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BILL ANALYSIS

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Senate Bill 410 (as enacted) **PUBLIC ACT 285 of 2023**
Sponsor: Senator Jeff Irwin
Senate Committee: Civil Rights, Judiciary, and Public Safety
House Committee: Judiciary

Date Completed: 9-10-24

RATIONALE

In 1995, Public Act (PA) 249 established a drug manufacturer's or seller's immunity from product liability if the drug was approved by the United States Food and Drug Administration (FDA). Since then, national drug liability cases have held drug manufacturers and sellers accountable for significant personal and societal injuries resulting from their FDA-approved drugs; however, according to testimony before the Senate Committee on Civil Rights, Judiciary, and Public Safety, PA 249's immunity prevented Michigan residents and attorneys general from participating in many of these cases. Michigan's immunity law relied too much on the FDA's approval and resulted in a lack of justice in the State. Accordingly, it was suggested that the drug product liability immunity be deleted.

CONTENT

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

The bill took effect February 13, 2024.

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

-- The drug was approved for safety and efficacy by the 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 specified that the immunity did not apply to a drug that was 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 did not apply if the manufacturer or seller at any time before the event that allegedly caused the injury did any of the following:

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information shared with the FDA concerning the drug that would have resulted in the drug's disapproval or withdrawn approval.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

The bill deleted the immunity and related provisions described above.

MCL 600.2946

BACKGROUND

As part of a larger package of tort litigation reforms in 1995 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 was recognized as the strongest immunity protection statute in the country. Michigan was the only state that statutorily offered drug manufacturers a blanket defense for products liability. The protection under previous law provided that drug makers and sellers were immune from tort liability for FDA-approved drugs, so long as FDA approval was not obtained fraudulently. The Michigan Supreme Court called this protection "an absolute defense to a products liability claim".[3] Potential plaintiffs, including individuals, local governments, or classes tried to file complaints out-of-state to avoid the immunity protection removed by the bill and failed.[4] By providing immunity for FDA approved drugs, Michigan relied solely on the FDA to regulate drugs in Michigan.

ARGUMENTS

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

Supporting Argument

The drug products liability immunity prevented Michigan residents and government from participating in injury lawsuits that awarded significant amounts for damages. According to testimony before the House Committee on Judiciary, many examples of Michigan residents and government missing out on injury claims exist. For example, a lawsuit against the manufacturer of the antipsychotic drug Risperdal resulted in a settlement of hundreds of millions of dollars for male plaintiffs alleging that the drug manufacturer failed to warn of one of the drug's side effects in which men grew breasts; however, Michigan plaintiffs were dismissed and unable to participate in the settlement because of the State's drug product liability immunity.[5] Testimony also indicated that Michigan Medicaid could not recuperate via lawsuit or settlement the funds used to pay for mastectomies for those men. Deleting the drug products liability immunity from statute may provide Michigan residents and government the opportunity to seek damages in future drugs product liability cases and class actions.

Supporting Argument

The drug products liability immunity thwarted lawsuits that attempted to recover damages from drug manufacturers in cases that did not rely on claims of product liability. In 2011, the Michigan Attorney General (AG) claimed that Merck & Co. Inc., the manufacturer of the painkiller Vioxx, defrauded the State's Medicaid program by misrepresenting the safety and efficacy of the drug.[6] Specifically, Vioxx increased the chances of heart attack and stroke. Under the Medicaid False Claim Act, the AG claimed the right to recover money spent to

[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] *Id.*
[6] *AG v. Merck Sharp & Dohme Corp*, 292 Mich App 1 (2011).

reimburse doctors who prescribed Vioxx because the State's Medicaid program would not have made reimbursements had Merck not made misrepresentations; however, the Michigan Court of Appeals eventually barred the lawsuit from moving forward because Vioxx had received FDA-approval and so the State's drug products liability immunity prohibited the suit. The State did not have the capacity to protect residents and seek justice before the bill deleted the drug product liability immunity.

