MICHIGAN ASSOCIATION FOR JUSTICE

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In support of S.B. 410 on behalf of the Michigan Association for Justice.

Weitz and Luxenberg is a national leader in the representation of people injured by defective drugs and devices. We also represent 62 Michigan cities and counties, as well as other local governments across the country, in the national opiate litigation. I personally spent the last five years working on the litigation including as a member of the trial team in the San Francisco matter that proved Walgreens substantially contributed to the create of a public nuisance of an opioid epidemic city. To date – and this number is still growing – Michigan and its local governments have recovered over a billion dollars in funds to abate the opioid epidemic in Michigan communities.

When the Michigan statutory immunity law was passed in 1995, Michigan was misled. In the nearly 30 years since, the truth has never been so apparent. This ill-advised statute did not keep in or bring pharmaceutical companies to our state. In fact, most drug companies are located in states where the laws are more fair to consumers. Michigan's immunity law has not made drugs safer or less expensive. Big Pharma's threats have never come true. The only thing this drug liability shield has done is to ensure there's no accountability for drug companies when Michiganders are injured or killed.

According to the CDC adverse drug events cause approximately 1.3 million ER visits each year.[1] Around 350,000 of those people require further treatment.[2] And many drug injuries are latent, like cancer, which do not ever get counted in the ER visits.

Courts have Shut the Door On Michigan and its People Because of MCL §2946(5)

This law immunizes drug manufacturers and sellers from liability in lawsuits contending that their drug was defective or unreasonably dangerous "if the drug was approved for safety and efficacy by [the FDA], and the drug and labeling were in compliance with [the FDA's] approval at the time the drug left the control of the manufacturer or seller." MCL §600.2946(5). In theory, the immunity is subject to an exception: if a manufacturer intentionally withholds or misrepresents material information about the drug required to be submitted under the Food and Drug Cosmetics Act ("FDCA") -- and the drug would not have been approved, or the FDA would have withdrawn approval if the information was accurately submitted to the FDA -- or if the manufacturer bribed an FDA official or employee to secure the drug's approval, then a suit can proceed.

[1] Adverse Drug Events in Adults. Centers for Disease Control and Prevention. (April 6, 2023) (https://www.cdc.gov/medicationsafety/adult_adversedrugevents.html#print) (Last accessed Oct. 9, 2023).
[2] *Id.*

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But, six years after the law was passed, *Buckman Company v. Plaintiffs' Legal Committee,* 531 U.S. 341 (2001) was decided. In that case, the United States Supreme Court decided that a state-law fraud-on-the-FDA claim conflicted with, and was thus impliedly preempted by, the FDCA and its amendments because the federal statutory scheme empowered the FDA (alone) to punish and deter fraud against the agency. *Buckman* involved only a claim of fraud on the FDA – it was not a common law product liability claim. In other words, the only way for someone from Michigan who has been injured or killed by a drug to hold the drug maker or seller accountable is if they prove something federal courts have said only the FDA can assert. This decision has been interpreted time and time again, including by the United States Court of Appeals for the Sixth Circuit in *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961, 964 (6th Cir. 2004), to bar Michigan plaintiffs from their day in court. The solution is to repeal this harmful section of the law.

What this means for Michigan Victims.

Here are just a few examples of medications causing serious injuries where courts held that the drug immunity shield deprived Michiganders from a remedy:

- The plaintiff, Julia Garcia, was prescribed the drug *Duract* to treat neck pain and she suffered liver failure requiring a liver transplant. The New Jersey pharma company Wyeth Ayerst was off the hook thanks to the liability immunity law while Ms. Garcia was left without recourse.[3] Notably, Duract was withdrawn from the market in 1998 because of liver toxicity.[4]

- Risperdal, an antipsychotic, causes boys and young men to grow breasts. Numerous cases went to trial in a Pennsylvania consolidated litigation against Pennsylvania defendant Smith Kline and then settled for hundreds of millions of dollars.[5] Michigan plaintiffs were thrown out of court due to the immunity law.[6] The various other state Medicaid agencies were reimbursed for the costly care including the mastectomies they funded.

[3] *Garcia v. Wyeth-Ayerst Laboratoriess*, 385 F.3d 961, 964 (6th Cir. 2004).
[4] Duract (bromfenac) Information. U.S. Food and Drug Administration. (Feb. 6, 2018) (https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/duract-bromfenac-information) (Last accessed Oct. 9, 2023).
[5] Thomas, Kate. "J.&J. to Pay $2.2 Billion in Risperdal Settlement," New York Times (Nov. 4, 2013)(https://www.nytimes.com/2013/11/05/business/johnson-johnson-to-settle-risperdal-improper-marketing-case.html) (*Last accessed* Oct. 9, 2023).
[6] *In Re Risperdal Litigation,* 2015 Phila. Ct. Com. Pl. LEXIS 254 (Phila. CCP October 1, 2015); *See also, Short v. Janssen Pharms., Inc.,* No. 1:14-CV-1025, 2015 WL 2201713, at *6 (W.D. Mich. May 11, 2015)(…"the "absolute defense" applies, and the Court ***GRANTS*** the motion to dismiss.").

