption as 'transaction or conduct specifically authorized.' Regulation and specific

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or condition [that] was completed before another specified past time or past action.' *Id.* Therefore, the term "dried" clearly indicates a completed condition." *People v Randall,* No. 318740, 2015 WL 159485 (Mich Ct App Jan. 13, 2015) at *2-3, leave to appeal denied, 498 Mich 919; 871 NW2d 168 (2015).

authorization are two vastly different concepts." *Robertson v State Farm Fire & Cas Co*, 890 F Supp 671, 678 (ED Mich, 1995).

C. ***The transaction must be specifically authorized "under laws administered by a regulatory board or officer acting under statutory authority of this state or the United States."***

The third textual requirement for invoking the MCPA exemption for a specifically authorized transaction is that the authorization must be "under laws administered by a regulatory board or officer acting under statutory authority of this state or the United States." Lilly has identified two statutes as the laws which purportedly provide for its "specifically authorized" transaction: 21 USC § 355 and 42 USC § 262(a). Lilly Br. 35.

Lilly's reliance on 21 USC 355(a) or 42 USC 262(a) is unavailing. First, none of the drug rebate agreements between Lilly and pharmaceutical benefit managers which the Attorney General is attempting to investigate, and for which the California Attorney General has already sued Lilly are reviewed by the FDA under these statutes. These rebate agreements are alleged to be the primary source of the artificial increase in insulin prices. *See, e.g.*, Ex. 1, ¶¶6-10. None of these rebate agreements are specifically authorized transactions and the FDA possesses no authority under the statutes cited by Lilly, 21 USC 355(a) and 42 USC 262(a), to even look at these agreements—much less authorize them. (Relatedly, although they have not sued Lilly, the Federal Trade Commission has also challenged the rebate agreements that Lilly has entered, under Section 5 of the FTC Act, 15 USC 45, as a cause of higher insulin prices in its lawsuit against several pharmacy benefit managers. Ex. 2, ¶¶6, 119-20.)

These rebate agreements were not authorized. Period.

But even as to consumer transactions in insulin, the statutes relied upon by Lilly do not provide authority for specific authorization of a transaction. Rather, the FDA's responsibilities

under the statutes cited by Lilly address the ***safety*** of drugs.[10] The agency possesses no authority over how drugs are priced, nor any ability to approve or disapprove the prices at which drugs are sold in a transaction. "The FDCA statutory regime is designed primarily to protect ***the health and safety*** of the public at large." *POM Wonderful LLC v Coca-Cola Co*, 573 US 102, 108; 134 S Ct 2228; 189 L Ed 2d 141 (2014), *citing 62 Cases, More or Less, Each Containing Six Jars of Jam v United States,* 340 US 593; 71 S Ct 515; 95 L Ed 566 (1951) (emphasis added).[11]

As an example, the FDA provided a regulatory application approval for Lilly's insulin product Humalog on June 14, 1996.[12] Ex. 3. Exhibit 3 does not reference any transaction, much

[10] As to 21 USC 355, the first statute cited by Lilly, the fundamental purpose of the FDA's review is to determine whether the proposed drug is "safe and effective." *Caraco Pharm Labs., Ltd v Novo Nordisk A/S,* 566 US 399, 404; 132 S Ct 1670; 182 L Ed 2d 678 (2012). ("When a brand manufacturer wishes to market a novel drug, it must submit a new drug application to the FDA for approval. The NDA must include...scientific data showing that the drug is safe and effective."); *Merck KGaA v Integra Lifesciences I, Ltd*, 545 US 193, 196; 125 S Ct 2372; 162 L Ed 2d 160 (2005) ("To obtain authorization to market a new drug, a drugmaker must submit a new drug application containing 'full reports of investigations which have been made to show whether or not the drug is safe for use and whether the drug is effective in use.'").

As to 42 USC 262(a), the second statute cited by Lilly, the fundamental purpose is similarly health and safety related. "A manufacturer of a biologic may market the drug only if the FDA has licensed it pursuant to either of two review processes set forth in § 262. The default pathway for approval, used for new biologics, is set forth in § 262(a). Under that subsection, the FDA may license a new biologic if, among other things, the manufacturer demonstrates that it is 'safe, pure, and potent.' § 262(a)(2)(C)(i)(I)." *Sandoz Inc v Amgen Inc,* 582 U.S. 1, 6–7; 137 S Ct 1664; 198 L Ed 2d 114 (2017).

[11] Even as to safety and efficacy issues, Lilly's claim that an FDA approval immunizes all conduct associated with a transaction for the drug under the MCPA is overly broad. A pharmaceutical company might market an FDA approved drug for uses that *are not included within the FDA approval* or as having attributes that the drug does not have. For example, Lilly entered a guilty plea with the United States Department of Justice related to misbranding and illegal marketing of its prescription drug, Zyprexa. Ex. 4. When a pharmaceutical company markets a drug in this manner, ***it is not specifically authorized and indeed, may face criminal prosecution.*** But under Lilly's overly broad analysis, any deceptive marketing of the drug, even criminal conduct, would be exempt from the MCPA as a specifically authorized "general" transaction.

[12] FDA regulatory approval letters for New Drug Applications submitted under the statutes cited by Lilly are maintained on the FDA website. *See* Drugs@FDA: FDA-Approved Drugs, U.S. Food & Drug Admin., https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm (last accessed

less one that the FDA has "specifically authorized." Nor does the statute under which the FDA approval letter was issued, section 505(a) of the Federal Food, Drug and Cosmetic Act, 21 USC 355(a), provide for the authorization of a transaction. 21 USC 355(a) states:

> No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

It is true that Lilly may not market a new drug without an application approval, as referenced in 21 USC 355(a). But that does **not** mean that the FDA has "specifically authorized" "a transaction" and nothing in the FDA's approval letter identifies "a transaction" that has been specifically authorized.

The FDA letter simply does not contain "specific authorization" of "a transaction."

