

## Michigan Drug Immunity Repeal Gives Shot in the Arm to Plaintiffs' Bar

By Drew W. Broaddus

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In 1995, as part of a larger package of tort litigation reforms, Michigan's Legislature granted immunity from products liability suits to pharmaceutical manufacturers and sellers. MCL 600.2946. As the Senate Bill Analysis to SB 410 noted, arguments for granting for this immunity included: 1) that tort liability economically limited the ability of drug manufacturers to invest in research; 2) that it stifled the creation of newer, safer drugs; and 3) that it inflated liability insurance premiums for manufacturers and sellers. Opponents of the 1995 legislation pointed out that punitive, or non-economic, damages were already capped in Michigan at that time, that products liability cases were on a statistical downswing, and that damage awards were not overly punitive beyond personal damages.

The protection conferred by MCL 600.2946 gave drug makers and sellers immunity from tort liability for FDA-approved drugs, so long as FDA approval was not obtained fraudulently. The Michigan Supreme Court has called this protection "an absolute defense to a products liability claims." *Taylor v Smithkline Beecham Corp*, 468 Mich 1, 7 (2003). As explained in the Senate Bill Analysis to SB 410, plaintiffs have tried to file complaints out-of-state to avoid the immunity protection that would be removed by the bill, and have failed. By providing immunity for FDA-approved drugs, Michigan relied solely on the FDA to regulate drugs in Michigan.

This immunity was controversial almost the entire time it was on the books. As the Senate Bill Analysis to SB 410 observed, there were at least 19 bills introduced between 1999 and 2021 to amend or rescind this statutory immunity since enactment. Although the tort protections conferred by MCL 600.2946 have long been controversial, the recent legislation passed with strong bipartisan support. SB 410 passed the Senate on a 30-8 vote, and passed the House 79-30.

According to Senator Jeff Irwin (D-Ann Arbor), who sponsored the bill, "[t]he repeal of our state's immunity law for the drug industry restores accountability for drug manufacturers, and vital access to justice for our state and

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On Since 1995, pharmaceutical manufacturers and sellers have enjoyed tort immunity in Michigan under MCL 600.2946 when (1) the drug was approved by the federal Food and Drug Administration ("FDA"), (2) the manufacturer or seller did not fraudulently obtain the approval, (3) the drug and its labeling complied with the approval, and (4) the approval was not withdrawn.

According to Senate Bill Analysis, this statute was generally recognized as the strongest such immunity protection in the United States. Indeed, as of 2023, Michigan was the only state that statutorily offered drug manufacturers a blanket defense for products liability.

This week, Governor Gretchen Whitmer (D) signed Senate Bill ("SB") 410, repealing this immunity.

its people....”<sup>1</sup> State Attorney General Dana Nessel (D) also praised the bill: “We all owe a debt of gratitude to the many legislators who took up this mantle in the past, and to Sen. Irwin, the legislature, and the governor for scoring this win for drug safety, for accountability, and for Michigan today....”<sup>2</sup>

Governor Whitmer described her support for the bill as follows: “Today, Michigan joins every other state in the nation as we create a stronger path to hold drug companies accountable in cases of wrongdoing....”<sup>3</sup> “When you take a prescription drug, you should have the confidence to know that it is safe, and if it harms you or your family, you deserve accountability.”<sup>4</sup> “By fighting for consumers, we will also ensure that companies doing good work can outcompete and outperform companies that prioritize padding their profits over delivering quality products for people.”<sup>5</sup>

But support for SB 410 was not universal. Wendy Block of the Michigan Chamber of Commerce, who submitted written testimony against the bill when it came before the Senate Civil Rights, Judiciary and Public Safety Committee in October, argued that while MCL 600.2946 was not perfect, it struck an appropriate balance between recognizing the risks associated with all prescription drugs and the ability to let Michigan residents file suit if the FDA determines that a drug manufacturer has committed wrongdoing.<sup>6</sup> “Rather than repealing Michigan’s current FDA defense law and opening the door to a new onslaught of new litigation against doctors, pharmacists and pharmaceutical companies, we would encourage you to look at how other states handle these claims and seek a more balanced approach,” Ms. Block said.<sup>7</sup>

The new legislation does not apply retroactively. According to Senate Bill Analysis, damages incurred while the immunity provision was in effect could not be the basis for future claims.

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**Product Liability Practice Group Chair**

[Bruce A. Truex](#) | [btruex@secretwardle.com](mailto:btruex@secretwardle.com) or 248-539-2818

**For questions pertaining to this article**

[Drew W. Broaddus](#) | [dbroaddus@secretwardle.com](mailto:dbroaddus@secretwardle.com) or 616-272-7966



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**Contributors**  
**Product Liability Practice Group**

**Chair**

Bruce A. Truex

**Editors**

Sandie Vertel  
Sue Willcock  
Brenna Scyzoryk

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<sup>1</sup><<https://www.fox2detroit.com/news/whitmer-repeals-immunity-law-that-shielded-drug-makers-from-liability>>(accessed December 9, 2023).

<sup>2</sup> *Id.*

<sup>3</sup> <<https://www.cbsnews.com/detroit/news/governor-gretchen-whitmer-signs-bill-drug-companies-accountable-last-state-michigan/>> (accessed December 9, 2023).

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> <<https://michiganadvance.com/2023/12/07/whitmer-signs-repeal-of-nations-only-immunity-law-that-shielded-drugmakers-from-legal-liability/#:~:text=With%20the%20stroke%20of%20a,drugs%20caused%20harm%20for%20Michiganders>> (accessed December 9, 2023).

<sup>7</sup> *Id.*