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- Vicki Marsh was prescribed the psoriasis medication *Raptiva*, made by Delaware company Genetech. *Raptiva* was later pulled from the market due to its propensity to induce infections and neurological disease.[7] Vicki Marsh developed viral meningitis, and then a collapsed lung among other injuries. She and three other Michigan plaintiffs with grave adverse events, one who died, were all thrown out of court due to the Michigan liability shield.[8]

- Just last week, the Delaware drug company Astra Zeneca announced it would pay $425 million to settle about 11,000 lawsuits of people who had developed chronic kidney disease after using its heartburn drugs Nexium and Prilosec PPIs.[9] Sadly, our Michigan citizens cannot participate in this settlement because the New Jersey federal court previously granted the Defendants' bid to toss the claims of all Michigan plaintiffs due to the immunity statute.[10] Our firm had approximately 500 Michigan clients who could not recover for their injuries. Many more Michigan consumers could not even find lawyers willing to try to help them because of the immunity law obstacle.

The list goes on and on. But behind each adverse effect are real people and families who suffer. Studies and history also show us that women suffer disproportionately from the effects of dangerous drugs.[11] It wasn't until 1993 when women were even required to be included in human subject research. *Id.* And still today women are consistently underrepresented in studies or outright excluded. *Id.*

[7] FDA Statement on the Voluntary Withdrawal of Raptiva from the U.S. Market. U.S. Food & Drug Administration (April 8, 2009)(https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fda-statement-voluntary-withdrawal-raptiva-us-market) (Last accessed Oct. 9, 2023).
[8] *Marsh v, Genentech*, 693 F.3d 546 (6th Cir. 2012)
[9] "Pierson, Brendan. "AstraZeneca to pay $425 million to end US lawsuits over heartburn drugs." Reuters. (Oct. 3, 2023). https://www.reuters.com/legal/astrazeneca-pay-425-mln-settle-nexium-prilosec-litigation-us-2023-10-03/#:~:text=Oct%203%20(Reuters)%20%2D%20Britain's,Prilosec%20caused%20chronic%20kidney%20disease. (Last accessed October 10, 2023).
[10] In Re: Proton-Pump Inhibitor Products Liability Litigation, Case 2:17-md-02789-CCC-LDW Document 885 Filed 12/22/22; https://www.druganddevicelawblog.com/2022/10/proton-pump-plaintiffs-cant-meet-burden-on-michigan-immunity-exception.html (last accessed October 10, 2023)
[11] "From Accutane to Zonite: A History of Dangerous Drugs and Devices Marketed to Women." American Association for Justice. (May 2017)(https://www.justice.org/resources/research/from-accutane-to-zonite) (Last accessed Oct. 9, 2023).

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What this Means for our State Budget.

The State of Michigan itself is also harmed by this liability shield law. Since its passage, the State has missed out on many millions of dollars it could have recouped for Medicaid services it provided to those injured or killed by bad drugs. In other states, Medicaid agencies have a right to recover from lawsuits when they expend money to treat injured persons. Only Michigan is deprived of the opportunity to recoup those costs. We cannot provide an exact amount of money we've left on the table, but it's hundreds of millions of dollars.

For example, you may have heard of a painkiller called Vioxx in the early 2000's that caused heart attacks in the people who took it. The drug was so bad, despite being a blockbuster drug, its maker Merck pulled it from the market.[12] The State of Michigan – along with other states and tens of thousands of individuals – sued.

In the lawsuit Michigan explained that it had paid out more than $20 million in Medicaid expenses to treat those injured by the drug. Unsurprisingly, our Courts agreed with the drug maker and found that because Vioxx had been approved by the FDA, the state's claims were barred by Section 5.[13]

In the end, Viox paid $4.85 billion to settle the tens of thousands of lawsuits brought by people it harmed or killed.[14] The company agreed to pay 43 states and the federal government $615 million in civil damages and penalties to compensate the states for the money they spend.[15] Georgia got over $15 million.[16] Michigan recouped nothing, and instead bore the loss of funerals and costs of hospital stays for our people.

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[12] Vioxx (rofecoxib) Questions and Answers. U.S. Food & Drug Administration. (Sept. 30, 2004). (https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/vioxx-rofecoxib-questions-and-answers#:~:text=13.,from%20the%20market%20by%20Merck.) (Last accessed Oct. 9, 2023).

[13] *Att'y Gen. v. Merck Sharp & Dohme Corp.*, 292 Mich. App. 1, 5, 807 N.W.2d 343, 344–45 (2011)("We hold that when, as here, the drug in question was approved by the FDA, the state's suit to recover Medicaid money premised on fraud by the drug company in its representations regarding the safety and efficacy of the drug is barred by MCL 600.2946(5), which exempts drug companies from products-liability suits regarding FDA-approved drugs.")