Lilly has not suggested in any of its briefing that the FDA possesses regulatory authority under the listed statutes to approve the price of its drugs in any general or specific transaction, or that the FDA possesses authority to approve Lilly's conduct related to pricing or rebate agreements with pharmaceutical benefits managers under these statutes. The safety determinations rendered by the FDA simply do not qualify as "specific authorization" of "a transaction" under any "laws administered by a regulatory board or officer acting under statutory authority of this state or the United States."

Aug. 25, 2025). Exhibit 3 is the FDA approval letter issued to Lilly for the drug Humalog as it issued on June 14, 1996.

D. ***Contrary to Lilly's assertions, the Attorney General's interpretation of "a transaction" that was "specifically authorized" does not eliminate the word "transaction" from the statutory exemption. Rather, it restores the term to its original meaning as intended by the Legislature.***

Lilly's suggestion that the Attorney General's interpretation of the word "transaction" renders the term a nullity (Lilly Br. 1) is nonsensical. It is Lilly that rewrites the statute to expand the term "a transaction" to broadly include things that ***are not*** "a transaction." To be clear, there are examples of regulatory action where "a transaction" is reviewed and "specifically authorized." These examples are vastly different than the safety determination for drugs that the FDA issued under federal statutes relied upon by Lilly, where no transaction had been reviewed.

For example, take Michigan Public Service Commission review and specific authorization of power supply contracts under the Public Utility Regulatory Policies Act of 1978. In *Association of Businesses Advocating Tariff Equity v. PSC*, 173 Mich App 647 (1989); 434 NW2d 648, the Court of Appeals described the regulatory scheme where a specific power supply contract entered between Consumers Power Company and Tondu Energy Systems was submitted for review and approval by the PSC. The specific terms of the contract were exhaustively reviewed, and the PSC requested modification of some of those terms, prior to its approval. The regulatory scheme reviewed by the court in that case further provided that the PSC-approved contract "shall be valid and binding in accordance with its terms and capacity charges paid pursuant to such a contract ***shall be recoverable costs of the utility for ratemaking purposes…"*** *Id.* at 653 (citing MCL 600.6j(b)). If the Attorney General or a private plaintiff alleged that the electricity rates charged as a result of the approved power supply contract were "grossly excessive" under §3(1)(z) of the MCPA, they would lose. The power supply contract was 1) "a transaction"; 2) "specifically

authorized"; and 3) the specific authorization was provided "under laws administered by a regulatory board or officer acting under statutory authority of this state or the United States."

Similarly, the U.S. Supreme Court found an example of specifically authorized transactions that were held exempt from U.S. antitrust laws in *Hughes Tool Co v Trans World Airlines, Inc.*, 409 U.S. 363, 93 S.Ct. 647 (1973). In that case, an airline brought an antitrust action against a corporation based on the manner in which the corporation had allegedly abused its controlling interest in the airline. 49 U.S.C. 1384,[13] since repealed, at the time granted immunity from antitrust actions as necessary to allow relevant parties "to do anything authorized, approved, or required" by an order of the Civil Aeronautics Board ("CAB"). The *Hughes* court held that "where the CAB specifically authorizes as in the public interest specific transactions between the parent and the subsidiary, the way in which that control is exercised in those precise situations is under the surveillance of the CAB, not in the hands of those who can invoke the sanctions of the antitrust laws." *Id.* at 389. In that case, the Supreme Court's ruling rested upon the fact that;

> [F]rom 1944 through 1960, every acquisition or lease of aircraft by TWA from Toolco and each financing of TWA by Toolco required board approval. Applications were made to the Board in each instance, with the terms and conditions of the transactions being described. Each was approved by the Board…

Id. at 375. Examples of "a transaction" that is "specifically authorized" are not difficult to find. But Lilly has simply failed to present such an example in this case.

II. ***SMITH* AND *LISS* WERE WRONGLY DECIDED.**

Let's name the elephant in the room: Lilly knows that: 1) it did not present "a transaction" to the FDA for "specific authorization"; and 2) any conduct that the FDA may have specifically authorized was entirely unrelated to the rebate agreements and other pricing conduct that the

[13] Available for reference at https://www.govinfo.gov/content/pkg/COMPS-221/pdf/COMPS-221.pdf (last accessed on Aug. 23, 2025).

Attorney General attempts to investigate as potentially violative of the MCPA. Consequently, the **conduct** prong of the specific authorization exemption is of no use to Lilly—the pricing conduct the Attorney General attempts to investigate was not authorized. So, Lilly must either prevail on the **transaction** prong of the exemption or comply with the Attorney General's subpoena.

As a result, Lilly turns to this Court's holdings in *Smith* and *Liss* in an attempt to convert its lack of transactional authorization into "general" transactional authorization. As outlined above, a straightforward reading of the plain meaning of the text of the statute doesn't support an exemption. In attempting to concoct such an exemption, Lilly demonstrates everything that is wrong with the Court's decisions in *Smith* and *Liss* to begin with. The decisions:

- violate long-held principles cherished by this Court by departing from the text of the statute and interposing the term "general" where it does not exist;
- violate other statutory interpretation aids, such as reading statutory terms *in pari materia* with other similarly worded statutes;
- run counter to decades of successful Attorney General enforcement of egregious pricing conduct in the pharmaceutical industry; and
- lead to absurd results. Lilly's interpretation of the decisions is so broad that it could support the notion that **even criminal conduct could be recharacterized as "specifically authorized" and exempt from the MCPA.**

As set forth below, the decisions have damaged credible enforcement of the Michigan Consumer Protection Act and should be reversed.

A. "A transaction" does not mean "a general transaction."

When counsel for Lilly told Justice Clement that "you simply need specific authorization to engage in a *type* of transaction[,]" he was likely seeking to draw from, or expand upon, the *Smith* court's statement that "it is whether the general transaction is specifically authorized by law." 460 Mich at 465. To the extent *Smith*'s use of the phrase "general transaction" is read to mean "type of transaction", § I.A above applies to "general transaction" too. But in any case, by inserting the

word "general" where it does not exist in the statute, the *Smith* Court brazenly overstepped its authority.

