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BILL ANALYSIS

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Senate Bill 410 (as introduced 6-27-23) *(Senate-passed version)*
Sponsor: Senator Jeff Irwin
Committee: Civil Rights, Judiciary, and Public Safety

Date Completed: 10-4-23

CONTENT

The bill would amend Part 29 (Provisions Concerning Specific Actions) of the Revised Judicature Act to eliminate a drug manufacturer's or seller's immunity from product liability.

Among other things, Part 29 governs product liability actions against drug manufacturers and sellers. It provides manufacturers and sellers with immunity from liability if the drug meets the following requirements:

-- The drug was approved for safety and efficacy by the United States Food and Drug Administration (FDA).
-- The drug and its labeling complied with the FDA's approval at the time it left the control of the manufacturer or seller.

Part 29 specifies that the immunity does not apply to a drug that is sold in the United States after the effective date of an FDA order removing the drug from market or withdrawing its approval. Additionally, the immunity does not apply if the manufacturer or seller at any time before the event that allegedly caused the injury does any of the following:

-- Intentionally withholds or misrepresents information shared with the FDA concerning the drug that would have resulted in the drug's disapproval or withdrawn approval.
-- Makes an illegal payment to an FDA official or employee to secure or maintain the drug's approval.

The bill would delete the immunity and related provisions described above.

MCL 600.2946

PREVIOUS LEGISLATION

(This section does not provide a comprehensive account of previous legislative efforts on this subject matter.)

The bill is a reintroduction of Senate Bill 961 from the 2021-2022 Legislative Session. At least 19 bills have been introduced to amend or rescind this statutory immunity since enactment, beginning in 1999 with House Bill 4165. House Bill 4044 from the 2007-2008 Legislative Session and House Bill 4316 from the 2009-2010 Legislative Session passed the House and were referred to the Senate but received no further action.

BACKGROUND

In 1995, as part of a larger package of tort litigation reforms, Michigan enacted immunity

protection from pharmaceutical products liability for drug manufacturers and sellers.[1] At that time, supporting arguments for the reforms included the following: 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. Opposing arguments 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.[2]

Michigan's pharmaceutical products liability immunity protection is recognized as the strongest immunity protection statute in the country. Michigan is the only state that statutorily offers drug manufacturers a blanket defense for products liability. Basically, the protection under current law provides that drug makers and sellers are immune 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 claim".[3] Potential plaintiffs, including individuals, local governments, or classes have tried to file complaints out-of-state to avoid the immunity protection that would be removed by the bill and have failed.[4] By providing immunity for FDA approved drugs, Michigan relies solely on the FDA to regulate drugs in Michigan.[5]

Legislative Analyst: Tyler P. VanHuyse

FISCAL IMPACT

The bill likely would have an indirect and indeterminate fiscal impact on the State and local governments as it would allow for high profile, high-dollar litigation for pharmaceutical products liability lawsuits against drug makers and sellers.

The Attorney General (AG) could find several new avenues of litigation available for pharmaceutical products liability cases on behalf of the people of Michigan. Previous pharmaceutical products liability complaints filed by AGs have failed. In 2011, AG Mike Cox's lawsuit against Merck for $20.0 million was dismissed under the immunity protection.[6] In 2020, a Circuit Court dismissed AG Dana Nessel's claims of negligence and public nuisance against opioid distributors, also under the immunity protection.[7]

Likewise, local governments, who previously failed in opioid-related lawsuits, would have a clearer path toward compensation by litigation. In 2020, claims made by Monroe County of negligence, public nuisance, unjust enrichment, fraud, and civil conspiracy related to the fraudulent marketing of opioids were dismissed as products liability actions under the immunity protection.[8]

Although the bill would not create or spend revenue directly, indirect revenue for the State and local governments through litigation would be likely. The amounts of any such benefit cannot be accurately determined, but some broad projections are possible with available data. Over the last 5 years in Michigan, products liability cases represented an average of 0.62%

[1] House Bill 4508 (1995) & Senate Bill 344 (1995) (Public Acts 161 and 249 of 1995, respectively).
[2] Senate Fiscal Agency, Revised Enrolled Analysis of Public Acts 249 & 161 of 1995, 1-11-1996.
[3] *Taylor v. Smith-Kline Beecham Corp.*, 658 N.W.2d 127, 130-31 (2003).
[4] E.g., *Ma.J.L. v. Janssen Pharms., Inc. (In re Risperdal Litig.),* 175 A.3d 1023 (2017).
[5] The Senate Fiscal Agency would like to thank the Legislative Services Bureau, specifically Attorney Kristen L. Stone, for providing supplemental research for this analysis.
[6] *AG v Merck Sharp & Dohme Corp,* 292 Mich App 1 (2011).
[7] *Mich. Ex rel. Nessel v Cardinal Health, Inc.*, 2020 Mich. Cir. LEXIS 1796.
[8] *In re Nat'l Prescription Opiate Litig.*, 458 F. Supp. 3d 665 (2020).

of all civil complaints.[9] After consideration of pre-pandemic statistics regarding civil case filings, this would mean roughly 250 products liability cases expected per year over the next several years statewide, of which an unknown handful could potentially be pharmaceutical products liability cases, should the bill be enacted. Potential judgement or settlement award amounts are indeterminate and would be based on the facts of each individual case. Nationwide, most pharmaceutical products liability cases allege off-label promotion and/or deceptive marketing.[10]

The most hidden economic impact could be deterrence. According to the Centers for Disease Control and Prevention, the combined cost to Michigan for opioid use disorder and overdose fatalities in 2017 was estimated at $41.4 billion dollars (nationwide estimates at $1.021 trillion).[11] The bill, if enacted, would not apply ex post facto. Any past damages while the immunity provision was in effect could not be the basis for future claims; however, enactment of the bill could alter pharmaceutical marketing and prescribing practices in anticipation of future litigation. This fiscal impact cannot be determined.

Fiscal Analyst: Michael Siracuse

[9] "State Court Administrative Office: Interactive Court Data Dashboard", https://www.courts.michigan.gov/publications/statistics-and-reports/interactive-court-data-dashboard/

[10] Garber, Steven, *Economic Effects of Product Liability and Other Litigation Involving the Safety and Effectiveness of Pharmaceuticals*, available at: https://www.rand.org/pubs/monographs/MG1259.html

[11] Luo, Li, *et al*., *State-Level Economic Costs of Opioid Use Disorder and Fatal Opioid Overdose – United States 2017*, available at: https://www.cdc.gov/mmwr/volumes/70/wr/mm7015a1.htm

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