[14] Prakah, Snigdha and Vikki Valentine. "Timeline: The Rise and Fall of Vioxx." National Public Radio. (Nov. 10, 2007)(https://www.npr.org/2007/11/10/5470430/timeline-the-rise-and-fall-of-vioxx) (Last accessed Oct. 9, 2023).

[15] Harris, Joe. "Merck Pays $615 Million in Vioxx Settlement." Courthouse News Service. (Nov. 28, 2011)(https://www.courthousenews.com/merck-pays-615-million-in-vioxx-settlement/) (Last accessed Oct. 9, 2023).

[16] Seward, Christopher. "Merck paying Georgia Medcaid $15.6M to settle Vioxx drug claims." The Atlanta Journal-Constitution. (Nov. 29, 2011)(https://www.ajc.com/news/local/merck-

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We are the ONLY state in the country who has ever had a law this strict.

Because of this law we were nearly blocked from recovery in the more than $50 billion opioid litigation. The only reason why Michigan, and our cities and counties were able to proceed, is because our claims were uniquely based in public nuisance and RICO – not the "product liability actions" covered by the immunity statute. But even in the opiate litigation, several of Michigan's local government's claims were thrown out due to the immunity law. As the Multi-District Litigation ("MDL") Judge Polster, who managed the federal opioids docket from Cleveland, said in his April 2020 decision, "absent an exception" (and there is none) this law precludes governments from asserting claims of negligence and fraud which are the more typical claims in pharmaceutical product liability cases.[17] But the people who have lost loved ones from opioid overdoses are the ones hurt by this law because their claims do fit within the immunity law's definition of a "product liability" claim.

The most egregious examples of how the immunity law applies to opioids can be seen in legal briefing submitted by drug manufacturers Purdue (the maker of Oxycontin run by the Sackler Family) and Insys. These drug manufacturers argued in the MDL litigation:

> Plaintiff's allegations that certain Manufacturer Defendants "engaged in off-label marketing" or "misbrand[ed]" their products cannot defeat immunity. The MPLA applies regardless of whether a plaintiff alleges that defendants promoted products for "off-label" uses or even "misbranded" them.[18]

The Court agreed and dismissed the negligence and fraud claims. Insys made and sold an under-the-tongue Fentanyl spray that was approved for use in very narrow circumstances like end-of-life cancer patients.[19] The company created a scheme to bribe practitioners of all kinds to off-label

paying-georgia-medicaid-settle-vioxx-drug-claims/Eh83hFiUXQ9LyRI03Nma5K/) (Last accessed Oct. 9, 2023).

[17] In Re: National Opiate Litigation. MDL 2804. Opinion and Order Regarding Defendants' Motions to Dismiss. (April 30, 2020)(Case: 1:17-md-02804-DAP, Doc # 3285.)

[18] In Re: National Opiate Litigation. MDL 2804. Manufacturer Defendants' Joint Motion to Dismiss Plaintiff's Second Amended Complaint. (June 8, 2018)(Case: 1:17-md-2804-DAP, Doc #595).

[19] Opioid Manufacturer Insys Agrees to Enter $225 Million Global Resolution of Criminal and Civil Investigations." U.S. Dept. of Health and Human Services, Office of the Inspector General. (June 5, 2019)(https://oig.hhs.gov/fraud/enforcement/opioid-manufacturer-insys-therapeutics-agrees-to-enter-225-million-global-resolution-of-criminal-and-civil-investigations/#:~:text=Both%20the%20criminal%20and%20civil,but%20highly%20addictive%2C%20opioid%20painkiller)

market the drug for unapproved uses.[20] Many of those at the top in that company went to prison for their roles in illegally marketing their fentanyl product. *Id.* But even though their conduct was so criminal that top corporate executives went to prison, claims for negligence and fraud against the company were thrown out of court under Michigan's immunity statute.

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 and any other defendant in a product liability case.[21] In other states with rebuttable presumptions there are similar presumptions in favor of the injured party.[22] 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. Motor vehicles subject to EPA and NHTSA regulations do not receive special treatment, nor to FDA approved devices or any food product regulated by the FDA. FDA approved drugs are no different.

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,

[20] Founder and Former Chairman of the Board of Insys Therapeutics Sentenced to 66 Months in Prison. United States Attorney's Office: District of Massachusetts. (Jan. 23, 2020) (https://oig.hhs.gov/fraud/enforcement/opioid-manufacturer-insys-therapeutics-agrees-to-enter-225-million-global-resolution-of-criminal-and-civil-investigations/#:~:text=Both%20the%20criminal%20and%20civil,but%20highly%20addictive%2C%20opioid%20painkiller.)

[21] MCL §600.2946(4).

[22] *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.")

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our people's damages are capped which could mean that even if Michiganders can assert claims, they may still get less than other Americans.[23]

Your vote for this bill will do one thing – it will get our grandparents, mothers and fathers, brother and sisters, spouses, neighbors and friends who have been injured to the courthouse steps. Just like every other American outside of Michigan. I strongly urge you to restore accountability for our people – Michigan deserves it.

[23] MCL §2946(a).

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