Returning to the plain language of the statute, § 4(1)(a) establishes an MCPA exemption for "A transaction or conduct specifically authorized" by state or federal regulatory bodies. **The only descriptor in this entire clause is the word "specifically".** The *Smith* Court's choice to interpret this clause so that the operative descriptor is "general"—essentially an antonym—"give[s] effect to an intent contrary to the language of the statute as written." *Wickham v Carlton Twp. School Dist. No. 2*, 325 Mich 94, 95; 37 NW2d 770 (1949).

Moreover, this act of legislating from the bench violated *stare decisis* in the process by contradicting *Diamond Mortgage*. The *Diamond Mortgage* Court explained clearly that "While the license generally authorizes Diamond to engage in the activities of a real estate broker, **it does not specifically authorize the . . . transactions that result**[.]" 414 Mich at 617 (emphasis added). But *Smith* knavishly evaded this issue by applying the rejected descriptor to the opposite noun, holding that "§ 4(1)(a) generally exempts the sale of credit life insurance from the provisions of the MCPA, because such 'transaction or conduct' is 'specifically authorized[.']" 460 Mich at 465.

The *Smith* Court feigns deference to *Diamond Mortgage*, claiming that the distinction is that "the transaction at issue, mortgage writing, was not 'specifically authorized' under the defendant's real estate broker's license." *Id.* at 464. But this is plainly not what *Diamond Mortgage*'s holding was based on; they specifically considered this issue and determined that the license *did* contemplate mortgage writing. ("Diamond was entitled to perform all the acts of a real estate broker contemplated by the real estate brokers licensing act. One of the activities contemplated by the act was that licensees would negotiate the mortgage of real estate." 414 Mich at 616 (internal citations omitted). Further, in the same paragraph *Smith* cites for *Diamond*

Mortgage's holding, the Court expressly stated that "the license generally authorizes Diamond to engage in the activities of a real estate broker" but "a real estate broker's license is not specific authority for all the conduct and transactions of the licensee's business." 460 Mich at 464 (quoting *Diamond Mortgage*, 414 Mich at 617). Clearly, the *Diamond Mortgage* Court was not suggesting that § 4(1)(a) failed to attach simply because the defendant had obtained the wrong license, but instead was holding that the general license did not exempt the indefinite list of subsequent transactions under such a license.

In *Liss*, the Court befouled § 4(1)(a) even more. It held that "the MCPA exemption applies to [people] who engage in the type of activities" that are "permitted by [statute or regulation] to be performed only by" those licensed under such statute or regulation. 478 Mich at 215. This was premised upon a blatant misrepresentation, pretending again that § 4(1)(a) was found to not apply in *Diamond Mortgage* because the conduct at issue was something the defendant's license "simply did not permit them to do," *id.*, despite the *Diamond Mortgage* Court's explicit recognition to the contrary. 414 Mich at 616 (internal citations omitted)). In other words, ***all*** workers in a generally licensed field—builders, plumbers, electricians, appraisers, funeral directors, polygraph examiners, even doctors and attorneys—are by definition immune from MCPA claims. Incredibly, *Liss* somehow postulates that this status of the activity being generally permitted when licensed is sufficient to identify when § 4(1)(a) attaches, ***even though*** "there are . . . instances where one can engage in the business . . . without having a license." 478 Mich at 215.

In effect, *Smith* and *Liss* completely reverse the holding of *Diamond Mortgage*. Where *Diamond Mortgage* instructs that general authorization of a specific transaction is insufficient for § 4(1)(a) to attach, *Smith* and *Liss* instruct that specific authorization of a general transaction is. The difference between the two appears to be none. **In all three cases, a defendant legally**

engaging in a regulated industry simply pointed to their industry license and claimed that it granted "specific authority for all the conduct and transactions of the licensee's business." *Id.* at 209 (quoting *Smith*, 460 Mich at 464 (quoting *Diamond Mortgage*, 414 Mich at 617)). ***Diamond Mortgage* said no; *Smith* said yes.**

Where *Diamond Mortgage* was improperly denied *stare decisis* deference by the Court in *Smith*, and where *Smith* improperly engaged in judicial legislation by inserting an antonymic word into its interpretation of the plain language of the statute, *Smith*'s interpretation was clearly judicial error. This error has only been further aggrieved by *Liss*.

B. ***The exemption claimed by Lilly should be construed* in pari materia *with a similar exemption under the Michigan Antitrust Reform Act (MARA). The overly broad exemption claimed by Lilly in this case contradicts twenty-five years of law enforcement precedent addressing unlawful pharmaceutical pricing behavior under the MCPA and the MARA.***

i. The Statutory Exemptions for "a Transaction or Conduct Specifically Authorized" Contained in Both the MCPA and the Michigan Antitrust Reform Act Should Be Read *in Pari Materia*.

The text of the "specific authorization" exemption in the MCPA, section 445.904 (1)(a), should not be reviewed in isolation. A nearly identical exemption is set forth in the Michigan Antitrust Reform Act (MARA), MCL 445.774, as follows:

> This act shall not apply to ***a transaction or conduct specifically authorized under the laws*** of this state or the United States, or specifically authorized under laws, rules, regulations, or orders administered, promulgated, or issued by a regulatory agency, board, or officer acting under statutory authority of this state or the United States. (Emphasis added.)

These statutory exemptions should be read together in a consistent fashion and interpreted *in pari materia* for both statutes. As this Court has explained:

> It is a well established rule that in the construction of a particular statute, or in the interpretation of its provisions, all statutes relating to the same subject or having the same general purpose, should be read in connection with it, as together constituting one law, although they were enacted at different times, and contain no reference to one another. [*Rathbun v State*, 284 Mich 521, 543; 280 NW 35 (1938).]

