MICHIGAN CHAMBER of Commerce

MEMORANDUM

TO: Members of the House Judiciary Committee

FROM: Wendy Block, Michigan Chamber of Commerce

SUBJECT: MI Chamber Voices Concerns Regarding FDA Defense Repeal (SB 410)

DATE: Oct. 25, 2023

This memo is to voice the **Michigan Chamber's opposition to Senate Bill 410 as written,** legislation to repeal Michigan's FDA defense law, and to ask the committee to **amend the bill to include a rebuttable presumption** (see attached language).

Adding a rebuttable presumption to MCL 600.2946 would balance the Legislature's desire to protect patients and their right to sue when drug manufacturers commit wrongdoing with the need to recognize the unique, gatekeeping role the US Food and Drug Administration (FDA) plays in assessing the efficacy and safety of drugs before they reach patients.

Other states have rebuttable presumption laws on the books, including Colorado, Kansas, Kentucky, Montana, Tennessee, Texas, Utah, and Wisconsin.

Our proposed amendment was drafted to reflect the unique context of FDA-approved medications and sound health policy and product liability law. Specifically, it would:

- Create new paths for those who believe they were harmed by a medication to proceed with a product liability lawsuit.
- Clarify that the exception applies to information concealed both before and after approval of the drug.
- Limit the rebuttable presumption to lawsuits challenging the adequacy of a medication's FDA-approved design/label.
- Have no application beyond product liability claims or to manufacturing defect claims (such as that a drug was contaminated or altered due to a manufacturing flaw or improper storage).

Unlike *existing* law, the amendment does not: (1) require a plaintiff to show a manufacturer intentionally withheld or misrepresented information from the FDA; (2) require a plaintiff to prove that the FDA would not have approved or would have withdrawn approval if the information were accurately submitted; or (3) require the FDA find a regulatory violation or fraud.

The amendatory language we're seeking is based on FDA regulations governing a manufacturer's responsibility to make or propose labeling changes to reflect new information. The exception is based solely on a manufacturer's alleged failure to act and does not require FDA action. The amendment requires complaints to include facts that support rebutting the presumption under an exception above. This provision will avoid vague allegations in a complaint that merely recites the standard for rebutting the presumption.

Thank you for your consideration. Please do not hesitate to contact me with any questions at 517-371-7678 or wblock@michamber.com.

SUBSTITUTE FOR SENATE BILL NO. 410

A bill to amend 1961 PA 236, entitled

"Revised judicature act of 1961,"

by amending section 2946 (MCL 600.2946), as amended by 1995 PA 249.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 2946. (1) It ~~shall be~~ **is** admissible as evidence in a product liability action that the production of the product was in accordance with the generally recognized and prevailing nongovernmental standards in existence at the time the specific unit of the product was sold or delivered by the defendant to the initial purchaser or user.

(2) In a product liability action brought against a manufacturer or seller for harm allegedly caused by a production defect, the manufacturer or seller is not liable unless the plaintiff establishes that the product was not reasonably safe at the time the specific unit of the product left the control of the manufacturer or seller and that, according to generally accepted production practices at the time the specific unit of the product left the control of the manufacturer or seller, a practical and technically feasible alternative production practice was available that would have prevented the harm without significantly impairing the usefulness or desirability of the product to users and without creating equal or greater risk of harm to others. An alternative production practice is practical and feasible only if the

technical, medical, or scientific knowledge relating to production of the product, at the time the specific unit of the product left the control of the manufacturer or seller, was developed, available, and capable of use in the production of the product and was economically feasible for use by the manufacturer. Technical, medical, or scientific knowledge is not economically feasible for use by the manufacturer if use of that knowledge in production of the product would significantly compromise the product's usefulness or desirability.

(3) With regard to the production of a product that is the subject of a product liability action, evidence of a philosophy, theory, knowledge, technique, or procedure that is learned, placed in use, or discontinued after the event resulting in the death of the person or injury to the person or property, which if learned, placed in use, or discontinued before the event would have made the event less likely to occur, is admissible only for the purpose of proving the feasibility of precautions, if controverted, or for impeachment.

(4) In a product liability action brought against a manufacturer or seller for harm allegedly caused by a product, **other than a product to which subsection (5) applies**, there is a rebuttable presumption that the manufacturer or seller is not liable if, at the time the specific unit of the product was sold or delivered to the initial purchaser or user, the aspect of the product that allegedly caused the harm was in compliance with standards relevant to the event causing the death or injury set forth in a federal or state statute or was approved by, or was in compliance with regulations or standards relevant to the event

causing the death or injury promulgated by, a federal or state agency responsible for reviewing the safety of the product. Noncompliance with a standard relevant to the event causing the death or injury set forth in a federal or state statute or lack of approval by, or noncompliance with regulations or standards relevant to the event causing the death or injury promulgated by, a federal or state agency does not raise a presumption of negligence on the part of a manufacturer or seller. Evidence of compliance or noncompliance with a regulation or standard not relevant to the event causing the death or injury is not admissible.

~~(5) In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:~~

~~(a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360,~~

~~360b to 376, and 378 to 395, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.~~

~~(b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.~~

(5) In a product liability action brought against a manufacturer or seller for an injury or death to a person allegedly caused by a drug approved for safety and efficacy by the United States food and drug administration, there is a rebuttable presumption that the drug is not defective or unreasonably dangerous in its design or labeling if the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller.

(a) A plaintiff may rebut this presumption by demonstrating through clear and convincing evidence that the defendant, at any time before the event that allegedly caused the injury, did any of the following:

(i) Before or after approval of the drug, the defendant concealed material information concerning risks of the drug that is causally related to the plaintiff's injury; or

(ii) The defendant knew with substantial scientific certainty that the approved or prescribed labeling was inadequate based on newly acquired information and failed to update or request the United States food and drug administration update the labeling to

reflect a clinically-significant risk necessitating such a labeling change that was causally related to the plaintiff's injury.

(b) In a product liability action described in this subsection, the complaint shall state with particularity the facts that are alleged to demonstrate that a defendant engaged in conduct provided by paragraph (a). A court shall dismiss a product liability action if it determines that the plaintiff has not alleged sufficient facts upon which a fact finder could reasonably find that the plaintiff has rebutted the presumption.

(c) This subsection is inapplicable to:

(i) Claims not meeting the definition of a product liability action as defined by Section 600.2945; or

(ii) Claims alleging an injury caused by a manufacturing defect.