MICHIGAN ASSOCIATION FOR JUSTICE

Tiffany R. Ellis
Attorney, Weitz & Luxenberg
In support of S.B. 410 on behalf of the Michigan Association for Justice.

Michigan law after repeal

Even if this horrible section of the law is deleted, claims by individuals will not be easy to prove. Injured parties will still face strict presumptions in favor of drug makers the same as any other defendant in a product liability case.[1] In other states with rebuttable presumptions there are similar presumptions in favor of the injured party.[2] Not so in Michigan.

What that means is that ALL products cases are difficult to prove in our state, and that will remain true even if section five is repealed. Any suggestion that a new carve out for FDA approved drugs may be better is simply a misnomer and is merely an attempt to substitute one bar to liability for drug makers and sellers with another. There is no reason to provide such special protection to drugmakers as compared to other industries. Motor vehicles are subject to EPA and NHTSA regulations and they do not receive special treatment, nor do FDA approved devices or any food product regulated by the FDA. FDA approved drugs are no different. In addition, the Consumer Product Safety Commission regulates, and sometimes recalls, a whole array of products, from children's toys to lawn mowers.[3] But manufacturers of those products also do not get any special treatment.

No matter the law, drug companies will also vigorously defend against any and all claims with high-priced lawyers like they do in other states. Plus, even in the absence of section five, any future drug case will also be subject to the robust jurisprudence that the United States Supreme Court and federal circuit courts around the country have developed. And even if we make it past those barriers, our people's damages are capped which could mean that even if Michiganders can assert claims, they may still get less than other Americans.[4]

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[1] MCL §600.2946(4).
[2] *See e.g.* CO Rev Stat § 13-21-403(2016)("Noncompliance with a government code, standard, or regulation existing and in effect at the time of a sale of the product by the manufacturer which contributed to the claim or injury shall create a rebuttable presumption that the product was defective or negligently manufactured."); Kan Stat Ann. §60-334(When the injury-causing aspect of the product was not, at the time of manufacture, in compliance with legislative regulatory standards or administrative regulatory safety standards relating to design, performance, warnings or instructions, the product shall be deemed defective unless the product seller proves by a preponderance of the evidence that its failure to comply was a reasonably prudent course of conduct under the circumstances.")
[3] https://www.cpsc.gov/Business--Manufacturing/Testing-Certification/Lab-Accreditation/Rules-Requiring-a-General-Certificate-of-Conformity
[4] MCL §2946(a).

p. 517.321.3073 **f.** 517.321.4694
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The Proposed Amendment

The proposed amendment from the Michigan Chamber of Commerce is not only unnecessary but deceitful. It does not provide those who are injured or killed by bad drugs with a plausible path forward under the law. Instead, it attempts to displace well settled Michigan and Federal rules related to burdens of proof and entirely ignores companies' negligence which can lead to death or injury.

In addition to creating a duplicative, unnecessary rebuttable presumption specific to FDA approved drugs, the amendment goes further:

- The proposed language ignores the reality of how FDA approved drugs make it to consumers. The distribution of drugs occurs through a complex supply chain involving many entities, contract arrangements, and payments that is regulated by the Drug Quality and Security Act.[5] By limiting any purported liability before "the time left the control of the manufacturer or seller" ignores the reality that drug makers should act and should be liable for their failure to do so when they learn about problems with drugs that are already in the hands of warehouses, distributors, pharmacies, and/or consumers. It also ignores the fact that manufacturers have sales representatives that visit with doctors, hospitals, pharmacies, clinics and front groups and sometimes provide misleading material promoting their products. All of this conduct relates to groups who occupy the space after the drug has "left the control of the manufacturer or seller."

- In civil cases the burden of proof is a preponderance of the evidence which means that something must be more likely true than not. The amendment inexplicably heightens the burden of proof in cases involving FDA approved drugs to a more difficult to prove "clear and convincing" standard.

- The alleged way the purported presumption can be rebutted would be nearly impossible to prove. The Chamber's language would require *actual* knowledge by a drug manufacturer or seller, proven with *substantial scientific certainty,* in order to establish liability. This standard ignores the reality that companies may learn facts about their drugs that should have caused them to act, but instead ignored those facts. Indeed, the proposed amendment would ***reward*** manufacturers who intentionally bury their heads in the sand. This language would essentially bar certain negligence claims in Michigan as compared to other states in the context of FDA approved drugs. Moreover, requiring proof of anything with substantial scientific certainty is a heightened standard over normal rules of civil litigation.

[5] https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa

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- The amendment also includes an unnecessary heightened pleading requirement. It is well settled law in this country that for any legal theory advanced, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.[6]

- Any suggestion that this language mirrors laws in other states is also misleading. The Chamber points to the laws of Colorado, Kansas, Kentucky, Montana, Tennessee, Texas, Utah, and Wisconsin. None of these laws are as strict as the Chamber's proposed language. In fact, many also feature rebuttable presumptions that favor plaintiffs – something the Chamber would never propose or support.

[6] *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

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MCL 600.2946

(4) In a product liability action brought against a manufacturer or seller for harm allegedly caused by a product, 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.