The Legislature enacted the MCPA in 1976 and the MARA a mere eight years later in 1984. MCL 445.771 *et seq*. Both statutes are included within Chapter 445, the "Trade and Commerce" Chapter, of the Michigan Compiled Laws Annotated. Both statutes have historically been drawn upon to address the integrity of consumer markets and to safeguard competition within those markets. And as addressed below, the Attorney General frequently cites to violations of either, or both, as the basis for civil law enforcement actions that challenge pricing and related transactional behavior by pharmaceutical manufacturers. Under *Rathbun*, interpretation of the virtually identical "specific authorization" statutory exemptions in the MCPA and the MARA should be read consistently and *in pari materia*.

ii. <u>The Michigan Attorney General Has Historically Applied *Both* the MCPA and the MARA to Enforce the Law Against Egregious Prices Charged in Transactions, and Conduct Causing Such Egregious Prices, in the Pharmaceuticals Industry. Such Conduct Has Successfully Been Challenged Even When the FDA Has "Approved" the Drug that Was the Subject of the Action.</u>

As demonstrated below, the Michigan Attorney General has a long track record of successfully challenging unlawful and anticompetitive transactions and price gouging conduct in the pharmaceutical industry—in spite of the fact that those challenges all involved FDA approved drugs. Until Lilly's invocation of FDA approvals as "specific authorization" in this proceeding, no court has applied an FDA approval as a basis for exempting unlawfully priced transactions or anticompetitive conduct involved in drug transactions from either the MCPA, MCL 445.904(1)(a), or the MARA, MCL 445.774(4). Lilly's requested broad application of an exemption—where the

FDA's review and approval of a drug's safety and efficacy could somehow exempt transactions related to that drug from liability for unlawful monopolization, price fixing, restraint of trade or price gouging—is unheralded. A brief recitation of some of the Attorney General's relevant law enforcement history follows.

Cardizem CD (extended-release diltiazem hydrochloride). In 1997–98, branded drug manufacturer Hoechst Marion Roussel, Inc. entered a "pay-for-delay" agreement,[14] where it paid generic drug manufacturer Andrx Inc. $89.83 million to stay off the market with Andrx's less expensive and ***FDA-approved*** version of the same drug.[15] The Hoechst/Andrx deal deprived consumers of the less expensive generic medication and forced them to continue paying the higher branded drug prices. A host of private plaintiffs filed a class action lawsuit challenging the conduct as an illegal restraint of trade under federal and state antitrust law, and Aetna Inc. (the health insurance company) ultimately served as the plaintiff class representative.[16] In May 2001, a number of state attorneys general, led by the Michigan and New York Attorneys General, similarly challenged the anticompetitive conduct[17] and represented consumers of the drugs. Ultimately, the agreement between Hoechst and Andrx was found to be a *per se* illegal violation of federal and state antitrust laws, including the Michigan Antitrust Reform Act.[18] Also of note, the court (the Honorable Nancy Edmunds presiding) rejected the defendants' argument that the federal FDA

[14] The United States Supreme Court has held that so-called "pay to delay" or reverse payment patent settlement agreements are subject to antitrust scrutiny under a rule of reason analysis. See also *FTC v Actavis, Inc,* 570 U.S. 136; 133 S Ct 2223; 186 L Ed 2d 343 (2013). See Federal Trade Commission, *Pay-for-Delay: When Drug Companies Agree Not to Compete.* https://www.ftc.gov/news-events/topics/competition-enforcement/pay-delay (accessed April 30, 2024).

[15] *In re Cardizem CD Antitrust Litig*, 105 F Supp 2d 618, 623 (ED Mich, 2000).

[16] *In re Cardizem CD Antitrust Litig*, 218 FRD 508, 516 (ED Mich, 2003).

[17] *Id*. at 514.

[18] *In re Cardizem CD Antitrust Litig*, 105 F Supp 2d 618, 627 n 6, 682 (ED Mich, 2000).

regulatory scheme preempts claims under state antitrust law.[19] The matter ultimately settled for $80 million.[20]

Clorazepate and Lorazepam. In 1998, pharmaceutical manufacturer Mylan Laboratories entered into an exclusive supply arrangement with the producer of an active pharmaceutical ingredient supplier for the generic drugs lorazepam (marketed under the brand name Ativan) and clorazepate. After locking up the market, Mylan jacked up the prices. For clorazepate, Mylan raised its prices between a range of 1,900 percent to over 3,200 percent. For lorazepam, Mylan raised the prices between a range of 1,900 percent to 2,600 percent.[21] Like the current action, the marketing of those drugs by generic manufacturer Mylan received ***FDA approval***.[22]

The Michigan Attorney General, and 31 other state attorneys general, challenged these outrageous price increases under state antitrust and consumer protection statutes and litigated the case jointly with the Federal Trade Commission which similarly challenged these price increases as violative of the "unfair competition" prohibition in the Federal Trade Commission Act, 15 USC 45,[23] as well as the Sherman Antitrust Act. The Michigan Attorney General sued under the identical

[19] *In re Cardizem CD Antitrust Litig*, 105 F Supp 2d 618, 659–663.

[20] *In re Cardizem CD Antitrust Litig*, 218 FRD 508 (ED Mich, 2003).

[21] *FTC v Mylan Labs., Inc*, 62 F Supp 2d 25, 34 (DDC), *on reconsideration in part sub nom. Fed Trade Comm'n v Mylan Labs., Inc*, 99 F Supp 2d 1 (DDC, 1999).

[22] "Mylan and other generic drug manufacturers require the approval of the Food and Drug Administration (FDA) to market a generic product in the United States. For each generic drug, the manufacturer must file an Abbreviated New Drug Application (ANDA) with the FDA to establish that its version of the drug is therapeutically equivalent to the branded drug." *FTC v Mylan Labs., Inc*, 62 F Supp 2d at 33.

[23] State consumer protections statutes across the country are sometimes referred to as mini-FTC Acts. Like the prohibition of "unfair, unconscionable, or deceptive methods, acts, or practices" defined in the Michigan Consumer Protection Act, MCL 445.903, the Federal Trade Commission Act prohibits unfair methods of competition and unfair or deceptive acts or practices. 15 USC 45.