Supporting Argument

According to testimony before the Senate Committee on Civil Rights, Judiciary, and Public Safety, the drug products liability immunity went against the FDA's notion that its drug approval process and civil litigation are supposed to serve as two distinct layers of consumer protection. Reportedly, FDA officials have considered its approval process and civil litigation as separate layers of consumer protection for several decades. The judicial consumer protection specifically provides the FDA with information about a drug's effects that may not have been studied or established before its approval, such as in the cases of Risperdal and Vioxx described above. Litigation helps bring concerns about drugs to the FDA's attention and may inform the FDA's decisions in rescinding FDA-approval or allowing manufacturers to apply for drug approval in the first place. Deleting the drug products liability immunity aligned Michigan drug products liability law with the FDA's approach to drug approval and consumer protection.

Opposing Argument

The FDA's drug approval process is rigorous, and the State's drug products liability immunity balanced that rigor with consumer protections well. The FDA's approval process consists of a preclinical period in which a drug manufacturer develops the drug and tests on animals; a clinical period in which the manufacturer tests on human patients to determine side effects, safety, and drug efficacy; a review period in which the FDA reviews results of the pre-clinical and clinical periods; and a post-marketing review period in which the FDA monitors safety issues after a drug's approval.[7] Acknowledging that rigor, the State established drug products liability immunity but recognized that bad actors could exist and so provided exceptions to the immunity if a manufacturer intentionally misrepresented information to the FDA. The drug products liability immunity should not have been deleted. Instead, concerns about consumer protection in the process should have been addressed by establishing a rebuttable presumption that a drug was safe if approved by the FDA.

Response: The exceptions to the immunity based on intentional misrepresentation were inadequate. According to testimony before the Senate Committee on Civil Rights, Judiciary, and Public Safety, intentional misrepresentation is hard to prove in civil litigation. Additionally, Federal law deters the FDA and other governmental agencies from pursuing cases against manufacturers based on intentional misrepresentation because a conviction would amount to criminal fraud, a felony that would prevent a manufacturer from selling to programs like Medicare and Medicaid. Deleting the immunity was the best choice for consumer protection.

Legislative Analyst: Eleni Lionas

FISCAL IMPACT

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

[7] U.S. FDA, "The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective," https://www.fda.gov. Retrieved 9-9-24.

The AG may 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 failed. In 2011, AG Mike Cox's lawsuit against Merck for $20.0 million was dismissed under the immunity protection.[8] In 2020, a Circuit Court dismissed AG Dana Nessel's claims of negligence and public nuisance against opioid distributors, also under the immunity protection.[9]

Likewise, local governments, who previously failed in opioid-related lawsuits, will 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.[10]

Although the bill does not create or spend revenue directly, indirect revenue for the State and local governments through litigation is likely. The amounts of any such benefit cannot be accurately determined, but some broad projections are possible with available data. Over the last five years in Michigan, products liability cases represented an average of 0.62% of all civil complaints.[11] After consideration of pre-pandemic statistics regarding civil case filings, this means roughly 250 products liability cases expected per year over the next several years statewide, of which an unknown handful may potentially be pharmaceutical products liability cases. Potential judgement or settlement award amounts are indeterminate and will be based on the facts of each individual case. Nationwide, most pharmaceutical products liability cases allege off-label promotion and/or deceptive marketing.[12]

The most hidden economic impact may 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).[13] The bill does not apply ex post facto. Any past damages while the immunity provision was in effect may not be the basis for future claims; however, the bill may alter pharmaceutical marketing and prescribing practices in anticipation of future litigation. This fiscal impact cannot be determined.

Fiscal Analyst: Michael Siracuse

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[8] *AG v. Merck Sharp & Dohme Corp*, 292 Mich App 1 (2011).
[9] *Mich. Ex rel. Nessel v Cardinal Health, Inc.*, 2020 Mich. Cir. LEXIS 1796.
[10] *In re Nat'l Prescription Opiate Litig.*, 458 F. Supp. 3d 665 (2020).
[11] "State Court Administrative Office: Interactive Court Data Dashboard", https://www.courts.michigan.gov/publications/statistics-and-reports/interactive-court-data-dashboard/
[12] 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
[13] 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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