"grossly excessive price" provision of the Michigan Consumer Protection Act, MCL 445.903(1)(z), that is at issue in the investigation of Lilly's pricing conduct, as well as illegal monopolization under the Michigan Antitrust Reform Act.[24] Michigan prevailed on a motion to dismiss filed by the pharmaceutical defendants[25] and the case ultimately settled for $100 million.[26]

TAXOL (paclitaxel). In 2003, the Michigan Attorney General similarly filed a lawsuit to enforce the MCPA, the MARA, and the Sherman Antitrust Act against Bristol Myers Squibb for its overpricing of the chemotherapy drug Taxol. The Attorney General's lawsuit alleged that:

> Bristol fraudulently procured patents from the United States Patent and Trademark Office ("PTO"), improperly listed these invalid patents in the FDA's "Approved Therapeutic Equivalence Evaluations," ("the Orange Book"), and prosecuted numerous baseless lawsuits and regulatory procedures against the market entry of competitive, FDA approved generic bioequivalents to Taxol® ("generic Taxol®"), the branded version of the generic chemotherapy drug paclitaxel. [*State of Ohio et al v Bristol Myers Squibb*, No. 02-CV-01080, 2003 WL 22331401 at *4 (DDC April 4, 2003).]

The Attorney General acknowledged in the complaint that Taxol had obtained ***FDA approval***, stating that "[o]n July 22, 1992, Bristol filed an NDA [New Drug Application] seeking approval to market Taxol® for the treatment of ovarian cancer. The FDA approved Bristol's application on December 27, 1992…" *Id*. at *9. Bristol Myers Squibb settled the lawsuit for $55 million.[27]

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[24] *FTC v Mylan Labs., Inc*, 62 F Supp 2d at 48.

[25] *Id*.

[26] *In re Lorazepam and Clorazepate Antitrust Litig*, 205 FRD 369 (DDC, 2002); See also National Association of Attorneys General, *Connecticut v Mylan Laboratories, Inc. (In re Lorazepam & Clorazepate Antitrust Litigation), MDL No. 1290 (D.D.C. June 15, 2000) 205 F.R.D. 369 (D.D.C. 2002); No. 98 CV 3115 (D.D.C. 2000) – complaint*, available at https://www.naag.org/multistate-case/connecticut-v-mylan-laboratories-inc-in-re-lorazepam-no-98-cv-3115-d-d-c-2000-complaint/ (accessed April 30, 2024).

[27] See National Association of Attorneys General, *Ohio, et al, v Bristol-Myers Squibb Co., et al. (D.D.C. 2002); see also In re Buspirone Antitrust Litigation,Case No. 01 CV 11401, MDL 1410, MDL 1413 (S .D.N.Y.)*, available at https://www.naag.org/multistate-case/ohio-et-al-v-bristol-

Other drugs. The Michigan Attorney General has waged similar challenges over the years concerning unfair, unconscionable, deceptive, and anticompetitive practices associated with ***FDA-approved*** drugs, including the anti-anxiety medication Buspar,[28] and the cholesterol drug Tricor,[29] under the MARA. And the Attorney General is presently litigating an action under both the MCPA and the MARA concerning anticompetitive pricing practices for the drug Doxy DR in *Connecticut et al. v Teva Pharmaceuticals et al.*, Civ. Action No. 3:16-CV-002056 (D Conn).[30]

Under each of these enforcement actions, the MCPA claims and/or the MARA claims in the Michigan Attorney General's lawsuits involved ***FDA-approved*** drugs. But FDA approval over the "safety and efficacy" of the drugs had nothing to do with the illegal pay-for-delay agreements (Cardizem), the anticompetitive exclusive supply arrangements (lorazepam and clorazepate), the fraudulently obtained patents (Buspar and Taxol) or the price fixing agreements (Doxy) that were alleged in those lawsuits and that caused consumers to pay ***exorbitant prices*** for those drugs. The FDA did not specifically approve the transaction or the conduct that was the cause of the high-priced drugs in any of those cases, just as the FDA has not specifically approved the transactions or the conduct that the Attorney General seeks to investigate in this proceeding. But under the

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myers-squibb-co-et-al-d-d-c-2002-see-also-in-re-buspirone-antitrust-litigationcase-no-01-cv-11401-mdl-1410-mdl-1413-s-d-n-y/.

[28] *In re Buspirone Patent Litig*, 185 F Supp 2d 363 (SDNY, 2002), settled for $93 million. See National Association of Attorneys General, *In re: Buspirone Antitrust Litigation,Case No. 01 CV 11401, MDL 1410, MDL 1413 (S .D.N.Y.) (see also Ohio v Bristol Myers Squibb)*, available at https://www.naag.org/multistate-case/in-re-buspirone-antitrust-litigationcase-no-01-cv-11401-mdl-1410-mdl-1413-s-d-n-y-see-also-ohio-v-bristol-myers-squibb/.

[29] See National Association of Attorneys General, *Florida et al. v Abbott Laboratories et al., No. 1:08-cv-00155-SLR (D.Del. 2007)* https://www.naag.org/multistate-case/florida-et-al-v-abbott-laboratories-et-al-no-108-cv-00155-slr-d-del-2007/.

[30] See Amended Complaint, *Connecticut et al. v Teva Pharmaceuticals et al.*, Civ. Action No. 3:16-cv-02056 (D Conn), available at https://www.naag.org/wp-content/uploads/2020/10/703.civil_.CT-v-Aurobindo-amended-complaint-3.pdf.

"general transaction" approval theory promoted by Lilly in this case, all kinds of otherwise illegal conduct are purportedly immunized from Michigan's Consumer Protection Act as part of a "general transaction."

Lilly's overly broad invocation of the specifically authorized exemption, as applied to the ***price*** of a drug charged in transactions that were not specifically authorized, violates years of precedent under both the MCPA and the MARA. Furthermore, these two statutes should be read *in pari materia* with each other. But applying the "specifically authorized" exemption as advocated by Lilly, would create a conflict between the interpretation of the exemption under the MCPA and the interpretation of the nearly identical exemption under the MARA.

As this Court explained when addressing conflicting interpretations of similar statutes:

> In attempting to find a harmonious construction of the statutes, we 'will regard all statutes upon the same general subject-matter as part of one system…' Further, 'statutes *in pari materia,* although in apparent conflict, should, so far as reasonably possible, be construed in harmony with each other, so as to give force and effect to each…" [*Intl Bus Machines Corp v Dept of Treasury*, 496 Mich 642, 652; 852 NW2d 865 (2014).]

Lilly could argue that the FDA's "specific authorization" of the "general transaction" of a drug as to safety and efficacy means that the drugmaker is exempt from both the MARA and the MCPA. That would be one way to "harmonize" the statutes. But this interpretation leads to absurd results.[31] Under such an interpretation, an FDA "safety and efficacy" determination for marketing a drug would immunize the drugmaker from illegal price fixing with its competitors, illegal agreements between competitors to divide the market, illegal monopolization claims, and illegal

[31] "[S]tatutes must be construed to prevent absurd results...." *People v Tennyson*, 487 Mich 730, 741; 790 NW2d 354 (2010) (quoting *Rafferty v Markovitz*, 461 Mich 265, 270; 602 NW2d 367 (1999)); "Under the absurd-results rule, 'a statute should be construed to avoid absurd results that are manifestly inconsistent with legislative intent[.]'" *Barrow v Detroit Election Comm'n*, 301 Mich App 404, 416; 836 NW2d 498 (2013) (quoting *Detroit Intern Bridge Co v Commodities Exp Co*, 279 Mich App 662; 760 NW2d 565 (2008) (citation omitted)).

price gouging. There is no indication that the Legislature intended to cast such an overly broad immunization of illegal and anti-consumer conduct when it provided an exemption for transactions or conduct that were "specifically authorized." But when one merely needs specific authorization of a "general" transaction, as advocated by Lilly, such absurd results are unavoidable.

The Court should harmonize the application of the "specifically authorized" exemption under both the MCPA and the MARA in a manner that is consistent with *Diamond Mortgage*. Since the "methods, acts, or practices" that are potentially unlawful under the MCPA in this case have not been "specifically authorized" in a "transaction or conduct", the statutory exemption in Section 4(1)(a) of the MCPA should not apply. This approach harmonizes the application of the specific authorization exemption under the MCPA and the MARA, recognizes how these statutes have been applied for over twenty-five years, avoids absurd results, and restores the requirement that an authorization should be "specific," not "general," in order for the exemption to apply.

The exemption claimed by Lilly should be construed *in pari materia* with a similar exemption under the Michigan Antitrust Reform Act (MARA). The overly broad exemption claimed by Lilly in this case contradicts more than twenty-five years of law enforcement precedent addressing unlawful pharmaceutical pricing behavior under the MCPA and the MARA.

C. ***Lilly's interpretation of a "general transaction" exemption would lead to absurd results as even criminal conduct could be relabeled as specifically authorized and thus, exempt from MCPA scrutiny.***

"[S]tatutes must be construed to prevent absurd results[.]" *People v Tennyson*, 487 Mich 730, 741; 790 NW2d 354 (2010) (quoting *Rafferty v Markovitz*, 461 Mich 265, 270; 602 NW2d 367 (1999)). "Under the absurd-results rule, 'a statute should be construed to avoid absurd results that are manifestly inconsistent with legislative intent[.]'" *Barrow v Detroit Election Comm'n*, 301

Mich App 404, 416; 836 NW2d 498 (2013) (quoting *Detroit Intern Bridge Co v Commodities Exp Co*, 279 Mich App 662; 760 NW2d 565 (2008) (citation omitted)).

With the broad reading of the term "transaction" proposed by Lilly, clearly illegal conduct may be interpreted as having been "specifically authorized", leaving consumers without a remedy. As Justice Kelly stated in her dissenting opinion in *Liss*, "A transaction or conduct that is actually prohibited by law cannot be deemed to be specifically authorized." *Liss*, 478 Mich at 222. Yet, this result is easily—and absurdly—envisionable under the arguments presented by Lilly to the Court.

For example, on January 14, 2009, Lilly entered a guilty plea and agreed to pay a total of $1.415 billion to the U.S. Department of Justice for "off label marketing" of its drug Zyprexa. Ex. 4. As the DOJ Memorandum submitted in conjunction with Lilly's guilty plea explains, Lilly was approved to market Zyprexa for the treatment of "schizophrenia and certain aspects of Bipolar Disorder." Ex. 5, p.3. Lilly, however, promoted Zyprexa "for the treatment of unapproved uses, including dementia, Alzheimer's dementia" and others. *Id.* "Eli Lilly's management created marketing materials for these off-label uses, trained the sales force, and directed the off-label marketing." Id. The FDA never approved these other uses for the drugs. And they certainly didn't authorize a "transaction" involving the purchase of Zyprexa for these uses. But under Lilly's expansive use of the term "general transaction" or "type of transaction", a consumer who unwittingly purchased Zyprexa for the treatment of Alzheimer's due to Lilly's criminally deceptive marketing cannot sue Lilly under MCL 445.903(1)(c) ("representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits …that they do not have…").

For another example, we can look to one of the amici in this very case: General Motors.[32] General Motors has faced numerous legal challenges over its faulty ignition switches, announced in a 2014 recall.[33] After investigation, this resulted in the filing of criminal charges and entry of a Deferred Prosecution Agreement ("GM DPA") where GM admitted that it "failed to disclose to its U.S. regulator and the public a potentially lethal safety defect . . . and that GM further affirmatively misled consumers about the safety of GM cars afflicted by the defect."[34] Related to this defect, "GM has acknowledged 15 deaths [and m]any other deaths have been alleged to be associated with the Defective Switch." GM DPA at 34, n.5. Overnight, consumers who had unknowingly purchased a defective vehicle saw the value of their cars decline precipitously. It seems impossible to imagine a scenario more appropriate for MCPA claims to be filed. But according to Lilly's interpretation of § 4(1)(a), GM would be immune from any such claims. Since all of the impacted vehicles were required to pass the broad federal regulatory requirements included in the Federal Motor Vehicle Safety Standards,[35] Lilly's interpretation would hold that the National Highway Traffic Safety Administration has "specifically authorized" the "general transaction" of selling these vehicles, thus all related conduct is immune from the MCPA—even where GM admits that it hid this fatal defect from the regulators.

[32] Motion for Leave to File *Amicus Curiae* Brief of General Motors LLC, *Dana Nessel v Eli Lilly & Co.*, No. 165961 (Mich Sup Ct May 1, 2024).

[33] *See generally* General Motors, LLC, Response to Special Order, National Highway Traffic Safety Administration (Apr. 3, 2014), available at https://www.nhtsa.gov/sites/nhtsa.gov/files/gm-response-to-special-order.pdf (last accessed Aug. 26, 2025).

[34] *United States v $900,000,000*, No. 1:15-cv-07342, Dkt. 1 (S.D.N.Y. Sept. 16, 2015); *United States v $900,000,000*, No. 1:15-cv-07342, Dkt. 1-1 (S.D.N.Y. Sept. 16, 2015) ("GM DPA").

[35] *See* 49 USC 30111; 49 USC 30112; 49 CFR 571.

III. THE *ROBINSON* FACTORS URGE THE COURT TO OVERTURN *SMITH* AND *LISS*.

When considering overturning precedent, "[t]he first question, of course, should be whether the earlier decision was wrongly decided." *Robinson*, 462 Mich at 464. As discussed above, it is abundantly clear that *Smith* and *Liss* were flawed decisions. Once it is determined that the earlier decision was in fact erroneous, the Court applies "a three-part test to examine the effects of overruling a previous incorrect judicial decision: (1) whether the questioned decision defies practical workability, (2) whether reliance interests would work an undue hardship if the decision were overturned, and (3) whether changes in the law or facts no longer justify the decision." *Stokes v Swofford*, 514 Mich 423, 451, 22 NW3d 97 (2024), reh'g denied sub nom. *Selliman v Colton*, 10 NW3d 651 (Mich 2024) (internal quotations omitted) (quoting *Robinson*, 462 Mich at 464). Here, as in *Stokes*, no change in the law or facts guides the decision, but "the totality of the remaining factors weigh in favor of overruling" *Smith* and *Liss*. *Stokes*, 514 Mich at 455.

The Attorney General's brief provides extensive analysis of the *stare decisis* implications of *Smith* and *Liss*, and we do not feel the need to repeat those points. However, we note below a few observations that further highlight the appropriateness of overturning these two wrongfully decided cases.

A. The MCPA is utterly unworkable under Smith and Liss.

The extent to which these two precedents thwart the protections of the MCPA can scarcely be overstated, and is largely discussed in § I above and § III of the Attorney General's brief. The resulting incapacitation of the MCPA is truly unconscionable. To say it plainly: *Smith* and *Liss* have gutted the MCPA, and this has never been a secret.

As Lilly has noted, *Smith*—and *Liss*, as premised upon *Smith*—"followed *Kekel*'s reading of *Diamond Mortgage[.]*" Lilly Br. at 47. But therein lies the flaw; *Kekel* was never solid footing

and has destabilized this doctrine ever since. Before *Smith* was decided, three separate federal judges had rejected *Kekel* as an illegitimate interpretation of *Diamond Mortgage*. "Therefore, the court agrees with Judges Churchill and Guy that ***the Kekel case is not soundly reasoned*** and that the Michigan Supreme Court would decide differently if given the opportunity. Lawson, supra, slip op. at 8, citing *Bridges v. Fire Ins. Co. of Quaker City*, No. 84–3179 (E.D.Mich.1985) (Guy, J.)." *Robertson* 890 F Supp at 676 (emphasis added). It was abundantly clear that *Smith*'s reasoning was absurd even before it was decided—and no less after.

When *Smith* was decided in 1999, Justice Michael Cavanagh—one of the Justices who decided MCL 445.904's original interpretation in *Diamond Mortgage*—authored a dissenting opinion and stated that: "In simple terms, the MCPA protects consumers from unfair business practices regarding the sale of personal, family, or household goods or services. Because such businesses are regulated, the consumer has little or no redress under the provisions of the MCPA according to the majority." *Smith*, 460 Mich at 481. Justice Marilyn Kelly joined in this dissent.

Even before *Liss* distorted the doctrine further, the principal author of the MCPA published an article denouncing the decision in *Smith*. In no uncertain terms, he wrote that, under *Smith*: "if the defendant in a MCPA action can point to the legal fact it is regulated by law, then it may obtain an exemption from the MCPA. This is utter absurdity." *Bladen*, *supra* note 4 at 15. Another article published in the Michigan Bar Journal observed after *Smith* that: "there may be little left of the power to protect consumers that the legislature had in mind when it passed the act" because "[a]pplying the Smith analysis, if the general transaction is specifically authorized by statute, e.g.,

selling credit life insurance; then even if the defendant has engaged in unfair or deceptive trade practices in selling the credit life insurance, the transaction is exempt from MCPA liability."[36]

When *Liss* was decided in 2007, Justice Marilyn Kelly authored a dissenting opinion which concluded that the majority holding in *Liss*: "decides that the exemption applies to any business that has a licensing scheme similar to that used by residential home builders. The result may well be that a large number of Michigan businesses will be able to engage in unfair or deceptive practices without running afoul of the MCPA." *Liss*, 478 Mich at 230. She goes on to highlight that, under *Smith* and *Liss*, the exception "permits illegal behavior to be exempt from the MCPA" and notes that in *Liss* itself, "plaintiffs accuse[d] defendants of behavior that is illegal . . . [y]et under *Smith*, even if plaintiffs' allegations are true, defendants would be exempt from liability under the MCPA." *Liss*, 478 Mich at 221-22.

Writing separately, and while concurring in part with Justice Kelly's dissent, Justice Cavanagh authored his own dissent in *Liss*. He stated explicitly that: "not only was *Smith* wrongly decided, the *Smith* decision defies practical workability because it disallows numerous claims that are actually *allowed* under the relevant statutory language." *Liss* 478 Mich at 216. Moreover, he stated directly: "I believe that *Smith* should be overruled on the basis of the factors set forth in *Robinson*[.]" *Id*.

There can scarcely be a more relevant argument that this doctrine is unworkable than the real-time recognition of this fact by two prescient Justices—and the author of the statute in question. From the day *Smith* was decided, and undoubtedly by the day *Liss* was decided, it was

[36] Gary M. Victor, *What's left after Smith v Globe?*, MICH BAR J (2003), available at https://www.michbar.org/file/barjournal/article/documents/pdf4article619.pdf (last accessed Aug. 20, 2025).

painfully obvious that these decisions defied workability, and the compelling need to overturn them has only become more apparent since.

B. ***There is no valid reliance interest in continuing to uphold Smith and Liss where reversal would simply allow liability for misconduct that is already prohibited, and the only change Lilly would make is to find new strategies to defend against liability.***

Lilly predictably claims that *Smith* and *Liss* must be maintained because they are "embedded, accepted, and fundamental in Michigan law. Courts and litigants understand how these decisions work." Lilly Br. 51 (internal quotations and citations omitted). But again, Lilly belies the absurdity of its own position. Indeed, courts and litigants do understand how *Smith* and *Liss* are applied; they wholesale erase the MCPA as it applies to myriad businesses operating within the state.

Boldly articulating the outcome it fears in the event that *Smith* and *Liss* are overturned, Lilly decries that "the countless Michigan-based businesses that are in the crosshairs of future litigation must be considered." *Id.* But a desire to evade liability is unquestionably NOT a valid reliance interest for purposes of a *stare decisis* analysis. "[T]o have reliance the knowledge must be of the sort that causes a person or entity to attempt to conform his conduct to a certain norm before the triggering event." *Robinson*, 462 at 467; *see also People v Hawthorne*, 474 Mich 174, 184; 713 NW2d 724 (2006); *Hamed v Wayne Cnty.*, 490 Mich 1, 27; 803 NW2d 237 (2011).

How has Lilly changed its conduct in Michigan in reliance upon *Smith* and *Liss*? It currently faces litigation waged by multiple other attorneys general, such as California, whose consumer protection statutes have never been impaired with an exemption provision as broad as Lilly's interpretation of *Smith* and *Liss.* Does Lilly behave differently in Michigan as compared to these other states? By no stretch of the imagination can Lilly's articulation of its reliance interest—or that of other businesses operating in Michigan—be construed as a statement that it is

affirmatively attempting to conform to the norms set forth in *Smith* or *Liss*. More accurately, Lilly recognizes that in the absence of *Smith* and *Liss*, it would have to conform to the MCPA, and it asks this Court to protect it from having to do so, at the expense of Michiganders' ability to claim the protections of the MCPA in any meaningful way. This falls well-short of *Robinson*'s standard for a reliance interest.

Moreover, while Lilly's interpretation of *Smith* and *Liss* all but exempt it from liability under the MCPA, a violation of virtually any subsection of the MCPA is separately violative of Section 5 of the FTC Act, 15 USC § 45(a)(1) and related consumer protection statutes in other states. Below is a non-exhaustive list of pertinent examples:

- *Compare* MCL 445.903(1)(a) ("Causing a probability of confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services") *with FTC v Colgate-Palmolive Co*, 380 US 374, 389-90; 85 S Ct 1035; 13 L Ed 2d 904 (1965) (considering an FTC Act § 5 claim regarding falsely stating that claims about a product have been certified);

- *Compare* MCL 445.903(1)(b) ("Using deceptive representations or deceptive designations of geographic origin in connection with goods or services") *with Newborn Bros Co, Inc v Albion Eng Co*, 481 F Supp 3d 312 (DNJ, 2020) (considering a Lanham Act claim regarding misleading statements about products' country-of-origin);

- *Compare* MCL 445.903(1)(c) ("Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has sponsorship, approval, status, affiliation, or connection that he or she does not have") *with POM Wonderful, LLC v FTC*, 777 F3d 478; 414 US App DC 111 (2015) (considering an FTC Act claim regarding unsubstantiated claims regarding medical efficacy as a characteristic or benefit of a product);

- *Compare* MCL 445.903(1)(d) ("Representing that goods are new if they are deteriorated, altered, reconditioned, used, or secondhand") *with Tuckish v Pompano Motor Co*, 337 F Supp 2d 1313 (SD Fla, 2004) (considering an FTC Act claim regarding a salesperson misrepresenting a used car as new);

- *Compare* MCL 445.903(1)(e) ("Representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another") *with Kraft, Inc v FTC*, 970 F2d 311 (CA 7, 1992) (considering an FTC Act claim regarding a cheese manufacturer misrepresenting the amount of calcium in its cheese slices);

The list goes on. Although overturning *Smith* and *Liss* would expose Lilly to scrutiny under the MCPA, it would only be additional scrutiny for conduct that may already be unlawful under federal law (the FTC Act) and the consumer protection statutes of multiple other states. Notably, all of these consumer protection statutes were considered "mini-FTC acts" when enacted. In other words, Lilly should already be conforming to the standards of the MCPA, but *Smith* and *Liss* merely reduce its potential liability for failure to do so.

Lilly understands this, too. Its attorney identified numerous examples, even beyond the FTC act, acknowledging that an exemption "under the Michigan Consumer Protection Act doesn't exempt a transaction under the occupational code, the construction code, the vehicle code, [] tort law, the law of contracts, federal law, [or] the antitrust examples under the MARA[.]" App. Oral Arg. at 34:02.

The only purported reliance interest is that, if Lilly engages in conduct it should already know is unlawful, it would have to find other strategies to defend itself against liability rather than rely comfortably on the liability shield afforded by *Smith* and *Liss*. But as noted in the Court's recent opinion in *Stokes v Swofford*, 514 Mich 423, 455, 22 NW3d 97 (2024), "there is no reliance interest when litigants need to adjust their litigation strategy."

RELIEF SOUGHT

The Michigan Association for Justice respectfully submits that to the extent that the Smith and Liss decisions require only "specific authorization" of a "general" transaction, the decisions should be reversed as inconsistent with the text of the MCPA, violative of statutory construction principles, and inconsistent with the Legislature's intent in enacting the Michigan Consumer Protection Act and the Michigan Antitrust Reform Act, which should be consistently interpreted *in pari materia* with each other. As such, the opinions of the lower courts should be reversed and Lilly must be ordered to comply with the Michigan Attorney General's investigative subpoena.

Dated: August 28, 2025

Respectfully submitted,

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WORD COUNT STATEMENT

This document complies with the type-volume limitation of the Michigan Court Rules 7.312(A) and 7.212(B) because, excluding the exempted sections, this **merits brief** contains 12.088 words, not in excess of the permitted 16,000 words.

Dated: August 28, 2025

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